UNDERSTANDING MEDICAL RECORDS IN THE INDIAN LEGAL CONTEXT: THE NEED FOR A COMPREHENSIVE REGULATORY FRAMEWORK FOR MEDICAL RECORDS

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Abstract

The medical record is an essential document to be prepared and maintained by all health care providers for various purposes such as therapeutic, research, surveillance, and legal. India is a fast-growing digital country, where the health information of individuals is gathered at various levels. Also, to note that the Government has initiated various programmes in connection with digitalising healthcare services. At this juncture, this study aims to bring out the effectiveness of legal regulations and professional norms existing in India to standardise medical records. The study emphasises general issues such as preparing, preserving and destroying medical records, patients' rights over medical records, and regulations regarding special category medical records. The study follows the doctrinal method. On reviewing the existing laws and ethical regulations, the study finds a legal vacuum for standardising the preparation, maintenance, retention, and destruction of medical records. The study also finds no comprehensive legislation to protect patients' rights over medical records and data ownership. In the light of these findings, the study recommends adopting a comprehensive regulatory framework with an appropriate enforcement mechanism.

Keywords: *Medical records, access to medical records, data ownership, medical confidentiality, right to information.*

I. Introduction

II. Regulatory Standards for Medical Records

III. Medical Records and Patients' Rights

IV. Law Relating to Special Category Medical Records

V. Conclusion

I. Introduction

OVER THE centuries, the hippocratic tradition of medical confidentiality has gone through several changes in accordance with the development of the health care system around the world. The principle of medical confidentiality is the golden rule that exists in a doctor-patient

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relationship. In the past, it was the individual professional responsibility of the doctor concerned to ensure the confidentiality of the health information of his/her patient. However, with the introduction of new healthcare system models, record keeping became a separate department of all health care institutions both at the Government and private sector. Today, all clinical establishments have their medical record-keeping department, which functions in an organised and systematic way to enable and facilitate medical record movement as per the norms and policies of the institution. In India, though it was recommended by committees constituted to study the functioning of healthcare administration, there existed no proper practice of medical records keeping among the medical practitioners since Independence. Thus in *Poona Medical Foundation Ruby Hall Clinic* v. *Marutirao L. Titkare,* the National Consumer Protection Redressal Commission, on a question of failure to supply hospital records to the complainant, held that 'there can be no question of negligence by reason of such failure to supply the papers unless there was a legal duty cast on the hospital to furnish such documents to a patient'[1].

Medical record-keeping became a part of medical practice only after adopting the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations in 2002. Apart from Indian Medical Council Regulations, the Medical Termination of Pregnancy Act, 1971, the Pre-conception and Prenatal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994, the Clinical Establishments Act, 2010, and the Mental Healthcare Act, 2017 have provisions dealing with medical records. But these legislations have only limited application, and there exist no uniform standards for clinical establishments in the private and public sector in respect of medical record keeping. The newly proposed Digital Information Security in Healthcare Bill, 2017 and the Personal Data Protection Bill, 2019 are not addressing many of the issues connected with medical records keeping. Against this backdrop, this study strives to examine the relevance of medical record-keeping and analyse the adequacy of the Indian regulatory regime for preparation, maintenance, retention, destruction, and patient rights on medical records. For that, the study follows the doctrinal method and will review all relevant statutes, rules and regulations in connection with medical record keeping

a. Medical Records: Meaning and Essentials

[1] NCDRC 1995 (1) CPJ 232.

The WHO guidelines on Medical Records Practice define a medical record as 'a collection of data compiled on a patient to assist in the clinical care of present and future illness'[2]. The medical records are not a mere repository of information, but it is a continuing record that acts as a source of future communication among the healthcare providers[3]. As per the WHO guidelines, a medical record should be:[4]

i. able to identify the patient,
ii. legible and able to be understood by anyone likely to use it,
iii. accurate, logical and concise in its organisation,
iv. consistent in layout and the size of papers used in it,
v. able to identify the people who are contributing to the record so that they may be asked for further information if necessary,
vi. promptly retrievable when required.

In the current scenario of medical records, be it paper or electronic or personal, have health information of patients/ individuals ranging from personal, professional, demographic, familial, financial, clinical, and genetic. It is used for better patient care, better management of health care system, health surveillance, medical and biomedical research, reimbursement of medical cost under Government and Private insurance schemes, evidence in medico-legal cases, predict the outbreak of epidemics, predictive and precision medicine, the process of clinical creativity[5], conditions of social life[6], and a reliable source for historians.[7] Hence, the WHO Guideline mandates for a Medical Records Department and a Medical Records Committee[8] to properly manage medical records. The Medical Records Department is the service department of the clinical establishment run by trained staff who works for efficient and effective medical records management. Whereas the Medical Records Committee will be an advisory body in respect of the following matters;[9]

i. General hospital rules relating to medical records;
ii. Control of and advice on medical record form and standardisation;

[2] Guidelines for Medical Record Practice, *WHO*,1980 at 29.
[3] *Ibid.*
[4] *Ibid.*
[5] John Harley Warner, 1 *The Uses of Patient Records by Historians: Patterns, Possibilities and Perplexities, Health and History* 101 -111 (Australian and New Zealand Societyof the History of Medicine, 1999).
[6] *Ibid.*
[7] *Ibid.*
[8] *Supra* note 2 at 59 & 69.
[9] In such committees membership typically consists of: Medical administrator, Surgeon, Pathologist, Senior nurse, Physician - Medical Record Officer & Radiologist; *Supra* note 2 at 69.

iii. Quality control measures, especially medical audit or Patient Care Evaluation;
iv. Decisions on retention periods for medical records.

The Indian Public Health Standards released by the Ministry of Health and Family Welfare under the National Health Mission in 2007 for public hospitals at various levels mandate a dedicated Medical Record Department (MRD) and Medical Audit Committee to ensure the proper management of patient records.[10] On the other hand, such standards are not prescribed under any regulations for private sector clinical establishments. However, modern hospitals cannot function without the support of a Medical Record Department due to the high flow of patients. Thus Medical Record Departments have an indispensable part of medium to large scale hospitals in India.

b. The practice of medical record-keeping: The relevance and its evolution

Health is a fundamental human right,[11] and it is an inherent right of everyone irrespective of their economic and social background. It has become a cardinal governing principle of all welfare countries globally, guaranteed through either Constitutional provisions or specific statutory provisions.[12] The United Nations Committee on Economic, Social and Cultural Rights, while drafting the core legal obligations of the State Governments in respect of implementing the right to health, way back in the year 2000, pointed out that information accessibility as an essential element of the right to health.[13] However, informational accessibility in its real terms still lacks proper implementation. More importantly, patients are unaware of their right to access medical information from healthcare establishments. As

[10] Indian Public Health Standards, *available at*: *https://nhm.gov.in/index1.php?lang=1&level=2&sublinkid=971&lid=154#:~:text=IPHS%20are%20a%20set%20of,especially%20for%20Non%2DCommunicable%20Diseases* (last visited on May 15, 2021).

[11] The Universal Declaration of Human Rights, 1948, art. 25(1); The International Covenant of Economic, Social and Cultural Rights, 1966, art.12(1); The International Convention on the Elimination of All Forms of Racial Discrimination, 1965, art. 5(e); The Convention on Elemination of All Forms of Discrimination Against Women, 1979, art.11(1), *etc.*

[12] 109 countries have recognised right to health in their Constitutions. See, WHO, *25 questions and Answers on Health and Human Rights*, Health and Human Rights Publication Series, WHO, July 2002 at 10.

