

CONCLUSION AND SUGGESTIONS

Improvement of one's health and health of one's family is a universal aspiration. 'Health' is a prerequisite for happy and productive life in the society for an individual. The First Five Year Plan¹ in India defined 'health' as:

a positive state of well-being in which harmonious development of mental and physical capacities of the individuals lead to the enjoyment of a rich and full life. It is not a negative state of mere absence of disease. Health further implies complete adjustment of the individual to his total environment-physical and social. Health involves primarily the application of medical science for the benefit of the individual and of society. But many other factors, social, economic and educational have an intimate bearing on the health of the community. Health is thus a vital part of a concurrent and integrated programme of development of all aspects of community life.

The meaning of the term health therefore, cannot be understood only as absence of disease or infirmity, but it has to be understood as a condition under which an individual is able to mobilize all his resources-intellectual, emotional and physical for optimum living.² The term must be broadened to include preventive, promotive and rehabilitative services.

The role of 'health' is varied and wider in an individual's life. The thesis therefore, starts with the understanding of the concept of health, its philosophical nature, and health as a human right. This is essential as the end of medicine more or less largely depends in great part on our understanding of the nature of health and illness along with the ethical concerns that loom over medical practitioners, policy makers and judiciary while conferring and protecting rights of patients. The discussion contemplates that the concept of health is highly subjective as health and being healthy means different things to different people. In the beginning it was the general belief that the absence of illness or disease, particularly physical disease was a sign of good health. Over the years the dimensions of the term health was widened

¹ See, First Five Year Plan, Chapter 32, para 2, viewed 12th May, 2014, <http://planningcommission.nic.in/plans/planrel/fiveyr/1st/welcome.html>.

² Goel, SL, *Primary Health Care Management*, Deep and Deep Publications, New Delhi (2004), p.4.

and it started to be understood not only in physical, but also in social, mental or emotional and in spiritual terms. Therefore, the concept has an obvious intersection between healthcare at individual as well as at the societal level and it also has an inter-relationship with aspects such as the provision of a clean living environment, protections against hazardous working conditions, education about disease-prevention and social security measures in respect of disability, unemployment, sickness and injury. Further, the discussions in the chapter show that the concept of health had kept on changing through passage of time and in the late nineteenth century it started to be recognized as fundamental right of every human being. The traditional notion of healthcare tended to be individual-centric and focused on aspects such as access to medical treatment, medicines and procedures. As human rights are interrelated and interdependent, the right to health is not confined to healthcare, but embraces a wide range of socio-economic conditions necessary for people to lead healthy lives, including the underlying determinants of health like nutrition, housing, sanitation, water etc. In other words it is universal and focuses on people as 'rights holders' rather than patients. The concept of patient's rights emerges from the principle of autonomy and self-determination enshrined in the 'right to life' in the human rights documents. With special reference to the doctor-patient relationship, it recognizes the vulnerability of the patient and seeks to mitigate this inequality. Medical treatment in the modern era involves principles of privacy, autonomy and self-determination, thus, the paternalistic approach, where patients meekly submit to the instructions of physician has become a part of history. Hence, advent of rights of patients has become more widespread worldwide.

The doctor-patient relationship is inherently fiduciary in nature. However, the role of the patient in medical treatment is constantly changing. Traditionally, physicians due to their supremacy in medical knowledge often perceived themselves as absolute authorities in judging patient's needs. With the sweeping changes within and outside the health care sector the modern day patient is often placed in the driver's seat directing healthcare needs. Thus, they are not simply passive recipients of care but active, informed individuals who wish to exert greater control over their own care. The second chapter examines the meaning and defines the term 'patient' in the light of physician-patient relationship, as the fundamental interaction in healthcare is the one between patient and physician. The chapter also briefly

discusses the kind of rights and protection which were available to patients during different ages. Against the background of an historical analysis, it is concluded that conventionally patients' rights were protected through ethical rules or codes of conduct. However, these codes acted only as guidelines that the medical professionals imposed in order to ensure that physician's behavior towards their colleagues and their patients met appropriate standards. It was only towards the midst of twentieth century that patients began to challenge medical paternalism and the protection of patients' rights became the focal point on the agenda of many national and international organizations and has become part of national legislation of various countries barring India.

