

# Knowledge, Attitude, Practices towards Informed Consent among Dental Practitioners in Western Maharashtra.

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#### ABSTRACT -

**Aim** – To assess the current knowledge, attitudes and perceptions towards Informed Consent and legal conflicts among dental Practitioners in western Maharashtra.

#### Material and Methods

The current cross-sectional questionnaire study was carried out among different Dental Practitioners on Western Maharashtra.. Through Gmail, a Google survey form was created, which was distributed using the "snowball exchange" method. The questionnaire consists of 30 questions divided under 3 headings a) Knowledge b) Attitude c) Practiced based.

**Result** – A total of 120 responses were collected in that maximum participants were between 21 to 25 years of age. Independent variables such as age , gender , qualification and type of Practice were assist for association with perceptions of informed consent. Majority of the study population felt the necessity of the informed consent in daily dental practices. In addition 83.3% of the professional population were aware of legal conflicts as they reported that if a doctor working in an institution does fault in providing treatment services without consent, then they will be liable before the law.

**Conclusion** – About 97.5% of the surveyed dentist are aware of importance of informed consent in practical dentistry and considered it as an ethical and legal obligation. Moreover, expressed consent is the preferred means of abtaining consent from patients for the most dental procedures. Majority (84.2%) of them responded that the questionnaire gave them additional information about law suites and preferred streamlining the process of informed consent through institutional review boards to avoid legal conflicts.

**KEYWORDS** - Conflicts, Dentistry , Ethics, Informed Consent , Legal

#### I. INTRODUCTION

In everyday practice, specialists and dentists encounter common ethical issues. The core issues of medical ethics are the ethics of the doctor-patient relationship, patient confidentiality, and the need to obtain informed consent, whereas bioethics is the overarching ethics of medicine and biomedical sciences<sup>(1,2)</sup>.

Informed consent is an essential tool in standard medical practice. The process of sharing information with patients is critical to their ability to make rational choices from multiple options for the best benefit<sup>(3)</sup>. This is generally recognized as an essential safeguard to ensure that individual rights are upheld<sup>(4)</sup>.

The basis for consent includes patient autonomy, adequate disclosure of significant risks, discussion of alternative treatments and outcomes, and the patient's ability to remain informed and make informed choices. From an ethical perspective, therefore, the role of consent to treatment is to protect patient autonomy<sup>(5,6)</sup>.

Conformed consent, routinely given in all health care settings, including dental school clinics, is an important source of information to help



patients make informed decisions about proposed treatments<sup>(7,8)</sup>. The concept of informed consent is based on moral, cultural and legal principles<sup>(9,10)</sup>. Informed consent is often considered necessary for legal protection against malpractice claims<sup>(11)</sup>.

In order for informed consent to be effective, it must contain sufficient information about the treatment or procedure. Furthermore, the information contained in the document should be clear and understandable to the patient. Several professional and government agencies have recognized the importance of consent by issuing guidelines on informed consent, and minimum legal requirements exist even at the state level. Informed consent is often considered necessary for legal protection against malpractice claims<sup>(12,13)</sup>.

It is not enough for a patient to sign a document to obtain informed consent. This includes communication between participants and their caregivers or researchers.

The consent form should contain five basic elements.

- Ability is the physical and cognitive capacity to participate fully in the informed consent process. Competence includes the ability to understand information on which one's beliefs and values are based and to make independent and rational decisions and choices<sup>(14)</sup>. "

- Patients should be informed about their dental problem and the nature, risks and benefits of the proposed treatment and other treatment options available to them, including non-treatment<sup>(15)</sup>.

- Effective consent requires understanding or comprehension of the consent process and information provided by the dentist. Dentists must actively involve patients in discussions, clarify problems, answer questions, and ensure that patients understand the information provided<sup>(14)</sup>. "

- Ensuring voluntarism protects the right of participants to make their own decisions. "Consent decisions should not be coerced or manipulated by the dentist or family.<sup>(16)</sup>" Dentists must share their concerns and justification for obtaining consent. Patients can change their minds and move on. When a dentist deliberately fails to do so, it violates ethical principles of charity<sup>(17)</sup>.

- A final decision or choice is very important to complete the consent process. Consent decisions can be made orally or in writing, but often require written documentation. To our knowledge, there are no micro- or macrolevel studies on dentists' perspectives on informed consent. Therefore, this study was conducted to assess knowledge, perceptions and attitudes towards informed consent among dental professionals.

## II. METHODOLOGY

A close ended questionnaire study was conducted among dental professionals in western Maharashtra to determine the knowledge, attitude, and practice among dental professionals about informed consent.

The participants were selected on the following educational criteria : BDS and MDS. The first part consisted of questions based on demographic data, second part consisted questions based on knowledge, third part consisted questions based on attitude, fourth part consisted questions based on practice about informed consent.