[13] U.N., The Committee on Economic, Social and Cultural Rights, *the General Comment No.14 (2000),* Para 12 states that the human right to health has the following essential components;

a. Availability
b. Accessibility
   i. Non-discrimination
   ii. Physicial accessibility
   iii. Economical Accessibility
   iv. Information Accessibility
c. Acceptability
d. Quality

healthcare systems generally follow a paternalistic approach, disclosure of the data is limited. Medical records are the source of the health information of patients. But those are typically retained by medical practitioners or health care institutions. Nevertheless, substantial changes have occurred in the doctor-patient relationship.

The modern doctor-patient relationship is primarily based on trust and confidentiality.[14] It facilitates the deep and close interaction between the doctor and his patient. Thus medical records are not just official documents for determining the treatment protocols; these are records of the actual life of the patients, including the basic details to the genetic profile. A medical record generally includes demographic, personal details, family and financial details, medical history, reports of clinical and diagnostic tests done, clinical findings, pre and post-operative care, and follow-ups.[15] In contrast to the earlier understanding that medical records are intended for ensuring the best care for patients, it has become an essential document in all medico-legal cases, biomedical research, insurance claims, *etc.*[16]

On tracing the history of medical records, it can be found that patients records were invented thousands of years ago by the father of medicine, Hippocrates.[17] He had shown keen interest in preparing notes about his patient's appearance, social situation, symptoms, etc. to decide the treatment and he also recommended storing these documents for future reference.[18] Historically, medical records were part of medical practice in Greek, Rome and Egypt. The system of record keeping as a regular medical practice evolved when the hospitals started to function in different jurisdictions during the 7th Century. The earliest example of institutions recognisable as hospitals were in Byzantium during the 7th Century.[19] The Islamic world also developed hospitals and by the 11th century, there were large hospitals in every major Muslim town.[20] During the 12th -14th Century, a large number of hospitals offered service to the sick.[21]

[14] Juhi Tripathi and Shalabh Rastogi, "Changing doctor patient relationship in India: a big concern" 6 *International Journal of Community Medicine and Public Health* 3160 (2019).
[15] Amit Bali, Deepika Bali,"Management of Medical Records: Facts and Figures for Surgeons" 10 *J. Maxillofac. Oral Surg.* 199-202 (2011).
[16] *Ibid.*
[17] Sarah Atkingson and Jane Macnauthton, *The Edinburgh Companion to The Critical Medical Humanities* 121 (Edinburgh University Press, 2016).
[18] Dalianis H., *Clinical Text Mining: Secondary Use of Electronic Patient Records* 5 (Spinger Open, Switzerland, 2018).
[19] Martin McKee and Judith Healy *Hospitals in Changing Europe* 14 (Open University Press, Bunkingham, Philadephis, 2002).
[20] *Ibid.*
[21] Syed Amin Tabish, *Hospital and Health Service Administration – Principles and Practice* 31 (Oxford University Press, New Delhi, 2002).

The physicians in such hospitals had maintained records of their patients.[22] The early modern medical practitioners who worked outside the hospital system maintained diaries, registers or testimonials to record the patient-related information. During the late seventeenth century it became a common practice among medical professionals, though it was not properly structured and standardized.[23] With the introduction of computer technologies during the 20th century, there occurred a transition from paper records to Electronic Medical Records (EMR)[24] and the 21st century marks the beginning of Personal Health Records (PHR)[25] in various jurisdictions like US, UK, Canada, India, *etc.* that are indented to give more autonomy to the patients in medical treatment and to safeguard their right to privacy and confidentiality through legal regulations framed to control the storage, use and the access to health information of patients.

c. Indian scenario of Medical Record-keeping

In contrast to other ancient systems of medicine, there is a dearth of manuscripts, inscriptions or other records to study the medical practices in ancient India.[26] The seals and tablets discovered from Harappa and Mohenjadaro are yet to be deciphered.[27] As there is no specific description available as to the practice of medical record-keeping practice in India, historians have well documented the development of the health care system in India. There are shreds of evidence to show that hospitals, under Ayurveda, the indigenous medical system in India was prominent even from the Vedic period, and hospitals were established in India during the Buddhist period (563–477 BC).[28] During the period of King Ashoka, more hospitals were established in different parts of the kingdom.[29] But the modern system of medicine was introduced to India by the Portuguese and hospitals under modern medicine were started to function from 1664 under the British Rulers.[30] As already pointed out that the system of health care and hospital administration was well developed in Europe during the 12th Century and

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[22] *Available at:* https://hekint.org/2017/02/22/byzantium-origin-of-the-modern-hospital/ (last visited on May 14, 2021).
[23] *Supra* note 18 at 122.
[24] R. S. Evans, Electronics Health Records: Then, Now, and in the Future, *IMIA Yearbook of Medical Informatics* (2016) at 48-50.
[25] Scott Endsley, David C. Kibbe "An Introduction to Personal Health Records" 10 *Family Practice Management* 57-62 (2006).
[26] Sharma D. K. and Goyal R.C., *Hospital Administration and Human Resource Management* 31 (PHI Learning Pvt. Ltd, New Delhi, 2017).
[27] *Ibid.*
[28] *Ibid.*
[29] *Supra* note 22 at 23.
[30] *Ibid.*

historians had commented on the record-keeping practice of physicians during the period. Since the Indian modern medical system was largely based on the British medical system, it may be assumed that patient records might have been maintained in some form. Various committees appointed in India after Independence had recommended developing proper medical records keeping practice.[31] Nevertheless, medical record-keeping became an obligation only after 2002 when the Medical Council of India issued the Ethical Guidelines. Later the Clinical Establishments Act, 2010, also made it mandatory for all clinical establishments registered under the Act to keep medical records of patients in electronic format.

Digital health is a buzzword in today's health care system. Heading towards digital health programmes, the Government of India has been introducing many services such as tele-consultations, e-hospital, mraktkosh, *etc*. since 2015 under the 'Digital India Programme'.[32] More importantly, India launched the 'National Digital Health Mission (NDHM)' on August 15, 2020,[33] which offers services for Electronic Medical Records (EMR) and Personal Health Records (UDHM Health Record). Electronic Medical Records provide the details of the patients' medical treatment history and other health information and are usually maintained by the health care facility. In contrast to this, the Personal Health Records system is introduced to ensure patients' control over their health information and it will be controlled by the account holders.[34] Even before the introduction of the National Digital Health Mission, the Ministry of Health and Family Welfare in collaboration with the Department of Electronics and IT had initiated a joint venture for a personal health record management system (named as My Health Record) for citizens to enable them to own and use their health records independently.[35] But it was not officially launched.

A major regulatory initiative was the adoption of the Telemedicine Practice Guidelines under the Medical Council of India Ethical Guidelines on March 25, 2020. The Telemedicine Guidelines empowers all Registered Medical Practitioner (RMP) to offer telemedicine services and it also binds such providers to maintain a digital trail or patient record. To create a

[31] Hospital Manual, *Directorate General of Health Services*, Ministry of Health and Family Welfare, 2002 at 88.
[32] *Available at:* https://www.digitalindia.gov.in/services?page=4 (last visited on May 14, 2021).
[33] PM Modi launches National Digital Health Mission, says every Indian to get unique health ID, *Indian Express,* August 14, 2020, *available at*: *https://indianexpress.com/article/india/national-digital-health-mission-indians-health-identity-cards-6555529/* (last visited on August 14, 2021).
[34] *Available at:* https://ndhm.gov.in/home/digital_systems (last visited on May 14, 2021).
[35] National Health Portal of India, *available at:* https://www.nhp.gov.in/myhealthrecord_pgv (last visited on May 15, 2021).

