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DATA PROTECTION IN HEALTHCARE SECTOR: A COMPARATIVE STUDY ON PATIENT PRIVACY

Under the Guidance and Supervision of

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CERTIFICATE

This is to certify that **Mr T S BHARATH KRISHNA, REG NO: LM0119020** has submitted his Dissertation titled "**DATA PROTECTION IN HEALTHCARE SECTOR: A COMPARATIVE STUDY ON PATIENT PRIVACY**" in partial fulfilment of the requirement for the award of Degree of Masters of Laws in Constitutional Law and Administrative 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.

Ms. Nandita Narayan

Guide and Supervisor

NUALS, Kochi

Date: 8/10/2020

Place: Ernakulam

DECLARATION

I declare that this Dissertation titled "**Data Protection in Healthcare Sector: A Comparative Study on Patient Privacy**" is researched and submitted by me to the National University of Advanced Legal Studies, Kochi in partial fulfilment of the requirement for the award of Degree of Master of Laws in Constitutional Law and Administrative Law, under the guidance and supervision of Ms Nandita Narayan, Assistant Professor and is an original, bona fide and legitimate work and it has been pursued for an academic interest. This work or any type thereof has not been submitted by me or anyone else for the award of another degree of either this University or any other University.

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PREFACE

"It is health that is real wealth and not pieces of gold and silver."

-Mahatma Gandhi

'The right to the highest attainable quality of health' means a specific set of legislative requirements for states to ensure that all citizens without prejudice have sufficient opportunities for the enjoyment of health.

A health strategy focused on human rights, and the preservation of the privacy of patients is a must in this modern society, and therefore it is imperative that legislations are modified in accordance with the advancements in technology and science.

The right to health is one of a number of principles of human rights that are internationally agreed and is inseparable or 'indivisible' from these other rights. This means that the realisation of other human rights, including food, housing, employment, education, knowledge and participation, is both fundamental and contingent on achieving the right to health.

The importance of patient data and the analysis of care and treatment given is essential, but confidentiality of patient is of utmost importance as it is directly attached to the patient's fundamental rights such as the right to life, liberty and Privacy.

There can be severe health implications of abuses or lack of commitment to human rights. Overt or implicit prejudice in the delivery of health services serves as a strong obstacle to health services, both within the health sector and between health workers and service users, and leads to low-quality care

ABBREVIATIONS

DISHA	Digital Information Security in Healthcare Act
NEHA	National Electronic Health Authority of India
EHRs	Electronic Health Record Standards
ICCPR	International Covenant on Civil and Political Rights
ICESCR	International Covenant on Economic Social and Cultural Rights
ECHR	European Convention on Human Rights
UDHR	Universal Declaration of Human Rights
ECHRB	European Convention on Human Rights and Biomedicine
CPR	Cardiopulmonary Resuscitation
DPSP	Directive Principles of State Policy
DNR	Do Not Resuscitate
NHRC	National Human Rights Commission
PVS	Permanent Vegetative State
HIPPA	Health Insurance Portability and Accountability Act
ICMR	Indian Council of Medical Research
IRFA	Indian Research Fund Association
RBI	Reserve Bank of India
IPCC	International Consortium for Pharmaceutical Privacy
IDRA	Insurance Regulatory and Development Authority
TPAs	Third-Party Administrators
FCNM	Framework Convention for Protection of National Minorities
ACHPR	African Commission on Human and Peoples Rights
ICERD	International Convention on The Elimination of All Forms of Racial Discrimination

CRPD	Convention on The Right of Persons with Disabilities
CEDAW	Convention on The Elimination of All Forms of Discrimination Against Women
ESC	European Society of Cardiology
SCC	Supreme Court Cases
AIR	All India Reporter
ACHPR	African Commission on Human and People's Rights
IT	Information and technology
MTP	The Medical Termination of Pregnancy Act
CDIT	Centre for Development of Imaging Technology
MCI	The Medical Council of India
DCGI	Drugs Controller General of India

LIST OF CASES

- Consumer Education and Research Centre V. Union of India (1995 SCC (3) 42)
- State of Punjab V. Mohinder Singh ((1983) 2 SCC 274)
- Bandhua Mukti Morcha V. Union of India (1984 AIR 802)
- C.E.S.C. Limited V. Subhas Chandra Bose (1992 AIR 573)
- Samira Kohli vs Dr Prabha Manchanda (AIR 2008 SC 138)
- I V. Finland (Application No. 20511/03)
- R V. Health Department, Ex P Source Informatics (1999 EWHC 510)
- Aruna Ramachandra Shanbaug V Union of India ((2011) 4 SCC 454)
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- Common Services Agency V. Scottish Information Commissioner ((2008) UKHL 47)
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- Mr `X' V. Hospital 'Z' (1998 Supp (1) SCR 723)
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- Sorrel V. IMS Health Inc (564 U.S. 552)
- IMS Health V. Ayott (07-1945 (1st Cir. Nov. 18, 2008)
- Govind V. State of Madhya Pradesh (1975 AIR 1378)
- Yepthomi V. Apollo Hospital Enterprises Ltd (AIR 1963 SC 1295)
- Selvi V. State of Karnataka (2010) 7 SCC 263)
- People's Union for Civil Liberties v. Union of India (1997 1 SCC 301)
- ESC Ltd v. Subhash Chandra Bose (1992 1 SCC 441 at 462)
- Paschim Banga Khet Mazdoor Samity v. State of West Bengal (AIR 1996 SC 2426 at 2429 para 9)
- State of Punjab v. Ram Lubhaya Bagga (1998 4 SCC 117)
- Sheela Barse v. Union of India (1986 3 SCC 596)
- Mehta v. Union of India (1987 4 SCC 463)

- MC Mehta v. Union of India (1999 6 SCC 12)
- Vincent v. Union of India (AIR 1987 SC 990)
- Vikram v. State of Bihar (AIR 1988 SC 1782)
- Death of 25 Chained Inmates in Asylum Fire in TN In re v. Union of India (2002 3 SCC 31)
- S. Mittal v. State of UP (AIR 1989 SC 1570).
- Parmanand Kataria v. Union of India (1989 4 SCC 286).
- S. Lal v. State of Bihar (1994 SCC [Cri] 506).
- Consumer Education and Research Centre v. Union of India (1995 3 SCC 42)
- Common Cause v. Union of India and Others (AIR 1996 SC 929)
- Murli S Deora v. Union of India (20018 SCC 765)
- Roe v. Wade, 410 U.S. 113 (1973)
- Suchita Srivastava & Anr. V. Chandigarh Administration (2009) 9 SCC 1
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1 CHAPTER 1 – INTRODUCTION

1.1 PRIVACY

Privacy is a persons or group's right to isolate themselves or knowledge about themselves and thus selectively express oneself. It generally means that when something is personal to a person, that something is inherently unique or precious to them. The right to privacy has not been widely acknowledged to this day. It is a term that is continually changing, and whose nature and extent depend primarily on the context which it is considered. The privacy domain significantly overlaps with security, which can include the principles of adequate usage as well as data security. Privacy can take the form of bodily integrity as well. In terms of the sense in which it is exercised, the right to privacy has different aspects, each distinct from the other. However, bodily privacy is the most protected aspect as the right to protect one's own body, including the organs, genetic material, and biological functions make up one 's health[1].

A patient has the right to proper healthcare and the right to privacy is an integral part of patient rights, and the current trend in society along with existing laws and legislations need to be analysed in this regard. Respecting the patient's privacy is important, and the fact that a patient is entitled to use health services in a way that is consistent with his personal values.

The right not to be subject by the government, companies or individuals to unlawful invasions of privacy is part of the privacy laws of many countries and, in some circumstances, constitutions. In a variety of domestic law, privacy regarding the healthcare system is used mainly in the sense of the framework of the fiduciary relationship between a doctor and a patient. This relationship stems from a rational assumption of mutual confidence between a doctor and his patient and is defined and sets out the code of ethics to which a doctor must at all times adhere by. [2] Privacy and confidentiality are essential to all trusting relationships, such as those between patients and doctors. In fact, patient confidentiality and preservation of privacy are the cornerstones of the relationship between doctor and patient in a healthcare setting. Patients need to feel confident exchanging private details about their body functions,

[1] M SRIDHAR ACHARYULU, PRIVACY AS SECRECY 153 VOL 1 Asia law house, 2018.
[2]H.Nissenbaum, *Privacy As Contextual Integrity,* 101-139, Washington Law Review, 79(1), (2004).

physical and sexual habits, and medical history. Healthcare workers need to collect, process, store, retrieve, and distribute clinical, administrative, and financial health details. Healthcare is a highly information-intensive sector[3]. The unfortunate aspect of robust data flows is the inherent problem of information misuse, disclosure of confidential information and the risk of breaches of privacy [4].

Healthcare privacy encompasses a range of things, but not limited to[5]

- Informational privacy (Confidentiality, Anonymity, Secrecy, and Data Security)
- Proprietary privacy (self-ownership and control over personal identifiers, genetic data, and body tissues)
- Decisional privacy (autonomy and choice in medical decision-making)

Confidentiality means securing patients' confidential knowledge. It demands that the confidential information collected from patients be safe and protected with health care officials. It is absolutely important to protect the confidentiality of patients as a requirement not only of the doctor's professional conduct but also of the moral duty and mandate of the constitution with impunity[6]. The duty to maintain confidentiality originates from the Hippocratic oath, an ethical code attributed to the ancient Greek physician Hippocrates, which was adopted as a guide for the medical profession throughout the ages. The oath is composed of two sections. The first is the apprentice/teacher relationship, and the second part is an ethical code. It is on this basis that the Universal Code of Medical Ethics stipulated that "A physician shall maintain absolute confidentiality of everything that he knows about his patients even after he's died". The Medical Council of India notes that it will not reveal the secrets of a patient acquired in the practice of the profession and it can only be revealed in front of a presiding judge in the court of law.[7]

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[3] ADAM CARLYLE BRECKENRIDGE, THE RIGHT TO PRIVACY, 152, Lincoln: University of Nebraska Press, 1970.

[4]Mishra, N., Parker, L, Nimgaonkar, V, & Deshpande S, *Indian Journal Of Medical Ethics*, 5(4), 158-161, (2008).

[5]Allen, Anita, *Privacy And Medicine*, THE STANFORD ENCYCLOPAEDIA OF PHILOSOPHY (Aug,15,2020 10:15) https://plato.stanford.edu/archives/win2016/entries/privacy-medicine/.

[6]Plaza, J., & Fischbach, R. (N.D*.). Current Issues In Research Ethics : Privacy And Confidentiality*, (December 5, 2020,10:15), http://ccnmtl.columbia.edu/projects/cire/pac/foundation/index.htm.

[7]Vishal K Vora, *Fight Between Right To Privacy And Right To Know*, 34, University of Florida, Levin College of Law, USA,2017.

Patient care is a protected and essential part of the right to health which deserves attention and scrutiny as a human rights issue. There is a vast and severe number of human rights abuses in the field of patient care, which violate not only the right to health but also many civil and political rights. Across specific settings, patients and health care providers are faced with a range of abuses that threaten fundamental human integrity and endanger health consequences, rather than the requisite compassionate and adequate health care. Such abuses vary from inevitable breaches of patient rights to informed consent, confidentiality, protection and non-discrimination to more serious abuses, such as violence, cruel, inhuman and degrading behaviour. Health care providers can also be faced with abuses such as dangerous working conditions, fines for offering evidence-based health care, limitations on their freedom of association and lack of due process if patients complain against them.[8]

1.2 DATA PROTECTION

Data are characteristics or data, typically numerical, gathered through observation.[9] Data is, in a more technical context, a collection of values of qualitative or quantitative variables for one or more persons or objects, while a single value of a single variable is a date (singular data)[10]. These terms have distinct meanings, although the terms "data" and "information" are sometimes used interchangeably. In some common journals, when presented in context or post-analysis, data is often said to be converted into information.

Data protection is present in all spectrums, but in respect to healthcare, it is at a bare minimum in countries like India when compared to countries like the UK, US and EU. The right to privacy in India has taken multiple turns. However, by acknowledging the Right to Privacy as a fundamental right, India has joined the US, UK, EU, Canada and many others in realizing the importance that privacy holds in this modern-day and age. But there is a stark contrast between the legislation regarding data protection of these countries and that of India. Countries such as the US have comprehensive legislation regarding the protection of privacy and patient data.

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[8]Jonathan Cohen And Tamar Ezer, *Human Rights In Patient Care: A Theoretical And Practical Framework*, 82-85, , University of Florida, Levin College of Law, USA,2017.
[9]RESEARCH WILLIAM W LOWRANCE, PRIVACY CONFIDENTIALITY, AND HEALTH, Cambridge University Press, 2012
[10]*Id.*

The importance of patient data and the analysis of care and treatment given is essential, but confidentiality of patient is of utmost importance as it is directly attached to the patient's fundamental rights such as the right to life, liberty and Privacy. Therefore, supplying information to patients is subject to individual confidentiality and is specific from patient to patient. As of now, India has no clear legislation in this regard, and it relies on the IT Act, 2000, which describes personal information in general and provides for some degree of privacy but does not clarify the rights in detail or has no penalties for the breaches. It provides for consent clause; however, does not explain the ownership clearly. The Indian Judiciary has proclaimed the "right to privacy" to be a constitutional right, but there is still no proper set of laws to avoid the violation of the individual privacy of the patient.

1.3 BREACH OF PRIVACY AND CONFIDENTIALITY

Violations in the healthcare sector including disclosure of personal health information to third parties without consent, failure to notify a patient of a data breach, unregulated or unnecessary collection of personal health information, collection of incomplete or sufficient personal health data, failure to explain the purpose to collect data, refusal to report medical information to patients on request, use of personal health data for public health, study and commercial use without de-identification of data and inadequate privacy, storage and disposal standards can all be considered as a breach of privacy or confidentiality

The **Sprinklr row** is the latest privacy dispute to emerge recently. The Kerala government was accused of allegedly violating the privacy of nearly 1.75 lakh people under quarantine in the State by entering into an arrangement with a US-based tech company by the name of sprinkler to manage the data compiled from them. This was done without taking their individual consent.

Staff at the grassroots level gathered the data, including descriptions of their symptoms and underlying health conditions, using a tool created by Sprinklr to enable doctors and medical officials to make educated decisions about future hospitalizations. It was alleged that in nominating Sprinklr, the government did not obey proper protocols and thus threatened the transfer of vital health data from thousands of people to pharmaceutical firms. It questioned why a foreign company was sponsored by the

administration when institutions such as the Centre for Development of Imaging Technology (CDIT) and the Kerala State IT Mission were able to do the same job.

Providing personal health information may be embarrassing, stigmatizing or discriminatory. Furthermore, if the flow of medical knowledge was not restricted, various factors, such as employment, life and health insurance, might be placed at risk[11].

However, there are certain situations where, for example, disclosure of personal health information is allowed[12]:

- Referral,
- By order of The Court or By the Police on A Written Requisition,
- For Insurance Companies, As Provided by The Insurance Act When the Patient Has Relinquished His Rights on Taking the Insurance, And
- For Specific Provisions of Workmen's Compensation Cases, Consumer Protection Cases, or for Income Tax Authorities[13],
- Disease Registration,
- Communicable Disease Investigations,
- Vaccination Studies,
- Drug Adverse Event Reporting.

Privacy and confidentiality must be respected but several existing methods and regulations are ineffective in matters of consent, identification, protection and data transfer and biospecimens. Laws related to clinical research are also not enough in the current pace of development of medical science around the globe. Specific ethical standards must be maintained at all times and laws for maintaining it as such must also be formulated, taking into consideration the latest developments in the medical field.

To understand the existing privacy protection system in the form of laws, we must understand the regulations, and guidelines and compare them with ongoing practices in government and other private hospitals and diagnostic laboratories to find out whether these are effective in meeting the required protection of privacy. Further, this study will take a look at international practices relating to the protection of privacy and then offers

[11] Nissenbaum H, *Privacy As Contextual Integrity*,101-139, 79(1), 2004, Washington Law Review.
[12] *Id.*
[13] Thomas, J, *Medical Records And Issues In Negligence*, 384 IJU 25(3) 388 (2009).

recommendations to create better mechanisms to determine the limits of unnecessary intrusions on the privacy of patients. Throughout this dissertation, in the following chapters, the author will try to address the following issues

- Whether existing privacy protection system in the health care sector is adequate and to find out the data protection norms and safeguards of Clinical Establishments and study if they are adequate enough in the present global scenario
- To address the lack of clarity about how to deal with privacy and confidentiality implications and a comparison of confidentiality aspects and laws of the USA UK and India along with the increased risk to privacy from the growth of data and biospecimen holdings, pooling and interlinking of data sets and other medical research data and if a breach of medical confidentiality should be considered as an offence and if explicit consent is always sought from patients for any use of their data apart from direct clinical care.
- A comprehensive study on the implementation of privacy regulations and patient rights regarding the healthcare sector in India and to explore the increased risk in computerization of medical records and the potential threat to the confidentiality of individual health information along with the scope of the proposed Digital Information Security in Healthcare, act (DISHA) India and the proposed National Electronic Health Authority of India (Neha)
- To study how the information collected should be restricted through the establishment of requisite safeguards at an institutional level which includes everything down to everyday practices of data collection, handling, and storage within healthcare institutions and the circumstances warranting the interference with the right to the confidentiality of the patients while exploring the various circumstances in which the patient's right to privacy and confidentiality can be interfered with which includes prevention of crime, public interest, the best interest of the patients, statutory requirements and genetic diseases.
- To understand domestic legislation relating to the healthcare sector and the specific provisions of the law that facilitate the protection of the privacy of individuals who furnish their personal information as well as genetic material to institutions of healthcare, either for the purpose of treatment or to contribute to research studies must be considered.

1.4 CHAPTERS

This dissertation consists of 5 chapters, as follows:

- The **First chapter** would be the introductory chapter and shall give a brief introduction to the topic. The aspects and issues that would be considered in this dissertation other relevant information
- The **Second chapter** analysis the importance of patient right and the privacy aspects related to patient rights and the current trend in society along with existing laws and legislations are analysed. Respecting the patient's privacy is important, and the fact that a patient is entitled to use health services in a way that is consistent with his personal values are looked into in detail in this chapter. The importance of patient data and the analysis of care and treatment given is essential, but confidentiality of patient is of utmost importance as it is directly attached to the patient's fundamental rights such as the right to life, liberty and privacy. These topics will be discussed in detail in this chapter
- The **Third chapter** discusses how medical research includes a wide variety of studies, including clinical research. It includes studies of individuals who may be participants of clinical trials and is regarded as an integral and significant part of medical research, and there are a number of ethical issues that need to be addressed in the conduct of medical research in this present day which also include the privacy aspects of research participants
- The **Fourth chapter** focuses on how the legal structures are unable to keep up with the speed of change in relation to data management in the health care sector which consists mostly of legislations designed for a pre-internet environment. It will also be a comparative study of the various legislation of the US, UK, EU and India. Various legislations in India that are proposed to be implemented will also be discussed in this chapter.
- The **Fifth chapter** shall consist of the conclusions along with any suggestions that I would have, with respect to building an effective legal framework in relation to the privacy in the health care sector.

CHAPTER 2

2 PATIENT RIGHTS

A patient is a person who is under medical care or treatment or a person or that undergoes some sort of medical procedure or is a sufferer or victim. A patient is any recipient of health care services performed by healthcare professionals. The patient is often ill or injured and in need of treatment by a physician or other health care provider. In India, the concept of patient rights and privacy has a very limited interpretation, and this aspect has not been greatly explored. The word health also has an interrelationship with issues such as ensuring a clean living environment, protections against unsafe working conditions, information about disease prevention and social security programs about illness, unemployment, sickness and injury. Over half a century's experience of waiting for the policy route to ensure healthcare, protection, and fulfilment is now behind us.

The right to healthcare is primarily a claim, a positive right and not a protective barrier[14]. When rights of entitlements are contrasted with freedoms, collective values, social responsibilities, or charitable actions, they become justified by state laws once they are legislated. Therefore, emphasis will change from ' respect ' and ' security ' in order to focus more on 'fulfil. For this to be practical, proper resources to fulfil core obligations must be made available. It must be ensured that there is no exclusion from the laws made to guarantee healthcare on any grounds including, employment status, purchasing power, age, ethnicity, caste, gender, disability, and any other basis of discrimination.[15] The purpose of this chapter is that the author intents to identify several rights under the constitution as well as provided under different statutes as well as a comparison between Indian and international perspectives. As health is one of the essential constitutional rights, it requires extra protection with the help of special legislations and laws. The main source of law in our country is the Constitution, which itself provides for health care of the people. The State is mandated by our Constitution to ensure the health and nutritional well-being of all individuals

[14]Ravi Duggal, *Operationalising Right To Healthcare In India*, The ICFAI Journal of Healthcare Law ,August 2004.
[15]*Id.*

2.1 INDIAN PERSPECTIVE

Access to health is a fundamental issue in Indian society. The responsibility for securing, upholding and honouring the right to health lies not only with the medical profession but with public officials such as administrators and judges as well. In this sense, public health care has been traditionally associated with statistical determinants such as life expectancy, mortality rates and access to new pharmaceutical products and procedures[16]. It is clear that such a definition does not express a wholesome image of all aspects of social health security and promotion. There is an apparent overlap between an individual as well as community health care and nutrition, clothes, and shelter provision.[17]

2.1.1 RIGHTS OF THE PATIENT UNDER THE CONSTITUTION OF INDIA

The preamble of the constitution of India outlines some of the fundamental values and principles that govern India's constitution. Although the preamble is deemed to be part of the Constitution and is not enforceable in a court of law but when the constitution is read in the light of the preamble and, in the majority of the judgments, the Supreme Court of India held that the principles of justice, democracy, equality and fraternity set out in the preamble as constituting the basic structure of the Constitution. The Preamble urges the State to implement steps aimed at ensuring justice, equality, upholding integrity, etc. which have a direct influence on people's health.[18]

When the right to healthcare is seen within the constitutional framework, it is clear that in no way does India's constitution provide for the right to health. In India, the right to health was evident through the various case laws decided from time to time by the Indian judiciary. Human rights are broken down into two separate parts in the Indian Constitution. Part III of the Constitution includes the ' Fundamental Rights, ' which include the right to life, the right to equality, the right to freedom of speech and expression, the right to freedom of movement, the right to freedom of religion, which can be considered civil and political rights in the modern language of human rights.[19]

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[16]Justice K.G. Balakrishnan, , *The Human Right To Health*, December 14, 2008, ,http/ supreme court of india.nic.in/speeches/speech2008.htm.
[17]K. Sharma, *Viewing Health As An Inalienable Right* , (April 10 11:00).
2020. Available At http://www.indiatogether.org/2005/oct/ksh-health.htm.
[18]N. B. SAROJINI & OTHERS, WOMEN'S RIGHT TO HEALTH, 85, New Delhi: National Human Rights Commission, 2006.

