THE NATIONAL UNIVERSITY OF ADVANCED LEGAL STUDIES

Kalamassery, Kochi – 683 503, Kerala, India

DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE AWARD OF

MASTER OF LAWS DEGREE IN PUBLIC HEALTH LAW (2020-2021)

ON THE TOPIC:

Rights of Patients in India: An Analysis

SUBMITTED BY:

K S Akshay Mohan

(Register Number: LM0320015)

UNDER THE GUIDANCE AND SUPERVISION OF

Mr. Abhayachandran K.

Assistant Professor, NUALS, Kochi

October 2021

NUALS, Kochi

CERTIFICATE

This is to Certify that **K S AKSHAY MOHAN**, Reg. No: **LM0320015** has submitted his Dissertation titled "**RIGHTS OF PATIENTS IN INDIA: AN ANALYSIS**" in Partial fulfillment of the requirement for the award of Degree of Master of Laws in Public Health Law to the National University of Advanced Legal Studies, Kochi under my Guidance and Supervision. It is also affirmed that the Dissertation submitted by him is original, bona fide and genuine.

Dated: October, 2021

Place: ERNAKULAM

Mr. Abhayachandran K.

Guide and Supervisor

NUALS, Kochi

DECLARATION

I hereby declare that this Dissertation titled, "**Rights of Patients in India: An Analysis**" researched and submitted by me to the National University of Advanced Legal Studies Kochi, in partial fulfillment of the requirement for the award of Degree of Master of Laws in Public Health Law under the guidance and supervision of **Mr. Abhayachandran K, Assistant Professor, NUALS, Kochi,** is the result of my original, legitimate and independent research work carried out in pursuance of academic interest and it has not been submitted by me or anyone else for the award of any degree on any university or institution.

Dated: October, 2021

Place: ERNAKULAM

K S AKSHAY MOHAN

Reg. No: LM0320015

LLM (Public Health Law)

NUALS, Kochi

ACKNOWLEDGEMENT

Working on this dissertation titled **"*Rights of Patients in India: an Analysis*"** has provided me with immense joy and delight. This was made sure by all good souls around me while carrying out the research work. I take this opportunity to convey my warmest thanks to all those who supported me directly and indirectly to complete the research on time.

I take this opportunity to express my profound respect and deep sense of gratitude to my eminent guide and supervisor, **Mr. Abhayachandran K**, Assistant Professor, NUALS, for his constant support, guidance and encouragement throughout the course of this work. He was always approachable, respected my ideas, and gave me clear, cogent and meaningful suggestions, which aided abundantly in successfully completing this dissertation.

I would like to covey my gratitude to **Prof. (Dr.) K.C. Sunny,** Vice-Chancellor, NUALS, for his constant encouragement and support. I extend my sincere gratitude to **Dr. Mini S**., Director of Centre for Post Graduate Legal Studies, NUALS, for her support and encouragement extended throughout the course.

I would like to further extend my deep-felt gratitude to all the faculties of NUALS for their constant encouragement. I also convey my thankfulness to all non-teaching staffs of NUALS, especially **Mrs. Jeeja V**.**T**., Assistant librarian and **Mr. Anil Kumar C.**, Library Assistant for their timely assistance and also the technical team of NUALS for providing me with accurate technical aid and support.

I would like to thank my parents, who have been the prime source of inspiration throughout my life. I would also like to thank my beloved friends, without whom I would not be able to complete this research work on time.

Above all, I express my acknowledgments to the almighty for the blessings showered on me which lead to the successful and timely completion of this dissertation.

K S AKSHAY MOHAN

LIST OF ABBREVIATIONS

CE	Clinical Establishment
AYUSH	Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy
NABH	National Accreditation Board for Hospitals
NABL	National Accreditation Board for Laboratories
UN	United Nations
WHO	World Health Organization
EU	European Union
UDHR	Universal Declaration of Human Rights
ICCPR	International Covenant on Civil and Political Rights
ICESCR	International Covenant on Economic Social and Cultural Rights
ECHR	European Convention on the Protection of Human Rights and Fundamental Freedoms
ESC	European Social Charter
UNCRC	United Nations Convention on the Rights of the Child
CAT	Convention against Torture
ICERD	International Convention on the Elimination of All Forms of Racial Discrimination
CEDAW	Convention on the Elimination of All Forms of Discrimination Against Women

ICRMW	International Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families
CRPD	Convention on the Rights of Persons with Disabilities
ACHPR	African Charter on Human and Peoples' Rights
WMA	World Medical Association
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome
PIL	Public Interest Litigation
GNCTD	Government of National Capital Territory of Delhi
RTI	Right To Information
IMC or MCI	Medical Council of India
COPRA	Consumer Protection Act
IPC	Indian Penal Code, 1860
MoHFW	Ministry of Health and Family Welfare
CIC	Central Information Commission
NC or NCDRC	National Commission or National Consumer Disputes Redressal Commission
SCDRC	State Consumer Disputes Redressal Commission
CCPA	Central Consumer Protection Authority
NHRC	National Human Rights Commission

NLEM	National List of Essential Medicines
NPPA	National Pharmaceutical Pricing Authority
ICMR	Indian Council of Medical Research
GCP	Good Clinical Practice
IPHS	Indian Public Health Standards
PHC	Primary Health Centres
CHC	Community Health Centres
FRU	First Referral Unit
BIS/FSSAI	Bureau of Indian Standards/ Food Safety and Standards Authority of India
INGRO	Internal Grievance Redressal Officer
MRP	Maximum Retail Price
AIR	All India Reporter
SCC	Supreme Court Cases
KLT	Kerala Law Times
CPJ	Consumer Protection Journal
SC	Supreme Court
HC	High Court
Bom	Bombay

Del	Delhi
U.P.	Uttar Pradesh
WB	West Bengal
UT	Union Territory
Pa.	Pennsylvania
Pg.	Page
Para	Paragraph
UOI	Union of India

LIST OF CASES

1. *Ashish Kumar Mazumdar v. Aishi Ram Batra Charitable Hospital Trust*, (2014) 9 SCC 256
2. *Bandhua Mukti Morcha v. Union of India*, AIR 1984 SC 802
3. *Common Cause (A Regd. Society) v. Union of India*, (2018) 5 SCC 1
4. *Consumer Education And Research Centre v. Union of India*, AIR 1995 SC 922
5. *Devesh Singh Chauhan v. State* 2017, SCC OnLine Del 8130
6. *D.K. Basu v. State of West Bengal*, AIR 1997 SC 610
7. *Dr. Arvind Shah v. Kamlaben Ramsingh Kushwaha,* III (2009) CPJ 121 (NC)
8. *Dr. Laxman Balkrishna Joshi v. Dr. Trimbak Bapu Godbole*, AIR 1969 SC 128
9. *Dr. Shyam Kumar v. Rameshbhai Harmanbhai Kachhiya*, I (2006) CPJ 16 (NC)
10. *Essar Oil Ltd v. Halar Utkarsh Samiti*, (2004) 2 SCC 392
11. *Gazula Dasaratha Rama Rao v. State of Andhra Pradesh*, AIR 1961 SC 564
12. *Indian Medical Association v. V.P Shantha*, AIR 1996 SC 550
13. *Joseph v. Dr. George Moonjerly*, AIR 1994 Ker 289
14. *Kharak Singh v. State of U. P.,* AIR 1963 SC 1295
15. *K.S. Puttaswamy v. Union of India*, (2017) 10 SCC 1
16. *Medical Superintendent, St. Gregorious Mission Hospital v. Jessy*, III (2009) CPJ 61 (NC)
17. *Manoj Narula v. Union of India*, (2014) 9 SCC 1
18. *Mr. X v. Hospital Z*, AIR 1999 SC 495
19. *Nisha Priya Bhatia v. Institute of Human Behaviour and Allied Sciences, GNCTD*, CIC/AD/A/2013/001681-SA
20. *Olga Tellis v. Bombay Municipal Corporation*, AIR 1986 SC 180
21. *Ozair Husain v. Union of India*, AIR 2003 Delhi 103
22. *Parmanand Katara v. Union of India*, (1989) 4 SCC 286; AIR 1989 SC 2039
23. *Paschim Banga Khet Mazdoor Samity v. State of West Bengal*, AIR 1996 SC 2426
24. *Prabhat Kumar v. Directorate of Health Services*, CIC/SA/A/2014/000004
25. *Pravat Kumar Mukherjee v. Ruby General Hospital*, II (2005) CPJ 35 (NC)

26. *Raghunath Raheja v. Maharashtra Medical Council*, AIR 1996 Bom 198
27. *Rajappan v. Sree Chitra Tirunal Institute for Medical Science and Technology*, 2004 (2) KLT 157
28. *Rekha Gupta v. Bombay Hospital Trust*, II (2003) CPJ 160 (NC)
29. *Samira Kohli v. Dr. Prabha Manchanda*, AIR 2008 SC 138
30. *Sanjay S Prajapati v. State of Maharashtra*, 2016 SCC OnLine Bom 4751
31. *Secretary, Ministry of Information and Broadcasting, Govt. of India v. Cricket Association of Bengal*, AIR 1995 SC 1236
32. *Shantisar Builders v. Narayan Khimlal Totame*, (1990) 1 SCC 520
33. *Sharda v. Dharmpal,* AIR 2003 SC 3450
34. *Shri. G.R. Rawal v. Director General of Income Tax (Investigation)* CIC/AT/A/2007/00490
35. *State of Kerala v. N. M. Thomas*, AIR 1976 SC 490
36. *State of Punjab v. Mohinder Singh Chawla,* (1997) 2 SCC 83
37. *State of Punjab v. Ram Lubhaya Bagga*, (1998) 4 SCC 117
38. *State of U.P. v. Raj Narayan*, AIR 1975 SC 865
39. *Subhash Kumar v. State of Bihar*, AIR 1991 SC 420
40. *Thompson v. Nason Hospital*, 527 Pa. 330 (1991)
41. *Trans Mediterranean Airways v. M/S. Universal Exports*, IV (2011) CPJ 13 (SC)
42. *Union of India v. M/S. Cipla Ltd*., AIR 2016 SC 5025
43. *Vincent Panikurlangara v. Union of India*, AIR 1987 SC 990
44. *Vishakha v. State of Rajasthan*, AIR 1997 SC 3011

TABLE OF CONTENTS

CERTIFICATE 2
DECLARATION 3
ACKNOWLEDGEMENT 4
LIST OF ABBREVIATIONS 5
LIST OF CASES 9
CHAPTER I - INTRODUCTION 13
Statement of problem 17
Scope, relevance and limitations of the study 18
Research objectives 19
Research questions 20
Hypothesis 20
Research methodology 20
Chapterization 21
CHAPTER II – RIGHTS OF PATIENTS IN INDIA 23
Right to information 26
Right to records and reports 29
Right to emergency medical care 32
Right to informed consent 34
Right to privacy, confidentiality and human dignity 36
Right to second opinion and right to choose alternative treatment options if available 38
Right to choose source for obtaining medicines or tests 40
Right to transparency in rates, and care according to prescribed rates wherever relevant 40
Right to non - discrimination 42
Right to safety and quality care according to standards 43
Right to proper referral and transfer, which is free from perverse commercial influences 45
Right to protection for patients involved in clinical trials 47
Right to protection of participants involved in biomedical and health research 49
Right to take discharge of patient, or receive body of deceased from hospital 50
Right to patient education 51

Right to be heard and seek redressal 52
CHAPTER III - ENFORCEMENT OF PATIENT'S RIGHTS IN INDIA 53
Patient's rights and human rights 54
Patient's rights under the Constitution of India 59
Patients as consumers 63
Draft Charter of Patients rights, 2018 66
CHAPTER IV – COMPARATIVE ANALYSIS 70
United States of America 71
European Union 74
England 79
Scotland 83
CHAPTER V - CONCLUSION AND SUGGESTIONS 87
Hypothesis testing 94
Suggestions 94
BIBLIOGRAPHY 97
APPENDIX 106

CHAPTER I - INTRODUCTION

A patient is any person who is a user of healthcare services, seeking any kind of medical attention from the medical facilitators including doctors, nurses, hospitals, clinics etc. A patient while using healthcare services may be healthy or sick.[1] Generally, when a patient as well as the family members visit a hospital or any other medical facility, they will be in a physically and mentally weaker position and thereby will take the word of the medical facilitators ultimate and for granted.

With the commercialization and privatization of the healthcare industry, many at times the patients are put at the receiving end of medical malpractices by the facilitators by taking unfair advantage of the vulnerability of the patients. Hence, the patients must be entitled to a certain extent of protection in this regard to be ensured by the medical practitioners as well as the state while rendering medical aid or attention and the patients must also be enlightened about the same. In many countries, these sets of protection are being codified into a specific set of rights to which the patients are entitled while seeking medical attention in the form of a Charter or Bill of rights on this regard. But the issue here is that in most of the countries these instruments are not legally enforceable. It has been passed solely with a view to act as a catalyst or as a model law to recognise and to be followed by the hospitals or clinics. Since, these charters mostly lack legal backing or recognition, enforcement and protection of patient rights at medical facilities are dubious in that scenario.

Mostly, across the countries, the rights of patients would somehow be recognised as being an inherent right from the Human Rights or as an indivisible part of the fundamental rights of the concerned states. Therefore, the rights of patients would be recognised as a legally enforceable right to the extent to which it has been embedded in the legal framework of that country and may not be comprehensively codified (similar to the position in India wherein only a draft Charter has been published and the rights are scattered). Problem may arise as to enforcement of these rights if they are not being codified comprehensively. Also, it will be difficult for the poor and vulnerable patients to understand their rights while seeking medical attention if these rights are not being codified and scattered across various legislations. These rights embedded in the legal

[1] WHO Declaration on the Promotion of Patients' Rights in Europe, 1994

framework which are uncodified may be enjoyed by people because of their status as being a citizen and not with the privilege of being a patient. Therefore, scattered rights of patients may not be recognised and enforced uniformly as a set of rights across the country. Therefore, every patient may not know or be aware of their rights unless codified into a single document and made accessible to each and every patient. Eg: in India, rights are scattered around various legal documents namely the Constitution of India, Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations 2002, Consumer Protection Act 1986; Drugs and Cosmetic Act, 1940, Clinical Establishment (Registration and Regulation) Act, 2010 and rules and standards framed therein and various judgments given by the Supreme Court, High Courts and National Consumer Disputes Redressal Commission.

Since, these instruments contain rights of patients, it may be safe to say that India may in a sense recognise these rights, but apparently may not be enforced uniformly and consistently throughout the country. Also, the mode of enforcement of the rights of patients embedded in precedence or judicial pronouncements may be different from the rights of patients mentioned in legislations and that too may be different from those mentioned through various standards, policies or regulations. Hence, there will not be uniformity in the enforcement of these rights. Therefore, codification of the rights of patients is very important in the country. Even in India, wherein some way or the other, traditional paternalistic medical model being rooted deep into the minds of patients as well as medical facilitators, upon which the input by patient is limited, codification and thereby enlightening the patients about the various rights available to them upon availing any medical aid or assistance is of high significance and pertinence.

Mere codification and stipulation of the rights of patients is not the ultimate solution. A right does not reveal its true sense and vigor unless there is a remedy attached for its violation. As the renowned maxim goes, *Ubi jus ibi remedium* denoting ‘where there is a right, there is a remedy’, implying where law has established or recognized a right, there should be a corresponding remedy attached to it for its breach in any sorts. Therefore, through recognizing the rights of patients, there should be appropriate remedies available to the patients if any of their rights are violated. Also, these remedies are to be set cleared through proper efficient and effective enforceable mechanisms.

Human rights and patients rights are indivisible. Patients' right is a subset of human rights. While human rights refer to the minimum standards by which every human being can expect to be treated by others, 'ethics' refers to the customary standards or etiquettes by which people should regard one another. As a result, rights and ethics are sometimes seen as two sides of the same coin, and every patient right is based on one or more of the established ethical principles.[2] The formulation of strongly outlined patient rights assists in the standardization of healthcare and allows patients to have consistent expectations throughout their treatment. With modern Charters enumerating patients' rights, they can anticipate specific standardized treatment regardless of their socioeconomic level, religious beliefs, gender, race or ethnicity. *Autonomy, beneficence, non-maleficence* and *justice* are some of the core ethical principles that commonly established rights of patients are based on. Another important aspect while dealing with rights of patients is the fiduciary doctor-patient relationship obtained through mutual consent. The doctor needs to uphold the best interest and welfare of the patient at all times and thereby advocate for the rights of patients during medical care.

When a legal norm does not exist with regard to protection of patients rights, it is the healthcare provider's responsibility to prioritize these ethical principles in order to reach a satisfactory outcome for the patient. Hippocrates' Oath, a short exposition of the principles for the conduct of physicians, was written in the fifth century before the Common Era (BCE). Its declarations defend patients' rights and obligate physicians to voluntarily act altruistically toward patients.[3] Ethical norms have always been a feature of the medical profession, dating back to the Hippocratic Oath. It was later modified and has been in use widely to act as a guide to ideal physician behaviours and conducts. Ethical codes are important in governing the medical profession as well as protecting the rights of patients and clinical trial participants. Ethical standards are unavoidable, especially in a field wherein life saving is the primary and ultimate goal.

In most of the cases wherein a charter enumerating patient rights has been established, it does not give them any formal legal rights. Rather, they act as a catalyst to rapidly and cost-effectively address and resolve individual patient concerns. Furthermore, a well-designed patient charter

---

[2] Jacob P. Olejarczyk & Michael Young, *Patient Rights And Ethics*, (accessed on March 18, 2021, 03.02 PM) https://www.ncbi.nlm.nih.gov/books/NBK538279/

[3] Frank Riddick Jr., *The code of medical ethics of the American Medical Association*. 5 OCHSNER J. 6 (2003)

could spur for system-wide improvements in the healthcare sector.[4] A patient rights charter usually encompasses the rights that already exists under the common law as well those scattered across various statutes. As a result, usually the charter provides a method for combining and consolidating existing patient rights, such as informed consent, access to health information, privacy etc.

The Charters on patient rights often augments the right for patients to have their concerns redressed and investigated by an independent authority, which may not be available under the ordinary legislations like in India. Although, patients already have many of these rights, having them all in one comprehensive document gives them more clarity and awareness. Patient rights charters with specialized complaints redressal mechanism allows issues to be settled informally at an early stage, avoiding the need for lengthy formal disciplinary proceedings or litigations.[5] A charter on this regard can be especially useful in helping patients to exercise their rights without incurring the heavy costs and delays associated with litigations in courts. The provisions pertaining to the right to emergency and timely care is becoming a more typical approach to establishing a patient charter. Thereby, as the privately financed sector is flourishing in healthcare delivery system, it is pertinent that patients have a fair mechanism of lodging concerns and having them promptly redressed.

With this view the Ministry of Health and Family Welfare (MoHFW) directed the National Human Rights Commission (NHRC) to come up with a comprehensive set of rights of patients. Thereby, the commission drafted and got published a Charter of Patients' Rights in 2018 by including 17 sets of rights to which every patient in India is entitled namely:

- Right to information;
- Right to records and reports;
- Right to emergency care;
- Right to informed consent;
- Right to confidentiality, human dignity and privacy;
- Right to second opinion;

[4] 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)
[5] Hajrija Mujovic-Zornic, *Legislation and patients' rights: some necessary remarks*, 26 MED. & L. 709 (2007).

- Right to transparency in rates and care according to prescribed rates wherever relevant;
- Right to non-discrimination;
- Right to safety and quality care according to standards;
- Right to choose alternative treatment options if available;
- Right to choose source for obtaining medicines or tests;
- Right to proper referral and transfer, which is free from perverse commercial influences;
- Right to protection for patients involved in clinical trials;
- Right to protection of participants involved in biomedical and health research;
- Right to take discharge of patient, or receive body of deceased from hospital;
- Right to patient education;
- Right to be heard and seek redressal.

The draft Charter 2018 was also outlined with a view that the patients while visiting a medical establishment are aware of the each and every right available to them which were previously scattered around various legal instruments and judgments, and were difficult to be comprehended by the patients and laymen. This was also drafted with an objective that the union and state governments would consider this as a foundation for an effective implementation and protection of the rights of patients throughout India and thereby step in with efficient mechanisms to effectuate rights of patients. Hence, the move to draft the Charter, better late than never, is a welcome step.

Does it encompasses every rights of patients is another question. How this draft Charter will head in the direction of protecting the rights of patients in India is a serious question that needs thorough introspection especially in this era which is experiencing an unprecedented, dreadful and appalling pandemic.

Statement of problem

The draft patient Charter has been prepared by the NHRC and MoHFW with a view to codify and encompass various rights of patients which are scattered around various legislations and judicial precedence and thereby enlighten the patients about their rights while seeking medical attention and also to prescribe a mechanism to provide efficient mechanism and timely redressal regarding patients rights. It has been drafted, mindful of receiving numerous complaints

regarding the violations of basic rights of patients by some of the dominant and influential medical establishments. The National Accreditation Board for Hospitals & Healthcare Providers (NABH), which is the accreditation body set to provide accreditation program for medical facilitators, has also set up certain standards for the protection of patient rights that is required to be followed by hospitals or clinics to get accredited for its functioning. This is merely a prerequisite to be followed for getting accreditation and does not prescribe a mechanism to effectively implement or protect the rights of patients. The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 which provides for numerous patients rights also does not prescribe a mechanism for the enforcement of the same, but contains only a set of standards if violated, results in the inception of disciplinary action against the medical practitioners. Similar is the position with the central Clinical Establishment (Registration and Regulation) Act, 2010 and rules and standards framed therein, which lacks an efficient mechanism to monitor the enforcement of patients rights and the same are not even uniformly applicable across the country.

Hence, the drafting of a Charter on this regard, is the pivotal initiative made towards the comprehensive envisioning of patients rights along with the prescription of a mechanism to uphold the same in the country. However, the draft, even if finalized as a proper charter, it may only have the force to act as a catalyst for the state governments to come up with their own regimes for the protection of patient rights in their respective states and hence, they will be put at liberty to add or even omit certain rights mentioned in the draft because public health and hospital regulation being matters under the state subjects under seventh schedule of the Constitution of India and thereby, central government having only limited power in such matters. Hence, it might be impossible or else take years for a charter or rights of patients to be implemented comprehensively and uniformly all across India and thereby continue lacking an efficient and timely rectification and redressal of patient rights violations.