Medicine is an ethical profession and a physician is always confronted with complex and sensitive medical issues. However, advances in medicine have created ethical dilemmas not previously a matter of concern to medical profession and to the society in general. Interestingly, the issues of morality confronted by the physicians go beyond issues of legality and in such instances, a physician is forced to take the help of philosophers to make sound ethical decisions. The third chapter makes a jurisprudential analysis of various theories of medical ethics. The chapter concludes with the argument that medical ethics and medical law is closely connected. While medical law sets down minimally acceptable standard for a physician, medical ethics include various approaches in deciding the ideal way for a physician to make choices when he or she has to balance the needs of the individual patient against the needs of all other patients. Moreover, the basis of both medical law and medical ethics is respect for autonomy, beneficence, non maleficence and justice, among others.

The fourth chapter focuses and discusses as to whether a patient has an absolute 'right' to receive medical treatment? The chapter contemplates that a patient in receipt of medical treatment is entitled to respect for his or her autonomy, physical integrity and privacy, but the entirety of such rights' protection no doubt presupposes that the patient has 'right to medical treatment'. However, access to healthcare is considered to be synonymous with the availability of financial and health system resources in a country. Interestingly, healthcare resources are always limited in comparison with the demand from the public. Thus, limited funding puts pressure on health providers and medical professionals and inevitably results in

some patients being denied the medical treatment which they need. Since the demand for health care services often exceeds supply, prioritization may become necessary. Prioritizing patients can raise ethical dilemmas as the principle of justice is weighed against the costs and benefits of living in a complex, diverse society. An analysis of case-laws from different countries including India suggests that courts are reluctant to be persuaded by economic arguments and continues to see the physicians' role as acting in the patient's good and less on the needs of the population as a whole. Therefore, the chapter comes to the conclusion that providing basic life-sustaining treatment for a patient who needs and desires it is a basic obligation upon a State and an important aspect of patient's right to life and autonomy. The chapter also focuses upon the duty of the physician to provide quality care to the patients as once a patient overcomes the hurdles presented by the scarcity of resources and obtains medical treatment, the focus turns to the quality of the treatment availed. The discussion of case-laws from various countries including India suggests that a certain minimum standard of care is imposed upon medical professionals and legal liability might ensue if treatment falling below that standard causes some harm to the patient. This is because in the healthcare context it is a general assumption that a doctor owes a duty of care to his patient. This assumption is based on the fundamental nature of the doctor-patient relationship which incorporates an obligation of caring as an inherent feature of it.

The right to have control over one's body and refusal of unwanted touching in medical law is founded on the principle of patient's right to autonomy and self-determination. The legal principle of consent is the conceptual mechanism through which the patient's right to self-determination is guaranteed and safeguarded. The fifth chapter analyses the ethical underpinnings of the whole concept of consent and the essential elements which have to be satisfied in order for a competent and incompetent patient to give a valid consent. The chapter concludes that for consent to treatment or a refusal of treatment to be legally valid it must be made by a person with competence, adequate information and voluntarily without coercion or undue influence. To be competent to give a legally effective consent, the patient must be endowed with the ability to weigh risks and benefits of the treatment that is being proposed to him. The law presumes that such ability is generally acquired with the attainment of age of so called maturity. Many countries have statutes specifically

mentioning the appropriate age for giving valid consent for medical examination and procedures. But, no statutes in India throw light on this matter nor do the existing laws make a clear reference regarding the age of consent and medical treatment. As a result, the laws dealing with consent in general are also being applied to the medical profession. According to the Indian Majority Act, persons who have attained the age of eighteen are generally considered competent to give consent.³ Hence, a person who has attained the age of eighteen and who has sound mind can give valid consent to the medical practitioner for any treatment. This therefore excludes children in India. Then, the chapter discusses as to the instances where a patient in spite of attainment of legally competent age is unable to consent to medical treatment. These patients may be categorized as unconscious or mentally incompetent. In relation to children, proxy consent may suffice but, principle of proxy consent is not considered an option for an adult patient who is incompetent. For the purpose of discussion with regard to the competency of incompetent adult patients, they are categorized into two distinct groups. The first group covers those patients who are usually competent but are, for some reason or other, incapacitated at the time when the need for consent to be obtained arises. The second category would cover people who can be described as long-term incapacitated patients. An analysis of various case laws, suggests that the 'doctrine of necessity' or application of 'best interests' principle is a viable defence to any proceedings for non-consensual treatment where an unconscious patient or long-term incompetent patient is involved and there is no known objection to treatment. The treatment undertaken, however, must not be more extensive than is required by the exigencies of the situation. The chapter also discusses the importance of advance directives in determining the kind of treatment a patient would or would not consent to in the event that he or she becomes incompetent. A discussion of case laws from western countries suggests that any valid advance refusal of treatment made when the patient was competent and on the basis of adequate information about the implications of his or her choice is legally binding and must be respected so far, it is clearly applicable to the patient's present circumstances and where there is no reason to believe that the patient had changed his or her mind. In India, at present the law pertaining to the advance directive made by incompetent patients can be found only

³ See, the Indian Majority Act, 1875 (9 of 1875).

in Mental Health Bill, 2013. But, it is to be specifically mentioned here that this Bill is introduced only in the Rajya Sabha and has not taken the form of a statute and hence not legally binding.