Part IV of the Constitution includes the Directive principles State Policy (DPSPs), which covers all legal, economic and cultural rights, such as the right to education, the right to live, the right to health and housing, etc. At the time of the creation of the Indian constitution, the right to health was put under the directive principles of state policy, because it was considered difficult for the makers of the constitution to explicitly implement the right to health. The supreme court, through various public interest litigations, enforced the right to health among people[20].

2.1.1.1 RIGHT TO HEALTH

Over time, the judiciary has found that the right to life under Article 21 is incomplete without the right to live with human dignity, including various other rights such as the right to education, the right to livelihood, the right to health and housing, etc.[21]

The right to health thus became part of fundamental rights and was adopted under Article 21 of the Constitution of India. The provisions, according to which the Indian Constitution defines the right to health are: Article 21 of the Indian constitution deals with the protection of life and personal liberty. It clearly states that no person shall be deprived of his life or personal liberty except in compliance with the procedure laid down by law. The object of this fundamental right under Article 21 is to avoid the violation of personal liberty and the deprivation of life, except in accordance with the procedure laid down by law. The right to life is fundamental to our very nature without which we cannot live as human beings and includes all those aspects of life that make the life of a human being significant, complete and worth living.[22]

The right to live with human dignity enshrined in Article 21 derives itself from the Directive Principles of State Policy and in particular Clauses (e) and (f) of Article 39 and Articles 41 and 42 and must therefore at least include the protection of children's health, incentives and facilities for safe, fair and humane working conditions, etc.[23] These are the minimum requirements that must exist in order to allow an individual to live with human dignity and no Government, neither the central government nor any

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[19]P Ramachandran, *Health For All*, PLANNING COMMISSION, (7thDecember 2020 12 :00)http://www.planningcommission.nic.in.

[20] Jayna Kothari, *Social Rights And The Indian Constitution*,21 LGD, Vol. 2, 23 2004.

[21]*Id.*

[22] V. Maheshwari, *India - The Expanding Horizons*, 5th January 2011. http://www.legalserviceindia.com/articles/art222.htm.

[23]Indian, Law: *Judicial Interpretation Of Article 21 Of The Indian Constitution* ,(7th December 2020 10:00), https://guide2lawyers.blogspot.com/2012/06/judicial-interpretation-of-article-21.html.

government of any State, has the right to take any action that would deprive a person of these fundamental elements[24].

- **ACCESS TO HEALTH**

According to Article 47 of the Indian Constitution, the State shall consider raising the nutritional and living standards of its citizens and improving public health as one of its primary duties and prohibit the consumption of intoxicating beverages and medicinal items that are harmful to health, except for medical purposes.[25]Nevertheless, it is not enforceable in a court of law, it may not be necessary to oblige the State, through the judicial process, to make provision by statute for ensuring this essential element, which constitutes a life of human dignity, but where laws are already enacted by the State which provides for these fundamental requirements, The State would definitely be obligated to ensure that the State's failure to comply with such legislation would lead to a violation of the right to live with human dignity[26].

The Supreme Court of India has formulated and accepted the right to health as an integral part of the right to life only since the mid-1990s compared to some of the other social rights. Recognition of the right to health has arisen from a range of different petitions and public interest litigations at the Supreme Court, ranging from PILs relating to worker's health hazards to petitions filed by individuals seeking health security rights, and incentives and facilities for children to grow in a safe, healthy and humane way, etc[27].

Since ancient times the right to healthcare has been recognised in India. It was acknowledged in various Constitutional provisions during post-independence India. Having regard to Article 19(6), public health is one of the limiting factors in relation to Article 19(1)(g) which gave all Indian citizens the right to practice any profession or to carry on any occupation, trade or business. In numerous cases, the Supreme Court and

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[24] Abhay, *Judicial Interpretation Of Article 21 Of The Indian Constitution*, (5 h January 2011 12:00). http://www.legalservicesindia.com/law/article/1105/10/Judicial-Interpretation-in-Right-to-Life-and-Personal-Liberty/.

[25] Sougata Talukdar, *Right To Health, Consumer Protection And Challenges In Health Care Services In India.* 14 vol 17 National Human Rights Commission.

[26] *Id.*

[27] Jayna Kothari, *Social Rights And The Indian Constitution*, EPW (Jan 8 2020 12 ;00). https://www.epw.in/tags/constitution-india.

the High Courts interpreted Article 21 in the light of various international instruments with a view to broadening the scope and purpose of Article 21 and effectively integrating the right to health care within Article 21 as a necessary component of the protection of life[28].

In *Sharda v. Dharmpal*[29], decided in 2003, the Supreme Court ruled that the courts could, against their will, force people to undergo medical exams. A man applied for divorce in this case on the grounds that his wife was suffering from a mental disorder. He asked the court to direct his wife to submit herself to a medical examination in order to build his case. His appeal was both granted by the trial court and the high court. On appeal to the Supreme Court, the woman challenged the order on the basis, first, that it would be contrary to her right to personal liberty, guaranteed under Article 21 of the Constitution, to oblige a person to undergo a medical examination by order of a court. Secondly, a court dealing with marriage cases cannot, in the absence of a clear empowering clause, subject a party to medical examination against its will. An adverse inference may simply be drawn by the court. These claims were dismissed by the Supreme Court, holding that the right to privacy in India was not absolute.

India is a party to the International Covenant Civil and Political Rights and to the International Covenant for Economic, Social and Cultural Rights. The Supreme Court held that Article 21 of the Constitution of India must be read in accordance with international law in relation to human rights [30]. Furthermore, the Supreme Court cited Article 25(2) of the Universal Declaration of Human Rights and Article 7(b) of the International Covenant on Economic, Social and Cultural Rights when upholding a worker's right to health [31].

These covenants find statutory acceptance in the Statement of Objects and Reasons of The Protection of Human Rights Act, 1993. In addition, human rights commissions are allowed to review human rights treaties and other international instruments and make recommendations to enforce them effectively[32]. In the recent past, several complaints have been filed with the national or State Human Rights Commissions regarding alleged medical negligence and inadequate treatment by private and government

[28]Francis Coralie Mullin V. The Administration, Union Territory Of Delhi, AIR 1981 SC 746 (India).
[29]Sharda v. Dharmpal ,2003 4 SCC 493.
[30]People's Union for Civil Liberties v. Union of India ,1997 1 SCC 301(India).
[31]ESC Ltd v. Subhash Chandra Bose, 1992 1 SCC 441 at 462 (India).
[32]The Protection of Human Rights Act, 1993, Chapter III, Section 12 (f).

hospitals and medical professionals. The Constitution contains clauses guaranteeing the right of citizens to the highest physical and mental health level attainable. Article 21 of the Constitution guarantees every individual the protection of life and personal liberty. The Supreme Court held that the right to a life of human dignity, enshrined in Article 21, is derived from the values of the directive principles of state policy and also involves the guarantee of health. In addition, the right to health is an integral part of the right to life, and the government has a statutory responsibility to provide healthcare facilities. Further, in *State of Punjab v. Mohinder Singh*,[33] the Supreme Court ruled that the right to health is now a settled law and is an integral part of the right to life.

If a government hospital fails to provide a patient with timely medical care, the patient's right to health is violated and then his right to life is violated as *in Paschim Banga Khet Mazdoor Samity v. State of West Bengal*[34]. Likewise, the Court has upheld the responsibility of the State to provide health care facilities in *State of Punjab v. Ram Lubhaya Bagga*[35]. In addition to violations of the right to health, public interest petitions have been filed pursuant to Article 21. They were applied for special care for children in prison *in Sheela Barse v. Union of India*[36] and against hazardous drugs in *Vincent v. Union of India*[37]; against inhuman conditions in after-care homes in *Vikram v. State of Bihar*[38].

The supreme court ruled on the health rights of mentally ill patients, *TN In re v. Union of India*[39]which resulted in the death of 25 chained inmates. The rights of patients in cataract surgery camps in *S. Mittal v. State of UP*[40] and for immediate medical aid to injured persons in *Parmanand Kataria v. Union of India*[41] and about conditions in tuberculosis hospitals in *S. Lal v. State of Bihar*[42]; The regulation of blood banks and availability of blood products in *Common Cause v. Union of India* and Others[43].

[33]State of Punjab v. Mohinder Singh ,AIR 1997 SC 1225.
[34]Paschim Banga Khet Mazdoor Samity v. State of West Bengal , AIR 1996 SC 2426 at 2429 para 9.
[35]State of Punjab v. Ram Lubhaya Bagga ,1998 4 SCC 117.
[36]Sheela Barse v. Union of India ,1986 3 SCC 596.
[37]Vincent v. Union of India**,** AIR 1987 SC 990.
[38]TN In re v. Union of India**,** AIR 1988 SC 1782
[39]TN In re v. Union of India**,** 2002 3 SCC 31.
[40]S. Mittal v. State of UP ,AIR 1989 SC 1570.
[41]Parmanand Kataria v. Union of India ,1989 4 SCC 286.
[42]S. Lal v. State of Bihar**,** 1994 SCC [Cri] 506.
[43]Common Cause v. Union of India and Others, AIR 1996 SC 929.

In *Consumer Education and Research Centre v. Union of India*[44], the Supreme Court held that according to Articles 39(e), 41, 43, 48A, the right to health, medical assistance to protect health and vigour of worker while on duty or after retirement is a fundamental right, and this recognition would help to make the life of the worker meaningful and meaningful enough for society.

In *Bandhua Mukti Morcha v. Union of India*[45], the Supreme Court observed that the right to live with human dignity enshrined in Article 21 derives its existence- from the directive principles of state policy and, in particular, Article 39(e) and (f) and Articles 41 and 42 and must, therefore, include at least the protection of the health and strength of workers, men and women and of the tender age of children against abuse, and there must be opportunities and facilities for children to develop in a healthy manner. These are the minimum requirements that must exist in order to allow an individual to live with human dignity, and no government of any State nor the central government has the right to take any action that will deprive a person of the enjoyment of these essential elements.

In *C.E.S.C Limited v. Subhas Chandra Bose*[46], by referring to the Universal Declaration of Human Rights and the International Covenant on Economic, Social and Cultural Rights, the Apex Court held that the right to medical care is a fundamental right.

2.1.1.2 RIGHT TO PRIVACY AND CONFIDENTIALITY

Respecting the patient's privacy is important. The patient is entitled to use health services in a way that is consistent with his personal values. The confidentiality and privacy of the patient and his family cannot be infringed except in situations established by law or where medical intervention is required to save a life. The patient can expressly request that his privacy be protected. All medical procedures must be conducted in a way that does not compromise the patient's confidentiality. Likewise, examination, diagnosis and treatment procedures must be performed as confidentially as is reasonably expected.[47]

[44]Consumer Education and Research Centre v. Union of India, AIR 1995 SC 922.
[45]Bandhua Mukti Morcha v. Union of India, (1984) 3 SCC 161.
[46]C.E.S.C Limited v. Subhas Chandra Bose, AIR 1992 SC 573.
[47]BMJ, *Israel Rules On Medical Confidentiality*, BMJ, 1120 Vol. 312, No. 7039 (1996).

Unless it is medically indicated there must be no interference with the personal and family life of the patient and Unless clinically contraindicated, the patient must be allowed to have someone close to him with him. Those who are not involved in treatment should not be involved in medical interventions[48]

It is a complicated matter to disclose information gathered by a doctor during the patient's assessment and examination or after laboratory tests. Giving information to a patient is not usually a problem, but it is almost always problematic to give information to the family or an unknown third party. The widespread misunderstanding is partly because there are two distinct ways of looking at the problem that doctors fail to realize, they are the legal angle and the medical ethics-based angle.

- **The Legal Perspective**

Torts law deal with the issue of slander and libel. Many people are protected or privileged in some cases. There may be an absolute or qualified privilege. There is an absolute privilege in parliament hearings, state legislatures, the army and the navy. For example, a member of the Parliament cannot be sued in a court of law for a defamatory statement about another member. It is possible for medical practitioners, bishops and others to claim what is called qualified privilege[49]. The critical justifications for claiming these rights are the absence of malice and the protection of society or an individual in particular. Only during a court hearing of the case can a claim for qualified privilege be accepted or denied, while absolute privilege prevents even the initiation of a lawsuit.

- **The Medical Perspective**

Medical practitioners have been taught for a long time that they should never disclose to another person what they learn about their patients. In fact, it is on this understanding that the patient places complete trust in the doctor, telling him personal issues that he may not tell others. This is a precondition to proper diagnosis and treatment. It is also the basis of the relationship between doctor and patient. This formulates the code of medical ethics accordingly. The code has no legal status, however. Doctors also give a

[48]Institute of Medicine. ,*Health Data in the Information Age: Use, Disclosure, and Privacy. Washington, DC*: The National Academies Press , 1994.
[49]Patrick Callioni, *Privacy & Health Care: Reconciling the Irreconcilable, AQ* , pp. 15-20, 40. Vol. 74, No. 5 (Sep. - Oct., 2002), Australian Quarterly.

great deal of respect to the term ethics. The problem arises when the doctor seeks to comply with the ethics code as he knows it, performing his duties to the community's broader interests without paying attention to the law of the land. In the way of maintaining the confidentiality of information between patient and doctor, not only the legal provisions but the moral obligation of the physician to act in society's broader interests often puts him/her in a dilemma[50]

In *Mr X v. Hospital Z*,[51] The Delhi High Court examined whether a foetus had a 'right to privacy' or whether the foetus's mother might claim on her behalf a right to privacy. A woman had given birth to a still-born child, and the All India Institute of Medical Sciences had preserved tissues from the foetus. Her husband approached them to obtain an order to carry out a DNA test to decide if he was the father. The woman asserted in her defence that this would offend her right to privacy. The high court reaffirmed the guidelines set out in the case of Gautam Kundu and also upheld the right of the petitioner to privacy over her own body. The court, however, took the stand that she did not have a right to privacy over the foetus until it was discharged from her body, so when a foetus was retained at the All India Institute of Medical Science, the petitioner, who had already discharged could not assert that it impaired her right to privacy.

If, however, the plaintiff was required to perform a blood test or otherwise, she could still raise protection that in a criminal case she could not be required to be a witness against herself or forced to provide proof against herself or in a civil case, but the situation herein is different. The petitioner is not obligated to conduct any such act. Anything that she herself has possibly discharged with her permission is said to be subject to DNA checking. In that view of the case, it cannot be considered that the plaintiff has the right to privacy in the peculiar evidence.[52]"

In *Shri Rohit Shekhar vs Shri Narayan Dutt*[53] Contrary to the pattern in the previous cases, it was the biological father who pleaded his right to privacy in this case that was called on the Delhi High to decide whether a man had the right to subject the

[50]JM Watw*, Disclosure of confidential medical information* , , 6(2):56-57, 01 Apr 1998, Issues in Medical Ethics.
[51]*Mr X v. Hospital Z* , 1998 8 SCC 296.
[52]The Centre for Internet and Society, *Limits to Privacy*. https://cis-india.org/internet-governance/blog/privacy/limits-to-privacy.
[53]Shri Rohit Shekhar vs Shri Narayan Dutta, LQ 2009 HC 8510.

person he identified as his biological father to a DNA test. The court relied on international agreements to confirm, regardless of its legality, the "right of the child to the kin of her biological antecedents. The court ruled that the essential interest of the child is, of course, not to be labelled invalid, but the conclusiveness of the assumption generated by the law in this regard must not be against the child's interests. If the child's interests are better sub-served by determining paternity for someone who is not her mother's spouse, the concern should not be absolutely shut down by the court.

2.1.1.2.1 LEGISLATIVE PROVISIONS

In this section, the author is trying to identify legislations which provide specific rights to patients with respect to their privacy, their data etc. It can be with respect to bodily privacy and with respect to the protection of patient data, there is a big gap in India with respect to patient rights whether it be right to health or right to privacy of a patient, there is no proper protection be it statutory or constitutional

- **The Medical Termination of Pregnancy Act (MTP)**

In *Suchita Srivastava*[54], a case involving living with mental disability and where the High Court held after setting up a Board to decide what to be done had ordered the termination of pregnancy when the Medical Board had noted that the woman had expressed her willingness to continue her pregnancy to term. In the challenge to the High Court judgement after noting the aforesaid facts, the Court observed that there is no doubt that a woman's right to make reproductive choices is also a dimension of personal liberty. The crucial consideration is that a woman's right to privacy, dignity and bodily integrity should be respected.

The Supreme Court further noted that having regard to the provisions of the Medical Termination of Pregnancy Act (MTP) which had the limit of 20 weeks within which termination of pregnancy is allowed and in her best interest looked at the decision in *Roe v. Wade*[55], where the right to privacy is recognised during a particular time. However, the decision goes on the footing of Article 21 of the Constitution of India and that there shall be no restrictions whatsoever on the woman's right to insist on the use of contraceptive methods

[54]Suchita Srivastava**,** 2009 9 SCC 1.
[55]Roe v. Wade , 410 U.S. 113 1973.

- **Mental Health Act, 1987**

The Mental Health Act, 1987[56] governs the law relating to the treatment and care of mentally ill persons. There is a Confidentiality Aspect of the Mental Health Act that we have to consider. Inspectors may enter and inspect any psychiatric hospital at any time and require any records to be produced. Furthermore, any patient receiving treatment and care may be interviewed privately to inquire about a complaint or if there is reason to believe that the patient does not receive proper care and treatment[57]. If the inspector is satisfied that the patient is not being treated and cared for properly, he may report the matter to the licensing authority. Otherwise, the inspector shall not reveal a patient's personal records and health details [58].

They need to analyse every patient's living condition and psychiatric hospital and nursing home management[59]. Inspectors must keep a book with their views and feedback[60].The book and its contents are not subject to data retention, security, and access standards. Two medical certificates from two medical practitioners must accompany the admission and detention of a person to a psychiatric hospital or nursing home [61]. Medical certificates specify the existence and severity of the mental illness that causes a person's incarceration in a psychiatric or psychiatric hospital[62]. Inspectors. conducting the joint inspection may have access to in-patient medical certificates. However, it is forbidden to inspect any personal records of in-patients that the medical officer-in-charge considers to be confidential[63].

There are two implications of privacy which surround this provision. Firstly, personal records are not specified in the Act. It is thus conflicting since inspectors can inspect medical certificates but not personal records. Second, the medical officer-in-charge has the authority to determine the confidential value of personal information. Such a test is too subjective; instead, a set objective standard should be in place to adjudicate personal record checks. The Mental Health Act notes that mentally ill people should not be

[56] The Mental Health Act, (1987). (Vol. 14).
[57] The Mental Health Act, (1987). (Vol. 14, Chapter 3, Section 13.2).
[58] The Mental Health Act, (1987). (Vol. 14, Chapter 3, Section 13.1).
[59] The Mental Health Act, (1987). (Vol. 14, Chapter 5, Section 38).
[60] The Mental Health Act, (1987). (Vol. 14, Chapter 5, Section 38).
[61] The Mental Health Act, (1987). (Vol. 14, Chapter 4, Section 30).
[62] The Mental Health Act, (1987). (Vol. 14, Chapter 4, Section 21).
[63] The Mental Health Act, (1987). (Vol. 14, Chapter 5, Section 38).

stigmatized because it is a curable illness. By doing so, it dismisses the need for extra security when there are different data categories[64].