regulatory environment for digital health records, the Ministry of Health and Family Welfare had also notified the Electronic Health Record Standards for India in 2013 and revised it in 2016.[36] But it was not made mandatory for all healthcare establishments. The precursor of the National Digital Health Mission was the report published by NITI Aayog in 2019 for transforming the Indian health care system and has made various recommendations for implementing the concept of digital health including Electronic Medical Records. It was followed by the adoption of the National Digital Health Blueprint.[37]

To focus more upon the legal issues revolving around the preparation, maintenance of medical records, this study identifies the following core issues.

a. Existing regulators for medical records including preparation, maintenance and destruction of medical records.
b. Patients' rights on medical records
c. Standards for special category medical records

II. Regulatory Standards for Medical Records

a. Regulations on Preparation and Preservation of Medical Records

After Independence, the health care system became more organised. However, there existed no regulations or guidelines either legal or medical as to the preparation and preservation of medical records in India. The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations in 2002 for the first time mandated the medical practitioners to maintain medical records of patients in the standard format (Appendix 3) and to computerise the records for quick retrieval.[38] Though it is the standard format prescribed for medical records in India, the hospitals in the private and public sector are not generally following this format mainly due to the lack of enforcement mechanism under the Indian Medical Council Guidelines.[39] Similarly the Homoeopathic Practitioners - (Professional Conduct, Etiquette & Code of Ethics) Regulations, 1982, and the Practitioners of Indian Medicine (Standards of Professional

[36] Electronic Health Records (EHR) Standards for India 2016, *Ministry of Health and Family Welfare*, Government of India, *available at:* https://main.mohfw.gov.in/sites/default/files/EMR-EHR_Standards_for_India_as_notified_by_MOHFW_2016_0.pdf (last visted on May 29, 2020).
[37] NITI Aayog, Health System for a New India: Building Blocks, Nov 2019; National Digital Health Blueprint, Ministry of Health and Family Welfare.
[38] Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, Regulation 1.3.1 and 1.3. 4.
[39] The Parliamentary Standing Committee, "92nd Report on the functioning of Medical Council of India" (March 2016) at 46-51.

Conduct, Etiquette and Code of Ethics) Regulations, 1982 also direct medical practitioners under these systems of medicine to maintain records of prescription and certificates issued.[40] Further, the Clinical Establishment (Registration and Regulation) Act, 2010, as part of the registration of clinical establishments, medical records keeping was made mandatory for all clinical establishments registered under the Act including clinics functioning under Ayurveda, Unani and Siddha.[41] Though as per the provisions of the Act, clinical establishments that are registered under the Act shall maintain medical records, there are no guidelines issued so far in respect of the methods of preparation and maintenance of medical records. Another crucial point is that the provisions of the Act are made applicable only to some states such as Haryana, Sikkim, Mizoram, HP, Arunachal Pradesh, Bihar, UP, Uttarakhand, Assam, Jharkhand, Rajasthan and Union Territories excluding Delhi.[42] In other states like Kerala,[43] Tamil Nadu,[44] West Bengal,[45] *etc*, have their laws and regulations to regulate clinical establishments. It shows that there is no uniformity with respect to the methods of preparation of medical records in our country.[46] Thus leaving this area unattended by the legislatures and policymakers will violate the basic right to health of people and it may also lead to the application of different standards in different regions as the laws are different in each state for medical record keeping.

Similarly, there exists an ambiguity in respect of the period for which the medical records shall be preserved by medical practitioners generally known as the retention period of medical records. As per the Medical Council of India Regulations, 2002, medical records shall be maintained for a period of three years from the date of commencement of treatment. Apart from that, the clinical establishments registered under the Clinical Establishments Act, 2010, are required to maintain medical records and electronic medical records as per the norms

[40] Homoeopathic Practitioners - (Professional Conduct, Etiquette & Code of Ethics) Regulations 1982, Regulation 5A & 38; The Practitioners of Indian Medicine (Standards of Professional Conduct, Etiquette and Code of Ethics) Regulations, 1982, Regulation 30.

[41] The Clinical Establishment (Registration and Regulation) Act, 2010, s. 12 ; The Clinical Establishments(Central Government) Rules 2012, rule 9 (iv).

[42] The Clinical Establishments (Registration and Regulation Act, 2010, s.1(2).

[43] The Kerala Clinical Establishments (Registration and Regulation) Act, 2018, and The Kerala Clinical Establishments (Registration and Regulation) Rules 2018.

[44] The Tamil Nadu Clinical Establishments (Regulation) Act, 1997, and The Tamil Nadu Clinical Establishments (Regulations) Rules, 2018.

[45] The West Bengal Clinical Establishments (Regulation and Registration) Act, 2010, and The West Bengal Clinical Establishments Rules, 2003.

[46] *Supra* note 2.

prescribed by the Central Government.[47] The office memorandum issued by the Ministry of Health and Family Welfare in 2014 directs that:[48]

a. Medical record of In-patients of the last ten years shall be kept in digital format and for future and medical records of all In-Patients shall be maintained on a regular and continuous basis for future reference indefinitely,
b. A hard copy of medical records of both In-Patient and Out-Patient shall be kept for three years,
c. Medical Register and case sheets of medico-legal cases shall be kept for ten years or till the final disposal of the ongoing cases.

The Hospital Manual published by the Directorate General of Health Services in 2002, directs to keep In-Patient records and Medico-Legal Registers for ten years and Out-Patient records for five years.[49] The office memorandum and Hospital Manual applies only to public sector health care institutions. Ironically, in India, the majority of the hospitals are in the private sector where these directions find no use with respect to medical records management.

After bringing medical services under the purview of the Consumer Protection Act[50], the number of medical negligence cases is on the rise. The limitation period for filing a complaint under the Consumer Protection Act, 2019 is two years and the period may be extended if there is sufficient reason to show.[51] In such circumstances, the hospitals will be liable to keep medical records even after three years, the period stipulated by Indian Medical Council Regulations, 2002. As per the Limitation Act, 1963 in the case of minors, their medical records shall be maintained until they attain majority.[52] Similarly, section 29 of the Pre-conception and Prenatal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 also prescribes a period of two years for keeping records, charts, consent letters, forms and reports. If there are any civil or criminal proceedings initiated against any clinics, they are responsible to keep records till the end of the proceedings.[53] Whereas the Medical Termination of Pregnancy Regulation, 2003 directs clinics to keep admission registers for a period of five years.[54] The recently adopted

[47] *Supra* note 38.
[48] *Office Memorandum*, Directorate of Health and Family Welfare, Ministry of Health and Family Welfare, dated October 28th, 2014.
[49] *Supra* note 32 at 90.
[50] *Indian Medical Association* v. *V.P Shantha,* 1996 AIR 550.
[51] The Consumer Protection Act, 2019, s.69..
[52] The Limitation Act, 1963, s. (6) (1).
[53] The Pre-conception and Prenatal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994, s.29 and The Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Rules, 1996, Rule 9.
[54] The Medical Termination of Pregnancy Regulation 2003, Regulation 5.

Mental Healthcare Act, 2017 mandates the clinics and hospitals rendering services to persons having a mental illness to keep records in prescribed format and the provisions are silent about the retention period. On the contrary, the most disputed issue, the transplantation of human organs, the law enacted to regulate organ transplantation does not prescribe any period for retention or format for preparing medical records. Also, it is important to note that there is another set of guidelines exists for hospital accreditation supervised by the National Accreditation Board for Hospitals (NABH). In India, the NABH accreditation was developed to ensure the quality standards of hospitals. As per the National Accreditation Board for Hospital standards, medical records shall be kept in the prescribed format for a period specified in the policy prepared by each health care institution in consonance with the law existing in the country.[55] However, in India, only a few hospitals have NABH Accreditation. Thus these guidelines will be applicable only for such institutions which pursue accreditation under NABH.

