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REVIEW PAPER

Emerging Trends Related to Consent and Medical Practice in India

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ABSTRACT

Consent is not merely a signing ceremony where the patient signs the consent from in front of the doctor. Consent is a mandatory exercise in medical practice that involves explaining and disclosing to the patient, the requisite information necessary for the patient to take an informed decision. Thereafter, the patient exercises the right to decide whether to give his/her consent or not. In a case before the National Consumer Dispute Redressal Commission (NCDRC), the patient alleged that, "the consent read as if the mastectomy had already been decided and only some of its features needed to be explained to the patient". Unfortunately, a majority of consents in India fall under this category). [R-6]
It is difficult for the Court to accept contention of the doctor that because the general consent is taken, he can perform the operation in the way he likes. But, that would not give surgeon any discretion to do whatever surgeon chooses. This would also be against the medical ethics, and the purpose for which express consent is obtained.This paper deals with emerging trends related to issue of consent and medical practice in India based on Indian case law.

Key Words: *Informed Consent, Oral Consent, General Consent, Negligence*

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INTRODUCTION

Issue of consent is a low priority area for most of the doctors due to lack of awareness on legal rights of others and illiteracy of patients and as well as no awareness about their rights and no faith on judiciary due to complexity of legal procedures and cost of litigation.[1]
The law as settled by the **Apex Court** inSpring Meadows HospitalandAnr. Vs. Harjol Ahluwalia andAnr. (1998)[2]:"………The relationship between the doctor and the patient is not always equally balanced. The attitude of a patient is poised between trust in the learning of another and the general distress of one who is in a state of uncertainty and such ambivalence naturally leads to a sense of inferiority and it is, therefore, the function of medical ethicsto ensure that the superiority of the doctor is not abused in any manner…"
In recent days there has been increasing pressure on hospital facilities, falling standard of professional competence and in addition to all, the ever-increasing complexity of therapeutic and diagnostic methods and all this together are responsible for the medical negligence. That apart, there has been a growing awareness in the public mind to bring the negligence of such professional doctors to light."[2]

CASE LAW ON SPECIFIC CONSENT

In a Consumer Court Case[3] where doctor performed Vaginal Hysterectomy (VH) and taken written consent for TAH, decided by the NCDRC, doctor deposes in Paras 18 and 19 of her affidavit that "*Under the circumstances Gynecologists, with experience in vaginal surgery, would certainly prefer to perform hysterectomy through vaginal route. In the same situation, I would have also performed, vaginal hysterectomy, as it would have been in the interest of the patient.*"

NCDRCobserved that then, in such set of circumstances, it cannot be said that the operating surgeon can carry out the surgery of his / her choice, because he / she may be expert in the field. If he/she does so, he/she does it at his/ her risk and mishap.[3]

ETHICAL ISSUES INVOLVED WITH CONSENT

The Complainant in a case, with regard to relevance of consent, has quoted excerpts of the Medical Code of Ethics**, as under:**

"The followings acts of commission or omission on the part of the physician shall constitute professional misconduct rendering him / her liable for disciplinary action. **7.16**: Before performing an operation the physician should obtain in writing the consent from the husband or wife, parent or guardian in the case of minor, or the patient himself as the case may be."[4]

AGE OF CONSENT (CAPACITY TO CONSENT)

Research paper titled "Age of Consent: Food for Thought"[1] has discussed in detail about the controversy in the literature on the issue of age of consent and its solutions. Even recently published guidelines and protocols for examination of woman for sexual offences[5] has mentioned the age of consent as 12 years, which has inherent conflict with the definition and meaning of 'Examination' under Section 53, 53A of the Criminal Procedure Code, 1973.

CASE LAW ON CAPACITY TO CONSENT

In another consumer court case[6] before NCDRC, following facts related to 'Issue of Consent' emerged:

Questions for Consideration: From the rival arguments summarised above, the issues that arise for determination in this case are as under:

(i.), (ii.) and (iii.)Whether.....?

iv. Whether the consent for the surgery obtained in this case can be considered a valid consent?

v. Whether, in the given circumstances, there is a case of medical negligence/deficiency in service on the part of the NIMS and the doctors attending on Kumari? [Para 11][6]

Question No. (iv and v) **was related to issue of consent**: NCDRC observed that as regards the **thirdissue ofconsent for the surgery**, the law on the subject has been laid down in Para 48 and 49 by the Apex Court in ***Samira Kohli vs. Dr. Prabha Manchanda*** [(2008)[7]:

(b) The original record of the case before the State Commission shows that the consent for the surgery was recorded on 18.09.1997 in the following words:

"***Consent for the surgery"***

We have been explained the surgery, its necessity, associated risks/complications and the procedure of mastectomy and hereby give consent for the surgery of mastectomy, anaesthesia and blood transfusion as required necessary.