2.1.1.2.2 PATIENTS RIGHT TO KNOW

In the sense of understanding the right of patients to know the truth about themselves, we see that this right is interpreted by doctors. Accordingly, it is considered legitimate to withhold information about the patient's diagnosis in cases where it could potentially aggravate the diagnosis by having an adverse effect on the patient's morale and where the course of the condition and is severe. It is left to the doctor's decision whether the patients and their family should be told about the patient's medical condition. A physician should always express the diagnosis of an incurable disease in a very tactful manner. Unless the patient has expressly prohibited it, such a diagnosis may be revealed to the family Nonetheless, this action will be a violation of the patient's right to know the truth[65]

2.1.1.2.3 RIGHT TO INFORMED CONSENT AND CONFIDENTIALITY

Permission provided with full knowledge of potential consequences, generally one offered to a doctor by a patient for treatment with knowledge of potential risks and benefits is known as informed consent. Patients have the right to request verbal or written information about their health status, medical interventions, their potential benefits, threats and drawbacks, alternative methods of treatment, possible consequences of refusing treatment, and the nature and prognosis of the disease. This information may be demanded by the patient or by the guardian in cases where the patient is not competent. A patient can authorize another person in his name to receive information. By advising the patient, even if the patient is not competent, he should be encouraged to participate as much as possible in the decision-making process. When it is certain that the patient may benefit from the procedure, and there is no authorization from the legal guardian, the courts can interfere. Where a conflict exists, it is up to the court to determine whether to include the client in a trial.[66]

The diagnosis must be explained in clear and intelligible terms when the patient is informed. As much as possible, medical terminology should be avoided. It is necessary

[64]The Mental Health Act- Statement Of Object And Reasons, Section 1. (1987). (Vol. 14, Pp. 296-338).
[65]*Id.*
[66]supra n1

to take into account the patient's mental state and use polite and respectful words. If the client is a foreigner, when needed, an interpreter may be used. This desire that the patient does not want any information to be given to himself or his family must be respected[67]

Also, informed consent may be withheld by the patient. This is permissible even if the operation has already started as long as medical contraindications are not present. The patient may refuse the medical doctor's recommended treatment. The person also has the right to ask for any treatment procedure that has already begun to be interrupted. The potential consequences of this should be clarified to the patient, or his legal representative or family, and a written report must certify this. If this patient subsequently decides to see the doctor he had previously rejected, he cannot use his previous decision against him.[68]

2.1.1.2.4 INFORMED CONSENT IN INDIA

One of the significant issues of medical care is the factor of consent. The patient has a fundamental right enshrined in Article 21 of the Indian Constitution to autonomy and self-determination. Except in an emergency case, where the doctor does not need to obtain consent for care, he can refuse medical treatment. Acquired consent should be legally valid. Under the rules of tort and criminal laws, a doctor who treats without legitimate consent would be accountable. The law presumes that the doctor is in a superior position, so consent should be obtained after all the relevant information is given. The Indian Supreme Court notes that consent is specified in the sense of a doctor-patient relationship as granting the patient permission for an act to be performed by the doctor, such as a diagnostic, surgical or therapeutic operation. There are some instances where consent can be inferred from the patient's conduct. This was highlighted in the case of *Samira Kohli vs Dr Prabha Manchanda*[69]. The order of these cases shows the consent principles regarding medical treatment and therapeutic investigations and not for medical research / clinical trials[70]:

[67]Faden, R.R., and Beauchamp, *A History and Theory of Informed Consent T.L*, 1986, Oxford University Press, New York.
[68]*Id.*
[69]Samira Kohli vs Dr Prabha Manchanda**,** 200 2 SCC 1 Para 32.
[70]*Id.*

- Before starting a 'treatment', a doctor must seek and secure the patient's consent. The consent thus obtained should be genuine and valid; the consent should be voluntary, and the consent should be based on adequate knowledge about the essence of the treatment plan, so that she/he knows what she/he is consenting to.
- A balance should be maintained between the need to disclose the necessary and adequate information, while at the same time avoiding the possibility of discouraging the patient from agreeing to the treatment necessary or offering to undergo unnecessary treatment.
- Consent given for a diagnostic test alone cannot be treated as consent for treatment. In some other treatment or procedure, Consent given for a specific treatment procedure is not valid for some other treatment or procedure.
- General consent can be obtained to diagnostic and operating procedures under which they are envisaged. There may also be a general agreement for a particular surgical procedure and an additional or supplementary procedure that may become required during the course of the operation.

The nature and extent of the information to be provided to the patient by the doctor in order to obtain the consent does not need to be of the strict and high degree mentioned as is in the us but should be of the extent accepted as normal and proper by a body of skilled and experienced medical men in that particular field. It will depend on the patient's physical and mental health, the quality of the procedure, and the potential risks and effects of the procedure.

2.1.1.2.5 INFORMED CONSENT AND EUTHANASIA

The fundamental right to privacy is perhaps the most definitive statement promoting voluntary euthanasia. This right first obtained constitutional protection in *Griswold v. Connecticut*[71], in which Justice Douglas expounded the notion of privacy zones If there is a restricted right to die within this privacy zone, when a state may, if ever, attempt to limit such a right.[72] Whether euthanasia is legally acceptable depends on whether there is a right within the 'shadow' of privacy to deny the continuation of life. The nature of the right to privacy lies in each individual being's unique destiny, which neither the law

[71] Griswold v. Connecticut ,381 U.S. 479.
[72]Sandra S. Klein, *The Right to Die as an Issue of Privacy: A Selective Bibliography*, Q. 137 (1994), 13 Legal Reference Services.

nor the State can prescribe. The reasoning is obvious-to do so will kill liberty at its very heart, for liberty, if it means anything at all, is not merely a liberation from constraint and coercion, but also the right to choose destiny[73].

Euthanasia is the process of intentionally ending a life to relieve pain and suffering. Euthanasia has become a widely debated topic throughout the world over the past few decades. Despite regular media and legislative storms and heated discussions about cases like Terri Schiavo in the US, rugby player Daniel James in the UK and *Aruna Shaunbagh* in India, only four European countries and three US states have laws that allow for some form of euthanasia. In several other nations, judicial or legislative action has been taken to create a euthanasia law. Nevertheless, outside such areas, any sort of assisted suicide or death is almost universally considered illegal.[74]

In Oregon, a north-western US territory, the first instance of legal sanction to euthanasia took place. In 1994, the State enacted the Oregon Death with Dignity Act that allowed people to take a lethal dose of prescribed medication and die willingly if they had been diagnosed with a terminal illness and had six months to live. Four hundred one people, most of them over 80 years of age and suffering from cancer, have embraced this measure since the enactment of the act. The U.S. Supreme Court upheld the rule in 2006 despite the opposition of President Bush. A similar act was passed in 2008 in Washington's neighbouring State. A trial court in Montana upheld in 2008 the right to assisted suicide. This was confirmed by the state supreme court in 2009.[75]

In 2002, assisted suicide and euthanasia were approved by the Netherlands government, which means that doctors were allowed to give a lethal injection. The law is not restricted to adults, nor must a euthanasia applicant be terminally ill. Hopeless and intolerable pain, irrespective of life expectancy, is the primary basis for an application. Belgium also passed a law that permitted euthanasia in the same year but was limited to adults. In 2009, Luxembourg passed a law allowing terminally ill patients to end their lives. under doctor supervision .[76]

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[73] *Id.*
[74] Subodh Varma, Euthanasia: *Widely debated, rarely approved*, TIMES OF INDIA, (Mar 8, 2011 10:15).
[75] *Id.*
[76] Mette L. Rurup, Hilde M. Buiting, H. Roeline W. Pasman, Paul J. van der Maas, Agnes van der Heide and Bregje D. Onwuteaka-Philipsen, *The Reporting Rate of Euthanasia and Physician-Assisted Suicide: A Study of the Trends, Medical Care*, pp. 1198-1202, Vol. 46, No. 12 (December 2008).

A preliminary legal framework is emerging in several countries. An example of this is the Shanbaugh decision that requires passive euthanasia (withdrawal of life support systems) in some situations. Two local court cases in Japan established requirements for active and passive euthanasia. These forms include the patient's express consent to incurable diseases.[77]

In Mexico, two provinces and Mexico City have laws that allow the medication to be declined by terminal ill patients or their closest family. Legislation applying these measures to the country as a whole is under debate in its parliament. In Colombia, although there has been no legislative follow-up, there is a 1997 constitutional court ruling providing for euthanasia. In the United Kingdom, the idea of double effect giving a painkiller is defined since a decision in 1957, realizing that it can cause death in the future. But a bill introduced in the Commons on the mercy killing was rejected in 2004.[78]

In many Western countries, assisted suicides, although formally illegal, are treated leniently by the courts and, following careful examination, doctors who help for death are granted minimal or suspended sentences. In many nations or territories, including Britain, Canada, Western and Southern Australia, Hawaii, New Hampshire, Israel, and France, efforts to pass laws that decriminalize euthanasia have recently been defeated.[79]

[77]Derek Humphry, *The Good Euthanasia Guide: Where ,What When And Who In Choices In Dying* ,122(1 St Ed .2004).
[78]*Id.*
[79]*Id.*

2.1.1.2.6 EUTHANASIA AND DNR IN INDIA

The Supreme Court of India has allowed people to draw up "living wills," which means they can look for what is known as passive euthanasia. It means that medical treatment can be withdrawn, if strict guidelines are followed, to hasten the death of a person. This would refer to terminally ill patients who are in a vegetative state. A living will set out the wishes of a patient as to how if they want to be treated in case, they are seriously ill.

Justice Dhananjay Y Chandrachud took the lead in examining and identifying the indivisible relationship between the "right to die" and the "right to privacy" as well as the freedom of a person over the body and said, "Decisions concerning death, such as those relating to birth, sex and marriage, are covered by the right to privacy by the Constitution." Life is not disconnected from death, Justice Chandrachud said to be is to die. He also said, Dignity is the central principle of life and personal freedom that infuses all phases of human life. Dignity in the process of death, as well as dignity in death, represents a long desire through the ages that pain should be devoid of the passage away from life. The Supreme Court ruled that the right to die with dignity was an essential aspect of the right to privacy, as the human life cycle was profoundly influenced by death.

The Indian judges said that the right to die with dignity was a fundamental right and that the courts must accept a person's advance directive in the form of a living will. In 2018, through a five-judge constitutional bench, the Supreme Court of India ruled that, if strict guidelines are followed, the government must uphold "living wills" to require patients to be passively euthanized if the patient suffers from a terminal disease or is in a vegetative state.

Aruna Shanbaug Case is very important case law in relation to Euthanasia in India. The Supreme Court allowed "passive euthanasia" to remove life support from patients in a permanent vegetative state (PVS) but prohibited solely active end-of-life euthanasia by administering lethal substances.[80]

Passive euthanasia happens when a patient dies when medical professionals either do not do anything necessary to keep the patient alive or stop doing something that is

[80]Aruna Ramachandra Shanbaug V Union Of India, (2011)4 SCC 454.

keeping the patient alive. This might include switching off life-support machines, disconnecting a feeding tube, not carrying out a life-extending operation and not administering life-extending drugs.

Refusing the killing of Aruna Shanbaug, who had been in a vegetative state for 37 years in a Mumbai hospital, a bench of two judges, Markandeya Katju and Gyan Sudha Mishra, laid down a set of tough guidelines under which passive euthanasia could be allowed by means of a system supervised by the high court. While defining the guidelines for passive euthanasia, the apex court declared that it would now become the law of the land until Parliament passed appropriate legislation to address the question.[81]

The bench also requested Parliament to abolish Section 309 IPC although it has become constitutionally valid. A person tries to commit suicide in a state of depression and therefore needs help instead of punishment. Although there is no constitutional provision to remove a person's life support system who is in a permanent vegetative state, the apex court said it was of the view that "passive euthanasia" might be appropriate in certain cases for which it set guidelines and put the burden on high courts to take decisions on pleas for killings of mercy.[82]

Do not resuscitate, also known as enabling natural death, is a written or oral legal order, meaning that if the heart of that person stops beating, a person should not receive cardiopulmonary resuscitation (CPR). Other medical interventions are also sometimes avoided. The legal status and enforcement of DNR orders vary from country to country. More generally, a physician imposes the order based on a mix of professional judgment and desires and expectations of the patient.[83]

Resuscitation was initially designed for and is most effective in, such cases in which death due to cardiac arrest is unexpected and sudden (e.g. a near-drowning, sudden lethal arrhythmia). Cardiopulmonary resuscitation (CPR) eventually became the default response in multiple situations unless an order prohibiting its use was given. Originally, do-not-resuscitate directives were not always recognized directly or openly.

[81] *Id.*
[82] *Id.*
[83] Ralph angero, *Problems with DNR and DNI orders*, (vol 39 no 3 Mar 2014) Ethics and medics.

Nevertheless, since their introduction to medicine in the 1970s, these directives have been used with increasing frequency.[84]

For clinical usage, withholding resuscitation can be viewed narrowly or widely. The order may include removing necessary cardiac life support and advanced cardiac life support in compliance with many standards while still requiring other necessary procedures, such as transfusion or surgery. Instead, certain physicians may be advised to delay or remove a wider range of medications such as antibiotics, antihypertensive drugs, anticoagulants, ventilation, anaesthesia, nutrition, and fluids.[85]

2.1.1.3 PSYCHIATRIST CONFIDENTIALITY

Confidentiality is one of the biggest reasons that person choose to enter a relationship of counselling. When a client chooses to visit a professional psychiatrist, they want to know that with a neutral party they can share their inner fears, secrets and desires and that the individual will not and cannot share this information with anyone else. Which occurs in a session does not always remain in a session, though, occasionally. [86]It is important to know when a therapist will violate confidentiality, why they choose to share private details and, most importantly, to whom they share it. reasons a therapist has to break confidentiality with a client[87]

- If the client is at immediate risk to himself or others
- If the client endangers a group that cannot defend itself, as in the case of a child or elder abuse
- Sharing diagnostic information when necessary to receive service payment
- As required by state laws or federal laws

2.1.1.4 RESTRICTIONS ON RIGHT TO HEALTH AND PRIVACY

Restrictions on Privacy mean allowing the State's authoritative intervention. The dignity of the individual again operates as a restriction on the power of the State from invading the privacy of the individual. The right to privacy is held to be implicit in the

[84]*Id.*
[85]*Id.*
[86]Roger Peele & Richard R. Palmer, *Patient Rights and Patient Chronicity,* 8 J. Psychiatry & L. 59 (1980).
[87]*Id.*

fundamental rights. Automatically attracts the exceptions or limitations, as explained in Part III of our Constitution.

The order in *KS Puttaswamy* states that "the right to privacy is protected as an intrinsic part of the right to life and personal liberty under Article 21 and as a part of the freedoms guaranteed by Part III of the Constitution".

- **Constitutional Restrictions**

The right to privacy is a fundamental right, without any doubt, as per the KS Puttaswamy" decision rendered by Nine Judge Bench of the Supreme Court. This right is rooted in Part III of Constitution of India, dealing with Fundamental Rights, Part III of the Indian Constitution (Articles 12 through 35) is called 'Fundamental Rights' and lists many rights that are considered fundamental to all Indian people (some extend to all individuals, whether people or not, in India). Article 13 prevents the State from introducing any legislation that eliminates or abridges the rights granted by this Portion.'

Thus, Article 19(1) (a) stipulates that all citizens shall have the right to freedom of speech and expression. This is, however, protected by Article 19(2), which states that it will not 'affect the functioning of any established law or preclude the State from enacting any law to the degree that such law imposes fair restrictions on the exercise of law in the interests of India's sovereignty and dignity, on the protection of the State, on friendly relations with foreign States, on public order, decency or morality. Accordingly, the freedom of expression guaranteed by point (a) of Article 19(1) is not absolute, but a qualified right which, under the Constitutional system, and is liable to be limited under defined conditions. Article 21, which reads 'No person shall be deprived of his or her life or personal liberty, except in accordance with the procedure provided for by statute, is another important fundamental right from the point of view of privacy jurisprudence.

- **Epidemic Diseases Act, 1897**

Under the Epidemic Diseases Act [88], if any part of the State is "visited by or threatened with an outbreak of any dangerous epidemic disease," the government of the State may enforce certain measures and prescribe regulations to prevent the outbreak or spread of

[88]The Epidemic Diseases Act. (1897), (Vol. 3).

such disease.[89] Such measures may include "inspection of persons travelling by rail or otherwise and the segregation of persons suspected of being infected with any such disease in hospital, temporary accommodation or otherwise." Whereas the Central Government may take steps including inspecting any vessel or ship and detaining any person leaving or arriving at any port. Implicit in the Epidemic Diseases Act is the presumption that the rights of infected individuals in the case of infectious diseases would give way to the overriding purpose of maintaining public health[90].

2.2 INTERNATIONAL INSTRUMENTS DEALING WITH PATIENT RIGHTS

Throughout international legal standards, the "right" approach to health problems is a growing and efficient approach. Since its establishment throughout 1919, the International Labour Organization has been operating, inter alia, to protect the health rights of labour around the world.

The 1945 United Nations Charter[91] promises under to protect health under human rights law without distinction as to race, sex, language or religion. International law, therefore, recognizes the enjoyment of the highest attainable health quality as a fundamental human right of every person, irrespective of economic or social conditions[92].

The 1948 Universal Declaration of Human Rights[93] mentioned health as part of the right to an adequate standard of living. Right to health was most explicitly recognised in the 1966 International Covenant on Economic, Social and Cultural Rights[94]. The Covenant states that the Parties to this Covenant have accepted the right of all to enjoy the highest physical and mental health requirements attainable. Conditions for all medical services and medical care should be established in the event of a disease being detected.

Consequently, the right to the highest attainable quality of health has national and international dimensions in that it imposes responsibilities on states with regard to the

[89]The Epidemic Diseases Act. (1897). (Vol. 3, Section 2.1).
[90]Ethics and HIV/AIDS in South Asia. *A Study of the Legal and Social Environment of the Epidemic in Bangladesh, India, Nepal and Sri Lanka,* UNDP (2004) Law.
[91]1945 United Nations Charter Articles 13(1)(B), 55, 57 And 62.
[92] See Alicia Ely Yamin, *The Right to Health Under International Law And Its Relevance To The United States,* Pp. 1156-1161, 95 (7) American Journal Of Public Health (2005).
[93]1948 Universal Declaration of Human Rights, Article 25.
[94]1966 International Covenant on Economic, Social and Cultural Rights, Article 12.

protection of the welfare of persons within their jurisdictions and those in a position to have human rights responsibility of international assistance and cooperation in the protection of health[95]. The 1979 Convention on Elimination of All Forms of Discrimination against Women[96] and the 1989 Convention on Rights of the Child[97] held right to health as a human right and has been given a strong foundation.

Since healthcare has become more sophisticated, technologically focused, organized, and business-like, there have been significant shifts in both the definition and meaning of the doctor-patient relationship. Once upon a time, the patient could probably rely on his doctor to be completely honest and stand by in illness and death. Today's relationship is more complicated, but it's just because modern doctors have much more to offer than compassion and leeches to their patients. There are literally thousands of medications, medical tests and procedures, surgery and mechanical devices that can be used to restore health and prolong life that simply did not exist before the last century[98]

It means that the doctor is more likely to help a sick patient, but also more likely to be involved in the condition of the patient than the rights of the patient. Doctors usually state that they are more interested in their patient's needs than in their patient's rights. The rights of patients are universal values that we have to recognize. Nevertheless, the implementation of these values and principles is not so straightforward. It is impossible to universally apply these values, because actions and attitudes differ from individual to individual, from society to society, and from country to country.[99]

It is hard to uniformly enforce these principles. If we want to draw a general conclusion on the State of patient rights in the world as a whole, the situation in individual countries should be analysed. The patient has the right to be informed about the doctor's and other health workers identities, duties, and titles. The patient also has the right to choose the staff that will take care of him, to change his attendant physician and to ask for other physicians to be consulted without breaking the regulations.[100] Besides this, the patient

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[95]Hernan L. Fuenzalida-Puelma And Susan Scholle Connor (Ed*.), The Right To Health In The Americas*, Pp. 596-607. Panamerican Health Organization, Scientific Publication, Washington, D.C, 1989.
[96]See Article 10, 11, 12, 14 Of Convention On The Elimination Of All Forms Of Discrimination Against Women, United Nations, 1979.
[97]See Article 3, 10, 24, 32 Of The Convention On The Rights Of The Child, United Nations, 1989.
[98]Bismi Gopalakrishnan*, Right To Health And Resultant Obligations*, 29 (1 & 2) The Academy Law Review.
[99]E. Aydin*, Rights Of Patients In Developing Countries: The Case Of Turkey*, Journal Of Medical Ethics, 555, 555-557, Vol. 30, No. 6, (Dec 2004).

has the right to demand that priority be decided according to reasonable medical ethics where the health service offered is inadequate.[101]

The patient may receive information from a doctor other than the one who treats him. In compliance with state-of-the-art health knowledge and technology, the patient has the right to ask for diagnosis, treatment and care. The client is entitled to access his or her documents and request a copy. Control over one's body can be expressed in terms of rights or personal interests, and a patient desiring to make his own treatment decisions must have the following prerogatives recognized[102]:

• The right to the whole truth,

• The right to privacy and personal dignity

• The right to refuse any test, procedure or treatment

• The right to read and copy all his medical records.

Not only is there a different kind of doctor-patient relationship once the patient enters the hospital, but there is also a hospital-patient relation In the physician's office the one-to-one relationship may still be there, but once in the hospital the patient may see his doctor less than five minutes a day, leaving hospital personnel to deal with patient's needs, questions and rights for the remaining 23+ hours.[103]

The modern patient rights movement has arisen as a result of growing concern about human rights abuses in healthcare settings, especially in countries where patients assume a more significant share of healthcare costs and expect their rights as "consumers" to be respected in return. Specific patient rights have been codified in specific regional instruments over the past 50 years.[104] It includes the European Convention on Human Rights and Biomedicine (ECHRB), the Agreement on the Protection of the Rights of Patients in Europe by the World Health Organization, and the European Charter of the Rights of Patients. In other parts of the world, national patient charters echo this development.[105]

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[101] *Id.*
[102] *Id.*
[103] Jonathan Cohen and Tamar Ezer*, Human rights in patient care: A theoretical and practical framework*, HHR ,Dec 2013.
[104] George J. Annas, *The Patient Has Rights: How Can We Protect Them,* pp. 8-9 Vol. 3, No. 4 (Sep., 1973), The Hastings Centre Report.
[105] *Id.*

The principles of human rights mandate that medical facilities comply with global and domestic human rights standards and agreements. These criteria can be found in significant treaties such as International Covenant on Civil and Political Rights, International Covenant on Economic, Social, and Cultural Rights Convention Against Torture African Charter on Human and Peoples' Rights, European Convention on the Protection of Human Rights and Fundamental Freedoms, European Social Charter, Convention on the Elimination of All Forms of Discrimination against Women, Convention on the Rights of the Child, Convention on the Rights of Persons with Disabilities, International Convention on the Elimination of All Forms of Racial Discrimination.