Scope, relevance and limitations of the study

The rights of patients in India are still not codified comprehensively into a single lawfully enforceable code or instrument for any patient to easily access and understand his rights while seeking medical attention. Only a draft Charter has been prepared in the country in 2018 enumerating various rights and discussing its legal backing superficially. Therefore, this study is

relevant in this aspect to understand all important rights possessed by the patients and its legal backing in detail which has been included in the draft Charter of rights of patients, 2018 as well as other rights scattered across various other legislations or judicial decisions if any. Mere knowledge about the various rights would not provide them with respite. Hence, how these rights are being enforced in the country also needs to be looked at. Therefore, this study also tries to figure out the mechanism and their approach in which these rights are being appropriately enforced and protected in India or else what can be done or implemented to efficiently protect and enforce these rights in India.

However, the study is limited to the aspect of rights of patients enjoyed while accessing medical care generally and not in specific care or treatment such as mental health, organ transplantation, medical termination of pregnancy etc. These specific treatments are being specifically regulated by the concerned legislations specifically applicable such as the Transplantation of Human Organs and Tissues Act, 1994, Mental Healthcare Act, 2017, Medical Termination of Pregnancy Act, 1971 etc. These legislations contain detailed provisions for the expected standard of care during the specific treatment and thereby also contain the provisions enumerating the specific rights of patients while seeking specific treatment. Hence, these rights are not covered in this study and those generally enjoyed by the patients (including the above set of patients) while seeking medical care is being covered in this study. The study also does not cover the rights specifically applicable to the particular marginalized and vulnerable patients or groups.

Research objectives

- To understand the significance of patients rights and its protection
- To understand whether patients have any rights in India besides the fundamental rights available to all citizens and if so what are they?
- To understand which legal instrument enshrines these rights
- To study the existing legal mechanisms established to protect these rights of patients and also the redressal mechanism
- To understand the remedies available to the patients in case of violations
- To have a comparative analysis of the rights of patients in India and other countries

- To understand the role played by state, medical facilitators and even private parties in protection of patient rights
- To understand whether caretakers have any right as a part of patients rights
- To identify when a person can avail the rights as a patient
- To understand the principles of medical ethics and its relation with patient rights
- To identify whether the enforcement of the rights are straight forward in India

Research questions

- Has the patients' rights been recognised and protected in India?
- What are the legal framework established internationally and nationally to protect and enforce rights of patients?
- Will the draft Charter 2018 suffice in protecting the rights of patients in India?
- Does the charter has the tooth, even if finalized, to effectively protect and enforce the rights enumerated specifically taking into account the Indian legal and social scenario?
- Whether the legal instruments provide or have the capacity to provide 'immediate remedy' as most importantly required by the patients in case of violation of their rights?
- Whether empowering states to protect the rights of patients in their respective state due to health being a state subject, effectively protect the rights of patients in India?
- Isn't it high time to confer an independent special status to the patients to provide them with immediate remedy and considering the enforcement of patients' rights?

Hypothesis

- The rights of patients in India are not recognised and codified comprehensively and lack an efficient mechanism in protecting and enforcing their rights.

Research methodology

The research methodology adopted in the dissertation is Doctrinal research method. Thereby, analysis of authoritative judgments of the Supreme Court and various High Courts, Statutes, books, online resources, articles, newspapers, etc. to accomplish the objectives of the dissertation and reference has been cited wherever necessary.

Chapterization

- CHAPTER I – INTRODUCTION

The first chapter deals with an introduction to the whole study. It contains a brief introduction to the topic and the present position of patients' rights in the country, statement of problem, scope, relevance and limitation of the study, objectives, research questions, hypothesis and the methodology adopted for the study.

- CHAPTER II - RIGHTS OF PATIENTS IN INDIA

The second chapter deals with the detailed analysis of various rights of patients recognised in India on the basis of the draft Charter 2018, since it is the latest advancement made towards the protection of patient rights. For the protection of patient rights, the primary aspect is to enlighten all stakeholders about the basic rights possessed by the patients while seeking medical aid or service. The draft specifies 17 sets of patient rights. However, the draft only discloses the backing of the rights superficially. Hence, this chapter in detail specifies and enlightens the reader, for easy comprehension about the rights and the legal backing of each and every right provided in the draft Charter. It discusses the various legal instruments, judicial decisions of various High Courts and Supreme Court and other relevant authorities connected with each of the rights of patients.

- CHAPTER III - ENFORCEMENT OF PATIENT'S RIGHTS IN INDIA

Having discussed the various rights of patients in the previous chapter, it paves way for the third chapter which deals with a detailed enquiry into the effective enforcement mechanism established for the said rights. Rights are not rights if they are not effectively enforced and remedied. The aggrieved patient needs to be provided with an effective and timely redressal mechanism in case of violation. Hence, how the said rights are being enforced and the redressal mechanism established in the country towards patients rights, has been discussed in detail in this chapter. Patients' rights, since India lacks a comprehensive legal instrument which effectuates their rights, it is to be enforced and protected through various other legislations or means. Therefore, the patients' rights can be enforced as human rights, consumer rights as well as through the Constitution of India since patients' rights takes it's backing from all of the above.

Hence, the provisions of various International and National legislations are discussed in this chapter. The chapter also discusses the way in which the draft Charter expects the patients' rights to be successfully enforced, protected and the redressal mechanism to be adopted to uphold rights of patients.

- CHAPTER IV - COMPARATIVE ANALYSIS

The fourth chapter strives to have an understanding of the rights of patients and its protection in few other countries in comparison with that of India. It discusses the legal instruments which particularly envisage the rights of patients in the said countries and also the mechanism established to protect the rights.

- CHAPTER V - CONCLUSION AND SUGGESTIONS

The fifth and concluding chapter of this dissertation deals with the final conclusions arrived by the researcher regarding the protection of patients rights in India. The Chapter also contains hypothesis testing and ends with certain suggestions of the researcher to comprehensively protect and enforce the rights of patients in India.

CHAPTER II – RIGHTS OF PATIENTS IN INDIA

Patients' rights are the legal representation of standards which everyone naturally expects from a doctor, medical personnel, and healthcare system in general.[6] Several countries have implemented patient charters as a part to push healthcare system towards patient-centered care. Patients' rights are basically derived from one or more established ethical principles and behind every patient right there would be a strong basis on the ethical principles.[7]

Medical ethics refers to the moral principles that guide and control medical professionals in their interactions with one another, patients, and the government. Its goal is to uphold and honour the medical profession's excellent traditions.[8] Medical ethics also establishes and promotes a variety of moral norms and concepts while dealing with healthcare delivery to patients. There are 4 major universally accepted ethical principles which can be found in almost all ethical codes or standards dealing with patient care namely: *Autonomy, beneficence, non-maleficence* and *justice*.

Autonomy is the capacity of a person to live according to one's own reasoning and intentions. Patients who are able to defend their own decisions have the right to make decisions that might differ from what the physician believes. It is a wider concept of ethics, not only applicable to patients but to every persons in general. Right to choose or refuse treatment, access to information, and medical records, informed consent, dignity etc takes its fundamental from the principle of autonomy.

The principle of non-maleficence means to "do no harm". This principle must be endorsed by every medical practitioner when making choices or rendering treatments. It must be ensured that patients are not harmed as a result of any therapy or procedure. All medical professionals must adhere to the principle of "*Primum non nocere*", which means, above all do no harm.

The principle of beneficence holds that medical professionals should do everything possible to benefit the patient in any situation. It essentially implies "doing well" and "doing what is best for the patient". At times the principle of beneficence and autonomy may contradict with each other. For instance, using autonomy, the patient may choose to refrain from a particular treatment

[6] *Ibid*.
[7] *Supra* n. 2
[8] NANDITA ADHIKARI, LAW & MEDICINE 62 (2017)

which may be pertinent to be taken considering the condition of the patient and in the opinion of the medical practitioner. The practitioner will be doing his best for the benefit of the patient as according to the principle of beneficence. With this conflict arising, it is important for the medical practitioner to explain and discuss more with the patients and family members about the particular situation and provide the patient to make a much better informed decision.[9]

The concept of justice, in healthcare context refers to the idea of “distributive justice” which infers all patients shall be treated equally and fairly. It entails not just respecting individual rights, but also treating all patients in a particular scenario equally, regardless of their identity. The idea of justice is used in healthcare laws and policies to ensure that everyone has access to the healthcare; they need to be alive, such as in an emergency.

There are international as well as domestic ethical codes or standards or rules that govern medical profession primarily based on the above principles. Adherence to these ethical codes is of top priority because the medical profession directly affects the lives of people and their families and thereby a breach of codes would be regarded as professional misconduct. Also, the profession’s intricacy puts professionals in tough situations where they require some sort of guidance and assistance to determine what needs to be done. In such situations, ethical codes provide clarity, allowing a decision to be made in the best interests of the patient and public in general. During any treatment or medical care, medical practitioners use their technical expertise and skill exclusively possessed by them that an untrained or ordinary person does not possess. The possession of these abilities provides a doctor with tremendous control and authority over the patients who are dependent, ailing, and vulnerable. The importance of ethical codes is that while a doctor makes various decisions during a treatment, the patients can expect as a matter of right that the decisions are made fairly according to the expertise and skill of the doctor. As a result, while ethical standards are primarily intended to regulate the profession, they attempt to meet the rights and expectations of patients as well.

Ethical codes prescribe the doctor’s responsibilities to the patient. Doctor’s duties are patient rights.[10] As a result, it is crucial that medical professionals follow all applicable ethical norms and thereby self-regulate. The absence of ethical norms would wreak turmoil in society, since

---

[9] *Supra* n. 2

[10] Amar Jesani, Medical Ethics and Patients' Rights, 54 INDIAN J. SOC. WORK 173 (1993)

medical professionals would be free to act in their own interests, perhaps jeopardizing the profession's essential ethical values and thereby patients' rights would be violated at all times. Hence, while practicing medicine and medical research, ethical standards must be prioritized to reduce risk and increase patient safety.

In India, the Medical Council of India (MCI) under Section 33 (m) of the Indian Medical Council Act, 1956 has notified and adopted the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 which regulates the conduct of medical professionals and also enumerates some of the rights of patients. Apart from the MCI regulations, various other instruments also depicts rights of patients in India. By virtue of patient also being a consumer as according to the SC decision[11], various consumer rights are also available to patients provided they satisfy certain criteria. Some of the rights of patients in India take its strong backing also from the Constitution of India, Drugs and Cosmetic Act 1940, Clinical Establishment Act 2010 and rules and standards framed etc.

Section 12 of the Clinical Establishments (Registration and Regulation) Act, 2010 provides for certain primary conditions to be fulfilled by every Clinical Establishments (CE) to get registration at the first instance and continuation of its working. It states that every CE shall abide by the minimum standards of facilities and services, the minimum requirement of personnel, provisions for maintenance of records and reporting, and such other conditions, as may be prescribed.[12] The minimum standards of CEs are implemented based on the mode of treatment and level of care provided by different CEs. As a result, the National Clinical Establishments Council[13] has issued different minimum standards to CEs involved in allopathic and *Ayurveda, Yoga and Naturopathy, Unani, Siddha* and *Homeopathy* (AYUSH) medicines.[14] Hospitals professing allopathic medicine are divided into different levels based on their capacity and other criteria. The minimum standards issued for Level 1 Hospitals list nine rights of patients

[11] *Indian Medical Association v. V.P Shantha*, AIR 1996 SC 550
[12] Section 12 Clinical Establishments (Registration and Regulation) Act, 2010
[13] National Clinical Establishments Council has been established by the Central Government under Section 3 of Clinical Establishments (Registration and Regulation) Act, 2010 to classify CEs into different categories, develop minimum standards and other related functions.
[14] Clinical Establishments (Registration and Regulation) Act, 2010, MoHFW, http://www.clinicalestablishments.gov.in/cms/Home.aspx (accessed on May 20, 2021, 8.05 AM)

with respect to CE.[15] Though these rights are mentioned only in the standard for hospital level 1, minimum standards of other CEs do mention that the CE must display the rights of patients in a conspicuous place in the CE.

Hence, the rights of patients are scattered around various legal instruments and in no way could the patients get access to a comprehensive document containing all patients' rights and what the draft Charter 2018 discussed in the previous chapter did was that it was able to encompass and enumerate comprehensively all the rights of patients which were scattered around various regulations and also lists down the basis from which the rights were derived or formed. This chapter discusses in detail the specific rights of patients and its legal basis and backing from various legal instruments as well as judicial pronouncements of the same to have a strong comprehension of the each and every right of patient on the basis of the draft Charter 2018 since it is the document which gives a clear picture on the same. For ease of comprehension, the researcher has discussed certain rights together, without different heads and therefore, would be slightly different from the draft Charter 2018.

Right to information

The patient's role in healthcare has changed from being an acceptor of the order or direction of the doctor, to being an active partner or participant in the therapeutic relationship.[16] For active participation from the part of the patient, they must be enlightened with relevant information regarding the treatment of such patient.

Minimum Standards of CE of Level 1 hospitals states that the patients or their representatives have the right to adequate, relevant information about the nature, cause of illness, proposed investigations and care, expected results of treatment, possible complications and expected costs.[17] The draft Charter mentions that in addition to the above mentioned right, the patients have the right to adequate information about the provisional or confirmed diagnosis conducted on the patient and also these relevant information has to be made available and explained to the patient at their level of understanding, in the language acquainted to them.[18] Moreover, this

[15] Annexure 8 of Clinical Establishment Act Standards for Hospital level 1
[16] Don Malcolmson, *The Patient's Right to Know,* 101 J. MED. REGUL. 32 (2015).
[17] Annexure 8 of Clinical Establishment Act Standards for Hospital level 1
[18] Draft Charter of Patients' Rights, 2018

information must be conveyed in the simplest form without confusing or overpowering the patients with overused technical words by the doctor himself or qualified assistants. Patients have the right to get informed of the name, dosage and adverse effects, if any possessed by the prescribed medication.[19]

Every CE, irrespective of the mode of treatment professed, has been mandated by their respective minimum standards to display the rights of patients at a conspicuous place in the CE so that the patients and their accompaniments get the easiest opportunity to get familiarized with the specific set of rights to which they are entitled while seeking medical attention. They also have the right to know about the identity and professional status of medical facilitators attending them and know the doctor taking primary responsibility of the patient in the medical treatment. The hospital authorities are duty bound to provide these information regularly to them in writing with an acknowledgement.[20] CEs shall display the certificate of registration at a conspicuous place in the CE, so that it is visible to any person visiting such CE.[21] In addition to the certificate, CEs shall display in the same manner, the details of rates of charge for each type of services and facilities provided by the CE in the local as well as the English language.[22] These are mandated with a view that the patients get informed of the basic information regarding the doctors or staffs attending them and also regarding the legality in the establishment of the hospital or clinic per se. If any of the above are not being properly displayed it can lead to the cancellation of the registration of the CE.

All patients or their accompaniments have the right to get complete information regarding the expected cost of treatment. The hospital authorities are put on duty to communicate this in writing to the patient or concerned person. Any change in the cost incurred due to the varying physical condition of the patient also has to be communicated in writing. Patients also have the right to information about the rules and regulations of the hospital.[23] Upon completion of the treatment, the patient has the right to obtain an itemized bill with various charges and expenses

[19] NABH charter of Patients Rights
[20] Draft Charter of Patients' Rights, 2018
[21] Section 18 Clinical Establishments (Registration and Regulation) Act, 2010
[22] Rule 9 Clinical Establishments (Central Government) Rules, 2012
[23] NABH charter of Patients Rights

specified, to receive an explanation regardless of the source or mode of payment and to receive payment receipts for any payment made therein.[24]

According to the International Covenant on Civil and Political Rights, 1966 (ICCPR), right to freedom of expression includes freedom to seek, receive and impart information and ideas of all kinds, regardless of frontiers, either orally, in writing or in print, in the form of art, or through any other media of his choice.[25] The European Convention on the Protection of Human Rights and Fundamental Freedoms (ECHR) also holds a similar view.[26]

The Supreme Court in *State of U.P. v. Raj Narayan*[27], held that right to information is a derivative of citizens freedom of speech and expression which is not absolute. Hence they have the right to receive information regarding every public act done by their public functionaries.[28] The Court in *Secretary, Ministry of Information and Broadcasting, Govt. of India v. Cricket Association of Bengal*[29] , reiterated that freedom of speech and expression includes right to acquire information under Art 19(1)(a) of the Constitution of India.

Since "service" rendered by medical practitioners are covered under the Consumer Protection Act, 1986 and the status of a consumer being conferred upon the patient while availing medical services,[30] certain rights available to the consumer will also be made available to the patients. Therefore, patient/consumer has the right to information about the quality, quantity, potency, purity, standard and price of goods so as to protect the patient/consumer against unfair trade practices.[31]

The Central Information Commission in *Nisha Priya Bhatia v. Institute of Human Behaviour and Allied Sciences, GNCTD*[32] held that a consumer of medical services has a right to know what treatment was given to him/her, what were the reports of diagnostic tests, what were the

[24] Draft Charter of Patients' Rights, 2018
[25] Article 19(2) ICCPR
[26] Article 10 ECHR
[27] *State of U.P. v. Raj Narayan*, AIR 1975 SC 865
[28] *Ibid* at para 74
[29] *Secretary, Ministry of Information and Broadcasting, Govt. of India and v. Cricket Association of Bengal*, AIR 1995 SC 1236
[30] *Indian Medical Association v. V.P Shantha*, AIR 1996 SC 550
[31] Consumer Rights – Department of Consumer Affairs, https://consumeraffairs.nic.in/organisation-and-units/division/consumer-protection-unit/consumer-rights (accessed on May 22, 2021, 2.05 PM)
[32] *Nisha Priya Bhatia v. Institute of Human Behaviour and Allied Sciences*, *GNCTD*, CIC/AD/A/2013/001681-SA

opinions expressed by doctors or specialists etc. There is a strong link between Art 21 and the right to know particularly where "secret Government decisions may affect health, life and livelihood".[33]

The Right To Information Act, 2005 established a practical regime to provide citizens with secured access to information controlled by the public authority to promote transparency and accountability in its working and thus, envision right to information. Thereby, it provides access to records held by government hospitals and through various decisions and initiatives, the right of citizens is expanded beyond public authorities to private bodies provided there is any legal access which will be discussed in detail in the forthcoming rights.

Right to records and reports

Maintaining medical record regarding the management of patients in the hospital during treatment is very important. This evolves as valid documentary evidence before any authorities in future. The only way for the doctor to assure the patient and other authorities that treatment has been properly carried out is through maintaining proper records regarding it.[34]

The requirements of medical records may vary with each jurisdictions, but all carries the same basic message that every record must give the patient's and doctor's identities, contain relevant legal documents, contain necessary patient information, as well as information concerning therapy, discharge, and follow-up as appropriate.[35]

Patients or their accompaniments have the right to access originals or copies of case papers, indoor patient records, investigation reports during period of admission and discharge (preferably within 24 and 72 hours respectively) and detailed bill.[36] Medical records shall be maintained either in physical or digital format.[37] The confidentiality, security and integrity of such records

---

[33] *Essar Oil Ltd v. Halar Utkarsh Samiti*, (2004) 2 SCC 392
[34] Thomas Joseph, *Medical records and issues in negligence*, 25 IND. J. UROL. 384 (2009).
[35] 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)
[36] Annexure 8 of Clinical Establishment Act Standards for Hospital level 1
[37] Section 9.2 Clinical Establishment Act Standards for Hospital level 1

shall be ensured by the concerned person or hospital.[38] The records of in-patients shall be maintained in consonance with the concerned laws, MCI guidelines and orders of Courts.[39]

It is the physician's duty to maintain proper medical records of the concerned indoor patient for a period of three years from the date of commencement of the treatment in the format[40] prescribed.[41] Physician shall make available the medical records upon request by the patient or competent person or authorities, within a period of 72 hours.[42] If the physician refuses to provide the same within the stipulated time upon request by the concerned person, it will be considered as an omission on the part of the physician which constitutes professional misconduct rendering him liable for disciplinary action[43] and an adverse inference could be drawn by the concerned authority as a consequence of denial of medical record.[44] The records or documents, wherever applicable may be made available to the patients after proper payment of appropriate fee, for photocopying or allowed to be photocopied by patients at their cost.[45]

The Kerala HC in *Rajappan v. Sree Chitra Tirunal Institute for Medical Science and Technology*[46] held that providing a copy of appendix 3 only, would not suffice the requirements under the above regulations; photocopy of entire sheet maintained by the hospital has to be provided. The case sheet is the one that contains the diagnostic results and the details of treatment provided. Appendix 3 will only contain a summary of the above. Hence, the patient has the right to access the entire documents (Appendix 3 along with supporting documents).

The patient or accompaniments have the right to get the discharge summary. In case of death of the patient, the accompaniments or relatives have the right to procure death summary along with the original copies of investigation. The hospital management has a duty to provide these records and reports and to instruct the responsible hospital staff, to ensure provision of the same are strictly followed without fail.[47] Annexure 10 of Clinical Establishment Act Standards for Hospital

[38] Section 9.3 Clinical Establishment Act Standards for Hospital level 1
[39] Section 9.4 Clinical Establishment Act Standards for Hospital level 1
[40] Appendix 3 Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002
[41] Regulation 1.3.1 Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002
[42] Regulation 1.3.2 Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002
[43] Regulations 7,7.2 Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002
[44] *Dr. Shyam Kumar v. Rameshbhai Harmanbhai Kachhiya*, I (2006) CPJ 16 NC
[45] Draft Charter of Patients' Rights, 2018
[46] *Rajappan v. Sree Chitra Tirunal Institute for Medical Science and Technology*, 2004 (2) KLT 157
[47] Draft Charter of Patients' Rights, 2018

Level1 provides for the contents to be included in the discharge summary and the same shall be mentioned in the language understandable to the patient and in prescribed format.

In *Raghunath Raheja v. Maharashtra Medical Council,*[48] the Bombay HC settled the position that patients have the right to their medical records and reports. The court opined that, the Medical Council should ensure through necessary direction to the hospitals and doctors to furnish case sheets and relevant documents regarding the concerned patient. Also hospitals cannot claim secrecy or confidentiality issues with respect to production of such documents to the patient.

The Delhi HC in *Ozair Husain v. Union of India*[49], held that consumer had the right to information about a product. Through this Public Interest Litigation (PIL), the petitioner sought the court to issue direction to voluntarily display the contents constituted in food products, drugs and cosmetics so as to protect the rights of consumers to get informed of the contents specifically relating to the presence of animal derivatives which are avoided by certain consumers as per their religious faith. The court held that the contents be displayed since consumers have the right to information.

