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JUDICIAL ACTIVISM ON PATIENT RIGHTS PROTECTION

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Abstract

A patient is any person who receives healthcare services and needs medical treatment from medical providers such as physicians, nurses, hospitals, clinics, and so on. A patient may be well or sick when obtaining healthcare treatments. In general, when a patient or family member enters a hospital or other medical facility, they are in a physically and psychologically weaker condition and so take the word of the medical provider as final and for granted. With the commercialization and privatization of the healthcare business, patients are frequently put at the receiving end of medical malpractices by facilitators who take unfair advantage of the patients' vulnerabilities. Generally, throughout countries, patients' rights are recognized as an inherent right under the Human Rights Convention or as an inseparable aspect of the fundamental rights of the concerned governments. As a result, patients' rights would've acknowledged as legally valid rights to the extent that they have been embedded in that country's legal framework. As well as, it may not be the comprehensive legal framework that people may enjoy uncodified because of their status as a citizen and not with the privilege of being patient. Simply codifying

and stipulating patients' rights is not the ultimate solution.

Keywords: Judicial Activism, Patient's right, Privacy, Constitution, Fundamental Rights, Healthcare

Introduction

A patient would be any individual who uses healthcare services and seeks treatment through healthcare practitioners such as physicians, nurses, hospitals, clinics, etc. A patient may be well and sick¹⁹⁷⁸ despite obtaining medical therapies. In general, when a patient's family member attends a hospital or even other health clinic, individuals are in a physically and psychologically weaker state and so take the word of the medical provider as final and for granted. With the industrialization and privatized health sector, patients are typically put at the receiver end of medical misconduct by facilitators who take unfair competitive advantage of the patients' weaknesses. Consequently, patients must be entitled to a particular level of protection in this respect, which must be provided by healthcare professionals and the state when administering medical help or treatment. It must inform patients about this. In several countries, these protections incorporate into a particular set of rights to which patients are entitled when requiring health assistance in the form of a Charter or Bill of Rights in this respect. The dilemma is that these mechanisms are not legally valid in most jurisdictions. It enacts as a catalyst or model law for other countries to acknowledge and follow.

Although these charters lack legal assistance or recognition, the enforcement and preservation of patient rights at healthcare facilities is questionable. Generally, throughout countries, patients' rights are acknowledged as an inherent right under the Human Rights Convention or as an inseparable aspect of the

¹⁹⁷⁸ Who Declaration On The Promotion Of Patients' Rights In Europe, 1994

fundamental rights of the concerned governments. As a result, patient rights acknowledge as lawful rights to the amount entrenched in that country's legal structure, which may not be wholly codified similar to the position in India wherein only a draught Charter has been published, and the rights are scattered.¹⁹⁷⁹

If all these rights are not fully specified, problems with execution may develop. Furthermore, if all these rights are not codified and distributed across several laws and regulations, it would be difficult for the poor and vulnerable people to comprehend their rights while seeking medical treatment.¹⁹⁸⁰ These uncodified rights entrenched in the legal framework may be enjoyed by persons due to their citizenship status rather than the privilege of being a patient. As a result, dispersed patient rights may not be legally recognized evenly across the country. Consequently, unless their rights are codified into a single document and made available to all patients, each patient may be unaware of their rights.

Because these agreements contain patient rights, it is reasonable to argue that India acknowledges such legal protections in specific ways. However, they do not appear to be implemented universally and consistently throughout the country. Furthermore, the enforcement of patient rights entrenched in precedence or judicial declarations may differ from those specified in the law, which might vary from those specified in other standards, policies, or regulations. As a result, there will be no consistency in executing these rights.

As a result, codification of patient rights is critical in the country, even in India, where traditional medical models are deeply embedded in patients' minds and healthcare facilitators. Limiting patient input, codification, and informing patients about the constitutional

protections obtainable to them until seeking medical aid or assistance is of great importance and pertinence.

Simply codifying and stipulating patients' rights is not the ideal solution. A right does not disclose its entire meaning and strength unless a remedy for its infringement accompanies it.

There's a maxim where there is a right, there is a remedy, suggesting that whenever law has established or acknowledged a right, there should be a commensurate remedy linked to it for any infringement of that right. As a result of respecting patients' rights, proper procedures should prescribe to people if any of their rights are infringed. Furthermore, must establish these remedies through appropriate, efficient, and effective enforcement processes. Human rights and patient rights are inextricably linked. The right of patients is just a subcategory of human rights. While human rights refer to the fundamental principles through which every human being could wanted to be treated by others, 'ethics' speaks to the rules and norms or etiquette that can be applied to any human being.

