Law on consent and confidentiality in India: A need for clarity

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ABSTRACT

The concept of informed consent specific to medical research and treatment is still alien to many medical researchers and practitioners and to millions of Indians. The doctor–patient relationship in India is governed more by trust where the doctor is the authoritative person. Therefore, the benefit of informed consent does not reach all patients in day-to-day medical practice. To complicate the issue, the Indian law is not specific about the age at which a person can give valid consent. The Indian Penal Code is silent about the legal validity of consent given by persons between 12 and 18 years of age. Similarly, the age at which the 'Right to Confidentiality' begins is yet to be defined either by the statute or by the courts. Hence, there is a need for a clear statutory provision to remove the anomalies and ambiguities regarding the age of consent to undergo invasive therapeutic or investigative procedures, participate in clinical trials, as well as define the age at which a person's right to medical confidentiality begins.

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INTRODUCTION

The foundation of the traditional theory of consent to treatment lies in the law of battery, and is found in decisions of US courts as early as 1905.[1] Justice Cardozo offered what has become perhaps the best-known statement of the principle of consent in the 1914 New York case of *Schoendorff v. New York Hospital*:[2] 'Every human being of adult years and sound mind has a right to determine what shall be done with his own body: and a surgeon who performs an operation without his patient's consent commits an assault...'

Consent may be express or implied. Express consent is an oral or written authority by the patient to render the proposed treatment. Consent may be implied from the conduct of the patient in a particular case, or from the application of law, to certain factual situations. A patient who voluntarily submits to treatment under circumstances which would indicate awareness of the planned treatment impliedly authorizes the treatment, even without express consent. A patient who presents himself or herself at the doctor's office for a routine procedure implies his or her consent to treatment.

CONSENT TO TREATMENT

In India, the doctor–patient relationship is governed more by trust where the doctor is the authoritative person. Therefore, the benefit of informed consent never reaches all patients in normal medical practice. Also, a large section of the population of India is handicapped by illiteracy and poverty, and remains outside the ambit of medical services rendered by qualified physicians of recognized medical systems. For them the issue of obtaining informed consent becomes inconsequential.

This fact was recognized by the Supreme Court of India in *Samira Kohli vs Dr Prabha Manchanda*[3] in which the judgment stated that in India, a majority of citizens requiring medical care and treatment fall below the poverty line. Most of them are illiterate or semiliterate. They cannot comprehend medical terms, concepts and treatment procedures. They cannot understand the functions of various organs or the effect of removal of such organs. They do not have access to effective but costly diagnostic procedures. Poor patients lying in the corridors of hospitals after admission for want of beds or patients waiting for days on the roadside for an admission or a mere examination is a common sight. For them, any treatment with reference to rough and ready diagnosis based on their outward symptoms and doctor's experience or intuition is acceptable and welcome so long as it is free or cheap; and whatever the doctor decides as being in their interest is usually unquestioningly accepted. They are a passive, ignorant and uninvolved participant in treatment procedures. The poor and needy face a hostile medical environment—inadequacy in the number of hospitals and beds, non-availability of adequate treatment facilities, lack of qualitative treatment, corruption, callousness and apathy. Many poor patients with serious ailments (for instance, patients with heart diseases and cancers) have to wait for months for their turn even for diagnosis, and due to limited treatment facilities, many die even before their turn comes for treatment. What choice do these poor patients have? For them, any treatment of whatever degree is a boon or a favour. The reality is that for a vast majority in India, the concept of informed consent or any form of consent, and choice in treatment, has little meaning or relevance.

CONSENT VIS-À-VIS INDIAN LAW

An invasive therapeutic or investigative procedure without consent is technically a battery (trespass) which can be tried either under criminal or tort (civil) law. When it is a criminal offence, the indictments are framed under the penal code and when compensation is involved, tort law is used.

