

Patients' Informed Consent in Dental Practice in Bulgaria

Nadia Avramova¹, Krassimira Yaneva²

¹ D.D.S. Assistant Professor, Department of Dental Public Health, Faculty of Dental Medicine, Medical University of Sofia, Bulgaria. ² D.D.S., Ph.D. Associate Professor, Department of Dental Public Health, Faculty of Dental Medicine, Medical University of Sofia, Bulgaria.

Abstract

Introduction: Patients' informed consent is a legal regulation and a moral principle, determined by legislation in Bulgaria and the European Union. It represents patients' rights to take part in the clinical decisions concerning their treatment. The authors report research showing informed consent's more important aspects related to daily relationships between dentists and patients. **Aims:** The main aims of this study were to investigate the use of patients' informed consent and the extent to which it is provided in Bulgarian dentists' practice. **Methods:** A questionnaire, which included questions on various aspects of the use of informed consent, was used to collect data from a convenience sample of 102 dentists working in the Medical University of Sofia, Faculty of Dental Medicine and the Military Medical Academy, Sofia, Bulgaria. Completed questionnaires were returned anonymously. **Results:** Eighty dentists completed the questionnaire. Seventy-eight (97.5%) replied that they thought informed consent was necessary. Seventy (87.5%) dentists reported that they took informed consent for all types of treatment. Of the remainder, 10 reported taking informed consent prior to surgical interventions, eight before orthodontic treatment and seven before prosthetic treatment. However, only 64 (80%) respondents reported that they always obtained informed consent from their patients. Thirty-seven (46.25%) dentists responded that they obtained the oral form of informed consent, 30 (37.5%) that they obtained written informed consent, and 13 (16.25%) that they obtained both forms. Surgical treatment was the most frequent case in which the written form was obtained. Almost all participants (70; 87.5%) reported that they should always take informed consent when they treated children. Forty-one (51.25%) reported that they obtained informed consent from all patients but 21 (26.25%) did not obtain it when treating colleagues, 29 (36.25%) from relatives, 15 (18.75%) from friends, and 10 (12.5%) from long-time patients. **Conclusions:** From the current survey, it can be concluded that the dentists as staff members of leading training and healthcare facilities may well have demonstrated greater awareness about questions concerning patients' informed consent than most other Bulgarian dentists. Informed consent plays a major role in the daily practice of the majority but many are not using written consent as a routine procedure. However, even though almost 100% of the dentists thought that it is necessary to get informed consent, only 80% of them obtained it in practice.

Key Words: Information, Informed Consent, Patients' Rights

Introduction

Progress in medicine and information technologies have enabled patients to be better informed about all aspects of healthcare. Increasingly, they are more likely to question their doctors, dentists, and other healthcare professionals and to express their different points of view, in order to understand their diseases and/or conditions.

In the light of these developments, patients are playing a more active role in their treatment and have new expectations and needs. These changes reflect some deeper changes in society, which have

encouraged greater personal independence and the respect of human rights.

In Bulgaria, the general rights of citizens, as consumers of health services, are enshrined in a number of legal acts in both Bulgarian and European Union (EU) legislation, as well as in a large number of international documents connected to ethical standards about physicians' behaviour and their patients. They include the Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects [1], the Declaration of Geneva [2], the International Code of Medical

Corresponding author: Assistant Prof. Dr. Nadia Avramova and Associate Prof. Dr. Krassimira Yaneva-Ribagina, Department of Dental Public Health, Faculty of Dental Medicine, Medical University-Sofia, Bulgaria, 1, G. Sofiiski Str., 1431 Sofia, Bulgaria; e-mail: avramova_nadia@abv.bg or ribagina@hotmail.com

Ethics [3], the European Charter of Patients' Rights [4], the Charter of Fundamental Rights of the European Union [5], the Bulgarian Code of Professional Ethics [6] and Bulgarian healthcare legislation [7]. It is considered that three of these rights either have intersections with the others or are a precondition for them. They are the rights for information, free and informed consent, and dignity.

Informed consent confirms patients' right to take part in decisions that involve them. It is one aspect of providing good quality healthcare [8]. It does not shift the whole responsibility to the patient but should be a partnership between a clinician and a patient in which each has rights and defined responsibilities.