The concept of privacy has roots in the principle of autonomy which requires individuals to be as free as possible from external forces so as to enable their actions to reflect as truly as possible their autonomous choices and intentions. The sixth chapter discusses the importance of privacy and medical confidentiality in protecting autonomy and self-determination of patients. The chapter contemplates that though physician-patient relationship is fiduciary in nature and privacy is viewed as a key governing principle of the patient-physician relationship, doctors have no absolute duty to keep confidential everything that is imparted to them by their patients. An analysis of various case-laws further, suggests that duty to maintain a confidential relationship between a physician and a patient is not mandatory and at times a doctor might be justified in disclosing certain information to the public. In the modern day, most of the information acquired by physician is recorded and preserved at the hospitals and these medical records are regarded as the property of the hospital by law. As a general rule, the medical record is a confidential document and access to it is limited. However, analysis of various case-laws suggests that though, medical records are the property of the physician, institution, or clinic which compiled them, the relationship between doctor and patient casts on the doctor a fiduciary duty to provide patient with access to his or her medical records and hence, patients have a general right of access to the 'information' in their record. A study of law on medical privacy in India shows that legal protection of medical privacy is scattered and inconsistent.

To summarize from the discussions being made in the previous chapters and above, we find that the specific rights of patients like right to medical treatment, informed consent, privacy and medical confidentiality has now been expressly recognized and guaranteed through various international documents. Also, statutes adopted by individual States like United States, Australia, countries from European Union, and even some countries from middle east has expressly conferred patients with the direct legal rights and remedies in their relationship with health care providers. An analysis of statutes from these countries brings to the light that

patients' rights vary in different countries and in different jurisdictions depending upon the prevailing political, cultural and social norms. However, all the States more or less recognize the following basic rights of patients: Right to health care, Right to be treated with dignity, Right to information, Right to informed consent, Right to refuse treatment, Right to privacy, Right to complaint etc.

Interestingly, in India the patients' rights have neither been expressly enunciated through a statute nor through judicial decisions. The discussions in the chapters above brings to the light that it is the judicial decisions mostly from the western countries which has concretely put forward a mechanism to address the grievance of the patients as these decisions have most often addressed the complex ethical questions concerning the medicine and law. India lacks a concrete mechanism through which patients rights can be protected or guaranteed. Against this backdrop, following suggestions has been put forth so that specific rights of patients in India is protected and guaranteed.

SUGGESTIONS

1. NEED FOR LEGISLATION TO PROTECT THE RIGHTS OF PATIENTS

To provide a patient-centred healthcare it is essential that rights of patient's are articulated clearly. In India, we have plethora of laws in the area of healthcare but, as these laws lack organization and clarity, it creates confusion in the mind of both patients and healthcare providers. Moreover, in our country we neither have legislation nor any patient's rights charter which specifically enumerates the rights and responsibilities of patients.

A. DEFINITIONS

The definition of the term 'patient' along with other terms like 'patient representative', 'right to healthcare', 'healthcare provider' and 'capacity to consent' are crucial for the efficacy of the implementation of the statute. Hence, an attempt is made to describe these terms.

a) Patient

The European Declaration on the Promotion of Patients' Rights, the only international instrument which defines the term 'patient' went on to state them as 'a

user of health care services, whether healthy or sick'.⁴ Accordingly, a patient is a person who receives, or received health care services at a hospital or at a clinic. However, there are various instances where patients depend upon their family doctor or a doctor in case of an emergency or where a doctor is invited to a patient's home or other places and medical treatment is obtained. For example, in *State v Pitchford*⁵ the court laid down that when physician attends to a person for purpose of giving professional aid, even though person attended is unconscious or unaware of physician's presence and does not consent, or actually objects to being treated, is a patient in the eyes of law. Thus, a 'patient' may be defined in the Act as any person who has requested for healthcare service or who has received or is receiving medical care, treatment or services from an individual or institution licensed to provide medical care or treatment. The treatment obtained by the patient may be for his own interest or in the interest of society.

b) Patient Representative

It is important to define the term 'patient representative' broadly. Patient Representative may be a person who has a personal interest in the health care of a patient for example, a member of the patient's family or the person whom the patient names as his or her kin or next of kin or a care-giver who performs the function either free or with remuneration. Family may include group of persons who are related to the patient by blood, adoption or marriage.⁶ If the patient is incapable of naming his or her next of kin, the next of kin shall be the person who to the greatest extent has had lasting and continuous contact with the patient, based however on the following order: spouse, registered partner, persons who live with the patient in a relationship resembling a marriage or partnership, children of full legal age and legal capacity, parents or other persons with parental responsibility, siblings of full legal age and legal capacity, grandparents, other family members who are close to the patient, guardian or provisional guardian or such other categories of person as the court considers appropriate.