As a result, rights and morality are frequently considered as two sides of the same coin, with each patient's right based on one or even more recognized ethical standards. The development of clearly defined patient rights helps to normalize healthcare & enables patients to behave similarly to expectations throughout their treatment. According to contemporary Charters enumerating their rights, patients can expect special regulated care regardless of their socioeconomic status, religious views, gender, colour, or ethnicity. Some of the critical ethical ideas upon which frequently acknowledged patient rights are founded include autonomy and fairness. Another significant consideration when dealing with patient rights is the fiduciary doctor-patient relationship established via mutual consent. As a result, rights and morality are commonly considered as two sides of the same coin, for

¹⁹⁷⁹ Jonathan Cohen & Tamar Ezer, Human Rights In Patient Care: A Theoretical And Practice Framework, 15 Health & Hum. Rts. 7 (2013)

¹⁹⁸⁰ Preamble, Who Constitution 1946

each patient's right based solely on a single or more recognized ethical norms.¹⁹⁸¹ The establishment of clearly defined patient rights contributes to the standardization of healthcare and allows patients to have identical expectations throughout their treatment. According to contemporary Charters, patients can expect precise regulated care regardless of their socioeconomic status, religious views, gender, colour, or ethnicity, according to current Charters enumerating their rights. Some of the critical ethical ideas upon which frequently acknowledged patient rights are founded include autonomy and fairness. Another significant consideration when dealing with patient rights is the fiduciary doctor-patient relationship established via mutual consent.

When there is no legislative framework to protect patients' rights, it is the obligation of the healthcare professional to emphasize these ethical values to achieve a satisfying outcome for the patient. Hippocrates' Oath is a brief explication of the principles governing the practice of medicine.

It was composed in the fifth century before the Common Era (BCE). Its declarations protect patients' rights and urge physicians to act altruistically toward patients willingly. Since the Hippocratic Oath, ethical norms have been a part of the medical profession. It was later refined and extensively used to guide ideal medical practices and conduct.¹⁹⁸²

Patient rights agreements frequently augment the right of patients to have their issues addressed and examined by an independent authority, which may not be accessible under ordinary legislation, such as in India. Although most of these entitlements are already available to patients, having everyone in one complete document provides them with more clarity and understanding. Patient rights

charters with specific complaint resolution mechanisms allow concerns to resolve informally early, eliminating the need for protracted formal disciplinary actions or litigation. A charter, in this respect, can be especially beneficial in assisting patients in exercising their first amendment rights without incurring the high expenses and delays associated with judicial action.¹⁹⁸³ The Ministry of Health and Family Welfare (MoHFW) instructed the National Human Rights Commission (NHRC) to develop a complete list of patient rights. As a result, in 2018, the commission drafted and published the Charter of Patients' Rights,¹⁹⁸⁴ which also included 17 categories of rights to which every patient in India is entitled, namely:

1. Right to information;
2. Right to records and reports;
3. Right to emergency care;
4. Right to informed consent;
5. Right to confidentiality, human dignity, and privacy;
6. Right to second opinion;
7. Right to transparency in rates and care according to prescribed rates wherever relevant;
8. Right to non-discrimination;
9. Right to safety and quality care according to standards;
10. Right to choose alternative treatment options if available;
11. Right to select the source for obtaining medicines or tests;
12. Right to proper referral and transfer, which is free from perverse commercial influences;
13. Right to protection for patients involved in clinical trials;
14. Right to the safety of participants involved in biomedical and health research;

¹⁹⁸¹ K S Jacob, *Informed consent, and India*, 27 THE NATIONAL MEDICAL JOURNAL OF INDIA 4 (2014).

¹⁹⁸² Frank Riddick Jr., *The Code Of Medical Ethics Of The American Medical Association*. 5 Ochsner J. 6 (2003) (Last Visited Jun 1, 2022)

¹⁹⁸³ Colleen M. Flood & Kathryn May, *A Patient Charter Of Rights: How To Avoid A Toothless Tiger And Achieve System Improvement*, 184 Can. Med. Assoc. J. 1583 (2012) (Last Visited Jun 1, 2022)

¹⁹⁸⁴ *charter_patient_rights_by_NHRC_2019.pdf*, https://nhrc.nic.in/sites/default/files/charter_patient_rights_by_NHRC_2019.pdf (last visited Oct 31, 2022).

15. Right to take the patient's discharge or receive the body of the deceased from the hospital;
16. Right to patient education;
17. Right to be heard and seek redress.

The proposed Charter 2018 too was designed to ensure that informed patients visiting a medical establishment of their rights, which were previously distributed over many legal instruments and decisions and were difficult for patients and non-specialists to grasp. It also wrote that the union and state governments regard it as a basis for the successful implementation and protection of patient rights throughout India and step in with efficient procedures to actualize patient rights. As a result, the initiative to create the Charter is a positive step. Further debate is that it protects all the patients' rights. How this draught Charter will defend patients' rights in India is a significant subject that requires careful consideration, especially in this period of an unprecedented, horrible, and appalling pandemic.

Rights of patients in India

Patients' rights are generated through one or more established moral concepts, and each patient's right will have a cornerstone based on ethical standards.¹⁹⁸⁵ All ethical norms or guidelines related to patient care involve four widely known ethical principles: autonomy, non-maleficence, beneficence, and fairness. In the healthcare world, the concept of justice relates to distributive justice, which implies that all patients must be treated equally and equitably. The medical profession is controlled through worldwide and regional ethical codes, regulations, and laws that are essentially founded on the above-mentioned concepts. Commitment to these ethical principles¹⁹⁸⁶ is

paramount since the medical profession significantly impacts people's lives and families.

Clinical Establishments (CE) Act of 2010 mandates whether specific essential requirements should be followed by each CE to be registered in the first instance and continue to operate. Minimum CE criteria are implemented based on the manner of treatment and degree of care offered by various uses.¹⁹⁸⁷ Patients' rights are dispersed over several legal instruments, and patients have no access to a complete report detailing all of their rights.