Above all, separate clinical establishment regulations exist in many States like Tamil Nadu, Kerala, Karnataka, *etc.* for public and private clinical establishments. Such State legislations have also prescribed different retention periods for medical records. Thus it is the need of the hour to address the issue of preparation and retention of medical records in different types of medical/healthcare institutions under all systems of medicine. Though there are directives issued by the Ministry of Health and Family Welfare for clinical establishments functioning under the Directorate of Health Service, there is no similar statutory provision or Rules or Regulations that apply to the private sector medical establishments that are working under different systems of medicine. The Indian Medical Council Regulations, 2002 is applicable only for the Allopathic system of medicine and it is confined to IP records. Thus it is imperative to have a proper legal regulation to standardise the format, preparation and retention of medical/health records.

b. Teleconsultations and Electronic Medical Records

The Board of Governors in Supersession of the Medical Council of India adopted the Telemedicine Practice Guidelines under the Indian Medical Council Ethical Regulations, 2002 to facilitate teleconsultations amid COVID 19 pandemic on March 25, 2020. As per the

[55] *Guide book to Accreditation Standards for Hospitals*, NABH, 4th edn., 2015 at 206.

Telemedicine Practice Guidelines, 2020 the Registered Medical Practitioners offering online teleconsultations shall maintain records of the following;[56]

i. Record of Teleconsultation including Phone logs, email records, chat/ text record, video interaction logs etc.,
ii. Patient records, reports, documents, images, diagnostics, data etc. (Digital or non-Digital) utilised in the telemedicine consultation,
iii. Prescription records in the same format as in-person consultations.

Though the Telemedicine Guidelines, 2020 directs medical practitioners to maintain medical records of online consultation, the format or method of maintaining such records are not illustrated in the Guidelines. However, it generally mandates that all online consultations shall adhere to the Indian Medical Council Regulations, 2002 and other relevant regulations. Thus Electronic Health Records (EHR) Standards, 2016 adopted for stipulating technical and infrastructural norms for electronic health records apply to medical records created on teleconsultations.

The Electronic Health Record Standards, 2016 provides a permanent system of lifelong medical record-keeping and on the demise of the patient and if there are no cases pending before any court of law such medical records may be moved from active status to inactive status.[57] Under the National Digital Health Mission (NDHM), health care institutions are responsible to maintain Electronic Medical Records (EMR). However, no legal regulations are existing for standardising Electronic Medical Records or records created on telemedicine consultation concerning the pattern, format, and removal of health information in medical records. In addition to that developing digital infrastructure to adopt the standard for Electronic Medical Records poses great financial responsibility upon healthcare providers. Thus the majority of Indian hospitals haven't adopted the Electronic Health Record standards, 2016. The participation of private sector healthcare institutions in the National Digital Health Mission is voluntary. Hence, there will no regulation for hospitals and clinics which functions outside the National Digital Health Mission, Thus this legal vacuum shall be rectified by adopted proper regulatory norms which can be made applicable to all healthcare institutions at the Government and Private level, that are offering online consultations or have Adopted Electronic Medical Records.

[56] Telemedicine Practice Guidelines, 2020, Guideline 3.7.2.
[57] *Supra* note 38 at 22.

c. Destruction of Medical Records

The life cycle of the medical records starts when it is prepared by clinical establishments and ends with destruction. The creation, utilisation, maintenance and destruction are four stages of the medical records life cycle.[58] Since medical records are the source of large scale health information of citizens, the Governments have to frame rules and regulations as to its retention and destruction. To periodically review the medical records, institutions should have a Medical Records Retention Schedule. The Retention Schedule must have guidelines;[59]

A. to ensure the information in the medical record is made available for continued patient treatment, research, education, legal requirements etc.,
B. to specify what information is kept, how long it should be kept and in what form and in which devise it is kept,
C. Ensure proper destruction of records for each medium on which information is kept.

However, it is important to note that there are no statutory provisions, rules, regulations or even any guidelines existing in India in respect of the destruction of medical records. The clinical establishments follow their convenient procedure and it is done without any involvement of independent third parties or representatives of the Govt. in most of the institutions. The existing and newly proposed legislation on data security have not addressed these issues. As medical records are sources of valuable health information, a lack of regulations for the destruction of data may pave the way for mismanagement of health information and infringement of the personal rights of patients.

III. Medical Records and Patients' Rights

a. Medical Confidentiality

In India, there is a total lack of specific legal regulations in respect of patients' rights over medical records. However, it is generally considered that health information is the patient's property under the custody of medical practitioners or hospitals or clinics on mutual trust and confidentiality. The concept of confidentiality is the cornerstone of the doctor-patient relationship and it is the most important ethical value to be followed by medical practitioners.

[58] Kathy Downing, "Retention and Destruction of Health Information", *available at*: https://library.ahima.org/PB/Retention Destruction (last visited on May 25, 2020).
[59] *Ibid.*

The principles of medical confidentiality were evolved from the Hippocratic tradition.[60] The ancient Indian medical text 'Charaka Samhitha' had also embodied the principles of medical confidentiality and it was the basic tenant of medical professionalism in other traditions of medicine.[61] The Hippocratic oath had twofold obligations. It directs physicians to preserve medical information and to exercise discretion in determining what is to be kept confidential.[62] These principles of 'decorum' and 'discretion' find expression in modern national and international ethical guidelines.[63]

Medical confidentiality has now moved from mere ethical value to a more concrete version of medical confidentiality protected under common law (breach of confidence) and statutory provisions. Again it is considered as an aspect of medical privacy in the modern era of transformative constitutionalism. The tort of 'breach of confidence' as a separate tort emerged during the mid of nineteenth century which covered information divulged by persons under trust and confidence. The boundaries of privacy and breach of confidence became blurred over these years due to varying interpretations given by courts.[64] But the tort of breach of confidence still protects the interest of patients in respect of his/her medical information passed to the health care providers in the absence of any specific statutes as in the case of India.

The tort of breach of confidence emerged as a separate tort in *Prince Albert* v. *Strange* in 1849[65] and it is considered as an aspect of privacy rights in the 21st century. To constitute the tort of breach of confidence, in *Coco* v. *A. N. Clark (Engineers) Ltd.*, it was held that:[66]

a. the information must be confidential in nature,
b. the information must have been communicated in circumstances importing an obligation of confidence,
c. the information must be used to the detriment of the other person communicating it.

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[60] Hippocratic Oath states that '……And whatsoever I shall see or hear in the course of my profession, as well as outside my profession in my intercourse with men, if it be what should not be published abroad, I will never divulge, holding such things to be holy secrets….".
Gerald L. Higgins, "The History of confidentiality in Medicine: The Physician Patient Relationship", 35 *Canadian Family Physician Medicin de Famille Canadien* 921 (April, 1989).
[61] *Id.,* at 922.
[62] *Ibid.*
[63] World Medical Association, International Code of Medical Ethics, 1949; American Medical Associtiion, Code of Medical Ethics, 1847; The Council for International Organizations of Medical Sciences (CIOMS), International Ethical Guidelines for Biomedical Research Involving Human Subjects, 2002, *etc.*
[64] Douglas Maule and Zhongdong Niu*, Media Law Essentials* 134-139 (Edinburgh University Press, 2010).
[65] His Royal Highness *Prince Albert* v. *Strange*, (1849) 47 ER 1302, *available at:* http://www.worldlii.org/int/cases/EngR/1849/255.pdf (last visted on May 22, 2020).
[66] [1968] F.S.R. 415 at 4 & 5, *available at*: http://achristie.com/wp-content/uploads/2014/12/Coco-v-AN-Clark-Ch-1968-WL.pdf (last visited on May 15, 2020).

