# Informed consent: a survey of general dental practitioners in Belgaum city

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***Abstract***

*The informed consent process allows the patient or legal guardian to participate in and retain autonomy over the medical service received. Obtaining informed consent may also decrease the practitioner's liability from claims associated with miscommunication. The aim of this study was to assess knowledge and practices of general dental practitioners (GDPs) regarding informed consent. 118 GDPs in Belgaum city, Karnataka, India, were given questionnaires asking for information on their knowledge and practices related to informed consent. The questions covered general information, treatment-specific issues and the consent process. 80 responses were received out of which 44 were complete. 63.6% of GDPs reported that they obtained written consent. All of them reported that they obtained only general consent. 4 of them obtained written consent in the local language. 37 said they gave a detailed explanation of the procedure. 3 said they did not inform their patients on radiation exposure. Dentists should upgrade their knowledge regarding legal jurisprudence and legal medicine to avoid any litigation.*

## Introduction

The treatment of a patient without his or her consent has been viewed as battery and can invoke legal action. Litigation involving consent issues has often concerned the nature and extent of information that is provided to a patient in the course of obtaining authorisation for treatment (1).

Much has been written in the medical literature on why informed consent is so important and what it is in theory and in practice (2-4). However, there is a limited discussion on this issue in the dental literature within India, despite the importance of this subject to dental providers. In dentistry, as in other branches of medicine, patients have trusted their providers to do what is clinically best for them. Discussions between dentists and their patients on treatment are more in the nature of a few notes for the dentist's records than a written account of a negotiated clinical plan with the options explained for the patient. This situation may not concern patients unduly, as they may feel that the potential hazards of dental treatment are few. At present, the level of information given to obtain informed consent can vary widely between individual dentists.

This situation is changing. Patients are demanding better and more information about their healthcare. Some have taken legal action when they have concluded that their clinicians have failed to provide sufficient information about the outcomes of selected treatments.

Dentists' obligation to obtain the patient's consent to treatment is based on ethical principles, legal requirements and professional policies. Any treatment or investigation performed without consent can result in legal action for damages and even criminal proceedings. The dentist may be found guilty of serious professional misconduct by the professional registration body (5-7).

In India, the Dental Council of India is concerned with maintaining ethics among dental professionals. The code of ethics for dentists specifies certain duties and rights of a dental practitioner, including those that concern the welfare of patients (8), Some steps have been taken to educate dentists on ethics. A notification of the Dental Council of India published in the Indian Gazette contains a separate section on forensic odontology which includes jurisprudence and ethics in dentistry. Reference is made to a 30-hour curriculum with didactic lectures and practical exams (9).

However, such steps are no assurance that dental practitioners will practise dentistry in an ethical manner (10).

The present study was conducted to assess the knowledge and practice of general dental practitioners (GDPs) in Belgaum city regarding informed consent. Belgaum city is situated in the south Indian state of Karnataka with a population of about 42,00,000 according to the 2001 census.

## Material and methods

A cross sectional survey was conducted using a self designed questionnaire. Institutional ethical clearance was obtained from the KLE VK Institute of Dental Sciences. The questionnaire covered general information, treatment specific issues and consent.

The list of 128 registered practising dentists in the city was obtained from the Belgaum branch of the Indian Dental Association. The questionnaire was pre-tested on 10 GDPs. Those interviewed in the pre-test were excluded from the final study. The remaining 118 practitioners were approached to participate in the study. The researchers approached the GDPs in person with the questionnaire. The GDPs were also given a written consent form to sign before they were enrolled into the study. 80 agreed to participate in this study and returned the signed questionnaires along with a signed consent form. The researchers personally collected the completed questionnaires from the GDPs. Of the 80 questionnaires that were returned, 44 questionnaires were completed; these 44 were included in the study. The results were tabulated and percentages were calculated.

## Results

*General information:* 42 of 44 GDPs were male. 23 GDPs had a bachelor's degree and 21 had a master's degree in dentistry. The duration of the dentist's practice ranged from six months to 29 years. All the GDPs offered all general dental treatments including consultation and treatment for oral and maxillofacial surgery and orthodontics. 2 GDPs said they also offered implants at their clinics. The Karnataka State Dental Council (the statutory body) registration certificate was displayed by 20 GDPs (45.5%).