⁴ See, European Declaration on the Promotion of Patients' Rights, Art.7.

⁵ 10 Kan.App.2d 293.

⁶ See, s. 2(b), Mental Health Bill, 2011.

c) Right to Healthcare

A right to health care must imply, on its face a right to certain services. It must entitle right-holders to the 'goods and services' that aid in the achievement of health and consequently must obligate the government to ensure access to these goods and services. Thus, healthcare may be defined as a means to an act which has a preventive, diagnostic, therapeutic, health-preserving or rehabilitating effect including emergency medical treatment and is carried out by health personnel for the purpose of nursing and care.

d) Healthcare Provider

Healthcare provider means a provider of services. In the modern day, healthcare services are not just restricted to physicians. There are various other personnel's involved in the provision of quality care to patients. Thus, the definition of healthcare provider must be broad enough to cover all the personnels who are involved in the care of patients. A 'healthcare provider' may therefore be defined as any physician who is authorized to practice medicine or surgery by the medical professional body or State. Further, as defined in American HIPPA Privacy Rules⁷, along with the physician, health care service must also include services and supplies furnished as an incident to a physician's professional service, or kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills. Along with the physician the definition may also include podiatrists, dentists, clinical psychologists, optometrists, chiropractors, nurses, midwives, clinical social workers, physician assistants or other appropriately trained and qualified person with specific skills relevant to particular health care, nursing, rehabilitative, palliative, convalescent, preventative or other health services.

e) Capacity to consent

For consent to treatment, or to a refusal of treatment, to be legally valid it must be made by a person with competence, adequate information and voluntarily without coercion or under undue influence. To be competent to give a legally effective consent, the patient must be endowed with the ability to weigh risks and

⁷ See, HIPPA Privacy Rules, Section 160.103.

benefits of the treatment that is being proposed to him. The law presumes that such ability is generally acquired with the attainment of age of so called maturity. According to the Indian Majority Act, persons who have attained the age of eighteen are generally considered to be competent to give consent.⁸ Thus, a person who has attained the age of eighteen and who has sound mind can give valid consent to the medical practitioner for any treatment. This therefore excludes children. However, there are instances where a patient in spite of attainment of legally competent age finds unable to consent to medical treatment. These patients may be categorized as unconscious or mentally incompetent.

The Act while defining ‘capacity’ of a person to consent or refuse treatment must, consider the ability of an individual, including a minor or a person with mental disability. The capacity of a person must be assessed by the relevant health service provider on an objective basis, to understand and appreciate the nature and consequences of a proposed treatment or of a proposed disclosure of health related information, and to make an informed decision concerning such health care or information disclosure along with the age of majority.

B. SPECIFIC ENUMERATION OF RIGHTS OF PATIENT

For an effective legislation in this area it is essential that rights are articulated clearly. Therefore, given below are some of the important rights which the researcher feels must explicitly be guaranteed for protection of rights of patients.

1) RIGHT TO HEALTHCARE

The statute in India must explicitly recognize the right of patients to healthcare. The inclusion of such a right may seem to empower patients to demand an absolute right to healthcare or timely treatment as a right. An absolute right to treatment is impossible in the light of scarce resources; hence such a guarantee must be phrased carefully. To overcome such a confusion right to healthcare in the statute must be expressed as limited by resource constraints. For example, Act on the Status and Rights of Patients in Finland has guaranteed every patient to health and medical

⁸ See the Indian Majority Act, 1875 (9 of 1875).

care required by his state of health within the resources available to healthcare at the time in question.⁹

2) RIGHT TO EMERGENCY TREATMENT

A patient must be entitled to have a basic life sustaining treatment necessary to ward off a situation imperiling his or her life irrespective of his ability to pay. In other words, whenever a physician is requested to give medical treatment to a patient in circumstances indicating *prima facie* a medical emergency the physician shall examine and treat the patient to the best of his ability. If the doctor is unable to provide the required treatment he or she must ensure that the patient is transferred to another hospital where the patient can receive appropriate treatment. This right must be extended to circumstances where it is not possible for ascertaining the patient's will because of unconsciousness or some other reason. However, if a competent patient has expressed his or her will concerning treatment given to him or her, it must be respected and no such treatment must be provided which is against his or her will.