The questionnaire was prepared using Google forms [Google LLC, Mountain View, California, United States] and the link was distributed to the selected participants via email and whatsapp number.

Pilot study was performed in a population of 20 participants. Data collected were entered in a spread sheets [Microsoft excel 2016]. Statistical analysis was done using descriptive statistics. SPSS [Statistical Package for Social Science] 21 version software [IBM Chicago, Illinois, united states] was used for analysis.

The input parameters for the sample size calculation used were as follows : 80% power of the study, Alpha error 0.05, Effect size 0.5, Degree of freedom as 5. The calculated sample size was 81 using G\* Power software version 3.1.9.2 [Heinrich Heine university, Dusseldorf]. The final considered sample size for the study was around 120. The convenient sampling technique was used in the study. The reliability statistics calculated using Croanbach's alpha was 0.88. A questionnaire validity [Aikens V] of 0.84 was found to be sufficient.

## III. **RESULTS**

Table 1 – There were total 120 dental professionals out of which 39 were male and 81 were female , maximum participants were between 21-25 years of age.

Out of 120 dental professionals 70 of them were BDS and 50 were MDS. Maximum participants were General Practitioners and mostly all of them were aware of informed consent. ( Figure 1)



**Table 2** – It shows that almost 93.3 % dental Practitioners were aware of informed consent. When treatment was given to vulnerable group 83.3% of dental professionals take consent from Parents/ caregiver. If a child is between 4 to 17 years of age 97.5% dental Practitioners take consent from parents/ guardian. Around 97.5% Dental Professionals are aware that consent should be taken in private, corporate and government hospitals. Patient is informed about Informed Consent in their regional language by around 97.5% of dental professionals. Around 84.2% of them are aware about Informed Consent is taken under section 13 of Indian Contract Act, 1872.

**Table 3** - Among 120 dental Practitioners around 97.5% of them agreed that informed consent is necessary in dental practice. Consent should be taken for all minor and major procedures was agreed by 93.35% of dental professionals. In case of emergency 62.5% dental practitioners agreed that treatment can perform without consent. Witness is necessary for taking informed consent was agreed by 83.4% of dental professionals.

**Table 4-** Out of 120 dental Practitioners 7 96.6% of them often take consent. For minor procedures performe 88.3% of dental Practitioners take informed consent. Around 55% of dental practioner face challenges with complex language and medical terminology regarding informed consent documents.57.5% of patient face challenges with anxiety and fear, health status, cognitive

impairment in providing consent. Around 55% of dental practioner face challenges with poor communication and lack of time during informed consent process.

## IV. DISCUSSION

The current study was conducted among 120 dental Practitioners of Andhra Pradesh, India to assess their knowledge and attitudes toward informed consent with a 100% response rate. Moreover, the self-administered questionnaire which was used in this study was validated for the present study population. Moreover, participants are assured that their responses would be used solely for the research. In the present study, 97.5% of dental professionals acknowledged that there is a necessity for informed consent in dental practice. The Brazilian code of dental ethics mandates that any treatment procedure without patient consent will breach the ethical principles. Moreover, the dentists are encouraged to provide a copy of the consent document to the patient so that this copy can be revisited by the patient and read out of the dental office.

## V. CONCLUSION

Nighty Seven percentages of the surveyed dentists, are aware of the importance of informed consent in practical dentistry and consider it as an ethical and legal obligation. Moreover, expressed consent is the preferred means of obtaining consent from patients for the most dental procedure.

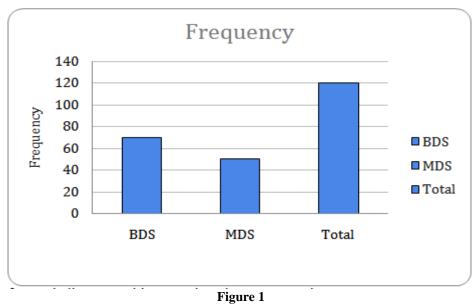




Table 1 : : AGE GROUP AND GENDER DISTRIBUTION COMPARISON						
SR.NO.		RESPONSES	FREQUENCY	PERCENTAGE(%)		
1)	Age	21-25 years	64	53.3 %		
		26-30 years	42	35 %		
		31-35 years	10	8.3 %		
		36-40 years	4	0.33 %		
2)	GENDER	MALE	39	32.5 %		
		FEMALE	81	67.5 %		
	TOTAL		120	100 %		

