J Indian Acad Forensic Med. October-December 2015, Vol. 37, No. 4 **ISSN 0971-0973**

Review Research Paper

Patient Autonomy and Informed Consent: The Core of Modern Day Ethical Medical

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Abstract

The UN Charter of Human Rights says: "All human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood." In the words of Judge Cardozo, "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable". This in complete contradiction to the Hippocratic Oath, which is the Oath taken by most medical graduates in the world.

The most important principle for modern medical ethics is respect for patient autonomy, informed consent and patient confidentiality. The goal of informed consent is to respect patient autonomy and enable him to make decisions regarding his medical care, of his free will, without coercion, after understanding fully what he is consenting for. The Principle of Autonomy, its implications on informed consent and patient care situations will be dealt with in this paper.

Key Words: Principle of Autonomy, Informed Consent, Ethical Medical Practice, Patient Autonomy,

Introduction:

The Original Hippocratic Oath states: "I swear by Apollo and Aesculepius that I will follow that system of regimen which according to ***my*** judgment ***I*** consider best for the benefit of ***my*** patients…. **Conceal** most things from the patient……give necessary orders with cheerfulness and serenity….**revealing nothing** of the patient's future or present condition". [1]

We have come a long way from that Paternalistic approach to the present, as exemplified by the words of Judge Cardozo in Schloendroff vs. Society of New York Hospital (1914, US)[2] and the United Nations Universal Charter of Human Rights adopted by the General Assembly in 1948. [3]

The foundation of modern day bioethics stands on four principles enunciated by Beauchamp and Childress [4]: Autonomy, Beneficence, Non-maleficence and Justice. They have withstood challenge for nearly three decades and still form the basis for most decision making in both clinical practice and biomedical research.

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DOR: 20.04.2015 DOA: 13.08.2015
DOI: 10.5958/0974-0848.2015.00106.2

They have withstood challenge for nearly three decades and still form the basis for most decision making in both clinical practice and biomedical research. Collectively, these four have been termed as 'principilism'. [5]

Autonomy requires the ability to decide for the self, free from control of the others, and with sufficient level of understanding so as to arrive at a meaningful choice. [6] A person should have the capacity to decide upon a course of action, and to put that plan into action.

Beneficence implies that we "do good" for the others and contribute towards their well being. In order to give the "optimum" good to the patient, the doctor should be able to understand "how much" good would give the best result to the patient; that is; he should weigh the benefits with the risks involved and then act accordingly.

However, Beneficence is hindered by Autonomy. It is not ethical to "do good" for the patient without obtaining an informed consent from him. Determining what is "good" to oneself is that person's personal decision and that may differ from what the doctor/ relatives etc, think would be best for the patient.

Non-maleficence: "Primium non nocere" – 'first does no harm', is another guiding principle of bioethics. It may also be taken to represent the risk side of risk-benefit analysis of any regimen. Whatever the doctor does for the patient should be done in 'Good Faith' and for his good health only.

[S. 52 IPC] [[7] states: Nothing is said to be done or believed in good faith if it is not done or believed with due care and attention. **Justice** addresses the question of

a. Distribution of scare health care resources.
b. Respect for people's rights and
c. Respect for morally acceptable laws.

It is also one of the toughest Principles of Bioethics as it raises one serious question – Is there a universal right to health care?

If there is not, how to provide care for those who cannot afford it? If there is, to what level in such case to be offered and who will fund it? How will fairness be ensured? [5]

The Principle of Autonomy:

The Greek definition of Autonomy implies "Self-rule & Self-determination", which comes from the term "autos nomos".

It implies that the doctor is obligated not only to respect the free choice of his patient, but more importantly, to facilitate in every reasonably possible way the making of such a free choice by the patient. Autonomy is the capacity for self-determination.

To respect a person's autonomy is to acknowledge his right to make choices and take action based on his own values and belief system. The principle of respect for autonomy implies that one should be free from coercion in deciding to act, and that others are obligated to protect confidentiality, respect privacy, and tell the truth. Respect for patient autonomy involves not only ethical obligations to respect patient choices, but also obligation to promote both patient autonomy and autonomous choice.