4) RIGHT TO QUALITY CARE

It is the duty of the State to ensure that every patient has a right to good quality healthcare and medical care. The care of the patient has to be arranged in such a way that he or she shall be treated with human dignity and his or her privacy is adequately respected. As far as possible there must be an endeavor on the part of healthcare providers to respect the individual and religious needs of the patient. Effort must be made by the physicians to communicate with the patient in their mother tongue as it is a prerequisite for achieving patient-centered healthcare. Further, every hospital or institution which provides healthcare services whether government or private must have an internal committee called 'control and quality committee' to evaluate medical facilities and improve the quality of the medical care.

⁹ See, s.3, Act on the Status and Rights of Patients, 1992, <http://www.finlex.fi/en/laki/kaanonkset/1992/en19920785.pdf>.

5) PATIENT'S RIGHT TO PARTICIPATION

Patient's right to participate in the implementation of his or her health care must be expressly recognized. This must necessarily include the patient's right to participate in choosing between available and medically sound methods of examination and treatment. The form of participation shall be adapted to the individual patient's ability to give and receive information. If the patient is not competent to give consent, the patient's next of kin must be entitled to participate together with the patient. If the patient wishes other persons to be present when health care is provided, his or her wishes shall be accommodated as far as possible.

6) RIGHT TO SELF-DETERMINATION

a) General rule

Medical care may only be given to the patient with his or her consent unless legal authority exists or there are other valid legal grounds for providing healthcare without consent. Consent may be given either explicitly or tacitly. Tacit consent may be considered to be given based on the patient's conduct and all other circumstances that he or she accepts the treatment. For written consent there must be standardized forms issued by the government for both government and private hospitals. The patient shall have the right to withdraw his consent at any stage of treatment. If the patient withdraws consent, the health care provider shall give the necessary information regarding the consequences of not subjecting himself to the required treatment.

b) Competence to give consent

Patients who have attained the age of majority and has the legal capacity may have the right to consent to medical treatment. In the case of minors who are above twelve years and showing necessary understanding and maturity, may consent to medical treatment. Competence to give consent may cease to apply wholly or partly if the patient, on account of a physical or mental disorder, senile dementia or mental retardation, is clearly incapable of understanding what the consent entails. The health care provider shall decide whether the patient lacks competence to give consent pursuant to the incompetent patients and minors. Based on the patient's age, mental state, maturity and experience, health professionals shall do their best to

enable the patient himself or herself to consent to health care. If the health professionals arrive at a decision that the concerned patient lacks necessary competence he or she shall state the reasons for the decision and the same may be given in writing to the patient, his care-givers and to the concerned authorities.

c) Consent on behalf of persons who are of full legal age and legal capacity and who are not competent to give consent

If a patient who is of full legal age and legal capacity is not competent to give consent, the health care provider may make decisions concerning health care that is not of a highly invasive nature with regard to its extent and duration. Health care may be provided to the extent which is deemed to be in the patient's best interests, and which the patient himself or herself perceived to have given permission for such care if in a competent state. The patient's next of kin may also consent to health care. For the purpose, information may be obtained from the patient's next of kin in order to determine what the patient would have wanted. A health care provider may also, in consultation with other qualified health personnel, consent to health care for patients who are not competent to give consent and who have no next of kin.

d) Consent on behalf of children

The parents or other persons with parental responsibility are entitled to consent to health care for patients below 18 years of age. If the State has taken a child into its care under *parens patriae* jurisdiction then the decision will be taken by the court in consultation with the concerned welfare authorities. However, otherwise consent to treatment by patients above twelve years may be given by the child himself or herself, if the physician arrives at a decision that the patient has necessary understanding and intelligence to arrive at a decision. Thus, as the child grows and matures the child's parents, other persons with parental responsibility must give importance to the child's views and opinion on questions concerning his or her own health.