Signature: D. B. Eswari

Relationship: Daughter"

NCDRC observed that it is totally unclear why, when that consent was taken on 18.09.1997, it could not be Kumari's own consent because she had already been admitted as an inpatient.

Consent is a Process of Communication and not an event:

NCDRC emphasised that the law laid-down on the subject (supra) is explicit that when a patient is in a position to give consent, the consent has to be taken from him/her only.

NCDRC further added that, the doctor concerned (or at least a member of the team of doctors attending on the patient) has to explain the pros and cons of the disease and as well as the available and suggested courses of treatment. In this case, it is obvious that neither the Surgical Oncologist himself nor the Dr.Sridhar (Senior Resident) came and explained to Kumari before obtaining her consent (or, for that matter consent of D. B. Eswari) the whole process appears to have been carried out by some student nurse. Hence, we have no hesitation in holding that the "consent" taken in this case was neither **"real"** nor "valid." [Para 13][6]

NCDRC concluded that, we have no hesitation in holding that the respondent NIMS was guilty of medical negligence and deficiency in service on the part of the main Doctors, viz., Dr. Raju and Dr. Prayag who provided treatment to D.H. Kumari that culminated in a hasty, medically unsupportable, rather insensitive and hence a most traumatic decision to remove her left breast. [Para 14][6]

COMPENSATION AWARDED

NCDRC observed that while no amount of money can indeed compensate a woman of 46 years for the physical pain and injury, feelings of personal violation and emotional trauma caused by a set of negligent acts leading to removal of a breast.

NCDRC holds that in our view, the ends of justice in this much-delayed case would perhaps be met if the sum of Rs. 10 lakh were awarded as compensation. [Para 15(a)][6]

CONSENT AND CIVIL AND /OR CRIMINAL ACTION

The **M.P. State Commission** observed in a case[8]that 'in medical field the word 'consent' carries a great importance. The concept of consent is not new to the modern world. Consent plays a remarkable legitimate role in the field of medical negligence. The consent should be **a free consent** as envisaged by **Section 10 of the Indian Contract Act** in the context of medical negligence.

A duty is cast upon a medical practitioner to provide that he did not use any **undue influence** in order to get a legally valid consent from a patient and he has at no point of time utilized his **dominant and superior position** in obtaining consent from **patient** who is always practically in **a precarious need** and **difficult position**. In case the consent is not obtained that will give rise to cause of action for seeking a remedy criminally for making any invasive procedure without consent of patient amounting to assault, with criminal force under **Section 350 IPC** and also seek civil remedy for compensation for the injury occurred to the patient in accordance with Law of Tort.[8]

According to **Law of Tort**, if the doctor does not seek a legally valid consent, and even if there are no damages in the form of negligence, the patient can sue the doctor for injury upon his personal or private rights encroached upon which has been endowed upon him by legislative enactment.[8]

The Commission further observed that the **principle requiring consent** applies in all the cases except in certain circumstances in which a doctor may be entitled to proceed without patient's consent, **firstly**, when the patient's balance of mind is disturbed; **secondly**, when the patient is incapable of giving consent by reason of unconsciousness; and **finally**, when the **patient is a minor**.[8]

ISSUE OF CONSENT IN AN UNUSUAL CASE

Division Bench of the SC, in a case[9], concerned with twominor girls, conjoint twins, faced with a situation where theirparental consent is not forthcoming either for investigation or for the surgical operation. [Para 10][9]

Saba and Farha, Craniopagus Twins (CTs), both female, are minors, togetherness, of course, will not bring joy to them or to their parents, to the family members or the people at large who happen to see them or heard about them. SC Bench observed that the doors of this Court have been knocked by a Good Samaritan and since this Court has a fundamental duty to look after the interest of minor children, especially when they are CTs, fighting for their lives. [Para 2][9]

SC had shown its dilemma in such situation in following words: we spent sleepless nights to find out a solution. Seldom society cares or knows the mental and psychological trauma, in such situations, Judges undergo, especially, when they are called upon to decide an issue touching human life, either to save or take away. [Para 2][9]

This case discussed "least detrimental test", Conflict of interest, rights of the minors, their right to life, their inter-se rights, inherent value of lives, right to bodily integrity, balancing of interests, best interest standards, parents views, courts' duty, doctors duty etc.[9]