In 1973, for the first time, informed consent in Republic of Bulgaria was mentioned in the Law on Public Health—articles 31-35 [9]. Exceptions to the principle of informed consent are also legally regulated [7,10].

Informed consent is a patient's written or oral agreement that is given after he or she has received sufficient information about the diagnostic or therapeutic procedure that is planned. The necessary information should be explained in words that the patient can understand and should include warning(s) of any large, evident or significant risks [7,10,11].

For many years, European countries and the European Commission have been looking into questions concerning patients' rights by accepting international charters and making legislative changes to establish these rights. It is obvious that these rights depend on the quality of the healthcare system and methods of delivering of treatment, together with the behaviour and cooperation of clinicians and patients themselves.

In 2002, the "Active Citizenship Network" was established as an organisation aiming to confirm citizens' position in public politics, proposed in the European Charter of Patients' Rights [4,12]. These rights are based on the Charter of Fundamental Rights of the European Union (article 35) and occupy an important place in the relations of European citizens with their healthcare system [5]. However, a study in which legislations of 13 countries—members of EU—are discussed has shown that the degree of protection accorded by these rights varies between countries [13].

It was therefore thought important to investigate how informed consent is provided as a part of general rights of citizens as consumers of dental services in the daily practice of Bulgarian dentists (dental doctors).

Aims

The main aims of this study were to investigate the use of patients' informed consent and the extent to which it is provided in Bulgarian dentists' practice.

Methods

Respondents

Data were collected from a convenience sample of 102 practising general dentists, working in two leading training and healthcare facilities, the Medical University of Sofia, Faculty of Dental Medicine and the Military Medical Academy, Sofia, Bulgaria. The majority also worked part-time in private clinics.

Procedure

Respondents were given a clear and detailed verbal briefing about the main aims of the study and how its results could contribute to dental practice in general. They were given the questionnaire (*Figure 1*) in their dental offices and were asked to respond to this survey anonymously. The completion of the questionnaire was taken as a dentist's approval and form of individual consent to participate in the study. As no patient or animal was involved, the dentists' anonymity was maintained, and they were free to refuse to take part in the study, it was deemed unnecessary to seek ethics approval for the study.

Material

The self-administrated questionnaire (*Figure 1*) consisted of nine questions, divided in several sub-sections. Before it was distributed to the dentists, it had been piloted (tested) on a group of 16 dentists to ensure that the questions were clear. Some of the questions required the respondents to respond merely with a "yes" or "no", such as the first question, "Do you think that it is necessary to take informed consent?". Other questions offered several possible answers from which respondents had to choose one or several. A third group of questions assessed respondents' self-perceived point of view in relation to getting patients' informed consent (open questions in which a blank was left for writing the answers). For example: "If you use a written form of informed consent, in which cases do you think it is necessary to employ this method in your dental practice?".

Results

Two dentists refused to take part in the survey. The other 100 all returned their questionnaires. Of

Dear colleagues,

This questionnaire is part of a study named "Patients' informed consent and its use in dental practice". The results obtained from this survey will contribute to raising the importance of informed consent and, it is hoped, increasing its use in dental practice.

Thanks for your collaboration.

1. Do you think that it is necessary to take informed consent?

- yes
- no

2. In which areas of dental medicine do you consider it is necessary to obtain informed consent?

- in all cases

Only in:

- surgical intervention
- endodontic treatment
- prosthetic treatment
- orthodontic treatment
- specific clinical examinations
- clinical trials in humans

3. Do you get informed consent from your patients?

- yes, always
- no
- in definite cases only.....
(indicate which)

4. What is the form of informed consent that you obtain in your practice?

- oral
- written
- both of them

5. If you use the written form of informed consent, in which cases do you think it should be obtained?

6. In your opinion about which of the following should patients be informed during treatment?

- diagnosis
- treatment plan and possible alternatives about type, materials and methods of treatment
- eventual involved risks
- possible complications
- expected results from treatment
- extra clinical examinations
- cost of treatment

7. Do you obtain parents' informed consent when treating their children?

- yes, always
- no
- in defined cases only.....
(indicate which)

8. Are there any patients from whom you might not wish to obtain informed consent?

- colleague
- relative
- friend
- long-time patient
- none of them

9. When you are a patient, is informed consent taken from you?

- yes
- no
- sometimes

Figure 1. The questionnaire.

these, 20 did not complete the questionnaires correctly and they were excluded from data analysis. The data from the other 80 questionnaires were processed and are presented in a series of figures.