7) RIGHT TO INFORMATION

Health care may only be provided with the patient's consent, unless there are other valid legal grounds for providing health care without consent. In order for the

consent to be valid, the patient must have received the necessary information concerning his health condition and the content of the health care. Physician therefore, must ensure that the patient has necessary information about his or her state of health and the significance of the treatment undergone for curing the disease. The patient shall also be informed of possible risks and side effects. If a patient seeks information about alternative forms of treatment and their effects on him or her; the physician must wholeheartedly share the information which are significant for the patient to arrive at a decision. Healthcare professionals must make an effort to provide all information in such a way that the patient can understand. Therefore, it is essential that the physician uses the language in which the patient can understand. Services of an interpreter shall be utilized in instances where the physician finds unable to communicate in the mother tongue of the patient or where a patient suffers from sensory handicap or from speech defect. However, no information shall be given to the patient against his or her expressed will unless it is necessary in order to prevent harmful effects caused by the treatment. Information can also be omitted in such instances where it is necessary to prevent causing of serious damage to the patient's health or life. Therefore, the information shall be provided in a considerate manner. It must be in consonance with the age, maturity, understanding, qualifications and also cultural and linguistic background of the individual recipient. As far as possible, health personnel shall ensure that the patient has understood the contents and significance of the information. The patient shall also be entitled to a brief and simple explanation of medical terms and such other doubts on request. An entry concerning the information that has been provided shall be made in the patient's medical records.

a) Providing Information to Minors

In India, if the patient is under twelve years, both the patient and his or her parents or other persons with parental responsibility shall be compulsorily informed. If the patient is above twelve and below eighteen, information can be withheld from the parents or persons with parental responsibility if the patient expresses his or her wish that the information shall not be divulged. However, information shall be provided to the parents or persons with parental responsibility if the doctor is satisfied that the patient does not have the sufficient understanding and maturity and

also in circumstances where the disease is life-threatening. In case of conflict between the patient, physician and the parent, the State must have the freedom to exercise its choice through child welfare authorities and the courts with respect to the medical treatment of the minors.

b) Providing Information to the Patient's Next of Kin

If the circumstances justify the patient's next of kin must be provided information with regard to the kind of treatment the patient has received. An adult patient who is incapable of safeguarding his or her own interests due to a physical or mental disorder, senile dementia or mental retardation, both the patient and his or her next of kin must be entitled to the information relating to the medical treatment.

8) THE PATIENT'S RIGHT TO REFUSE TREATMENT

The patient may be entitled to refuse to receive blood transfusion and may also be entitled to object to life-prolonging treatment. If the patient is incapable of communicating his or her wishes as regards treatment, the health professionals shall refrain from providing health care if the patient's next of kin express similar wishes, and the health personnel, based on an independent assessment, find that this is also the patient's wish and that the wish should clearly be respected. Health personnel must make sure that the patient is of full legal age and legal capacity, and that he or she has been given adequate information and has understood the consequences of refusing treatment for his or her own health.

9) ADVANCE DIRECTIVE

An advance directive is an instruction by a patient as to the withholding or withdrawing of certain medical treatment in advance of the patient suffering a condition rendering the patient unable to refuse such treatment. Any person who has attained the age of eighteen years in India may make an advance directive. Any valid advance refusal of treatment one made when the patient was competent and on the basis of adequate information about the implications of his or her choice shall be legally binding and must be respected where it is clearly applicable to the patient's present circumstances and where there is no reason to believe that the patient had changed his or her mind. The legal guardian shall have right to make an advance directive in writing in respect of a minor and all the provisions relating to advance

directive relating to the adult may apply to such minor till such time he attains majority.

a) Manner of making advance directive

An advance directive to be legally valid, first and foremost, it must be in writing with the person's signature or thumb impression attested by two witnesses, clearly stating the way the person wishes to be cared for and the circumstances in which he or she is not to be cared for. It may include the list of individual or individuals in order of precedence he or she wants to appoint as his or her nominated representative. It must be compulsorily registered. No fee may be charged. For the purpose the Central Government may constitute a Health Review Commission under whose authority a Health Review Board may be constituted at every district in the State. The advance directive may be registered with the Health Review Board in the district where the person is ordinarily resident. Further, the directive must be signed by the medical practitioner certifying that the person has the capacity to make healthcare and treatment decisions at the time of making the advance directive and that the advance directive has been made out of his own free will. Where the advance directive is for withdrawal of life saving treatment such advance directive may be held valid only after it has been submitted to the Health Review Board and the Board after a hearing has to certify that the advance directive is valid. If the advance directive is not been registered or signed by the medical practitioner the decision may be taken by the treating physician by applying the 'best interest' principle. An advance directive shall not apply to the person who seeks emergency treatment.

b) Revocation, amendment or cancellation of advance directive

An advance directive may be revoked, amended or cancelled by the person who made it at any time. The procedure for revoking, amending or cancelling an advance directive may be the same as for making an advance directive as discussed above.

c) Power to review, alter, modify or cancel advance directive by the patient representative or medical professional