The Indian Penal Code (IPC) is not specific about the age at which a person can give valid consent. At present, the minimum legal age to give valid consent to undergo medical treatment is ambiguous. Section 87 of the IPC says that a person above 18 years of age can give valid consent and Section 89 of the IPC says that a child under 12 years of age cannot give a valid consent. However, the Indian Contract Act (Sec 11) states that every person who is of the age of majority is competent to contract. According to the Indian Majority Act (Sec 3 (1)) every person attains the age of majority on his completing the age of 18 years.

These statutory provisions do not provide clarity on whether a person between 12 and 18 years of age can give consent to undergo an invasive therapeutic procedure or investigation. It is important to explicitly state whether a person of this age group can give consent independently to undergo medical treatment or his/her consent should be accompanied by parental/guardian consent.

Similarly, Section 92 of the IPC offers legal immunity to a registered medical practitioner to proceed with appropriate treatment even without the consent of the patient in an emergency when the victim is incapable of understanding the nature of the treatment or when there are no legal heirs to sign the consent. If the patient is conscious and refuses treatment without which that person might endanger his/her life, then the surgeon can inform

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the judicial magistrate and get the sovereign power of guardianship over persons under disability (*parens patriae*).[4]

Further, Section 375 of the IPC exempts the husband of a girl above the age of 15 years from indictment of rape, even if he has sexual intercourse with her against her will. Nevertheless, a girl under 18 years of age cannot give valid consent to undergo medical termination of pregnancy as per the Medical Termination of Pregnancy (MTP) Act, 1971 (Sec (3) (4) (a)).

The absence of firm and unambiguous legal provisions regarding informed consent in relation to the medical treatment is reflected in the following incident. In November 1993, when a 16-year-old girl eloped and got married, her father preferred a complaint with the police. (According to Indian law, if a girl under 18 years elopes, the person with whom she elopes can be charged for the offence of kidnapping a minor girl.) The police traced the couple and the boy was released on bail by a Judicial Magistrate while the girl was taken to the boy's house. On a *habeas corpus* petition filed by the father of the girl, the Madras High Court directed the girl be sent to a shelter for women. After a month, the girl was found to be pregnant and the father filed another *habeas corpus* petition in the Madras High Court seeking a direction for medical termination of his daughter's pregnancy. (As per provisions of the MTP Act, only a girl above 18 years can give consent to undergo abortion. But the onus of verifying the age is not on the doctor.) The Division Bench of the Madras High Court after listening to the girl, who was firm on continuing with the pregnancy, refused to order termination of the pregnancy.[5]

In yet another incident, in February 1994, hysterectomy was done on 16 mentally retarded women in a state-run asylum at Pune upon the order of the state government. The reason mentioned was personal hygiene and protection from unwanted pregnancies. For those women who had parents, the consent of the parents was obtained. This incident evoked a nationwide protest in the media. The National Commission for Women referred the matter to the Medical Council of India (MCI) for its opinion. The MCI held that it was an unethical and inappropriate way to deal with social evils or hygiene.[6]

RIGHT TO CONFIDENTIALITY

The age at which the 'Right to Confidentiality' begins is yet to be defined by either the statute or the courts. For instance, the issue of confidentiality arises when a 16-year-old girl wants to know about the contraceptive procedures. Under the present legal provisions, it is unclear whether a healthcare professional should inform the parents or respect the right to confidentiality of the patient.

MTP can be done if the pregnancy is alleged by the pregnant woman to have been caused by rape, since the anguish caused by such pregnancy is presumed to constitute a grave injury to the mental health of the pregnant woman. In such situations, either the consent of the woman if she is ≥18 years or the consent of the parents/guardian if she is <18 years is obtained (Sections 3 (2) (i) and 4 (a) of the MTP Act, 1971).

Also, according to the MTP Regulations, 2003 (Section 6), the admission register recording the name and other particulars of the pregnant woman who undergoes termination is a confidential document and the information contained therein should not be disclosed to any person other than those authorized by the Regulations.