Figure 2 shows the answers to question 1. Almost all (78/100; 97.5%) respondents considered that it was necessary to take informed consent from their patients. Two (2.5%) did not consider that it was necessary.

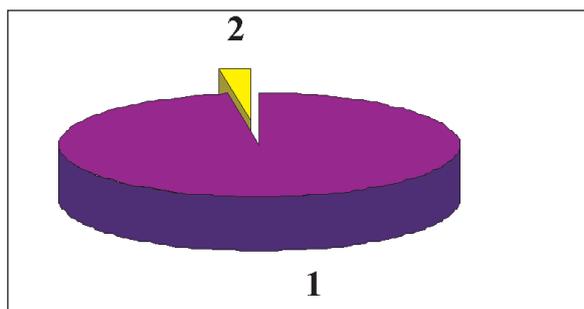


Figure 2. Necessity of taking informed consent.
Key: 1=Yes (97.5%). 2=No (2.5%).

Figure 3 shows the answers to question 2, which was: "In which areas of dental medicine do you consider it is necessary to obtain informed consent?". Seventy (87.5%) answered that they took it before all types of treatment. Of the other 10 (12.5%), all reported obtaining informed consent for surgical treatment only, 8 (10%) for orthodontic treatment, 7 (8.75%) for prosthetic treatment, 5 (6.25%) for endodontic treatment, and 4 (5%) if specific clinical examinations were necessary, and in all cases of clinical trials in humans.

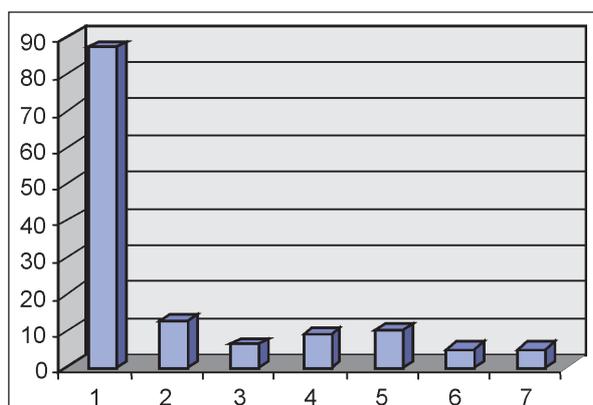


Figure 3. Areas of dentistry in which to obtain informed consent.

Key: 1. All cases (87.5%). 2. Surgical intervention (12.5%). 3. Endodontic treatment (6.25%). 4. Prosthetic treatment (8.75%). 5. Orthodontic treatment (10%). 6. Specific clinical examinations (5%). 7. Clinical trials in humans (5%).

Figure 4 shows the answers to question 3. Only 64 (80%) respondents reported that they always obtained informed consent from their patients. Eleven (13.75%) responded that they asked for informed consent in definite cases only and the remaining 5 (6.25%) replied that they never asked.

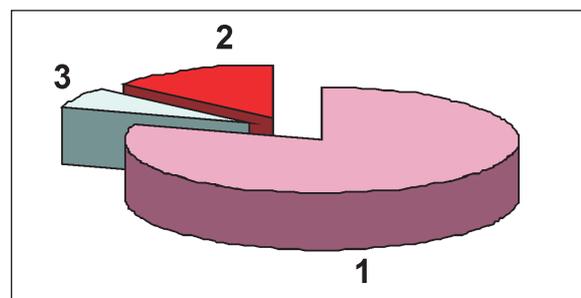


Figure 4. Putting informed consent into practice.
Key: 1. Yes (80%). 2. In definite cases only (13.75%). 3. No (6.25%).

Figure 5 shows the answers to question 4. It can be seen that 37 (46.25%) dentists responded that they obtained the oral form of informed consent, 30 (37.5%) that they obtained written informed consent, and 13 (16.25%) that they obtained both forms.

