

ELECTRONIC HEALTH RECORDS IN INDIA: LEGAL FRAMEWORK AND REGULATORY ISSUES

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ABSTRACT

The demand for healthcare is increasing globally. In India, a dual burden of communicable and non-communicable diseases along with an ageing population is affecting the demand for healthcare. Concerns for providing efficient and effective healthcare to the vulnerable population have led to the adoption of digital health records by countries. Different regulatory structures have been designed globally in order to use these health records while maintaining privacy and security of the data so generated. India is currently debating on the framework to be followed by it for the adoption and regulation of digital health records. The present article studies the evolution and structure of global models on regulation of digital health records. The proposed interventions in India are analysed based on the global study. Proposals for the way forward are made. It is suggested that India adopts a legal framework for digital health independent of the data protection laws. Clarity of objective and appropriate provisioning of incentives are critical elements of such a framework.

I. INTRODUCTION

Healthcare delivery institutions across the globe are evolving digitally in record-keeping and decision-making. This is being achieved through digital health records. These records can be designed for various purposes.

In this article, the adoption of digital health records regulatory framework is discussed with a focus on the status in India. In recent time, the policymakers in India have been debating on the type of health record system to be adopted, the regulatory framework for digital health and data protection framework surrounding it. These proposed regulatory frameworks of India are studied with respect to the experience of the US, UK, and Australia. These countries have used different approaches for digital health systems.

The US framework establishes a system of digital health records through legislation as primary mode of regulation. Australia provides a rights-based health records system to its citizens. The UK follows a hybrid model but does not have a dedicated digital health legislative framework.

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All three countries also have overarching data protection frameworks supplementing the digital health systems.¹

India is at the crossroads in adoption of its digital health framework. While the Draft Digital Information Security in Healthcare Act, 2018 (“DISHA”) suggests adoption of an Electronic Health Records (“EHR”) system with patient rights at its core, National Digital Health Blueprint (“NDHP”) document envisages a mission-mode framework. The Personal Data Protection Bill, 2019 (“PDP Bill”) has conflicting provisions with respect to DISHA on components related to healthcare.

This article identifies three challenges in the way ahead for India in the digital health records domain. The *first* is the challenge of choosing a type of digital health record amongst the available models. The *second* challenge is of incentivising adoption of such digital health records. The *third* challenge is of contemplating a legal framework for digital health records that also addresses the first two challenges.

The rest of the article is structured as follows. Section 2 contains background for adoption of digital health records in the context of India. Section 3 describes the global challenges in adoption and implementation of digital health records. Section 4 discusses the current Indian scenario and section 5 concludes.

II. BACKGROUND

Healthcare establishments are now increasingly dealing with complex diseases and conditions. Developing countries like India face a double burden of communicable and non-communicable diseases.² This, in combination with changing demography, would increase the demand for healthcare of vulnerable persons across age-groups with time. To assuage the healthcare demands of the population, there has been a proliferation of Government funded Health Insurance Schemes (“GFHISs”) in India.³ GFHISs like the Rashtriya Swasthya Bima Yojana (“RSBY”) and the Pradhan Mantri Jan Arogya Yojana (“PMJAY”) are designed to provide healthcare services to persons through public & private healthcare

¹ See Health Information Technology for Economic and Clinical Health Act, 2009 (United States); My Health Records Act, 2012 (Australia); Privacy Act, 1988 (Australia); National Programmes and Plans and Data Privacy Act, 2018 (United Kingdom).

² See Ministry of Health and Family Welfare, Government of India, *India: Health of the Nation's States -The India State-Level Disease Burden Initiative*, available at https://www.healthdata.org/sites/default/files/files/policy_report/2017/India_Health_of_the_Nation%27s_States_Report_2017.pdf, last seen on 1/12/2019.

³ I. Patnaik, S. Roy & A. Shah, *The rise of government-funded health insurance in India*, NIPFP Working Paper Series, 27, Working Paper Number NIPFP/WP/2018/231, National Institute of Public Finance and Policy, New Delhi (2018), available at https://www.nipfp.org.in/media/medialibrary/2018/05/WP_231.pdf, last seen on 10/02/2020.

providers. Identified members of the population, based on their income, are assured free hospital services for specific conditions within network hospitals.⁴ The premiums for these schemes are paid by the government.⁵ These schemes provide greater access to hospital related services to the poorer sections of the society. A digital implementation framework for the PMJAY scheme is under consideration wherein electronic health records will be generated and used.⁶ On the private healthcare front, the healthcare institutions are showing trends towards consolidation, i.e., bringing together multi-specialty fields of healthcare under one roof rather than single specialty hospitals.⁷ With increasing patient-generated demand for healthcare in the private sector, incorporating IT mechanisms for better coordination of patient care in the growing network of healthcare establishments is seen to be required.

India introduced its voluntary Electronic Health Records standards in 2013.⁸ A survey by Indian School of Business shows that some forms of electronic medical records are being used in private or corporate hospitals in cities.⁹ However, most of these systems are self-sufficient within institutions and do not allow sharing of information due to lack of interoperability.¹⁰ The government hospitals are sought to be brought under the digital health network through *eHospital*, a Hospital Management Information System (“HMIS”) by the government.¹¹

The primary intent to digitize health records is to achieve better quality of patient care while reducing costs. The data generated by these systems can also be used for population-based healthcare services and public health interventions as well as for research. The present section discusses

⁴ See *About Pradhan Mantri Jan Arogya Yojana (PM-JAY)*, National Health Authority, available at <https://pmjay.gov.in/about-pmjay>, last seen on 10/02/2020.