However, the Protection of Children from Sexual Offences Act, 2012 (Sections 2 (1) (d), 19 (1) and 21 (1)) and the Criminal Law Amendment Act, 2013 (Criminal Procedure Code Section 357C and IPC Section 375) criminalizes sex below 18 years of age, even if it is consensual; thereby it is presumed that pregnancy is a result of rape—a criminal offence reportable to the police. Further, under Section 202 of the IPC, it is the duty of a person to communicate any criminal offence (such as rape) that he/she comes to know of to the law-enforcing authority (Table I).

Such contradicting statutory provisions leave healthcare professionals in a quandary whether a pregnancy under 18 years is a reportable offence or not. Therefore, a holistic approach that addresses the concerns of healthcare professionals, safeguards the rights of a minor girl to undergo safe and legal MTP as well as her right to confidentiality is needed, lest the present scenario drive pregnant minor girls to the unsafe services of quacks.

CONSENT IN MEDICAL RESEARCH/CLINICAL TRIALS

One incident of clinical research without consent by using political authority in ancient India is illustrated by a story concerning Emperor Asoka. The Emperor in his later years took a young wife, Tisyaraksita, who made amorous advances to the crown prince Kunala, who indignantly rejected her, though he did not report his stepmother's conduct to his father. Soon after this, Asoka was taken seriously ill with a rare disease involving unpleasant symptoms. Tisyaraksita feared that if he died Kunala would come to the throne and punish her for her immoral behaviour, and so she decided to restore Asoka to health at all costs. She told him that if he would grant her whatever boon she desired, she would cure him, and he put himself entirely in her hands. She ordered a search to be made for a sick man with exactly the same symptoms as the king. When such a person was found he was brought to her private chambers, and she killed him on the spot. She cut open his stomach and found that it contained an enormous worm. She treated the worm with strong and pungent substances such as pepper and ginger, but it was unaffected. At last, she tried onions, and these killed it. So she fed Asoka with large quantities of onions and the worm was eliminated.[7] This story, incredible though it may be, indicates that in some circles of ancient India at least the idea of dissecting a live person to discover the cause of a disease to cure a king's illness was not abhorred. It also establishes the presence of ideas prefiguring modern scientific methods of investigations and experiments were at work.

The Declaration of Helsinki[8] changed the ethical reasoning of using human beings for experimentation from consequentialist (or utilitarian) lines to deontological (duties and obligations). According to the Helsinki Declaration, it is the doctor's duty to ensure that all patients are '…adequately informed of the aim, methods, anticipated benefits, and potential hazards of the study and the discomforts it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participate at any time. The doctor should then obtain the subject's freely-given informed consent, preferably in writing.'

Explaining every aspect of the experimental therapy for the introduction of a new molecule or any such equally important research to every potential human subject is difficult. Most doctors involved in trials of patients with HIV claim that they have obtained informed consent of the patients. However, it is possible that this consent may be at best be partly informed. With a majority of patients being economically and socially disadvantaged, it is unclear whether the complete implications of a study are explained to them. There is possible misuse of patients who could agree to enrol in a study without a complete understanding of the research.[9]

In a clinical trial of human papillomavirus (HPV) vaccine carried out by the Program for Appropriate Technology and

Table I. The statutory sections related to informed consent

Indian Penal Code, 1860

87. Act not intended and not known to be likely to cause Death or Grievous Hurt, done by consent

Nothing which is not intended to cause death, or grievous hurt, and which is not known by the doer to be likely to cause death or grievous hurt, is an offence by reason of any harm which it may cause, or be intended by the doer to cause, to any person, above eighteen years of age, who has given consent, whether express or implied, to suffer that harm; or by reason of any harm which it may be known by the doer to be likely to cause to any such person who has consented to take the risk of that harm.

89. Act done in Good Faith for Benefit of Child or Insane Person, by or by Consent of Guardian

Nothing which is done in good faith for the benefit of a person under twelve years of age, or of unsound mind, by or by consent, either express or implied, of the guardian or other person having lawful charge of that person, is an offence by reason of any harm which it may cause, or be intended by the doer to cause or be known by the doer to be likely to cause to that person.