The Central Information Commission in *Nisha Priya Bhatia v. Institute of Human Behaviour and Allied Sciences, GNCTD*[50] extended the principle in *Ozair Hussain* (*supra*) to medical services and held that a consumer of medical services also has a right to know all details and information regarding the treatment, reports of diagnostic tests, opinions expressed by doctors or specialists, reason for admitting in the hospital etc. Consumer's right to information extends both to the products and services, including medical service.[51] The Commission opined that the right of patient to obtain his medical records or reports is not only protected under Right to Information (RTI) Act, but also under MCI Regulations, which has its basis on world medical ethics, and also under Consumer Protection Act (COPRA). Also, hospital has a duty to develop a mechanism wherein copy of medical record of patients from the date of admitting to

[48] *Raghunath Raheja v. Maharashtra Medical Council*, AIR 1996 Bom 198
[49] *Ozair Husain v. Union of India*, AIR 2003 Delhi 103
[50] *Nisha Priya Bhatia v. Institute of Human Behaviour and Allied Sciences, GNCTD*, CIC/AD/A/2013/001681-SA
[51] *Ibid* at para 12

discharge is provided to him or authorized persons even without request from such person, as a regular procedure at the juncture of discharge.[52]

In *Prabhat Kumar v. Directorate of Health Services and ors,*[53] CIC recommended the govt. to take note that right to information of medical records of patient is equally applicable against public as well as private hospitals and any attempt to disregard the enforcement of this right by any private hospital will amount to discrimination which is in violation of Art 14 of the Constitution of India.

Right to emergency medical care

Art. 21 of the Constitution envisage right to life and personal liberty. It states that no one shall be deprived of his life or personal liberty except according to the procedure established by law.[54] By the term 'life', something more than mere animal existence is meant.[55] The Supreme Court over the years has time and again interpreted Art 21 to include various other rights though not finding its place as a Fundamental Right in the Constitution, but necessary to envision right to life. One such right the SC has considered being an intrinsic part of Art. 21 is the right to health.[56] Health of citizens should be focused and given priority not only to make one's life meaningful but to obtain optimal output.[57] Therefore, the government is put at an obligation to provide all necessary health services and facilities to ensure right to health.[58] Right to medical care was also held to be a part of Art 21 read with Articles 39(e), 41 and 43 of the Constitution to make life meaningful and purposeful with dignity of person.[59]

In *Parmanand Katara v. Union of India*[60], a PIL was filed on the basis of a newspaper report wherein a person involved in an accident was refused treatment in a nearby hospital and was directed to be taken to a hospital authorized to attend medico-legal cases, which was 20 km away. The patient succumbed en route. SC stressed upon the fact that preservation of human life

---

[52] *Ibid* at para 29
[53] *Prabhat Kumar v. Directorate of Health Services*, CIC/SA/A/2014/000004
[54] Article 21 Constitution Of India 1949
[55] *Kharak Singh v. State Of U. P.*, AIR 1963 SC 1295
[56] *Bandhua Mukti Morcha v. Union of India*, AIR 1984 SC 802
[57] *State of Punjab v. Ram Lubhaya Bagga*, (1998) 4 SCC 117
[58] *State of Punjab v. Mohinder Singh Chawla*, (1997) 2 SCC 83
[59] *Consumer Education and Research Centre v. Union Of India*, AIR 1995 SC 922
[60] *Parmanand Katara v. Union of India*, (1989) 4 SCC 286: AIR 1989 SC 2039

was of paramount importance. Since, resurrection was beyond human capacity, every doctor be it in a government or private hospital is professionally obligated to extend his service with due expertise for protecting and preserving life.

When tasked upon to decide whether legal formalities were to be followed prior to providing medical care to accident victims, the Court held that there was no legal impediment on a medical practitioner when called upon to provide immediate medical assistance. Top priority must be to save the patient not only with respect to medical practitioners, but also police or other persons connected with the accident or happen to see the accident or situation of the patient. Therefore, no law or state action could intervene or delay the commission of paramount obligation cast upon the medical practitioners and any such law which hampers emergency medical care should therefore, be set aside.[61]

In *Paschim Banga Khet Mazdoor Samity v. State of West Bengal*[62] a patient was denied emergency medical care at various government hospitals and was thereby taken to a private hospital which charged an exorbitant amount for the medical treatment. It was held that failure of a government hospital to provide a patient with timely medical care results in the violation of right to life of patients.[63] SC also held that though financial resources are needed for ensuring emergency care, nevertheless, the constitutional obligation of the states to provide adequate medical services to the people cannot be neglected and therefore, everything necessary to ensure emergency medical care must be done whatsoever.[64]

Though a physician is free to exert his choice upon whom he wish to provide medical service, a physician should be ready to treat the sick or injured anytime and during emergency he should not turn down the patient arbitrarily.[65] The physician should take action to emergency medical request without hesitation and once having entertained a case, he should not neglect the patient or withdraw from treating such patient without prior intimation to the patient or family members.[66]

---

[61] *Ibid* at para 8
[62] *Paschim Banga Khet Mazdoor Samity v. State of West Bengal*, AIR 1996 SC 2426
[63] *Ibid* at para 9
[64] *Ibid* at para 16
[65] Regulation 2.1 Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002
[66] Regulation 2.4 Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002

Right to informed consent

Informed consent is one of the critical issues in the medical fraternity in the recent times.[67] It is a well established concept that patients must consent to any form of treatment or therapy being conducted on them. It can be defined as "*the grant of permission by a patient for an act to be carried out by a doctor, such as a diagnostic, surgical, or therapeutic procedure*."[68] The absolute applicability of the concept of informed consent raises several ethical issues.[69]

Modern informed consent takes its root from the basic principle enunciated in the Nuremberg Code of 1947, regarding the respect and value of autonomy of a person.[70] The Declaration of Helsinki adopted by the World Medical Association in 1964 emphasizes the importance of obtaining voluntary informed consent of human subjects involved in research. The primary objective of informed consent is to uphold a person's autonomy and right to choose through a rationale decision making.[71] Upholding patient's autonomy means conceding their right to have opinions, make decisions or choices, and perform acts based on their values and beliefs.[72] The main elements of informed consent is that it should be voluntary, informed and the person making should have the capacity to do so.

Right to autonomy which is enshrined under Art 21 of the Constitution of India forms the cornerstone of informed consent as well as other vital aspects of patient rights in India. Every patient shall have the right to an informed consent prior to specific tests or treatment.[73] It shall be obtained from the patient or near relative or legal guardian whenever mandated by law or guidelines in the understandable language of the patient (e.g. before invasive procedure, blood transfusion, HIV testing, etc.) and the same shall have the contents as mentioned in Annexure 9[74]

---

[67] Omprakash Nandimath, *Consent and medical treatment: The legal paradigm in India*, 25 IND. J. UROL. 343 (2009).
[68] *Samira Kohli v. Dr. Prabha Manchanda*, AIR 2008 SC 138 at para 14
[69] Applicability during emergency and critical medical care
[70] Cecilia Nardini, *The ethics of clinical trials,* (accessed on June 04,2021,12.47 PM), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3894239/
[71] Furkhan Ali et al., *Consent in current psychiatric practice and research: An Indian perspective*, 6 IND. J PSYCH. 667 (2019).
[72] TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS 57 (2001)
[73] Annexure 8 of Clinical Establishment Act Standards for Hospital level 1
[74] 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

of Clinical Establishment Act Standards for Hospital level 1.[75] Potential risks or complications of the treatment or diagnosis must be explained.

Before conducting an operation, a written consent from patient himself or from the husband or wife, parent or guardian (in case of minor) should be obtained and in cases of operation resulting in sterility, consent of both husband and wife is required.[76] Process of in vitro fertilization or artificial insemination shall be done only with the informed consent of the female patient, her spouse and the donor, provided that they have been informed at their level of comprehension about the potential methods, risks, hazards or threats involved.[77] Also, consent as mandated by the Indian Council of Medical Research (ICMR) guidelines during clinical drug trials or other research involving patients or others should be obtained accordingly.[78] The process of obtaining informed consent is expected to be carried out with utmost diligence and transparency and any failure or deviation from the part of the physician in obtaining such consent mentioned in any of the above, may result him being answerable for misconduct. The hospital authorities are at duty to propagate a policy whereby, it is ensured that its doctors are adequately instructed to obtain informed consent in proper manner as an obligation.[79]

During potentially hazardous tests or treatment, the primary treating doctor has an obligation to explain clearly the main risks or threats involved in the procedure to the patient or his accompaniments and only after obtaining written consent shall the concerned doctor proceed with the procedure as prescribed by the Drugs and Cosmetics Act and Rules[80] which will be discussed in detail in the forthcoming sections.

In *Samira Kohli v. Dr. Prabha Manchanda*[81] the SC held that, consent given by patient for diagnostic procedure would not entitle the medical practitioner to conduct surgery. Here the patient (unmarried and 44 years old) consented to undergo diagnostic and operative laproscopy, and “laparotomy if needed”. During this procedure medical practitioner while the patient was under anesthesia, obtained consent from the mother of the patient to undergo hysterectomy and

---

[75] Section 10.23 Clinical Establishment Act Standards for Hospital level 1
[76] Regulation 7.16 Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002
[77] Regulation 7.21 Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002
[78] Regulation 7.22 Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002
[79] Draft Charter of Patients’ Rights, 2018
[80] *Ibid*
[81] *Samira Kohli v. Dr. Prabha Manchanda*, AIR 2008 SC 138

thereby, removed completely the uterus, ovaries and fallopian tubes of the patient. Though she was under anesthesia, there was no emergency or critical condition for the medical practitioner to conduct surgery by obtaining consent from her mother. The practitioner could have waited for her to regain consciousness and obtain proper informed consent and therefore, there is no question of consent on her behalf since she is not a minor or mentally challenged or incapacitated and absence of emergency. Hence the Court established that however broad may be the consent for diagnostic procedure, it would not suffice for conducting therapeutic surgery.

Patients (also a consumer), has the right to get informed of certain basic information regarding the service such as its quality, quantity, potency, purity, standard and price so as to make a choice or decision about the product or service in order to abstain themselves from falling prey to unfair trade practices.

Informed consent though widely accepted as a norm in almost every healthcare intervention, there are certain exceptions to the applicability of informed consent in certain cases. The patient being minor or incapacitated or not being in a position to give consent due to the ailment or otherwise are certain basic exceptions. Emergency medical care can be considered another exception to informed consent. Therefore it can be bypassed and the doctors shall render their duty to preserve and protect life without waiting for consent in critical conditions.[82]

In *Ozair Husain v. Union of India*[83]it was held that information regarding life saving drugs need not be disclosed to the patient since it is meant to fight the disease and save life. The ailment would be fatal if the life saving drug is not being administered to the patient and need not be informed to keep in tune with his interest as it is instrumental to preserve life under Article 21.

Right to privacy, confidentiality and human dignity

Privacy and confidentiality are implications of patient's right to autonomy. Like informed consent, privacy and confidentiality forms its basis from patient's autonomy. Privacy and confidentiality contributes to a sense of reverence and dignity.[84] Hence, it is pertinent for the

[82] *Pravat Kumar Mukherjee v. Ruby General Hospital*, II (2005) CPJ 35 (NC)
[83] *Ozair Husain v. Union of India*, AIR 2003 Delhi 103
[84] 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).

creation and sustenance of a professional and fruitful clinical relationship.[85] Privacy refers to the control and right to restrict the extent of intervention to their physical, behavioral or intellectual life by others. Informational privacy and physical privacy are among the most important kinds of privacy in relation to patients. The SC in *K.S. Puttaswamy v. Union of India*[86] held that the Constitution recognizes right to privacy as an intrinsic part of Right to life and personal liberty.

The relationship between a doctor and a patient is of fiduciary in nature which is based on trust and confidence. Though the relationship is basically commercial, it is professionally a matter of confidence and the doctor is ethically and morally bound to maintain confidence.[87] For accurate diagnosis and treatment, patients would be required to disclose personal information to the physician. Thus, providing such intimate information to the physician, casts an obligation of confidence on the physician to never let go of the information to others. Revealing of confident information by the doctors is not considered ethically acceptable in almost every society. Confidentiality guarantees patient's privacy.[88] It is the guarantee that the privacy, be it informational or otherwise, of a patient will not be disclosed to another person.

Every patient has the right to confidentiality, human dignity and privacy during any treatment.[89] Doctors are duty bound to hold the information regarding the health condition, treatment plan, defects in the disposition, character of patients etc. in strict confidence unless the doctor is required to communicate it under extraordinary circumstances such as public health concerns or protection of health of people in the society or required by law or order of Court or an information regarding communicable diseases.[90] Other than the cases above mentioned, the doctor shall not publish anywhere, photographs or case reports of patients without their consent unless their name or identity is not disclosed.[91]

Female patients have been provided with a right to the presence of another female person during a physical examination by a male practitioner and the same has to be ensured by the hospital.

---

[85] 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).
[86] *K.S. Puttaswamy v. Union of India*, (2017) 10 SCC 1
[87] *Mr. X v. Hospital Z*, AIR 1999 SC 495 at para 26
[88] Simone Vigod et al., *Privacy of patients' information in hospital lifts: observational study,* 327 B.M.J. 1024 (2003).
[89] Annexure 8 of Clinical Establishment Act Standards for Hospital level 1
[90] Regulation 2.2,7.14 Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002
[91] Regulation 7.17 Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002

Special and cultural preferences of the patients are to be respected by the medical facilitators. Moreover, the hospital authorities must ensure that their staffs uphold patient' dignity in all circumstances. Also, the information obtained from the patients has to be strictly protected without any leakage.[92]

Right to privacy and confidentiality is not an absolute right and its breach may at times be morally and legally acceptable as discussed above. An exception to the duty of confidentiality is public interest, mainly when there is an immediate or future health risk to others.[93] The SC while demarcating the lines between privacy and 'greater good' in *Sharda v. Dharmpal,*[94] leaned towards the latter. Here, a husband filed for divorce citing mental illness of the wife. Thereby, the wife was compelled to undergo medical tests. She claimed right to privacy and the Court held that it is not an absolute right and deficiency of such data would be detrimental to the fate of the case. RTI Act under Section 8(1)(j) excludes disclosure of personal information which has no relation to public interest and which could cause unwanted invasion into privacy. However this exclusion is not applicable when larger public interest is at stake.[95]

Right to second opinion and right to choose alternative treatment options if available

Patient's right to autonomy and self determination forms the basis of his right to second opinion and right to choose alternative treatment options, if available. Several diseases are intrinsically complex, with no apparent solutions in terms of accurate diagnosis or optimum course of treatment and in some situations, the physician primarily responsible, may lack sufficient expertise.[96] How much ever precaution may be taken by doctors or hospital authorities, unforeseeable circumstances of diagnostic errors, erroneous treatment or overdose of medication is a possibility which cannot be completely ignored.[97] However, most patients in the fear of offending the treating doctor and a potential vengeance, would abstain from invoking the

---

[92] Draft Charter of Patients' Rights, 2018
[93] *Mr. X v. Hospital Z*, AIR 1999 SC 495 at p.499-500
[94] *Sharda v. Dharmpal*, AIR 2003 SC 3450
[95] *Shri. G.R. Rawal v. Director General of Income Tax (Investigation),* CIC/AT/A/2007/00490
[96] Inder Maurya, *Medical 2nd Opinion – Trends & Challenges,* (accessed on June 06, 2021, 1.15PM), http://bwhealthcareworld.businessworld.in/article/Medical-2nd-Opinion-Trends-Challenges/29-11-2019-179592/
[97] Nomal Chandra Borah, *Doctors' dilemma and patients' right to second medical opinion,* (accessed on June 05, 2021, 8.45PM), https://health.economictimes.indiatimes.com/health-files/doctors-dilemma-and-patients-right-to-second-medical-opinion/676

opportunity of second opinion or hesitant to reveal the opinion garnered from the secondary doctor to the treating doctor. Nonetheless, it is the interest of the patient that has been put at jeopardy in any of the above circumstances.[98] Hence, medical practitioners must be in a position to entertain the option of second opinion considering the best interest of the patients as well as the doctors. Scientific balance requires the appropriate thoughtfulness of a second opinion from the side of practitioners who care for their patients and recognise their humanity.[99]

Every patient has a right to seek second opinion from an appropriate clinician of patient's or caregiver's choice.[100] Accordingly, the hospital authorities or doctors are put at duty to respect this right and provide the patients with their records and information required for seeking such second opinion without any delay or cost. Also, the exercise of this right should not cause any prejudice in the minds of the treating doctor and should not cause any adverse influence in the care provided by the primary doctor or hospital to that patient while under treatment. Any such practice would amount to discrimination and human rights violation.[101] If a patient finds that there is no respite in the treatment of a doctor and wants to consult another doctor, it would be baseless for any further consultations if the first doctor has not written a proper prescription or note of his clinical observations and diagnosis.[102] They also have the right to choose any alternative treatment or management options if available. It is the responsibility of the hospital authorities to inform the patient on these options and to respect the patient's and caregiver's informed choices in a properly recorded manner.

A patient's right to choose alternate treatment options includes his right to refuse a specific care or treatment with the responsibility of such refusal solely on his shoulders except in emergency cases or upon necessity wherein the doctors need not wait for the consent. Every adult with a consent capacity has the right to self determination and autonomy. This allows for the patient's right to refuse specific or all treatment or choose alternate treatment, even if it puts them in a

---

[98] Regulation 7.17 Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002

[99] Daniel Wechter & Donna Harrison, *A Second Opinion: Response to 100 Professors*, 29 Issues L. & MED. 147 (2014).

[100] Annexure 8 of Clinical Establishment Act Standards for Hospital level 1

[101] Draft Charter of Patients' Rights, 2018

[102] *Dr. Arvind Shah v. Kamlaben Ramsingh Kushwaha*, III (2009) CPJ 121 (NC) at para 49

danger of death. Right to life and personal liberty is meaningless unless individual dignity is envisioned under its domain.[103]

Consumers have a right to choose and whenever practical, a right to be assured of access to a wide gamut of goods and services at a reasonable price. This also ensures the right to be assured of appropriate quality and service at a reasonable price in the case of monopolies.

Right to choose source for obtaining medicines or tests

As a part of the right of consumer to choose and access to a variety of authoritative goods and services, patients thereby have the right to choose the source or centre, for obtaining the medicine or test or diagnosis prescribed. Patients can approach any registered pharmacy for procuring the prescribed medicine or drug according to their freedom and choice. Similar is the case when a test or diagnosis or investigation to a particular condition is prescribed, they have the right to get the prescribed test done according to their choice from any registered laboratory or diagnostic centre having qualified personals and accredited by the National Accreditation Board for Testing and Calibration Laboratories (NABL).[104]

All doctors or hospital authorities must advice the patient or accompaniments that they are free to obtain the prescribed medicine or tests from any pharmacy or diagnostic centre of their preference and should not exert their influence or control on this option. The free choice made by the patient or accompaniments in this regard must be respected by the doctors and hospital authorities and should not cause any adverse or mistreatments towards them for exercising this right.

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

CE laws in India mandate every CE to display the rates charged for each service and facilities available at a conspicuous place in the local and English language for patient's benefit and the rates charged for the service and facilities by every CE shall be within the range determined and

[103] *Common Cause (A Regd. Society) v. Union of India*, (2018) 5 SCC 1 at para 195
[104] Draft Charter of Patients' Rights, 2018

issued by the central government in consultation with state governments.[105] The compliance to these rules is mandatory for the registration and continued working of CEs. Efforts must be made by the hospital authorities to enlighten the patient and accompaniments about the rates charged through brochures, tables displayed at striking points or booklet forms. Also, the patient has the right to obtain a detailed itemized bill. Physicians should give precedence to the interest of the patients and should not clash with their financial interest while rendering medical attention. The rates charged by a physician should be intimated prior to rendering such treatment and not after such procedure or treatment has begun. The remuneration received shall be in the form and numbers specifically agreed prior to the treatment. It is considered unethical for the doctors to engage in '*no cure no payment*' contracts. The government doctors should refrain from accepting any consideration from the patients.[106]

In developing countries, around 40% of the healthcare budget is comprised of drugs and other pharmaceuticals.[107] However a major chunk of population often lacks access to the most basic medicines. Various factors including poverty may influence this crisis. According to World Health Organization (WHO), essential drugs or medicines are "*those drugs that satisfy the healthcare needs of majority of the population*".[108] Hence, these drugs or medicines should be made available always in adequate amounts and doses, at an affordable price to the community. After the formulation of the concept of essential medicine, WHO adopted the first model list of essential drugs in 1977 and has been updated ever since its inception. The concept of essential medicines was adopted by member nations and thereby, formed their own list of essential medicines. India formulated its National List of Essential Medicines (NLEM) in 1996. In India, the final pricing of the drugs enumerated in NLEM will be done by the National Pharmaceutical Pricing Authority (NPPA) after incorporating the suggestion and concerns of committees formed for such purposes. The Indian Pharmacopoeia Commission which sets the standards of drugs in India, regularly updates the standards of drugs, which are commonly required for treatment of

[105] Rules 9(i) and 9(ii) of Clinical establishments (Central Government) Rules 2012
[106] Regulation 1.8 Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002
[107] Maiti, Rituparna et al., *Essential Medicines: An Indian Perspective*. 40 INDIAN J. COMMUNITY MED. 223 (2015).
[108] The selection and use of essential medicines, Report of the WHO Expert Committee, 2002

diseases. It also publishes official documents in the form of Indian Pharmacopoeia (IP) for improving the medicine's quality by adding new and updating existing monographs.[109]

'Drugs' have been considered an essential commodity under the Essential Commodities Act, 1955 and it adopts the same meaning as under the Drugs and Cosmetics Act, 1940. Therefore the central government has the power to control production, supply, distribution, etc., of essential commodities.[110] In accordance with the above power, the central government issued the Drugs (Prices Control) Order, 2013 thereby empowering NPPA with price regulation of essential drugs.

As per India Pharmacopeia, every patient has the right to get essential medicines, devices and implants according to the rates prescribed by NPPA and other authorities and receive healthcare services as per the rate fixed by the central and state governments. However, choice of the patients must be given due respect in accessing medicines, devices or standard treatment guideline considering their affordability issues or choices or autonomy. The hospital authorities must ensure that essential medicines under NLEM are being provided to the patients at a price not above the prescribed rate or MRP.[111] The purpose behind fixing the retail price and ceiling price is to make them affordable and ultimately, 'benefit the consumer' of medicines, which should be the real concern.[112]

Right to non - discrimination

People belonging to socially disadvantaged or vulnerable or marginalized groups face innumerable challenges with respect to their health and discrimination based on their group status such as sex, birthplace, race/ethnicity, or religion, is itself a primary health concern.[113] Individuals' trust and contentment with the healthcare system may be debilitated due to the instances of discrimination during medical service thereby raising the possibilities of halting or delaying or abandoning the care or treatment which may cause detrimental effects on the health of the person.

