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Beyond Consent: The Need for a Comprehensive Legal Framework for Informed Consent in Medical Treatment in India

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INTRODUCTION

Consent is an integral component of every medical treatment, whether therapeutic or surgical. More importantly, such consent must be informed. If a medical practitioner treats a patient without his/her consent then it will lead to trespass of body under tort and several other criminal laws for assault and battery. In rare cases, a patient's organs may be removed without valid consent. The answer of the following argument can be easily given by the Article 21 of the Indian Constitution, which clearly says that every person has the bodily autonomy. Consent reflects the right to autonomy each person has on his body. Taking an informed consent prior to every treatment is legally as well as ethically important. The exception only left with the cases of emergency. If a medical practitioner waits for the consent of patient in emergency or does not treat the patient in emergency situation giving the reason of lack of consent then the medical practitioner will be held legally as well ethically liable for the same. In other words, consent is not a mandate during the time of emergency cases, the only mandate at that time is patient's life**. National Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations of 2019** [1]talks about informed consent doctrine which is American in origin. A patient has the right to know

[1] National Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations, 2023- reg

every risk and benefit of the treatment, about his condition, timeline of the treatment, nature of the disease, nature of the treatment, situation of his body, side effects of the treatment, cost of the treatment, past experience of the doctor, including the other options he can opt to treat his disease. Information imparted makes a patient eligible to make a balanced decision whether he has to submit himself to the treatment or not. This article in its later phase will explain why India does need separate legislation for the consent in medical treatment.

WHERE DOES CONSENT COME FROM?

The setting up of this fundamental expression of autonomy starts from the Nuremberg Code of 1947 after World War II require to take voluntary and informed consent of human subjects.[2]In the same way, the declaration of Helsinki adopted by World Medical Association in 1964, brief the importance of informed consent in medical treatment. [3]Consent can be oral, written, implied or explicit and nature of the consent is acceptable on the premises of the situation. Situation can be analyzed through the treatment which patient has been demanding. Implied consent can work for diagnoses but nor for intimate diagnoses. Similarly, oral consent can be applicable in therapeutic treatment not in operative treatment. India does not have a comprehensive standalone legislation governing informed consent in medical treatment. Although, consent is the core element in medical treatment. Cases of medical negligence govern through tort law and criminal law in India.

What is Consent?

Consent is the voluntary and active agreement to do something or allow an action to happen. Consent given by a patient to medical practitioner is allowing the him an action to his body. Consent is defined under Section 13 of the Indian contract Act, 1872 for the purpose of official agreement between two parties.[4] It is up to the patient to accept or reject the treatment even when it is vital for him to be treated by the doctor. No doctor can forcefully provide the treatment to the

[2] Neurenberg Code 1947

[3] Declaration of Helsinki 1964

[4] Indian Contract Act, Sec 12; 1872.

patient if he is denying to give consent. In tort law, usage of force against any human body, without proper justification, is actionable irrespective of quantum of force.

There are different types of consent:

Implied Consent: Implied consent can be decoded when a patient enters into the cabin of the doctor and communicate his problem with him to treat the disease or giving him further guidance. This type of consent can be applicable simply for the purpose of basic clinical diagnoses. In which doctor examine the patient to identify the disease primarily based on the symptoms, reports and medical history of the patient.

Oral Consent: Consent given by the patient orally in the presence of the witness to treat the doctor for the purpose of intimidate diagnoses (vaginal examination) or treatment such as therapeutic, counselling sessions and mainly the treatment where there is no such kind of risk which can have negative consequences on the body of the patient.

Written Consent: Written consent comes into picture when treatment of the disease can risk the life of the patient. This can include surgical operations where doctor has to remove some organ from the body such as appendix or removing of gall bladder. Bypass surgery, surgery to remove the cancer from the body or in the operation for sterilization. Written consent is always easier to prove. The written consent form must be in the language understandable by the patient or may be in his regional language. If the patient is illiterate than the thumb impression should be taken after delivering every information to him in front of the witness who should be the close family member and literate. Sometimes video recording of the consent when there is the case of organ transplant.