*General clinical practices followed by GDPs:* 41 GDPs (93.2%) stated that they discussed the various treatment modalities available at their clinic with their patients before starting treatment. 3 GDPs (6.8%) reported that they did not explain the various treatment modalities available.

39 said they noted all findings and treatment on the patient's case paper. Of these 39 GDPs, 28 reported that they took the signature of patients on the case papers. 11 said they did not take the patient's signature.

6 GDPs (13.6%) stated that they took the final decision on the treatment to be carried out on the patient. 30 GDPs (68.1%) stated that they left this to the patient to decide. 5 GDPs (11.3%) said that they decided on the best treatment option along with their patient. 3 GDPs (6.7%) said that this depended on the type of cases that they received.

*Information given on risks and discomforts of procedures:* 37 (84.1%) said they gave a detailed explanation of any procedure to be carried out and the complications associated with local anaesthesia. 36 (81.8%) said they gave the success and failure rate of root canal therapy before treatment. 37 (84.1%) said they explained the success and failure rate of periodontal surgery and its associated complications. 30 GDPs (68.2%) said that they did not find it necessary to discuss the gag reflex and how to overcome it.34 GDPs (77.3%) said that they did not advise their patients about the various treatment facilities available during replacement of teeth. 34 GDPs (77.3%) stated that that they did not inform their patients on the amount of radiation exposure while taking radiographs. 35 GDPs (79.5%) said they explained in detail the procedures, duration and costs associated with orthodontic treatment.

*Taking consent*: all 44 GDPs stated that they took consent before starting any procedure. 28 GDPs (63.6%) took written consent from the patient. 16 GDPs (36.4%) stated that they took only oral consent. All 28 of those who took written consent took general consent, not treatment-specific consent. 4 of them obtained written consent in the local language; the remaining obtained consent in English.

When taking consent from illiterate patients, 21 GDPs (47.7%) reported taking verbal consent. Of the remaining, 7 took the patient's thumbprint, 9 GDPs stated that they took the relative's signature, and 7 GDPs stated that they obtained verbal consent, as well as the patient's thumbprint on the consent form.

16 GDPs (36.4%) said that they provided a copy of the consent form to the patient if asked. 20 (45.5%) said they asked for a reason before giving the form, 8 GDPs (18.2%) said they refused to give a copy of the consent form to the patient.

| GDPs' awareness of informed consent | | | | |
|---|---|---|---|---|
| **Question** | **Number** | **%** | **Number** | **%** |
| Are you aware that one copy of the informed consent form should be given to the patient if asked for? | 11 | 25% | 33 | 75% |
| Do you find taking written consent time consuming? | 18 | 40.9% | 26 | 59.1 |
| Do you believe that a consent form is necessary for every treatment provided at your clinic? | 23 | 52.3% | 21 | 47.7% |
| What are consent forms for? | | | | |
| (i) To protect the doctor | 31 | 70.4% | | |
| (ii) To protect the patient | 1 | 2.3% | | |
| (iii) Both | 12 | 27.3% | | |
| Are you aware of the Consumer Protection Act? | 44 | 100% | | |

11 GDPs were aware that a copy of the informed consent form should be given to the patient if asked. 18 GDPs (40.9%) stated that they found obtaining written consent time consuming. 23 GDPs (52.3%) said written consent should be obtained for every treatment.

31 GDPs stated that consent forms are to protect the doctor. 1 said it was to protect the patient. 12 said it was for both.

All 44 GDPs were aware of the Consumer Protection Act.

## Discussion

An important medico-legal concern is improper consent and withholding complete information from the patient. This has been the subject matter of judicial scrutiny in various cases under the Consumer Protection Act (CPA) as it pertains to patients' rights.

