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# Rights of Patients in India: Analysis and Way Ahead

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The paper is a bird's eye view to understand Patient rights are those basic rules of conduct between patients and medical caregivers as well as the institutions and people that support them.

Every **patient** has the **right** to receive treatment without any discrimination based on his or her illnesses or conditions, including HIV status or other health conditions, religion, caste, ethnicity, gender, age, sexual orientation, linguistic or geographical/social origins

the informative model, by contrast, sees the patient as a consumer who is in the best position to judge what is in her own interest, and thus views the doctor as chiefly a provider of information. There continues to be enormous debate about how best to conceive of this relationship, but there is also growing international consensus that all patients have a fundamental right to privacy, to the confidentiality of their medical information, to consent to or to refuse treatment, and to be informed about relevant risk to them of medical procedures.

**Key Words:** Patients, Rights, Medical ethics, Clinical trials, Confidentiality, Abandonment

# **Rights of Patients:**

#### **Patient**

A person who is ill or is undergoing treatment for disease. The words client, resident, and at times guest can also be used to refer to a person receiving treatment.

#### **Introduction:**

Those rights attributed to a person seeking health care. In 1973 the American Hospital Association approved a statement called the "Patient's Bill of Rights," regarding a patient's rights during hospitalization. (A revised document was subsequently approved in 1992.) This was published with the expectation that observance of patient's rights would contribute to more effective care and greater satisfaction for the patient, health care providers, and the hospital organization in general.

In general, the rights of a patient are concerned with the patient being fully informed about his or her illness, the diagnostic and therapeutic measures anticipated, and the written records of the care received.

The patient has the right to considerate and respectful care, delivered in response to a request for services and in a manner that provides continuity of care. In regard to payment for services, the patient has the right to examine and receive an explanation of the bill regardless of source of payment.

#### **Definition**

Patient rights are those basic rules of conduct between patients and medical caregivers as well as the institutions and people that support them. A patient is anyone who has requested to be evaluated by or who is being evaluated by any healthcare professional. Patient rights encompass legal and ethical issues in the provider-patient relationship, including a person's right to privacy, the right to quality medical care without prejudice, the right to make informed decisions about care and treatment options, and the right to refuse treatment.

# **Purpose**

The purpose of delineating patient rights is to ensure the ethical treatment of persons receiving medical or other professional health care services. Without exception, all persons in all settings are entitled to receive ethical treatment.

#### What are Patient Rights?

Patient rights are those basic rule of conduct between patients and medical caregivers as well as the institutions and people that support them. A patient is anyone who has requested to be evaluated by or who is being evaluated by any healthcare professional. Medical caregivers include hospitals, healthcare personnel, as well as insurance agencies or any payers of medical-related costs.

### Communication

Open and honest communication is an integral part of the doctor-patient relationship.

The AMA's Code of Medical Ethics clearly states that it is a fundamental ethical requirement that a physician should at all times deal honestly and openly with patients. Patients have a right to know their past and present medical status and to be free of any mistaken beliefs concerning their conditions. Situations occasionally occur in which a patient suffers significant medical complications that may have resulted from the physician's mistake or judgment. In these situations, the physician is ethically required to inform the patient of all the facts necessary to ensure understanding of what has occurred.

Only through full disclosure is a patient able to make informed decisions regarding future medical care.

Past patient surveys have found that virtually all patients desired some acknowledgment of even minor errors. For both moderate and severe mistakes, patients were significantly more Likely to consider legal action if the physician did not disclose the error. Findings such as these reinforce the importance of open communication between physician and patient.

#### **Right to information**

Every patient has a right to adequate relevant information about the nature, cause of illness, provisional / confirmed diagnosis, proposed investigations and management, and possible complications To be explained at their level of understanding in language known to them. The treating physician has a duty to ensure that this information is provided in simple and intelligible language to the patient to be communicated either personally by the physician, or by means of his / her qualified assistants.