Informed Consent: Critical element of any medical treatment is informed consent not merely consent. A patient can give voluntary consent on the basis of the information provided by the doctor but that consent can not be claimed as valid until the doctor give all the relevant information covering the patient. In other words, a patient can be called as disguised by the doctor just to opt the consent by the doctor. A completed informed consent should be backed by complete information of each and every minute detail related to the treatment to the patient by the medical practitioner. Patient should have the complete idea about the disease diagnosed by the doctor, treatment to cure it, expense of the treatment, experience of the doctor, other related alternatives to treat the disease and the doubts which remain to the patient should be clear by the doctor in the

language understandable to him. First case in India which talks about importance of informed consent is ***Ram Bihari Lal v. Dr. I.N. Shrivastava***[5]**.** In addition to this if patient has the right to know each and every of the disease and about the doctor. Doctor should also have the complete right to know even the minute detail of the concerned patient to treat the disease. There is no valid consent if it is opted for illegal operation or procedure.

This is the duty of the doctor to keep each and every detail of the patient with him only to respect the right to privacy of the patient. Publication of any report, scanning of the patient must not disclose on social media or at any other platform. If the name of the patient and details of his disease leak by the doctor or hospital it will come under the breach of right to privacy of the patient given under Article 21 of the Indian constitution with the landmark judgement of ***K.S Puttaswamy v. Union of India and others.***[6]One exception where physician can behold his duty in giving full information is when patient refused to be informed or if patient is anxious but he has to disclose it to patient's close relative, family or both.[7]

Blanket Consent: Consent cannot be blanket it should be procedural. For each and every treatment doctors have to take separate consent. Oral Consent for physical examination cannot work for therapeutic treatment. ***M.Chinnaiyan v. Sri. Gokulam Hospital and Anr.*** [8]Represents the prefect example where court awarded compensation as patient was transfused blood in absence of specific consent for the same. Even for re-exploration a fresh consent has to be obtained ***Dr. Shailesh Shah v. Abhraim Jayanand Rathod.***[9]

Who can give Consent?

According to the Indian Majority Act, 1875 the legal age of giving consent is 18 years and 12 to 18 years children for giving consent to physical examination. [10]The person who attains the age of 18 years should be of sound mind, should not be in influence of any drug or alcohol, should not be

[5] Ram Bihari Lal v Dr. J. N. Srivastava, AIR 1985 MP 150.
[6] Justice K.S. Puttaswamy (Retd.) and Another v. Union of India and Others, (2017) 10 SCC 1
[7] Kannan JK, Mathiharan K. Legal and ethical aspects of medical practice. In: Modi A, editor. Textbook of Medical Jurisprudence and Toxicology. 24th ed. Nagpur: Lexis Nexis Butterworths Wadhwa; 2012. p. 61-118
[8] M. Chinnaiyan vs. Sri. Gokulam Hospital and Anr on 25 September, 2006. III (2007) CPJ 228 NC.
[9] Dr Shailesh Shah vs Aphraim Jayanand Rathod. National Consumer Disputes Redressal Commission New Delhi, FA No. 597 of 1995. From the order dated 8 Nov, 1995 in complaint No. 31/94, State Commission Gujarat
[10] The Indian Majority Act, 1875 Sec 3,

disqualified by the law and capable of understanding the consequences of the treatment. The consent should be free from coercion, undue influence and misrepresentation. The law presumes that a person attains rationality, autonomy and freedom when he reaches the age of 18 years. No one can consent on behalf of competent adult. If patient is not capable of giving consent then consent can be taken from a proxy decision maker who is next to kin (Spouse/adult child/parent/sibling/lawful guardian). [11]

For the consent in case the patient is minor then the consent of parents, legal guardian or loco parentis is considered as valid. Consent of minor according to Indian Contract Act, 1872 is not considered as a valid consent. In the cases of sterilization consent of spouse is mandatory as directed by ministry of health and family welfare.[12]