The consumer movement in the 1980s led the government of India to enact the CPA in 1986, paving the way for the establishment of consumer courts. The CPA is meant to protect the rights and interests of consumers, those who hire or avail of services from others. Compensation is judged and decided upon the doctrine of deficient service, unfair trade practice. The Supreme Court of India, in a landmark judgment on November 13, 1995, included the healthcare profession under section 2 (1) (0) of the CPA, 1986 (11). This includes a) all medical and dental practitioners doing independent medical or dental practice unless rendering only free service; b) private hospitals charging all patients; c) all hospitals having free as well as paying patients and all paying and free category patients receiving treatment in such hospitals, and d) medical or dental practitioners and hospitals paid by an insurance firm for the treatment of a client, or by an employer for the treatment of an employee. The CPA exempts only those hospitals, and medical or dental practitioners in such hospitals, offering free services to all patients.

The Supreme Court of India has also given the following guidelines on informed consent: A doctor must seek and secure the consent of the patient before starting treatment. The consent so obtained should be real and valid. The information should include the nature and procedure of the treatment and its purpose, benefits and effect, alternative treatment if any available, an outline of the substantial risks and the adverse consequences of refusing treatment. The Supreme Court judgment emphasised the need for specificity of consent. Consent given only for a diagnostic procedure cannot be considered as consent for a therapeutic procedure. Consent given for a specific procedure will not be valid for conducting another procedure. However, there can be a common consent for diagnostic and operative procedures where they are contemplated. Consent can also be sought for a particular surgical procedure that also explicitly covers additional or further procedures that may become necessary during the course of surgery. The nature and extent of information to be furnished by the doctor to the patient to secure the consent should be acceptable as normal and proper by a body of medical men skilled and experienced in the particular field (12).

*Record keeping:* Only 20 GDPs (45.4%) had displayed the Karnataka State Dental Council registration certificate. In India, the Dentists Act of 1948 (13) regulates the profession of dentistry by constituting a Dental Council of India (DCI) under section 3 and state dental councils under section 21. The DCI maintains the Indian Dentists Register which contains information on all the dentists registered in the state. State dental councils are empowered to punish persons who claim to be registered and/or practise dentistry without registration with a fine or imprisonment or both (9). Display of the registration certificate lets the patient know that the person who is treating them is authorised to render treatment.

| Clinical practices followed by GDPs | | |
|---|---|---|
| **Question** | **Yes** | **No** |
| Before starting the treatment do you inform the patient of all the treatment options available? | 41(93.2%) | 3(6.8%) |
| Do you note down all the findings and treatment to be followed on the case paper? | 39(88.6%) | 5(11.4%) |
| If yes, do you take the patient's signature on the records? | 28/39(71.7%) | 11/39(28.2%) |

All 44 GDPs stated that they maintained patients' records. This could be seen as an indication of their professional conduct and their awareness of the need to maintain records for further treatment. However, 5 GDPs (11.4%) said that they did not write down their findings on the case paper, so it is not clear what these dentists' records included. 11 GDPs (25%) said that they did not take the patient's signature on the case papers. 5 GDPs (11.4%) said that they neither recorded their findings nor took the patient's signature. If these dentists are accused of negligence they will not have documentation to support their case.

*Discussing treatment options:* 41 GDPs (93.1%) stated that they discussed the various treatment modalities available at their clinic with their patients. 3 GDPs (6.8%) reported that they did not explain the various treatment modalities available. The present study did not take into account the reasons for not informing patients about the various treatment modalities.

*Discussing risks:* The questionnaire contained questions on procedures routinely performed at the dentists' clinics. It is important for a dentist to convey that all treatments can have risks as well as side effects. This is especially so in aesthetic dentistry. The dentist should explain every aspect of the treatment to a patient who wants the implant or orthodontic surgical procedure, especially when it is cosmetic in nature. It should be emphasised to the patient that there are risks and side effects. Some of them are mildly inconvenient, others can cause inconvenience in routine life and others are serious. The recovery time and the extent of benefits can vary. Certain diagnostic investigations such as taking impressions can trigger a gag reflex. Patients need to be prepared for this discomfort. Dentists also need to convey information prudently; sensible dentists will use their discretion in deciding what to reveal and how to discuss the risks and benefits of the treatment.