In the practice of health care, a person's autonomy is exercised through the process of obtaining informed consent. Patients who do not comply with the instructions given by the doctor or who refuse investigations/ blood transfusions, etc. pose a great challenge for their doctors.

The main reason is that non-compliance generally leads to undesirable/ bad medical outcomes; whereas patient's good health is the main goal of the physician. Hence, these doctors tend to develop a "paternalistic" attitude towards their patients and try to influence/ manipulate/ or outright coerce the patients into following the treatment regimen to the hilt.

Many doctors/ health care workers tend to override the patient's autonomous decision in the mistaken belief that their primary duty is the good, healthy outcome for their patient. This is an instance of '**Medical Paternalism**', which, according to Zenbaty: [8] "Paternalism is the interference with a patient's autonomy justified by reasons referring exclusively to welfare; good, happiness, needs, interests, or values of the person being constrained."

Even with such justifications, paternalism presents number of moral problems and has been held to be an unethical practice. It negates patient autonomy completely and is considered an unethical practice. Such doctors do not respect their patients as autonomous individuals and perceive informed consent as a mere legal formality designed to protect them from malpractice litigations.

Failure to obtain informed consent of the patient is an infringement on the autonomy of the patient, regardless of the fact whether a potential for harm exists and is a failure on part of the doctor to respect a patient as an equal individual. Even when only one type of medical treatment available to the patient, he still has two choices: Accept/ Refuse the said treatment.

Thus, the principle of beneficence appears to contradict the principle of patient autonomy. But, both these principles, when brought to play in such a way as to complement each other, form the basis for another very important concept of Bioethics Informed Consent. The doctor explains to the patient in a simple, clear, non technical language the ailment/ disease condition he is suffering from, the proposed treatment which the doctor thinks is the best for the patient, the proposed cons (including risks, etc), alternatives, prognosis with the proposed plan and without it.

The patient, after understanding the whole proposed treatment regime and after satisfying himself completely, makes a decision-accepting or refusing the same. The doctor has to abide by this decision.

Informed consent is not just a legal duty to warn the patient about potential risks and obtain this signature on the dotted line. It is not just a formality for ensuring that the "conditions of understanding between the doctors and his patient are placed in writing". [9]

It is a process that underlies the doctor - patient relationship an ongoing "dialogue" between the patient and his doctor and not merely a dateable event that occurs when ever a decision must be made because of the potential harmful consequences. [10]

It brings about a different equation to the doctor-patient relationship: one based on mutual trust and respect. It becomes an ongoing dialogue where in the risks and benefits of all treatment alternatives are explained and explored so as to customize (tailor) the same for the patient, keeping in view his personal values, interests and goals.

The principle of autonomy also places important responsibilities on the patient. The most important of these is the fact that the patient accepts responsibility for his own decisions. Once, it is clear that there was no deception /manipulation /undue influence/ coercion and that there was no negligence on part of the doctor, once an autonomous decision is made by the patient, the responsibility for all the consequences of that decision lies with him only. This responsibility does not shift even if the decision so taken was "medically in correct."

The second responsibility of the patient is to "contribute freely and truthfully to the going medical dialogue" for obtaining his informed consent. [11]

One important duty of an individual is to respect other individuals as beings with dignity. This implies that a person should respect another person's decisions and not override those decisions.

It means that no person should use another as merely a means to achieve some result, even if that result benefits the other person. By doing so, the patient is not perceived as an individual with dignity. Hence, the principal foundation of informed consent is the principle of autonomy; the primary goal is the protection and enhancement of autonomy.

In Harnish vs. Children's Hospital Medical Center [12], the court ruled: "A physician owes to his patient the duty to disclose in a reasonable manner all significant medical information that he possess or should reasonably possess that is material to an intelligent decision by the patient whether or not to undergo that procedure". It is important for the physician to understand that for proper decision making, 'not all medical facts are material ones and not all material facts are medical ones'.

Let's take an example: Ankita and Harleen are 39 years old and both are diagnosed as case of breast cancer (2 cm lump). They were told by their doctors that they have two choices, each with almost similar cure rates: Lumpectomy with adjunctive chemotherapy or mastectomy with chemotherapy. Ankita decides to undergo lumpectomy as she is more interested in having minimal recovery time and a minimal surgical scar, confident in the belief that there would be almost no recurrence.

