ABSTRACT
Consent is required in all walks of life. Be it marriage, business contract, sports, dare devilry acts, informed consent is mandatory. It is better to be specific by mentioning it as ‘Medical Consent’ when we refer to consent in medical practice. Of late, there are many cases filed against doctor for erring as far as consent is concerned and thus trespassing rights of an individual. Invalid consent has a grave ethical issues & legal ramifications. Consent is a legal requirement for examination and treatment of the patient. The nature of the consent varies according to needs. Failure to obtain consent can make physician liable for prosecution and damages. It amounts to Negligence even without any damage and also a professional misconduct.

KEY WORDS: Consent, Medical practice, Liability, Legal & Ethical Issues

Introduction
Consent word is a Latin word, consentirez, meaning to feel or sense with.

Indian Contract Act, 1872, Section 13–19, states two or more persons are said to consent when they agree upon the same thing in the same sense. Consent has been defined as mean “voluntary agreement, compliance, or permission for specified act or purpose”.

Consent is valid only if it is given after knowing the nature and consequence of the consent and those of the act for which consent is given[1].

Types of consent: - It is of two types.
1. Implied 2. Express. Express is subdivided into
   a. Oral b. Informed written

From whom consent to be obtained?
Consent should be obtained from adult years, conscious mentally sound patients. If a person is unconscious, the consent can be obtained from legal heir/friend. If no relative/friend is available then consent need not be taken and physician should proceed in good faith in an emergency. For minors (<18 years) consent can be obtained from parent/guardian or near relative. A child below 12 years and mentally unsound of any age cannot give consent. A child above 12
years but below 18 years can give consent only for routine medical examination but not for any procedure, surgery, etc. In situations, where there is difference of opinion among the family members regarding patient care, legal proceedings are advised to determine who can give consent for incompetent patient[2].

Failure to take consent attracts legal action except in emergency cases where in Law Implies consent (Sec 92 IPC). The doctor can be charged of:-

1. Assault/ Battery under section 351 IPC
2. Professional Negligence
3. Professional misconduct
4. Deficiency in medical service as per section 2 (1) of Consumer Protection Act.
5. Indecent Assault by female patient when private parts examined without consent and In absence of Lady Doctor. But it is a common practice to examine in front of a lady which ideally invalid. Consent is a defence in civil negligence but not in criminal negligence.

**When to take Consent?**

The Law expects that consent for any procedure must be taken just prior to the procedure[3]. It has not specified how much before. But one thing is clear that it should not be obtained many hours or days before.

**Implied Consent**

When a patient has come to the physician for treatment and has waited for his turn to come and paid the professional fee, he has supposedly consented for the treatment. A patient obtaining an OPD slip and going to respective department for checkup is also an implied act. This is called as implied consent. But this consent is valid only for the routine physical examination and not for any invasive procedure, examination of private parts, etc. where informed written consent is mandatory. It may be noted that this consent is only for inspection, palpation, percussion and auscultation. Even in this physician should request the patient’s permission to access the body.

**Express Consent**

Anything other than implied consent described above is express consent. It may be oral or written consent. For minor examination like giving injections, IV fluids, withdrawal of blood, etc. an oral consent is sufficient but for elaborate procedure, consent should be obtained in writing. The oral consent should be obtained in the presence of disinterested person (Avoid patient’s relative, hospital staff). Although oral consent has the same validity as written consent in eyes of law but it is undocumented. It is better to obtain written consent and use the document as defence in future litigation suits[4].

Written consent is must for all potentially harmful, invasive diagnostic and surgical interventions. It should be specific for a particular procedure. It should not be ‘Blanket consent’. Unfortunately an invalid consent called ‘Blanket Consent’ is in vogue and most rampanty used. It is only because of ignorance of doctors about consent. It is recorded in following manner from the patient.

“I hereby authorize staff of this hospital to perform any surgical or anaesthetice procedure on me”. Further worse is, it is obtained at the time of admission and procedure is done many hours, days later! This has opened floodgate of litigations against doctors.