Right to Liberty and Security of Person-Everyone has the right to liberty and security of person. No one shall be subjected to arbitrary arrest or detention[106] . The European convention on human rights also talks about the right to liberty[107] Instances of Patients being detained because they were unable to pay at the hospital.

Right to Privacy and Confidentiality- No one shall be subjected to arbitrary or unlawful interference with his privacy, family, home or correspondence, nor to unlawful attacks on his honour and reputation[108], it's also mentioned in The European convention on human rights[109]. Instances such as where patients are required to provide their employer with their medical diagnosis in order to obtain leave from work, medical examinations take place in public conditions, the medical information of the patients is available for all staff.

Right to Information- Everyone shall have the right to freedom of expression, this right shall include freedom to seek, receive and impart information and ideas of all kinds[110]. The African Commission on human rights and people's rights[111], Council of Europe Framework Convention for the Protection of National Minorities[112] and European Convention on Human Rights and Biomedicine also mention this[113]. Instances include when a state fails to provide information on health care services, and patients are denied

[106]International Covenant on Civil and Political Rights ,Section 9(1).
[107]European convention on human rights, Section 5(1).
[108]International Covenant on Civil and Political Rights, Section 17(1).
[109]European convention on human rights, Section 8(1).
[110]International Covenant on Civil and Political Rights, Section 19(2).
[111]The African Commission on human rights and people's rights, Section 9(1).
[112]Europe Framework Convention for the Protection of National Minorities , Section9(1).
[113]European Convention on Human Rights and Biomedicine, Section 10(2).

access to their medical files, doctors fail to advise patients of treatment options and the possible risks and benefits associated with each procedure, information services are unavailable for people who speak certain languages.

Right to Bodily Integrity -The right to bodily integrity is not expressly recognised under the ICCPR, ICESCR, ECHR or ESC, but has been described as part of a person's right to security, the right to freedom from torture or cruel inhuman or degrading treatment, and the right to the highest attainable standard of health, Patients are not allowed to switch physicians or health care providers. When conducting medical procedures, physicians fail to receive "free and informed" consent from patients.

Right to Life – Every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life.[114]Complications from pregnancy are a leading cause of death for young women due to inadequate reproductive health and prenatal care. Ambulances fail to arrive at certain communities or for specific individuals in a timely manner.

Right to The Highest Attainable Standard of Health- The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.[115] Maternal and reproductive health services are lacking. Doctors and health facilities are not located near neighbourhoods of certain communities. Social policies disproportionately exclude patients from access to health insurance in certain areas, and patients are given inferior care.

Right to Freedom from Torture and Cruel, Inhuman and Degrading Treatment – No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation.[116]Prisoners are denied adequate medical treatment. Women are sterilized without their consent while giving birth by caesarean section. National laws that limit the availability and usage of opioids cause unnecessary suffering for patients with cancer and AIDS.

Right to Participation in Public Policy-ICCPR 25 talks about this aspect. Citizens lack an opportunity to comment on and participate in the setting of public health priorities.

[114]International Covenant on Civil and Political Rights , Article 6(1).
[115]International Covenant on Economic Social and Cultural Rights , Article 12.
[116]International Covenant on Civil and Political Rights, Article 7.

Right to Non-Discrimination and Equality-Article 21(1) of ICCPR talks about aspects such as in the case of delivery of a baby, mothers belonging to certain ethnic groups are forced to remain in separate wards. Doctors refuse to care for people living with Aids, sex workers, or drug users. Reproductive health services for women are not addressed in national policy.[117]

2.2.1 PATIENT RIGHTS CHARTER

The Universal Declaration of Human Rights (1948) emphasizes all human beings ' basic dignity and equality. Building on this definition, over the past few decades, the idea of patient rights have been developed around the globe. At the international level, there is a growing consensus that all patients must possess such fundamental rights. In other words, the patient is entitled to some amount of protection to be given by doctors, healthcare providers and the state, codified in various societies and countries in the form of the Patient Rights Charter. Throughout India, there are various legal regulations relating to the rights of patients that are distributed across various legal documents, for example. The Constitution of India, Article 21, Regulations 2002 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics), the Consumer Protection Act 1986, the 1940 Pharmaceutical and Cosmetic Act 2010[118]

This Charter of Patient Rights adopted by the National Commission on Human Rights draws on all existing laws, influenced by international charters and driven by legislation at the national level, with the intention of consolidating them into a single document, thus making them publicly known in a coherent way. It is an expected that this document will act as a guide for the Union Government and State government Governments shall devise substantive mechanisms to give adequate protection to the rights of patients, and operational frameworks shall be established to make these rights effective and enforceable by law.[119]

This is particularly important and urgent at this juncture as India, like other nations, does not have a dedicated regulator and the existing regulations in the interest of patients, governing the healthcare delivery system is on the anvil, Several States have adopted the 2010 National Clinical Establishments Act, while others have passed their

[117]Tamar Ezer and Jonathan Cohe, *Human rights in patient care: A theoretical and practical framework*, pp. 7-19, Vol. 15, No. 2 (December 2013), Health and Human Rights.
[118]Charter of Patients' Rights for adoption by NHRC.
[119]*Id.*

own national laws, such as the Nursing Homes Act, to govern hospitals, while others are in the process of adopting such legislation.[120]

The Charter of Patient Rights was adopted in the expectation that it will be implemented by policymakers in all current and new legislative laws related to the healthcare sector. The charter would also allow various types of health care providers to actively engage with this patient rights system to ensure compliance, while also benefiting from the structured codification of patient obligations.

Another aim of this Charter is to create widespread public awareness and inform citizens in health care settings about what they should expect from their governments and health care providers about the type of treatment they deserve as patients and individuals. NHRC strongly believes that educated and informed people will play a vital role in raising the standard of health care when they have codified rights guide them and knowledge of their obligations. NHRC hopes that this Charter of Patient Rights will be an empowering document to ensure that those who are among the most disadvantaged sections of society, regular patients and people seeking health care across India are covered and supported by human rights.[121]

[120] I*d.*
[121] *Id.*

2.2.1.1 PATIENT RIGHTS CHARTER IN INDIA

In India, the Union Health Ministry has decided to implement a "patient rights charter" which includes, among other things, patients ' freedom to choose medicines or diagnostic tests from sources other than the ones which are recommended by their doctors or hospitals. The draft Charter introduced by the National Commission on Human Rights outlined various rights to which patients are entitled under existing legal provisions and introduced a three-tier structure to resolve complaints of patients.[122]

The charter, released for public comment by the health ministry for up to 30 days, proposed that complaints be resolved through internal grievance redress units in clinical establishments, then district-level authorities, and then state councils for clinical establishments

The charter, released by the health ministry for public comments, has recommended that grievances should be addressed by internal grievance redress units in clinical establishments, then district-level authorities and then state councils for clinical establishments. The document outlines the rights of patients to information about their disease, proposed diagnostic tests, potential complications as well as likely additional costs due to changes in the course of the disease.[123]

Patients are also entitled to emergency medical care irrespective of their long-standing suspicion of kickbacks being received in the healthcare sector, and the charter further recognizes patients ' right to choose drugs or diagnostic facilities from any licensed pharmacy or diagnostic centre. Often patients are nudged into specific service channels for diagnosis. The charter specified that "it is the duty" to treat physicians or hospital administrators to tell patients that "they are free to access prescription medications or testing from a diagnostic centre pharmacy of their choosing." The decision of patients should not adversely affect the care given by doctors or hospitals in any way.[124]

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[122]Ms. Avni Kritika, *Right to Health Under Article 21 of the Indian Constitution.* LAJ, Volume 1 & issue 2, December 2018.
[123]Lisa R. Staffen, Heroic Medicine, *Physician Autonomy, and Patient Rights*, 19 Law & Soc. Inquiry 753 (1994).
[124]Dieter Giesen, *Vindicating the Patient's Rights: A Comparative Perspective,* 9 J. Contemp. Health L. & Pol'y 273 (1993).

The rights of the charter are related to existing legal rules such as the code of ethics of the Medical Council of India and judgment on emergency care of the Supreme Court- but will require states to enforce them.

Health critics, however, point out that the Clinical Establishment Act passed by Parliament in 2010 which is a comprehensive bill to govern healthcare services and guarantee patients of certain rights still remains largely unimplemented in most states. The NHRC expects that the Charter will serve as a "guidance document" for the Centre and states that concrete mechanisms will be developed to protect the rights of patients and "operational mechanisms to enforce them by law." This is particularly important and urgent at this juncture as India has no dedicated regulator like other countries," said the NHRC. "Another goal is to generate broad public awareness and inform people about what their governments and health care providers should expect."[125]

2.3 CONCLUSION

The Environment of health rights now in India is a very grey one. Even existing laws are not sufficient to tackle both public health and private health care challenges. Each of these challenges affects society at large. Compared to countries like the US, India has no proper legislation to deal with health care as such and those legislations which mention procedures regarding the protection of health and welfare are not sufficient in the current scenario. For instance, India has no dedicated laws or legislations to deal with patient confidentiality, while countries like the US have acts such as HIPPA[126]. Therefore, legislation regarding the right to health, right of patients and other healthcare aspects need to be enacted to deal with a wide variety of problems which will appear in the foreseeable future due to the changing circumstances and development taking place all over the world. New challenges will arise in the health care sector, and India must be well equipped to deal with them in all manners. Since mythological times in India, the right to health has been recognised. The Constitution of India also recognizes the said right as a fundamental right, as does international human rights law. Proper implementation of current legislation is the way forward to safeguarding health rights. Quality doctors and trained medical professionals are necessary for the proper realization of health rights.

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[125] *Id.*

[126] Health Insurance Portability and Accountability Act.

We can say that if we take all the necessary steps from the political aspect and build people's awareness of the right to health, then we can solve the current challenges and ensure our next generation's right to health and health care. Indian medical councils and government should set the standard of care to be observed by the medical professional with regard to diagnosis, duty to communicate to the patient with regard to inherent risk, treatment, surgery, post-operative care, etc. only then will health care for all not remain a dream but become a reality. A legally protected right to health can only be met by careful planning, which in turn depends on the reliable and frequent collection of information and on timely reports on government health needs, which are often unavailable. The movement of judicial perspective from the early health discussions to the late 1990s clearly shows that the right to health and access to medical treatment has become part of Article 21. A significant development is that while the negative language of Article 21 was meant to impose on the State only a negative duty not to interfere with an individual's life or rights without the sanction of law, judges have now put a positive duty on the State to take steps to ensure better enjoyment of life and dignity for the person.

The concept of informed consent specific to medical research and treatment is still a new concept to many medical researchers and practitioners and to millions of Indians. The doctor-patient relationship in India is governed more by the trust where the doctor is the authoritative person. Therefore, in ordinary medical practice, the advantage of informed consent does not cover all patients. To make the matter more complicated, Indian law is not specific about the age at which a person can give valid consent. The Indian Penal Code is silent about the legal validity of consent given by individuals aged between 12 and 18. Likewise, the age at which the ' right to confidentiality ' begins has yet to be defined by either the statute or the courts. Therefore, an explicit statutory provision is needed to eliminate the anomalies and ambiguities regarding the age of consent to undergo therapeutic procedures, to participate in clinical trials, and to define the age at which a person's right to medical confidentiality begins.

CHAPTER 3

3 MEDICAL RESEARCH AND ETHICS

3.1 INTRODUCTION

Over the past century, the increased lifespan of humans may be substantially due to advances arising from medical research. Vaccines are among the main advantages of medical research. Medical research includes a wide variety of studies, including clinical research which is a fundamental part in the creation of vaccines. The importance of vaccines was highlighted with the current coronavirus pandemic medical research includes studies of individuals who may be participants of clinical trials and is regarded as an integral and significant part of medical research, and there are a number of ethical issues that need to be addressed in the conduct of medical research in this present day. For research undertakings, researchers and all organizations that support, supervise, monitor and disseminate research results by participating in the relationships of privacy and confidentiality that is necessary to obtain the trust that enables the public to participate in research. When any type of medical procedure is done by a person, it is self-regulation, there is no perfect law in place. Therefore the concept of medical ethics gains more importance as the doctors are ethically bound to refrain from doing certain activities which will invade the privacy of the patient.

When these matters are not carefully dealt with, a breach of confidentiality can occur and offend the individuals to whom data relate. They may hate intrusions due to misrepresentation, such as inappropriate recruiting methods for clinical trials or targeted promotion of dreaded diseases[127]. They may be subjected to embarrassment, intimidation, harassment, violence, extortion, identity theft or financial fraud, or denial of access to health or life insurance, schooling, work advancement, or loans, or fear of being exposed. So, their trust towards institutions or research programs will decrease[128].

[127]Marian Arning, Nikolaus Forgó and Tina Krügel, *Data Protection in Grid-Based Multicentric Clinical Trials: Killjoy or Confidence-Building Measure*, Vol.367, No. 1898, Philosophical Transactions: Mathematical, Physical and Engineering Sciences.

[128]Crossing Boundaries: Computational Science, e-Science and Global eInfrastructure II. pp. 2729-2739 Selected Papers from the 2008 (Jul. 13,2009) UK e-Science All Hands Meeting.

Researchers or organizations who offend may experience negative publicity, litigation or cash loss. A loss of trust by university administrators or clinical or corporate executives and their attorneys and public relations personnel can cost months or years of remediation effort, and a sullied reputation can be a long-term burden[129].

3.2 CLINICAL TRIALS AND HUMAN EXPERIMENTATION

A clinical trial is a study conducted in medical research to find solutions to health issues. Sometimes, clinical trials are undertaken to examine new drugs, a combination of drugs, or new ways of using current treatments.

Clinical trials are also performed to assess new tests, devices and methods to treat and identify health conditions and to find vaccines for disease prevention. Before a clinical trial assesses an experimental treatment, it must have demonstrated efficacy in laboratory testing, animal research tests, or study in a small group of people. In order to preserve the health of patients, clinical trials must meet the same ethical and legal standards as a standard medical practice. A clinical trial is a biomedical or behavioural trial designed to answer specific questions about biomedical or behavioural treatments (vaccines, medications, treatments, devices, or new ways of using existing medicines, treatments, or devices).[130]

Clinical studies are used to assess whether new biomedical or behavioural treatments are secure, efficient and successful. Clinical trials include research on clinical human subjects involving behaviour modification intervention (increasing the use of intervention, willingness to pay for intervention, etc. Testing on human subjects to create or assess clinical laboratory tests (e.g., imaging or molecular diagnostic tests) may be considered a clinical trial if the test is used to make medical decisions for the subject or if the test itself places more than minimal risk on subjects.[131]

The experimental drug, procedure, system or behavioural modification, biomedical, clinical trials may be performed in four phases:

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[129] *Id.*

[130] Robert M. Nelson and Jon F. Merz, *Voluntariness of Consent for Research: An Empirical and Conceptual Review*, Medical Care, pp. V69-V80, Vol. 40, No. 9, Supplement: Making Informed Consent Meaningful (Sep., 2002),Medical Care.

[131] World Health Research Centre, BMJ , pp. 1653-1654,Vol. 1, No. 5399 (Jun. 27, 1964).

Phase I clinical trials test a new biomedical intervention for the first time in a small group of people (e.g., 20-80) to assess safety (e.g., to determine a safe dosage range and to determine side effects).

Phase II clinical trials evaluate the biomedical or behavioural intervention in a larger group of people (several hundred) to determine their efficacy and further assess their health.

Phase III studies examine the effectiveness of the biomedical or behavioural intervention in large groups of human subjects (from several hundred to several thousand) by contrasting intervention with other normal or experimental procedures, as well as tracking adverse effects, and gathering information to allow safe use of the intervention.

Phase IV studies are performed after the marketing of the intervention. These studies are designed to monitor the effectiveness of the approved general population intervention and to gather information on any adverse effects associated with widespread use.[132]

Clinical research participants have rights that they should expect, including:

- Right to Informed Consent
- Shared Decision-Making
- Privacy for Research Participants
- Return of Results
- Right to Withdraw

3.2.1 CLINICAL RESEARCH AND INFORMED CONSENT

The consent process is not just about informing research participants of risk. It is also about giving members of the public an opportunity to choose to participate in an activity for the public good. Research participants want simple information about the research that will be done, the extent of their obligation to participate, and an analysis of the

[132]Health Research In Industry, BMJ, pp. 125-126, Vol. 1, No. 4386 (Jan. 27, 1945).

risks and benefits of participation that includes a discussion of psychosocial and group risks[133].

Traditionally, informed consent in clinical trials has been seen through the narrow lens of the relationship between patient and doctor. The patient is given the facts about the choices for diagnosis, prognosis, and rehabilitation, which may include participating in a clinical protocol. The selection of the patient is thought to be based on principles such as risk-taking and risk avoidance, or virtues that allow the patient to make trade-offs between pain and suffering, and opportunities to potentially prolong their lifetime and achieve other social goals[134].

Various characteristics of individuals that affect their ability to participate in research on a voluntary basis, making them vulnerable to being enrolled in research without voluntarily informed consent or being unable to withdraw. Characteristics that may impair a person's ability to make voluntary decisions include diminished cognitive or other skills, socio-economic status, and other positions such as the disease status and family position. Some characteristics and roles may be risk factors for vulnerability to undue influence or coercion, suggesting the need for limitations on participation in research or special precautions to empower subjects to make decisions free of coercive or manipulative pressure[135]

Since children are generally unable to give voluntary and informed consent to their own participation in research, there are additional restrictions on the research risks that a child can be exposed to. Such restrictions define the conditions under which a parent has the moral and legal authority to allow a child to participate in research[136].

Consent is considered ethically acceptable for children over the age of 13 who are able to understand and make a well-considered decision on participation. Also, approval from children as young as 6 or 7 years of age is considered appropriate. However, consent and assent might be interpreted as a limited right of dissent because parents

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[133]Julian Peto, Olivia Fletcher and Clare Gilham, *Data protection, informed consent, and research: Medical research suffers because pointless obstacles*, BMJ Vol. 328, No. 7447 (1 May 2004), pp. 1029-1030.
[134]*Id.*
[135]Charles L. Bosk*, Obtaining Voluntary Consent for Research in Desperately III Patients, Medical Care*, , pp. V64-V68, Vol. 40, No. 9, Supplement: Making Informed Consent Meaningful(Sep., 2002),
[136]*Id.*

may enrol children without assent if the research holds the prospect of direct benefit to the child[137].

Many individuals may feel compelled to participate in research because of their health or disease and because of family pressure to participate in some types of research. Whether or not individual suffering from a severe and life-threatening disease can choose voluntarily has been the subject of much debate. Like prisoners, the seriously ill may have few options, constrained as they are by their situation. The situation may not necessarily make decisions less voluntary, but it indicates that patients who are seriously ill may be particularly vulnerable to unreasonable temptations and manipulation of hope. Factors such as the state of illness, prognosis, medical environment and substance abuse influence decisions, but it remains unclear whether the effect of these factors on research involvement is inappropriate or coercive. Finally, Family and friends can influence research participation decisions either indirectly by providing social support and assistance or by directly influencing a family member to participate.[138]

3.2.2 GUIDELINES IN INDIA FOR BIOMEDICAL RESEARCH ON HUMAN SUBJECTS

In 2006, the Indian Council of Medical Research (ICMR) published the Ethical Guidelines for Biomedical Research on Human Subjects[139]. The Guidelines define basic rules that must be followed when conducting human participant studies.

The Medical Council of India (MCI) Act and The Drugs and Cosmetics Act, specifies that all clinical trials in India shall follow the ICMR guidelines established. The ICMR has its own review process, and so do other government departments. The MCI Act regulates every doctor. In a trial or in practice, any doctor doing wrong will be sued, and the hospital could be closed. MCI Act is very strong, and MCI has the power to take disciplinary actions. The Drugs Controller General of India (DCGI) is responsible for the regulatory approvals of clinical trials in India.

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[137]Jon Harkness, Susan E. Lederer, & Daniel Wikler, *Laying ethical foundations for clinical research, Public Health Classics*. pp 22.

[138]Julian Peto, Olivia Fletcher and Clare Gilham, *Data protection, informed consent, and research: Medical research suffers because pointless obstacles*, BMJ , pp. 1029-1030 Vol. 328, No. 7447 (1 May 2004),

[139]Ethical Guidelines for Biomedical Research on Human Subjects. (2006) Indian Council of Medical Research New Delhi.

There is a number of laws governing clinical research in India, at present, the following Acts are in force in order to govern the manufacture, sale, import, export and clinical research of drugs and cosmetics in India. they are

- Drugs and Cosmetics Act - 1940
- Medical Council of India Act - 1956, (amended in the year2002)
- Central Council for Indian Medicine Act - 1970
- Guidelines for Exchange of Biological Material (MOH order, 1997)
- Right to Information Act - 2005,
- The Biomedical Research on Human Subjects (regulation, control and safeguards) Bill - 2005

The aim of the Acts is to regulate the import, manufacture, distribution and sale of drugs and cosmetics. Provisions of this are in addition and not in derogation of the Dangerous Drugs Act, 1930. They also have responsibility for clinical trials and quality standards. In India, clinical trials are regulated through various mechanisms, including the Drugs and Cosmetics Act 1940 and Rules 1945, and guidelines for interpreting the regulations, such as the Indian Council of Medical Research guidelines and the Indian Good Clinical Practice (GCP) Guidelines

3.2.3 INTERNATIONAL SITUATION

There have been human experiments since ancient history. But there were no laws or regulations to protect human experimentation participants because the subjects were generally inmates, slaves, family members, or the experimenter himself. After World War II, the world population was horrified by the barbarism and human experimentation. Consequently, the Universal Declaration of Human Rights was adopted at the United Nations General Assembly in 1948. The declaration was not legally binding, but it encouraged member nations to uphold a number of humans, civil economic and social rights, affirming that these rights are part of the foundation of the world's democracy, justice and peace.