Where a medical professional or a relative or a care-giver of a person desire not to follow an advance directive while treating a person, such medical professional, relative or care-giver may make an application to the Health Review Board to review, alter, modify or cancel the advance directive. Upon receipt of the application for review, alter, modify or cancel, the Board has to consider whether the advance directive was made by the person out of his own free will and free from force, undue influence or coercion; whether the person intended the advance directive to apply to the present circumstances, which may be different from those anticipated; whether the person was sufficiently well informed to make the decision; whether the person had capacity to make decisions relating to his health care or treatment when such advanced directive was made and whether the content of the advance directive is contrary to other laws or constitutional provisions. The Board after giving an opportunity of hearing to all concerned parties may uphold, modify, alter or cancel the advance directive.

d) Liability of medical professionals in relation to advance directives

A medical professional shall not be held liable for any unforeseen consequences on following a valid advance directive. Also, the medical professional shall not be held liable for not following a valid advance directive if he or she has not been given a copy of the valid advance directive.

10) CONFIDENTIALITY OF INFORMATION IN PATIENT DOCUMENTS

The information contained in the patient documents shall be confidential and health care professionals or other persons working in a healthcare unit or carrying out its tasks shall not give information contained by patient documents to outsiders without a written consent by the patient. If a patient is not capable of assessing the significance of the consent, information may be given by his or her legal representative's written consent. The outsiders may be referred as persons other than those who participate in the care of the patient or in carrying out jobs related to it in the health care unit in question or by its order. The secrecy obligation shall remain in force even after termination of the employment relationship or the job. However,

information included in patient documents may be disclosed if there are express provisions or on the right of access to it in the law; information necessary for the arranging of examination and treatment of the patient may be given to another health care unit or health care professional, and a summary of the treatment provided may be given to the hospital or the health care professional that referred the patient for treatment and to a physician possibly appointed to be responsible for the care of the patient in accordance with the patient's or his or her legal representative's orally given consent or consent that is otherwise obvious from the context; and information necessary for arranging and providing the examination and care of a patient may be given to hospital or health care professional, if the patient, owing to mental health disturbance, mental handicap or for comparable reason is not capable of assessing the significance of the consent and he or she has no legal representative, or if the patient cannot give the consent because of unconsciousness or for comparable reason; information about the identity and state of health of a patient may be given to a family member of the patient or to other person close to the patient, if the patient is receiving treatment because of unconsciousness or for other comparable reason, unless there is reason to believe that the patient would forbid this; and information on the health and medical care of a deceased person provided when the person was still living may be given upon a justified written application to anyone who needs the information in order to find out his or her vital interests or rights, to the extent the information is necessary for that purpose; the acquiring party may not use or forward the information for some other purpose.

In the case of supply of information contained in patient's documents for scientific research and compilation of statistics Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011 may be made applicable.

11) RIGHT OF ACCESS TO MEDICAL RECORDS

The Medical Council of India Regulations, 2002 has made it mandatory for the physicians to maintain medical records pertaining to the treatment given to the patient's and has recognized the right of the patients to claim his or her medical

record.¹⁰ However, it is silent on the circumstances when a patient may be denied access or on what circumstances a patient is allowed to have access or who can have access to the medical records after the death of the patient. A patient may be entitled to have access to his or her medical records and on special request may be entitled to have a copy of the same. However, he or she may be denied access to his or her medical records only if this is absolutely necessary in order to avoid endangering the patient's life or causing serious damage to the patient's health, or if access is clearly inadvisable out of consideration for persons close to the patient. Where a patient is denied access his or her representative may have access to the medical records unless the representative is considered to be unfit for the same. After the death of the patient the next of kin of the patient may have access to the medical records.

C. COMPLAINT MECHANISM

The evidentiary burden, costs and delays associated with ordinary litigation makes it cumbersome for enforcing patient rights in an effective manner. If patient's rights are to be meaningful, it must provide patients with an inexpensive, readily accessible, independent means by which to file a complaint and have it quickly resolved. For example, in New Zealand, the health and disability commissioner uses various methods of dispute resolution, advocacy, mediation, etc., with a focus on promoting resolution directly between providers and patients.¹¹ It is important that patients have recourse to an adjudicative body which they perceive as impartial. Establishment of an independent patient ombudsman to resolve complaints using a variety of informal and formal mechanisms is one suggestion. A 'Patient Ombudsman' may be appointed in India for the purpose of advising patients in issues concerning the application of the provisions of the statute. He may also have the power to settle disputes through negotiation, conciliation and mediation and in circumstances where the ombudsman fails in resolving disputes, a report must be drafted and this report may be summoned to the court in appropriate instances leading to litigation. It is also important for an ombudsman to have an information-gathering function with respect to healthcare system issues and to advise health care