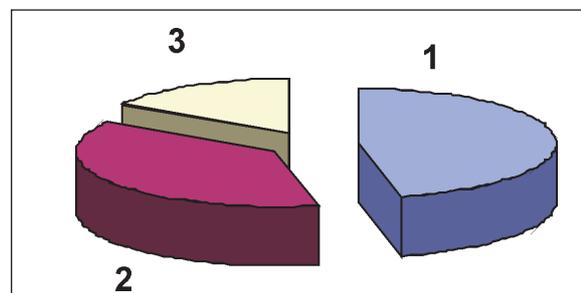


Figure 5. Forms of informed consent used in dental practice.

Key: 1. Oral (46.25%). 2. Written (37.5%). 3. Both (16.25%).

Figure 6 shows the answers to question 5, which asked which cases require written informed consent. Twenty-five respondents (31.25%) answered for all cases. The others answered in cases of surgical treatment (9; 11.25%), endodontic treatment (4; 5%), prosthetic treatment (4; 5%), orthodontic treatment (2; 2.5%), and more complicated and risky treatment (2; 2.5%). A range of reasons was suggested: before local anaesthesia (1; 1.25%), treatment of illiterate patient (1; 1.25%), risk of unsuccessful treatment (1; 1.25%), and legal problems (1; 1.25%), cosmetic dentistry (1; 1.25%), and clinical trials in humans (1; 1.25%). Twenty-eight (35%) did not provide any answer.

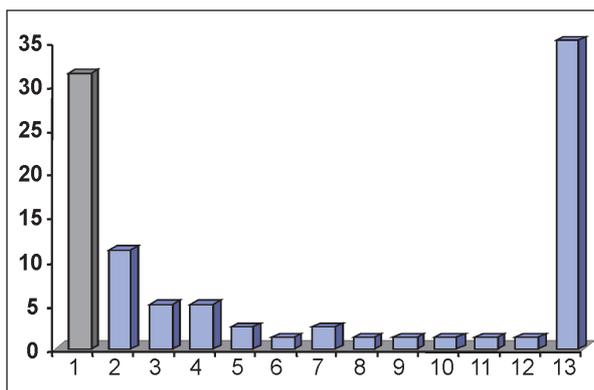


Figure 6. Cases in which the written form of informed consent is being used.

Key: 1. In all cases (31.25%). 2. Surgical treatment (11.25%). 3. Endodontic treatment (5%). 4. Prosthetic treatment (5%). 5. Orthodontic treatment (2.5%). 6. Anaesthesia (1.25%). 7. Complicated and risky treatment (2.5%). 8. Illiterate patient (1.25%). 9. Unsuccessful treatment risk (1.25%). 10. Legal problems risk (1.25%). 11. Cosmetic dentistry (1.25%). 12. Clinical trials (1.25%). 13. Did not answer (35%).

Figure 7 shows the answers to question 6, which related to topics which patients should be informed about when obtaining informed consent. It can be seen that 74 (92.5%) dentists answered that they informed their patients about the treatment plan and possible alternatives for treatment, 62 (77.5%) about possible complications during treatment; 61 (76.25%) about long-term risks involved in treatment, 61 (76.25%) about the cost of treatment, 58 (72.5%) about expected results; 53 (66.25%) claimed they informed their patients of the diagnosis of their disease and 40 (50%) if extra clinical examinations are necessary.

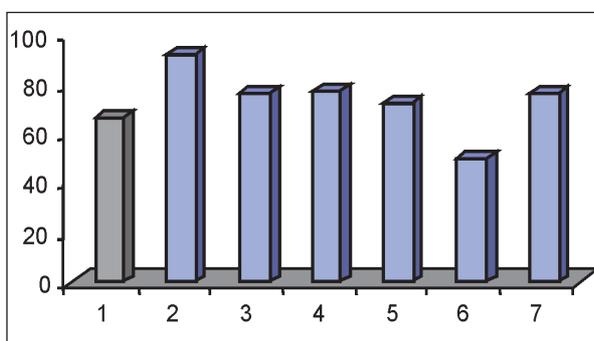


Figure 7. Topics patients are informed about prior to giving consent.

Key: Informed about: 1. Diagnosis (66.25%). 2. Treatment plan and alternatives (92.5%). 3. Eventual involved risks (76.25%). 4. Possible complications (77.5%). 5. Expected results (72.5%). 6. Extra clinical examinations (50%). 7. Cost of treatment (76.25%).