⁵ Ibid.

⁶ See *National Health Stack: Strategy and Approach*, NITI Aayog, Government of India, available at https://niti.gov.in/writereaddata/files/document_publication/NHS-Strategy-and-Approach-Documents-for-consultation.pdf, last seen on 11/02/2020.

⁷ T. Thacker, *M&A deal value in hospital sector jumped by 155% in FY19*, Livemint (06/05/2019), available at <https://www.livemint.com/companies/news/m-a-deal-value-in-hospital-sector-jumped-by-155-in-fy19-1557144845883.html>, last seen on 15/01/2020.

⁸ See *Notification of Electronic Health Records (EHR) Standards 2016 for India*, MoHFW Circular No. Q-11011/3/2015-eGov (30/12/2016), available at <https://mohfw.gov.in/sites/default/files/17739294021483341357.pdf>, last seen on 10/02/2020.

⁹ A.C. Powell, H. Tyagi & J.K. Ludhar, *Digitising Indian Healthcare Records*, ISB Insight (28/08/2018), available at <https://isbinsight.isb.edu/digitising-indian-healthcare-records/>, last seen on 12/01/2020.

¹⁰ S. Balsari et al, *Reimagining Health Data Exchange: An Application Programming Interface-Enabled Roadmap for India*, 20(7) Journal of Medical Internet Research (2018), available at <https://pdfs.semanticscholar.org/3c4d/667298df5ec61f4ccb908729e8f0345aba8a.pdf>, last seen on 12/01/2020.

¹¹ *EHR-National Standardization Initiative*, Centre for Development of Advanced Computing, available at https://www.nrccs.in/download/files/pdf/nrccs_ehr_nsi.pdf, last seen on 13/01/2020.

the healthcare landscape in India. This is done with intent to contextualize the policies for adoption of digital health records as studied in later stages. It also describes the various types of digital health records available globally and their uses. Understanding the distinction between these records is important to identify the intent of digitization of health records by a nation.

1. The Healthcare landscape of India

In order to understand the adoption and usage of digital health records in India, it is essential to study the healthcare landscape in India in which the system is set to operate. The healthcare landscape in India is best described as fragmented. A patient has recourse to public and private healthcare providers which use various systems of medicine for treatment. A healthcare provider can be a single doctor, a nursing home or a large hospital. Types of treatment provided in these institutes can vary considerably too. Therefore, the healthcare landscape in India can be understood on the basis of funding/ownership, type of services provided as well as the type of medicine system followed. These are described below:

- **Based on funding and ownership:** Healthcare is provided through public and private hospitals in the country. These hospitals may constitute of a single doctor clinic or a super-specialty care centre. The public healthcare providers are modelled on the three-tier healthcare system set-up by the Bhole Committee in 1946.¹² Private single doctor clinics and nursing homes have been parallelly providing healthcare services, especially in urban areas. After liberalization of the Indian economy, the private providers have increased in number and scale throughout the country.¹³ The private healthcare providers now operate through individual, corporate or non-profit models. India also has a large number of non-registered medical practitioners.¹⁴

¹² Ministry of Health, Government of India, *JW Bhole Report of the national health survey and development committee (Bhole Committee Report) 1946*, available at https://www.nhp.gov.in/bhole-committee-1946_pg, last seen on 12/12/2019.

¹³ See S. Kumar, *Private Sector in Healthcare Delivery Market in India: Structure, Growth and Implications*, ISID Working Paper, Working Paper Number ISID/WP/2015/185, Institute for Studies in Industrial Development, New Delhi (2015), available at <http://isid.org.in/pdf/WP185.pdf>, last seen on 10/02/2020.

¹⁴ See S. Chandra, *Unqualified Medical Practitioners In India- The Legal, Medical and Social Dimensions Of Their Practice*, Centre for Public Affairs and Critical Theory-C-Pact, Shiv Nadar University, available at <https://snu.edu.in/sites/default/files/UMP-BOOK.pdf>, last seen on 04/01/2020.

- **Based on the type of system of medicine:** Healthcare providers in the country follow allopathic, ayurvedic, homeopathic and many other systems of medicine. While the central ministry for health, the Ministry of Health and Family Welfare (“MoHFW”) usually works for the modern medicine system, the Government of India established a Ministry of AYUSH in 2014 to ensure the optimal development and propagation of AYUSH systems of healthcare which include Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy.¹⁵
- **Based on the type of services:** Depending on the type of care given to the patients, healthcare services can be classified into primary, secondary, tertiary and quaternary. Primary and preventative services are the first point of care services provided to patients. Primary healthcare providers are also the source of referral to higher specializations. Secondary, tertiary and quaternary services are increasing levels of specialized care provided to the patients.

Digital health records adoption in this fragmented healthcare system is a challenge. One of the foremost tasks at this stage is to identify the type of healthcare records which should be available to the patients, healthcare providers and the State.

2. Types of digital health records

There are three broad types of digital records for patient care. These are Electronic Medical Records (“EMRs”), Electronic Health Records (“EHRs”) and Personal Health Records (“PHRs”).¹⁶

EMRs are localized, partial health records within a single healthcare provider.¹⁷ These records are maintained to aid in patient care and improve management and administration of their services. They are confined to the institutes which are maintaining them and are not accessible to patients or other healthcare providers.