¹⁰ See, Rule 1.3 of The Indian Medical Council (Professional Conduct, Etiquette and Ethic) Regulations, 2002

¹¹ Sladden N, Graydon S, "Liability for medical malpractice - recent New Zealand developments", 28 *Med Law* 301 (2009).

institutions, the government and the public on pertinent matters.¹² In addition, in the pursuit of a more patient-centered system, an ombudsman is also typically required to publicly promote the observance of patients' rights and to issue public reports on matters affecting patients. For carrying out the entrusted tasks effectively he may take the help of internal 'control and quality committee', suggested to be set up by the hospitals (refer under the heading right to quality care). Further, he may also take the help of governmental departments, local self-government bodies and other non-governmental organizations. A Patient Ombudsman may appoint any number of persons under him for ensuring conditions and circumstances in realizing the rights of patients. It is important that a Patient Ombudsman and all other officers working in the Patient Ombudsman's office to have sufficient training in matters that may come before this office. Often, but not always, it is also useful to have someone with clinical experience, who understands the language of healthcare professionals. Legal training is also needed as a Patient Ombudsman may have to deal with conflicts that could be taken to court or require some kind of semi-legal settlement between the parties. It is crucial that all complaints are handled in a systematic way, that they are identified, documented, categorized and analyzed. Though, an Ombudsman is not empowered to make binding recommendations or unlike a court, the power to award damages, this has been found successful in most countries. For example, annual report of the Quebec ombudsman for the year 2009-10 shows that 98% of recommendations *vis-a-vis* patient complaints had been accepted by the relevant health care providers.¹³ According to Colleen M. Flood¹⁴ 'partial explanation for this success may be that an ombudsman whose recommendations are not binding makes the complaints process less contentious, and health care providers are thus more receptive to the process than if it were binding and more adversarial'.

2. NEED FOR EVOLUTION FROM DOCTOR-CENTRIC TO PATIENT-CENTRIC CARE

Laws and their enforcement no doubt play an important role in protecting rights of patients but these alone are not enough. What is necessary is to reinvent the

¹² Paterson R, "The patients' complaints system in New Zealand", 21 *Health Aff* 70 (2002), p.73.

¹³ Annual Report Quebec (QC), The Ombudsman (2010), viewed 14th May 2014, www.proteccurducitoyen.qc.ca/en/cases-and-documentation/index.html.

¹⁴ Colleen M. Flood, A patient charter of rights: how to avoid a toothless tiger and achieve system improvement, *CMAJ* (2012), p.3.

relationship between doctor and patient. In other words, there must be a shift from doctor-centric care to patient-centered care. Creating trust, respect and emotional comfort should be an important focus of the physician's responsibility and this will go a long way towards enhancing the quality of healthcare services. This can be done by the physician by giving emphasis on three important elements:

a) Transparency

Transparency between physician and patient in the consultation and intervention process is only possible when a doctor treats a patient as an equal partner in the process. An open consultation with the patient is essential where diagnoses are discussed, treatment options are evaluated and interventions are initiated. If the patient has a full understanding of what is being done to his body, what side-effects to anticipate and how to manage these, treatment compliance as well as outcome tends to be better.

b) Confidentiality

The relationship between body, mind and the sense of self is unique to each individual and is the individual's own business and no concern of anybody else, even those who are considered to be related to the individual. Thus, the primary line of confidentiality that the doctor has is with the patient and no one else. However, if the patient permits or desires expanding the line of confidentiality to include or designate to others is acceptable. When a patient realizes that the doctor is serious about keeping personal information confidential even if the information is not particularly damaging, it engenders a feeling of trust in the doctor and immediately create an excellent platform for healing to begin.

c) Defining limits

A physician must have a definitive awareness of his own limitations and limits, thereby strengthening the possibility of defining boundaries in the relationship with the patient. Apart from learning how to say 'I don't know', referring a patient to another competent physician for a second opinion, limiting the consulting hours to physically manageable proportions, determining the level of telephonic accessibility to be provided to patients, clarifying how emotionally close one gets to a patient etc. are issues that requires conscious attention and discussion.

An important aspect of defining boundaries is the consultation fee, for this ensures that the relationship remains on a consultative platform. Often fees are charged on the basis of perceived affordability of the patient. While this may be an apparently egalitarian approach to the issue, it immediately creates a potentially discordant class division in the patient population. Application of mind to defining the fee structure has the added advantage of ensuring that the physician need not supplement his income by resorting to dodgy alternatives.

To conclude, the above mentioned suggestions and legal framework for protection of rights of patients if implemented will go a long way in guaranteeing the rights to patients in India.