Figure 8 shows the answers to question 7, which was about taking parents' informed consent before treating their children. Seventy (87.5%) respondents replied in all cases, 7 (8.75%) in defined cases only, and 3 (3.75%) that they did not obtain parents' consent.

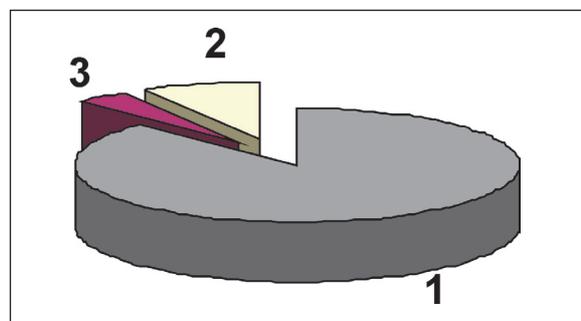


Figure 8. Getting parents' informed consent when treating their children.

Key: 1. Yes, always (87.5%). 2. In defined cases (8.75%). 3. No (3.75%).

Figure 9 shows the answers to question 8. The respondents felt that there were some cases in which dentists did not need to obtain informed consent. In their opinion, these cases were supposed to be connected with the treatment of colleagues (21; 26.25%), relatives (29; 36.25%), friends (15; 18.75%), and long-time patients (10; 12.5%). More than half of the respondents (41; 51.25%) replied that they should obtain informed consent no matter whom they treated.

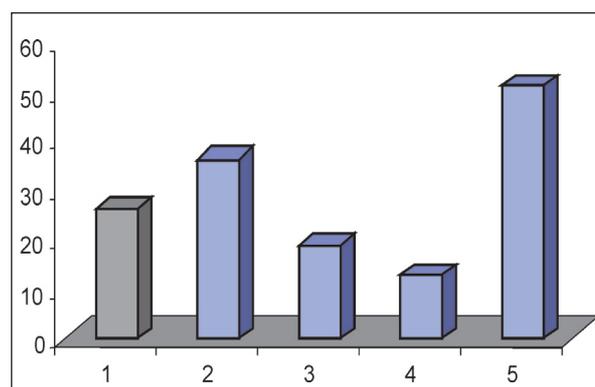


Figure 9. Patients not asked for informed consent.

Key: 1. Colleague (26.25%). 2. Relative (36.25%). 3. Friend (18.75%). 4. Long-time patient (12.5%). 5. None of them (51.25%).

Figure 10 shows the answers to question 9, which related to whether they were asked for informed consent when they were patients. Thirty-one (38.75%) answered yes, 21 (26.25%) answered

sometimes and, interestingly, 28 (35%) answered that they had never been asked for informed consent.

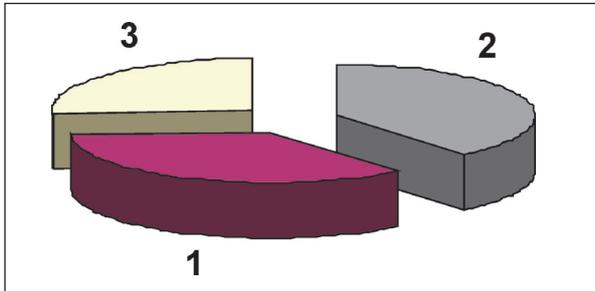


Figure 10. Getting dentists' informed consent in their capacity as patients.

Key: 1. Yes (38.75%). 2. No (35%). 3. Sometimes (26.25%).

Discussion

In any survey, there is always a doubt about whether or not the respondents answer the questions truthfully. There can be a suspicion that they either give the answers that they feel will please the investigators or give what they perceive to be the "correct" answer, even if it is not what they actually do on a day-to-day basis. Anonymised self-completion questionnaires can limit these problems as there is no direct contact between the respondent and the investigator. Nevertheless, the possibility that the answers given may not necessarily reflect what the respondents do on a day-to-day basis must be considered.