Harleen is also worried about the surgical scar and recovery time but she is afraid of recurrence as her mother died of breast cancer after protracted treatment and suffering.

She hence, goes for bilateral mastectomy to ease her fears of recurrence. Even though the facts are the same for both the ladies, their decisions are different, based on non-medical issues: minimal recovery period and surgical scar for Ankita and the past experience of her mother's prolonged fight with breast cancer for Harleen.

Components of Patient Autonomy:

Patient autonomy includes **confidentiality** and their **right to privacy** regarding their body, health information and their decisions. When they choose to surrender some of their privacy, they expect that what they say or what is done to them is kept confidential.

This expectation dates way back to the Hippocratic Oath [3], when physicians were cautioned not to disclose what was said to them in confidence by their patients – "And whatever I shall see or hear in the course of my profession, as well as outside my profession in any interaction with men, if it be what shall not be published abroad, I will never divulge, holding such things to be holy secrets…".

The Oath by Charaka, [13] which predates the Hippocratic Oath says, "….. The peculiar customs of the household of the patient shall not be made public…"

What about patient confidentiality in today's world of electronic record maintenance, billing, etc and the Right to Information Act? [14] Electronic data can be retrieved/ and is being retrieved by unauthorized personnel and hackers for reasons best known to them. The RTI Act has made it possible for 3rd party persons to have access to one's medical record on one ground or the other.

The wards, OPDs, semi private/ private rooms and corridors of the hospitals are usually full of relatives/ friends of the patients, other patients, their relatives and friends, etc making it almost impossible to maintain strict confidentiality while dealing with a patient.

The case file needs to be sent to different investigative departments. Paramedical staff, OT attendants, pharmacy, laboratories, etc all have to be given information regarding the case to enable them to do their part in the whole treatment regimen. Number of hospitals post OT lists on the notice board near their OT, detailing the patient's particulars, ailment and surgery to be performed for the convenience of the staff and the relatives. But what if someone with an ulterior motive got hold of a copy of that OT list or for that matter someone, whom the patient did not want to know, reads the list and gets to know of the patient's condition? All these compromise the patient confidentiality and require special care to be taken by the treating doctor in a bid to

protect it. Otherwise, patients, in the fear of their secrets becoming public would not approach the doctor with their ailments and problems, resulting in more harm than good and completely negating both the principles of autonomy and beneficence.

Truth telling (Veracity) is another vital ingredient of Autonomy. A patient expects that his doctor give him truthfully, without mincing words, a clear picture of his condition.

The fiduciary genre of the doctor-patient relationship demands that the physician owe the highest degree of fidelity, honesty and lack of self-interest to his patient. However, absolute truth may not be digestible to the patient and may actually be harmful to him.

That is when; the doctor can invoke the **Doctrine of Therapeutic Privilege** and refrain from telling the whole truth to the patient. [If the doctor is of the opinion that disclosure of the complete information can seriously harm the patient's life, he has the privilege to withhold such information, but he has to take any of the close relatives of the patient in to confidence and share this information with them; otherwise he cannot claim this privilege.]

Many doctors choose to give information in pieces over a period of time so as not to overwhelm the patient. This is ethically acceptable and justified because no one ultimately knows how well the patient would respond to treatment.

Fidelity or 'promise-keeping' is also important ingredient of Autonomy. For any relationship to sustain, the partners must keep their promises. Same is the case in a doctor-patient relationship. The doctor, by getting the license to practice puts forth the promise to treat the patients with dignity and fairness and provide due care in "good faith". The society expects this from him. The doctor, on his part, expects the patient to promise to tell the truth and diligently follow his instructions.

Informed consent:

Informed consent, in the medical field, is the procedure whereby a patient consents to or refuses (**informed refusal**) a medical intervention based on the information provided by a health care worker regarding the nature and potential consequences of the proposed treatment regimen. The goal of the informed consent is to respect patient autonomy and enable him to make important decisions regarding his medical care. The principle of autonomy emphasizes that a competent adult always has the right to decide what ought or ought not to be done to them.