Exception lies in the case of an emergency a medical practitioner need not to take the consent. Apex court has ruled that a medical practitioner has the duty to treat a patient in emergency. It does not amount to battery (intentional, unconsented and unlawful force used against someone body without their consent) if medical practitioner treats the patient in case of emergency without taking his consent. Refusing treatment in life threatening situation due to absence of consent can held a doctor liable provided there is no prior documented refusal by the patient as directed in case of ***Dr.TT Thomas v. Smt. Elisa and ors case.***[13]

Failure on the part of government hospital to provide timely medical assistance to a person in need of such treatment results in violating of his Right to Life guaranteed under Article 21 of the Indian constitution. The laws which speak against this right must be give away as detailed in Article 13 of the Indian Constitution.[14]

India has witnessed the paternalistic notion of the doctor. Where doctors acting as sans valid without the consent of patient to provide the best treatment to the patient. But this nature is considered as unlawful. ***Samira Kohli v. Dr. Prabha Manchanda and Anr, the doctor was held negligent for performing the additional procedure without taking the consent of the patient.***

[11] Arora V. Role of consent in medical practice. J Evol Med Dent Sci 2013;2:1225-9.
[12] Standards for Female Sterilization (1.4.4), Standards for Male Sterilization (2.4.4). In: Standards for Female and Male Sterilization Services. Research Studies and Standards Division, Ministry of Health and Family Welfare Government of India; October, 2006.
[13] TT Thomas (Dr.) vs Elisa, AIR 1987 Ker. 52.
[14] Paschim Banga Khet Mazdoor Samity and Ors v State of West Bengal and Another, (1996) 4 SCC 37.

This case is the perfect example of professional paternalism.[15] An additional procedure maybe done in the situation where it is important to save the life of the patient. Patient can withdraw his consent at any time in between the treatment and medical practitioner has to stop the treatment when withdrawn by the patient. If stopping the procedure in between puts the life of the patient in danger doctor may proceed with it.

CONCLUSION

India does not have separate legislation for consent in medical treatment. It is a must need of the time to make a separate legislation which can punish the doctor for not taking informed consent, conceals any fact from the concerned patient or intentionally giving any wrong advice to the patient. Similarly goes with the patient, a patient should be held liable if he conceals any information from the doctor required for the treatment.

There should be the proper format for the written consent form which must include:

- Date and Time
- Patient related: Name, age and signature of the patient/proxy decision maker
- Doctor related: Name, registration number and signature of the doctor
- Witness: Name and signature of witness
- Disease-related: Diagnosis along with co-morbidities if any
- Surgical procedure related: Type of surgery (elective/emergency), nature of surgery with antecedent risks and benefits, alternative treatment available, adverse consequences of refusing treatment
- Anaesthesia related: Type of anaesthesia (general and/or regional, local anaesthesia, sedation) including risks
- Blood transfusion: Requirement and related risks
- Special risks: Need for post-operative ventilation, intensive care, etc

[15] Samera Kohli v Dr. Prabha Manchanda and Another, 2008(1) SCALE 442.

- Document the fact that patient and relatives were allowed to ask questions, and their queries were answered to their satisfaction.[16]

Consent form should be in the most preferred language of the patient. After giving the form doctors should also explain thoroughly to the patient. It is the right of the patient to know each and every detail of the treatment by the doctor. In the years of 19th century there were not too much literacy in India. But as we are with the year 2026 life of people is changing swiftly. People are increasingly aware of the medical terminologies better than before. They may know the nature of the treatment even before consulting to the doctors. As society is changing faster, law has to be with the society. In the medical field doctor is always considered as on the dominating position than the patient. Patient believe the doctor as much as they could. This is the responsibility of the doctor to work in every good faith of the patient. Medical treatment give autonomy to the patient but it gives accountability of the doctor. Patient can only claim the accountability from the doctor when he has something definitive to claim and prove. A definitive legal framework would work in favor of both medical practitioner and patient.

[16] Kumar A, Mullick P, Prakash S, Bharadwaj A. Consent and the Indian medical practitioner. Indian J Anaesth 2015;59:695-700.