EHR is the most common of all the digital records. They contain patient data collected from many healthcare institutes. The information is made

¹⁵ *About us*, Ministry of AYUSH, available at <https://main.ayush.gov.in/about-us/about-the-ministry>, last seen on 01/01/2020.

¹⁶ See *What are the differences between electronic medical records, electronic health records, and personal health records?*, HealthIT.gov, available at <https://www.healthit.gov/faq/what-are-differences-between-electronic-medical-records-electronic-health-records-and-personal>, last seen on 26/12/2019.

¹⁷ *Ibid.*

shareable by following standards of interoperability laid down at the national/international level.

PHRs are records generated by various stakeholders including providers (doctors, hospitals, laboratory, patient) across various institutes. The information in a PHR is patient-centric as it is aimed to provide information to the patient about their healthcare status directly.¹⁸ As PHRs also collate information from various stakeholders and is not limited to healthcare providers, it requires meeting interoperability standards laid down at the national/international level. The key features of EMR, EHR and PHR are discussed in table 1.

Table 1: Types of digital patient data formats¹⁹

Electronic Medical Records (EMR)	Electronic Health Records (EHR)	Personal Health Records (PHR)
Electronic version of standard clinical data <i>with a single healthcare provider</i>	Electronic version of data <i>with multiple healthcare providers</i> including clinicians, diagnosticians, across institutes	Electronic version of data with multiple healthcare providers including clinicians, diagnosticians, across institutes <i>designed to be accessible to the patients</i>
Linear records within one healthcare institute	Longitudinal records aimed to follow the patient across different healthcare institutes	Longitudinal records aimed to follow the patient across different healthcare institutes and beyond

¹⁸ Ibid.

¹⁹ Supra 16; *Differences Between EMR, EHR AND PHR*, Health Information Management, available at <http://www.himconnect.ca/meet-him/faqs/differences-between-emr-ehr-and-phr>, last seen on 11/02/2020; *Understanding EHRs, EMRs and PHRs*, Canada Health Infoway, available at <https://www.infoway-inforoute.ca/en/solutions/digital-health-foundation/understanding-ehrs-emrs-and-phrs> last seen on 11/02/2020.

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Controlled by a single doctors/hospital	Controlled by a network of doctors/hospitals	Controlled by patients
Does not require following interoperability standards	Requires following interoperability standards	Requires following interoperability standards

The primary aim for introducing digital health records is to provide efficient and effective healthcare to the patient. They also help in improving administration and management of healthcare providers, reduce wasteful spending and are a source of epidemiological data for the State.

Currently, India seems to be working towards developing an EHR framework. This framework would allow collation of health data of an individual from their birth to death across various healthcare providers. This would be helpful to the patient given the fragmented healthcare landscape and the current status of health data generated and used in the country. Under the Indian federal system of government, hospitals and public health are regulated primarily by the States and not the Union Government.²⁰ This leads to variable quality of health data across states and regions. One of the foremost challenges of the fragmented healthcare landscape in India has been the challenge of measurement. The health data in India is informed through census and surveys by the Government of India. These include, the civil registration of births and deaths in India, National Sample Survey Organization (NSSO) reports etc.²¹ This is supplemented by the data generated from the public healthcare providers and regulators. The Health Management Information System (“HMIS”) is a database for information available in the public healthcare sector. HMIS has been marred by challenges of quality assurance.²² Because the

²⁰ Art. 246, the Constitution of India; Schedule 7 (Entry 6, List II), the Constitution of India.

²¹ See *Statistics*, Ministry of Health and Family Welfare, available at <https://main.mohfw.gov.in/documents/staistics>, last seen on 12/02/2020.

²² S. Sharma, *Problems of the Health Management Information System (HMIS): the experience of Haryana*, The Leap Blog, available at <https://blog.theleapjournal.org/2016/06/problems-of-health-management.html>, last seen on 13/02/2020.

private healthcare providers are largely unregulated, the information generated by them is not available to the government or the public. Due to this, the availability of timely and accurate data is still a challenge. For instance, the information available about the number of doctors and healthcare providers in the country is incomplete till now.²³

Within these challenges, the advocacy for EHR adoption in India is underway.²⁴ Consequently, the government has introduced standards for EHR in India.²⁵ Presently, adoption of EHR in any healthcare institute is voluntary and the standards set by the government do not have coercive value. However, the adoption of EHR is seen to be an essential component of the long-term healthcare delivery. A systemic shift in the healthcare delivery through adoption of EHR is underway. In this context, the experience of developed countries in providing digital health services is studied in the next section. This comparative analysis would be useful in navigating barriers for adoption and implementation of EHR in India.

3. The Challenge of Digital Health Records Adoption: Global Perspective

While the usage of health IT had started by the 90s, the adoption of EHR became a global interest at the turn of the new millennium. A study by the RAND Corporation in 2005 estimated that adoption of EHR in the USA could potentially save \$81 billion (“bn”) annually while improving the quality of care.²⁶ This quantification of benefits through this estimation gave a huge push to EHR systems in the US and the rest of the world. It is claimed that EHRs are useful for patients, healthcare providers as well as the State.²⁷ While the veracity of the claims about savings through adoption of EHR were questioned then and were reassessed by RAND itself in 2013, the 2005 report has played an

²³ H. Kaur, *Do Indian Patients Even Know Their Rights?*, The Wire, available at <https://thewire.in/health/do-indian-patients-even-know-their-rights/amp/>, last seen on 02/01/2020.