This declaration was also the first international legal effort to restrict states ' behaviour and impose obligations on their citizens in accordance with human rights standards. The Universal Declaration of Human Rights was also recalled in any subsequent declarations, treaties or guidelines on biomedical research, clinical research, genetics

and science technology embraced by the world society. Here are other declarations and principles accepted and declared by the world society since 1948. The Helsinki Declaration established by the World Medical Association is a set of human experimentation ethical principles for the medical community. Originally adopted in June 1964, it has been updated several times since; the latest in 2004 was in Tokyo[140]. The declaration was the medical community's first major effort to govern itself. This takes into account the conduct of clinical research and makes a significant distinction between therapeutic and non-therapeutic studies[141].

3.2.3.1 ETHICAL FOUNDATIONS FOR CLINICAL RESEARCH

International health advancement may involve more research involving human subjects, which can often occur in developing countries. Human research has been fraught by controversy in recent years. Scientists from industrialized countries, where rigid ethical standards protect study participants and help win public confidence, have been accused of using double standards when conducting research in poorer countries that they would not be allowed to do at home. Although these debates continue in scientific journals and in the popular press, it is worth remembering that study participants in the wealthiest countries have not always had this kind of security.[142]

3.2.3.2 UNETHICAL HUMAN EXPERIMENTATION

Although much human experimentation has been carried out to elucidate otherwise unobtainable information, there are many recorded instances of unethical human experimentation. There is also a tradition of crimes committed and disguised as human experiments, best illustrated by the actions of some doctors from 1933 to 1945 in Nazi Germany. A war-crime tribunal during World War II resulted in the creation of the Nuremberg Code as a direct result of these actions to guide future human experimentation. Nevertheless, immoral experiments were carried out in the years following World War II by otherwise respectable doctors at major academic institutions in the United States who did not feel that the Nuremberg Code applied to them directly[143], there are several possible explanations for such behaviours, but among them

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[140]Wma Declaration Of Helsinki – *Ethical Principles For Medical Research Involving Human Subjects.*
[141]*Id.*
[142] Barry R. Bloom, *Health Research and Developing Nations*, pp. 9-12, Vol. 6, No. 6 (Dec., 1976), The Hastings Centre Report.
[143]Tomasz Ciesielski, Line-Kristin Larsen, Claudia Melis, Chia-Wei Vivian Wang, *Experiments on humans.*

is widespread the desire for personal advancement. Episodes of scientific misconduct such as falsification of experimental data or personal credentials seem to have been recorded more regularly recently and have been portrayed in the popular press as well. This practice may also be motivated by the desire for personal advancement, which gives it a contrast to unethical human experimentation. Education may be the best way to prevent similar motivating factors from carrying out these practices.[144]

The development of new pharmaceuticals poses a widespread ethical problem, although one that has not yet received much publicity. All new drugs are tested mainly on human volunteers. In addition, there is no way in which subjects can be fully understood of the risks in advance, as that is what the assessments are supposed to assess. This situation is generally considered appropriate, provided that "informed" consent is given by volunteers. Nevertheless, many of the medicines currently in development provide no clinical benefit beyond those available from proven therapies. Many are actually being created to establish a patentable improvement on an existing drug. To develop new drug therapies for a disease they are suffering from or for which current drugs are ineffective, it is easy to justify asking educated, consenting individuals to risk limited harm. The same may not occur when the medication being tested does not give the participants any new benefits because they are safe volunteers, or when the drug provides no significant benefits to anyone because it is merely a replication of an existing drug.[145]

3.2.3.3 HISTORICAL PERSPECTIVE OF HUMAN EXPERIMENTATION

Animal experiments produce significant, fresh and generally reliable outcomes, but some findings needed confirmation on humans. In clinical research, human experimentation is particularly relevant. But there have been conflicts: on the one hand, the goal of providing each patient with the most appropriate care and doing no harm, and, on the other hand, the aim of obtaining valuable information that is vital to the progress of medicine and cannot be accessed otherwise. Through time, human experimentation and ethics of research have grown. There are numerous examples that involve human exploitation by failure to disclose the purpose of the experiments, failure to warn subjects of threats, intimidation, undisclosed personal gain by researchers, unethical actions of nations, and many other circumstances that are often cited as human

[144] Scientific misconduct and unethical human experimentation: historic parallels and moral implications.
[145] Charles L. Bosk, *Obtaining Voluntary Consent for Research in Desperately Ill Patients,* , pp. V64-V68, Vol. 40, No. 9, (Sep., 2002), pp. V64-V68. Medical Care.

atrocities. Several times, human experimentation subjects are prisoners, slaves, family members, or even the experimenter himself[146].

3.2.3.4 TO THE MIDDLE OF THE 20TH CENTURY

Occasional human studies have been performed out of interest or to learn about illness and therapy since ancient times. These studies were mostly performed in a haphazard, non-systematic and often inconclusive manner. Sometimes for this purpose, prisoners condemned to death were used and subjected to grisly proceedings. Some of the studies performed self-experiments. Johann Jorg, who swallowed 17 drugs in different doses to document their effects, was a famous example of such work. He tested smallpox vaccines on his children in his son and community in experiments with Edward Jenner. It was recognized at the end of the 18th century that more systematic human studies are needed. At that time, a new method was implemented. Pierre Charles Alexandre Louis's work is a good example. In the year 1830. He carried out carefully planned research using patients who were able to persuade that bloodletting was not an effective therapy. That was contradictory to that time's orthodox teaching[147].

There is no question. However, that striking abuses of human experimentation took place in many nations, apart from fair prosecutions, long before the horrific crimes of the Nazis and before the Nuremberg Trials. Breslau's famous dermatologist Albert Neisser (1855-1916) was reported to have transmitted syphilis to eight participants in one of the more dramatic early instances of controversial human experimentation by administering a cell-free serum that had been obtained from syphilitic patients and was believed to provide immunity from the disease. As a result, the Russian Ministry of Education decision was the first effort by any official authority worldwide to establish standardized protocols for governing human experimentation. In a few events, after the First World War, the issue of human experimentation and the moral question about it remained unanswered. Some experiments were done in a responsible manner on volunteers, but there was also inappropriate experimentation for the mentally retarded or children on inmates and prisoners in institutions. Many studies have been conducted without seeking approval[148].

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[146] *Id.*
[147] Elinor Langer, *Human Experimentation: New York Verdict Affirms Patient's Rights*,), pp. 663-666, Vol. 151, No. 3711 (Feb. 11, 1966) Science, New Series.
[148] *Id.*

3.2.3.5 THE NAZI-ERA

The worst cases were the barbaric, brutal and disgusting experiments carried out in Manchuria after 1932 in Nazi concentration camps and in special facilities set up by the Japanese army. From 1933 to 1945, Japanese doctors conducted, and murdered, thousands in cruel experiments in China on Chinese, Russians, Mongolians, and Koreans. At least 3,000 men were tortured and killed [149]

The absolute power of the professors over their disciples is suggested among the reasons why these cruel experiments where possible. In comparison to the Nazi human experiments and the human radiation tests in the United States, it is very typical of the Japanese program. The experiments were possible based on Japanese ethics which is of authoritarian nature. It is claimed that the ideals of Japan and East Asia in the Japanese medical profession, such as respect for authority and peace, not only allowed the genocide to be carried out by human experimentation in China during the period 1933-1945, but also avoided a post-war public inquiry. One of the most disturbing chapters of human experimentation history involves experiments on human beings performed under the auspices of the Nazi regime from 1933 to 1945. At the end of the war, 23 Nazi doctors and scientists were prosecuted as research subjects for the murder of concentration camp prisoners. Of the 23 Nuremberg practitioners prosecuted, 15 were convicted. Seven of them were condemned to death by hanging, and eight prison sentences were acquitted from 10 years to life.[150]

In human experimentation, the Nuremberg Code marks the beginning of a new era. Nevertheless, the Nuremberg Code did not address the problem of proxy consent for experiments with an incompetent subject and ignored a variety of other ethical issues that are relevant to human subject medical research[151].

3.2.3.6 THE 20TH CENTURY – UNTIL TODAY

Despite the several laws that emerged after the Nuremberg trial about the control of human experiments, unethical experiments were performed. In his article (1966), Dr

[149]Experiments on humans - Foersøkdyrelære – NTNU, November 2006.
[150]*Id.*
[151]Ghooi, Ravindra. *The Nuremberg Code–A critique. Perspectives in clinical research*. 2. 72-6. 10.4103/2229-3485.80371, 2011.

Henry Beecher cited 22 cases of human experimentation conducted primarily in the post-World War II research centres in the United States. These experiments included testicular irradiation, live tumour cell injection into humans, documented effective therapy retention, and others. Obviously, these subjects had no clear idea of what was being done to them. Many American doctors saw the Nuremberg Code as applicable to ' them ' and thus not to ' us ', and it was an ethical code for barbarians but an inappropriate code for ordinary doctors.[152]'

The defining moment for a change in attitudes towards human experimentation in the U.S. came when the nature of a non-therapeutic syphilis experiment became a topic in a Washington, so-called Tuskegee syphilis trial. Other ethical issues in human research that have arisen in the past and are still being debated include safety trials and side effects of medications or therapies[153].

3.2.3.7 HUMAN TEST SUBJECTS

Human medical studies can provide answers to how human medications or therapies work. For medical experiments, animals are widely used as test subjects, but the effect found for animal studies may vary from the results obtained with human subjects. Because medical experiments are often dangerous to human health, few people willingly join research that may cause harm or death for the greater good's cause. This has led to some controversial experiments where, in the interest of science, the scientist loses track of the test subjects as human beings and hurts them. Some experiments solved this problem by misleading the people attending the study and continuing to use test groups with few other options[154].

Human beings belonging to weak groups in society appear to be the individuals that might end up in studies using human beings. The reason for this is most people's unwillingness to volunteer in the name of human benefit for potentially harmful studies. Therefore, individuals who actually sign up are often people who do not have or have few other options to earn income. The studies often pay the study subjects a large sum of money. Disloyal test subjects are an increasing problem for medical studies using

[152]Supra n 34.
[153]*Id.*
[154] Macneill, Paul. *Experimentation on human beings: a history, and discussion of current regulation*s. Aug1998,https://www.academia.edu/30921283/Experimentation_on_human_beings_a_history_and_discussion_of_current_regulations.

humans. It indicates that many participants participate at the same time in more than one study in order to increase the profit from the trials. This is likely to have harmful consequences for both the test subject and the study. For example, individuals attending various studies testing the effect of drugs can have severe side effects by mixing drugs, and the mix may also alter the reaction that the study aims to find[155].

3.2.3.8 BEHAVIOURAL RESEARCH ON HUMANS

Many studies aimed at researching sociology or human behaviour require human subjects to collect data. Such data can be obtained either through observational studies or through direct interrogation of the subjects. A study of observation is one in which the researcher actually' observes' the subjects and has little or no contact with them. It is the most successful way to study young children who are unable to answer questions, it is known to be more convenient and less intrusive to the subject, and it is meant to catch the real reaction of a person. This method's disadvantages are that it is limited to collecting data on observable features or behaviour, and it takes longer to reach a sufficiently large sample size to draw valid conclusions. The data collection interviewing method involves direct interaction by using interviews or surveys between the researcher and the subjects. Questioning is a powerful way to gather knowledge about non-observable variables like emotions, motivations, beliefs, behaviours, etc. The advantages are that it is a less time-consuming method of capturing enough data, while the disadvantages of this method are that the questions, or the mere fact of being questioned, may affect the responses of a subject. Nowadays, research on human behaviour is obtained by maintaining the privacy and minimizing participants ' psychological consequences. Many behavioural studies performed on people in the early stages of human behavioural science would now be challenged ethically for both the psychological consequences they could have on subjects and their unknown scientific merit[156].

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[155] *Id.*

[156] Holdershaw, Judith & Gendall, Philip. *Understanding and predicting human behaviour*.(June 15 10:00.)https://www.researchgate.net/publication/228475561_Understanding_and_predicting_human_behaviour

3.2.3.9 GENETIC AND HUMAN EMBRYONIC STEM CELL RESEARCH

The main feature of genetic research is that it will impact not only the individuals tested but the whole family both in the past and in the future. A common problem is whether the genetic material suppliers have any rights to the products created with it. Some forms of consent exclude the subjects ' ownership rights. Human embryonic stem cell research may have great potential to treat diseases that are known to occur in cell degeneration. These include Type 1 diabetes mellitus, Parkinson's disease, cancer, and spinal injuries. Nonetheless, some people believe that pre-implantation embryos are potential human beings and this type of study is therefore unethical[157].

3.2.3.10 ETHICAL ISSUES AND PRESENT STATUS

The central issue of human embryonic stem cell research is the status of the early embryo, whether it is a human being that needs to be protected or whether it is a collection of cells that will not become part of humanity until further development. On August 23, 2006, Nature Scientific Journal's online edition published a letter from Dr Robert Lanza (Medical Director of Advanced Cell Technology in Worcester, MA) reporting that his team had found a way to harvest embryonic stem cells without killing the actual embryo. This technological achievement could allow scientists to work with new lines of embryonic stem cells, more recently, this paper has been criticized as its analysis shows that the process described is highly inefficient and no embryos have survived the manipulation[158].

3.2.4 PRIVACY ASPECT OF MEDICAL RESEARCH

Researchers must keep full and complete research records, including data and notes. Records should be kept for a reasonable period required for post-research monitoring, research assessment, further study (whether by the original researcher or otherwise). While interviewing participants, protection of privacy and confidentiality, specifically related to identity and records, is expressly required[159]. Researchers need the

[157]Deryck Beyleveld*, Data Protection and Genetics: Medical Research and the Public Good*, 18 K.L.J. 275 (2007).
[158]*Id.*
[159]Ethical Guidelines for Biomedical Research on Human Subjects, *General Ethical Issues,* P. 29 (2006), Indian Council of Medical Research New Delhi.

participant's written permission or consent, or someone allowed on their behalf, to reveal individual participant data.

Principles which protect the privacy of patients include the principle of informed consent, the principle of privacy and confidentiality, the principle of accountability and transparency and compliance and Principle of informed Consent[160] Investigators must receive informed consent for all scientific research involving human subjects in a document known as the Informed Consent Form with Participant / Patient Information Sheet[161]. In a clear and easily understandable way, researchers have to provide sufficient details about the work.

Privacy-related information contained in the Participant / Patient Information Sheet includes the ability to avoid the use of their biological sample, the degree to which records of confidentiality may be protected and the implications of violation of confidentiality, potential current and future use of biological material and the data to be produced from the study. The possibility of disclosure of biologically sensitive details and documents, including photos and lineage maps are high if the data is likely to be used for secondary purposes or shared with others.

Researchers must, however, ensure that the disclosure of the human participant's identity and records does not result in hardship, discrimination or stigmatization as a result of having participated in the research or experiment. Lawful Disclosure of the identity or records of a patient, without written consent, is allowed for medical and legal purposes, which may be necessary for therapeutic or other treatments. Details of individual participants can be revealed under the following circumstances: in a court of law under the presiding judge's order, if there is a danger to the life of a person, disclosure of cases of severe adverse reaction to the drug registry authority and disclosure to the health authority where there is a risk to public health [162]. Additionally, records should be available, if necessary, for scrutiny by the appropriate legal and administrative authority. It is suggested that all records should be kept safe for a period

[160]Ethical Guidelines for Biomedical Research on Human Subjects, *Informed Consent Process,* P. 21 ,(2006).,Indian Council of Medical Research New Delhi.
[161]*Id.*
[162]Ethical Guidelines for Biomedical Research on Human Subjects, *Statement of Specific Principles for Epidemiological Studies,* P. 37. (2006). Indian Council of Medical Research New Delhi .

of three years after the conclusion of the research if it is not possible to keep the same for more than that due to resource crunch and lack of resources and infrastructure.

If the information is needed to be put in the public domain, it is advised that anonymisation be used, especially when necessary during disaster incidents, mental health and health system assessment. The Guidelines detail extra caution to be taken in the surveillance studies, disaster management studies, epidemiological studies and pedigree studies to protect the privacy and confidentiality of participants and communities. Principle of compliance researchers must observe the letter and spirit of the regulations and comply with them. Surveillance studies require the ongoing, systematic collection, analysis, interpretation and processing of information concerning a health event or to measure the burden of disease[163]. Obtaining true disease burden rates, however, requires high-risk population identification and dissemination of data. Investigators need to take extra care to keep confidentiality, to avoid stigmatization.

The privacy should be protected because people should be valued, privacy is widely regarded as the core human need and requirement for living in dignity, the issue of privacy and data protection in relation to such health research should be considered in the case of research companies, researchers and all organizations that support controlling and revealing health-related data. Often sceptics frame the overall issue as privacy versus research casting research as primarily serving scientists ' intellectual curiosity and self-advancement. This is a short-sighted approach. Scientists hope for fame and fortune, or at least for a good reputation and a reasonable income, like everyone else.[164]

And it is a prerequisite to be a scientist to have a deep sense of curiosity. But the work is complicated, and there are rare moments of pure exploration. Researchers are working hard to solve and help health-related problems. The issue is privacy versus health development through research to the extent that there is a balance in well-established research. All health research and preservation of privacy are sources of public interest. The realizations leading to such a conviction are familiar, and the logic is common, but the reasoning deserves to be summarized at the beginning[165].

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[163]Updated Guidelines for Evaluating Public Health Surveillance Systems. (2001) 50(RR13);1-35, Centre for Disease Control.
[164]William W. Lowrance, *Privacy, Confidentiality, and Health Research*, Cambridge University Press.
[165] *Id.*

3.2.4.1 PRIVACY OF RESEARCH PARTICIPANTS

Privacy for research participants is a research ethics term that states that when engaging in research, an individual in human subject research has a right to privacy. Some examples are that a social research surveyor conducts an interview where the participant is a respondent, or when a clinical trial researcher asks a participant for a blood sample to see if there is a relationship between something that can be measured in the blood and the health of a person.[166]

In both cases, the ideal result is that any participant can join the study and no participant in the study would ever be identified by either the researcher or the study design or the publication of the study results. For a number of different reasons, people decide to participate in research, such as a personal interest, a desire to promote research that benefits their community, or for some other reasons. Different guidelines for human subject research protect study participants who choose to engage in research, and the international consensus is that the interests of study participants are best protected when the study participant can be assured that researchers will not associate study participants ' identities with their input into the study.[167] After participating in research, many study participants experienced problems when their privacy was not upheld. Security is sometimes not preserved due to insufficient research security, but it is also often due to unexpected study design issues that accidentally compromise security. Research participants ' privacy is typically protected by the organizer, but a designated supervisor is the institutional review board that monitors the organizer to provide study participants with protection[168].

The skills, attitudes, and dedication of the people who maintain and use a research database are as essential as the policies and measures used to respect the confidentiality of its data subjects. A program of training is required for employees, at whatever level their job allows them to access the data. Staff must recognize that even if the data they collect is aggregated or de-identified, these initiatives are not perfect, and the data still

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[166]Jim Chalmers and Rod Muir, *Patient Privacy And Confidentiality: The Debate Goes On; The Issues Are Complex, But A Consensus Is Emerging*, BMJ, pp. 725-726 , Vol. 326, No. 7392 (Apr. 5, 2003).
[167]Simone N. Vigod, Chaim M. Bell and John M. A. Bohnen, *Privacy Of Patients' Information In Hospital Lifts: Observational Study*, BMJ ,pp. 1024-1025: , Vol. 327, No. 7422 (Nov. 1, 2003).
[168]Dipak Kalra, Renate Gertz, Peter Singleton And Hazel M Inskip, *Confidentiality And Consent In Medical Research: Confidentiality Of Personal Health Information Used For Research* BMJ Pp. 196-198, Vol. 333, No. 7560 (22 July 2006).

need to be treated carefully[169]. People and organizations should have policies which should be followed by clearly specified penalties for intentional misconduct or carelessness.

Many research organizations grant contracts to new employees for confidentiality. A separate agreement for each new project requiring access to sensitive data may usefully re-emphasize this. These must state the sanctions which will result from any breach of confidentiality. It is essential to plan with the legal profession and others in the unlikely event of litigation to ensure that confidentiality clauses with study participants are honoured as far as reasonably possible within the courtroom."[170].

3.2.4.2 INFORMATION PRIVACY

Scientists publish data from participants that they collect. To protect the privacy of the participants, the data is de-identified through a procedure. The goal would be to remove protected health information that could be used to connect a participant in the study to their contribution to a research project so that participants would not suffer from re-identification of data.[171]

3.2.4.3 PRIVACY ATTACKS

A privacy attack is leveraging an opportunity for somebody to identify a participant in the study based on data from public research. The way this works is for researchers to collect data from participants in the study, including confidential identity data. That generates an identified dataset.[172]

It is "de-identified" before the data is sent for research processing, which ensures that the personally identifying data is excluded from the dataset. Ideally, this means that a person could not be identified using the dataset alone. In some cases, the researchers simply misjudge the information in a de-identified dataset. The researchers simply misjudge the details in a de-identified dataset in some situations and actually identify it, or perhaps the advent of new technologies would make the data identifying.

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[169]NHS National Institute of Health Research. *Implementation plan 3.1* NHS, 2006 http/www.nihr.acuk/faculty.aspx (accessed 24 June).
[170]*Id.*
[171]*Id.*
[172]J.M. Last, Individual Privacy And Health Information: *An Ethical Dilemma, Canadian Journal of Public Health* ,pp. 168-169, Vol. 77, No. 3 (1986).