| Information given before initiation of treatment | | |
|---|---|---|
| **Question** | **Yes** | **No** |
| Do you give a detailed explanation of the procedure and explain the complications associated with local anaesthesia? | 37 (84.1%) | 7(15.9%) |
| Do you give the success and failure rate of root canal therapy before treatment? | 36 (81.8%) | 8(18.2%) |
| Do you explain the success and failure rate of periodontal surgery and its associated complications? | 37(84.1%) | 7(15.9%) |
| Do you ask patients about the degree of gag reflex that they have before taking an impression? | 14 (31.8%) | 30(68.2%) |
| Are your patients advised about the various treatment modalities available during replacement of teeth? | 10 (22.7%) | 34(77.3%) |
| Before taking a radiograph, do you tell the patient about the amount of exposure to radiation | 10(22.7%) | 34(77.3%) |
| Do you explain in detail the procedures, duration and costs associated with orthodontic treatment? | 35(79.5%) | 9(20.5%) |

Patients need to be informed about these outcomes before starting with the procedure. 30 GDPs (68.1%) said that they did not find it necessary to warn the patient about the gag reflex or to educate the patient on how to overcome the gag reflex. 34 GDPs (77.3%) stated that it was not necessary to inform their patients of the amount of radiation exposure while taking radiographs. The reason they gave was that the hazard associated with it is minimal. The minimum exposure time for an intra oral radiograph using a standard X-ray machine with 60-70kvp is 3.6-4.8mAs (miliampere seconds). The dose of exposure should not exceed 50mSv (mili Sievert) in persons who are not exposed to radiation in the workplace. In cases of frequent exposure these limits may be exceeded (14). L Doyal and H Cannell in their article on informed consent and the practice of good dentistry have discussed a case of negligence

against a dentist, in which the plaintiff stated that the doctor did not tell her about the hazards of radiation exposure. Her radiographs were taken shortly after she became pregnant. At that time, she knew nothing of the risks of radiation. Once she learned of the risks, her anxiety about the safety of her baby sent her into serious depression for which she needed treatment. This effectively ruined the experience of pregnancy for her and her partner. The authors concluded that a written note of treatment options explained to patients and countersigned by them should become a part of normal treatment practice (2).

| GDPs' practices regarding obtaining informed consent | | | | |
|---|---|---|---|---|
| | Yes | | No | |
| Question | Number | % | Number | % |
| Do you take consent before starting any procedures? | 44 | 100% | | |
| If yes (44) * | | | | |
| (i) Written | 28 | 63.6% | | |
| (ii) Oral | 16 | 36.4% | | |
| If written (28) * | | | | |
| (i) General consent | 28 | | | |
| (ii) Treatment-specific consent | Nil | | | |
| Is the written consent obtained in the local language? | 4 | | 24 | |
| Type of consent obtained from an illiterate patient | | | | |
| (i) Verbal consent | 21 | 47.7% | | |
| (ii) Patient's thumbprint | 7 | 15.9% | | |
| (iii) Signature of relative | 9 | 20.5% | | |
| (iv) Verbal consent and thumbprint | 7 | 15.9% | | |
| | | | | |
| If patient asks to take a copy of the consent form do you provide a copy? | | | | |
| (i) Provide the form willingly | 16 | 36.4% | | |
| (ii) Ask for a reason before giving form | 20 | 45.5% | | |
| (iii) Refuse to give the form | 8 | 18.2% | | |

*Consent:* In general, the consent process provides an opportunity for the dentist to create a good patient-clinician relationship by communicating with the patient regarding the details of the treatment, tailoring the information to the specific needs and understanding of the patient. It also allows for the patient to express his/her opinion and concerns. This can build patients' trust and confidence in the dentist as they feel that they are in control of the decisions in their treatment.

28 GDPs (63.6%) took written consent from the patient. 16 GDPs (36.4%) stated that they felt the need to take only oral consent. Most dental treatments involve "implied consent". For example, the patient opens his mouth for examination and allows a procedure to be done. However, implied consent may not provide sufficient protection for the dentist against legal action. Expressed consent is obtained from a patient for a specific procedure and should be obtained for all procedures that are not routine and carry a material risk (5). Oral consent is one form of expressed consent and is normally adequate for routine treatment such as fillings and prophylaxis (15). But it should be witnessed and properly documented in the patient's record. Apart from this oral discussion, written consent should be obtained for any proposed therapy, and the information provided should include the risks and benefits of the treatment and also possible alternative therapies. Written consent is advisable as it may decrease liability from miscommunication (16).