Right to get Information

The patient's function in healthcare has evolved from an acceptance of the doctor's instruction or direction to a proactive member or participant in the therapy session.¹⁹⁸⁸ For patients to actively participate, they should provide individuals with pertinent details on the patient's therapy.¹⁹⁸⁹ According to the Essential C.E. Standards of Tier 1 hospitals, patients or their representatives have the right to appropriate, relevant information on the nature, source of sickness, proposed investigations and care, expected treatment results, potential problems, and estimated expenses.¹⁹⁹⁰ In addition to the rights discussed above, the interim Charter affirms that patients have enough right to obtain information about the provisional or confirmed diagnosis. This information must be made available and explained to the patient at their level of understanding in the familiar language.¹⁹⁹¹ Furthermore, the doctor or competent assistants should communicate essential knowledge easily without misleading or overloading the patients using excessive scientific terms. Patients have the right to be

¹⁹⁸⁷ Nandita Adhikari, *Law & Medicine* 62 (2017)

¹⁹⁸⁸ Don Malcolmson, *The Patient's Right To Know*, 101 *J. Med. Regul.* 32 (2015).

¹⁹⁸⁹ *Supra* N. 2

¹⁹⁹⁰ Annexure 8 Of Clinical Establishment Act Standards For Hospital Level 1

¹⁹⁹¹ Draft Charter Of Patients' Rights, 2018

¹⁹⁸⁵ Hajrija Mujovic-Zornic, *Legislation And Patients' Rights: Some Necessary Remarks*, 26 *Med. & L.* 709 (2007). (Last Visited Jun 1, 2022)

¹⁹⁸⁶ *Supra* N. 2

informed¹⁹⁹² about the name, dose, and any detrimental consequences that the prescription medications may have.¹⁹⁹³

According to Universal Declaration Covenant on Civil and Political Rights (ICCPR), the right to freedom of speech¹⁹⁹⁴ implies the opportunity to explore, receive, and transmit thoughts and information of all kinds, regardless of boundaries, verbally, in writing or print, in the form of art, or via any other media of his choice. The European Convention on Human Rights and Fundamental Freedoms (ECHR) takes a similar stance.¹⁹⁹⁵ In **State of U.P. v. Raj Narayan**,¹⁹⁹⁶ the Supreme Court concluded that the right to knowledge is a derivative of citizens' freedom of speech and expression, which is not absolute. As a result, people have the right to be informed about every public act performed by their public servants.¹⁹⁹⁷

In Secretary, Ministry of Information and Broadcasting, **Government of India v. Cricket Association of Bengal**,¹⁹⁹⁸ the Court explained that freedom of speech and expression means the right to obtain information under Article 19(1)(a) of the Indian Constitution. Since "service"¹⁹⁹⁹ provided by health doctors is protected under the Consumer Protection Act of 1986, and the patient's status as a consumer is bestowed upon them while receiving medical services,²⁰⁰⁰ fundamental rights available to the consumer will also be made available to the patients.

Consequently, the patient/consumer has the right to information regarding the quality, quantity, potency, purity, standard, and price of

goods to defend themselves from unfair trade practices.

In **Nisha Priya Bhatia v. Institute of Human Behavior and Allied Sciences**, GNCTD,²⁰⁰¹ the Central Information Commission dominated that a consumer of medical services has the right to know which diagnosis was given to oneself, what diagnoses testing results were, what doctors' or specialists' viewpoints were, and so on. There is a significant connection between Art 21 and the right to know, particularly when secret Government decisions may damage health, life, and livelihood.²⁰⁰² The Right to Information Act of 2005 created a practical framework to enable individuals with secure access to information owned by public authorities to enhance openness and transparency in its operations and thereby envision the right to information.

The Right to Information Act of 2005 establishes a concrete framework to enable consumers with secured access to the information controlled by public authorities to enhance openness and accountability in its operations and thereby envision the right to information. As a result, it gives access to documents maintained by government hospitals. Through different rulings and initiatives, citizens' rights are expanded beyond public authorities to private entities, providing any lawful availability, as explained clearly in the future rights.

Right to records and reports

It is essential to preserve a health record of patients' services in hospitals while receiving therapy. It will accept as documented evidence even before the authority in the future. The only way for the doctor to reassure the patient and other authorities that treatment is performed appropriately is to keep accurate records.²⁰⁰³ Medical record requirements vary by

¹⁹⁹² Amar Jesani, Medical Ethics And Patients' Rights, 54 Indian J. Soc. Work 173 (1993)

¹⁹⁹³ Nabh Charter Of Patients' Rights

¹⁹⁹⁴ Article 19(2) Icpr

¹⁹⁹⁵ Article 10 Echr

¹⁹⁹⁶ State Of U.P. V. Raj Narayan, Air 1975 Sc 865

¹⁹⁹⁷ Ibid

¹⁹⁹⁸ Secretary, Ministry Of Information And Broadcasting, Govt. Of India And V. Cricket Association Of Bengal, Air 1995 Sc 1236

¹⁹⁹⁹ Indian Medical Association V. V.P Shantha, Air 1996 Sc 550

²⁰⁰⁰ Consumer Rights - Department Of Consumer Affairs, <https://consumeraffairs.nic.in/Organisation-Andunits/Division/Consumer-Protection-Unit/Consumer-Rights> (Last Visited Jun 1, 2022)