---

[109] US Pharmacopeia, https://www.usp.org/news/indian-pharmacopoeia-commission-and-us-pharmacopeial-convention-partner-strengthen-quality-medicines-and-public-health (accessed on May 30, 2021, 10.36 PM)
[110] Section 3 Essential Commodities Act, 1955
[111] Draft Charter of Patients' Rights, 2018
[112] *Union of India v. M/S. Cipla Ltd*., AIR 2016 SC 5025 at para 28, 111
[113] Joshua G. Rivenbark & Mathieu Ichou, *Discrimination in healthcare as a barrier to care: experiences of socially disadvantaged populations in France from a nationally representative survey,* (accessed on June 08, 2021, 11.45PM), https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-019-8124-z

In India, Articles 14, 15 and 16 of the Constitution forms part of a set of constitutionally guaranteed Fundamental Rights underlining the principle of equality in treatment and these rights supplement each other.[114] The Constitution guarantees equal status and opportunity for socially, economically and educationally backward.[115] Art 14 ensures equality. Art 15 prohibits discrimination on the basis of religion, race, caste, sex or birthplace. Art 16 is another facet guaranteeing equality in public employment.[116] While Art 14 is a general right, Art 15 and 16 are examples of the same right allowed in specific situations.[117] Hence discrimination based on the above facets is prohibited under the Constitution in all sectors and healthcare is no exception.

As a result it is a Constitutional guarantee that every patient shall have the right to treatment without any discrimination regardless of the illness, any health condition, HIV status, religion, caste, ethnicity, gender, age, sexual orientation or linguistic/geographic/social origin.[118] It is the corresponding duty of the hospital authorities to ensure that no patient is being subjected to any form of discriminatory action or treatment and the same must be strictly instructed and oriented to the doctors as well as staffs regularly.[119]

Right to safety and quality care according to standards

Duties of hospitals against patients are multifold. Patient safety and security extends beyond medical error and may at times be caused due to administrative error.[120] The Pennsylvania Supreme Court in *Thompson v. Nason Hospital*[121] ruled that the duty of hospitals have been classified into four general areas: duty to use reasonable care in the maintenance of safe and adequate facilities and equipment; duty to select and retain only competent physicians; duty to oversee all persons who practice medicine within its walls as to patient care; and duty to formulate, adopt and enforce adequate rules and policies to ensure quality care for the patients.[122]

[114] *State of Kerala v. N. M. Thomas*, AIR 1976 SC 490 at para 21, 54
[115] *Ibid* at para 44
[116] *Ibid* at para 54
[117] *Gazula Dasaratha Rama Rao v. State of Andhra Pradesh*, AIR 1961 SC 564
[118] Draft Charter of Patients' Rights, 2018: Annexure 8 of Clinical Establishment Act Standards for Hospital level 1
[119] Draft Charter of Patients' Rights, 2018
[120] Mukesh Yadav & Pooja Rastogi, *Patient Safety due to Administrative Negligence: Neglected Area in India?,* 1 ANN. OF INT. MED. & DEN. RES. 72 (2015)
[121] *Thompson v. Nason Hospital,* 527 Pa. 330 (1991)
[122] *Ibid* at para 15

In *Ashish Kumar Mazumdar v. Aishi Ram Batra Charitable Hospital Trust*[123], the SC reaffirmed the observation of the lower court that hospital's duty is not limited to diagnosis and treatment of the patient but also extends to looking after their safety and security, particularly of those who are sick or under medication. The lower court also held that the hospital authorities should be held liable for not maintaining necessary vigil in the premises of the hospital to ensure the safety of its patients and it is due to the absence of such vigil that the patient, despite his poor health, was able to roam around and thereby sustained injuries.[124] In a similar case wherein a patient was allowed to roam around in the hospital admitted for de-addiction due to acute usage of drugs and alcohol, the patient was found to have committed suicide in the hospital. The National Commission held that the hospital authorities should have taken due care and safety of patients while in the hospital and therefore, liable for negligence.[125]

Therefore, patients have the right to safety and security in the hospital and its premises. They have the right to be cared for in an environment with proper cleanliness, adequate infection controlling measures, safe drinking water that meets BIS/FSSAI standards and sanitation facilities.[126] As a consumer, every patient has the right to safety and be protected from the marketing of goods and services that endangers life or property. The products or service should meet their long-term goals.

The CE laws have set standards for the working of every CE and adherence and compliance to the said laws have been mandated. The central government has issued Standard Treatment Guidelines for almost every important department in the CE with a view to ensure patient safety and quality care.[127] Patients have the right to minimum quality care set by the said standards, norms and also under the accreditation standards of NABH[128].

---

[123] *Ashish Kumar Mazumdar v. Aishi Ram Batra Charitable Hospital Trust*, (2014) 9 SCC 256
[124] *Ibid* at para 6
[125] *Medical Superintendent, St. Gregorious Mission Hospital v. Jessy*, III (2009) CPJ 61 (NC)
[126] Draft Charter of Patients' Rights, 2018
[127] Clinical Establishments (Registration and Regulation) Act, 2010, MoHFW, http://clinicalestablishments.gov.in/En/1068-standard-treatment-guidelines.aspx (accessed on May 20, 2021, 8.15 AM)
[128] Chapter 6 (Patient Safety and Quality Improvement) and Chapter 8 (Facility Management and Safety) of NABH Accreditation Standards For Hospitals 2020 provides specifically for the hospitals to ensure safety and quality care for its patients and their accompaniments

When a person declares that he is ready to provide medical advice or treatment, he impliedly undertakes that he possesses the skill and knowledge for the purpose.[129] When a patient consults with the medical facilitator, he owes the patient certain duties, including a duty of care in deciding whether to undertake the case, a duty of care in deciding the treatment to be given or a duty of care in administering the treatment. A breach of any of those duties gives the patient a right to seek redressal against medical negligence or deficiency in service. A reasonable degree of skill and knowledge must be imparted into his task by the medical practitioner and also he must exercise a reasonable degree of care to ensure the patients with their right to a quality care in harmony with the principles and theories of medical ethics. Hence, the medical facilitators must abide by the duty to offer quality health care in compliance with the existing standards of care and standard treatment guidelines and stay away from medical negligence or deficiency in service.[130] Neither the maximum nor the lowest degree of care and competence is what the law requires according to the facts and circumstances of each case.[131]

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

Access to better health care is a vital right of the patients. So a patient approaching a healthcare which is lacking specific expertise essential for that patient need to be transferred or referred to a healthcare facility with the said proficiency. A patient cannot be neglected whatsoever. IMC regulation speaks about the obligation of the doctors while doing so. The doctor referring the patient as well as the doctor to whom the patient has been referred has certain duties and liabilities under the Regulation. While doing so, the continuity of care should not be denied to the patient whatever the circumstances are.

Every patient while attending any health facility has a right to get registered and get the necessary emergency care without any neglect. Generally, when the facilities or expertise are not top notch, be a patient required to get transferred or referred to access better quality healthcare. While doing so, the patient must be clearly explained for the rationale behind such a transfer. The patients or accompaniments have the right to be completely informed about the continuing

---

[129] *Dr. Laxman Balkrishna Joshi v. Dr. Trimbak Bapu Godbole*, AIR 1969 SC 128 para 11
[130] Draft Charter of Patients' Rights, 2018
[131] *Dr. Laxman Balkrishna Joshi v. Dr. Trimbak Bapu Godbole,* AIR 1969 SC 128 para 11

healthcare requirements following discharge. It has to be ensured by the transferring authority that the transfer has been confirmed from the receiving end as well. The hospital authorities must ensure the safety of patients undergoing shift in care. Such shift or transfer or referral must be done taking into consideration the best interest of the patient and free from any influence ensuing kickbacks, commissions, incentives, or other perverse business practices to anyone.[132]

WHO has prescribes certain guidelines for the management of health systems and a proper referral system.[133] It highlights the importance of an effective referral system which is to ensure a nexus between all levels of healthcare systems and makes sure patients get access to better quality care or treatment near their homes. It prescribes the standard upon which a referral or a transfer of the patient be done. It speaks about the referral notes which are to be strictly handled by the primary and secondary health care facilities while handling the referred patients. Also the communication part while referral has been clearly mentioned. The ultimate goal of the said referral notes is to protect the rights of the patient during a referral.

In order to strengthen health system in rural and urban areas, National Rural Health Mission and National Urban Health Mission were initiated. As a result, to enhance and strengthen rural healthcare system in India, the National Rural Health Mission was launched in 2005 with a vision to propagate an effective health care system to rural population particularly in those states or union territories with weak public health infrastructure. As a result the Indian Public Health Standards (IPHS) has been published in 2007 for every Sub-centres, Primary Health Centres (PHC), Community Health Centres (CHC), Sub-District and District Hospitals for promoting healthcare infrastructure planning and up-gradation.[134] It is a set of standards or guidelines envisioned to advance the quality of health care and its delivery in India and have been revised from time to time. States and Union Territories are expected to keep adherence and compliance to the IPHS documents to strengthen and develop the Public Health Care Institutions and come with their best endeavors to ensure that health care is of high quality across the country. Similar

[132] Draft Charter of Patients' Rights, 2018
[133] WHO Referral Notes, https://www.who.int/management/Referralnotes.doc (accessed on June 03, 2021, 8.33 PM)
[134] National Health Mission – Rural, http://www.nhm.gov.in/index1.php?lang=1&level=2&sublinkid=971&lid=154 (accessed on June 01, 2021, 6.25 PM)

guidelines under the National Urban Health Mission have been formulated in the urban sector health centers as well.[135]

In general, PHCs serves as a referral unit for six Sub-centres whereas CHC serves as a referral centre for four PHCs. However, any existing health facility (District Hospital, Sub-divisional Hospital, CHC etc.) can be declared as a fully functional First Referral Unit (FRU) provided it is equipped and prepared to render 24 hours emergency services for obstetric and new born care as well as other emergencies. Various IPHS documents provide for the way in which referrals and transfer of patients are to be contemplated. It specifically provides for the exact methods or conditions to be fulfilled in particular diseases or circumstances as well, such as emergency medical care, maternal care, sexually transmitted infections etc. in various health facilities. For e.g. during emergency medical care, first aid is to be provided, stitching of wounds, stabilize the condition of the patient before any referrals. Hence compliance to the mandates prescribed during referrals of particular cases or diseases are essential by the concerned health facility.

Right to protection for patients involved in clinical trials

The Central Government by virtue of the power conferred to it under the Drugs and Cosmetics Act, issued the New Drugs and Clinical Trials Rules, 2019. As a result, it provides for the mandates to be followed while engaging in a clinical trial. A clinical trial with respect to a new drug or investigational new drug is defined as any systematic study of such a drug in human subjects to generate data for discovering or verifying its clinical, pharmacological, (including *pharmacodynamics* and *pharmacokinetics*) or adverse effects, with the objective of determining the safety, efficacy or tolerance of such drug.[136] The said Rule provides for the proper channel through which a clinical trial be commenced and its other requirements. A clinical trial can only be commenced with the approval of an ethics committee formed for such purpose and the Central Licencing Authority. Prior to the initiation of the trial, it needs to be registered with the Clinical Trial Registry of India maintained by ICMR. The Rules prescribes provisions explaining in detail upon how informed consent is to be obtained from human beings or patients volunteering for the trial.

---

[135] National Health Mission – Urban, http://www.nhm.gov.in/index1.php?lang=1&level=1&sublinkid=970&lid=137 (accessed on June 01, 2021, 6.36 PM)

[136] Rule 2(1)(j) New Drugs and Clinical Trials Rules, 2019

Also every clinical trial must be done with due recognition and compliance with the Good Clinical Practice (GCP) Guidelines issued by the Central Drugs Standard Control Organisation and other applicable guidelines/rules/statutes. GCP guidelines mandate that every clinical experiment involving human beings must be in compliance with the Helsinki Declaration and the main principles such as *justice, respect, beneficence* and *non-maleficence*.

Another instrument which is of relevance is the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017 issued by ICMR. Though it does not have a binding character, it can act as a guiding document while involving in trials on human beings. In furtherance to the 4 principles of medical ethics aforesaid, the ICMR guidelines have issued 12 other principles required to be followed during trial some of them directly affecting the participants are essentiality, voluntariness, non-exploitation, privacy and confidentiality etc. It also mentions the issues such as informed consent, privacy and confidentiality, distributive justice, payment for participation, compensation for harm due the research, ancillary care etc. which must be comprehended while engaging in such a research.

Analysing the above documents provide the rights to which the research participant or patients are entitled to. The involvement of every participant/patient in such a clinical trial must be based on informed consent obtained in accordance with the prevailing statutes or provisions without fail or negligence. The right of patient to agree or refuse consent should be respected and should not adversely affect their routine care. The patient should have all information about the drug administered on him. Strict adherence to the right of privacy and confidentiality of the patients must be ensured. In case of any adverse events during their participation, they are entitled to free medical management as long as required or till it has been established that the injury caused is not due to the trial. Financial as well as other assistance must be provided to compensate in case of any disability or death. Ancillary care may be provided whenever required. Proper institutional mechanism should be set up for insurance coverage to diseases, injuries or death directly related to trial or otherwise (ancillary care) and award of compensation whenever required to be paid by the researchers according to the concerned Ethics Committee. After the

completion of the trial, the participants should be ensured access to the best treatment proven to be successful by the study.[137]

Right to protection of participants involved in biomedical and health research

The National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017 issued by ICMR is the guiding document relating to biomedical and health research in India. However, the documents discussed above are applicable here as well when engaging in research involving human beings. Therefore GCP guidelines and Helsinki Declaration are equally applicable. The New Drugs and Clinical Trials Rules, 2019 provides for the initiation of a biomedical and health research in India. it has been defined as a research including studies on basic, applied and operational research or clinical research, designed primarily to increase scientific knowledge about diseases and conditions (physical or socio-behavioral), their detection and cause; and evolving strategies for health promotion, prevention, or amelioration of disease and rehabilitation but does not include clinical trial.[138] Chapter 4 of the said Rules deals with the establishment of an Ethics Committee to review and oversee the research as according to the ICMR guidelines. The said guidelines forms basis for a biomedical and health research in India but this does not have a legal backing or enforcement as compared to the said Rules in clinical trials since it is only a guideline. However, adherence and compliance to it is necessary to conduct such research.

Almost every right discussed in the above section in clinical trial, is applicable here as well such as documented informed consent, additional safeguards in case of vulnerable groups or populations, right to dignity, privacy and confidentiality, right to financial, medical or other assistance to compensate for any harm, injury or disability and right to access the benefits accruing out of the research. Any person involved or engaged in such a biomedical and health research are duty bound to ensure the strict compliance of the above guidelines.[139]

---

[137] Draft Charter of Patients' Rights, 2018
[138] Rule 2(1)(h) New Drugs and Clinical Trials Rules, 2019
[139] Draft Charter of Patients' Rights, 2018

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

Detention of patients or withholding the body of dead patient is the primary trick deployed by the hospitals to acquire the outstanding bill amounts. There have been various instances of the same happening in India.[140] However, it is to be noted that detention of patients blatantly violates the rights envisaged under various international instruments on human rights and other rights (UDHR, ICCPR, ICESCR, UNCRC etc.), the Constitution of India as well as invites the provisions of Indian Penal Code, 1860. Hence every patient has the right to discharge and the accompaniment has the right to receive body of the deceased patient in case of death and the same cannot be denied due to outstanding bill amount or other procedural grounds.[141]

The Delhi HC in *Devesh Singh Chauhan v. State*[142], while attending a habeas corpus writ filed by the petitioner for the release of his father detained in hospital over unpaid bills, the court held that bills being unpaid cannot be a reason for the hospital to withhold the patient when the next kin wishes to take responsibility for the removal of such patient from the hospital.[143] The court depreciated such practice and thereby directed the hospital to issue the discharge summary and release the patient.[144]

The Bombay HC has held that detention of patients over unpaid bills will amount to the offence of wrongful confinement.[145] Wrongful confinement and wrongful restraint are punishable under Indian Penal Code 1860 (IPC). It is an offence of wrongful restraint when a person voluntarily causes obstruction to any other person by preventing that person from proceeding in any direction in which he has a right to proceed and the same is punishable with simple imprisonment up to one month, or with a fine up to Rs. 500/- or both.[146] Wrongful confinement

---

[140] Hospital 'detains' newborn as parents fail to pay bill, https://www.thehindu.com/news/national/other-states/hospital-detains-newborn-as-parents-fail-to-pay-bill/article7653045.ece accessed on June 06, 2021, 12.40 PM) : Kenyan Journalist Detained In India Over Hospital Bills, https://www.ghettoradio.co.ke/kenyanjournalist-detained-in-india-over-hospital-bills/ (accessed on June 06, 2021, 01.20 PM) : Can hospitals detain patients for unpaid bills?, https://timesofindia.indiatimes.com/india/can-hospitals-detain-patients-for-unpaid-bills/articleshow/76402589.cms accessed on June 05, 2021, 11.57 PM)

[141] Draft Charter of Patients' Rights, 2018

[142] *Devesh Singh Chauhan v. State*, 2017 SCC OnLine Del 8130

[143] *Ibid* at para 8

[144] *Ibid* at para 9

[145] *Sanjay S Prajapati v. State of Maharashtra*, 2016 SCC OnLine Bom 4751

[146] Section 339, 341 IPC

is when a person wrongfully restrains any other person in such a way to prevent that person from proceeding beyond certain circumscribing limits and it is punishable with imprisonment of either description up to one year, or with fine up to Rs. 1000/- or both.[147] Wrongful confinement for three or more days is punishable with imprisonment of either description for a term which may extend to two years, or with fine, or with both,[148] whereas wrongful confinement for ten or more days is punishable with imprisonment of either description for a term which may extend to three years and shall also be liable to fine.[149]

Right to patient education

For the healthcare industry to upgrade more towards patient-centric, comprehending patient education is integral since the most important goal of the model is to integrate patients as partners in healthcare system.[150] It helps to cut short the patient's average length of stay at hospitals and upholds their expectations of their healthcare facilitators.[151]

As discussed earlier, every patient has the right to be informed and get educated about the relevant facts concerning the condition of the patient and healthy lifestyle. Also, they have the right to get educated about their various rights and liabilities along with relevant available insurance schemes and relevant benefits to which they are eligible in case of charitable hospitals. Moreover, they must be enlightened about the way in which to seek proper redressal of their grievances. These informations must be provided to them in the language easily known to the patients. Hence, the hospital authorities and doctors are duty bound to educate the patients in the above perspectives according to the prescribed standard and procedure as established.[152] Even as a consumer, the patient the right to gain information, knowledge and skill to be an informed consumer when availing services.

---

[147] Section 340, 342 IPC
[148] Section 343 IPC
[149] Section 344 IPC
[150] Sara Heath, *Why Patient Education is Vital for Engagement, Better Outcomes*, (accessed on June 14, 2021, 08.22PM), https://patientengagementhit.com/news/why-patient-education-is-vital-for-engagement-better-outcomes
[151] Upasana Agrawal et al., *Awareness of Patients' Rights among Inpatients of a Tertiary Care Teaching Hospital- A Cross-sectional Study.* 11 J. CLIN. & DIAGN. RES. 1 (2017)
[152] Draft Charter of Patients' Rights, 2018

Right to be heard and seek redressal

Every person has been empowered with the freedom to express his opinion. So does the patients. Patients, also a consumer, have the right to be heard about their opinion regarding the services rendered to them. Therefore, every patient or accompaniment has the right to make their opinions or comments or feedbacks for the service given. They also have the right to lodge complaints regarding the service, to the concerned authority. They also can get informed about the manner in which a complaint, opinion, comments or feedback is to be raised or lodged to the concerned authority.[153] The right of consumer to be heard makes assurance of the protection of interests of the consumers at the concerned forum and the right to be represented at the said forum designated to safeguard their interests.

The Charter provides for the patient with a right to seek redressal in case of any infringement of any of the above rights mentioned. They can lodge a complaint to the official designated through this Charter or otherwise in the hospital or in regulatory authority or Tribunal as established for this purpose and also for appeal if aggrieved by the order. They have the right to a fair and timely resolution of their complaints and to know the outcome of the complaint within fifteen days from the date of receiving the complaint. Every hospital and CEs are duty bound to establish an internal redressal mechanism for this purpose and comply with the orders of the said mechanism as according to the Charter or concerned law established and applicable.[154] As a consumer, they also have the right to seek redressal at the concerned forum for the deficiency in service or unfair trade practices and thereby a fair settlement of the dispute.

---

[153] Draft Charter of Patients' Rights, 2018
[154] *Ibid*

CHAPTER III - ENFORCEMENT OF PATIENT'S RIGHTS IN INDIA

The WHO Constitution stipulates that enjoyment of the highest attainable standard of health without distinction of race, religion, political belief, economic or social condition is one of the fundamental rights of every human being, signaling the start of international law recognising health as a right. Thereby, UDHR under Art 25 envisioned it ensuring requisite standard of living necessary for the health and wellbeing of people. ICESCR also recognises the right to highest attainable standard of mental and physical health. But the wordings in these rights to highest attainable standard as discussed above were too vague and weak. It did not have concrete measures to define what exactly the highest attainable standard was and therefore it did not pave way for the protection of right to health as understood today specifically in the patient care context.

There were multiple attempts to define a positive right to health. The comment 114 of the United Nations' Committee on Economic, Social and Cultural Rights 2000 elevated the human right to health from "being healthy" to an entitlement or claim against the obligation of the state to provide with necessary health insurance and healthcare facilities and also proscribe any form or discrimination while seeking health care or services. This actually paved the way for an apparent interlink between the human rights and patients rights and the need for a separate notion regarding the latter. Patient's rights have been deeply rooted in the inherent human rights. Considering the vulnerability of the patients while seeking medical aid, the need arose for a separate set of rights in patient care taking its basis from the human rights. Some of the basic human rights such as free from cruel, inhumane treatment, privacy and confidentiality have special independent meaning during patient care.

The position in India is that, patients rights in addition to its basis from inherent human rights, it takes its foundation from other aspects also which has been discussed in detail in this chapter. Since India lacks a comprehensively codified legal document envisaging all the patients' rights, a comprehension of how these rights are protection and enforced in the country is pertinent.