3.2.4.4 RISK MITIGATION

From a research perspective, the ideal situation is the free exchange of data. Because privacy is a concern for research participants, however, various proposals have been made for different purposes to protect participants. Replacing real data with synthetic data allows researchers to display data that gives a similar conclusion to that drawn by researchers, but the data may have problems such as being unfit to repurpose for other research. Other strategies include "noise addition" by exchanging values across entries by making random value changes or "data swapping." One strategy is to isolate the recognizable variables from the rest of the data, collect the identifiable variables and re-attach them to the rest of the data. The idea has been widely used to build diabetes maps in Australia and the United Kingdom using confidential clinical data from General Practice[173].

3.2.4.5 BIOBANK PRIVACY

A biobank is a location where human biological specimens are stored for study and where genomics data are often mixed with phenotype data and personal data. Biobank research has created new challenges for fulfilling student participant rights and researcher's requirement to access resources for their work for many reasons. The problem is that if even a small amount of genetic information is available, this information can be used to uniquely identify the person it came from. Studies have shown that even the reporting of aggregate data can be used to determine whether an individual participated in a study.[174]

3.2.4.6 NEGATIVE CONSEQUENCES

Once participants in the study have their identities disclosed, they may have issues. An insurance company or employer faces racial discrimination. Respondents in the U.S. expressed a desire to restrict their research data from access by law enforcement agencies and wished to avoid a connection between study participation and legal consequences of the same. One concern study participant may have been about the studies exposing private personal behaviours that a person may not want to disclose,

[173] *Id.*
[174] Ruth Gilbert, Harvey Goldstein and Harry Hemingway, *The market in healthcare data*, BMJ, Vol. 351 (02 Nov 2015 - 08 Nov 2015).

such as a medical history that involves a sexually transmitted disease, substance abuse, psychiatric treatment, or elective abortion.

Genetic screening can show that paternity is different from what was expected to be in the case of family genomic studies. Many people may find, for no particular reason, that if their private information is revealed due to research activity, they may feel threatened and disagree with the whole program. An Australian study examining abuse, intimidation, and discrimination against LGBTIQ individuals found that some of the participants, who were all part of the LGBTIQ community, were exposed to levels of violence that would constitute a crime. The participants, however, were unwilling to report to the police their victimization. It meant that the researchers might report a crime to the police. Ethical principles, however, indicated that they had to respect the participants ' privacy and desires and could not do so.

3.2.4.7 COMPLEXITY IS RISING IN MANY CHALLENGES

Increased privacy threats from the development of data collections and biospecimens, pooling and interlinking of data sets, and ramping up dispersal of regional and institutional data and biospecimens. Decentralization and outsourcing of a large amount of data storage and analysis that could make accountability dissipate. Problems have recently arisen, or have escalated. Among the latest issues are those related to the use of data and biospecimens, which until recently had been ethically or legally off-limits in many jurisdictions for study and the Availability of certain entirely new forms of data that may be useful for analysis but may contain information about people's identities, behaviours and interactions, such as geospatial tracking of movements and exposures, dissemination of personal data via social networking.

The danger of unauthorized access to research data under information protection or anti-terrorism legislation Privacy risks as torrents of data is spread across borders as work continues to globalize in a society where private security has hardly been globalized. The persistent policy problems are growing. Severe barriers to privacy and confidentiality continue to obstruct study, but in particular complexities and conflicts over the systematic creation of 'personal data' or 'Personally identifiable information' and overall identity concepts, public debate on the ethical and legal appropriateness of consent to complicated research and data sharing via research platforms is currently underway. Lack of clarification as to how to deal with the implications of privacy and

confidentiality for the families of individuals engaged in study. The apprehension of researchers' legal power to resist involuntary access to sensitive research data by police, courts, banks, health or life insurers or other external parties.

3.2.5 MEDICAL RESEARCH AND PUBLIC INTEREST

Everyone is exposed to myriad health risks from conception onwards. Many of the risks are either attracted by human activity, induced, exacerbated, or transmitted, and many can be mitigated or compensated for by human activity. Society at all organizational levels, whether village, region, regional, global, or supranational, attaches high priority to mitigating health risks, promoting wellness, and providing health care. Good health is linked to each person's risks and resources at any stage of life. Nevertheless, despite the difficulty of explicitly identifying it, health is widely regarded as a core human need and a prerequisite for a dignified life.[175]

Today we live thoroughly interconnected lives in which disease risks and costs are widely shared, although not equally or fairly. The burdens of disease and disability suffered in resource-poor, and unstable countries are burdens on the world in the most severe economic, social, and security context, as well as in high moral sense and the world's weak exchange contagion vectors with the wealthy, and the affluent share with the less fortunate vectors of unhealthy lifestyles. Pathogens can spread at any time. Without regard to political boundaries, epidemics and natural disasters hit[176]. We are helpless together. None of us can predict what illnesses and disorders we or our families or friends will encounter as our lives go on – and when these afflictions arise, we continue to earnestly hope that the experiences of many people have been researched in-depth and have led to the development of proven effective diagnosis and curative or at least palliative strategies and products to deal with them. Since we are all to benefit from the collective knowledge, we should all contribute to the common knowledge to help others, including people we never know. Research involvement is an excellent opportunity.[177]

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[175]Patricia Barr, *Medical research and patient rights, Issues in Science and Technology*, p. 16 Vol. 13, No. 2 (WINTER 1996-97),
[176]*Id.*
[177]Matthew Hay, *Public Health Research*, BMJ, p. 1385 Vol. 1, No. 2790 (Jun. 20, 1914).

Costs contribute to all of this. Health care is an industrial-scale enterprise in all developed countries and particularly in developing countries, the expense of which is paid by the state at least in part, and in many cases almost entirely. These costs, as well as a cost-effective prevention and care provision, are and will always be of crushing concern to states, and so states depend on research to understand causes, evaluate what works best and is most cost-effective, innovative, and improve. Although the private sector has different financial concerns for healthcare providers and insurers, they also need to worry about costs and efficiency, and they also need to depend on studies to understand and develop[178].

In many cases, it is the world's disadvantaged that stand to make the most of research across relation to their health and socio-economic pressures – not only in terms of infectious scourges such as tuberculosis, measles, HIV, schistosomiasis, leprosy, and river blindness, but also in terms of draining non-communicable afflictions such as child malnutrition, diabetes, cardiovascular diseases, and cancer. The encouraging thing is that the results of health research continue to circulate remarkably quickly and broadly, be it basic knowledge, practice advice, strategies, or products. The implementation of research results and new healthcare technology will always have budgetary and cultural limits, even in the wealthiest societies. But no other universal progressive effort approaches the critical screening and efficiency with which scientific and medical ideas and information are generated, distributed through newspapers, the web, and conferences, assessed for quality and relevance, and translated into practice. Knowledge developed throughout the world on mastitis, burns, glaucoma, migraine, organic solvent toxicity, wood dust allergies, hospital hygiene, and countless other problems.[179]

Health research is of great public interest, and this is underlined by the fact that much of it is financially supported or carried out by government bodies, organisations to which governments give non-profit, tax-exempt status, and international organizations in which governments are interested.[180]

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[178] *Id.*
[179] Victoria McGovern and Queta Bond, *Editorial: Global Health Research*, *Science, New Series*, p. 2003 Vol. 300, No. 5628 (Jun. 27, 2003).
[180] *Id.*

3.3 CONCLUSION

Debates over privacy, confidentiality and data protection law in relation to the principles of medical research are governed by two camps, each of which employs a relationship based on a conflict model. On the one hand, there are medical researchers who see anonymity, confidentiality, data security and so on as a hindrance to the much more relevant medical (including genetic) research issues. At the other hand, there are those who think the study participant's agreement is sacrosanct and can never be overridden by anything at all. We can see that at least neither situation is tenable from the perspective of the governing human rights law. As this governing law conceives of privacy, medical research and privacy are not necessarily in conflict at all. Correlatively, we are led away from a picture of the interests of patients being in conflict with the interests of researchers who, of course, represent the interests of society[181]. We are reminded that researchers do have interests in privacy and may also be patients and that patients do have interests in research. Such an image makes it easier for those who are opposed to any privacy infringement to agree that there are grounds for exempting certain practices from certain privacy criteria, as these are to be exempted for what are, in essence, reasons for enhancing privacy. Conversely, it makes it easier for those who are disregarding the interests of privacy to give their proper due to these interests, since they are also research interests. Of course, it can be objected to all of this, as always, that while this may be the way the human rights law views the matter, the law is not ethically sacrosanct[182].law is Medical Research and the Public Good along the right lines ethically[183].

In order to reassure the research ethics committees and the public that the confidentiality of personal medical data will be respected, we need to strengthen many areas of research practice. The steps mentioned include new policies and procedures for confidentiality steps to be enforced and audited, database overhaul, and technological security enhancements such as biometry authentication, encryption, server safety, and backup securing[184]. Researchers may also require expert guidance in complicated cases

[181]C T Di Iorio, F Carinci and J Oderkirk*, Health research and systems' governance are at risk: should the right to data protection override health*, JME, pp. 488-492, Vol. 40, No. 7 (July 2014), pp. 488-492.
[182]*Id.*
[183]18 K.L.J. 275 (2007).
[184]Kalra D. Clinical foundations and information architecture for the imple mentation of a federated health record service [PhD thesis]. London: University of London.

about the interpretation of the applicable laws and common law. Making those improvements would add to the study costs. Research funding agencies will need to ensure that researchers, hosts, and flinders have a clear understanding of who is responsible (and will meet the increasing costs) for maintaining sensitive databases. Public confidence in medical research needs to be sustained and improved since most medical research is dependent on volunteers[185]. First, however, we need to understand what contemporary public issues are and work towards a consensus that can effectively balance these against the advantages of using data for analysis. That is important before the good practice of confidentiality can be properly established in research[186].

[185] *Id*.

[186] Dipak Kalra, Renate Gertz, Peter Singleton and Hazel M Inskip, *Confidentiality and consent in medical research: Confidentiality of personal health information used for research*, BMJ, pp. 196-198, Vol. 333, No. 7560 (22 July 2006).

CHAPTER 4

4 PRIVACY AND DATA PROTECTION IN HEALTH CARE SECTOR

We leave a pattern and health trajectory in our wake as we move through life in the digital age. Phones, shopping habits and doctor's visits create a record of data that can be used not only to assess our past and current well-being but also to predict the future. To some, this is an unprecedented opportunity to strengthen healthcare, while for others, it constitutes a growing challenge to civil rights. Many of us camp somewhere between the two poles we see the benefits and the concerns. The problem is how we move past this stage where market models and legal structures are unable to keep up with the speed of change, designed for a pre-internet environment.

The importance of patient data and the analysis of care and treatment given is essential, but confidentiality of patient is of utmost importance as it is directly attached to the patient's fundamental rights such as the right to life, liberty and Privacy. Therefore, supplying information to patients is subject to individual confidentiality and is specific from patient to patient[187].

From monitoring illegal drug orders to evaluating the impact of specific procedures on patients, the ability to automatically process data provided by thousands of patients has become invaluable to health care service providers worldwide[188]. It has also become critical for health care providers to consider the Privacy of patients and data protection when using patient data, especially where such information has stigmatizing consequences [189]. It's therefore essential to secure patient information since it is now stored more often in electronic documents that have more possibility of exposure due to persistent threats such as hacking, etc.

One could ask how many privacy intrusions occurred for evaluation and what harms people experienced. Several countries have seen hundreds of unwarranted leaks,

[187]Mr. Ilayanambi.B ,*Challenges Before Data Privacy Laws In India: With Special Reference To Protection Of Patients Information*, Law Audience ,Journal volume 1, Issue 4, June 2019.
[188]M. A. Rodwin, *Patient Data: Property, Privacy & the Public Interest*, 36 Am. J. L. and Med. 591 (2010).
[189]See L. Sweeney, *Patient Identifiability in Pharmaceutical Marketing Data* available at http:// dataprivacylab.org/projects/identifiability/pharma1.pdf (February 18, 2020).

lawsuits and theft of health care data and some successful hacking attacks. However, very few direct material injuries can be identified to the data subjects, and not many lawsuits are brought before the Court. Probably the greatest harm was the misuse of credit cards and identity theft. Most of the recorded infringements resulted from incompetent, ineffective, or unlawful acts, the kind that professional care and organizational safeguards would be able to prevent. The scale and sophistication of most healthcare data systems and the fact that they have patient payment specifics will always make them a possible target of attack.

Data from health research could incur some of the dreaded events recited above. Lots of work databases have been lost, stolen, or hacked into over the last few years. Health research develops in new ways, and such development causes new vulnerabilities. The challenges Ethical, legal, cultural, technical, administrative, and day-to-day operating adjustments are made everywhere to try to cope with the problems. It is vital to bear in mind the variety of problems from the outset, partly because most of the problems emerge as problem clusters and need to be addressed.

Anonymous patient information requires that the data controller make adjustments to the data subjects' information and delete all the personal details.[190] The details should be such that the Processor who has the details cannot recognize the de-identified subject's personal information. Accessing the personal information of the patients without authorization is a punishable offence[191] In the United States, under Part-C of the Health Insurance Portability and Accountability Act,1996 (HIPPA). The 1995 Directive of the European Union has a similar policy to that of the United States with respect to Personal patient Information set out in the EU Data Protection Directive[192]. While this method tends to be an alternative, the anonymization method can also be unreliable because even the de-identified information can be traced back to the subject[193].

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[190]L. Sweeney, *Patient Identifiability in Pharmaceutical Marketing Data* available at http:// dataprivacylab.org/projects/identifiability/pharma1.pdf. (29.03.2019).

[191]J. Kulynych & D. Korn*, Use and Disclosure of Health Information in Genetic Research: Weighing the Impact of the New Federal Medical Privacy Rule,* 28 Am. J. L. And med. 309 (2002). (Accessed on 29.03.2019).

[192]Directive 95/46/EC of the European Parliament and Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data [1995] OJL 281 (Data Protection Directive).

[193] I v. Finland, Application No. 20511/03: 2008 ECHR 623 (17 July)2008.

The individuals' electronic records had been exposed at different stages & situations, leading to the risk of detection at different levels and in order to prevent this, the data protectors have two choices either to anonymize the information that poses the risk of identification or to make it available to the physician only. Finding and implementing a midway point is the only feasible solution to this ethical dilemma. While rendering information anonymously, there is a risk of information being misused by intermediaries. However, this choice will lead the way to a solution if regulated by a set of rules and regulations. Healthcare providers must, therefore, ensure an in-built mechanism for patient privacy protection in processing electronic medical records.

There comes the second alternative that is also not feasible due to the uncertainty that occurs between the physician-patient relationship due to the involvement of other stakeholders, insurers and pharmaceutical manufacturers. The administrative costs of data processing in developed countries have resulted in patient information being outsourced to under-regulated jurisdictions, where costs are reduced by about half[194]. The dangers underlying the cross-border flow of personal information became evident in 2003, when a data transcriber in Pakistan threatened to reveal patient details unless the offshoring firm, in this case, the San Francisco Health Centre University of California, paid back its salaries.[195] A similar incident occurred in an offshore data-processing facility in Bangalore. Such cases are early warning signs of the effects of a weak data security policy in India.

The Indian Government has taken a step forward by implementing NeHA. In 2015, the Ministry of Health launched NeHA (National eHealth Authority) to control the management of electronic records in India and also to cope with that of international standards. In 2017, NeHA submitted a draft law for DISHA that is still awaiting passage. However, to make it alongside the International Standard, the Indian Government had enacted the IT Rules "Reasonable Security practices and procedures and sensitive personal data or information", 2011.[196] IT Rules 6, 7 & 8 require

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[194]N. P. Terry, Symposium*: The Politics of Health Law: Under-regulated Health Care Phenomena in a Flat World,* 441 (2007),Medical Tourism and Outsourcing, 29 W. N Eng. L. Rev.

[195]David Lazarus*, A Tough Lesson on Medical Privacy, Pakistani Transcriber Threatens UCSF Over Back Pay*, S.F. Chron. (San Francisco), October 22, 2003, available at http://articles.sfgate.com/2003-10-22/news/17513957_1_medical-transcription-ucsf-medical-center-medicalprivacy (February 18, 2020)

[196]Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011.

transparency and confidentiality in managing Sensitive data. The latest law forbids the use of medical knowledge without authorization. Though strengthening India's data protection law may have been an important step in the right direction, some of the regulations can seem like a bureaucratic nightmare for data processors whose main concern is to cut costs.[197] India's current legislation is not effective enough. It presents a significant threat to the current structure, needing more efficient solutions that improve Privacy.[198]

4.1 DATA PROTECTION IN EU, US & UK

Not all information requires protection under the laws of data or information security, but the ones containing a certain amount of confidential information does so. Only certain information treated by data processors and data controllers can be regarded as personal, and under this regime, only such information is activated for security[199]. Information affecting the Individual Privacy shall be regarded as Personal Information,[200] and the controller or designated person shall be responsible for the data of the processed subjects and the manner in which the data is processed [201].

[197]IT Rules 2011 ,Rule 5(2).
[198]Press Association, *Tougher Penalties Planned for NHS Data Losses*, The guardian (London), July 1, 2011.
[199]UK Data Protection Act, 1998 (c. 29), S-1(1) (This implementing legislation ensures compliance with the data protection principles enunciated in the Data Protection Directive).
[200]Durant v. Financial Services Authority, 2003 EWCA Civ 1746.
[201]UK Data Protection Act, 1998, s.1(1).

4.1.1 EU'S POSITION ON HEALTH INFORMATION AND ITS PRIVACY

The data protection laws of the EU member states are more focused on the EC Data Protection Directive. Reasonable and lawful collection of personal information was the central concept of the data protection regime[202] , and such information must be collected and processed for lawful and specific reasons [203]

The data given are also subject to the time limit, and the person receiving the data should no longer have the information after the aim for such data has been fulfilled or the time limit has expired. It is also the responsibility of both the Processor and the controller to avoid any unauthorized use of the protected information, and they are also obliged to implement effective organizational and technological steps to deter or avoid any unauthorized infringement and processing.

The Guideline also looks after cross-border health care and research and sets out a general rule regarding the adequacy of third-country data protection laws[204] . It also requires equal protection by utilizing minimum security standards for data shared across the EU by patients. If the transfer takes place between states that implement the Directive, the controller will view the transaction as the host country[205], But if not, the third country's data protection legislation will be assessed based on circumstances such as data origin, intention and duration.

In 2008, in the case of I v. Finland[206], the European Court of Human Rights explained the importance of the protection of health data and the Right to Privacy of a person, in this case, an eye clinic employee and also a former patient of that clinic HIV status was exposed due to the easy access to the registry of patients containing confidential details such as diagnosis and clinical details. In this case, the European Court of Human Rights noted and held that confidential information involving patient data should be kept away from unauthorized use and protected against such use.

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[202]Data Protection Directive (These principles were part of the Council of Europe's attempts to harmonise national laws on data protection in its 1973 and 1974 resolutions, and are laid down in Schedule I of the Data Protection Act, 1998).
[203]UK Data Protection Act, 1998, Schedule 2 and 3.
[204]European Protection Directive, Articles: 25 & 26.
[205]E. Mossialos, G. Permanand, R. Baeten & T. K.*, Health Systems governance in Europe: The Role of EU Law and policy* 564 Hervey eds., 2010.
[206]See I v. Finland.

The new EU regulation on personal data was published in May 2016, which implemented and guaranteed the right of patients to be heard, the right to rectification, the right to erase, the right to transfer the object and access to their information. The privileges and limitations of patient data organizations have been developed and, more significantly, a "Research Work" exemption provision has been implemented to improve the health sector. However, it is subject to the patient's right to be heard where it is necessary to warn the patient of any use of information and the risk involved. The new regulation gives a better view of patients and citizens' rights than the previous one, and the EU intends to continue gathering and communicating the viewpoint of patients on protecting and exchanging patient data[207].

4.1.2 UK'S UNDER THE UK DATA PROTECTION ACT, 1998

Normally, anonymized information should not present much of an ethical dilemma to healthcare professionals. According to S.1(1) of the DPA, personal data is defined as "information relating to a living person who may be identified-

- From the information.
- From those data and other information which is in the care of or is likely to come into the possession of the data controller."

The EC Data Protection Directive states that Security requirements shall not extend to data which has been rendered anonymous because the data subject is no longer identifiable from such data.[208] Nevertheless, the mere de-personalization of patient data does not provide adequate justification for a reduction in the degree of Privacy usually provided to personal data. It is therefore clear that the data de-personalization procedure will require more than pure anonymization of the data

In a recent decision, the European Court of Human Rights highlighted the significance of the concept of "private life". It offered a wider understanding of the term by incorporating the life of a person, his family and his health records. Therefore, it can be inferred that it is the right of a person to access and protect all aspects of his or her own. This opinion was confirmed by the United Kingdom in the Court of Appeal in the case

[207]EU Regulation on the protection of personal data: *what does it mean for patients? A guide for patients and patient*s, organisations (EPF), pg. 1-22, , European Patients Forum.
[208]*Id*

of *R v. Health Department, Ex p Source informatics,*[209] In this case, A company that collects de-personalized pharmacist data had an intention to sell it to ascertain the general physician's prescribing process. The Court of Appeal ruled that there is no obligation of confidence concerning information which is entirely anonymized. This line of reasoning misleadingly suggests that the fair concern of a patient regarding Privacy is limited to primary uses of identifiable information

As for S. 11 Under the DPA Act of the United Kingdom, 1998, a person has the right to be heard, and the right to avoid his data from commercial use by notifying the data controller and, in the Source Informatics case, patients whose data is anonymized are entitled under the second data privacy principle to be informed by data controllers of the aims of such 'processing.'[210] What's more, in S. 1(1) of the DPA Act, 1998, describes 'processing as 'alteration or modification,' which essentially requires notice of the purpose of such de-personalization to a patient whose data is de-personalized[211].