²⁰⁰¹ Nisha Priya Bhatia V. Institute Of Human Behaviour And Allied Sciences, Gnctd, Cic/Ad/A/2013/001681-Sa

²⁰⁰² Essar Oil Ltd V. Halar Utkarsh Samiti, (2004) 2 Sc 392

²⁰⁰³ Thomas Joseph, Medical Records And Issues In Negligence, 25 Ind. J. Urol. 384 (2009)

jurisdiction, yet all carry the same fundamental message: every record must include the patient's and doctor's names, contain essential legal papers, required patient information, and information about the therapy, discharge, and follow-up as needed.²⁰⁰⁴

Patients, including any accompanying persons, have the right to investigate originals or copies of documentation, indoor patient records, investigation results, and detailed invoices during admission and discharge (ideally within 24 and 72 hours, respectively).²⁰⁰⁵ It must retain medical data in either physical or digital form.²⁰⁰⁶

The concerned person or hospital should safeguard such documents' privacy, security, and integrity.²⁰⁰⁷

It must maintain in-patient information following applicable laws, MCI standards,²⁰⁰⁸ and court orders. It is the physician's responsibility²⁰⁰⁹ to keep proper medical records of the concerned indoor patient for three years from the start of therapy in the manner provided.²⁰¹⁰ Within 72 hours²⁰¹¹ of receiving a request from the patient or a responsible person or authority, the doctor should disclose the available medical records. Suppose the physician refuses to provide the same within the time frame specified by the concerned person. In that case, it will be considered an omission on the part of the physician, which constitutes professional misconduct, making him liable for disciplinary action.²⁰¹² The

concerned authority may draw an adverse inference due to the denial of the medical record.²⁰¹³ The records or papers, when applicable, may be made accessible to patients for photocopying following receipt of the relevant price or permitted to be photocopied by patients at their own expense.²⁰¹⁴ In *Rajappan v. Sree Chitra Tirunal Institute for Medical Science and Technology*,²⁰¹⁵ the Kerala High Court ruled that supplying a copy of appendix 3 alone would not submit the criteria requirements xerox of the entire sheet retained the hospital. The case sheet comprises the diagnostic results and the specifics of the treatment performed.²⁰¹⁶ Appendix 3 will merely offer a summary of the preceding information. As a result, the patient has the right to view all records.

The Bombay High Court declared in *Raghunath Raheja v. Maharashtra Medical Council*²⁰¹⁷ that patients have the right to access their medical data and reports. According to the court, the Medical Council shall guarantee that case sheets and related papers regarding the concerned patient care are provided by issuing required directives to medical providers. In addition, hospitals cannot claim secrecy or confidentiality concerns about transmitting such records to the patient.

In *Ozair Husain v. Union of India*,²⁰¹⁸ the Delhi High Court ruled that consumers have the right to product description. The petitioner decided to seek a court ruling to voluntary basis display the contents of food products, drugs, and cosmetics in designed to safeguard consumers' rights to be notified of the content material, especially when it relates to the presence of animal derivatives, that are avoided by such consumers due to religious beliefs. The court ruled that the contents must be displayed

²⁰⁰⁴ Hayley Rosenman, Patients' Rights To Access Their Medical Records: An Argument For Uniform Recognition Of A Right Of Access In The United States And Australia, 21 Fordham Int. Law J. 1500, 1503 (1997); Dieter Giesen, International Medical Malpractice Law 416-24 (1988)

²⁰⁰⁵ Annexure 8 Of Clinical Establishment Act Standards For Hospital Level 1

²⁰⁰⁶ Section 9.2 Clinical Establishment Act Standards For Hospital Level 1

²⁰⁰⁷ Section 9.3 Clinical Establishment Act Standards For Hospital Level 1

²⁰⁰⁸ Section 9.4 Clinical Establishment Act Standards For Hospital Level 1

²⁰⁰⁹ Appendix 3 Indian Medical Council (Professional Conduct, Etiquette And Ethics) Regulations, 2002

²⁰¹⁰ Regulation 1.3.1 Indian Medical Council (Professional Conduct, Etiquette And Ethics) Regulations, 2002

²⁰¹¹ Regulation 1.3.2 Indian Medical Council (Professional Conduct, Etiquette And Ethics) Regulations, 2002

²⁰¹² Regulations 7.7.2 Indian Medical Council (Professional Conduct, Etiquette And Ethics) Regulations, 2002

²⁰¹³ Dr. Shyam Kumar V. Rameshbhai Harmanbhai Kachhiya, I (2006) Cpj 16 Nc

²⁰¹⁴ Draft Charter Of Patients' Rights, 2018

²⁰¹⁵ Rajappan V. Sree Chitra Tirunal Institute For Medical Science And Technology, 2004 (2) Klt 157

²⁰¹⁶ Draft Charter Of Patients' Rights, 2018

²⁰¹⁷ Raghunath Raheja V. Maharashtra Medical Council, Air 1996 Bom 198

²⁰¹⁸ Ozair Husain V. Union Of India, Air 2003 Delhi 103

because customers have the right to be informed. In *Prabhat Kumar v. Directorate of Health Services and Others*,²⁰¹⁹ the CIC suggested the government implement notification that the right to information about a patient's medical records applies equally to public and private hospitals. Any attempt by a private hospital to blatantly ignore the enforcement of this right will amount to discrimination under article 14 of the Indian Constitution.