Patient's rights and human rights

Human Rights are rights to which every human is entitled merely because of his/her existence as a human. Human rights are universal, fundamental and inalienable rights and are inherent in all human beings irrespective of nationality, sex, national or ethnic origin, color, religion, language, or any other status of people. These rights range from the most fundamental for a human, such as right to life, to those which make the life meaningful such as the right to food, education, work, health and liberty.[155]

Patients are no exception to human rights. They are entitled to every rights conferred by virtue of them being humans. Patients' rights are human rights.[156] Human rights form the basis for almost all patients rights recognized. Medical law is 'a subset of human rights law'.[157] The concept of 'human rights in patient care' refers to the application of general principles of human rights in patient care or medical services.[158] It provides a principled substitute to the growing concerns in the rights of patients' arena and gathered pace due to severe violations of human rights during medical care.[159] Patient's rights that are deeply rooted in the consumer framework, human rights in patient care derive from the concept of human dignity, which is embedded in all beings and thereby applied universally. It includes the right to highest attainable standard of health as well as the civil and political rights (to be free from torture and inhumane treatment, liberty and security etc.).[160]

Health which is the state of complete physical, mental and social well-being and not merely the absence of disease or infirmity, has been identified by the WHO as a fundamental human right of all people.[161] The States, by virtue of identifying health as a human right, are obliged to ensure patients with access to timely and affordable medical services of proper quality as well as health

---

[155] What are human rights?, https://www.ohchr.org/en/issues/pages/whatarehumanrights.aspx (accessed on August 03, 2021, 1.53 PM)
[156] Draft Charter of Patients' Rights, 2018
[157] IAN KENNEDY & ANDREW GRUBB, PRINCIPLES OF MEDICAL LAW 3 (2000)
[158] Maya Peled-Raz, *Human rights in patient care and public health—a common ground,* (accessed on July 03, 2021, 08.52PM), https://publichealthreviews.biomedcentral.com/articles/10.1186/s40985-017-0075-2
[159] Jonathan Cohen & Tamar Ezer, *Human Rights in Patient Care: A Theoretical and Practice Framework*, 15 HEALTH & HUM. RTS. 7 (2013)
[160] *ibid*
[161] Preamble, WHO Constitution 1946

related information and education.[162] This is to be made sure without showing any distinction or discrimination on the people based on their race, religion, political belief, economic or social condition.[163] Right to health apart from its positive guarantee of the availability, accessibility, acceptability and quality of healthcare, the negative realization of the right such as rights against discrimination and torture or inhumane treatment etc. upon healthcare delivery against the state as well as the medical facilitators are also to be understood while taking into account Right to health as a fundamental human right.

The source of the right to health as a fundamental human right can be traced to the International Bills of Human Rights as well as other international instruments. The Universal Declaration of Human Rights, 1948 (UDHR) which is the cornerstone of human rights enshrines the concept of equality and dignity of all human beings.[164] It provides for the right of humans to life, liberty and security.[165] Incidentally, all people are entitled to a basic standard of living, necessary for health and well being of himself and his family, including medical care and to security during sickness.[166] The International Covenant on Economic, Social and Cultural Rights, 1966 (ICESCR) urges the state to recognize the human right to the enjoyment of the highest attainable standard of physical and mental health.[167] For the absolute comprehension of the said right, the parties are to develop strategies to prevent, treat or control diseases and to create a system that assures to everyone medical service and attention during sickness.[168]

The International Convention on the Elimination of All Forms of Racial Discrimination, 1965 (ICERD) ensures the enjoyment of a variety of rights including the right to public health, medical care, social security and social services to everyone without discrimination.[169] The Convention on the Elimination of All Forms of Discrimination against Women, 1979 (CEDAW), requires the state parties to make sure there is equality in access to healthcare services and there is no discrimination against women in healthcare, also to be made sure that appropriate services

---

[162] Human rights and health, https://www.who.int/news-room/fact-sheets/detail/human-rights-and-health (accessed on August 20, 2021, 2.38 PM)
[163] Preamble, WHO Constitution 1946
[164] Article 1, UDHR
[165] Article 3, UDHR
[166] Article 25, UDHR
[167] Article 25, ICESCR
[168] *Ibid*
[169] Article 5, ICERD

pertaining to pregnancy and its allied services are available free of service wherever necessary.[170] The Convention on the Rights of the Child, 1989 (CRC) identifies the children's right to the enjoyment of highest attainable standard of health and the States are mandated to make sure every child has the right to access such health services.[171] Migrant workers and their family members under the International Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families, 1990 (ICRMW) has the right to emergency medical care necessary for preserving lives or avoiding irreparable harm, in parity with the nationals of the state parties and the same cannot be denied to them on the basis of technicalities such as residence or employment.[172] Migrant workers and their family members, provided they meet the requirements of various schemes, shall have the right to the equal treatment with that of the nationals of the state parties while accessing social and health services.[173] The Convention on the Rights of Persons with Disabilities, 2006 (CRPD) mandates the state parties to make sure that there is no discrimination against persons with disabilities for the enjoyment of the right to highest attainable standard of health.[174] Other international instruments specifically applicable in this regard are ICCPR, Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, 1987 (CAT), African Charter on Human and Peoples' Rights, 2005 (ACHPR), European Convention on the Protection of Human Rights and Fundamental Freedoms, 1950 (ECHR), European Social Charter, 1961 (ESC) etc.

Human rights in patient care only cover those human rights in the ambit of healthcare delivery system to the patients and specifically to patient care whereas Right to health as a general fundamental human right also includes the above human rights specifically applicable in patient care by virtue of its correlation with health but also encompasses a wide range of other human rights that even falls outside the purview of health care delivery system often referred to as the "*underlying determinants of health*" including social and economic rights (housing, water, food etc.) as well as civil and political rights (freedom against violation, torture etc.) having an impact on the health of people.[175] It may be concluded that human rights in patient care are a subset of right to health or in other words these contain overlapping rights wherein the former contains a

[170] Article 12, CEDAW
[171] Article 24, CRC
[172] Article 28, ICRMW
[173] Article 43, 45 ICRMW
[174] Article 25, CRPD
[175] *Supra* n. 159 at 10

series of rights including right to health specifically applicable in patient care while the latter contains a set of health related rights covering the context of health in general covering patient care as well as otherwise. Individually enforceable rights of patients would be rendered meaningless if a universal access to healthcare and right to health does not exist.[176]

Some of the rights of patients specifically protected as human rights during patient care are as follows:[177]

Human Rights of Patients	Provisions
Right to liberty and security	• Art 9(1) ICCPR, • Art 6 ACHPR, • Art 5(1) ECHR
Right to privacy and confidentiality	• Art 17(1) ICCPR, • Art 16(1) CRC, • Art 8(1) ECHR
Right to information	• Art 19(2) ICCPR, • Art 9(1) ACHPR
Right to life	• Art 6(1) ICCPR, • Art 4 ACHPR, • Art 2(1) ECHR
Right to bodily integrity	• Art 5(b) ICERD, • Art 4 ACHPR, • Art 19(1) CRC
Right to the highest attainable standard of health	• Art 12 ICESCR, • Art 5 ICERD, • Art 24 CRC, • Art 12(1) CEDAW,

[176] Malwina Anna Wojcik, *The Origins of Patients' Rights in Cross-Border Healthcare: Balancing the Individual and Collective Right to Health*, 7 PENN UNDERGRADUATE L.J. 102, 122 (2019).
[177] *Supra* n. 159 at 12 : TAMAR EZER ET AL., HUMAN RIGHTS IN PATIENT CARE: A PRACTITIONER GUIDE 23-64 (2012)

	• Art 16 ACHPR, • Art 11, 13 ESC
Right to freedom from torture and cruel, inhuman and degrading treatment	• Art 7 ICCPR, • Various provisions of CAT, • Art 5 ACHPR, • Art 3 ECHR
Right to Participate in Public Policy	• Art 25 ICCPR, • Art 7 CEDAW, • Art 12 ICESCR
Right to non-discrimination and equality	• Art 26 ICCPR, • Art 2(2) ICESCR, • Various provisions of ICERD, • Art 2, 3, 19 ACHPR**,** • Art 14 ECHR
Right to remedy	• Art 2(3) ICCPR, • Art 6 ICERD, • Art 2 CEDAW, • Art 26 ACHPR, • Art 13 ECHR

With the advent of International instruments envisioning the protection of human rights, the member states are expected to incorporate these instruments into their own national laws and thereby adopt appropriate mechanisms to protect human rights. As a result of their obligation, many states have thereby adopted mechanisms for the protection of human rights into their municipal laws. In India, the Protection of Human Rights Act, 1993 was enacted due to the emerging need for the protection of human rights at the international as well as national level.[178] International covenants are not applicable directly and justifiable before the courts of law in India. Hence, there should be laws enacted in line with the covenants due to the state's international obligation to make it applicable in the state. Hence, the Protection of Human Rights

[178] Amartish Kaur, *Protection Of Human Rights In India: A Review,* 2 JAMIA L. J. 22, 29 (2017)

Act, 1993 has been enacted which specifically deals with the protection of the Human Rights of people in India. The Act defines human rights as those rights relating to life, liberty, equality and dignity of individuals guaranteed by the Constitution of India or enshrined in the International Covenants and enforceable by the courts in India.[179] It also provides for the establishment of NHRC, State Human Rights Commissions as well as Human Rights Courts for the better protection of human rights of people. NHRC has recommended for adoption by all governments a draft Charter of Patients Rights in 2018 containing a comprehensive set of patients rights which is discussed in the upcoming sections.

Patient's rights under the Constitution of India

The Constitution of India does not overtly mention any rights of patients while seeking medical aid or attention. However, it speaks about certain rights to which people are entitled relating to health or public health. Though Constitution does not expressly provide for rights of patients, many of the rights of patients as discussed previously, take its legal backing from the Constitution. Hence any of the rights of patients having the characteristics of fundamental rights enunciated in Part III of the Constitution can be enforced through the Constitutional Courts of India.

Right to health as a fundamental human right has been discussed in the previous section and also the role of state in ensuring right to health to its people. How right to health is recognized in India under the Constitution of India or otherwise shall be discussed in this section.

Right to health which has been considered as a human right, is not expressly mentioned as a fundamental right in the Constitution of India. However, its presence in the Constitution cannot be fully negated. The right has got its basis covered in the conscience of the Constitution giving it as much significance as a fundamental right. The Constitution recognizes the right to life and personal liberty of people under Article 21. Various Courts have interpreted the term 'life' in the said Article means to lead a life with dignity and not mere survival or animal existence. The Court, over the years have identified various other rights to be an inherent part of this Article such as the right to livelihood[180], right to shelter[181] right to pollution free environment[182] etc.

---

[179] Section 2(d) Protection of Human Rights Act, 1993
[180] *Olga Tellis v. Bombay Municipal Corporation*, AIR 1986 SC 180

How the Courts have interpreted Right to health as a fundamental right and as a part of Art 21 have been widely discussed in the previous chapter. Apart from Art 21 there are various other provisions in the Constitution dealing with the concept of health or public health. Also, there are few provisions in the Constitution that indirectly envisions health, such as Articles 23 and 24 in which the former speaks about the prohibition of human trafficking and forced labour which has a huge impact on the victim's health and the latter about the prohibition of child labour which impacts the health of children.

While identifying right to health as a fundamental right and as an intrinsic part of Right to life, it should be read with Articles 38, 42, 47 etc. to understand the role of state to ensure the proper comprehension of the right in the country. These above mentioned provisions which fall under Part IV which is the Directive Principles of State Policy (DPSP), impose certain corresponding duties to ensure health or public health for that matter.

Under Article 38, state is under an obligation to promote the welfare of the people with justice, social, economic and political social order affecting all institutions.[183] The state shall direct its policies ensuring non abuse of the health and strength of workers, men, women, children and shall also make sure that the citizens are not forced by economic constraints to enter occupations that are not suited to their age or ability.[184] Also, the policies shall include and provide for opportunities and facilities for children to develop and progress in a healthy manner with freedom and dignity as well as be protected against exploitation and abandonment.[185] The states shall also provide assistance during sickness and disablement[186] and also secure just and humane conditions for working class and maternity benefit.[187] Art 47 sets a primary duty of the state to improve public health through increasing standards of nutrition intake and the standard of living of the people.[188] It shall also be the duty of the state to curb or prevent the use or consumption of items such as drugs or drinks other than therapeutic which are injurious to the health of the

---

[181] *Shantisar Builders v. Narayan Khimalal Totame* (1990) 1 SCC 520
[182] *Subhash Kumar v. State of Bihar*, AIR 1991 SC 420
[183] Article 38 Constitution of India
[184] Article 39(e) Constitution of India
[185] Article 39(f) Constitution of India
[186] Article 41 Constitution of India
[187] Article 42 Constitution of India
[188] Article 47 Constitution of India

people.[189] Hence, the state shall mold its policies and directives in such a way that the health of people are not jeopardized and also be made sure that such policies are meant to augment health of the people.

Apart from these provisions, the Panchayats and Municipalities may be empowered to function as self-governing institutions through the provisions of law by the state with appropriate conditions and requisites, to prepare plans for the economic development and social justice in relation to matters stipulated in the eleventh and twelfth schedule respectively of the Constitution.[190] The matters mentioned therein in the schedules respectively which are of pertinence in relation to health are as follows:

- Drinking water (Entry 11),
- Health and sanitation, including hospitals, PHCs and dispensaries (Entry 23),
- Family welfare (Entry 24),
- Women and child development (Entry 25),
- Social welfare, including those of handicapped and mentally retarded (Entry 26),
- Welfare of the weaker sections, SC/ST in particular (Entry 27)[191] and
- Water supply for various purposes (Entry 5),
- Public health, sanitation conservancy and solid waste management (Entry 6)[192].

The SC in *Bandhua Mukti Morcha v. Union of India*[193] considered health and dignity to be an intrinsic part of life under Article 21. Right to live with dignity (Art 21) takes its "*life breath*" from DPSP (Arts. 39(e), 39(f), 41 and 42).[194] These are some of the basic minimum requirements for a person to live with dignity and governments cannot initiate any action which tends to deprive the basic minimum facilities mentioned therein. Though DPSP is not enforceable in a court of law, states cannot evade from their obligation of providing basic facilities.[195]

[189] Article 47 Constitution of India
[190] Article 243G, 243W Constitution of India
[191] Eleventh schedule Constitution of India
[192] Twelfth schedule Constitution of India
[193] *Bandhua Mukti Morcha v. Union of India*, AIR 1984 SC 802
[194] *Ibid* at para 14
[195] *ibid*

As held by SC in *Vincent Panikurlangara v. Union of India,*[196] a healthy body is the very foundation for all human activities.[197] Since health is crucial to the community's physical survival and its improvement affects the development of the society as envisioned by the framers of the constitution, maintenance and enhancement of public health must be of top priority, perhaps on the top of the list.[198]

The SC decision *Paschim Banga Khet Mazdoor Samity v. State of West Bengal*[199] discussed earlier in the arena of emergency medical care is worth mentioning again. Being a welfare state as prescribed by the Constitution of India, ensuring the welfare of its people is the primary duty of the governments and providing vital medical facilities is a crucial requisite in a welfare state. These are to be ensured by the Government through hospitals, health centers or clinics established for providing medical care to the person seeking medical attention. Since Art 21 ensures right to life, preservation of life is of paramount importance and therefore, an obligation is being cast upon the state to ensure the same. Hence every hospital or clinics or health centers for that matter, must be in line with the enforcement of the said right and government hospitals are no exception to the same. Failure on the part of a government hospital to provide appropriate medical attention to those in need of the same will result in the violation of Art 21.[200] The court thereinafter put forward certain guidelines which are to be accounted for ensuring adequate medical facilities during emergency medical care cases, that:

- Adequate facilities be made available at the PHCs wherein patients can be given immediate primary treatment so as to stabilize their critical condition;
- District level and Sub- Division level hospitals be upgraded so that serious emergency case can be treated therein without any delay;
- Facilities for giving specialist treatment be increased and made available at the District and Sub- Division level hospitals having regard to the emerging requirements.
- In order to ensure availability of beds in an emergency situation at state level hospitals, a centralized communication system be established to send a patient immediately to the hospital where bed is available in respect of the treatment as required.

---

196 *Vincent Panikurlangara v. Union of India*, AIR 1987 SC 990
197 *Ibid* at para 16
198 *Ibid*
199 *Paschim Banga Khet Mazdoor Samity v. State of West Bengal*, AIR 1996 SC 2426
200 *Ibid* at para 9

- Proper arrangements of ambulances be made available for the transport of patients from the PHC to the District or Sub- Division hospitals or from the District or Sub Division hospitals to the State hospital.
- The ambulances be adequately provided with all necessary pieces of equipments and medical personnel.
- Medical personnel in the Health Centers and hospitals be geared up to deal with a larger number of patients intake needing emergency medical care on account of the higher risk of accidents during certain seasons or occasions.[201]

In *State of Punjab v. Ram Lubhaya Bagga*[202] it was considered that going by the well known principle; right of a person creates an obligation on another or correlates a corresponding duty on another. Accordingly the citizen's right to live (Art 21) casts an obligation on the state to ensure the same which is reinforced under Art 47 which identifies it as a primary duty of the state. To keep with the utmost consonance with the said duty, the state shall provide all basic facilities and services required through setting up government hospitals with all facilities and increasing its reach to people, reduce queues and waiting lists, proper maintenance and cleanliness, make the greatest use of its resources and efficient staffs through proper orientation and training and thereby improve its management in order to put in a meaningful contribution towards patient care. Since the said right is considered to be the most 'sacrosanct' as well as the State's equally sacred corresponding duty, citizens of this welfare state looks into the state with an expectation to accomplish this obligation with top priority including its fund allocation and thereby achieve its social, political and economic goals.[203]

Patients as consumers

The Consumer Protection Act, 2019 came into being on the 20th day of July, 2020 thereby replacing the previous 1986 law. Though many striking changes were brought in to protect and promote the interest of consumers, not many was brought in pertaining to patients and medical services. However, an ambiguity arises regarding the inclusion of medical services under the purview of consumer laws with the advent of new law. It is to be noted that even the 1986 law

---

[201] *Ibid* at para 15
[202] *State of Punjab v. Ram Lubhaya Bagga*, (1998) 4 SCC 117
[203] *Ibid* at para 26

does not explicitly include medical services as ‘services’. Nevertheless, it was through various judicial precedence the position was settled. However, the new law also follows the same footsteps by not mentioning medical service (though list is non exhaustive).[204] This needs to be clarified by upcoming judicial interventions if required. However, nothing adverse regarding the inclusion of medical service is stated in the new law. Therefore the prevailing stance by the judiciary is still applicable to the new law.

A consumer is any person who buys or avails (or hires) any goods or services for a consideration paid or promised, be it partly or fully or through deferred payment and include any users or beneficiaries of such goods or services other than the person buying or availing or hiring with his/her consent.[205] However persons who buy or avails goods or services for commercial purposes or resale (goods) are excluded from the purview of consumers under the Act. Online transactions are also included under the new law.

The Act recognizes certain consumer rights such as the right to protection against marketing of hazardous goods or services, right to information regarding quality, quantity, potency, purity, standard and price of goods or services, right to access variety of goods or services, right to be heard and seek redressal and the right to consumer awareness.[206] Chapter II of the Act enunciates the establishment of protection councils and its composition at the Center, State and District levels with the objective to provide aid and advice for the promotion and protection of consumer rights. Chapter III provides for the establishment and composition of a Central Consumer Protection Authority (CCPA) with the primary objective to protect and enforce consumer rights and to regulate matters pertaining to its violation, unfair trade practices or misleading advertisements detrimental to the interest of consumers and public.[207] Complaints pertaining to the violation of the rights of the consumers or unfair trade practices or false/misleading advertisements detrimental to the interest of the consumers as a class may be lodged either towards the District Collector or Commissioner of regional office or CCPA under the Act.[208] CCPA has been provided with wide powers with regard to the enforcement of consumer rights

[204] Section 2(42) Consumer Protection Act, 2019
[205] Section 2(7) Consumer Protection Act, 2019
[206] Section 2(9) Consumer Protection Act, 2019
[207] Section 10 Consumer Protection Act, 2019
[208] Section 17 Consumer Protection Act, 2019

such as inquiry through an investigation wing,[209] search and seizures,[210] filing of complaints, intervene in the matters of redressal forums or commissions, advice, review, recommend etc for the effective enforcement of consumer rights in India.[211] Chapter IV prescribes for the establishment and composition of consumer disputes redressal commissions at 3 levels considering the value of goods or service paid as consideration. The District Consumer Disputes Redressal Commission shall entertain matters were value does not exceed Rs. 1 crore whereas the State Consumer Disputes Redressal Commission (SCDRC) deals with matters when value lies between Rs 1 crore to Rs. 10 crore and the National Consumer Disputes Redressal Commission (NCDRC) in case of value exceeding Rs. 10 crore.[212] SCDRC and NCDRC are also being provided with appellate jurisdictions. Persons aggrieved by the order of NCDRC may appeal to the Supreme Court.[213]

Ever since the inception of the COPRA 1986, an ambiguity loomed over the courts as to whether patients can be considered as consumers and would medical service fall under the purview of 'service' under the Act. However, the Supreme Court in 1995 in *Indian Medical Association v. V.P. Shantha*[214] cleared all ambiguities and ruled in the affirmative with certain exceptions. It was held that medical services be it consultation, diagnosis, treatment, both medicinal and surgical, rendered to a patient except where it is not rendered free of charge to all patients or under a contract of personal service would fall under the ambit of 'service'. Services rendered by availing charges from some patients and free to other patients who cannot afford the charge would also fall under COPRA. However, services rendered absolutely free to all patients by hospitals or clinics, be it governmental or otherwise, are excluded. It is to be noted that fees charged for registration would not have any implication on this position. In case the payment made by the insurer or the employer to the hospital for the service rendered would also fall under the same. Though every patient cannot be considered as consumers, a majority of them can be considered as consumers based on the medical service rendered to them by the medical facilitators and accordingly they have the rights to which every consumer is entitled under COPRA. As a result, the eligible patients can move to the concerned commission or authority to

[209] Section 15 Consumer Protection Act, 2019
[210] Section 22 Consumer Protection Act, 2019
[211] Section 18 Consumer Protection Act, 2019
[212] Section 34, 47, 58 Consumer Protection Act, 2019
[213] Section 67 Consumer Protection Act, 2019
[214] *Indian Medical Association v. V.P. Shantha*, AIR 1996 SC 550

enforce their rights relating to consumers and in case of instances such as unfair trade practices, deficiency in service or other related cases. It is to be noted that under a change brought in by new COPRA, unfair trade practice includes the disclosure of any personal information given by the consumer in confidence, to any other person unless in accordance with the provisions of any law for the time being in force.

Rights of patient as a consumer are more important than the rights of a general or ordinary consumer because patients usually have very little choice in the treatment at least in India and also due to the fact that majority of the health care services are managed by private sector and thereby hugely affected by commercialization.[215]

The patients can approach the commission in case of medical negligence and deficiency of service on the part of doctors and the hospital will be vicariously liable for the negligent act of their medical practitioners. For the establishment of medical negligence, it needs to be proved that the standard care was not abided by the practitioner of medicine as discussed in the above chapter and also various other tests have been established for identifying medical negligence.