Every patient and his/her designated caretaker have the right to factual information regarding the expected cost of treatment based on evidence. The hospital management has a duty to communicate this information in writing to the patient and his/her designated caretaker. They should also be informed about any additional cost to be incurred due to change in the physical condition of the patient or line of treatment in writing. On completion of treatment, the patient has the right to receive an itemized bill, to receive an explanation for the bill(s) regardless of the source of payment or the mode of payment, and receive payment receipt(s) for any payment made. Patients and their caretakers also have a right to know the identity and professional status of various care providers who are providing service to him / her and to know which Doctor / Consultant is primarily responsible for his / her care. The hospital management has a duty to provide this information routinely to all patients and their caregivers in writing with an acknowledgement.

#### **Informed Consent**

Part of communication in medicine involves informed consent for treatment and procedures. This is considered a basic patient right. **Informed consent involves the patient's understanding of the following:** 

- What the doctor is proposing to do
- Whether the doctor's proposal is a minor procedure or major surgery
- The nature and purpose of the treatment

- Intended effects versus possible side effects
- The risks and anticipated benefits involved
- All reasonable alternatives including risks and possible benefits.

Closely associated with informed consent, voluntary consent means that the patient understands these concepts; the patient rights include the following:

- Freedom from force, fraud, deceit, duress, overreaching or other ulterior form of constraint or coercion
- The right to refuse or withdraw without influencing the patient's future healthcare
- The right to ask questions and to negotiate aspects of treatment, A patient must be competent in order to give voluntary and informed consent Thus, competent consent involves the ability to make and stand by an informed, freely made decision. In clinical practice, competence is often equated with capacity.

Decision-making capacity refers to a patient's ability to make decisions about accepting healthcare

recommendations. To have adequate decision-making capacity, a patient must understand the options, the consequences associated with the various options, and the costs and benefits of these consequences by relating them to personal values and priorities.

Some factors may make a patient incapable of providing competent consent either temporarily or permanently. Examples include the following:

- Mental illness or mental retardation
- Alcohol or drug intoxication
- Altered mental status
- Brain injury
- Being too young to Legally make decisions concerning health care

Patients that are judged incompetent (often determined by two independent physicians or in some instances, by a legal decree) can have others legally permitted to make medical decisions for the patient.

#### Right to protection for patients involved in clinical trials

Every person / patient who is approached to participate in a clinical trial has a right to due protection in this context. All clinical trials must be conducted in compliance with the protocols and Good Clinical Practice Guidelines issued by Central Drugs Standard Control Organisation, Directorate General of Health

Services, Govt. of India as well as all applicable statutory provisions of Amended Drugs and Cosmetics Act, 1940 and Rules, 1945, including observance of the following provisions related to patients' rights:

a) Participation of patients in clinical trials must always be based on informed consent, given after provision of all relevant information. The patient must be given a copy of the signed informed consent form, which provides him / her with a record containing basic information about the trial and also becomes documentary evidence to prove their participation in the trial.

- b) A participant's right to agree or decline consent to take part in a clinical trial must be respected and her/his refusal should not affect routine care.
- c) The patient should also be informed in writing about the name of the drug / intervention that is undergoing trial along with dates, dose and

duration of administration.

- d) At all times, the privacy of a trial participant must be maintained and any information gathered from the participant must be kept strictly confidential.
- e) Trial participants who suffer any adverse impact during their participation in a trial are entitled to free medical management of adverse events, irrespective of relatedness to the clinical trial, which should be given for as long as required or till such time as it is established that the injury is not related to the clinical trial. In addition, financial or other assistance must be given to compensate them for any impairment or disability. In case of death, their dependents have the right to compensation.
- f) Ancillary care may be provided to clinical trial participants for non-study/trial related illnesses arising during the period of the trial. This could be in the form of medical care or reference to facilities, as may be appropriate.
- g) Institutional mechanisms must be established to allow for insurance coverage of trial related or unrelated illnesses (ancillary care) and award of compensation wherever deemed necessary by the concerned Ethics Committee.
- h) After the trial, participants should be assured of access to the best treatment methods that may have been proven by the study.