²⁴ See S.K. Srivastava, *Adoption of Electronic Health Records: A Roadmap for India*, 22(4) Healthcare Informatics Research (2016), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5116537/>, last seen on 6/1/2020.

²⁵ *Supra* 8.

²⁶ R. Hillestad et al, *Can Electronic Medical Record Systems Transform Health Care? Potential Health Benefits, Savings, And Costs*, 24(5) Health Affairs (2005), available at <https://www.healthaffairs.org/doi/10.1377/hlthaff.24.5.1103>, last seen on 01/1/2020.

²⁷ See *Benefits of EHRs*, HealthIT.gov, available at <https://www.healthit.gov/topic/health-it-basics/benefits-ehrs>, last seen on 01/1/2020; *Benefits of Electronic Health Records*, USFHealth, available at <https://www.usfhealthonline.com/resources/healthcare/benefits-of-ehr/>, last seen on 01/1/2020; P. Coorevits et al, *Electronic health records: new opportunities for clinical research*, 274(6) Journal of Internal Medicine (2013), available at <https://onlinelibrary.wiley.com/doi/full/10.1111/joim.12119>, last seen on 11/02/2020.

important role as a catalyst for adoption of EHR systems globally.²⁸ In the present section, the process of adoption of digital health records in the US, UK and Australia is studied. Considering these are developed countries which have been on the digitization journey for a long time, this study informs about the common challenges in their adoption and usage. After a country decides on the type of digital medical record (“EMR, EHR or PHR”) it aims to build, there are three broad challenges faced by it.

The *first challenge* observed in the adoption stage is the high cost of digital health records system that are adaptable to the interoperability standards set by the government. The need for interoperability standards is to allow sharing of data across multiple institutes. All the studied countries have had an incentive program to get the healthcare institutions to adopt systems compatible with interoperability standards. These programs are discussed in detail below.

The *second challenge* is defining the ownership of the data. As health records contain sensitive personal data that can be used for multiple purposes, deciding the ownership in favour of data generator (healthcare institute) or the source of data (patient) is the next challenge. Providing ownership to patients ensures better protection to their data and increases usage of the digital health records by the patients. However, high investment required from healthcare institutes in building digital systems as well as the potential usage beyond patient care are used to favour healthcare institutes as the owner of the data.

The *third challenge* is deciding on the governance and regulatory structure for the digital health records system. The regulating structure can be defined through legislation or a plan/program. General privacy and data protection laws of the country are also applicable to these systems, whether they have an origin in legal framework or not. The regulatory framework also defines the role of standard setting and implementing authority within the system.

Health Information Technology for Economic and Clinical Health Act (“HITECH”) of 2009 introduced incentives for EHR adoption according to prescribed standards in the USA.²⁹ Use of Medicare and Medicaid has provided an institutional framework for execution of these incentives. An

²⁸ See A.L. Kellermann & S.S. Jones, *What It Will Take To Achieve The As-Yet-Unfulfilled Promises Of Health Information Technology*, 32(1) Health Affairs (2013), available at <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2012.0693>, last seen on 7/1/2020.

²⁹ Health Information Technology for Economic and Clinical Health Act, 2009 (United States).

amount of \$27bn was set aside by the government for these incentives.³⁰ Till May 2016, \$34bn had been given to hospitals for adoption and meaningful use of EHR by the government.³¹ The law defines ‘meaningful use’ as the use of the certified EHR technology in a manner that provides for the electronic exchange of health information to improve the quality of care.³² Electronic prescribing, sharing patient discharge notes within institutes are examples of meaningful use. The adoption and meaningful use are being inducted in a phase wise manner using legislation. The ownership of data generated through EHRs is dependent on state legislation. New Hampshire is the only state which allows patients to own and control the EHR data.³³ For defining interoperability standards, the Office of National Coordinator for Health Information Technology (ONC) is responsible to standardize building blocks including health care vocabulary, using secure email protocols through the use of encryption standards with open and accessible APIs.

Adoption of EHR in the UK has not been through legislative intervention. Instead, National Health Service (“NHS”) programmes and plans have aimed for gradual introduction and use of EHR for patients. The National Programme for Information Technology (“NPfIT”) of 2002 by the government was aimed to make EHR usage ubiquitous in the UK.³⁴ An amount of £6bn was earmarked for this exercise.³⁵ The UK followed a top-down approach towards implementing the programme wherein a central agency, Connecting For Health (“CFH”), was the responsible implementing body. However, the NPfIT programme was criticized for being behind schedule by the Public Accounts Committee in 2009.³⁶ The revised estimated cost for the exercise was put to be

³⁰ *The Federal Government Has Put Billions into Promoting Electronic Health Record Use: How Is It Going?*, The Commonwealth Fund, available at <https://www.commonwealthfund.org/publications/newsletter-article/federal-government-has-put-billions-promoting-electronic-health>, last seen on 12/02/2020.

³¹ *EHR Incentive Programme*, Centers for Medicare and Medicaid Services, available at https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/May2016_SummaryReport.pdf, last seen on 01/01/2020.

³² Department of Health and Human Services, *Electronic Health Record Incentive Program; Final Rule*, 75(144) Federal Register 2010, available at <https://www.govinfo.gov/content/pkg/FR-2010-07-28/pdf/2010-17207.pdf>, last seen on 02/02/2020.