Remedies such as removal, replacement, return price amount or compensation are provided under COPRA for any unfair trade practices or deficiency of service.[216] Section 100 (previously Section 3) of COPRA states that, the provisions shall be in addition to any law applicable and not in derogation to other laws. Therefore it gives an additional remedy for the consumers and that remedy is not in derogation of any other remedy under any law.[217] Remedies under COPRA do not extinguish the remedies available under any other Statute but provides an additional or alternative remedy.[218] Hence the patients are at liberty to approach the Consumer Commissions as well as other forums or courts seeking remedy against any violations of their rights.

Draft Charter of Patients rights, 2018

The NHRC in April, 2018 submitted to the MoHFW, a 'draft Charter of Patient Rights' encompassing 17 set of rights of patients (discussed in the previous chapter) to be adopted in the country for the public to be made aware of their rights as a patient with coherence. This draft was

---

[215] Veeresh V.G., *Patient Bill of Rights and Responsibilities*, 4 A. J. N. E. R 376 (2014)
[216] Section 39 Consumer Protection Act, 2019
[217] *Trans Mediterranean Airways v. M/S. Universal Exports*, IV (2011) CPJ 13 (SC) at para 24
[218] *Ibid* at para 32

prepared as a result of receiving numerous complaints regarding malpractices by the CEs. This document was drafted with the prospect of it being functioning as a guiding document for the central and state govt. to arrive at solid mechanisms to protect and promote the rights of patients and its lawful enforcement. It is with the expectation that the contents of the Charter will be incorporated throughout the country by the concerned policy makers into existing as well as upcoming regulatory frameworks or legislations relating to healthcare sector for the protection and promotion of the rights of patients. NHRC considers ordinary patients or citizens to be vulnerable when accessing medical care and therefore expects the draft charter to be the enabling document to protect their rights.[219]

The National Council for Clinical Establishments in its eleventh meeting convened on the 13th day of July, 2018 took the matter up for consideration. The draft Charter was discussed in the meeting and the same was adopted with certain suggestions.[220] The council recommended the MoHFW or NHRC to invite suggestions, opinions or recommendations from the public regarding the same and as a result the MoHFW on the 30th day of August, 2018, released the draft Charter. Thereby, the Secretary of MoHFW on the 2nd day of June, 2019, issued a letter to all states/UTs in the country to adopt the draft Charter with the recommendations from the National Council for Clinical Establishments regarding certain dos and don’ts in the form of patients rights and responsibilities so that their grievances and concerns are addressed and thereby a smooth and pleasant atmosphere is made sure in every CE.[221] Notably, most of the recommendations by the National Council for Clinical Establishments and those contained in the said letter, regarding patient rights, were encompassed by the draft Charter. However, several important rights which were identified by NHRC in the draft were omitted by the Secretary in the letter. Nonetheless, it is left for the States/UTs, whether to include the same or omit them.

NHRC, having found that there has been a severe lapse in the effective implementation and enforcement of the rights of patients in India, also recommended in the draft Charter a mechanism for the same. NHRC advocated for a serious adoption and incorporation of the Charter in the prevailing or upcoming regulatory frameworks pertaining to healthcare by every

[219] Draft Charter of Patients’ Rights, 2018

[220] Minutes of 11th Meeting of National Council for Clinical Establishments dated 13.07.2018 http://www.clinicalestablishments.gov.in/WriteReadData/7961.pdf

[221] Letter Issued by MoHFW Government of India to all States/UTs for adoption of Dos and Don’ts of Patient Rights and Responsibilities dated 02.06.2019 http://www.clinicalestablishments.gov.in/WriteReadData/9901.pdf

State/UT government in their respective jurisdictions. Thereby, every administrative and regulatory authority related to healthcare, irrespective of its extent of relatedness, shall adopt, promote and incorporate the said Charter whenever and wherever applicable. The draft identifies but does not limit to around twenty authorities in this regard.[222] Also, every State Human Rights Commissions shall consider the draft as a guiding document in every cases pertaining to human rights violations of patients and other stakeholders. Once the Charter has been adopted by the concerned government or administration, every CE, irrespective of its ownership, funding, or control, shall display this Charter at a conspicuous place in the CE, orient and educate their staffs as regards to the Charter and thereby uphold the Charter in its true essence and spirit without fail.

To effectively implement and enforce the rights of patients, the draft prescribes for the installation of an additional grievance redressal mechanism exclusively set up for upholding the rights of patients as a part of current or upcoming frameworks concerning CE by making necessary changes in the statutes or instruments as required. Primarily, the patient's charter of rights and the grievance redressal mechanism need to be made a vital aspect of the CE laws as applicable across the country. Therefore, the states which have adopted the Clinical Establishment (Registration and Regulation) Act 2010 and those States which has their own separate laws concerning the regulation of CEs shall adopt the Charter in such a way that the patients' rights are protected and their grievances concerning their rights are being properly redressed.

According to NHRC, the grievance redressal mechanism shall have an internal component at each and every CE in the name of '*Internal Grievance Redressal Officer'* (INGRO), who can be approached by the patients or their concerned representatives in case of grievances. The INGRO set up at every CE, upon receiving a complaint, shall without any delay acknowledge the complaint within 24 hours and assign a registration number for its proper tracking. Thereinafter the officer shall try to arrive at a conclusion in accordance with the Charter and the rights of patients.

If the patients feel aggrieved by the order of INGRO, they are at liberty to approach the '*District Registering Authority'* set up under Section 10 of the Clinical Establishment (Registration and

[222] Draft Charter of Patients' Rights, 2018 pg 22

Regulation) Act 2010 in those States which have adopted it or the concerned district level authority in States which have their own legislation regarding the regulation of CE. The authority on receipt of such appeal, after verification of the facts of the appeal may issue necessary executive orders against the concerned CE upon finding any form of violation of the patient's rights. Disputes arising out of the ambiguity in the interpretation of the provisions of the Charter or other regulation concerning patient's rights may be resolved by the authority through mediation within thirty days from the date of receiving such appeal.

Any patient or representatives still aggrieved may move to the '*State Council of Clinical Establishments'* established under Section 8 of the Clinical Establishment (Registration and Regulation) Act 2010 in those states which have adopted the same. The State Council has been empowered to hear appeals from the District authority under the Act.[223] The State Council may pass such orders as it may deem fit which can be made binding on the CE within thirty days from the date of receiving such appeal. The objective of the State Council may be altered in such a way that the rights of patients are being protected and enforced in those respective CE. The powers of the State Council should not be limited to granting monetary compensations in case of violation of patient rights.[224]

It is to be noted that the aforementioned grievance redressal mechanism proposed by the NHRC is no hindrance against the patients or representatives to approach the Medical Councils, seeking disciplinary actions against medical practitioners or Consumer Commissions, seeking compensation for deficiency in service or unfair trade practices or concerning civil, criminal or other courts seeking respective actions regarding the nature of complaint and violations. The Charter shall not extinguish other remedies available to the patients under various capacities held by them be it civil or criminal or otherwise, under the existing framework of law.

[223] Section 8(5)(e) Clinical Establishment (Registration and Regulation) Act 2010
[224] Draft Charter of Patients' Rights, 2018

CHAPTER IV – COMPARATIVE ANALYSIS

Parallel to the development of right to health as a fundamental human right at the international level and the obligation of the states to ensure the same, there were efforts put in at international levels to expressly recognise some of the rights of patients to be accepted universally. Firstly, the efforts were based crucially on focusing the responsibility of medical practitioners towards their patients while rendering medical aid. Gradually, the focus shifted towards patients and their individually enforceable rights. These shifts were evident on some of the international efforts. Initial efforts to codify patient's rights were begun by the international association of physicians namely the World Medical Association (WMA) founded in 1947. WMA was established to protect physicians' independence and to advocate for the best possible ethical and medical care standards at all times. It offers a venue for its members to communicate openly, actively collaborate, reach consensus on the optimum medical ethics standards and professional competence, and promote physician's professional freedom around the world. The WMA's goal is to serve humanity by striving for the most incredible international standards in medical education, medical science, medical art and medical ethics, and healthcare for everyone. This facilitates the patients to receive high-quality, humane care in a healthy setting, improving the quality of life for everyone across the globe.[225]

Since its formation in 1947, WMA has been working on a system of ethical obligations, or professional deontology that better defines the role of the physician in relation to individual patient rights. Patient rights do not emerge as a self-contained notion either in the Geneva Declaration, 1948 or the first International Code of Medical Ethics, 1949. Rather, they are the outcome of a complex system of physician-patient obligations. With the advent of Helsinki Declaration in 1964 which established the rules pertaining to research and experiments involving human beings, informed consent became a powerful instrument for defending patient autonomy. This was originally intended to prevent against inappropriate insertion of humans in research, but it has now become the widely accepted standard for consent during medical treatment. The WMA declaration of Tokyo 1975 urged physicians around the world to refrain from participating in torture and degrading treatment.

[225] World Medical Association, https://www.wma.net/who-we-are/about-us/ (accessed on August 25, 2021, 2.05 PM)

WMA in 1981 began drafting the first declaration on patient rights. The Declaration of Lisbon on the rights of patient transformed health from a desire to individual rights for each and every person. Originally a brief document, it was expanded in 1995, listing a variety of rights and its description, including:

- Right to medical care of good quality without discrimination
- Right to freedom of choice
- Right to dignity and self-determination
- Right to information and know
- Right to confidentiality
- Right to Health Education
- Right to religious assistance etc.

It also provides for the guidelines when the patient is unconscious, legally incompetent and other exceptional cases wherein the treatment can be proceeded against the will of the patient.

A number of countries had already adopted similar sets of rights at the time not always referred to as “patient rights,” but they did exist in the domestic legal systems one way or the other. They were brought together by WMA as an international declaration.

United States of America

In United States, federal legislations regulates patient rights arena particularly in the matters concerning confidentiality, patient self-determination, discrimination and disability. However, the routine circumstances regarding the rights of patients have fallen to the individual states to legislate and regulate upon.[226] Thereby individual states have got their own charter of rights of patients. eg: New York State Hospital Patients' Bill of Rights, New Jersey Patient Bill of Rights etc.

The American Hospital Association in 1973 released the first document expressing patients’ rights while in the hospital seeking medical attention in America. The original thirteen specified rights in the American Hospital Association Patient Bill of Rights became a widely adopted

---

[226] Melanie Silver, *Patients' rights in England and the United States of America: The Patient's Charter and the New Jersey Patient Bill of Rights: a comparison,* 23 J. MED. ETHICS 213, 215 (1997)

model for American hospitals. The American Hospital Association's Patient Bill of Rights was utilized to explain what all patients could expect in a hospital setting while also giving hospitals a real way to show their dedication to their patients and in the 1990s, the Joint Commission made it a nationwide criterion for hospital accreditation to inform every patient about their rights while during medical care. The text had a big impact on hospitals around the country, and it prompted many states to pass their own patient rights legislations.

In 2001, efforts were made in the Congress to enact a federal Patients' Bill of Rights (McCain-Edwards-Kennedy Patients' Bill of Rights or the Bipartisan Patient Protection Act of 2001). There seemed to be certain ambiguities and differences regarding the language and provisions contained in the Bills passed by the US House of Representatives and Senate.[227] Eventually the Bill failed to gather momentum and thereby did not get enacted as a federal law. However, as discussed earlier different States in US have enacted State laws and defined accreditation standards for hospitals regarding patients' rights.

The American Medical Association (AMA) founded in 1847 is a professional association and lobbying group of physicians and medical students which established and maintains the AMA Code of Medical Ethics which is considered to be the world's first such national code established for the ethical discourse of medical practice. The AMA Code of Medical Ethics has expressed the values to which physicians dedicate themselves as members of the medical profession ever since its adoption in 1847.[228] The Principles of Medical Ethics along with the Opinions of the AMA's Council on Ethical and Judicial Affairs compose the Code

Chapter 1 which deals with the ethics of patient-physician relationship specifies the rights of patients. Patients' health and well being are reliant on a mutually respected collaborative effort between the patient and physician. Patients participate and contribute fruitfully to this relationship by carrying out their responsibilities, seeking care, and being open with their

[227] Michael Paasche-Orlow et al., *National survey of patients' bill of rights statutes*, 24 J GEN INTERN MED. 489 (2009)

[228] AMA Code of Medical Ethics https://www.ama-assn.org/delivering-care/ethics/code-medical-ethics-overview (accessed on August 31, 2021, 4.12 PM)

physicians. Physicians can most effectively contribute to a mutually respectful relationship with patients by acting as advocates for their patients and respecting their rights including:[229]

1. Right to courtesy, respect, dignity, and timely, responsive attention to the needs of the patient
2. Right to receive information and have the opportunity to discuss the benefits, risks, and costs of appropriate treatment alternatives, including the risks, benefits and costs of forgoing treatment with the physician.
3. Right to question health status or recommended treatment when the information provided is not comprehendible by the patient
4. Right to make decisions about the treatment and care recommended by the physician and to have those decisions respected including the right to accept or refuse such treatment or care or medical intervention
5. Right to have medical facilitators respect the privacy and confidentiality of patients.
6. Right to obtain their medical records, copies or summaries.
7. Right to get a second opinion.
8. Right to be advised or informed of any conflicts of interest their physician might have pertaining to their care.
9. Right to continuity of care. Sufficient notice and reasonable assistance is to be provided for making alternate arrangement of care in case of further treatment prescribed.

The Patient Protection and Affordable Care Act, 2010 enacted for the protection of patients while dealing with health insurance companies, resulted in the creation of a Patient's Bill of Rights pertaining to the health insurance coverage. The primary goal of the healthcare reform legislation was to return back the control of health services coverage and care to American consumers. Insurance companies, frequently leave patients without coverage when they are in dire need, forcing them to delay the required care, jeopardizing their health and shooting up the cost of care if they do receive it. The Act addresses some of the insurance industry's most egregious practices while also providing the stability and freedom.[230] The US Departments of Health and Human Services, Labor, and Treasury each issued regulations to implement the

[229] Chapter 1.1.3 AMA Code of Medical Ethics
[230] CMS.gov: Affordable Care Act's New Patient's Bill of Rights https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca-new-patients-bill-of-rights#ftn1 (accessed on August 31, 2021, 9.19 PM)

Patient's Bill of Rights under the Act which applies to almost all health insurance plans. This will help Americans with pre-existing conditions gain coverage, choice of doctors, end lifetime limits on care etc.

The Patient's Bill of Rights includes the following provisions:[231]

- *Prohibition of Pre-existing Condition Exclusions* - The exclusion of benefits ore from a plan or coverage associated with a pre-existing condition is prohibited
- *Ban on Rescissions* - Except for fraud or misrepresentation, the rescission or cancellation of a policy due to an inadvertent mistake or omission is prohibited.
- *Ban on Lifetime and Annual Limits* – Act prohibits imposing lifetime/annual limits on the value of health benefits.
- *Choice of Health Care Professional* - right to designate primary care provider of their choice
- *Emergency Services* – If plan covers emergency services, it is to be done without prior authorization
- *Right to Appeal against the Decisions Made by Health Plans* - decisions of health insurance companies can be appealed as a matter of right internally and decision to be rendered in a timely manner. Also as a right, consumers have the right to further appeal to an outside independent decision maker, such as an insurance ombudsman or otherwise.
- *Covering Young Adults on Parent's Plan* – for children until the age of 26 irrespective of student status, residency, marital status, employment, or financial support
- *Covering Preventive Care with No Cost* - coverage for suggested preventive services without out-of-pocket expenditures.[232]

European Union

The scope of patients' rights established in domestic legislation differs obviously between European Union (EU) Member States. However, there seems to be a broad accord among member states regarding the protection of certain basic rights of patients across Europe such as

---

[231] The Affordable Care Act: A Working Guide for Maternal and Child Health Professionals http://www.amchp.org/Transformation-Station/Documents/ACA3-patient-bill-of-rights.pdf (accessed August 31, 2021, 9.36 PM)

[232] *ibid*

right to privacy and confidentiality, right to dignity specifically consent to treatment, and the right to information.[233] Apart from being protected by the domestic national laws of the member states, these rights are also protected under the European Convention of Human Rights and Biomedicine, 1997 (ECHRB), which is a legally binding transnational treaty aiming to safeguard human right in the fields of biomedical research, genetics, and health care and often considered as a 'patients' rights treaty' in Europe due to its sufficient precision capable of direct application in monist countries.[234] Other rights of patients can be derived directly from ECHR which is the primary source of human rights in Europe, for e.g. Art 3 which prohibits inhuman and degrading treatment and Art 8 which enunciates right to private and family life.[235]

Patients' right to access to health care in EU are contingent on both individual and social rights of patients as enshrined in the domestic laws of various member states, as well as recognition of these rights in international (especially European) law.[236] Under the international law, the right to health is primarily viewed as a collective entitlement; hence, it could scarcely be utilized to substantiate individual allegations of patient rights violations.[237] Patients are guaranteed a certain amount of access to medical care by the state's legal framework itself. A wide network of rules and regulations regulates 'right to healthcare' which governs the actions of patients, health care providers, governments, and 'third-party payers.' At the national and European level, these rules and regulations serve a variety of purposes.

In terms of patient rights, each of the EU countries' national health systems reflects very distinctive realities. Some system of laws may have patient rights charters, particular legislations, administrative regulations, service charters, ombudspersons, and alternative conflict resolution methods to address the issue of rights of patients while others might not have any of these mechanisms. It is in this regard the European Charter of Patients' Rights was brought up to act as a guiding document for the states to comprehensively address the issue and come up with a unified mechanism.

[233] *Supra* n. 157
[234] *Supra* n. 176
[235] *Supra* n. 176 at 126
[236] Herbert Hermans, *Patients' rights in the European Union*, 7 EUR. J. PUBLIC HEALTH 11 (1997)
[237] *Supra* n. 176 at 122

The European Charter of Patients' Rights drawn up in 2002 by the Active Citizenship Network[238], is not a legally binding document but is regarded generally as the most clearest and comprehensive declaration of the rights of patients.[239] It tries to translate 14 specific provisions for the rights of patients from regional documents on health and human rights. It has encouraged the patients to play a livelier role in molding healthcare setup. The charter and its rights have served as a benchmark for monitoring and evaluating healthcare systems across Europe, as well as a model for national legislations for the recognition and adoption of the rights it tries to address.

The Charter has the potential to fortify the extent of protection provided to patients/citizens' rights in various national settings, as well as to serve as a tool for standardizing national health systems in favour of the rights of patients across Europe which is critical, given the EU's freedom of movement and the enlargement process.[240]

The EU Charter of Fundamental Rights is the main source of European Charter of patients' rights and forms its primary basis on Art 35 of the Charter of Fundamental Rights which envisions protection of health as the "right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices".[241] The said provision sets an expectation for the governments to reach the highest standard of healthcare.

In furtherance to the said provision, the Fundamental Rights charter contains certain other provisions that are specifically applicable while looking at the angle of patients rights namely: right to human dignity[242], life[243], integrity[244], prohibition of torture and inhuman or degrading treatment[245], security[246], protection of personal data[247], non-discrimination[248], rights of

---

[238] a European network of civic, consumer, and patient organizations
[239] *Supra* TAMAR EZER n. 177 at 100
[240] Preamble European Charter Of Patients' Rights
[241] Part 1: European Charter Of Patients' Rights
[242] Article 1 Charter of Fundamental Rights
[243] Article 2 Charter of Fundamental Rights
[244] Article 3 Charter of Fundamental Rights
[245] Article 4 Charter of Fundamental Rights
[246] Article 6 Charter of Fundamental Rights
[247] Article 8 Charter of Fundamental Rights
[248] Article 21 Charter of Fundamental Rights

children[249], elderly[250], disabled persons[251], social security benefits and social services[252], healthcare[253], consumer protection[254] etc.

Part II of the European charter of patient rights enunciate a set of 14 solid patient rights which when read together is expected to accomplish the fundamental rights fruitful in the context of healthcare in Europe. It aims to guarantee the 'highest level of health protection' under Art 35 of charter of Fundamental rights. These rights are expected to be made applicable for every individual seeking medical aid throughout the territory of EU. The 14 rights of patients recognized, are a manifestation of the fundamental rights, and they must be recognized and protected as it is regardless of the financial, economic, or political restraints, while also taking into account the standards of appropriateness of care. Respect for these rights necessitates both technical and organizational requirements, as well as a set of behavioural and professional patterns. As a result, they necessitate a global overhaul of the working of national healthcare systems especially towards patient care.[255]

The 14 rights of patients recognised by the charter are.

1. ***Right to preventive measures*** - right to proper services to prevent illness
2. ***Right of access*** - access health services according to the health requirements. Equal access to health services must be guaranteed to everyone without any discrimination.
3. ***Right to information*** - to be informed of the state of health, health services and how to use them, etc.
4. ***Right to consent***, - right to be provided with all necessary information and thereby enable him to take an active role in the decision making process pertaining to his health as a prerequisite before any treatment or procedure.
5. ***Right to free choice*** –free to choose from a variety of treatment options or procedures and providers on the basis of adequate information provided to the patient.

[249] Article 24 Charter of Fundamental Rights
[250] Article 25 Charter of Fundamental Rights
[251] Article 26 Charter of Fundamental Rights
[252] Article 34 Charter of Fundamental Rights
[253] Article 35 Charter of Fundamental Rights
[254] Article 38 Charter of Fundamental Rights
[255] European Charter Of Patients' Rights

6. ***Right to privacy and confidentiality*** - physical privacy and confidentiality of personal information
7. ***Right to respect of patients' time*** - right to obtain necessary medical care in a timely and planned manner at each stage of the treatment.
8. ***Right to observance of quality standards*** - high quality healthcare services based on detailed specifications and adherence to proper guidelines
9. ***Right to safety*** - right to access treatments and healthcare services meeting high safety standards and to be free from any harm caused by the poor functioning of health services, medical malpractice and errors
10. ***Right to innovation*** - access innovative procedures and techniques including diagnostic according to the international standards
11. ***Right to avoid of unnecessary suffering and pain*** – avoid suffering and pain caused unnecessarily at each stage of treatment
12. ***Right to personalized treatment*** - right to diagnostic or therapeutic procedures that are customized as much as possible to the personal needs of the patient
13. ***Right to file complaints*** – whenever suffered any harm and right to receive a response or feedbacks of the complaint
14. ***Right to Compensation*** – right to adequate compensation within reasonable time when bodily, moral, or psychological harm caused due to healthcare treatment.