Any doctor or hospital who is involved in a clinical trial has a duty to ensure that all these guidelines are followed in case of any persons / patients involved in such a trial. (National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017)

#### Right to second opinion

Every patient has the right to seek second opinion from an appropriate clinician of patients/ caregivers choice. The hospital management has a duty to respect the patient's right to second opinion, and should provide to the patient's caregivers all necessary records and information required for seeking such opinion without any extra cost or delay.

The hospital management has a duty to ensure that any decision to seek such second opinion by the patient / caregivers must not adversely influence the quality of care being provided by the treating hospital as long as the patient is under care of that hospital. Any kind discriminatory practice adopted by the hospital or the service providers will be deemed as Human Rights' violation.

#### Right to transparency in rates, and care according to prescribed rates wherever relevant

Every patient and their caregivers have a right to information on the rates to be charged by the hospital for each type of service provided and facilities available on a prominent display board and a brochure. They have a right to receive an itemized detailed bill at the time of payment. It would be the duty of the Hospital / Clinical Establishment to display key rates at a conspicuous place in local as well as English language, and to make available the detailed schedule of rates in a booklet form to all patients / caregivers.

Every patient has a right to obtain essential medicines as per India Pharmacopeia, devices and implants at rates fixed by the National Pharmaceutical Pricing Authority (NPPA) and other relevant authorities. Every patient has a right to receive health care services within the range of rates for procedures and services prescribed by Central and State Governments from time to time, wherever relevant. However, no patient can be denied choice in terms of medicines, devices and standard treatment guidelines based on the affordability of the patients' right to choice. Every hospital and clinical establishment has a duty to ensure that essential medicines under NLEM as per Government of India and World Health Organisation, devices, implants and services are provided to patients at rates that are not higher than the prescribed rates or the maximum retail price marked on the packaging.

#### **Confidentiality**

Law and ethics state that the doctor-patient interaction should remain confidential. The physician should never reveal confidential information unless the patient wants this information disclosed to others, or unless required to do so by law. If the release of information is warranted, information should be released in the form of an official signed document.

Confidentiality is subject to certain exceptions because of Legal, ethical and social considerations.

• When patients are at risk of physically harming another person, or if those patients are at risk of harming themselves, the physician has the Legal obligation to protect the potential victim and notify Law enforcement authorities.

This is another special case in which patient confidentiality does not exist. Doctors that reasonably suspect child abuse and report it are not liable if Child Protective Services ultimately find there was no abuse. New changes also extend this Law to elderly patients.

- In addition to child and elderly abuse, certain aspects relating to confidentiality does not apply to cases involving some specific communicable diseases, gunshot wounds, and knife wounds that are related to illegal or criminal activity,
- The subject of minors creates a special situation regarding confidentiality.
- An exception is made for emancipated minors, who are considered self-reliant because, for example, they are married or have children themselves. Emancipated minors are usually regarded as adult's in reference to their medical, care.
- Minors who live with their parents but are self-reliant and independent are considered mature minors. In some states, a mature minor may be considered an adult regarding medical treatment. In various states and depending on the situation, minors can consent to treatment for contraception, drug and alcohol problems, psychiatric conditions, pregnancy, abortion, and sexually transmitted diseases (STDs, venereal diseases) without the knowledge of their parents. It is best for doctors and patients to know the laws that pertain to the State where the medical situation is to be assessed and treated.

# The Right to Healthcare

Most people agree that everyone deserves the basic right to healthcare. Within the existing social

structure, inequities in access to healthcare are widespread. Because of numerous inequities in healthcare that often involve such factors as race, socioeconomic status, and gender, politicians have tried for many years to change the healthcare system and are Likely to continue to intervene and change these "patient rights".

An example of such a law is the Consolidated Omnibus Budget Reconciliation Act (COBRA). The COBRA regulations are federal legislation that mandates an evaluation of patients who seek medical attention at emergency facilities. If an emergency care institution refuses to provide care, the institution and health care providers are held responsible and Liable. These regulations prevent health care institutions from refusing needed care to people without money or health insurance.