## Table 2 : Knowledge based

	Correct N (%)	Incorrect N (%)	P value (using Chi square test)
1. What is informed consent ?	117 (97.5%)	3 (2.5%)	P< 0.001**
2. What are the types of consent	119 (99.2%)	1 (0.8%)	P< 0.001**
3. What are the aspects of the treatment included under informed consent ?	118 (98.3%)	2 (1.7%)	P< 0.001**
4. Which of the following element is included in valid informed consent ?	118 (98.3%)	2 (17%)	P< 0.001**
5. What is Nuremberg Code?	112 (93.3%)	8 (6.7%)	P< 0.001**
6.How the Nuremberg Code (1947) help in the evolution of informed consent?	116 (96.7%)	4 (3.3%)	P< 0.001**
7.From whom consent is taken for treating vulnerable group ?	100 (83.3%)	20 (16.7%)	P< 0.001**
8. If a child is between 4 to 17 years of age , from whom the consent is taken?	117 (97.5%)	3 (2.5%)	P< 0.001**
9. How the consent is taken if the child requires treatment without the presence of parent or guardian?	112 (93.3%)	8 (6.7%)	P< 0.001**
10. Informed consent should be taken in?	117 (97.5%)	3 (2.5%)	P< 0.001**
11.In which language do you explain the informed consent to the patient?	117 (97.5%)	3 (2.5%)	P< 0.001**
<b>12.Role of Institutional Review Board (IRB)in informed consent for clinical trials</b>	117 (97.5%)	3 (2.5%)	P< 0.001**
13. In which condition the consent is not valid	117 (97.5%)	3 (2.5%)	P< 0.001**
14. What are the objectives of Consumer Protection Act?	119 (99.2%)	1 (0.8%)	P< 0.001**



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15. Under which section informed consent is taken?	101 (84.2%)	19 (15.8%)	P< 0.001**
16. What steps a doctor take in the event of a medical mishap (when patient flies a complaint)?	100 (83.3%)	20 (16.7%)	P< 0.001**

\*\*p< 0.001 – highly statistical significant dfference

Table 3: Attitude based								
	Strongly agree N (%)	Agree N (%)	Neutral N (%)	Disagree N (%)	Strongly Disgaree N (%)	P value		
17. Informed consent is necessary in dental practices	85 (70.8%)	32 (26.7%)	3 (2.5%)	0 (0%)	0 (0%)	P<0.001**		
18. Do you think patients consent helps to gain confidence and cooperation of patient for treatment	71 (59.2%)	44 (36.7%)	3 (2.5%)	0 (0%)	2 (1.7%)	P< 0.001**		
19. Does informed consent provide respect for autonomy	51 (42.5%)	60 (50%)	7 (5.8%)	2 (1.7%)	0 (0%)	P<0.001**		
20. If a professional working in an institution does the fault in providing treatment services without consent,do you think an individual hospital or both should be liable before the law?	40 (33.3%)	60 (50%)	19 (15.8%)	1 (0.8%)	0 (0%)	P<0.001**		
21. Consent should be taken for all the minor and major procedures	72 (60%)	40 (33.35)	8 (6.7%)	0 (0%)	0 (0%)	P<0.001**		
22.Do you feel any indiminity insurance or any policies protect the professional from malpractice law suites	44 (36.7%)	53 (44.2%))	21 (17.5%)	2 (1.7%)	0 (0%)	P<0.001**		
23. In case of emergency the practitioner can perform the procedure without the consent	32 (26.7%)	43 (35.8%)	27 (22.5%)	16 (13.3%)	2 (1.7%)	P<0.001**		
24. Do you feel that witness is absolutely necessary for taking informed consent?	41 (34.2%)	59 (49.2%)	16 (13.35)	3 (2.5%)	1 (0.8%)	P<0.001**		

Table 3: Attitude based

\*\*p< 0.001 – highly statistical significant dfference



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Table 4: Practice based						
	Always N (%)	Often N (%)	Rarely N (%)	Disagree N (%)	P value	
25.How often do you take informed consent	94 (78.3%)	22 (18.3%)	2 (1.7%)	2 (1.7%)	p<0.001**	
26. Do you take consent for minor procedures ?	78 (65%)	28 (23.3%)	9 (7.5%)	5 (4.2%)	p< 0.001**	
27. When a trauma case/ emergency patient come to your clinic do you perform the immediate procedure without consent?	33 (27.5%)	31 (25.8%)	35 (29.25)	21 (17.5%)	p =0.276 (NS)	
28. Do you face challenges with complex language and medical terminology regarding informed consent documents?	35 (29.2%)	31 (25.8%)	46 (38.3%)	8 (6.7%)	p<0.001**	
29. Does patient face challenges with anxiety and fear,health status, cognitive impairment in providing consent ?	35 (29.2%)	34 (28.3%)	45 (37.5%)	6 (5%)	p<0.001**	
30. Do you ( Practitioner) face challenges with poor communication and lack of time during informed consent process?	42 (35%) * <b>n&lt;0.05 - s</b>	24 (20%)	35 (29.2%)	19 (15.8%)	p =0.012*	

p>0.05 – no significant difference (NS)

\*p<0.05 – significant

\*\*p< 0.001 – highly significant

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