**Informed Consent**

Nowadays, patients are getting aware of their civil rights and now we see more assertion of
“right to know”. Informed consent deals with patients’ rights and obligations. Patient has right to know what disease he / she is suffering from and how the diagnosis and treatment are planned. He / She has the right to know the potential risks involved and if any alternative treatment is available or not. Patient has also the right to know about the approximate costs of the treatment. Last but not the least, patient has right to refuse in spite of all efforts are made by doctor to convince the graveness of ill health and importance of timely medical intervention.

**Doctrine of Informed Consent**

Since every adult (Major, 18 years or more) human being has the right to decide as to what is best for his own body. A doctor prescribing a particular diagnostic or therapeutic procedure must necessarily disclose all the risks associated with the procedure to the patient so as to enable him to decide whether to undergo the same or not. The following points must be borne in mind.

- All relevant information about the ailment and treatment options must be outlined.
- Significant common risks associated with every medical procedure being contemplated be disclosed.
- Under therapeutic privilege, one should not scare patient by highlighting remote, rare complications to avoid denial & psychological harm.
- The patient must be informed about all available alternative treatment options.
- Everything that is told to the patient must be explained in simple (vernacular) language that is comprehensible to him.

It should be voluntary, free, fair, clear, Informed, direct & personal. To be obtained without pressure, fraud, fear or favor. Failure to take informed consent can expose a doctor to legal action if anything goes wrong during a particular procedure. Even if informed consent has been obtained in a given case, it can be deemed invalid if the doctor exceeds his brief, for instance, carrying out a different procedure from what was originally contemplated, or extending the scope of operation beyond what was told to the patient.

**Extension Doctrine**

However, the courts have recognized possibility that complete diagnosis of which an internal ailment may not be certain even after detailed investigations, references in a bizarre case. In such a situation surgeon should have briefed the patient, relatives and for safety to enter in case sheet and take consent for extension of surgery whatever deemed fit at that moment on operation table. He is legally justified and protected by Law in the event of litigation in extending the operation and doing whatever is necessary to save the life of the patient. But the rider is that case must have been thoroughly investigated, expert opinions have been obtained before exploring. Honourable Supreme Court has stressed the importance of obtaining ‘prior’ consent in its judgment pronounced in 2008, Sammera Koily case where in mother’s consent was taken for Hysterectomy ignoring that of patient. Doctor was held guilty for extending surgery without prior permission from legally competent patient taken before surgery.

The signature of the patient and in minor or mentally ill of any age from parent, legal heir should be obtained in presence of a disinterested person as a witness. Finally it should be counter-signed by the physician in charge of the patient.

**When consent is not required?**

In following conditions, consent of the patient is not required as per law:

1. When an accused is brought for medical
examination with written request
by police officer no below the rank
of Police Sub Inspector in cases of
alcoholic intoxication, sexual assault etc.
(53 CrPC). No consent of the patient is
required for medical examination but
no treatment can be enforced without
consent of the patient.

2. In case of arrested person brought by
police to take blood sample / sample of
hair or anything required for evidence,
consent of the detained is not necessary
and even reasonable force can be applied
to obtain sample. (53 A CrPC)

3. In case of rape victim, even Court cannot
compel her for lodging complaint,
medical examination.

4. Consent is not needed for medical
examination if the medical examination
is statutory like in armed forces,
immigration etc.

5. Consent is not mandatory for
immunization.

6. In convicted prisoner, treatment can be
given without permission.

7. As per Law (92 IPC) patient can be
examined, treated without consent in an
emergency. Law implies consent.

8. Do not detain any patient against will in
hospital- Wrongful confinement (339-
344 IPC). Discharge against medical
advice (DAMA).

9. Inmate of hostel > 12 years suffering
from infectious disease is advised to
vacate hostel. If refuses, treat without
consent.

10. No consent required in Medico-legal Post
mortem examination but consent from
legal heir mandatory for Pathological
autopsy.

11. The patient’s record can be used without
consent for statistical purpose and in
publication provided identity is not
revealed.

12. The information about patient can be
divulged to concerned authority under
privileged communication.

13. If doctor fails to inform ‘would be spouse’
the danger of getting infected by AIDS/
HIV, is punishable as per Supreme Court
verdict. Negligent act (269 IPC) and
malignant act (270 IPC) which are likely
to spread infection of disease dangerous
to life is punishable.