In the UK, the tort of breach of confidence and its underlying principles have changed to such an extent that the conditions discussed in 1968 became unimportant, that it may be applied in a situation where there is no duty of confidentiality[67] and it moved to a more comprehensive frame of privacy concerns.[68] Though confidentiality is an aspect of privacy rights, all private information is not confidential. The legal wrangling over confidentiality and privacy principles is still going on among the jurists.[69] Amid such legal debates, it is considered that doctor-patient communications are by nature confidential in nature because it is recognised as an aspect of patient autonomy and dignity.[70] Hence divulging any patient information to public/third party except in permitted circumstances, may lead to a tort of breach of confidence. The principle of confidentiality is not absolute and the information may be passed, if there is consent, if it is required by a court of law[71], for continued treatment, to authorities under a statutory provision[72], or if related to communicable diseases[73] or if there a public interest.[74]

In India, Hospital Manual, 2002 strictly prohibits sharing of health information of patients. On the contrary, the Indian Medical Council Regulations, 2002 have conflicting provisions. Regulation 2.2 states that 'Confidences concerning individual or domestic life entrusted by patients to a physician and defects in the disposition or character of patients observed during medical attendance should never be revealed unless their revelation is required by the laws of the State'. Whereas Regulation 2.3 states that 'physician shall ensure himself that the patient, his relatives or his responsible friends have such knowledge of the patient's condition as will serve the best interests of the patient.' As per Regulation 7.14 in the following circumstances a physician may disclose the secrets of his patients;

i. in a court of law under orders of the Presiding Judge;
ii. in circumstances where there is a serious and identified risk to a specific person and/or community; and
iii. notifiable diseases.

[67] *Spycatcher* case (*Attorney-General* v. *Guardian Newspapers Ltd (No 2)* 1990] 1 AC 109.
[68] *Quilty* v. *Windsor,* 1999 SLT 346.
[69] Ronald Goldfarb, *In Confidence: When to Protect Secrecy and When to Require Disclosure* 19-36 (Yale University Press, 2009).
[70] Alan B. Vickery, "Breach of Confidence : An Emerging Tort", 82 *Columbia Law Review* 1426-1468 (Nov., 1982).
[71] The Evidence Act, 1872, s.3.
[72] The Medical Termination of Pregnancy Act, 1971; The Mental Healthcare Act, 2017; The Registration of Births and Deaths Act, 1969, *etc.*
[73] The Epidemic Diseases Act, 1897.
[74] *Mr. X* v. *Hospital Z* (1998) 8 SCC 296.

Apart from the Indian Medical Council Ethical Regulations, there is no specific provision in the Clinical Establishment Act or in the Pre-conception and Prenatal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 for protecting the patients' right to medical confidentiality. The recently adopted statutes like the Medical Termination of Pregnancy (Amendment)Act 2020,[75] the Mental Healthcare Act, 2017[76] *etc*. are having provisions to protect the right to privacy of patients. However, it may be noted that these directions are very specific and can be made applicable only for cases falling under the ambit of these statutes. The Patients' Charter adopted in the year 2017 also guarantees medical confidentiality.

It is evident from the above discussion that the regulatory provisions existing in India have incorporated the inviolability of medical confidentiality. However, these regulations do not offer any remedy to patients in case of violation of medical confidentiality other than under the Consumer Protection Act. The Patients' Charter also stands in the same position. Additionally, India lacks umbrella legislation that can be applied in all situations of breach of medical confidentiality. In these circumstances in India, the tort of breach of confidence offers remedies under common law to the aggrieved under all circumstances of the breach of confidence.

b. Medical Privacy

The ever-expanding opportunities of information technology and changing landscapes of health information leads to large scale aggregation of health-related data of individuals and sharing or even selling of such health information have become the current concern of Governments and institutions.[77] In the complex network of patients, doctors, health care service providers, government regulatory agencies, insurance providers, third party administrators, online health applications, etc. the conventional concept of the tort of breach of confidence seems to be having only limited application in protecting health data and privacy rights of patients. Health information generated in clinical institutions/insurance agencies and online settings needs to be addressed for facilitating data protection and privacy concerns of patients.[78] The Health Insurance and Portability and Accountability Act of 1996 was one of the earliest

[75] The Medical Termination of Pregnancy (Amendment) Act, 2020, s.5A.
[76] The Mental Healthcare Act, 2017, s. 20 and The Mental Healthcare (Rights of Persons with Mental Illness) Rules, 2018, Rule 5.
[77] Lawrence O. Gostin, Sam F. Halabi, *et. al*., "Health Data and Privacy in Digital Era", 320 *Journal of Americal Medical Association* 233 (July, 2018).
[78] *Ibid.*

legislation enacted by the US government to protect health information.[79] But with the advent of new medical and information technologies, even such regulations are ineffective in ensuring data privacy.[80]

In India, the right to privacy emerged as part of the constitutional law jurisprudence and the recent judgment in *K.S. Puttaswamy* v. *Union of India* augmented the process of developing privacy regulations. On being considering it as a fundamental right, the patients have the general public law remedies and due to the development of constitutional torts, the patients may also seek compensatory remedies.[81] The Hospital Manual, 2002 has no specific provision to deal with the privacy rights of patients. However, it directs that on the loss of medical records the medical records officer shall enquire about it and shall bring it to the notice of the hospital administration.[82]

In India at present, the issues of data protection and privacy rights on information are governed by the Information Technology Act, 2000. As per the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011, medical records are categorised as sensitive personal data or information of a person.[83] And any body-corporate who is possessing, dealing or handling any sensitive personal data or information must follow the reasonable security practices to avoid the wrongful loss or gain to any person and the body corporate may be held liable under section 43A of the Act if there is any negligence in following the reasonable security practices.[84] Apart from these statutory provisions, the Mental Healthcare Act, 2017 and the Medical Termination of Pregnancy (Amendment) Act, 2020 are also providing provisions to protect the general right to privacy of patients.[85]

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[79] Daniel J. Solove, A Brief History of Information Privacy Law, *available* at: https*://scholarship.law.gwu.edu/cgi/ view content.cgi?article=2076&context=faculty_publications* (last visited on May 30, 2020).

[80] *Supra* note 85.

[81] The Supreme Court of India declared right to privacy as a fundamental right in *K.S. Puttaswamy* v. *Union of India* (2019) 1 SCC 1; The concept of constitutional torts emerged as new private law remedy in realm of public law through various case laws such as *Sunil Batra* v. *Delhi Administration,* AIR 1978 SC 1575; *Rudul Shah* v. *State of Bihar,* AIR 1983 SC 1107; *Sheela Barse* v. *State of Maharashtra,* AIR 1983 SC 378; *Sebastian M. Hongray* v. *UOI,* AIR 1984 SC 1026 ; *Nilabati Behra* v. *State of Orissa,* AIR 1993 SC 1960 ; SAHELI *a Woman's Resource Centre* v. *Comms. of Police, Delhi,* AIR 1990 SC 513; *Vishaka* v. *State of Rajasthan,* AIR 1997 SC 625, *State of A.P.* v. *Challa Ramakrishna Reddy,* AIR 2000 SC 2083, *etc.*

[82] *Supra* note 32 at 89.

[83] The Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011, r. 3.

[84] Information Technology Act, 2000, s. 43.

[85] *Supra* notes 83 and 84.

The Electronic Medical Records Standards, 2016 have a detailed description of standards to be adopted for protecting the privacy rights of patients. Though it mandates medical privacy, the implementation of these standards is not made mandatory. Thus at present, the patient's right to medical privacy is governed under the Constitutional Law and the scope and ambit of the fundamental right to privacy are in the process of evolution in India. But the issue of health information privacy in connection with electronic health records should be regulated through proper statutes. In this context, the two Bill introduced recently such as the Digital Information Security in Healthcare Act (DISHA), 2018 and the Personal Data Protection Bill, 2019 are relevant.