- Perform an appropriate medical screening examination by a qualified provider to determine whether an emergency condition exists
- Provide further examination and treatment to stabilize the patient, and if necessary and appropriate, to arrange a transfer
- Consider patients in Labor unstable for transfer, under special conditions
- EMTALA requires that all emergency departments and Medicare-participating hospitals to screen anyone who is in active Labor or is seeking emergency care. If such a screening reveals the presence of an emergency medical condition such as severe pain, serious threat to Life or Limb, or active Labor the hospital is required to perform stabilizing treatment to the best of its capabilities.

In order to provide continuing health insurance for the recently unemployed, COBRA provisions also permit continuation of coverage through the workplace. Recently, many federal and civil lawsuits have been filed and both won and Lost against HMOs for failing to provide needed care because of the drive to reduce health care costs, The outcome of such Lawsuits is sometimes unclear, but the quality of provided care is on the minds of all who obtain health care.

#### **Abandonment**

The doctor has the duty to continue a patient's healthcare after consenting to provide medical care unless the patient no longer requires treatment for the illness. The doctor must notify the patient and transfer care to another acceptable doctor if planning to withdraw care. The doctors may be charged with negligent abandonment for ending the relationship with the patient without appropriate referral, transfer, or discharge. Although doctors are free to choose which patients they will treat, doctors should offer optimal care for patients who need emergency first-aid treatment.

#### **Right to Refuse Care**

Adults, Parents, and Children along with the right to adequate and appropriate healthcare, competent adult patients have the right to refuse health care (it is wise to document that the patient clearly understands the risks and benefits of their decision), but exceptions do occur.

- Patients with an altered mental status because of alcohol, drugs, brain injury, or medical or psychiatric illness may not be able to make a competent decision: then the patient may need to have a person legally appointed to make medical decisions.
- Although Laws have established the right of an adult to refuse life-sustaining treatment, they do not allow parents or guardians to deny children necessary medical care.

#### Right to safety and quality care according to standards

Patients have a right to safety and security in the hospital premises. They have a right to be provided with care in an environment having requisite cleanliness, infection control measures, safe drinking water as per BIS/FSSAI Standards and sanitation facilities. The hospital management has a duty to ensure safety of all patients in its premises including clean premises and provision for infection control. Patients have a right to receive quality health care according to currently accepted standards, norms and standard guidelines as per National Accreditation Board for Hospitals (NABH) or similar. They have a right to be attended to, treated and cared for with due skill, and in a professional manner in complete consonance with the principles of medical ethics. Patients and caretakers have a right to seek redressal in case of perceived medical negligence or damaged caused due to deliberate deficiency in service delivery.

The hospital management and treating doctors have a duty to provide quality health care in accordance with current standards of care and standard treatment guidelines and to avoid medical negligence or deficiency in service delivery system in any form. (The Consumer Protection Act, 1986)

#### Right to proper referral and transfer, which is free from perverse commercial influences

A patient has the right to continuity of care, and the right to be duly registered at the first healthcare facility where treatment has been sought, as well as at any subsequent facilities where care is sought. When being transferred from one healthcare facility to another, the patient / caregiver must receive a complete explanation of the justification for the transfer, the alternative options for a transfer and it must be confirmed that the transfer is acceptable to the receiving facility. The patient and caregivers have the right to be informed by the hospital about any continuing healthcare requirements following discharge from the hospital. The hospital management has a duty to ensure proper referral and transfer of patients regarding such a shift in care. In regard to all referrals of patients, including referrals to other hospitals, specialists, laboratories or imaging services, the decision regarding facility to which referral is made must be guided entirely by the best interest of the patient. The referral process must not be influenced by any commercial consideration such as kickbacks, commissions, incentives, or other perverse business practices. (Medical Council of India code of ethics section 3.6)

# Right to take discharge of patient, or receive body of deceased from hospital

A patient has the right to take discharge and cannot be detained in a hospital, on procedural grounds such as dispute in payment of hospital charges. Similarly, caretakers have the right to the dead body of a patient who had been treated in a hospital and the dead body cannot be detailed on procedural grounds, including non-payment/dispute regarding payment of hospital charges against wishes of the caretakers. The hospital management has a duty to observe these rights and not to indulge in wrongful confinement of any patient, or dead body of patient, treated in the hospital under any circumstances. (Consumer Protection Act 1986)