**When Consent from spouse to be taken?[5,6]**

It is advisable to take consent of the
spouse in the following procedures.

1. Medical termination of pregnancy.
Though as per Law, one need not take
husband’s consent. But to avoid marital
discord, it is better to take consent.

2. Contraceptive sterilization operation.

3. Artificial insemination.

4. Donation of the sperms.

5. Any operation that can result in sexual
dysfunction of the spouse.

**When Consent is not Valid**

In the following cases, consent given is not
valid:

Consent given by mentally unsound patient.
Blanket consent.

Consent obtained for a criminal activity
like criminal abortion, euthanasia or any
mutilating operation.

When consent is obtained by force, fear or
fraud and by impersonation (92 IPC).

If only signature/ LTP is taken by mentioning
consent taken / obtained.
**Laws in Relation to Consent[7]**

- As per section 53(A) CrPC, 164 A CrPC - If rape victim consents any registered doctor can examine. If accused brought by police with written requisition from police officer not below the rank of Sub Inspector, resisting accused can be examined without consent if refusals by using reasonable force.
- As per section 53 (B) CrPC, examine lady in presence of lady doctor and not a female attendant being widely practiced.
- As per 89 IPC obtain consent of parent / guardian if child is below 12 yrs. & mentally unsound of any age.
- As per 52 IPC, nothing is said to be done or believe in ‘good faith’ which is done or believed without due care and attention.
- As per section 87 IPC consent for operation risk involved, dare devilry sports a person > 18 years can give valid consent.
- As per section 88 IPC, consent for operation (minor or major), invasive investigations, procedure and detailed examination a person > 18 years can give valid consent.
- As per section 92 IPC Law implies consent only in emergency.
- As per section 93 IPC, no communication made in good faith is an offence by reason of any harm to person to whom it is made, if it is made for benefit for person. E.g. Doctor communicating seriousness of disease and patient may not survive.
- As per section 90 IPC consent is invalid when it is taken under force, fear, fraud, influence of alcohol, drugs & for an unlawful act (Criminal abortion).

**MISCELLANEOUS[8]**

**A. Prudent (sensible) Patient Rule:-**

It means what a prudent person in patient’s position would have decided if adequately & lucidly, informed about all reasonably foreseeable risks.

**B. Presumed Consent:-**

Assumes that individual agrees in principle. If not he / she can opt out.

**C. Proxy Consent:-**

It is also called Substitute / Surrogate consent. It refers to parent, guardian or legal heir giving consent instead of patient in child < 12 years and in mentally unsound of any age.

**D. Conflict of Consent:-**

When two legally competent to give consent differ in medico legal cases in minor and mentally unsound, seek clarification of court through police. The court shall direct whose consent is valid.

**E. Doctrine of Loco parentis:-**

Loco parentis is a Latin phrase meaning ‘in place of a parent’.

It is applicable in an emergency when child needs urgent medical attention and parent or guardian is not accessible. In such a situation person in charge such as teacher, warden, tour coordinator, etc. can give consent. But it shall suffice only in emergency and in cold conditions[9].

**F. An adult of 18 years of age can donate skin, one kidney if fit and not harmful. This is as per informed witnessed consent under section 3 of Human Organ Transplantation Act.**

**G. Eye donation, cadaver organ donation is legally valid only by obtaining the consent of legal heir after death of the person though person has pledged during one’s life[10].**

**H. Grave risk Consent:-**

Also known as high risk consent is
popular among clinicians but it is invalid. Consent to be valid is to be obtained only after the graveness of condition and all pros & cons explained lucidly.

I. Paternalism:

It is related to autonomy of patient. Autonomy is derived from Greek word, Autonoma - Greek word meaning 'Self Rule'. It refers to the right of patient to make decision about their medical care without their health care provider trying to unduly influence. Patient autonomy does allow ‘Health care provider’ to educate patient but not allow to make unilateral decision for the patient on his own. If practiced, it destroys doctor-patient relationship.