There are essentially two types of consent:

1. The **'clinician–centered'** one which, according to the doctor, involves divulging the minimum required to be told to the patient to protect the doctor from a charge of assault on the patient.
2. The **'patient – centered'** one in which the doctor gives all information required by the patient to make an informed choice. This is the "Informed Consent" and is always patient-specific.

The patient should be able to understand:

1. Nature of the procedure – what is to be done and how is it to be done
2. Risks involved – the most likely risks; if a patient asks about a risk not told to him, he should be explained about it.
3. Consequences – likely outcomes of the procedure and alternatives
4. Alternatives – what would be the possible outcome if the patient chooses not to have the procedure performed/ have an alternative procedure.

Full disclosure includes:

- The condition/ disorder/disease that the patient is suffering from
- Necessity for further testing
- Natural course of condition and possible complications
- Consequences of non-treatment
- Treatment options available
- Potential risks and benefits of treatment options
- Duration and approximate cost of treatment
- Expected outcome
- Follow—up required

The patient should be given opportunity to ask questions and clarify all doubts. There must not be any kind of coercion, misconception or misrepresentation of facts and the consent must be "full, free and voluntary". The patient should also have the freedom to revoke the consent, if he feels like it, at any later stage.

The elements of informed consent include: disclosure of information, competence, understanding, voluntariness and decision-making. A doctor provides information to a competent patient, who after understanding the information, makes a valid decision.

Consent is based on the Latin maxim "volenti non fit injuria" – he who consents cannot complain. It may be defined as "A free and voluntary agreement, compliance or permission given for a specified act or purpose."

As per S. 90 IPC [7] Consent is not valid if given:

a) By a person under fear/ injury or
b) By a person under misconception of facts and the person obtaining knows or has a reason to believe this or
c) By an intoxicated person or
d) By a person of unsound mind or
e) By a person of less than 12 years

As per S.13 of the Indian Contract Act [15]: two or more persons are said to be in consent if they agree upon the same thing in the same sense. S. 14 [15] says: consent is "free and voluntary" when it is NOT obtained by

a) coercion/ force, b) fraud, c) under influence, d) intoxication, e) misrepresentation, f) from mistaken subjects, and g) mentally unsound persons.

Informed Consent has become extremely important in the present day settings.

As the doctor-patient relationship is primarily contractual by nature, it requires agreement between the parties as to the proposed medical intervention. Hence, patient's consent is fundamental to lawful medical interventions. This includes the physician's ability to properly explain to the patient regarding his condition and answer all possible queries of the patient; combined with the patient's understanding of the same and ability to form a valid decision (consent/refusal) based on the facts put forward to him.

In a number of cases, improper/partial or faulty explanation by doctor results in distrust by patient and his relatives, culminating in allegations of substandard medical care; even though there is no fault in the doctor's medical judgment or treatment skill.

In various kinds of medical and surgical procedures, the likelyhood of an accident or misfortune leading to death can't be ruled out.

A patient willingly takes such a risk. This is part of the doctor-patient relationship and the mutual trust between them. This forms the basis for informed consent/ informed refusal.

Finally, a physician who undertakes to treat a patient should keep in mind that his patient has three fundamental rights with regard to his condition:

1. Right to expect a reasonable degree of skill and care from his doctor
2. Right to complete confidentiality, i.e., Professional Secrecy
3. Right to be informed what is wrong with him and what is to be done about it, i.e., Full Disclosure

Conclusion:

Autonomy as a principle of ethics assumes a certain level of respect for persons and their ability to take actions. It includes issues of informed consent, confidentiality of information, truth telling and promise keeping.

The principles of Privacy and Confidentiality are intimately related to Autonomy as disclosure and dissemination of a person's intimate information and thoughts destroys this important Ethical and Moral Principle. The patient, in fear of the dissemination of his intimate secrets, would never confide in the doctor and this will lead to a number of problems in future both to the doctor and to the patient.

The consent given by the patient should be voluntarily, free, fair, uninhibited, clear, direct and personal; without any fear, force, fraud, misrepresentation of facts, threat of physical injury or death, etc. The information given by the physician to the patient must include the disease condition, nature and consequences of the treatment procedure/ examination, alternatives, prognosis, etc. The disclosure so made should be complete, honest and truthful and should be made prior to implementation of the procedure.

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