The DISHA Bill was introduced to bring all-inclusive legislation for prescribing standards and to ensure the security and privacy of health information. Subsequently, the MoHFW, forwarded the Bill to the Ministry of Electronics and Information Technology (MeitY) for their inputs and to prepare a comprehensive enactment for data protection.[86] On December 11, 2019, the Minister of MeitT, Mr Ravi Shankar Prasad, in the light of the Justice Sreekrishna Committee Report on Data Protection introduced the Personal Data Protection Bill, 2019.[87] The Personal Data Protection Bill was introduced to enact umbrella legislation for all types of personal data including health information. Both the proposed legislations have included provisions for ensuring the health information privacy of individuals.[88] As teleconsultations and electronic medical records have come to common parlance, it is imperative to have a dedicated authority to supervise the flow of health information at different levels, report breach of health data, scrutinise security measures and ensure the privacy of patients.

c. Access to Medical Records

Since the medical records are under the possession of the health care providers, the obligation to provide access to health information is an essential aspect of the medical record-keeping practice. More than that right to get information or access to health information is a fundamental right under article 19(1)(a) and 21 of the Constitution.[89] The earliest of the regulations providing access to medical record was the Indian Medical Council Regulations,

[86] Data Transfer of Dgital Health Records, Press information Bureau, Government of India, Ministry of Health and Family Welfare, *available at*: https://pib.gov.in/Pressreleaseshare.aspx?PRID=1578929 (last visited on May 10, 2020).
[87] The Personal Data Protection Bill, 2019, s. 20.
[88] The Digital Information Security in Healthcare Bill 2018, s. 28.
[89] *M.Nagaraj* v. *Union of India* (2006) 8 SCC 212; *Bennett Coleman & Co* v. *Union of India* (1972) 2 SCC 788; *PUCL* v. *Union of India* (2004) 2 SCC 476.

2002 which directs medical practitioners to issue a copy of medical records to patients or authorised attendants or legal authorities on their application within 72 hours.[90] It remains a standard norm for access to medical records in India. The doctors or the healthcare providers have no immunity to retain any part of the medical record as per the Indian Medical Council Regulations and they must issue copies of the entire medical report in the standard format.

The Electronic Health Record Standards, 2016 have more detailed provisions for data access with some limitations imposed on accessing health information. As per the Electronic Health Record Standards, 2016 patients may;

a. view and inspect their health data without any time limit and they may restrict access to individually identifiable health information.
b. get a copy of medical records from the healthcare providers within 30 days after submitting a request for that.
c. restrict the health care providers from disclosing any specific information temporarily or permanently that he/she does not want to disclose.
d. demand details of the disclosures made including the following;
    a. Date and purpose of disclosure
    b. Name of the person/entity received the information
    c. Brief description of the information disclosed.
e. Amend the record to correct errors recorded.

The Electronic Health Record Standards, 2016 also reserves some exceptions to the right to access medical records. As per Electronic Health Record Standards the healthcare providers may deny information to a patient, representative or third party in certain circumstances like the following;

a. Information received under the promise of confidentiality,
b. Psychotherapy notes,
c. Information compiled for civil, criminal administration.

The Patients' Charter also states that patients will have the right to access the original or copies of their case papers. As per the Charter, investigation reports shall be made available within 24 hours of admission or 72 hours of discharge. Under the Consumer Protection Act, the denial of

[90] *Supra* note 40, regulation 1.3.2.

access to a medical record is considered as a deficiency in service. *Kanaiyalal Ramanlal Trivedi* v. *Dr Satyanarayan Vishwakarma*[91] was one of the earliest cases where doctors were held liable for medical negligence as they failed to produce the medical records to prove the standard of care they provided. The Bombay High Court reaffirmed the patient's right to access records in *Raghunath Raheja* v. *Maharashtra Medical Council,*[92] with a note to ensure that Medical Councils give direction to all hospitals to provide patient's record on request for a fee which is reasonable. The decision of *S. A. Quereshi* v. *Padode Memorial Hospital and Research Centre II*[93] and *Dr. Shyam Kumar* v. *Rameshbhai, Harmanbhai Kachiya*[94] reiterated the right to access medical records. In *Rajappan* v. *Sree Chitra Tirunal Institute for Medical Science and Technology*[95] the Hon'ble High Court of Kerala while deciding a dispute as to whether healthcare providers have the right to retain any parts of the medical record, opined that:

> It is also to be noticed that Regulations do not provide any immunity for any medical record to be retained by any medical practitioner of the hospital from being given to the patient. On the other hand, it is expressly provided that a patient should be given medical records in Appendix 3 with supporting documents. Therefore in the absence of any immunity either under the Regulations or under any other law, the respondent Hospital is bound to give photocopies of the entire documents of the patient. Standing counsel for the respondent - Hospital submitted that the documents once furnished will be used as evidence against the hospital and against the doctors concerned. I do not think this apprehension will justify for claiming immunity against furnishing the documents. If proper service was rendered in the course of treatment, I see no reason why the hospital, or staff, or doctors should be apprehensive of any litigation. A patient or victim's relative is entitled to know whether proper medical care was rendered to the patient entrusted with the hospital, which will be revealed from case sheet and medical records. There should be absolute transparency with regard to the treatment of a patient and a patient or victim's relative is entitled to get copies of medical records. This is recognised by the Medical Council Regulations and therefore petitioner is entitled to have copies of the entire medical records of his daughter which should be furnished in full. The

[91] I (1997) CPJ 332 (Guj).
[92] AIR 1996 Bom 198.
[93] II 2000 CPJ 463.
[94] 2002 (1) CPR 320.
[95] ILR 2004 (2) Kerala 150.

respondent Hospital is entitled to retain the original for their purpose and need furnish only the true certified copy of the originals.

Though there have been multiple judicial pronouncements and statutory provisions ensuring access to medical records, its implementation remains weak. All the more important, people are not aware of their right to get copies of medical records either partly or in full. Additionally, despite having regulations to ensure access to medical records, due to a lack of uniform medical record-keeping pattern, the extent of disclosure of information may vary. Thus it is suggested to adopt measures for the enforcement of the right to access medical information against healthcare institutions in the private and public sector uniformly.

d. Right to Information under RTI

With the adoption of the Right to Information Act, the health information of any person may be obtained without showing the reason for seeking the information from any health service provider. Thus there is an inherent tension between medical confidentiality/privacy and the right to information. However, the exemption provided in section 8(e) (g) and (j), though it is general in nature, may be applied to safeguard medical confidentiality and privacy of patients. As per the provisions of the Act, public authorities are responsible to give information within thirty days from the date of receipt of the request. However, if it is information concerning the life or liberty of the applicant, then the information shall be provided within forty-eight hours of the receipt of the request.[96]

In *Ms. Nisha Priya Bhatia* v. *Institute of Human Behaviour and Allied Sciences, GNCTD*[97] the Central Information Commission rightly pointed out that 'the patients' right to information is protected not only under the Right to Information Act but also under the Consumer Protection Act, Medical Council Ethical Regulation and it is rooted in the Fundamental Rights under article 19(1) and 21 of the Constitution of India'.[98] The statutory obligation to provide information relating to medical treatment is not only upon the public authorities but also upon

[96] The Right to Information Act, 2005, s.7.

[97] CIC/AD/A/2013/001681 - SA decided on August 24, 2014, *available at:* https://ciconline.nic.in/cic_decisions/CIC_AD_A_2013_001681-SA_M_136162.pdf (last visited on May 20, 2021).