28 GDPs (63.6%) who stated that they took written consent took only general consent, though they had specialty consultants visiting their clinics to treat their patients. This could be because of lack of awareness. Consent forms should be procedure-specific, and multiple forms may need to be used. For example, the risks associated with restorative procedures will differ from those associated with an extraction. Separate forms or separate sections for each procedure within one form are necessary to accurately advise patients regarding each procedure. Consent for sedation or behaviour guidance techniques such as protective stabilisation (immobilisation) should be obtained separately from consent for other procedures. Consent may need to be updated or changed as changes in the treatment plan occur. For example, a primary tooth originally planned for pulp therapy is found to be non-restorable at the time of treatment. In such cases consent should be updated to reflect the change in treatment (17).

Out of 28 GDPs who took written consent, only 4 (9%) were aware of the need to obtain written consent in the local language (Kannada and Marathi). 24 GDPs (91%) obtained written consent in the English language. India is a multi-lingual country where every state has its own language. So people of one area cannot communicate with others in the local languages. English is a universal language for Indians. Even then, most patients from rural India will know only the local language. Urban patients may know both English and local languages and schools in these areas teach both the languages. This study was conducted in an urban area where most patients would be aware of English. However, their familiarity with English would depend partly on their socioeconomic backgrounds. If consent is not taken according to the language with which the patient is familiar it becomes difficult to communicate with the patient. The dentist may require reliable interpreters to explain the procedure to the patient. It is important for the clinician to be aware of the interpreter's ability to accurately communicate information to the patients or their guardians (5).

In the case of illiterate patients, 21 GDPs (47.7%) reported taking verbal consent, 7 said they obtained the patient's thumbprint, 9 GDPs (20.5%) stated that they took the relative's signature and 7 GDPs (15.9%) stated that they obtained verbal consent and also took the patient's thumbprint on the consent form.

Although consent is generally sought from the patients themselves, there are occasions in which others may be involved. In situations where a patient cannot give consent, the patient's relative can give consent (1). Even verbal consent, if obtained properly, is valid. But later the patient may deny having been given information either because they have genuinely forgotten or because they have a grievance and wish

to strengthen a legal case against the dentist (2). Hence when the patient cannot give consent it is always advisable to take the signature of the family member along with a third party witness signature.

8 GDPs (18.1%) said they refused to give a copy of the consent form to the patient. This suggests that GDPs do not see the need to respect a patient's rights or they are not aware of changing trends in obtaining consent from patients.

33 GDPs (75%) said that they were not aware that if a patient asks for a copy of the consent form, it should be handed over.21 GDPs (47.7%) felt that there is no requirement of consent for every treatment provided at their clinic. The reason given was that routine dental treatments do not require written consent and oral consent is sufficient.

The Hippocratic Oath that granted doctors the right to decide in the patients best interest has been in conflict with the 21st century trend in the West of patient autonomy. However, the doctor-patient relationship in India is somewhat different from that in the West; here it is predominantly governed by trust, the doctor is an authority figure and considered the right person to decide treatment modalities. Patients' ability to provide informed consent is also influenced by factors like the overburdened health services, low literacy levels (18) and poor awareness about consumer rights (19). However in recent years, patients' increasing awareness of their rights has resulted in more formal complaints being filed against dentists for treatment without consent (2).

## Limitations

The conclusions of this study cannot be generalised due to the small sample size and the low response rate.

## Conclusion

The importance of consent to treatment cannot be over emphasised. It is believed that the best arguments in favour of fully informed consent are moral rather than legal. In the present study it was noticed that GDPs were less aware of the concept of written consent and its importance. They knew about the CPA but lacked knowledge regarding obtaining written consent. Emphasis should be given in undergraduate and postgraduate training on legal jurisprudence and legal medicine as this is essential for dentists to protect themselves from civil litigation (trespass, assault or battery) and even criminal proceedings for common aggravated or indecent assault. The effective procurement of informed consent promotes patient autonomy, engenders trust and confidence in medical professionals and reduces the risk of unnecessary legal claims premised on incorrect assumptions regarding appropriate medical care.

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