³³ See *Who Owns Medical Records: 50 State Comparison*, Health Information and the Law, available at <http://www.healthinfolaw.org/comparative-analysis/who-owns-medical-records-50-state-comparison>, last seen on 10/10/2019.

³⁴ See O. Campion-Awwad, A. Hayton, L. Smith & M. Vuaran, *The National Programme for IT in the NHS: A Case History*, MPhil Public Policy 2014, University of Cambridge, available at <https://www.cl.cam.ac.uk/~rja14/Papers/npfit-mpp-2014-case-history.pdf>, last seen on 03/12/2019.

³⁵ *Ibid.*

³⁶ Public Accounts Committee, House of Commons, *The National Programme for IT in the NHS: Progress since 2006*, 2009, available at <https://publications.parliament.uk/pa/cm200809/cmselect/cmpubacc/153/153.pdf>, last seen on 12/01/2020.

£12.7bn.³⁷ Due to its slow progress and ineffectiveness, the programme was dismantled by the UK government in 2011.³⁸ The components of the programme are still functional within separate management and accountability structures. Due to this, the pace of adoption of digital health records varies across the UK. NHS is using policy interventions for promotion of EHR standardization and usage.³⁹

Australia started its adoption of digital health records journey by setting up a regulatory authority, the National Electronic Health Transition Authority (“NEHTA”), in 2005.⁴⁰ As a part of its mandate, NEHTA developed specifications, standards and infrastructure; selected a common language for health communications; and created unique health care identification numbers for all individuals, providers and organizations.⁴¹ Personally Controlled Electronic Health Records Act (“PCEHR” Act) in 2012 brought the EHR system within a legal framework.⁴² Its review in 2014 identified issues in uptake of the PCEHR system. Recommendations for a new governance structure, richer clinical content and a move to an opt out model of uptake were made. Following this, Australian Digital Health Agency was formed in 2016 which focused on meaningful use while protecting privacy. PCEHR Act was superseded by the My Health Records Act, 2012.⁴³ A new opt-out PHR model, by the name of ‘My Health Records’ was introduced across Australia and strengthening of privacy for these records was assured through legislative means.⁴⁴ A PWC study in 2015 estimated that the total costs to the Australian government for implementation of EHR is \$10bn.⁴⁵ Australian Privacy Foundation states that the conservative estimates for the cost of My Health Records is \$2bn with an annual recurring cost of \$500mn.⁴⁶

³⁷ Ibid.

³⁸ Public Accounts Committee, House of Commons, *The dismantled National Programme for IT in the NHS*, 2013, available at <https://publications.parliament.uk/pa/cm201314/cmselect/cmpubacc/294/294.pdf>, last seen on 01/01/2020.

³⁹ See *NHS Digital, Interoperability Toolkit*, NHS Digital, available at <https://digital.nhs.uk/services/interoperability-toolkit>, last seen on 13/02/2020.

⁴⁰ See S.J. Hambleton & J. Aloizos AM, *Australia's digital health journey*, 210(6) *The Medical Journal of Australia* (2019), available at <https://www.mja.com.au/journal/2019/210/6/australias-digital-health-journey#12>, last seen on 02/01/2020.

⁴¹ Ibid.

⁴² Personally Controlled Electronic Health Records Act, 2012 (Australia).

⁴³ My Health Records Act, 2012 (Australia).

⁴⁴ My Health Records Amendment (Strengthening Privacy) Act, 2018 (Australia).

⁴⁵ See J. Forsythe et al, *Australia can see further by standing on the shoulders of giants*, PricewaterhouseCoopers, available at <https://www.pwc.com.au/publications/pdf/digital-hospital-2016.pdf>, last seen on 13/12/2019.

⁴⁶ *Value of My Health Record*, Australian Privacy Foundation, available at <https://privacy.org.au/campaigns/myhr/value-of-myhr/>, last seen on 12/12/2019.

Government interventions are necessary for incentivizing and regulating the digital health records system adopted by a nation. Intense debates around what the country expects from its systems before the design and roll out at a national level are critical. For example, when Australia tried the opt-in PCEHR system, the uptake was less due to concerns about data security and privacy.⁴⁷ This led to strengthening of privacy systems and the PHR design as well as use of opt-out system to increase the uptake by the people. Similarly, it is claimed that in the US, initial technical claims have now been replaced by procedural, professional, social, political, and ethical issues.⁴⁸

Issues with standardization of health records are widespread. Despite being in force for more than a decade, these global systems are still in progress for both adoption and implementation. For instance, the NHS was unable to get a top-down EHR system implemented in the UK and is now working at a smaller scale to nudge the use of EHR and PHR.⁴⁹ Table 2 summarizes the system of EHR adoption in the US, UK, and Australia as described in the present study. In the next section, EHR adoption in India is studied with reference to the present global analysis.

Table 2: EHR systems: Global comparison

Criteria	US	Australia	UK
Type of record	HER	PHR	EHR & PHR hybrid model
Data Owner	Decided by State law	Patients	-
Legal	HITECH Act	My Health	National

⁴⁷ T. Patten, *A Healthy Dose of Caution: An Analysis of Australia's My Health Record*, Baker McKenzie, available at <https://www.bakermckenzie.com/en/insight/publications/2019/04/a-healthy-dose-of-caution>, last seen on 12/02/2020.