# **Right to Patient Education**

Patients have the right to receive education about major facts relevant to his/her condition and healthy living practices, their rights and responsibilities, officially supported health insurance schemes relevant to the patient, relevant entitlements in case of charitable hospitals, and how to seek redressal of grievances in the language the patients understand or seek the education. The hospital management and treating physician have a duty to provide such education to each patient according to standard procedure in the language the patients understand and communicate in a simple and easy to understand manner. (Consumer Protection Act 1986)

# Right to be heard and seek redressal

Every patient and their caregivers have the right to give feedback, make comments, or lodge complaints about the health care they are receiving or had received from a doctor or hospital. This includes the right to be given information and advice on how to give feedback, make comments, or make a complaint in a simple and user-friendly manner.

Patients and caregivers have the right to seek redressal in case they are aggrieved, on account of infringement of any of the above mentioned rights in this charter. This may be done by lodging a complaint with an official designated for this purpose by the hospital / healthcare provider and further with an official mechanism constituted by the government such as Patients' rights Tribunal Forum or Clinical establishments regulatory authority as the case may be. All complaints must be registered by providing a registration number and there should be a robust tracking and tracing mechanism to ascertain the status of the complaint resolution. The patient and caregivers have the right to a fair and prompt redressal of their grievances. Further, they have the right to receive in writing the outcome of the complaint within 15 days from the date of the receipt of the complaint. Every hospital and clinical establishment has the duty to set up an internal redressal mechanism as well as to fully comply and cooperate with official redressal mechanisms including making available all relevant information and taking action in full accordance with orders of the redressal body as per the Patient's Right Charter or as per the applicable existing laws. (Consumer Protection Act 1986)

# **Legal Principles in Patents Rights**

One way to look at patients' rights is to view the legal implications that occur when patients' rights are violated, Torts, which are defined as civil injustices recognized as grounds for a Lawsuit, are often involved in medical injury claims and malpractice claims. Negligence is the basis for the majority of claims involving medical issues in the United States. A civil negligence claim involves a plaintiff and a defendant.

In order to succeed in court, the plaintiff (the patient, in this case) must prove four elements in medical malpractice: (l) a pre-existing duty, (2) a breach of duty, (3) damage, and (4) immediate cause.

- 1. "Duty to treat" implies that the Licensed physician agrees to practice medicine and accepts a patient for the purposes of medical treatment. In doing so, a physician-patient relationship is established and a contract to provide care exists. The physician owes each patient the duty to possess and to bring to bear on the patient's behalf that degree of knowledge, skill, and care usually exercised by reasonable and careful practitioners under similar circumstances, given the current medical knowledge and the available resources.
- 2. Once a duty to treat has been established, the plaintiff must prove that a breach of duty has occurred. When a health professional fails to comply with minimum standards of his or her specialty, a breach of duty may exist. The physician is expected to act professionally according to the standard of care expected of the similarly trained, reasonable, careful professional under

the same or similar circumstances. Unfortunately, the 'standard of care' changes over time and frequently is not even clearly defined in many instances.

- 3. After the plaintiff proves that a duty to treat exists and that a breach of duty occurred, he or she next has to prove that damage has occurred. Damage is demonstrated through personal loss, injury, or deterioration because of the physician's negligence. Without damage, negligence cannot be established. Damages may include physical and mental disability, pain and suffering, loss of income, present and future medical expenses and death.
- 4. Causation is the last aspect of negligence. If a duty to treat exists, and the standard of care was not met, the plaintiff must prove that the defendant's breach of duty reasonably caused the plaintiff's damage.

In order for the plaintiff to prove negligence of the physician, all four of these components must exist at least in the opinion of a judge or jury that decides the outcome.

#### Conclusion:

In light of the present need for increased awareness of human rights as they relate to health, and to patient rights more particularly, this section provides information on the rights of patients in various countries, including examples of exercised rights.

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