Right to emergency medical care

It recognizes the right to life and liberty in Article 21 of the Constitution.⁴³ It stipulates that nobody else shall be stripped of his life or personal liberty unless following legal procedure. The concept life refers to something greater than just animal existence.²⁰²⁰ The Supreme Court has often construed Article 21 to cover several additional rights, even though it is not a Fundamental Right in the Constitution but is required to establish the right to life. The right to health is one right that the Supreme Court has deemed an inherent feature of Article 21.²⁰²¹ It should emphasize citizens' health to make one's life meaningful and achieve maximum production.²⁰²²

As a result, the government must provide all essential health services and infrastructure to safeguard the right to health.²⁰²³ The right to medical treatment was also determined to be part of Art 21, read with Articles 39(e), 41, and 43 of the Constitution, to make life meaningful and purposeful while maintaining the individual's dignity.²⁰²⁴ In the *Parmanand Katara v. Union of India*,²⁰²⁵ a Petition was filed based on a newspaper article where a patient was refused care at a nearby hospital and was directed to

be brought to a hospital licensed to address medico-legal cases, which was 20 km far. The patient died en route. The Supreme Court emphasized the importance of human life security.

When questioned if legal procedures had to be fulfilled before providing medical treatment to accident victims, the Court ruled that there was no legal barrier to a medical practitioner offering emergency medical help. Priority must be given to saving the patient not just by medical personnel but also by police or other individuals involved in the accident or who had a chance to witness the accident or the patient's predicament.²⁰²⁶

In *Paschim Banga Khet Mazdoor Samity v. State of West Bengal*,²⁰²⁷ a patient was refused urgent medical attention at several government hospitals and was sent to a private clinic that demanded excessive fees for medical treatment. It decided that a government hospital's failure to provide timely medical care to a patient constituted a breach of its right to life.²⁰²⁸ The Supreme Court also held that while financial resources are required to assure emergency treatment, they cannot disregard the states' fundamental commitment to providing relevant treatment services to people. So, whatever is necessary to ensure emergency medical care must be done. Though a physician is allowed to choose whoever they want to offer medical services to, a physician must be prepared to treat the sick or injured at any moment and must not turn away a patient unilaterally when in an emergency.²⁰²⁹ The physician should respond immediately to an emergency medical request.²⁰³⁰ Once a case has been accepted, he should not abandon the

²⁰¹⁹ Prabhat Kumar V. Directorate Of Health Services, Cic/Sa/A/2014/000004

²⁰²⁰ Kharak Singh V. State Of U. P., Air 1963 Sc 1295

²⁰²¹ Bandhua Mukti Morcha V. Union Of India, Air 1984 Sc 802

²⁰²² State Of Punjab V. Ram Lubhaya Bagga, (1998) 4 Sc 117

²⁰²³ State Of Punjab V. Mohinder Singh Chawla, (1997) 2 Sc 83

²⁰²⁴ Consumer Education And Research Centre V. Union Of India, Air 1995 Sc 922

²⁰²⁵ Parmanand Katara V. Union Of India, (1989) 4 Sc 286; Air 1989 Sc 2039

²⁰²⁶ Parmanand Katara V. Union Of India, (1989) 4 Sc 286; Air 1989 Sc 2039

²⁰²⁷ Paschim Banga Khet Mazdoor Samity V. State Of West Bengal, Air 1996 Sc 2426

²⁰²⁸ Ibid

²⁰²⁹ Ibid

²⁰³⁰ Regulation 2.1 Indian Medical Council (Professional Conduct, Etiquette And Ethics) Regulations, 2002

patient or discontinue treatment without first informing the patient's family members.²⁰³¹

Right to get Valid Consent

Valid consent has been a contentious issue in the healthcare field in recent years.²⁰³² It is a common belief that patients must agree to any treatment or therapy undertaken. It's characterized as permission given by a patient for a physician doing an act, such as a diagnostic, surgical, or therapeutic operation.²⁰³³ The idea of informed consent's universal application presents various valid questions.²⁰³⁴

As entrenched in Article 21 of the Indian Constitution, the right to autonomy²⁰³⁵ serves as a foundation for explicit consent and other essential parts of patient rights in India. Every patient has the right to give informed consent before undergoing any tests or treatments.²⁰³⁶ It must be acquired from the patient or a close relative or legal guardian whenever required by law or guidelines. It must contain the information specified in Annexure 9 of the Clinical Establishment Act Standards for Hospital Level 1.²⁰³⁷ Before operating, should acquire a signed agreement from the patient and his or her husband or wife,²⁰³⁸ parent or guardian (child). Also, in cases of sterility, consent from both husband and wife is essential.²⁰³⁹

The IVF/ZIFT/GIFT procedure carries out the written agreement of the female patient, her spouse, and the donor. They should know about

potential procedures, hazards, and threats involved²⁰⁴⁰ at their level of comprehension. Furthermore, consent must be acquired under the Indian Council of Medical Research (ICMR) recommendations for clinical drug trials or other research involving patients or others.²⁰⁴¹ The gaining of informed consent carries out the most significant effort and openness. Any mistake or variation on the part of the physician in obtaining such permission specified in any of the opening sentences may result in him being held accountable for misconduct.²⁰⁴²

The hospital management was responsible for enforcing a policy that ensures that its doctors are appropriately trained to get valid consent properly. During potential hazards tests or treatment, the primary treatment process doctor must explain to the patient clearly and his companions the main vulnerabilities and threats involved. However, after obtaining written consent, the concerned doctor shall proceed with the procedure as prescribed by the Drugs and Cosmetics Act and Rules,²⁰⁴³ which will be discussed in-depth later.