[98] *Ibid.*

every hospital, whether public or private. The Commission is empowered to enforce the right under section 2(f) of the RTI Act. The Commission directed all doctors/hospitals to develop a mechanism to provide a copy of medical records to the patient or his legal representatives as a routine procedure at the time of discharge of the patient.[99] The Commission addressed the issue of access to information of patients in private sector hospitals in the case *Mrs. Anita Singh* v. *Directorate of Health Services, GNCTD*[100] and the Commission recommended the Government of India, States and Union Territories to take necessary steps to enforce the right to information of patients and to ensure the private sector hospitals are providing information to the patients on a day to day basis to avoid unethical and undesirable practices of record manipulation, prescribing unwanted tests, conducting wanted surgeries, c-section etc.[101]

The medical information is considered as personal/private information and such information that had been made available in the doctor-patient relationship is confidential in nature and the disclosure of the same to a third person/public may amount to an invasion of the right to privacy of individuals.[102] The Bombay High Court on deciding the question under the Right to Information Act as to the right of the public to get information and the right to confidentiality and privacy of an individual in *Surupsingh Hrya Naik* v. *State of Maharashtra (through Additional Secretary) General Administration Dept.* held that;[103]

> The confidentiality required to be maintained of the medical records of a patient including a convict considering the Regulations framed by the Medical Council of India cannot override the provisions of the Right to Information Act. If there be inconsistency between the Regulations and the Right to Information Act, the provisions of the Act would prevail over the Regulations and the information will have to be made available in terms of the Act. The Act, however, carves out some exceptions, including the release of personal information, the disclosure of which has no relationship to any public activity or interest or which would cause unwarranted invasion of the right to privacy. In such cases a discretion has been conferred on the concerned Public Information Officer to make available the

[99] *Ibid.*

[100] CIC/SA/A/2015/001894 decided on March 16, 2016, *available at*: https://indiankanoon.org/doc/138170762/?type=print (last visited on May 20, 2020).

[101] *Ibid.*

[102] N.N. Mishra, Lisa S. Parker, *et. al.,* "Privacy and the Right to Information Act, 2005", 5 *Indian J. Med. Ethics.* 158 – 161 (2008).

[103] AIR 2007 Bom 121.

> information, if satisfied, that the larger public interest justifies the disclosure. This discretion must be exercised, bearing in mind the facts of each case and the larger public interest. Normally records of a person sentenced or convicted or remanded to police or judicial custody, if during that period such person is admitted in hospital and nursing home, should be made available to the person asking the information provided such hopital nursing home is maintained by the State or Public Authority or any other Public Body. It is only in rare and in exceptional cases and for good and valid reasons recorded in writing can the information may be denied.

These judicial pronouncements have emphatically stated that access to medical information is a statutorily protected right. However, this has been denied to patients especially by the private sector hospitals as there is no specific legislation to deal with it. The Right to Information Act and the Consumer Protection Act have only limited application. Though the Information Commissioner had directed to enforce the right against private sector hospitals, it finds little implementation. Similarly, some medical services are outside the purview of the Consumer Protection Act. Thus a proper regulatory mechanism shall be installed that would apply to all service providers.

e. Rights of Data Principal under the DISHA, 2018

Apart from the right to confidentiality/Privacy and access to digital data the Digital Information Security in Healthcare Act (DISHA) proposes to guarantee the following rights to the owner of digital health data;[104]

i. Right to give or refuse to give consent for data generation by Clinical Establishments,
ii. Right to give, refuse or withdraw consent for data storage and transmission,
iii. Right to give or refuse to give consent for access and disclosure of health data,
iv. Right to ensure that the data collected is specific, relevant and not excessive in relation to the purpose for which it is sought,
v. Right to know the entity who have accessed the digital health data and to whom it is transmitted.

[104] The Digital Information Security in Healthcare Act (DISHA BILL), 2018, s.28.

vi. The owner of the data will have the right to access the health data,

vii. Right to rectify any inaccurate and incomplete digital health data,

viii. Right to require explicit prior permission before each instance of transmission or use of digital health data,

ix. Right to be notified each time when the health data has been used by any clinical establishment,

x. Right to ensure that the health data may be shared with the family members in case of any emergency,

xi. Right to prevent the transmission or disclosure of any sensitive health data which may cause damage or distress to the owner,

xii. Right not to be refused health service in case of refusal to give consent for generation, storage, transmission or disclosure of digital health data,

xiii. Right to seek compensation for damages on breach of digital health data.

f. Data ownership of patients

The linkage between medical records and data ownership was not much discussed until recently in India though it was a matter much debated in other countries.[105] The existing regulations dealing with medical records, be it the Indian Medical Council Regulations, 2002 or the Clinical Establishments Act, 2010 or other statutes mentioned in the above section have no specific provisions to fix data ownership over medical/health information. As per the Hospital Manual, 2002 prepared by the Directorate General of Health Service, the permission of the Head of the Department/Hospital Administration is made mandatory for accessing/parting with a third party any information included in the medical records.[106] There is nothing mentioned in the Office Memorandum issued by the Ministry of Health and Family Welfare in 2014 in this regard.

The issue of data ownership came to the forefront when India initiated the endeavour to implement digital health programmes. Hence, the Electronic Health Record Standards, 2016 for the first time stated that medical record either physical or electronic will be held in trust by the healthcare provider on behalf of the patient. The data entered in medical records are protected health information and it will be under the ownership of the patient. Also states that

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[105] Mary L. M. Gilhooly and Sarah M. McGhee, "Medical Records: Practicalities and Principles of Patient Possession", 17 *Journal of Medical Ethics*, 138-143 (Sept., 1991).

[106] *Supra* note 32 at 90.

the medium of storage or transmission of such medical record will be owned by the healthcare provider.[107] The Digital Information Security in Healthcare Act, 2018, also proposed data ownership and it had enlisted the rights of owners of digital health information. However, the Personal Data Protection Bill, 2019 consciously avoided the term data owner, instead it uses the term 'data principal' and provisions of the Act is silent about the data ownership over the health information. Though there is no clarity as to the data ownership, it has enlisted some rights of the data principal.

Another major initiative to ensure data ownership over medical records is the Personal Health Record services offered under the National Digital Health Mission (NDHM Health Record).[108] Earlier a similar facility was provided on the National Health Portal.[109] The 'NDHM Health Record' is an initiative similar to the line of Personal Health Record (PHR) in the US. The advantage of the NDHM Health Record is that it is maintained by service providers authorised and sponsored by the Government. Thus it enables complete data ownership, easy access, and patient autonomy in medical treatment, though it is in the nascent stage in India. Thus Personal Health Record System facilitates complete control over the personal health data of patients in contrast to the Electronic Health Records, where the control is retained by healthcare institutions.

The introduction of the National Digital Health Mission and the Electronic Health Record and Personal Health Record systems offered under it are laudable and will take India to the global digital health world. However, it is very important to set standards about patients' control over their health information. Since the majority of the Indian population are not aware of the importance of health information, the Governments shall give due weightage to this subject from the beginning itself. Lack of clarity and strict regulatory provisions may lead to data breaches and violation right to privacy.

IV. Law Relating to Special Category Medical Records

a. Psychiatric Medical Records

[107] *Supra* note 38 at 20.
[108] *Supra* note 35.
[109] My health record website is a personal health record locker hosted by the Centre for Health Informatics. The website has not yet launched by the Government, *available at*: https://myhealthrecord.nhp.gov.in/ (last visited on May 30, 2020).

The nature and importance of psychiatric medical records are different from ordinary medical records. The psychiatric medical records are intended to be lifelong records of patients containing details of emotional disorders. Apart from the patients, a significant number of other individuals are involved like family members, friends, relatives etc in respect of psychiatric medical records are concerned. Thus it very essential to maintain confidentiality not only for protecting the best interest of the patient but also for other people who are involved in the treatment of such patients even after their death.[110] The Mental Healthcare Act, 2017 and the Rules adopted are pathbreaking attempts in transforming mental healthcare policies in India.