⁴⁸ R.S. Evans, *Electronic Health Records: Then, Now, and in the Future*, 25(1) IIMIA Yearbook of Medical Informatics (2016), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5171496/pdf/yimi-11-0s48.pdf>, last seen on 02/12/2019.

⁴⁹ Supra 38.

framework	2009 and HIPAA Act 1996	Records Act 2012 and Privacy Act 1988	Programmes and Plans and Data Privacy Act 2018
Interoperability	Interoperability Standards Advisory * Since 2017, updated by the Office of National Coordinator for Health Information Technology (ONC)	Interoperable standards by 2022	NHS Policy
Financial incentives	Built in law	Budgeted by the union govt	NHS funded policies

4. EHR Adoption in India: Status and Concerns

Unlike its global counterparts, India does not have a single regulatory framework for digital health records yet. Presently, limited regulation is available under the IT Rules, 2011.⁵⁰ Under these rules, health data is considered sensitive personal data for which a notice and consent framework for the collection, use, disclosure, transfer and deletion is described. This is applicable only to a part of healthcare providers, i.e. those that have a body corporate structure. It also does not deal with the interoperability component required for an EHR system. The Clinical Establishment rules mandate all healthcare providers in the country to

⁵⁰ IT (Reasonable Security Practices and Sensitive Personal Data or Information) Rules, 2011.

use EHR/EMR system as prescribed by the government.⁵¹ However, these are not being implemented in practice due to inaction by the State. Separately, the MoHFW has notified EHR Standards.⁵² These are voluntary standards for identification and demographics, patient identifiers, architectural and functional requirements, terminology and coding system, imaging and data exchange. These standards are supplemented by the endorsement of accreditation bodies like the National Accreditation Board for Hospitals (“NABH”) in India.

The current EHR standards and rules are inadequate to nudge adoption by healthcare providers. Given their shortcomings, a draft right-based law for digital healthcare, DISHA, was introduced in 2018. Another policy document, the NDHB was also put out for public comments in 2019. In this section, a study of both of the proposed frameworks and their implications for the future is performed.

A Framework for EHR Regulation in India

A regulatory framework for EHR adoption and implementation is a relatively new exercise in India. So far, two frameworks for regulations have been proposed. These are the DISHA and the NDHB. Apart from these regulatory structures, the umbrella law for data protection, which would be applicable to the health IT records domain is also under consideration in the Parliament by January 2020.⁵³ The two proposed frameworks for EHR in India are diametrically opposite in their structure. While one is a draft law, another is a policy blueprint. The structure under the two proposed frameworks is discussed here:

I. Draft Digital Information Security in Healthcare Act, 2018 (“DISHA”) seeks to set up a nodal body for adoption of e-health standards, protect privacy & confidentiality while ensuring security and standardisation.⁵⁴ A federal system of nodal agencies with National Electronic Health Authority (“NeHA”) at the union level and State Electronic Health Authorities (“SeHAs”) at the state level are envisaged. The role of NeHA would be to formulate standards and guidelines for the generation, collection, storage, and transfer of digital health data.⁵⁵ Setting interoperability standards and ensuring their compliance would also be a function of NeHA. Government would develop Health Information Exchanges (“HIE”) that will aid in sharing data within healthcare establishments. Under clause 3(j) of the Act, patients are the owners of their medical data while the healthcare establishments of the

⁵¹ Rule 9(iv), The Clinical Establishments (Central Government) Rules, 2012.

⁵² Supra 8.

⁵³ Personal Data Protection Bill, 2019 (pending).

⁵⁴ The Digital Information Security in Healthcare Act, 2018.

⁵⁵ Ibid.

HIEs act as trustees of the data so generated. The use of data generated by the EHR is specified and any commercial use is prohibited.

II. National Digital Health Blueprint, 2019 (“NDHB”) is aimed to identify building blocks, standards, regulations and institutional framework required to adopt EHR in India.⁵⁶ One of the tasks of the committee was to study the proposed National Health Stack document which aimed to serve digitization for Ayushman Bharat, a large government funded health insurance scheme.⁵⁷ However, the scope of NDHB is not limited to commentary on the National Health Stack. The committee recommendations have four sub-themes. These are, *i) defining scope of NDHB, overarching principles and target digital services, ii) identify, define and recommend ways to use building blocks of NDHB, including Universal Health Id, iii) identify standards and regulations, iv) and identify reforms required in institutional framework to achieve EHR adoption at scale.*⁵⁸ One of the significant developments under the NDHB is the advocacy for establishing a National Digital Health Mission (NDHM) as a regulatory body. The NDHM is envisaged as a government owned body which is aimed *to be the best healthcare network globally* and this would be achieved by providing every Indian with access to digital health services.⁵⁹ This is proposed to be done by prescribing interventions like, creating National Health Electronic Registries as a single source of information and manage master health data of the nation; a federated PHR framework; a National Health Analytics Platform; unique digital health ID; health data dictionaries; and supply chain management for drugs, payment gateways shared across all health programs.

The DISHA and NDHB aim at developing a framework for EHR in India using two different approaches. The DISHA seeks to set standards through a central nodal body. The NDHB envisages a NDHM to be introduced. This mission, may or may not be formed under a law and is proposed to be structured upon existing government agencies like the UIDAI and GSTN.