92. Act done in Good Faith for Benefit of a Person without Consent

Nothing is an offence by reason of any harm which it may cause to a person for whose benefit it is done in good faith, even without that person's consent, if the circumstances are such that it is impossible for that person to signify consent, or if that person is incapable of giving consent, and has no guardian or other person in lawful charge of him from whom it is possible to obtain consent in time for the thing to be done with benefit.

202. Intentional omission to give information of offence by person bound to inform

Intentional omission to give information of offence by person bound to inform.—Whoever, knowing or having reason to believe that an offence has been committed, intentionally omits to give any information respecting that offence which he is legally bound to give, shall be punished with imprisonment of either description for a term which may extend to six months, or with fine, or with both.

The Criminal Law (Amendment) Act, 2013, (Amendments to Indian Penal Code, 1860)

375. Rape

Sixthly. With or without her consent, whom she is under eighteen years of age

Exception 2—Sexual intercourse by a man with his own wife, the wife not being under fifteen years of age, is not rape.

The Criminal Law (Amendment) Act, 2013, (Amendments to Criminal Procedure Code, 1973)

357C. All hospitals, public or private, whether run by the Central Government, the State Government, local bodies or any other person, shall immediately, provide the first-aid or medical treatment, free of cost, to the victims of any offence covered under section 326A, 376, 376A, 376B, 376C, 376D or section 376E of the Indian Penal Code, and shall immediately inform the police of such incident.

Indian Contract Act, 1872

11. Who are competent to contract. Every person is competent to contract who is of the age of majority according to the law to which he is subject and who is of sound mind, and is not disqualified from contracting by any law to which he is subject.

The Indian Majority Act, 1875

3. Age of majority of persons domiciled in India.

(1) Every person domiciled in India shall attain the age of majority on his completing the age of eighteen years and not before.

The Medical Termination of Pregnancy Act, 1971

3. When Pregnancies may be terminated by registered medical practitioners.

(2) (i) the continuance of the pregnancy would involve a risk to the life of the pregnant woman or of grave injury physical or mental health

Explanation 1.—Where any pregnancy is alleged by the pregnant woman to have been caused by rape, the anguish caused by such pregnancy shall be presumed to constitute a grave injury to the mental health of the pregnant woman.

(4) (a) No pregnancy of a woman, who has not attained the age of eighteen years, or, who, having attained the age of eighteen years, is a lunatic, shall be terminated except with the consent in writing of her guardian.

Medical Termination of Pregnancy Regulations, 2003

6. Admission Register not to be open to inspection.

The Admission Register shall be kept in the safe custody of the head of the hospital or owner of the approved place, or by any person authorized by such head or owner and save as otherwise provided in sub-regulation (5) of regulation 4 shall not be open for inspection by any person except under the authority of law:

Provided that the registered medical practitioner on the application of an employed woman whose pregnancy has been terminated, grant a certificate for the purpose of enabling her to obtain leave from her employer; Provided further that any such employer shall not disclose this information to any other person.

The Protection of Children from Sexual Offences Act, 2012

2. (1) (d) 'child' means any person below the age of eighteen years

19. (1) Notwithstanding anything contained in the Code of Criminal Procedure, 1973, any person (including the child), who has apprehension that an offence under this Act is likely to be committed or has knowledge that such an offence has been committed, he shall provide such information to,

(a) the Special Juvenile Police Unit; or (b) the local police.

21. (1) Any person who fails to report the commission of an offence under sub-section (1) of section 19 shall be punished with imprisonment of either description which may extend to six months or with fine or with both.

Health (PATH), a non-governmental organization, in collaboration with the Andhra Pradesh and Gujarat governments and the Indian Council of Medical Research (ICMR), large-scale ethical violations were reported in obtaining consent of young girls included in the trial. The trial included nearly 23 500 girls in the age group of 10–14 years in Khammam district (Andhra Pradesh) and Vadodara (Gujarat). The informed consent forms were filled with incomplete and probably inaccurate data, in a casual manner. In Andhra Pradesh, nearly 2800 consent forms were signed by a hostel warden or headmaster, as the 'guardian' with the justification that parents were not easily reachable. Should the girls have been enrolled without the parents consent as the treatment involved was not emergent. There is no ethical justification for a warden or headmaster to act as a 'legally acceptable representative'. The fact that teachers played a primary role in explaining and obtaining consent since students have reduced autonomy means that the

consent was obtained in an inappropriate manner, i.e. in a legally untenable way.[10]