Similar to the Indian draft charter of patients' rights, the European draft charter is a non binding document, expected to be integrated into the national as well as European laws to protect the rights of patients comprehensively.

Patient mobility in EU encompasses a broad gamut of issues surrounding patient movements across the union.[256] Hence, there also raises the issue of protection of patients' rights across EU. While considering patient mobility across Europe and availability of treatment issues, individual patients' rights might seem to be not as important comparatively. Having identified that the individual patients' rights cannot be disregarded in cross-border healthcare and its effective implementation a major challenge during patient mobility, EU Member States were expected to collaborate to ensure that mobile patient's rights to privacy, dignity, and information are

[256] *Supra* n. 176

maintained regardless of their place of treatment. A step toward developing a framework for such collaboration is evident in the *European Directive* on *Patient Rights* which establishes duties of Member States of Treatment and Member States of Affiliation in the protection of basic rights of patients.[257] The Directive No. 2011/24/EU has been made applicable in the EU member states since 25th day of October, 2013, and in the European Economic Area (Iceland, Liechtenstein, and Norway) since 1st day of August, 2015. But, it does not apply to Switzerland and ceased its application in the United Kingdom as of 1st day of January, 2021.[258] The coordination rules of EU ensures that an insured person travelling within the EU receives the same healthcare as if he or she were a member of the healthcare system of the country in which treatment is administered. The Directive aims at facilitating access to safe, high quality cross border healthcare and promote healthcare related cooperation between EU and European Economic Area member states while preserving the independent authority of each state to organize and provide healthcare services through a variety of measures, wherein the establishment of a National Point in every country to enlighten patients about all of their rights is one among the Directive's goals.

England

In England, National Health Service (NHS) is the publicly financed healthcare system and one of the United Kingdom's four NHS systems. During the early 1970s, the Patients Association particularly being worried about the practice of using patients in teaching at hospitals without their consent for the purposes of medical education endeavored to establish a formal Patients' Rights Bill. However Bill never got enacted, in part because health ministers deemed the problem unfit for legislation, and authorities deemed the bill to be poorly worded and also due to lack of clarity as to the legal backing of certain rights especially the right to refuse during those days.[259]

In 1991, with great optimism and critical acclaim the Patient's Charter, a citizen's charter initiative in the NHS, was launched by the British government. This booklet was widely

---

[257] *Supra* n. 176 at 126

[258] European directive on patients' rights https://www.cleiss.fr/docs/directive_en.html (accessed on August 28, 2021, 3.15 PM)

[259] Alex Mold, *Patients´ Rights and the National Health Service in Britain, 1960s–1980s*, 102 AM. J. PUBLIC HEALTH 2030, 2033 (2012)

distributed which contained a series of 10 rights that referred to a patient's entitlement to care in the NHS, as well as two other categories of standards, such as National Charter Standards (service standards that a patient could expect to receive while seeking care anywhere in the NHS) and Local Charter Standards (standards that local health care providers would be expected to fulfill). This was the first document, since the inception of NHS in 1948, to state the rights of patients in England, however limited they may be. Those rights enumerated were declared pre-existing by the charter, which also increased the number of patient rights.[260] The said Patients Charter was subsequently replaced by the subsequent NHS Constitution for England.

The NHS Constitution for England was introduced in 2009, and it outlined a set of rights, obligations, and pledges, intended to embody the NHS's "principles and ideals." Patients were informed that they have 25 rights that covered a wide range of healthcare issues. The NHS Constitution claims to have gathered "for the first time in the history of the NHS what staff, patients, and the general public may expect from the NHS" in one go.[261] However the Constitution is only a 'declaratory text,' describing existing legal rights, as opposed to a law with an expectation that NHS organisations takes into account the full extent of the Constitution and its values and principles while delivering services.

The section on patients and the public in the NHS Constitution drew heavy precedence from other countries, government departments, and the past history, particularly the Patients Charter 1991, which outlined what patients were entitled to and what they may expect. The said section enumerates in detail the legal rights to which every person while accessing NHS is entitled to and stipulates the method of enforcement of the right. The NHS is likewise committed to achieving the pledges contained in the Constitution, though not legally enforceable, they do indicate the NHS's commitment to providing a comprehensive and high quality services.[262]

Thereby the patients have the following rights:[263]

- Right to access health services

[260] *Supra* n. 226 at 241
[261] *Supra* n. 259
[262] Part 3a NHS Constitution 2013
[263] *ibid*

- Right to receive NHS services free of charge with certain exceptions, without unreasonable refusal or discrimination.
    - Right to assess the health requirements of your community
    - Right to go for treatment to other EU members states or European Economic Area countries or Switzerland in certain circumstances
    - Right to access certain NHS within maximum waiting times as stipulated or for alternate providers through NHS if this is not possible
- Right to quality of care and environment
    - Right to be treated with professional standard of care by sufficiently skilled and experienced personnel at a properly approved or registered organization with required safety and quality standards.
    - Right to expect bodies of NHS to monitor and make efforts to improve continuously, the quality of healthcare provided
- Right to nationally approved treatments, drugs and programs
    - Right to drugs and treatments as recommended by the National Institute for Health and Care Excellence under prescription
    - Right to other drugs and treatments to be made rationally following a proper consideration of the evidence by practitioners. (If your doctor feels a medicine not funded by NHS is right for a patient, they will explain that decision).
    - Right to receive the vaccinations under the NHS provided national immunization schemes.
- Right to respect, consent and confidentiality
    - Right to be treated with respect and dignity
    - Right to accept or refuse treatment
    - Right to information about tests and treatments, how patient's information is used, safety of the preferred treatment, likely outcome or result of the treatment etc.
    - Right of access to your own health records
    - Right to privacy and confidentiality
    - Right to request confidential information is used only for the patient's care and treatment
- Right to an Informed choice

    - Right to choose GP practice and get the practice accepted
    - Right to articulate any preference towards the service of any particular doctor within the GP practice
    - Right to make choices regarding services by NHS bodies and to information supporting these choices
- Right to Involvement in your healthcare and in the NHS
    - Right to be involved in discussions or decisions about a patient's health, treatment and care, including end of life decisions, and to be given information to enable a patient to do this. (This right also applicable to family members and carers)
    - Right to have an open and transparent relationship with the organization providing care
    - Right to be involved in the planning, development, consideration of new proposals and decisions of NHS commissioned services either directly or through representatives.
- Right to Complaint and redress
    - Right to have any complaint against NHS acknowledged within 3 working days and to have it properly investigated.
    - Right to discuss how the complaint will be handled, as well as the time frame in which the investigation will be concluded and get the response delivered.
    - Right to be informed about the progress and outcome of any such investigation into the complaint, including information about the action that has been taken or to be taken in consequence of the findings in the complaint
    - Right to take the complaint to the independent Parliamentary and Health Service Ombudsman or Local Government Ombudsman, if aggrieved by the way NHS responded to the complaint
    - Right to seek for judicial review having felt or being directly affected by an unlawful act or decision of an NHS body or local authority.
    - Right to compensation if harmed by negligent treatment.

Scotland

The Scottish Parliament on the 24th day of February 2011 enacted the Patient Rights (Scotland) Act, 2011, and it gained royal assent on the 31st day of March, 2011. Scottish Ministers were required under the Act to publish a "*Charter of Patient Rights and Obligations*", which outlines the existing rights and responsibilities of persons who uses NHS services and receive NHS care in Scotland.[264] The ministers after coming up with the charter must publish the same and notify each of the relevant NHS body regarding its publication.[265] Thereby, each relevant NHS body must provide the charter to patients, staffs and public without charge.[266] It also provides for the review and revision of the charter.[267] In addition to the right to be mentioned in the Charter, the Act itself identifies and stipulates certain rights of patients.

The Act requires healthcare to be patient focused i.e. anything done pertaining to a patient must be done as according to the needs of the patient. Optimum benefit towards the health and well being of patient is to be provided during healthcare. Patients should be allowed and encouraged maximum, to participate in the decisions pertaining to their healthcare and provide them with all related information to make them competent to make decisions and otherwise to make them informed about the treatment and care.[268] Patients have the right to provide feedback, comment or raise concerns, complaints regarding the received healthcare.[269]

A chapter dealing with treatment time guarantee is set in the legislation to ensure that an eligible patient receives treatment within the maximum waiting time set forth and other related matter including cases of violations of the same.[270]

It also provides for a relevant NHS body to encourage patients to provide comments or feedback or concerns or complaints regarding the received healthcare services. In case, the said feedback or comment or concern or complaint to the provider of the patient advice and support service, it may be forwarded to the concerned relevant NHS body dealing with the same. The relevant NHS body must consider the same and may provide the same to the Scottish Ministers view to

[264] Section 1 Patient Rights (Scotland) Act, 2011
[265] Section 1(8) Patient Rights (Scotland) Act, 2011
[266] Section 1(9) Patient Rights (Scotland) Act, 2011
[267] Section 2 Patient Rights (Scotland) Act, 2011
[268] Section 3(2) Patient Rights (Scotland) Act, 2011
[269] Section 3(3) Patient Rights (Scotland) Act, 2011
[270] Chapter 4 Patient Rights (Scotland) Act, 2011

improve the performance of its functions and the same may.[271] The relevant NHS body is to be provided with adequate facilities and arrangements while dealing with the comments, feedbacks, concerns or complaints from the patient or general public.[272] Also adequate agencies are to be set for patient advice and support services with the primary goal to spread awareness and comprehension of the rights and responsibilities of patients (the Charter in particular), advice and support patients to give feedback, comments, concerns or complaints, inform and advice matters likely to be patient's interest, or other aid, advice or support.[273]

The Charter of Patient Rights and Responsibilities outlines in detail patients' rights and responsibilities while receiving NHS services and care in Scotland, and also the remedies to which patients are entitled in case of violation of any of the rights enumerated. The contents pertaining to the rights of patients in the charter are divided into the following areas

• *Rights while Accessing and availing NHS services in Scotland* – Non discrimination, respect, health needs and preferences, free cost for NHS services, registering with a GP practice, dentist etc., appointments, Medicines, Safe and effective care and treatment, Health, Hygiene and cleanliness standards and Treatment Time Guarantee

• *Communication and involving you* –information, Communication support, decision making, support while decision making, support to managing conditions and taking part in designing and providing local services

• *Privacy and confidentiality* - right to be informed, access information, right to correct, delete, object and restrict the use of information, right to move or transfer information, right to be informed during Automated decision making and profiling, information protection during tele-care and Feedback and complaints about data protection

• *Feedback, complaints and my rights* – patients or their carers or family members can provide feedbacks or comments (negative or positive) the concerned NHS member or body to improve the services provided. Also, they are to be informed, advice and supported about the manner in which feedback, comment, concern, complaint to be administered and its management.

---

[271] Section 14 Patient Rights (Scotland) Act, 2011
[272] Section 15 Patient Rights (Scotland) Act, 2011
[273] Section 17,18 Patient Rights (Scotland) Act, 2011

The Patient Advice and Support Service (PASS) provide patients, carers and families with free, accessible, independent and confidential information to raise awareness of their rights and responsibilities while using NHS Scotland. It also assists in the submission of feedback, comments, concerns, or complaints from patients or others.

The NHS complaint procedure under the Charter, stipulates in detail, the procedural mechanisms in case of violation of any of the rights of patients or their concerns. It ensures that any complaint raised will not jeopardize the access to treatment or care. It speaks about 2 stages or steps wherein firstly the complaint is to be administered towards an NHS staff to try and sort out the issue at a go. If complaint not resolved locally, it moves on to stage two wherein the complaints would be complicated and require a detailed investigation. It is to be noted that NHS complaints procedure does not deal with claims for compensation for injury or harm caused by negligence. During investigation or on its completion patients have the right to be informed of the outcome of the inquiry and also about the action taken or to be taken to resolve the issue. If the investigation points out a mistake committed from the part of NHS towards the complainant, they should apologize to the complainant. Delay in investigation is to be properly communicated to the complainant.

Patients if aggrieved or unhappy with the investigation conducted or how the complaint was dealt with, they also have the right to raise the complaint to the Scottish Public Services Ombudsman through multiple ways such as post, phone, e-mail, website or online form.

The charter also provides for when the rights have not been respected and thereby harmed by negligent treatment which is when the treatment or care falls below acceptable norm or practice and thereby causes physical or mental injury or even death. The patient would be entitled to compensation if found to be a victim of negligent treatment. The patient or legal representative can raise a claim in case of negligent treatment to the NHS Scotland's Central Legal Office, which will investigate into the same. The patients also have the right to complain or take legal action or a claim for compensation to the Information Commissioner's Office Scotland, in case of violation of privacy, confidentiality or data protection or its principles by NHS Scotland. Apart from these mechanisms the patients are the right to approach for judicial review if the patient seems to be directly affected by NHS Scotland's unlawful acts or decisions.

The protection of patient right seem to be more productive and effective in Scotland because the law mandates the protection of certain rights of patients and in addition to it the Charter with precision and detail stipulates the rights and the different ways in which the patient can proceed in case of violations of their rights.

Though not binding, the NHS Constitution in England seems to be more comprehensive. The position in US is somewhat similar to that of India, wherein the States are being provided with the power to come up with their own initiatives to protect the rights of patients. The situation is Scotland seem to be more effective. It includes detailed contents regarding the protection and enforcement of patients. It also stipulates the method to be pursued in case of negligence, what to be done, whom to approach etc. which are pertinent considering patients rights. Also it has an easy mechanism in case of violation of the rights.

CHAPTER V - CONCLUSION AND SUGGESTIONS

Every person involved in the healthcare delivery system should respect the rights of patients. Mostly, the patients come into touch firstly with the allied healthcare providers. Hence, they are also not precluded from maintaining patient confidentiality and respecting their right to autonomy. Informed consent, medical treatment in an emergency, and continuity of care should all be handled by nurses. However, the physicians are ultimately responsible for providing ethical care and adhering to hospital norms and laws regarding patients' rights.[274]

A hospital cannot evade liability by claiming that it cannot undertake any treatment procedure on its own and that it simply provides infrastructure, nursing services, support workers, and technicians.[275] The hospital is accountable not just for its own employees, but also for outside contractors (anesthetists/surgeons) or doctors who admit or operate specific cases.

When a patient is accepted for treatment, hospitals are required to provide reasonable care and skill to alleviate the patient's ailment or condition. However, hospitals do not have the ears to listen to the stethoscope or the hands to handle the surgeon's knife, to treat the patient.[276] It must do it through its employees, and if its employees are irresponsible in providing treatment, they are guilty just as anyone who hires others to perform his work for him.[277]

It is also a common practice among some private organisations or establishments, adopting their own declaration or lists of patient rights to enlighten the patients about their rights while visiting the said organization and even augment the said rights not explicitly stipulated by law. In so far as the same does not contradict any of the rights mentioned in the charter or law, it would not create a problem.

Every interaction with patients should be guided by ethical principles and patient rights. Proper training and awareness regarding the ethical principles and its applicability to ensure patients' rights is pertinent at all establishments. Without adequate training or understanding, the healthcare staffs may be prone to violate the rights unintentionally such as failure to respect

---

[274] *Supra* n. 2
[275] *Rekha Gupta v. Bombay Hospital Trust*, II (2003) CPJ 160 (NC)
[276] *Joseph v. Dr. George Moonjerly*, AIR 1994 Ker 289 at para 17
[277] *Ibid*

patient autonomy by being unduly paternalistic or making therapeutic choices on patients' or families' behalf. Other examples include situations wherein proper information is not disclosed regarding the treatment options, risks, or side effects. Apart from patient autonomy, various other patients' rights get infringed if the healthcare professionals and facilitators are not vigilant. This can be mitigated by frequent collaboration with the patients regarding their expectation of care and making patients effectively participate in the 'shared decision-making'. Also, another element is that the medical facilitators need to comprehend the essential components of ethical principles and patients rights.[278]

The factors impacting the recognition of patients' rights at hospitals are manifold. While disclosing information or choice, the gender, age and education of the patients are decisive factors. Though female patients may be provided with strict confidentiality, the information and choice provided to them are questionable. Patients from the higher socio-economic strata receive better quality treatment and have more autonomy than those from the lower socio-economic strata. This is inevitable since money is a decisive factor in access to better healthcare. As a result, patients in rural areas may be treated without respect to patient autonomy than in urban areas. In terms of patient rights, the physician's attitude is also a crucial determinant. It is a general notion in the country that higher the qualification, status and education of the physician, lesser is his patient's autonomy. Though minimal, there are physicians who irrespective of their qualification or experience respect patient autonomy and provide all of the necessary information to their patients.[279]

Patients' rights seem to be protected and enforced only when the healthcare system is stable, at least in India. In India, during the pandemic or medical emergency it was manifest that many of the patients were denied treatment due to various reasons and there was no compliance to the rights of patients.[280,281] Many of the patients rights were seemed to be violated during the pandemic, be it privacy, confidentiality, non-discharge of patients over unpaid exorbitant bills, denial of treatments etc. Some of the rights were not practically protectable due to the

[278] *Supra* n. 2
[279] Ravindra Ghooi & Shailesh Deshpande, *Patients' rights in India: an ethical perspective*, 9 INDIAN J. MED. ETHICS 277, 280 (2012)
[280] Covid-19 in India: Patients struggle at home as hospitals choke, https://www.bbc.com/news/world-asia-india-56882167 (accessed on September 30, 2021, 12.06 AM)
[281] India coronavirus: Desperate Covid-19 patients turn to black market for drugs, https://www.bbc.com/news/world-asia-india-56757405 (accessed on September 30, 2021, 12.11 AM)

contingency, and therefore at least in India patients rights are protected only when the medical system is steady. Hence, the healthcare system needs to develop and grow so much to the point that even during a pandemic or emergency, basic patients rights are given proper conformity, no matter what. There also need to be certain clarity as to whether patients' rights are absolute since in India patients rights take its basis from a variety of legal instruments. For instance, Art 21 is not absolute. Therefore, patients' rights taking its foundation from Art 21 are also not absolute. Nevertheless, there may be other legal instruments giving the same right other forms of backing. Hence, there is a clarity required to be made in this aspect concerning the patients' rights during a contingency.

Most of the patients' rights are interlinked. Therefore, a violation of any one of such right would result in the violation of the other. For instance, consider a situation wherein adequate information regarding the patient is not provided by the medical facilitators and thus violating their right to information. Here, as a result of the patient being provided with inadequate information, the patient may not be in a position to take an informed decision or choice and thereby, violating other related rights of informed consent, choice, autonomy etc.

During the pandemic wreaking mayhem in the country, there were numerous instances of the private hospitals overcharging the patients and not even discharging the dead body, citing unpaid bills, in sheer violations of the rights of patients.[282] The law does not prescribe for any provisions allowing for the patients to have an immediate remedy or rectification in case of any infringement of the patient rights. Here in the above mentioned cases as well as in most of the issues concerning patient rights violations, immediate remedy or rectification is what the patients or their family members hope for at least in the specific cases discussed above, to get your loved one's body back immediately, to conduct the final rites rather than being provided with a compensation if any (that too doubtful) after constant litigation struggles and battles in the court of law. Hence, the patients more often require what is an immediate remedy in case of any violation which can be resolved right away without any unnecessary delay as far as the patients are concerned. This is where a dynamic remedying machinery or authority should be established in every hospital or clinic or for a fixed low number of hospitals or clinics. This best possible

[282] Kerala: 'Hospitals can't detain dead body over bill', http://timesofindia.indiatimes.com/articleshow/82513231.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst (accessed on September 30, 2021, 12.22 AM)

resolution has been provided for in the draft charter with the establishment of INGRO or ombudsman or related authority in the CE itself to timely resolve the issues of violation of patient rights, yet not implemented across the country. Overpricing, not providing information etc are all issues that require immediate remedy. Consider a situation where emergency medical care is to be provided to the patient and a hospital refuses such emergency medical care citing the patient does not possess the income level to meet its demand. Here the patient can immediately approach the INGRO or ombudsman or concerned authority, if established in the clinical establishment as required in the draft charter, and the authority can provide an instant remedy, otherwise, the patient would be required to be taken to another hospital which might result in the patient succumbing and then proceed with the legal litigations under scattered patients rights (as in India currently) to provide for compensation and criminal liability if any. Hence, an independent authority established and the notion of immediate remedy can, to a certain agreeable extent, protect the rights of patients in India effectively. Without patients being provided with an immediate remedy, the so-called patients' rights recognized in India are toothless.

A patient charter of rights should increase understanding of the nature and scope of patients' rights. It should aid in promoting improvements in the quality and timeliness of care, improve overall accountability of healthcare system participants and prevent costly litigation. However, a patient charter by far becomes powerless, serving only as an instrument to converse about enhancing the patient experience and overhauling the healthcare system. To be effective, the Charter must provide patients with a lower cost, easily accessible, and independent way to make a complaint and have it rapidly resolved through an impartial ombudsman or commissioner who can handle their complaints or concerns in a timely and cost-efficient manner. This can perhaps drive a positive change and make the patient charter more powerful and effective.[283]

See in the case of *N.P. Bhatia* (*supra*) for instance, the patient required the hospital authorities to provide her medical records. But the same was denied by them (see facts). Eventually she had to go till the National Information Commission to get access to her medical records which is considered to be one of the basic rights of patients to get access to their medical records and documents. The commission in this case in conformity with the Bombay High Court in

[283] *Supra* n. 4 at 1586

Raghunath Raheja (*supra*) required the Medical Council to issue necessary direction to the doctors and hospitals to ensure that copies of medical documents and case papers are produced to the patient or near relative without any delay.[284] Had there been an option for an independent authority or ombudsman established to ensure the protection and enforcement of patients' rights right away and perhaps the possibility of an immediate remedy, the petitioner in *N.P. Bhatia* would not have had to struggle with the litigation procedures for almost 1077 days to get access to her medical records. In addition to the above, since the patients' rights are being scattered around various legislations, the enforcement of the said rights are not straightforward. The patient has to first prove that the said patient is a consumer under COPRA (even to which not all patients are considered consumers)[285] or if going under RTI, the petitioner has to face many other hurdles with the exceptions provided under the Act. Hence, the enforcement of the rights, if there is no independent authority established, would be a cumbersome experience for the patients. Therefore, it is high time to consider patients with a special status and privilege in India rather than considering them under the wide umbrella of citizens or consumers in so far as the timely enforcement of rights of patients is concerned. It is to be noted that the special status needs to be considered while addressing the immediate resolution mechanism and also in furtherance to the consumer, civil and criminal law.