Nevertheless, it is risky to believe that anonymization of data eliminates the data controller's duty to comply with data protection legislation because there are unique situations that would establish liabilities. In the case of *Common Services Agency v. Scottish Information Commissioner*,[212] The release of information concerning the prevalence of childhood leukaemia in specific communities has been denied by the Public Services Agency, citing a high risk of detection due to the low prevalence of individuals suffering from the disorder in those areas. The House of Lords held that the anonymized information should be sufficiently de-personalized before disclosure and the matter was referred to the jurisdiction of the Information Commissioner. Under the law of the United Kingdom, the use of patient's identifying information is strictly forbidden, this principle does not resolve questions about secondary uses of anonymized information, where the impact on the private life of the data subject is unclear. At the other end of the continuum is the rights-centric approach of the ECtHR, which may have the effect of placing prohibitively high costs on the globalized healthcare industry of today. However, both the legislation and the courts are vague as to its role in situations where the patient's information is anonymized but may still

[209]R v. Health Department, Ex p Source informatics ,(1995) 4 All ER 185, rev‟d (2001) QB 424 (CA).
[210] See principles of medical Law, supra note 15, 659.
[211] Supra note 9.
[212]Common Services Agency v. Scottish Information Commissioner ,(2008) UKHL 47.

present a danger. A more realistic solution will ensure data collectors use the straightforward collection, processing, and storage methods.

4.1.3 UNITED STATES

In the case of the United States, the electronic transmission of patient information is regulated by HIPAA[213]. In the United States, the HIPAA seeks to increase the efficacy and quality of the healthcare system by promoting the implementation of a health information system by developing standards and criteria for the electronic transmission of certain health information[214] Patient Privacy can be assured at various stages of the collection, processing and disclosure of information. The object of protecting patient privacy can be information which is de-identified at the collection point. Furthermore, the spectrum of justifiable reasons for personal data collection can be limited exclusively to such purposes, such as diagnosis[215]. Informative Privacy thus means the information is not revealed to corporate bodies.[216] However, as healthcare delivery systems changes, the relationship between doctor and patient becomes more complex, other interested stakeholders are now gaining a stronger foothold in the healthcare industry[217].

HIPAA fails to include a strict implementation concerning the information process of the patient, nor does it address the consent to be provided by the data subject. With the development of the patient data market worldwide, other than the US administration of food and drugs,[218] Researchers and drug manufacturers use health information continuously for commercial purposes, and there is no meaningful regulation to this degree that protects patient information from misuse. No state law prohibits the sale of patient information. Moreover, their laws could not be defended against data mining companies that say that these laws affect their fundamental rights.[219]

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[213]Health Insurance Portability and Accountability Act, 1996.
[214]Health Insurance Portability and Accountability Act, 1996, S. 261.
[215]N. P. Terry, Symposium, *The Politics of Health Law: Under-regulated Health Care Phenomena in a Flat World,* 29 W. n Eng. L. Rev. 441 (2007), Medical Tourism and Outsourcing.
[216]*Id.*
[217]Jeroo S. Kotval, *Market-Driven Managed Care and The Confidentiality of Genetic Tests: The Institution as Double Agent*, 9 ALB. L.J. SCi. & TeCh. 1 (1998).
[218]M. A. Rodwin*, Patient Data: Property, Privacy & the Public Interest*, 36 Am. J. L. And Med. 591 (2010).
[219]Electronic Privacy Information Centre, IMS Health v. Ayott.

In early 2011, with the Supreme Court struck down a prescription confidentiality statute in Vermont, companies in America were granted a free rein to potentially misuse patient information. Vermont had limitations on both the quality of the information and who was allowed to use the information for marketing purposes which pharmaceutical manufacturers claimed were violations of their free speech rights[220]. The US Supreme Court struck down a ban on drug secrecy because in this case, the State did not prove that the law had "Substantive Public Value" and further the Court found that the content-based requirement[221] in S. 4631(d) of the Vermont Law, concerned expression protected by the First Amendment and failed to carry out an expanded scrutiny test[222]. The Supreme Court also noted that if the law is focused on more transparent Privacy and had made a narrow list in which this sale of information is allowed in certain conditions rather than absolutely prevented, then it would have survived the judicial scrutiny[223].

4.2 INDIAN POSITION

4.2.1 RIGHT TO PRIVACY

The Right to Privacy in India has taken multiple turns. However, by acknowledging the Right to Privacy as a fundamental right, India has joined the US, UK, EU, Canada and South Africa and many others in realizing the importance that Privacy holds in this modern-day and age. In Justice K. S. Puttaswamy & Anr v. Union of India[224] Case, the nine-judge bench of the Supreme Court, unanimously declared that Privacy is the constitutional core of human dignity. The honourable Chief Justice Khehar, borrowing the words of US Supreme Court Justice Louis Brandeis, wrote, "The right to be left alone is part of the right to enjoy life."

Also, the freedom to enjoy life is part of an individual's fundamental right to life. Therefore, it was held that the Right to Privacy is a fundamental right under Article 21 of India's Constitution. Contrary to the trend in the United Kingdom and the United States, the Indian Judiciary has exercised the Right to Privacy as an exception to the

[220]Sorrel v. IMS Health Inc, 131 S. Ct. 2653 (2011).
[221]Vt. Stat. Ann., Tit. 18, §4631 (Supp. 2010).
[222]*Id.*
[223]Supra note 30.
[224] Justice K. S. Puttaswamy & Anr v. Union of India, 2017) 10 SCC 1.

law requiring public authorities to intervene in the private life of a person[225]. The Supreme Court has stressed on many occasions that the Right to Privacy is not absolute [226].

The Court then decided to take a case-by-case approach to define the Right to Privacy[227]. There have been cases in which the Court has required a hospital to warn the future partner of the patient of his HIV positive status [228]. The justification for disclosure in these cases was the public welfare claim that the reckless transmission of an infectious disease is an offence towards public safety. In resolving the conflict between the public "right to be left alone" and the "greater good" the judiciary has shifted towards upholding public interest over individual privacy[229]. In *Sharda v. Dharmpal*, a husband filed for divorce on the basis that his wife was mentally ill.[230] The wife was compelled to undergo a medical exam to prove this fact. She believed that pressuring her to do so without her permission would violate her personal freedom. While noting that the 'right to privacy' is not an absolute right, the Court ruled that the lack of such data will make a decision on the facts of the case impossible.

Perhaps controversially, the Court ruled that information found in a public record cannot be covered under the Right to Privacy[231]. The Court has held that the Right to Privacy cannot shield information stored in a public record because public records may include hospital records, prison records and any other information obtained by a state body, this decision could have the effect of circumventing any requirement for authorization to obtain patient data that is not in public records. It is therefore critical that a robust data protection legislation is implemented to control the flow of information in the hands of the State.

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[225]Aparna Vishwanathan, *Outsourcing to India: Cross Border Legal Issues* 318 (June 15 2020) /outsourcing-India-Cross-Border-Legal-Issues/dp/8180381730.
[226]Sharda v. Dharmpal, AIR 2003 SC 3450; see also Selvi v. State of Karnataka, (2010) 7 SCC 263; Ms. X v. Mr. Z, 96 (2002) DLT 354.
[227]Govind v. State of Madhya Pradesh, AIR 1975 SC 1378.
[228]Yepthomi v. Apollo Hospital Enterprises Ltd., AIR 1999 SC 495; Mr. 'X' v Hospital 'Z', (1998) 8 SCC 296.
[229]Sharda v. Dharmpal, AIR 2003 SC 3450.
[230]*Id.*
[231]Mr `X' v. Hospital 'Z', (1998) 8 SCC 296.

4.2.2 EXISTING POSITION AND RECENT DEVELOPMENTS

There are no clear regulations available to protect the medical records and personal details of patients. Although the physicians must protect their patients' confidentiality due to doctor-patient confidentiality and disclosure of such information would result in professional misconduct as per the Indian Medical Council Regulations.[232] However, there are no such responsibilities between any other private or State entities which have no duty to protect such knowledge. Therefore, there is a high risk of misuse of details, so separate legislation is required. The Indian Legislature's first step to solving this crisis was by amending the IT Act, 2000. The IT Rules adopted and enacted in 2011 were the first legislation defining the term Sensitive Personal Data[233].

The rules stipulated the rights applicable to the information provider, and the rules explicitly stated that all corporate entities or other individuals accessing confidential private information for any purpose must obtain written consent from the provider of such data. The data provider must also be aware of the collection of such data, and they must also notify the provider of the reasons for such collection.[234] And all the collection of such data should be for a lawful purpose and in a lawful manner, and the work done by the body or an individual should be related to that purpose.

There are instances where confidential information can be revealed to third parties, such as government departments who may gather the information for a particular reason alone[235] but it is subject to the requirement that the collection and its purpose should be reported to the individual from which the information is collected [236] And were a corporate body or an individual wants to exchange confidential information, such information can be transmitted after the consent has been obtained. The only basis on which a company in India can send data to other such bodies (whether within or outside India) is if it maintains the same data protection standard [237].

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[232]The Indian Medical Council (Professional Conduct, Etiquette and Ethic) Regulations, 2002 (102 of 1956).
(Medical Council Regulations)
[233]Information Technology Rules, 2011, Rule 3.
[234]Information Technology Rules, 2011, Rule 5.
[235]Information Technology Rules, 2011, Rule 6.
[236]Information Technology Rules, 2011, Rule 6-proviso.
[237]Information Technology Rules, 2011, Rule 7.

The Indian rules simply require that information providers obtain written consent. Furthermore, the general clause allowing the Government to collect information without the provider's consent does not define the purposes for which its discretionary power can be used. Given the relatively diluted level of data security introduced in the IT Rules, there were still complaints from lobbyists for pharmaceutical firms on the ground that the minimal protections found in the Rules prohibiting abuse of SPD would complicate the data collection method. One of the key lobbyists for this role is the International Consortium for Pharmaceutical Privacy (IPCC), which advocates sound policies for patient privacy in pharmaceutical companies operating in India[238].

Their position is that pharmaceutical companies are responsible for the safety of their products and require them to provide identifying information to patients when dealing with reports of adverse drug reactions. Therefore, it is important that these organizations continue to collect personal health data in order to ensure proper execution of safety measures. If the proposed good practices were to be fully enforced for pharmaceutical firms, these firms would have to keep track of details about patients taking the drug and doctors prescribing it. The IT rules requiring written consent are therefore intended to cover non-physical damages such as Privacy and confidentiality. The Indian pharmacovigilance lobby (the research and prevention of adverse effects of a drug) currently consists mostly of pharmaceutical conglomerates. They advocate using partly de-identified knowledge to advance medical research that could contribute to the discovery of new therapies. Nevertheless, their advocacy for the use of pseudonymized (or partially de-identified) information may lead to an erosion of data privacy principles[239].

In India, patients are classified using different combinations by each health care provider. This complicates the whole process. Comprehensively, there are two forms of patient information: information about patient identity, and information about patient health. These are handled by various departments and information systems, thereby raising the complexity of the information as a whole. By comparison, the patients do not own their medical records. Besides, the whole environment requires numerous third-party administrators. These services also have local control over the health data.

[238] I*d.*
[239] International Conference on Harmonization (ICH) - Draft Guidance for Industry: E2D Post- Approval Safety Data Management: Definitions and Standards for Expedited Reporting.

The technology used by these providers to allow healthcare providers to exchange data make the data vulnerable to various types of malware, cyberattacks and eventually lead to severe data breaches[240].

4.2.2.1 RIGHT TO INFORMATION ACT

The Right to Information Act (RTI) 2005[241] entitles citizens to request and access information that is publicly available and related to the public interest. Disclosure of information is limited to information provided in a fiduciary relationship, personal information not related to any public activity or interest, or in the event of an unjustified invasion of the individual's privacy.

The Medical Council of India cannot override the provisions of the Right to Information Act by using confidentiality standards that are involved in maintaining a patient's medical records, including a convict. However, the Act carries out some exceptions, such as the release of personal information, the release of which has no connection to any public activity or interest or which would not trigger the unwarranted invasion of the right to privacy. In such cases, discretion was conferred on the concerned Public Information Officer to make the information accessible, if he is satisfied that the disclosure is justified by the greater public interest. The RTI Act could be seen as a threat to the privacy of patients and research subjects, particularly in government institutions[242].

4.2.2.2 INFORMATION TECHNOLOGY ACT

The Information Technology Act that was notified in 2000 (IT Act) provides formal recognition for e-commerce and computer abuse sanctions [243] . The IT Act is a general law that articulates on a range of topics, such as public key infrastructure, e-governance, cyber-crimes, cyber-crimes, confidentiality and privacy [244]. It deals with the question of data protection and privacy in a piece by piece way because there are no basic

[240] *Id.*
[241] Right to Information Act (2005) (Volume 22).
[242] *Id.*
[243] The Information Technology Act (2000) (Vol. 21).
[244] Videha's, Kan & Karishma. (n.a.) *Data Protection And The It Act India (*Aug 2020). https://www.kankrishme.com/sharad_vadehra.php.

principles of data protection or privacy or actual legal structure in the form of data protection authority, data quality and proportionality, data transparency in India [245].

The IT Act contains certain provisions: penalty and compensation for damage to the computer, computer system etc.[246], compensation for failure to protect data[247], and voyeurism and violation of privacy[248], the penalty for breach of confidentiality and privacy[249] and punishment for disclosure of information in breach of a lawful contract[250], Protecting health information systems, data security, safety and education. The owner's permission is necessary for an individual to access or protect access to a computer resource[251].

4.2.2.3 CORPORATE RESPONSIBILITY FOR DATA PROTECTION

Corporate entities managing confidential personal information or data (related to physical, physiological and mental health; medical records and history as well as any relevant details) in a computer platform are obligated to adopt and enforce 'fair safety standards and procedures' and failure to do so will make them liable to pay damages[252].

The law explaining the description of 'reasonable security practices' has yet to be established and/or the central government still has to frame its rules on it.[253]. In addition, corporate bodies are mandated to provide privacy and information disclosure policies.

Public health is among others, a factor under the IT Act (national security, economy, etc.) which dictates whether information infrastructure is treated as critical. Computer resources consisting of critical information infrastructures are protected systems because their destruction can adversely affect national security, economy, public health or security. This is a very significant measure because today, IT infrastructure can also be used to handle some services provided to the general public, whose loss can have a direct effect on public health and safety [254]. Any Indian company collecting and/or

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[245] *Id.*
[246]The Information Technology Act (2000) (Vol. 21) Section 43.
[247]The Information Technology Act (2000) (Vol. 21) Section 43a.
[248]The Information Technology Act (2000) (Vol. 21) Section 66e
[249]The Information Technology Act (2000) (Vol. 21) Section 72.
[250]The Information Technology Act (2000) (Vol. 21) Section 72a
[251]*Id.*
[252]The Information Technology Act (2000) (Vol. 21) Section 43a.
[253]Seth, K. IT Act 2000 vs 2008- Implementation, Challenges, and the Role of Adjudicating Officers.,. P. 4. (May 2010) Enforcement of Cyberlaw.
[254]Seth, K., *IT Act 2000 vs 2008 Implementation, Challenges, and the Role of Adjudicating Officers*. P. 12.,(May 2010) Enforcement of Cyberlaw.

processing personal data shall obtain prior written consent from the information provider. Adherence with the additional consent requirement posed major challenges for outsourcers in the processing of personal data, especially those who have no direct interaction with the individuals to whom the data relates.[255]

4.2.2.4 HEALTH INSURANCE RECORDS

India's insurance regulator, Insurance Regulatory and Development Authority (IDRA), has provided a set of guidelines regulating third-party administrators, function outsourcing, database sharing and functionality of health insurance that cumulatively foster customer confidentiality and privacy in the health insurance industry[256].

The key characteristics of the Code of Conduct in relation to the privacy of health information require TPAs(Third-party administrators) to refrain from trading information and records of their business, to preserve the confidentiality of the data collected by them in the course of their agreement, to keep appropriate records of all transactions conducted out by them on behalf of an insurance company and to keep them for a period not less than three years[257]. An exemption to the maintenance and confidentiality of data confidentiality clause in the Code of Conduct requires TPAs to make available relevant information to any court, government or authority in the case of any investigation conducted or proposed against the insurance company by the authority, TPA or any other person or for any other reason[258].

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[255]The Information Technology (Reasonable Security Practices And Procedures And Sensitive Personal Information) Rules, 2011.

[256]Iyengar ,P. *Privacy in India*: Country Report,(22June9:00) https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2302978

[257]See List of TPAs Updated as on 19th December, 2011, Insurance Regulatory and Development Authority(2011),http://www.irda.gov.in/ADMINCMS/cms/NormalData_Layout.aspx?page=PageNo646 (lDec 19, 2020).

[258]The IRDA (Third Party Administrators - Health Services) Regulations 2001, (2001), Chapter 5. Section 2.

4.2.3 PROPOSED LEGISLATIONS

4.2.3.1 DRAFT DNA PROFILING BILL, 2007

The Draft DNA Profiling Bill, 2007 [259] aims to regulate all Indian DNA laboratories by forming a centralized-national DNA database. State databases will be consolidated to form a National DNA database. The aim of the bill is to standardize the entire DNA profiling process including access, health, infrastructure, quality control, quality assurance, personnel qualifications and training standards. The draft DNA Bill includes provisions for a DNA profiling commission, consisting of scientists, administrators and law enforcement officers[260]. The DNA Profiling Board can recommend statutes, regulations and practices on the availability, storage and analysis of DNA samples for privacy protection [261].

DNA databases can only be made accessible in legal cases, for prosecution purposes, a database of population statistics or to locate victims of accidents, disasters or the missing persons [262]. This should also be reported only to any judge, tribunal, law enforcement agency or laboratory. Sharing of DNA profiles with foreign states is permitted with the Central Government's approval[263].

- **Confidentiality and Access**

All DNA profiles, samples and records sent to the DNA laboratory, or any laboratory authority, must be kept confidential. For the reasons of forensic comparison permitted under this Act, authorised personnel may access information stored on the DNA database system, accessing any information contained therein by law enforcement officials or any other person,

[259]Draft DNA Profiling Bill (2007).
[260]Draft DNA Profiling Bill, Section 3 Constitution of DNA Profiling Board. Chapter 3.DNA Profiling Board, its Constitution, Powers and Functions.
[261]Draft DNA Profiling Bill, Section13-1-xv Powers and functions of DNA Profiling Board. Chapter 3 DNA Profiling Board, its Constitution, Powers and Functions.
[262]Draft DNA Profiling Bill, Section 40. Availability of DNA profiles, samples and DNA identification records. Chapter 7 DNA Data Bank.
[263]Draft DNA Profiling Bill Section 34. Matching of Profiles. Chapter 7 DNA Data Bank.

- **Privacy Concerns**

DNA's delicate and deeply permanent nature raises many concerns regarding privacy. Not only can the tissue from these DNA samples be used to identify individuals, but it "can also be used to generate information about health, paternity, and other personal issues."[264] The samples are of interest due to the ability of the DNA samples to produce information related to health and paternity to third parties such as insurers, employers, and government agencies. This could lead to genetic discrimination and restriction of access to health care, employment, and government services.

4.2.3.2 PRIVACY BILL

The draft Privacy Bill defines privacy, mandates privacy safeguards, permissible violations and outlines criminal penalties for privacy infringements.[265] The right to privacy concept includes confidentiality of medical records, protection from misuse of patient identification, protection from the use of fingerprints, DNA samples and other samples obtained at police stations or other locations, safety and health information privacy.

The draft Privacy Bill describes general privacy-related principles such as access, collection, disclosure and preservation of individually identifiable health data. Please consent. The draft Privacy Act proposes that any health information of any Indian citizen collected with his or her consent or authorized by law shall not be disclosed in public [266] .

Permission is necessary for the collection, use and disposal of information concerning health. Health information should only be kept for as long as is essential for the purpose or as required by law. The Bill provides for the disclosing, without permission, of health information if necessary or approved by or by law. The health information "shall be kept and retained for such period and in such a manner and used for such purposes" as required by law and "subsequently returned or destroyed in accordance with the law". The protection of health information should have been clearly defined, including various types of data (electronic, written, oral) and the specific parties managing health

[264]Rooker,K, *The Impact of DNA Databases on Privacy,* The University of Dayton School of Law(15 Jan 12 :00) https://www.bib.irb.hr/670840?rad=670840
[265]The Right to Privacy Bill, 2011.
[266]The Right to Privacy Bill, 2011, Section 27.

information (primary care provider, insurance program, public health authority or outsourcing of health care services)[267].

4.2.3.3 DIGITAL INFORMATION SECURITY IN HEALTHCARE ACT

The Ministry of Health and Family Welfare has put the draft Digital Information Security in Healthcare Act (DISHA) in place with the goal of securing data from the healthcare sector in India, giving people full control of their health data. For example, if you go to the doctor for a medical check-up, and the doctor puts the results in an electronic health record (EHR), the information is fully covered by DISHA because it is placed within the health system[268].

DISHA proposes three main objectives:

- Setting up digital health authority at national and state levels
- Implementing privacy and security measures for electronic health data and
- Regulating storage and exchange of electronic health records

India has taken a broader step by suggesting a separate Health Privacy Act with far more clarification than any other country, as this is the only legislation that appoints authorities at the state level, as well as the Health Information Exchange Authorities for each State separately, and their roles and powers have been clearly explained.

Data Ownership has been given to the data subjects, and the rights of the owner have been clearly elucidated in the same way as the EU Directive, under which the owner has been granted the right to access, the right to consent, the right to withhold information, the right to rectify, the right to know the place of presence, the right to know the intention of using his information are the many rights granted under DISHA. Further information on the establishment of national and state electronic health authorities (NeHA) are also given in the draft. In addition, it would provide Indian subjects with comprehensive data security and regulate the portability of data[269].