In December 2019, the PDP Bill was introduced in the Parliament in India. It is currently under review within a Joint Select Committee. The PDP Bill, 2019, once passed as a law would serve to provide an overarching legal framework for personal data protection in India. Table

⁵⁶ *Placing the report on National Digital Health Blueprint (NDHB) in public domain for comments/views regarding*, MoHFW Notice No. T-21016/78/2018-eHealth (15/07/2019), available at https://www.nhp.gov.in/NHPfiles/National_Digital_Health_Blueprint_Report_comments_invited.pdf, last seen on 02/01/2020.

⁵⁷ *Supra* 6.

⁵⁸ *Ibid.*

⁵⁹ *Ibid.*

3 compares the basic features of the PDP Bill with DISHA. There are significant differences between the two laws. While DISHA envisages the patient to be the owner of the data generated and restricts the use of data so generated, the PDP Bill does not define data owner. The PDP Bill also allows any legal activity to be performed by the data fiduciary within restrictions provided under the law. The DISHA does not allow sharing of data by regulated entities for commercial use, specifically to insurance companies and human resource companies. There is no such barrier to commercial use in the PDP Bill. This comparison shows that in the current form, it is difficult to harmoniously interpret the two, if enacted.

Provision	DISHA	PDP Bill
Ownership	Patient (Clause 3(j))	-
Definition of health data	Includes information about the health status, health services, donation or examination of a body part and details of clinical establishment accessed by the individual (Clause 3(e))	Includes data about physical or mental health, includes records regarding the past, present or future state of the health, data collected/associated in the course of registration for, or provision of health services (Clause 3(21))
Regulatory body	National electronic Health Authority (NeHA) (Clause 4)	Data Protection Authority of India (Clause 41)
Regulated entities	Clinical establishments (Clause 21 2(b)), Health Information Exchanges (Clause 19, 20), any entity with custody of health data (Clause 22)	Data fiduciaries (Clauses 2 A (C), 4-11), Data processors (Clause 2 A (C))

Commercial use	Not allowed (Clause 29 (5))	Allowed (Clause 4)
Interoperability provisions	NeHA to prescribe standards (Clause 22)	Limited to protection of privacy & right to data portability (Clause 19)
Usage of data	Concise, restrictive	Expansive
Consent requirement	Yes (Clauses 28, 29, 30, 33 & 44(2))	Yes (Clauses 7, 9, 11, 16, 20, 23, 34, 40, 50, 82, 94)

Table 3: Comparing DISHA and PDP Bill

5. The Way Ahead

The DISHA is a progressive piece of legislation. However, under the current scenario, adoption of a healthcare specific regulatory framework under the DISHA seems to be unlikely. The MoHFW in India recently stated that it had shared the DISHA to the Ministry of Electronics and Information Technology (MeitY) to be subsumed into the PDP Bill.⁶⁰ However, the recommendations of the MoHFW in the form of DISHA have not been taken into account as the provisions related to health in PDP 2018 and PDP 2019 have no considerable difference.⁶¹

Therefore, it seems likely that the EHR adoption in India shall be driven by the principles in NDHB document in conjunction with the provisions in the PDP Bill. However, the present study indicates that a well-defined legal framework would enable adoption and implementation of digital health records for the benefit of patients, healthcare providers, states as well as other stakeholders.

Given this understanding, the DISHA should be brought to the public domain for further consultations. The DISHA will need to overcome

⁶⁰ *Data Transfer of Digital Health Records*, Press Information Bureau, available at <https://pib.gov.in/Pressreleaseshare.aspx?PRID=1578929>, last seen on 13/10/2019.

⁶¹ See Personal Data Protection Bill, 2018 (Draft Bill, 2018); Supra 53.

certain impediments to widespread adoption and usage of the technology. These are discussed below:

What kind of digital patient records should be encouraged?

The answer to choosing a type of patient health record is complex. It depends on the existing factors as well as the anticipated gains of using one type over the other.

In the US, usage of EHRs is encouraged under the HITECH Act. The use is considered meaningful when it contributes towards improving i) quality, safety, efficiency, and reducing health disparities; ii) engaging patients and families in their health; iii) improving care coordination; iv) improving population and public health; all the while ensuring adequate privacy and security protection for personal health information. After defining the outcomes, the outputs expected of the EHR usage are set by government agencies. The healthcare institutes are rewarded for compliance with the standards and meaningfully using them under the HITECH Act and rules. Despite this, the system is at a nascent stage. While there is availability of EHR systems across hospitals, its usage is still limited. Alongside the EHR development, a strong legal framework to preserve the privacy and security of persons using consent framework, and purpose limitation by the State and non-State entities is done.

In the UK, various NHS agencies are independently responsible for developing an EHR/PHR framework for themselves. Currently, various forms of EMRs, EHRs and PHRs exist within the NHS. Electronic Summary Care Record (“SCR”) containing limited patient information regarding prescriptions, allergies and adverse reactions is shared between healthcare providers and can be accessed by the patient. The NHS sets standards for EHRs and uses mechanisms like accreditation of agencies to ensure their uniform adoption.

Australia provides PHR through ‘My Health Records’ application to its people. It uses an opt-out method of adoption. By staying opted-in this framework, consent is given to registered healthcare providers to view patient information related to allergies, medicines, medical conditions and pathology tests in case of an emergency. At the same time, healthcare providers can add information about the patient in the record. The ultimate access to manage this database rests within the patient. Insurance companies or employers are not permitted to use the data. A framework for secondary use of the patients’ data guides the usage of the data for research purposes. It is impermissible to be used for commercial purposes.