As per the Mental Healthcare Act, 2017 and the Rules thereunder,[111] mental healthcare establishments are required to maintain four types of records permanently;

i. Basic Medical Record of all outpatients
ii. Basic Medical Record of In-Patients
iii. Basic Psychological Assessment Report
iv. Basic Therapy Sessions Note

Rule 6 of the Mental Healthcare (Rights of Persons with Mental Illness) Rules 2018, enables the person with mental illness to receive the documented medical information pertaining to diagnosis, investigation, assessment and treatment which is recorded in the basic medical records within fifteen days of making the request. However, the medical officer in charge of the medical records may withhold specific information in the medical records, if the disclosure would result in;

i. Serious mental harm to the person with mental illness, or
ii. Likelihood of harm to others.

In case if the information sought by the person with mental illness is denied by the medical officer, he may make an application to the Mental Health Review Board and the Board after hearing such person, may issue an appropriate order.[112] Section 23 of the Act embodies the principles of medical confidentiality and the health professional is allowed to release

[110] *Viqar Ahmad* v. *Institute of Human Behaviour and Allied Sciences*, CIC/SA/A/2015/000289 decided on July 13, 2015, *available at:* https://ciconline.nic.in/ rti/docs/cic_decisions /CIC_SA_A_2015_000289_M_ 158860 . pdf (last visited on May 20, 2020).
[111] The Mental Healthcare (Rights of Persons with Mental Illnes) Rules, 2018.
[112] The Mental Healthcare Act, 2017, s. 25 and the Mental Healthcare Rights of Persons with Mental Illness Rules, 2018, rule 6 (4) and (5).

information relating to a patient with mental illness to a third party on the following circumstances;

i. To enable the nominated representative to perform his duties,
ii. To health care professionals to enable them to provide care and treatment,
iii. To protect other persons from harm and violence,
iv. In the interest of public safety and security
v. Under the order of Central authority, or High Court or Supreme Court or any other statutory authority competent to do so.

In 2015 the Central Information Commissioner while deciding a question on access to psychiatric records by a third party had opined that the guardian of the patient can have access only in the best interest of the patient. Otherwise, the hospital shall keep the record in trust and shall decide whether the third party who seeking the information is in the best interest of the patient.[113] On the contrary, the provisions of the new Act have embodied definite conditions for the release of information to a third party. Since it is a specific statute for the person with mental illness the ruling of the CIC and decision in *Surupsingh Hrya Naik* v. *State of Maharashtra (through Additional Secretary) General Administration Dept*.[114] will not be applicable and the provisions of the Mental Healthcare Act will prevail over the Right to Information Act.

b. Pediatric Medical Records

Pediatric records are another category that is considered as a special case because of the incompetency of minors in accessing and managing medical information. For them, generally, the parents/grandparents will be acting on their behalf and there are no specific regulations as in the case of psychiatric medical records. As far as pediatric records are concerned there is no proper regulation existing in our country in respect of the method of preparation, maintenance, retention, access to medical records etc. As per section 7 of the Limitation Act, a minor may file a suit within three years after attaining majority. Thus most of the hospitals maintain pediatric records for more than 18 years. Hence, similar to the psychiatrist records, there shall be regulations for pediatric medical records.

[113] *Supra* note 121.
[114] *Supra* note 112.

V. Conclusion

The importance of medical records has been recognised since the Hippocratic period. All healthcare systems worldwide follow medical record-keeping primarily for therapeutic purpose. However, with the advent of new medical and digital technologies, medical records and health information of individuals are created, transmitted and used at various levels for a multitude of causes. Thus the regulation of medical records assumes great importance. The study focused on three core issues such as the general regulatory norms for preparation, retention and destruction of medical records; patients' rights over medical records and regulatory standards for special category medical records. On detailed analysis, the study proved that the existing regulatory framework inadequate both for conventional paper records and to meet the challenges of the new age digital medical records. In the backdrop of analysing the Indian regulatory regime, the study comes to the following findings and suggestions -

1. Medical Records, be it paper or electronic, are important sources of health information, which is very valuable for various purposes including therapeutic, research studies, surveillance, predicting epidemics or pandemics. More importantly, it is a legal document in medico-legal cases.
2. Since Independence, though hospitals generally followed a medical record-keeping system, it has not been legally implemented. The Indian Medical Council Regulations, 2002 directs the hospitals to maintain medical records. Additionally, there are statutory provisions for clinical establishments offering services such as medical termination of pregnancy, prenatal diagnostic services, mental health services, etc. However, India lacks a comprehensive regulation on medical records. Thus, it is strongly recommended to enact comprehensive legislation for all healthcare institutions.
3. India follows a mixed healthcare structure with both the private and public sector. Thus the directives issued by the Directorate of Health Services do not apply to private sector hospitals. To ensure the uniform implantation of regulations on medical records, central legislation is suggested.
4. There is no uniform standard adopted in India for preparing medical records, the retention period of medical records varies under different legislation. Similarly, the private and public sector hospitals also follow different retention period. Thus is suggested to adopt strict regulations for the method of preparation, pattern and retention period of medical records.

5. In the context of advanced digital technologies and the importance assigned to health information, the destruction of medical records also demands attention. There is a total lack of regulatory framework concerning the destruction of medical records. This can pave the way for misappropriation and mismanagement of the health information of patients. Thus it is imperative to incorporate provision for the safe disposal of health information.
6. The rights of patients and ownership rights over the medical records shall be also be detailed in the legislation. Apart from that, institutional authorities like Medical Record Department and Medical Report Ethical Committees shall be made responsible for the proper implementation of regulations on medical records.
7. Access to medical information is a right under the Consumer Protection Act, the Medical Council of India Regulations, 2002 and under the Right to Information Act, 2005. Nevertheless, it is being denied to patients. The hospitals generally take advantage of the legal vacuum and thus it is imperative to enforce it against all healthcare institutions in the private and public sector.
8. Medical confidentiality and medical privacy are established human rights and are the basic norm of the medical profession. It falls well within the ambit of the right privacy enunciated under article 21 of the Constitution. However, it is necessary to point out the scope and ambit of the right to medical privacy in the light of the *Puttuswamy* Judgement and to adopt guiding principles for publishing medical information in the interest of the public.
9. The Telemedicine Guidelines, 2020, authorises all Registered Medical Practitioners to offer telemedicine services. It also mandates to maintain medical records of teleconsultations. However, there are no regulations existing in India prescribing standards for medical records of teleconsultations except the Electronic Health Record Standards, 2016. But the Electronic Health Record Standards, 2016 lacks proper implementation as it leads to a high level of financial investment for developing digital infrastructure and which would not be feasible for a large majority of hospitals in our country in the current position. Though teleconsultations facilitate medical care during COVID 19 pandemic situation, it is imperative to adopt strict regulatory norms for electronic medical records.
10. The National Digital Health Mission is greatly appreciated for its vision to promote digital health care technologies in ensuring cost-effective medical care. However, our country has not yet attained a digital ecosystem that is safe and secured. The absence

of necessary legal regulations and enforcement mechanisms will seriously hamper the functioning of new digital programmes and can lead to infringement of privacy rights and illegal data transactions. Another important factor is that NDHM is a Government initiative and private sector hospitals can participate voluntarily. Thus, NDHM regulation and security standards need not be followed by other institutions. Thus it is strongly recommended to adopt umbrella legislation for medical records and personal health records.

11. Similar to the Mental Healthcare Act, 2017, proper regulatory measures shall be introduced for paediatric records too.