Scope of consent and need for 'Specific Consent': NIMS vs. Prasanth S. Dhananka and Ors.,2009[10] was the First case in India where compensation of more than one crore has been awarded by the court of law. [Para 35][10] The complainant, who has argued his own case, had submitted before the SC in appeal, claimed about 7.50 Crores as compensation under various heads. He had, in addition sought a direction that a further sum of Rs. 2 crores be set aside to be used by him should some developments beneficial to him in the medical field take place. [Para 37][10]

Para 16-19 of the Judgment[10]deals with issue of 'consent' as follows:

……It was also pleaded that the consent that had been taken was only for the purpose of an excision biopsy which was an exploratory procedure, but Dr. Satyanarayana had carried out a complete excision removing the tumour mass and the fourth rib thereby destroying the inter-costal blood vessels leading to paraplegia and had a Neuro-surgeon been associated with the operation, this problem could well have been avoided. [Para 2][10]

NCDRC believed on 'Implied Consent':

The NCDRC has observed that as blood had been donated by the relatives of the complainant, it was likely that they had the information that a surgery was planned, as they were educated and enlightened persons. The Commission has, accordingly, held on the basis of the evidence of Dr.Satyanarayana "that once the consent for excision biopsy through thoractomy was given, the consent for a moment (sic) (removal?) of the mass was implied." [Para 16][10]

NEED FOR SPECIFIC CONSENT EMPHASIZED BY THE SC

It must, therefore, be held that the withholding of the aforesaid document raises a presumption against the NIMS and the attending Doctors. **We find that the consent given by the complainant for the excision biopsy cannot, by inference, be taken as an implied consent for a surgery (save in exceptional cases)**.

STERILIZATION OPERATION CANNOT BE JUSTIFIED UNDER THE PRINCIPLES OF NECESSITY

In Murrary vs. McMurchy (1949)[11], the Supreme Court of British Columbia, Canada, was considering a claim for battery by a patient who underwent a caesarean section. During the course of caesarean section, the doctor found fibroid tumours in the patient's uterus. Being of the view that such tumours would be a danger in case of future pregnancy, he performed a sterilization operation. The Court upheld the claim for damages for battery. It held that sterilization could not be justified under the principles of necessity, as there was no immediate threat or danger to the patient's health or life and it would not have been unreasonable to postpone the operation to secure the patient's consent. The fact that the doctor found it convenient to perform the sterilization operation without consent as the patient was already under general anesthesia was held to be not a valid defense.

The Court of Appeal in England in F. expressed a somewhat similar view, In re, (1933)[12]. It was held that the additional or further treatmentwhich can be given (outside the consented procedure) should be confined to only such treatment as is necessary to meet the emergency, and as such needs to be carried out at once and before the patient is likely to be in a position to make a decision for himself.

Lord Goff observed (All ER p.566g-j)

"...Where, for example, a surgeon performs an operation without his consent on a patient temporarily rendered unconscious in an accident, he should do no more than is reasonably required, in the best interests of the patient, before he recovers consciousness. I can see no practical difficulty arising from this requirement, which derives from the fact that the patient is expected before long to regain consciousness and can then be consulted about longer term measures." [Para 17][10]

The Court also considered the possibility that had the patient been conscious during surgery and in a position to give his consent, he might have done so to avoid a second surgery but observed that this was a non-issue as the patient's right to decide whether he should undergo surgery was inviolable. This is what the Court had to say:

"It is quite possible that had the patient been conscious, and informed about the need for the additional procedure, the patient might have agreed to it. It may be that the additional procedure is beneficial and in the interests of the patient. It may be that postponement of the additional procedure (say removal of an organ) may require another surgery, whereas removal of the affected organ during the initial diagnostic or exploratory surgery would save the patient from the pain and cost of a second operation. Howsoever practical or convenient the reasons may be, they are not relevant. What is relevant and of importance is the inviolable nature of the patient's right in regard to his body and his right to decide whether he should

undergo the particular treatment or surgery or not. Therefore at the risk of repetition, we may add that unless the unauthorized additional or further procedure is necessary in order to save the life or preserve the health of the patient and it would be unreasonable (as contrasted from being merely inconvenient) to delay the further procedure until the patient regains consciousness and takes a decision, a doctor cannot perform such procedure without the consent of the patient." [Para 18][10]

Issue of Confidentiality and Privileged Communication and Consent:

Cases came before Hon'ble SC[13, 14] in the year 1998, 2002 on the issue of 'Breach of Confidentiality' and 'Privileged Communication' where 'Right to Privacy' has been comprehensively discussed in relation to Consent.