The Supreme Court decided in **Samira Kohli v. Dr. Prabha Manchanda**²⁰⁴⁴ that consent obtained by the patient for a diagnostic procedure does not entitle a medical practitioner to perform surgery. In this case, the patient agreed to diagnostic and surgical laparoscopy and laparotomy if necessary. During this treatment, the medical professional sought authorization from the patient's mother to perform a hysterectomy, which removed the patient's uterus, ovaries, and Fallopian tubes. Despite being under anaesthesia, there was no emergency or difficult situation that required the medical practitioner to do surgery with her mother's approval.

²⁰³¹ Regulation 2.4 Indian Medical Council (Professional Conduct, Etiquette And Ethics) Regulations, 2002

²⁰³² Omprakash Nandimath, Consent And Medical Treatment: The Legal Paradigm In India, 25 Ind. J. Urol. 343 (2009)

²⁰³³ Samira Kohli V. Dr. Prabha Manchanda, Air 2008 Sc 138 At Para 14

²⁰³⁴ Applicability During Emergency And Critical Medical Care

²⁰³⁵ Cecilia Nardini, The Ethics Of Clinical Trials, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3894239/>

²⁰³⁶ Tom L. Beauchamp & James F. Childress, Principles Of Biomedical Ethics 57 (2001)

²⁰³⁷ Furkhan Ali Et Al., Consent In Current Psychiatric Practice And Research: An Indian Perspective, 6 Ind. J Psych. 667 (2019). Annexure 8 Of Clinical Establishment Act Standards For Hospital Level 1

²⁰³⁸ Section 10.23 Clinical Establishment Act Standards For Hospital Level 1

²⁰³⁹ Annexure 9 Of Clinical Establishment Act Standards For Hospital Level 1: The Contents Required Are Details Of Patient, Doctor, Procedure/Operation/Blood Transfusion/Anaesthesia, Admission Date And Signature Of The Patient Or Guardian

²⁰⁴⁰ Regulation 7.21 Indian Medical Council (Professional Conduct, Etiquette And Ethics) Regulations, 2002

²⁰⁴¹ Regulation 7.22 Indian Medical Council (Professional Conduct, Etiquette And Ethics) Regulations, 2002

²⁰⁴² Draft Charter Of Patients' Rights, 2018

²⁰⁴³ Ibid

²⁰⁴⁴ Samira Kohli V. Dr. Prabha Manchanda, Air 2008 Sc 138

The practitioner could have waited for her to recover consciousness and receive fully informed consent, so there is no need for consent on her behalf because she is not a juvenile, intellectually retarded, or disabled, and there is no urgency. As a result, the Court determined that it is insufficient to perform therapeutic surgery, no matter how comprehensive the consent for diagnostic procedures. Patients (also known as consumers) have had the right to know certain basic information about the service, such as its quality, quantity, potency, purity, standard, and price, to make an informed decision about the good or service and avoid falling victim to unfair business practices.

Permission after being informed Though written permission is universally regarded as a norm in practically every healthcare intervention. There are certain caveats to its application in particular instances. Some fundamental exclusions include the patient being a juvenile or incapable or not able to provide permission owing to illness or otherwise. Another exemption to informed consent is emergency medical care. As a result, it can be avoided, and doctors must perform their obligation to maintain and defend life in emergencies before seeking permission.²⁰⁴⁵ **Ozair Husain v. Union of India**²⁰⁴⁶ determined that information about life-saving medications does not need to be provided to the patient because it is intended to treat the disease and preserve lives. The condition would be deadly if the patient did not supply the life-saving medicine and did not have to be notified since it is necessary to save life under Article 21.

Privacy Rights

Privacy and confidentiality are consequences of the right to autonomy of the patient. Privacy and confidentiality, like explicit consent, are based on the patient's autonomy. Respect and

dignity²⁰⁴⁷ are strengthened through privacy and secrecy.²⁰⁴⁸ As a result, it's essential again to establish and maintain a professional and productive clinical relationship. Privacy refers to the ability and right of a person to limit the number of others that can interfere in their physical, psychological, or intellectual lives. Among the essential types of security regarding healthcare are data security and physical confidentiality. The Supreme Court decided in **K.S. Puttaswamy v. Union of India**²⁰⁴⁹ that the right to privacy is an essential facet of the right to life and personal liberty. A doctor's relationship with a patient is fiscal, founded on trust and confidence.²⁰⁵⁰ However, the connection is primarily financial, it is a professional question of faith, and the doctor is ethical and socially responsible manner obligated to preserve trust. Patients would be forced to submit confidential info to the physician to enable appropriate treatment. Thus, revealing such private information to the physician imposes a trust duty on the practitioner to never reveal the information to others. Every society doesn't believe it ethical for doctors to disclose confidential information.