In the Indian scenario, the case for adoption of EHR is not clear. The DISHA specifies the purpose which is centred on patient care and research. A consent framework is set for data usage. Commercialization of health data by private entities is restricted under the Act but there are some exceptions wherein the State can use the health data. The NDHB, on the other hand, has a much wider scope of usage of health data. This ranges from health and well-being for all at all ages to Universal Health Coverage and includes citizen-centric efficient and effective services; accountability for performance and creation of a holistic and comprehensive health ecosystem. The broad functions defined for the NDHM vests high power in the State as it is responsible for the regulation as well as appropriate use of the data so generated for any of the above mentioned purposes.⁶² Therefore, there is a need to define the purpose of EHR adoption so that the standards developed under the framework are amenable to such clearly defined objectives.

Incentivizing adoption

Whatever be the type of digital health records, it is seen that globally at the adoption stage, *incentive programmes* are put to encourage private players to adopt EHR as per government standards. No such incentives are put in any of the proposed interventions in India. One of the reasons for this could be reliance on Public-Private-Partnerships or Government Funded Health Insurance Schemes to drive such adoption. Laws like the Clinical Establishment Act have been historically unable to regulate the private sector healthcare providers in India. Due to this, incorporation of some incentive technique shall be required for initiating adoption by these entities. The healthcare landscape in India is fragmented with measurement and economic challenges. To incentivize adoption, the government would need to provide funds as well as an enabling environment to the stakeholders. Regulatory framework for ensuring credible measurement would require funding to be sustainable. With the current low level of government spending in health, a judicious prioritisation of spending on building the basic blocks of data generation, through regulation as well as financing is advisable.

Legal framework for EHR use

An overarching legal framework for adoption and use of EHRs is present in the US and Australia. The HITECH Act and the My Health Records Act provide the framework wherein the statutory regulatory bodies are set/identified and outcomes and procedural checks are defined. This is supplemented by the laws for data protection. Using a legal framework is

⁶² Supra 56.

advantageous as setting up and implementation of digital health records is a long-term objective of the State which requires considerable funding and regulatory governance. The current proposed legislative and policy frameworks in India are at crossroads. Designing and implementing a strong, patient-centric legislative framework is the imminent requirement for the country before incurring expenditure on conversion to digital health records.

The DISHA in India envisages such legal framework, but is not likely to be enacted in its present form. The framework under the NDHB envisages setting up of a NDHM as the focal regulatory agency implementing the blueprint. The framework also iterates a five-year level action plan to achieve the identified targets. These include, “*establishing and managing the core digital health data and the infrastructure required for its exchange... promotion of adoption of open standards...creating a system of PHR based on international standards*”. In contrast, the US HITECH Act has been inducing a phase-wise induction of EHR adoption since 2009.⁶³ The meaningful adoption of EHRs is still underway. On its own, the principles stated under the NDHB do not sufficiently deal with domains like telemedicine, consent withdrawal and right to be forgotten, de-identification of data etc. In absence of a legal mandate and financial support, the incentives to adopt the blueprint by the private healthcare market are inadequate. Further, the PDP Bill, 2019 puts the patient in charge of their health data through a consent framework but refrains from calling the patient the data owner. Any lawful commercial use of health data would be allowed under the PDP bill with the consent of the patient. However, broad exceptions, specifically to the State to use the data without consent have been provided in the law under clauses 12-15. These include undertaking any measure to provide assistance or services during any disaster or any breakdown of public order. Another important concern with the PDP Bill is the power of the State to define Sensitive Personal Data and make regulations thereon.

Presently, India is hoping to create a system of standards that help achieve interoperability and increase uptake of EHRs. It is important to note that the push towards EHR adoption is occurring in the absence of any data protection law or health data protection law. For instance, the MoHFW is promoting Integrated Health Information Platform (“IHIP”) which aims to enable the creation of standards compliant EHR of the citizens on a pan-India basis. IHIP also aims to integrate interoperable EHRs through a State-owned platform, the HIE.

⁶³ See *Public Health and Promoting Interoperability Programs (formerly, known as Electronic Health Records Meaningful Use)*, Centre for Disease Control and Prevention, available at <https://www.cdc.gov/ehrmeaningfuluse/introduction.html>, last seen on 05/02/2020.

In these circumstances, the DISHA can play an important role in building a legal framework of digital health data. The framework adopted under it puts the patient at the centre of the digital health system. The law is clear in its objective of patient safety. However, some provisions of the draft law, like the powers of the HIEs, NeHA and other state authorities; complete ban on commercial activities, need to be reassessed.

The challenge of diverse population served by a fragmented healthcare network will make it difficult to achieve the aim of interoperable EHR use throughout the country without a legal mandate for the regulated entities to do so. It is also important to note that mere legal mandate, without a practical roadmap for adoption and use will be challenging to implement in the country as seen in the case of provisions under the Clinical Establishment Act. A careful discussion on the objective of the exercise powered by scientific examination through regulatory impact assessments, followed by strengthening of the existing regulatory regime for healthcare are prerequisite to designing a legal framework for action. These measures will ensure that the legal framework under the DISHA protect the patient from inappropriate use of their data from the State as well as other stakeholders in the network while incentivizing adoption and use of digital health technologies.