Modified Model Informed Consent Form[11]

OP/IP No ______________________________
Name _______________________________
Sex : _______ Age : _____
Son/ Daughter / Wife of ______________________
Address ______________________________
_____________________________________

Authorization for medical treatment / performance of surgical operation under GA or spinal or LA / diagnostic procedure (tick relevant one)

I hereby authorize Dr------------------- - of (name of hospital ) to perform upon me (name) _______________________________
Sex------------- Age.............the following medical treatment, surgical operation and / or diagnostic/ therapeutic procedure.

It has been explained to me that, during the courses of the operation / procedure, unforeseen conditions may be revealed or encountered which necessitate surgical or other emergency procedures in addition to or different from those contemplated at the time of initial diagnosis. I, therefore, further authorize the above designated Doctor to perform such additional surgical or other procedures as they deem necessary or advisable to restore my health.

3. I consent to the administration of anaesthesia and to use such anaesthetics as may be deemed necessary or desirable.

I state that I am / am not suffering from Hypertension / Diabetes / Bleeding disorders / Heart diseases or _______________________

4. I also state that I am not suffering from any known allergies or drug reactions.

5. To the best of my knowledge, I further consent to the administration of such drugs, infusions, plasma or blood transfusions or any other treatment or procedures deemed necessary.

6. I consent to the photographing or televising of the operations or procedures to be performed, including appropriate portions of my body, for medical, scientific or educational purposes without revealing my identity. I do consent admittance of students for learning purpose.

Two identification marks

Signature of the patient/LTP

Name:
Date:

Signature, name and address of two witnesses:
1. _______________________________
2. _______________________________
Date:  
Signature of Doctor:  
Name:  
Designation:  

**Note:**

1. Better to take consent in patient’s hand writing in vernacular language. If time does not permit, for safety take following statement in writing of patient / legal heir in illiterate “I have understood the content of consent fully and willingly signing and agreeing for treatment.”

2. In sensitive cases, better to video graph whole procedure along with written consent.

3. Some hospitals take multiple consent for one procedure for surgery, anaesthesia. It is cumbersome and not practical. We feel a comprehensive consent for all that is done such as surgery/procedure done, anaesthesia given, photographs taken for academic purpose etc. lucidly explained shall suffice.

**Modified Model Informed Refusal form[12]**

NAME………………………………………….
SEX/AGE……………….. OP/IP No.………
ADDRESS……………………………………

I am fully aware of my health condition and the treatment modalities available. It has been explicitly explained by Dr……………………………..The risk involved in refusal of particular investigation and or treatment are clearly understood by me. After understanding lucidly pros & cons of refusal, I express my denial of treatment or investigation advised. (Note: In case of minor take signature of parent/legal heir).

I am alone held responsible for adverse consequences and seek discharge against medical advise (DAMA).

Two identification marks:  

Patient’s signature/ltp

Doctor’s Signature:

Name & Seal:

Date:

**Note:**

1. Ideal to take in patient’s hand writing in vernacular language.

2. If time does not permit, for safety take following statement in writing of patient/ Legalheir in illiterate “I have understood the content of informed refusal form fully and willingly signing.

**Conclusion**

Susruta Samhita says….

“The patient may doubt his relatives, his sons (children) and even his parents but, he has full faith in Physician. He gives himself up in the doctor’s hand and has no misgivings about him. Therefore it is the physician’s duty to look after him as his own son (child).”

It is obligatory on the part of doctors to take valid consent while examining & treating patient. Doctors must know their rights, privileges and laws in relation to practice to avoid harassment and mental agony by frivolous charges. Consent is not a defence in criminal negligence. The literacy and legal awareness are making public aware of their rights and also unfortunately resulting in rise in litigations. Best defence for doctor is ethical practice knowing legal & ethical limitations. It
is better to go for Medical Indemnity insurance which takes care of legal expenditures and compensation to be paid in the event of losing legal battle. Last but not the least one should aim at becoming a ‘reputed’ doctor rather a ‘famous’ doctor. Roman writer Cornelius Celsus nearly 2000 years ago defined an ideal doctor which holds good till today.

**An Ideal Doctor**

The ideal doctor is the one who respects his art (profession), is never far from his/her patients but those who practice for profit, since there is greater profit in a numerous clientele, gladly follow school of teaching that does not demand such constant care.

- Cornelius Celsus

**References**