INFORMED CONSENT FOR UNDERTAKING HIV TEST OR TREATMENT:

Subject to the provisions of HIV Act

i. No HIV test shall be undertaken or performed upon any person; or [Chapter III, Informed Consent, Section 5(1)(a)][15]

ii. No protected person shall be subject to medical treatment, medical interventions or research, except with the informed consent of such person or his representative and in such manner, as may be specified in the guidelines. [Chapter III, Informed Consent, Section 5(1)(b)][15]

Not a one time event, but an ongoing process: The informed consent for HIV test shall include pre-test and post-test counseling to the person being tested or such person's representative in the manner as may be specified in the guidelines. [Chapter III, Informed Consent, Section 5(2)][15]

CONSENT EMERGING TRENDS IN INDIA

HIV Bill, 2014 important provisions:

1. There are 50 Clause and XIV Chapters in HIV/AIDS Bill, 2014 introduced by then Union Minister of Health and Family Welfare, Mr.GhulamNabi Azad on *The* 31st *January*, 2014[15]

2. To prohibit certain specific acts of HIV-related discrimination, provide for informed consent for undertaking HIV test or treatment and also for disclosure of HIV status to ensure confidentiality and privacy, obligation of the establishments.

3. To ensure confidentiality and privacy while providing HIV and AIDS related services **"Informed consent"** means consent given by any individual or his representative specific to a proposed intervention without any coercion, undue influence, fraud, mistake or misrepresentation and such consent obtained after informing such individual or his representative, as the case may be, such information, as specified in the guidelines, relating to risks and benefits of, and alternatives to, the proposed intervention in such language and in such manner as understood by that individual or his representative, as the case may be; [Section 2(n)][15]

4. **"Capacity to consent"** means ability of an individual, determined on an objective basis, to understand and appreciate the nature and consequences of a proposed action and to make an informed decision concerning such action; [Section 2(b)][15]

5. **"Child affected by HIV"** means a person below the age of eighteen years, who is HIV-positive or whose parents or guardian (with whom such child normally resides) is HIV-positive or has lost a parent or guardian (with whom such child resided) due to AIDS or lives in a household fostering children orphaned by AIDS; [Section 2(c)][15]

6. **"HIV-related information"** means any information relating to the HIV status of a person and includes:

- Information relating to the undertaking performing the HIV test or result of an HIV test;
- Information relating to the care, support or treatment of that person;
- Information which may identify that person; and
- Any other information concerning that person, which is collected, received, accessed or recorded in connection with an HIV test, HIV treatment or HIV-related research or the HIV status of that person; [Section 2(l)(i), (ii), (iii), (iv)][15]

7. **"HIV test"** means a test to determine the presence of an antibody or antigen of HIV; [Section 2(m)][15]

CONCLUSIONS

Consent is an issue of respect for human rights of an individual under international law and under Indian Constitution. It is a low priority area among medical fraternity due to lack of proper training and understanding in curriculum for medical education.

There is need to include topics on consent in the medical curriculum with adequate time allotted for its teaching at the level of Medical Council of India, responsible for maintaining quality of medical education and healthcare in India.

Ethical Regulations, 2002[4] of framed by MCI hardly discussed on the issue, even age of the consent has not been mentioned in it causing confusing literature in textbooks published in India. There is need for comprehensivedocumentlike UK's GMC Guidelines with Problem Based case laws.

Recently introduced HIV/AIDS Bill[15] is a comprehensive document on the issue of 'Informed Consent' discussed from definition, capacity for consent till provision of information and counseling for HIV/AIDS testing and treatment with consent.

Many research papers[16, 17, 18]has covered various relevant issues related to consent, age of consent, real vs. informed consent, etc. to create awareness among medical fraternity.Properly informed written consent before operation is the necessity.[17]

It was suggested that either by filing a PIL, the issue of age of consent in medical profession can be solved. Alternatively Medical Council of India in consultation with Indian Medical Association and other professional and ethical bodies can come to a consensus about the age of consent. Accordingly authors of the books dealing with this topic edit their books to provide clear information about this human rights issue.[1]

With the creation of "Social Justice Bench" of the Hon'ble Supreme Court, court cases related to public interest, human rights issue related to health and consent are bound to come before the SC in future.[19] It is advisable to medical fraternity to start respecting fundamental rights of patients, especially related to issue of consent.

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Dr. Arijit Dey, Post Graduate Trainee of NRS Medical College, Calcutta, India was awarded the best Poster at ICFMT conference held at Greater Noida, UP in 2014