The law would allow the use of anonymized health data that cannot be tracked to people for specific purposes of public health, such as early detection and rapid response to

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[267] *Id.*
[268] Digital Information Security in Healthcare Act, Draft for Public Consultation, Ministry of Health & Family Welfare, November, 2017, pg. 4-31.
[269] *Id.*

emergencies of public health such as bioterror attacks and outbreaks of infectious diseases. Moreover, the draft stipulates, for data in recognizable form, that the digital data owner will require express prior permission before any transfer or usage. For example, businesses also give all workers free medical check-ups. Such tests may imperil the situation of an employee with his employer by disclosing a pregnancy or a severe chronic condition. A staff member may refuse to allow the pathology laboratory to share their data with the employer under the proposed legislation. DISHA addresses any issue arising from the confidentiality of the rights of the applicant, appointment, powers and functions of the national and state health authority, infringements and punishment & violations of such infringements of Privacy and confidentiality[270].

In consideration of significant privacy and security concerns regarding digital health data uses and abuse, the new legislation would fully ban the use of digital health data for 'economic purposes,' whether in an identifiable or anonymous form. The Act stresses that all health data, including physiological, physical & medical data, medical records, etc. pertain to an individual and any breach of such data amounts to an offence. It also notes that the data owners are entitled to privacy, confidentiality and data protection. Like most other legislation around the world, DISHA has restricted the freedoms, responsibilities and access & exceptions. Yet the law has not yet been passed, as the Ministry of Health awaits the verdict of the Supreme Court on Aadhaar, which concerns the question of privacy of individuals.[271]

[270] *Id.*
[271] *Id.*

4.2.4 CONTEMPORARY ISSUES

4.2.4.1 SPRINKLR CONTROVERSY

A petition was recently filed in the Kerala High Court questioning the agreement between the Kerala Government and the US-based Sprinklr Company to process COVID-19 patient-related data. The petition lodged by one lawyer, Balu Gopalakrishnan, alleges foul play in the Pinarayi Vijayan government's decision to select the services of a foreign-based private company for the storage and analysis of COVID-19 data. The applicant asks the decision to entrust the job to a foreign company, ignoring state agencies such as the C-DIT and NIC. The complainant notes that citizens' data are collected without their informed consent and stored on a foreign server. According to the complainant, COVID's more than 1.5 lakh-sensitive medical data of COVID -19 patients are with the company. “If information as sensitive is stored on private third party web servers, it is reasonable civility on the part of the State to notify and request consent from those from whom the data is obtained and also to assess if there will be potential misuse. Government departments are well prepared to manage data storage. Hence the big question: why the State chose the 3rd Respondent (Sprinkler) to store confidential information, " is what is stated in the petition filed by Advocate Jaykar K. S.

The petitioner points out that the corporation is facing lawsuits in cases alleging data theft in the United States. Citing the SC decision in *KS Puttaswamy's case*, the petitioner claims that the arrangement resulted in the violation of individuals' right to privacy under Article 21 of the Constitution. The data aggregated and distributed to the 3rd Respondent (Sprinklr) is a valuable asset on the data market that could raise millions of dollars. So, why it was done so is a mystery. The first respondent is unable to conceal ignorance from the above reality. It has the country's best IT minds and consultants[272].

[272] *THE SPRINKLER OF FATAL ERRORS: Kerala Govt sweats blood,* INDUSSCROLLS, (22 June 13 :00).https://indusscrolls.com/the-sprinkler-of-fatal-errors-kerala-govt-sweats-blood-plea-in-hc-challenges-kerala-govt-contract.

Data transfer was carried out by a State and not by any layman. It is a joint decision made jointly by a team of experts and not by a single person, taking both the pros and cons of the action into consideration. In the case, the petitioner added the Union of India as a respondent and claimed that the decision to enter into a contract with a foreign corporation could not have been taken without a central government. The second respondent (Union) is the authority that should be in agreement with such state decisions. It is a sad reality that before implementing the alleged agreement, the 2nd Respondent was never consulted and their participation was never pursued. The first respondent feels that these significant decisions that allow the government of the Union to compete can be given a go by and the decisions it makes will prevail, said the petitioner. The petitioner claims that the arrangement violates the rules of the Information Technology Act 2000. The Act provides for the protection of classified information and how it can be transmitted. The first respondent, with all legal paraphernalia, has haphazardly entered into an illegal contract. The contract sets in the hands of a private party the knowledge of common laymen. This was the State's binding duty to protect its people, but it chose to open it to a third party's vagaries, "the petitioner claims[273].

The petition seeks to direct the government of the state to terminate the arrangement with Sprinkler company and to appoint a government-IT company to store and examine COVID-19 details. The petitioner also seeks guidance from the central government to conduct a forensic audit to find out the "foul play" in the IT contract. The petitioner, as an interim relief is requesting a way to avoid uploading COVID-19 details to Sprinkler's web servers. The agreement with Sprinklr has resulted in a major political controversy in the state, with the opposition alleging serious irregularities in the contract. M Sivasankar, the IT Secretary, appearing in Saturday's media interviews, explained that the agreement was entered in the background of the public exigency created by the COVID-19 pandemic. He acknowledged that the legal department's opinion was not there before the contract due to the emergency situation. Denying the claims of data theft, the IT Secretary said that the State had full control over the data and that the company was only processing it to present the information in an organized manner.[274]

[273] *Id.*
[274] *Id.*

4.2.4.2 AAROGYA SETU APP

With 90 million downloads, Aarogya Setu has become one of the country's most-downloaded apps within two weeks of its launch. And one of the explanations for its success is that Prime Minister Narendra Modi had urged the country's 1.3 billion people to use it. While at the time of the announcement, the app was suggested to be voluntary, many private and public organizations recently made installing the app mandatory for their employees. For its alleged privacy and security vulnerabilities, the software has faced a great deal of flack. French hacker Elliot Alderson has also recently raised questions about the safety of the app. Now, MIT University has analysed the Aarogya Setu app to clarify how effective the app is, how secure it is to use, and how it compares with other contact tracing apps that are used in numerous parts of the world.

Unlike with the ongoing practice of arrest and fine threats in the country for people who don't have the Aarogya Setu app installed on their phone, the analysis reveals that the app's policy says it's voluntary to use. The MIT also says that India is the only democratic nation in the world that made use of the device compulsory for the people. According to Arnab Kumar, the head of this project, the app was built to the guidelines of a draft data privacy bill that is currently in the parliament of the country, and says that access to information it collects is strictly controlled[275].

The app isn't open-source, and many critics have raised this issue. Kumar says it'll happen down the line but hasn't confirmed any dates expected. The review further clearly shows that since the app is not open source, third parties cannot easily review its code and methodologies. However, Kumar has stated that sick person data will be deleted in 60 days, and in 30 days for healthy people. Digital rights advocacy group Internet India Foundation has written to the Standing Committee on Information Technology, a parliamentary body chaired by MP Shashi Tharoor, to initiate an urgent hearing on alleged violations of privacy associated with the government's contact-tracing app.

IIF recommended that the hearing include input from medical practitioners, IIT academics and digital rights experts and public policy experts in particular. Contact

[275] *Aarogya setu app* FIRSTPOST ,(June 22 10:00),https://www.firstpost.com/tech/news-analysis/aarogya-setu-the-mandatory-contact-tracing-app-of-india-gets-reviewed-by-mit-university-here-is-what-they-think-8354661.html.

tracing apps suffer from transparency issues, as they are launched without any legislative framework underlying them, IIF said in a blog post. It also cited the UK government's example, which on Wednesday prohibited the rollout of a contact tracing app unless there was legislation to protect the data collected from such an app. The group has released a working paper on comparative analysis of the app that highlights flaws and risks to personal data of people.[276] The Aarogya Setu app, developed by the government to track those with the disease and alert people about their close vicinity, has given rise to fears of state surveillance and the safety of the personal data that a user needs to fill in after downloading. Nonetheless, the government has said the device is absolutely secure and that all saved data will be removed once the Covid-19 crisis is over.

4.2.5 THE E-HEALTH REVOLUTION

The use of computer technology in the collection and management of health-related data takes many forms and can perform many functions, ranging from medical record-keeping, practice planning and logistics of procedures, online prescription ordering (e-pharmacy), fully automated bedside or home collection and transmission of patient data, to providing clinical decision guidance based on accumulated medical experience, to compile research databases

This set of transformations in health care and research is now in full swing, even though some elements are developing more quickly than others. Electronic health records (EHRs) are detailed digital patient records that carry or are linked to other data relating to health. They are designed to be much more than conventional paper charts in digital versions. The vision for EHRs involves their collection of long-term, preferably over life, knowledge from a person's health and health care experience, and being connected to prescription data, biospecimens, medical photographs, family health and reproductive history, genomic data, disease and other records, and other knowledge. The task is to build them so that they can accommodate the enormous variety of data handled in health care and payment, act efficiently as networked or at least intercommunicating systems in a variety of environments, make information available at the designated point of need for a large number of points and needs, and do all this safely and securely.

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[276] *Id.*

4.3 CONCLUSION

When we deal with sensitive details, as we often are in the health sector, it is safe to agree that there is a limit on what can be freely shared. Unless clear consent has been obtained for disclosure, information may need to be abstracted or omitted to protect the person. It is not easy to strike the right balance between anonymization and retaining valuable information as it often involves a trade-off between risk and benefit. The only answer to the ethical dilemma posed by the use of patient information for marketing purposes is to find the proverbial middle path. There is no clear law in India on the release of medical records. Nevertheless, under the Indian Medical Council Regulations, every medical practitioner is obliged to maintain confidentiality between doctor and patient[277]

While a physician may be found guilty of professional misconduct by revealing personal information about his or her patients[278] , this responsibility does not apply to any individuals responsible for processing patient data, either under the mandate of a state body or corporate body[279] . Doctors are only required to report patient information to public health authorities under specific situations, such as under the case of a 'significant and defined risk to a single individual and/or society'[280] .

DISHA Draft Bill would be a landmark change if approved as even countries like the US, the UK, the EU couldn't make it happen because of the resistance of the pharmaceutical companies, India will be the only nation that was able to enact such a comprehensive data protection statute. All countries have adopted a wider law on the use of health information and medical records, but DISHA has limited it.

As of now, India has no clear legislation in this regard, and it relies on the IT Act, 2000, which describes personal information in general and provides for some degree of privacy but does not clarify the rights in detail or has no penalties for the breaches. It provides for consent clause; however, does not explain the ownership clearly. The

[277]The Indian Medical Council (Professional Conduct, Etiquette and Ethic) Regulations, 2002 (102 of 1956). ('Medical Council Regulations').
[278] Medical Council Regulations, Chapter 8 (Disciplinary action may be taken against physicians for any offences committed in violation of the regulations).
[279]Medical Council Regulations, Rule 1.1 ('Character of Physician' covers only "Doctors with qualification of MBBS or MBBS with post-graduate degree/diploma or with equivalent qualification in any medical discipline" are covered under the Regulations).
[280]Medical Council Regulations, Rule 7.14.

Indian Judiciary has proclaimed the "right to privacy" to be a constitutional right, but there is still no proper set of laws to avoid the violation of the individual Privacy of the patient, and the anticipation continues for DISHA and similar laws to be enacted.

The United States and the United Kingdom are experiencing similar problems, although they have separate legislation, they also could not adequately identify the personal word information and could not limit the rights and control of access and the exemptions to such information. Although the EU has nearly taken it closer to DISHA Draft by leaving out some regions, the EU Directive clarified the owner's rights in detail but failed to narrow down the access aspect and in its 2016 amendment did not mention commercial exploitation.

So far, health data has been spared. This may be due to security, or chance. Health care records are more tempting targets for intrusion because they tend to be easier to pry into than other study files, more readily reveal comprehensible patient information, and more exploitable financial details. Privacy must be clearly and deeply appreciated if people are to be respected. Despite its personal and contextual uncertainty and complexity in defining it, Privacy is widely recognized as a fundamental human need and a prerequisite for a dignified life.

CHAPTER 5

5 CONCLUSIONS

Health care is a core concern to governments and individuals alike, more than any other issue. That's because we all need the health care system departments to varying degrees and at various points in our lives. It is clear that the right to health is a part of the right to life. The Supreme Court of India has construed the right to health as a part of the right to life and made it come under article 21 of the Indian Constitution. Therefore, it is the responsibility of the state to uphold the legislation and provide quality medical care. As a vast country, India has all the infrastructure, but there is a lack of proper execution, so it is the responsibility of the public and private sectors of health care to organise and work to improve the current status of health care. This paper dwells upon a few contemporary issues in India's healthcare sector, pointing out some weak links which call for strengthening them

In this dissertation, we touched upon three concepts regarding health which were divided into three chapters. They are patient rights, medical research and protection of data in the health care sector. In the case of all three, their relation to the aspect of privacy and confidentiality was also discussed in each chapter. Each of these three aspects is considered integral to the proper functioning of any health care sector around the world. The existing health care apparatus in India has yet to cope with and catch up to the pace of development around the world. One of the areas which need to be addressed is dissemination, exchange and protection of information of a patient. The health-related laws in India are grossly inadequate to cope with the changes taking place. Legislations regarding medical confidentiality are yet to find a foothold in the realm of Indian law and the importance of creating such laws has not been stressed enough.

Laws are dynamic, reflecting the social attitude at a given time and being enacted to control society's behaviour and practice[281]. Current examples include the enactment of the Persons with Disabilities Act to empower, promote equality and involve disabled persons The Pre-Natal Diagnostic Techniques Act to curb female feticide and India's

[281]Bhujang, P.M. *Legal Aspects in Healthcare: Guide for Healthcare Institution in India,* P.3. (Feb 2020) http://www.cehat.org/cehat/uploads/files/Lhcp.pdf.

Medical Council, Code of Ethics Regulations setting the medical practice professional standards. Invariably, the general health-care related legislation is not comprehensive enough because it does not sufficiently contain privacy and confidentiality protections.

There is no national law expressly protecting health information privacy in India. The existing legislative framework is[282] , in a sense, weak and complex. The topics include lack of safeguards, implementation, redress mechanisms and inactivity in the judiciary.

The Two most notable cases regarding the right to medical privacy are Mr. *"X" v. Hospital "Z"*[283] and *Ms X vs Mr Z & Anr*[284] . Currently, in India, questions related to privacy, disclosure, confidentiality, and ethical use of information, informed consent, data sharing and security of information are slowly being raised.

5.1 PRIVACY AND CONFIDENTIALITY

The patient is entitled to use health services in a way that is consistent with his personal values. Respecting the patient's privacy is important. The confidentiality and privacy of the patient and his family cannot be infringed except in situations established by law or where medical intervention is required to save a life. The patient can expressly request that his privacy be protected. All medical procedures must be conducted in a way that does not compromise the patient's confidentiality. Likewise, examination, diagnosis and treatment procedures must be performed as confidentially as is reasonably expected. Medical researchers have been allowed confidential access to medical records throughout the ages, and such access without informed consent must not be allowed.

The communication and information obtained and collected about the patient are important for the purpose of evaluation and overall management. The informants often offer the details under the assumption that it is being kept secret. Specifically, few attendants warn the doctor not to tell the patient what they've told the doctor.

In India, the doctor-patient relationship is administered more by the trust where the doctor is the authoritative person. In the case of informed consent, consideration must be given to the type and scope of the information to be presented by the doctor to the

[282] Iyengar, P. *Privacy in India: Country Report*. (Jan 2020) https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2302978
[283]Mr. X v. Hospital Z, (1998) 8 SCC 296.
[284]Ms. X vs Mr. Z & Anr ,(2002) 96 DLT 354.

patient for the purpose of obtaining consent. The reality is that the notion of informed consent or any form of consent, and preference in care, has little sense of significance for the vast majority in India. In standard medical practice, the advantage of informed consent seldom reaches all patients. A significant portion of India's population is also disabled by illiteracy and hunger. They can not understand medical terminology, principles and protocols for treatment. The functions of different organs or the effect of eliminating those organs can not be understood by them.

Written consent is also a validation of patient autonomy as the foundation of contemporary bioethics, aside from being documentary evidence in a judicial trial. Therefore, in order to undergo intrusive medical or investigative procedures and clinical trials and to determine the age at which a person's right to medical confidentiality starts, it is important to re-examine the inconsistencies and ambiguities surrounding the age of consent. In addition, procedures for obtaining consent from illiterate and mentally ill individuals and children need to be established.

5.2 MEDICAL RESEARCH

India is seen as an ideal location for conducting cheap clinical trials to meet the requirements of international regulators. Trials cost less than in developing countries, and the healthcare facilities will meet international expectations with English-speaking healthcare professionals along with information management systems. There is a vast and heterogeneous population of people with infectious diseases characteristic of poor societies, along with disorders such as heart disease, diabetes, cancers, and mental diseases which are of greater concern to drug firms.

In our nation, scientific work is not particularly terrible. Across other areas of science, innovation and technological growth, we have less than impressive results. However, the poor performance of scientific research has more severe consequences because it directly affects people's health, and therefore the nations. Of course, we need to ensure a much greater scope of quality scientific research. For research undertakings, researchers and all organisations that help, administer, track and disseminate research results, engaging in the Privacy and confidentiality relationships that serve it is important to obtain the trust that enables the public to engage in the study,

Data should be protected because people need to be respected, data is generally regarded as the central human right and necessity to live in dignity, the question of privacy and data security in relation to such health research should be recognized in the case of research firms, researchers and all organizations that support monitoring and revealing health-related data. Most study participants encountered issues after engaging in the research when their Privacy was not protected. Security is often not maintained due to inadequate research security, but it is also frequently attributable to unforeseen study design problems that unintentionally compromise protection.

Infringement of research data concerning the research participant, including identity information, causes them to be subjected to harassment, intimidation, stigma, violence, coercion, identity theft, or financial fraud, or denial of access to health or life insurance, schooling, work promotion, or loans, or fear of publicity. The Indian pharma lobby (for the research and prevention of adverse effects of a drug) like the actually consists mostly of pharmaceutical conglomerates. They recommend using partly de-identified knowledge to advance scientific research that could contribute to the discovery of new therapies. However, their support for the use of pseudonymised (or partially de-identified) data may lead to a degradation of data privacy principles

If one thinks that research, particularly biomedical research, is an activity of interest to our society, it is not too much for a researcher to ask for protection from harassment by summons. If researchers willingly participate as expert witnesses in private litigation, they must expect to be asked to supply the documents which form the basis for their opinions.

5.3 DATA PROTECTION IN HEALTHCARE

To India, a rising market in healthcare is very exciting because it is expected to introduce new medical technology, create more job opportunities and increase treatment rates. Yet these also carry risks, because in healthcare IT, it can be more difficult to avoid the disclosure of each individual's personally identifiable and sensitive information. Individual Privacy and open government are dynamic and sometimes at odds with a wide symbolic appeal. In recent years, increasing public concern about threats to personal Privacy and bureaucratic secrecy syndromes has generated litigation. Healthcare companies use technology to regularly process high-profile data from a wide number of patients. With more data stored electronically, there is a greater vulnerability

to hacking and data theft. That is why this health industry needs to be treated more carefully.

While India has been working on the Privacy and Protection bill for health care data since 2018, the bill has not yet come into force. Protecting the security of health information through rigorous data protection legislation is of the utmost importance to preserve individual patient trust and confidence. In India's first legislative step completely committed to the security of health information and the confidentiality of the patient's and the privacy rights of their health records was done when on 21 March 2018, the Ministry of Health & Family Welfare of India released DISHA Draft Bill to the public domain for comment.

The consequence of incorporating the definition of 'sensitive personal data' into the Indian IT Rules is still to be determined. The implementation of these new requirements is likely to be decided in line with the jurisprudence on 'right to privacy' established by the Indian courts. Nevertheless, as the amendments verbatim replicate the UK Data Protection Act, which enforces the Data Protection Directive, it is expected that the courts will find both common law and ECHR jurisprudence in protecting patient-identifiable information.

As of now, Indian organizations are not obligated to inform their end-customers or other individuals of a data breach when this occurs, except banks that are expected to notify the Reserve Bank of India within six hours of a data breach. According to the 2002 Indian Medical Council Regulations, physicians must maintain confidentiality related to personal or domestic life that is entrusted by patients at various stages of their medical attendance and procedures. This rule, however, simply does not define the limit for accessing patient information. In fact, it also fails to consider the IP addresses and other publicly identifiable online information as confidential personal information, which is of utmost importance in an Internet-driven world.

5.4 RECOMMENDATIONS AND SUGGESTIONS

- Legislation regarding the right to health, right of patients and other healthcare aspects need to be enacted
- Take all the essential steps from the governmental aspect and build people's awareness of the right to health
- Indian medical councils and government should set the standard of care to be observed by the medical professional concerning diagnosis, duty to communicate to the patient about inherent risk, treatment, surgery, post-operative care, etc.
- An explicit statutory provision is needed to eliminate the anomalies and ambiguities regarding the age of consent to undergo therapeutic procedures, to participate in clinical trials, and to define the stage at which a person's right to medical confidentiality begins.
- A legally protected right to health can only be met by careful planning, which in turn depends on a reliable and frequent collection of information and on timely reports on government health needs.
- We need to strengthen many areas of Medical research. This includes new policies and procedures for confidentiality steps to be enforced and audited, database overhaul, and technological security enhancements such as biometry authentication, encryption, server safety, and backup securing.
- Researchers may also require expert guidance in complicated cases about the interpretation of the applicable laws and common law.
- Research funding agencies will need to ensure that researchers, hosts, and flinders have a clear understanding of who is responsible for maintaining sensitive databases.
- Public confidence in medical research needs to be sustained and improved since most medical research is dependent on volunteers
- A proper set of laws to avoid the violation of the individual Privacy and breach of personal health data of the patient must be enacted.

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- Convention on the Right of Persons with Disabilities
- Convention on the Elimination of All Forms of Discrimination Against Women
- African Commission on Human and People's Rights

7 APPENDIX

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