It is very likely that the dentists who responded were not representative of all Bulgarian dentists because they worked in a dental school. As a result, many have postgraduate qualifications and treat patients with "difficult" oral health problems who have been referred to them. It is also likely that there is peer pressure to provide quality care, including ensuring that their patients give informed consent. These factors would not influence many Bulgarian dentists, especially those who work in isolation (single-handed) in rural areas. It is therefore possible that the dentists who responded to the questionnaire were more aware of the need for informed consent from patients than many other Bulgarian dentists. The only way to check this point would be to perform the same study, sending the questionnaire to a random sample of all Bulgarian dentists. It would also be interesting to ascertain whether a dentist's gender, age and postgraduate qualifications influence whether or not informed consent is obtained from a patient.

It was surprising that 2.5% of the respondents did not consider informed consent to be necessary and that 6.25% responded that they had not incorporated informed consent into their practice. In a previous study in India, 100% of respondents claimed that they obtained informed consent [14].

It was not surprising that among those who reported that they did not obtain informed consent in all cases, surgical intervention was the most likely procedure to cause them to seek consent. The risks of complications following third molar extraction are well documented [15] and the use of consent forms for patients to sign prior to such surgery is widespread [15-17]. However, one study has reported that the majority of patients undergoing oral surgery did not remember the information that they had received prior to signing their consent forms [15].

In the current study, 54% of respondents reported that they routinely used written consent forms. This was a rather low percentage because written consent provides some evidence that patients have been informed of the details and costs of their proposed treatment. In a study in India, 64% of dentists reported that they routinely obtained written consent [14]. The importance of obtaining written consent was underlined by the results of a Spanish study, which found that in 78% of cases of dental malpractice there was no written consent [18]. However, although written consent may help a dentist to contest malpractice claims, it does not necessarily imply that the patient knows or fully understands the nature of the treatment that they are about to receive [19].

In the current study, in response to the question on the use of written informed consent for specific treatment, 31% of dentists reported that they used it for all cases and a further 11% (total 42%) before surgical treatment. For the reasons stated previously, it was unsurprising that written consent was most commonly obtained prior to surgical treatment. In view of the potential costs if the patient is unhappy with the outcomes of treatment, it was surprising that only one of the dentists reported taking written informed consent prior to cosmetic dentistry. However, it seems likely that 92% of patients received information, in either written or oral form, on a treatment plan and alternatives and 76% of the costs of treatment.

The issue of obtaining informed consent prior to treating children can be difficult [20]. It was therefore encouraging to see that nearly 90% of

respondents in the current study always obtained consent from a child's parent (or guardian) and only three reported that they did not obtain such informed consent for children.

The findings of this study with regard to whom the dentists did not ask for informed consent and whether or not they were asked for their informed consent when they were patients are interesting. The authors have been unable to find previous studies that asked these questions and therefore cannot compare the answers with those from other such studies.

As mentioned previously, one such future study should be in Bulgaria to assess how all Bulgarian dentists are using informed consent rather than just a select band from institutions in Sofia.

Although the current study investigated dentists, it is essential to bear in mind that patients' informed consent is a part of patients' general rights and is based on legal regulations. Furthermore, it must be based on information that the patient understands. The question arises, are doctors, dentists and other clinicians aware enough of patients' rights and do they incorporate these rights in their practice? The authors hope that this survey is a small step towards answering these questions in Bulgaria. The findings suggest that the majority of the Bulgarian dentists who took part realise the necessity of observing patients' rights.

Conclusions

Cases in which it is necessary to get patients' informed consent are indicated clearly and precisely in Bulgarian and EU legislation. From the current survey it can be concluded that:

1. The responding dentists as staff members of leading training and healthcare facilities may well have demonstrated greater awareness about questions concerning patients' informed consent than most other Bulgarian dentists.
2. Informed consent played a major role in the daily practice of the majority but many were not using written consent as a routine procedure.
3. Even though almost 100% of the dentists thought that it is necessary to get informed consent, only 80% of them obtained it in practice.
4. Most of the dentists could incorporate informed consent into their practice in all cases, no matter what clinical case or patient they treated.

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Contribution of each author

NA prepared the questionnaire form, distributed it to the dentists to complete, collected and processed the data obtained and drafted the paper.

KY-R planned the study, prepared the questionnaire form, supervised the study, checked and edited the paper.

Statement of conflict of interests

As far as the authors are aware, there is no conflict of interests.

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