Confidentiality protects the patient's privacy.²⁰⁵¹ It ensures that a patient's confidentiality, either information or otherwise, will not be compromised. Each patient has a right to privacy, human dignity, and privacy during surgery.²⁰⁵² Practitioners are bound to keep information about a patient's medical problems, treatment plans, defects in disposition, character, and strictly confidential unless the doctor is required to communicate it. Under extraordinary circumstances such as health and safety concerns or the safeguard of

²⁰⁴⁷ Mohammad Mohammadi Et Al., Do Patients Know That Physicians Should Be Confidential? Study On Patients' Awareness Of Privacy And Confidentiality, 11 J Med Ethics Hist Med 1 (2018).

²⁰⁴⁸ Hui Zhang Et Al., Patient Privacy And Autonomy: A Comparative Analysis Of Cases Of Ethical Dilemmas In China And The United States, 22 BMC Med. Eth. 1, 8 (2021).

²⁰⁴⁹ K.S. Puttaswamy V. Union Of India, (2017) 10 Sc 1

²⁰⁵⁰ Mr. X V. Hospital Z, Air 1999 Sc 495 At Para 26

²⁰⁵¹ Simone Vigod Et Al., Privacy Of Patients' Information In Hospital Lifts: Observational Study, 327 B.M.J. 1024 (2003).

²⁰⁵² Annexure 8 Of Clinical Establishment Act Standards For Hospital Level 1

²⁰⁴⁵ Pravat Kumar Mukherjee V. Ruby General Hospital, Ii (2005) Cpj 35 (Ne)

²⁰⁴⁶ Ozair Husain V. Union Of India, Air 2003 Delhi 103

the population lives in society, or if required by law or court order, or if the information is about infectious diseases.²⁰⁵³ Aside from the earlier instances, the doctor may not publish photographs or case reports of patients without their authorization unless their name or identity is not revealed.²⁰⁵⁴ The right to privacy and secrecy is not absolute, and its violation may be ethically and legally justifiable at times. The public interest is an exemption to the requirement of confidentiality, particularly where there is an immediate or future health danger to others.²⁰⁵⁵ In *Sharda v. Dharmpal*,²⁰⁵⁶ the Supreme Court went toward the latter while drawing the boundary between private and the "better good." In this case, a husband sued for divorce, alleging his wife's mental condition. As a result, the wife was forced to undergo medical testing. She asserted her privacy rights, but the Court ruled it was not an absolute right and that a lack of such data would damage the case's outcome. She asserted her privacy rights, but the Judge decided that it is not an inherent right and that an absence of such data would be adverse to the case's outcome. Section 8(1)(j) of the RTI Specifically prohibits the publication of personally identifiable information unrelated to the public interest and might result in an invasion of privacy. This exclusion, however, does not apply whenever the general public interest is in jeopardy.²⁰⁵⁷

Right to second opinion and right to choose alternative treatment

The patient's right to liberty and self-determination underlines his right to a second opinion and, when feasible, the freedom to choose other treatment alternatives. Several diseases are inherently complicated, with no apparent answers in terms of correct diagnosis or even the correct course of action of therapy.

²⁰⁵³ Regulation 2.2.7.14 Indian Medical Council (Professional Conduct, Etiquette And Ethics) Regulations, 2002

²⁰⁵⁴ Regulation 7.17 Indian Medical Council (Professional Conduct, Etiquette And Ethics) Regulations, 2002

²⁰⁵⁵ Draft Charter Of Patients' Rights, 2018

²⁰⁵⁶ Mr. X V. Hospital Z, Air 1999 Sc 495 At P.499-500

²⁰⁵⁷ Sharda V. Dharmpal, Air 2003 Sc 3450

In other instances, the primary accountable physician may lack appropriate experience.²⁰⁵⁸ Whatever precautions doctors or hospital administrators take cannot avoid unexpected scenarios such as diagnostic mistakes, incorrect treatment, or pharmaceutical overdose. However, fearful of offending the treating doctor and incurring revenge, most patients would forego seeking a second opinion or be unwilling to share the statement obtained from the second doctor with the treating doctor.²⁰⁵⁹

Nonetheless, in any preceding scenarios, the patient's interests have been endangered. As a result, health professionals must be willing to seek second opinions in the best interests of both doctors and patients. The scientific balance needs the thoughtfulness of a second view from practitioners who care about their patients and respect their humanity.²⁰⁶⁰ Every patient has the right to obtain a second opinion from a doctor of the patient's or caregiver's choosing.²⁰⁶¹ As a result, hospital authorities or doctors are expected to respect this right and give patients their records and information needed to seek such a second opinion without delay or cost.

Furthermore, exercising this privilege should not create any bias in the minds of the treating doctor and have any negative impact on the care provided by the primary doctor or hospital to that patient while under treatment. Any such approach would constitute discrimination and a breach of civil rights.²⁰⁶² If a patient finds no relief in a doctor's therapy and wants to contact another doctor, any additional consultations would've been futile if the original doctor did not

²⁰⁵⁸ Inder Maurya, Medical 2nd Opinion [Http://Bwhealthcareworld.Businessworld.In/Article/Medical-2nd-Opinion-Trends-Challenges/29-11-2019-179592/](http://Bwhealthcareworld.Businessworld.In/Article/Medical-2nd-Opinion-Trends-Challenges/29-11-2019-179592/)