In another recent episode in Indore, doctors were accused of doing clinical trials for a multinational drug company on patients without obtaining their consent, which is mandatory as per the guidelines of the Drug Controller General of India (DCGI). The doctors were also alleged to have been given monetary incentives and free foreign trips for doing the trials.[11]

The recently amended Schedule Y of the Drugs and Cosmetics Act states that when an illiterate person signs an informed consent to undergo clinical trials, it should be obtained in the presence of an impartial person. However, in practice, this will not be a hindrance to misuse gullible persons. In brief, the concept of informed consent specific to medical research and treatment is still alien to many medical researchers and practitioners and to millions of Indians.

THE SUPREME COURT ON CONSENT

In *Samira Kohli vs Dr Prabha Manchanda*,[12] the Supreme Court of India states that consent in the context of a doctor–patient relationship is defined as grant of permission by the patient for an act to be carried out by the doctor, such as a diagnostic, surgical or therapeutic procedure. Consent can be implied in some circumstances from the action of the patient. This order gives the principles of consent with regard to medical treatment and therapeutic investigations and not for medical research/clinical trials as follows:

1. A doctor has to seek and secure the consent of the patient before commencing a 'treatment'. The consent so obtained should be real and valid; the consent should be voluntary; and the consent should be on the basis of adequate information concerning the nature of the treatment procedure, so that she/he knows what she/he is consenting to.
2. A balance should be maintained between the need for disclosing necessary and adequate information and at the same time avoid the possibility of the patient being deterred from agreeing to a necessary treatment or offering to undergo an unnecessary treatment.
3. Consent given only for a diagnostic procedure cannot be considered as consent for treatment. Consent given for a specific treatment procedure is not valid for some other treatment or procedure.
4. There can be a common consent for diagnostic and operative procedures where they are contemplated. There can also be a common consent for a particular surgical procedure and an additional or further procedure that may become necessary during the course of surgery.
5. The nature and extent of information to be furnished by the doctor to the patient to secure the consent need not be of the stringent and high degree mentioned in *Canterbury*[13] but should be of the extent which is accepted as normal and proper by a body of medical men skilled and experienced in that particular field. It will depend upon the physical and mental condition of the patient, the nature of treatment, and the risk and consequences attached to the treatment.

However, there is a significant difference in the nature of express consent of the patient, known as 'real consent' in the UK and as 'informed consent' in the USA. In the UK, the elements of consent are defined with reference to the patient and a consent is considered to be valid and 'real' when (i) the patient gives it voluntarily without any coercion; (ii) the patient has the capacity and competence to give consent; and (iii) the patient has a minimum level of information about the nature of the procedure to which she/he is consenting to. On the other hand, the concept of 'informed consent' developed by American courts, while retaining the basic requirements of consent, shifts the emphasis to the doctor to disclose necessary information to the patient to secure his/her consent.[14]

The Supreme Court of India states that the 'real consent' concept evolved in *Bolam*[15] and *Sidaway*[16] have been preferred to the 'reasonably prudent patient test' in *Canterbury*,[13] in view of the ground realities in medical and healthcare situation in India. If medical practitioners and private hospitals become more and more commercialized, and if there is a corresponding increase in the awareness of patient's rights among the public, inevitably, a day may come when it may be shifted towards *Canterbury*.[17]

THE NEED OF THE HOUR

Written consent, apart from becoming documentary evidence in a judicial trial, is also a confirmation of patient autonomy—the basis of modern bioethics. Hence, there is a need for a relook into the anomalies and ambiguities regarding the age of consent to undergo invasive therapeutic or investigative procedures and clinical trials and also to define the age at which a person's right to medical confidentiality begins. Further, protocols need to be evolved to get consent from illiterate and mentally ill persons and children.

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