While drafting a charter of patient's rights containing the general rights of patients while seeking medical assistance, the needs and rights of marginalized and vulnerable patients need to be taken account of, along with the general rights applicable to patients or make necessary provisions for ensuring adequate needs of the marginalized or vulnerable group of patients. The marginalized or vulnerable patients may be entitled to furthermore rights under the specific laws such as Mental Healthcare Act, 2017, Medical Termination of Pregnancy Act, 1971 etc. Hence the charter which intended to cover the general rights of patients should also consider the specific rights to which these groups of patients are entitled and should have provisions for protecting and enforcing these specific rights in the hospital or clinic.

The striking initiative towards the protection of patients' rights arena in India was the drafting of the Charter of Patients rights in 2018 by NHRC, encompassing 17 set of rights of patients to be

---

[284] *Nisha Priya Bhatia v. Institute of Human Behaviour and Allied Sciences, GNCTD*, CIC/AD/A/2013/001681-SA at para 30

[285] *Indian Medical Association v. V.P Shantha*, AIR 1996 SC 550

adopted in the country for the public to be made aware of their rights as a patient with coherence. MoHFW, having taken into consideration the suggestions and recommendations from the National Council for Clinical Establishments and the public, released the draft Charter and the secretary of MoHFW in its letter required every States/UTs to adopt the Charter for the protection of patients rights. Notably, in the letter from the secretary, it was stated that the govt. thought of drafting a charter for patients rights in the light of receiving numerous complaints and grievances alleging malpractices from the part of CEs, particularly large corporate CEs, and thereby the draft charter was comprehensively drafted. However, it is unfortunate that the letter recommended the states to adopt their own draft having a set of rights of patients by taking into account a set of do's and don'ts in respect to patients rights and responsibilities apparently contained in the letter. The letter encompasses a set of 13 patients rights. It is clearly seen that the letter does not recommend including the whole 17 rights identified in the draft Charter 2018. The letter omits certain rights which were noticeably important and prepared in the light of numerous complaints received. However, it is left for the states to include the 17 mentioned rights in the draft or to include more or omit the rights according to their conscience. However, this does not pave the way for a comprehensive identification and protection of patients rights across the country. Hence, the future of upbringing and adopting a comprehensive document or instrument containing patients' rights in the country seems bleak.

Also the draft Charter requires it to be made a part of the CE laws of the states. To the utter dismay, even the CE laws are not comprehensively followed in every state. Though central government has adopted a central CE law, since public health and hospital regulation are state subjects, the states are at liberty to either adopt the central legislation (as done by Arunachal Pradesh, Himachal Pradesh, Mizoram, Sikkim and all UTs and later, Uttar Pradesh, Rajasthan and Jharkhand) or create their own state legislations (Kerala[286], West Bengal[287] etc.). There is lack of uniformity in the application of CE laws across the country. For instance, even in defining CE, there is no uniformity between centre and various states.[288] Hence, the idea of

[286] Kerala Clinical Establishments (Registration And Regulation) Act, 2018
[287] West Bengal Clinical Establishments (Registration, Regulation And Transparency) Act, 2017
[288] WB includes a wide scope of healthcare services and also expressly mention services such as vaccination, fertility (also Kerala), dental (Kerala) etc. which are expressly not mentioned in Central law. Kerala does not include CE with only consultation services. Similar with WB, CEs solely for consultation and advice are excluded WB does not include CE maintained /controlled by government and also Mental healthcare institutions under Mental Healthcare Act

patients rights to be implemented solely through the CE laws of the country does not seem to be a good notion and requires an alternative methodology.

Another issue with the draft Charter is that though it mentions about a mechanism to be adopted for the immediate resolution of the grievances, the charter is silent about the remedy available to the patients. As stated before, what the patient requires more in case of any violation of their rights is an immediate remedy or redressal or rectification at the hospital itself. But the draft is silent about the immediate rectification or the time frame within which the INGRO is to rectify the issue and provide the remedy. Generally, the avenues available for the patients for redressal of their complaints regarding violation of rights are the medical council (disciplinary action against the medical practitioner), claim for compensation before civil, consumer and Constitutional courts and also criminal action to penalize the medical professionals. There is no mechanism set to rectify the violation immediately, which the INGRO would perhaps be able to do. Hence, for the patients' rights to be comprehensively adopted, the concept of immediate remedy or rectification is to be taken into account.

For the protection of patient rights to be effectuated in any country, the charter or bill of rights needs to have a legal or legislative recognition for the proper and adequate enforcement and also an effective monitoring mechanism. The program must entice credibility in the eyes of patients. If a patient believes that a right has been infringed, perhaps the optimal way is to provide them with an efficient, accessible, and user-friendly mechanism of redressal.[289] While drafting a patient rights bill or charter, the readability and language of the document is to be particularly taken care of by the framers since these are documents intended explicitly for public access and comprehension by simple and ordinary patients. Complex documents framed in this regard would instill fear among patients and might increase the possibility of patients not even caring to read the same.[290]

If necessary, the judiciary can develop a set of guidelines under the principle of Constitutional silence or abeyance wherein Court can bring up guidelines to fill up the gaps in areas in the interest of justice and larger public interest.[291] So in dire need, courts can bring guidelines for the

[289] *Supra* n. 226
[290] *Supra* n. 227
[291] *Manoj Narula v. UOI*, (2014) 9 SCC 1 at para 65

comprehensive implementation of the patients' rights. Though it is not the primary duty of the judiciary, the Courts have previously done the same in the absence of a law or a directive considering the public interest (see *Vishaka*[292] and *D.K Basu*[293] guidelines).

Hypothesis testing – Patient's rights, on the face of it are recognised in the eyes of law in India. But the recognition of these rights are scattered around various legislations. Hence, the rights are not comprehensively codified into a single instrument for easy comprehension. Since it is for the larger public to comprehend their rights while seeking medical aid, the scattered and uncodified rights do not serve its purpose. Hence, to a greater extent it can be concluded that the rights are not recognised in the country. Also, a dedicated mechanism has not been established for the protection of patients rights. Though the draft Charter prescribes for a machinery to be established, it does not have the potency to effectuate the establishment since it is the prerogative of the states to whether or not to do so and also regarding the recognition of patients rights. Hence, India lacks an effective and efficient mechanism to protect the rights of patients.

Suggestions

The country needs a comprehensive adoption of a Charter of patients' rights valid across the nation. Patients' rights must be adequately outlined, in order to be effective. Long lists stipulating rights which lack order and clarity, causes ambiguity among the patients and health care providers.[294] While drafting any charter or law regarding the protection of patients rights, the doctor-patient relationship should not be adversely affected. The draft or any further directive needs to be framed and issued regarding the remedies available to the patients for them to comprehend easily.

The Indian Charter of patients rights needs to be provided with a legal recognition and thereby give it more potency and power. If a nationwide applicability of the Charter is not possible to be made, the states must be given directives for a strict adherence for the adoption of all the rights of patients contained in the draft Charter.

[292] *Vishakha v. State of Rajasthan*, AIR 1997 SC 3011
[293] *D.K. Basu v. State of WB*, AIR 1997 SC 610
[294] *Supra* n. 5

The states must adopt almost all rights stipulated in the draft charter since these rights are considered essential and have legal or ethical backing. An authority needs to be established so as to ensure whether every state/UTs have adopted every set of patients rights recognized under the draft Charter or otherwise.

Since, patients' rights are to be made applicable through the CE laws of the country, primarily, for at least its application; every state must immediately have a CE law in place (since public health and hospitals are state subjects).

There needs to be a consideration of moving public health into the concurrent list so that hospitals and clinics can be regulated uniformly across the nation. Also, considering the importance of protection of patient rights and its uniformity across states, a law regarding the protection of patients rights can be made applicable across the nation, giving it much more effectiveness and comprehension. This seems to be important considering the enforcement of patients rights because most of the patients rights have got strong legal backing from various legal instruments and therefore, it is pertinent for the enforcement of the said rights uniformly across nation.

The central and state/UTs govt. should consider the notion of immediate remedy or rectification for the patients in case of any violation of their rights. Hence, the charter or the new instrument which facilitates the comprehensive adoption of the rights of patients concerned, should mention about patients to be provided with immediate remedy and rectification at the hospital in case of violations of their rights.

It is necessary that a redressal authority independent from the affairs and influence of the hospital be established to protect and enforce the rights of patients at every hospitals or clinics as prescribed in the draft Charter. The draft Charter is silent about the powers of INGRO proposed to be established at every hospital. Usually, the authority or ombudsman established at hospitals facilitates the enforcement of patients rights by making the establishment abide by the established norms or standards regarding patients' rights. For compensatory, penal or disciplinary action, there are other avenues available for the patients.

Since the letter from the secretary is silent about the adoption of the redressal mechanism stipulated in the draft Charter, the central govt. should immediately come up with a directive to

the States/UTs to abide by the mechanism prescribed in the draft considering the importance of immediate remedy or rectification to the patients.

The functioning and redressal by the authority or ombudsman or INGRO as may be established to ensure the protection and enforcement of patients rights at each or group of hospitals, need to be overseen by a superior authority preferably established at district levels. Also, a clarity is required to be obtained regarding the absoluteness of the rights of patients. Central and state govt. needs to consider having a special status or privilege to patients while immediately remedying the patients' rights is considered. However, this status shall not adversely affect the other redressal avenues available to the patients.

The charter of patients' rights should consider the rights of marginalized or vulnerable groups of patients. A proper mechanism should be established to protect the rights of marginalized or vulnerable groups of patients in addition to the general rights of patients.

Considering the lagging of proper adoption, implementation and enforcement of patients' rights in the country, even the judiciary can bring certain guidelines considering the comprehensive protection of patients' rights across India.

BIBLIOGRAPHY

Articles

Alex Mold, *Patients´ Rights and the National Health Service in Britain, 1960s–1980s*, 102 AM. J. PUBLIC HEALTH 2030 (2012)

Amar Jesani, *Medical Ethics and Patients' Rights*, 54 INDIAN J. SOC. WORK 173 (1993)

Amartish Kaur, *Protection Of Human Rights In India: A Review,* 2 JAMIA L. J. 22 (2017)

Cecilia Nardini, *The ethics of clinical trials,* (accessed on June 04, 2021, 12.47PM), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3894239/

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)

Daniel Wechter & Donna Harrison, *A Second Opinion: Response to 100 Professors*, 29 ISSUES L. & MED. 147 (2014).

Don Malcolmson, *The Patient's Right to Know,* 101 J. MED. REGUL. 32 (2015).

Frank Riddick Jr., *The code of medical ethics of the American Medical Association*. 5 OCHSNER J. 6 (2003)

Furkhan Ali et al., *Consent in current psychiatric practice and research: An Indian perspective*, 6 IND. J PSYCH. 667 (2019).

Hajrija Mujovic-Zornic, *Legislation and patients' rights: some necessary remarks*, 26 MED. & L. 709 (2007).

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 (1997).

Herbert Hermans, *Patients' rights in the European Union*, 7 EUR. J. PUBLIC HEALTH 11 (1997)

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. 8 (2021)

Inder Maurya, *Medical 2nd Opinion – Trends & Challenges,* (accessed on June 06, 2021, 1.15PM), http://bwhealthcareworld.businessworld.in/article/Medical-2nd-Opinion-Trends-Challenges/29-11-2019-179592/

Jacob P. Olejarczyk & Michael Young, *Patient Rights And Ethics* (accessed on March 18, 2021, 03.02 PM), https://www.ncbi.nlm.nih.gov/books/NBK538279/

Jonathan Cohen & Tamar Ezer, *Human Rights in Patient Care: A Theoretical and Practice Framework*, 15 HEALTH & HUM. Rts. 7 (2013)

Joshua G. Rivenbark & Mathieu Ichou, *Discrimination in healthcare as a barrier to care: experiences of socially disadvantaged populations in France from a nationally representative survey,* (accessed on June 08, 2021, 11.45 PM), https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-019-8124-z

Krisna Handayani et al., *Global Problem of Hospital Detention Practices*, 9 INT. J. HEALTH POLICY MANAG. 319 (2020)

Maiti, Rituparna et al., *Essential Medicines: An Indian Perspective*. 40 INDIAN J. COMMUNITY MED. 223 (2015).

Malwina Anna Wojcik, *The Origins of Patients' Rights in Cross-Border Healthcare: Balancing the Individual and Collective Right to Health*, 7 PENN UNDERGRADUATE L.J. 102 (2019).

Maya Peled-Raz, *Human rights in patient care and public health—a common ground,* (accessed on July 03, 2021, 08.52 PM), https://publichealthreviews.biomedcentral.com/articles/10.1186/s40985-017-0075-2

Melanie Silver, *Patients' rights in England and the United States of America: The Patient's Charter and the New Jersey Patient Bill of Rights: a comparison,* 23 J. MED. ETHICS 213 (1997)

Michael Paasche-Orlow et al., *National survey of patients' bill of rights statutes*, 24 J GEN INTERN MED. 489 (2009)

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)

Mukesh Yadav & Pooja Rastogi, *Patient Safety due to Administrative Negligence: Neglected Area in India?,* 1 ANN. OF INT. MED. & DEN. RES. 72 (2015)

Nomal Chandra Borah, *Doctors' dilemma and patients' right to second medical opinion,* (accessed on June 05, 2021, 8.45 PM), https://health.economictimes.indiatimes.com/health-files/doctors-dilemma-and-patients-right-to-second-medical-opinion/676

Omprakash Nandimath, *Consent and medical treatment: The legal paradigm in India*, 25 IND. J. UROL. 343 (2009).

Ravindra Ghooi & Shailesh Deshpande, *Patients' rights in India: an ethical perspective*, 9 INDIAN J. MED. ETHICS 277 (2012)

Sara Heath, *Why Patient Education is Vital for Engagement, Better Outcomes, (*accessed on June 14, 2021, 08.22 PM), https://patientengagementhit.com/news/why-patient-education-is-vital-for-engagement-better-outcomes

Simone Vigod et al*., Privacy of patients' information in hospital lifts: observational study,* 327 B.M.J. 1024 (2003).

Thomas Joseph, *Medical records and issues in negligence*, 25 IND. J. UROL. 384 (2009).

Upasana Agrawal et al., *Awareness of Patients' Rights among Inpatients of a Tertiary Care Teaching Hospital- A Cross-sectional Study,* 11 J. CLIN. & DIAGN. RES. 1 (2017)

Veeresh V.G., *Patient Bill of Rights and Responsibilities*, 4 A.J.N.E.R 376 (2014)

Books

DIETER GIESEN, INTERNATIONAL MEDICAL MALPRACTICE LAW (1988)

IAN KENNEDY & ANDREW GRUBB, PRINCIPLES OF MEDICAL LAW (2000)

LISA YOUNT, PATIENTS' RIGHTS IN THE AGE OF MANAGED HEALTH CARE (2001)

NANDITA ADHIKARI, LAW & MEDICINE (2017)

TAMAR EZER ET AL., HUMAN RIGHTS IN PATIENT CARE: A PRACTITIONER GUIDE (2012)

TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS (2001)

Reports

The selection and use of essential medicines, Report of the WHO Expert Committee, 2002

The use of essential drugs: Report of a WHO expert committee, Geneva: WHO, 2000.

The rational use of drugs: Report, Geneva: WHO, 1987

The selection of essential drugs, Report of a WHO expert committee, Geneva: WHO, 1977.

Websites

Clinical Establishments (Registration and Regulation) Act, 2010, MoHFW, http://www.clinicalestablishments.gov.in/cms/Home.aspx (accessed on May 20, 2021, 8.05 AM)

Clinical Establishments (Registration and Regulation) Act, 2010, MoHFW, http://clinicalestablishments.gov.in/En/1068-standard-treatment-guidelines.aspx (accessed on May 20, 2021, 8.15 AM)

Consumer Rights – Department of Consumer Affairs, https://consumeraffairs.nic.in/organisation-and-units/division/consumer-protection-unit/consumer-rights (accessed on May 22, 2021, 2.05 PM)

NABH patients charter, https://nabh.co/Images/pdf/Patient_Charter-DMAI_NABH.pdf (accessed on May 24, 2021, 8.55 PM)

BWHEALTHCAREWORLD, http://bwhealthcareworld.businessworld.in/article/Medical-2nd-Opinion-Trends-Challenges/29-11-2019-179592/ (accessed on May 28, 2021, 7.07 PM)

Healthworld.com, https://health.economictimes.indiatimes.com/health-files/doctors-dilemma-and-patients-right-to-second-medical-opinion/676 (accessed on May 28, 2021, 8.02 PM)

US Pharmacopeia, https://www.usp.org/news/indian-pharmacopoeia-commission-and-us-pharmacopeial-convention-partner-strengthen-quality-medicines-and-public-health (accessed on May 30, 2021, 10.36 PM)

National Health Mission – Rural, http://www.nhm.gov.in/index1.php?lang=1&level=2&sublinkid=971&lid=154 (accessed on June 01, 2021, 6.25 PM)

National Health Mission – Urban, http://www.nhm.gov.in/index1.php?lang=1&level=1&sublinkid=970&lid=137 (accessed on June 01, 2021, 6.36 PM)

WHO Referral Notes, https://www.who.int/management/Referralnotes.doc (accessed on June 03, 2021, 8.33 PM)

Hospitals Can't Detain Patients Over Unpaid Bills, Each Citizen Must Know This: Bombay HC, https://www.news18.com/news/india/detaining-patients-for-unpaid-billsis-illegal-bombay-high-court-1630805.html (accessed on June 05, 2021, 9.08 PM)

Can hospitals detain patients for unpaid bills?, https://timesofindia.indiatimes.com/india/can-hospitals-detain-patients-for-unpaid-bills/articleshow/76402589.cms accessed on June 05, 2021, 11.57 PM)

Hospital 'detains' newborn as parents fail to pay bill, https://www.thehindu.com/news/

national/other-states/hospital-detains-newborn-as-parents-fail-to-pay-bill/article7653045.ece accessed on June 06, 2021, 12.40 PM)

Kenyan Journalist Detained In India Over Hospital Bills, https://www.ghettoradio.co.ke/kenyanjournalist-detained-in-india-over-hospital-bills/ (accessed on June 06, 2021, 01.20 PM)

Minutes of the 11th Meeting of National Council for Clinical Establishments dated 13.07.2018 http://www.clinicalestablishments.gov.in/WriteReadData/7961.pdf (accessed on August 02, 2021, 4.55 PM)

Letter Issued by MoHFW Government of India to all States/UTs for adoption of Dos and Don'ts of Patient Rights and Responsibilities dated 02.06.2019 http://www.clinicalestablishments.gov.in/WriteReadData/9901.pdf (accessed on August 02, 2021, 6.05 PM)

What are human rights?, https://www.ohchr.org/en/issues/pages/whatarehumanrights.aspx (accessed on August 03, 2021, 1.53 PM)

Human rights and health, https://www.who.int/news-room/fact-sheets/detail/human-rights-and-health (accessed on August 20, 2021, 2.38 PM)

World Medical Association, https://www.wma.net/who-we-are/about-us/ (accessed on August 25, 2021, 2.05 PM)

European directive on patients' rights https://www.cleiss.fr/docs/directive_en.html (accessed on August 28, 2021, 3.15 PM)

AMA Code of Medical Ethics https://www.ama-assn.org/delivering-care/ethics/code-medical-ethics-overview (accessed on August 31, 2021, 4.12 PM)

CMS.gov: Affordable Care Act's New Patient's Bill of Rights https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca-new-patients-bill-of-rights#ftn1 (accessed on August 31, 2021, 9.19 PM)

The Affordable Care Act: A Working Guide for Maternal and Child Health Professionals http://www.amchp.org/Transformation-Station/Documents/ACA3-patient-bill-of-rights.pdf (accessed August 31, 2021, 9.36 PM)

Covid-19 in India: Patients struggle at home as hospitals choke, https://www.bbc.com/news/world-asia-india-56882167 (accessed on September 30, 2021, 12.06 AM)

India coronavirus: Desperate Covid-19 patients turn to black market for drugs, https://www.bbc.com/news/world-asia-india-56757405 (accessed on September 30, 2021, 12.11 AM)

Kerala: 'Hospitals can't detain dead body over bill', http://timesofindia.indiatimes.com/articleshow/82513231.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst (accessed on September 30, 2021, 12.22 AM)

Statutes / Rules / Regulations

Clinical Establishments (Registration and Regulation) Act, 2010

Clinical Establishments (Central Government) Rules, 2012

Consumer Protection Act, 1986

Consumer Protection Act, 2019

Disaster Management Act, 2005

Drugs and Cosmetics Act, 1940

Drugs and Cosmetics Rules, 1945

Essential Commodities Act, 1955

Indian Medical Council Act, 1956

Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002

Indian Penal Code, 1860

Kerala Clinical Establishments (Registration and Regulation) Act, 2018

New Drugs and Clinical Trials Rules, 2019

Protection of Human Rights Act, 1993

Right To Information Act, 2005

West Bengal Clinical Establishments (Registration, Regulation and Transparency) Act, 2017

International Conventions / Agreements / Declarations / Codes

African Charter on Human and Peoples' Rights, 2005

Charter of Fundamental Rights of the European Union, 2000

Constitution of the World Health Organisation, 1946

Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, 1987

Convention on the Elimination of All Forms of Discrimination against Women, 1979

Convention on the Rights of Persons with Disabilities, 2006

Convention on the Rights of the Child, 1989

European Convention of Human Rights and Biomedicine, 1997

European Convention on the Protection of Human Rights and Fundamental Freedoms, 1950

European Social Charter, 1961

Helsinki Declaration, 1964

International Covenant on Economic, Social and Cultural Rights, 1966

International Covenant on Civil and Political Rights, 1966

International Convention on the Elimination of All Forms of Racial Discrimination, 1965

International Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families, 1990

Nuremberg Code, 1947

Universal Declaration of Human Rights, 1948

WMA Declaration of Lisbon on the Rights of Patient, 1981

World Health Organisation Declaration on the Promotion of Patients' Rights in Europe, 1994

APPENDIX

THE NATIONAL UNIVERSITY OF ADVANCED LEGAL STUDIES

Kalamassery, Kochi – 683 503, Kerala, India

CERTIFICATE ON PLAGIARISM CHECK

1.	Name of the Candidate	K S AKSHAY MOHAN
2.	Title of Thesis/Dissertation	RIGHTS OF PATIENTS IN INDIA : AN ANALYSIS
3.	Name of the Supervisor	Mr. Abhayachandran K (Assistant Professor, NUALS)
4.	Similar Content Identified (%)	
5.	Acceptable Maximum Limit (%)	
6.	Software Used	
7.	Date of Verification	

**Report on plagiarism check, specifying included/excluded items with % of similarityto be attached in the Appendix*

Checked By (Name, Designation & Signature) :

Name and Signature of the Candidate : K S Akshay Mohan

Name & Signature of the Supervisor : Mr. Abhayachandran K.