²⁰⁵⁹ Nomal Chandra Borah, Doctors' Dilemma And Patients' Right To Second Medical Opinion, <https://Health.Economictimes.Indiatimes.Com/Health-Files/Doctors-Dilemma-And-Patients-Right-To-Second-Medical-Opinion/676>

²⁰⁶⁰ Regulation 7.17 Indian Medical Council (Professional Conduct, Etiquette And Ethics) Regulations, 2002

²⁰⁶¹ Daniel Wechter & Donna Harrison, A Second Opinion: Response To 100 Professors, 29 Issues L. & Med. 147 (2014)

²⁰⁶² Annexure 8 Of Clinical Establishment Act Standards For Hospital Level

write a valid prescription or note of his clinical observations and diagnosis.²⁰⁶³ They also have the right to select any alternative treatment or management alternatives offered to them. The hospital must tell patients about the other options and respect the informed decisions of the patient and the nurse in a timely and accurate way.

The ability of a patient to pick other treatment choices includes the authority to decline a specific treatment or care, with the responsibility for such denial falling solely on his shoulders, save in emergencies or, where necessary, when doctors do not need to wait for consent. Every adult with the capacity to agree has the right to self-determination and autonomy. It protects the patient's right to refuse particular treatment or select alternative therapy, even if it puts them in danger of death. Individual dignity cannot be envisioned under both the right to life and personal liberty. Consumers have the right to choose and, where possible, the right to have access to a diverse range of goods and services at a reasonable price. In the context of cartels, this also provides the right to be still guaranteed adequate standards and service at an affordable price.

Right to transparent rates in medicines

CE laws in India require every CE to display the rates charged for each service and facility available in a prominent location inside the local and English language for both the treatment of people. The prices charged by every CE shall be within the range determined and provided by the central government in consultation with state governments. Compliance with these standards is required for CE registration and ongoing operation. The health sector should educate patients and their companions about the prices charged via pamphlets, tables displayed at key spots, or booklet formats. In addition, the patient has the right to a comprehensive summarized charge.

While assisting, physicians should emphasize the patient's needs over their financial interests. It should communicate the form of economic by a physician before providing such service, not after it has begun. The money received must be in the form and amount agreed upon before the treatment. It is unethical for doctors to get into contracts with no cure and no compensation. The government physicians should refuse any consideration from the patients. Drugs and other medicines contribute to approximately 40% of the healthcare costs in underdeveloped nations. However, a large portion of the population frequently lacks access to essential medicines. Several variables, including poverty, might influence the problem.

The World Health Organization (WHO) describes necessary pharmaceuticals or medicines as those drugs that meet the bulk of the population's healthcare needs. As a result, pharmaceuticals or medicines should always be provided in enough quantities and dosages to the population at a reasonable cost; following the concept of essential medicine, WHO established the first model list of necessary medications in 1977, which has subsequently been revised. Member countries accepted the principle of essential medicines and created their respective list of essential medicines. In 1996, India developed the National List of Essential Medicines (NLEM). In India, the National Pharmaceutical Pricing Authority (NPPA) would settle the prices of the pharmaceuticals included in NLEM after considering the suggestions and reservations of committees established for that purpose. The Indian Pharmacopoeia Commission determines medication standards in India and routinely updates drug standards that have been generally required for illness treatment. It also produces written documents in the form of Indian Pharmacopoeia (IP) to increase the effectiveness of medicines by adding new and upgrading current summaries.

²⁰⁶³ Draft Charter Of Patients' Rights, 2018

The term "drugs" has been designated an essential element under the Essential Commodities Act of 1955. It has the same meaning as under the Drugs and Cosmetics Act of 1940. As a result, the central government has the authority to control the production, supply, distribution, and critical goods. By the source mentioned above, the central government enacted the Pharmaceuticals (Prices Control) Order, 2013, entrusting the NPPA with the price regulation of vital drugs. As per the India Pharmacopeia, each patient has a right to necessary medications, devices, and implants at the prices set by the NPPA and other authorities and healthcare services at the rates set by the national and state governments. However, patients' preferences must be respected when obtaining medications, equipment, or standards. The hospital administration must guarantee that necessary medications under NLEM are delivered to patients at a price that is not more than the prescribed rate or MRP. Implementing a retail price and a ceiling price would make medicines more expensive and, ultimately, benefit the customer, which is the primary priority.

Conclusion

The analysis of the entire research conducted on Big Data in healthcare indicates the innovative method in Digitalization of healthcare services and the cybersecurity issues related to patient health records and their rights to protect it. Owing to Covid-19 when the whole world transforms all their sectors in digital platform patients are not connect with the technology easily as they prefer traditional mode of visiting the doctors for their health issues. As all the patients are helpless because of deadly Corona virus several conventions and legislations appear in order to safeguard patient rights like Information Technology Act, Intellectual Property, clinical establishment Act, IMC Regulation 2002, Drugs and Cosmetics Act of 1940, Pharmacy Act 1948 etc. These entire regulations are there to ensure the availability

and accessibility of healthcare services during the COVID 19 pandemic scenario, and it has necessitated a serious approach towards the Digitalization of health care services. Digital health is in vogue in all countries, and WHO and various digital technology platforms recommend it. However, the veracity and reliability of digital technologies, cybersecurity, patient safety and privacy, modes of electronic consent etc., put significant strain on the policymakers to draft new legislation to facilitate digital health care initiatives without compromising the patients' fundamental rights.