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National eHealth Authority (NeHA)

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National eHealth Authority (NeHA)

ICT India Working Paper #29

Manisha Wadhwa

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Abstract

The Government of India has embarked on a path to achieve Universal Health Coverage for all the citizens of India as envisaged by the National Health Policy 2017. To achieve this, the National Health Policy 2017 recommends a paradigm shift from the health system existing in silos to a more comprehensive and a holistic healthcare system, based on the foundation of digital technologies. Digital health technologies are the most powerful tool towards the attainment of Universal Health Coverage.

The National Health Policy 2017 recommends the creation of National electronic Health Authority (NeHA) or National Digital Health Authority (NDHA) as a regulatory body for the deployment of digital health interventions in the healthcare sector. The National electronic Health Authority (NeHA) will be the nodal authority to streamline all the efforts needed to develop integrated national health information architecture. The Government of India proposes to establish National electronic Health Authority (NeHA) as a statutory body through a Parliament act called "Digital Information Security in Healthcare, Act (DISHA)".

The present paper is about the National electronic Health Authority. The document gives a detailed account of its purpose, mission, vision, objectives and functions. An act of parliament called "Digital Information Security in Healthcare, Act (DISHA)" under which the National eHealth Authority is proposed to be established is discussed. The role of state electronic Health Authorities is also discussed in brief. The document outlines key challenges for National eHealth Authority to achieve its objectives. This paper also presents a review of International experiences as a guide to establish National electronic Health Authority in India. A brief account of National Digital Health Mission is also given.

Introduction

National Health Policy 2017 recognizes the role of Information and Communications Technology (ICT) to be integral in the delivery of healthcare services and advocates extensive use of digital tools to improve the efficiency and outcomes of the healthcare system in India. In this regard, National Health Policy 2017 clearly outlines three specific goals. First, *“Ensure district-level electronic database of information on health system components by 2020”*; second, *“Strengthen the health surveillance system and establish registries for diseases of public health importance by 2020”*; third, *“Establish federated integrated health information architecture, Health Information Exchanges and National Health Information Network by 2025”* (Ministry of Health & Family Welfare, Government of India 2017b). National Health Policy 2017 identifies the need of setting up a National eHealth Authority (NeHA) (or National Digital Health Authority (NDHA)) for the purpose of regulating, developing and deploying digital health across the continuum of care. NeHA will be a statutory body for creating frameworks, regulations and guidelines for interoperability and exchange of digital information. The Ministry of Health and Family Welfare, GoI proposed setting up of NeHA in the year 2015 (Ministry of Health & Family Welfare, Government of India 2017a). The NeHA will be the apex organization supporting India’s journey in the deployment of ICT interventions in the healthcare sector. NeHA will be responsible for the development of an integrated health information system and enforce laws and regulations related to patients’ digital health records.

National eHealth Authority (NeHA)

Mission

“NeHA will be the nodal authority that will be responsible for development of an Integrated Health Information System (including Telemedicine and mHealth) in India, while collaborating with all the stakeholders, viz., healthcare providers, consumers, healthcare technology industries, and policymakers. It will also be responsible for enforcing the laws & regulations relating to the privacy and security of the patients health information & records.” (Ministry of Health & Family Welfare, Government of India 2015)

Vision

“Attainment of high quality of health services for all Indians through the cost-effective and secure use of information and communication technologies in health and health-related fields.” (Ministry of Health & Family Welfare, Government of India 2017a)

Goal

“To ensure development and promotion of eHealth ecosystem in India for enabling, the organization, management and provision of effective people-centred health services to all in an efficient, cost-effective and transparent manner.” (Ministry of Health & Family Welfare, Government of India 2017a)

Objectives

Table 1 outlines the objectives of the proposed National electronic Health Authority (NeHA).

Table 1 : Objectives of National electronic Health Authority (NeHA)

1.	To formulate “National eHealth Policy and Strategy” for coordinated eHealth adoption in the country
2.	To oversee orderly evolution of eHealth initiatives (state and nationwide) and to guide adoption of eHealth at various levels and in different geographical and health system areas
3.	To promote setting up of state health records repositories and health information exchanges (HIEs) to facilitate interoperability
4.	To formulate and manage all health informatics standards for India
5.	To lay down data management, privacy and security policies, guidelines and health records of patients in accordance with statutory provisions
6.	To enforce the laws and regulations relating to the privacy, confidentiality, and security of the patient's health information and records
7.	To coordinate efforts across departments and ministries, and liaise with other related policy/regulatory groups to ensure consistency and coherence
8.	To help enable ecosystem that involves stakeholders to improve care delivery and health outcomes
9.	To map continuous evolution of the eHealth landscape and take on new functions as needed

Source: (Ministry of Health & Family Welfare, Government of India 2017a)

Core Functions

Table 2 outlines the core functions of the proposed National electronic Health Authority (NeHA).

Table 2: Core Functions of the proposed National electronic Health Authority (NeHA)

<u>Policy and Promotion</u> <ul style="list-style-type: none">To work out vision, strategy and adoption time plans, with timeframes, priorities, and road-map in respect of eHealth adoption by all stakeholders, both public and private providers, large scale hospitals and stand-alone clinics

- To formulate policies for eHealth adoption that are best suited to Indian context and enable accelerated health outcomes in terms of access, affordability, quality and reduction in disease mortality and morbidity
- To engage with stakeholders through various means so that eHealth plans are adopted and other policy, regulatory and legal provisions are implemented by both the public and private stakeholders
- To provide thought leadership, in the areas of eHealth
- To effectively promote adoption of eHealth in the country, NeHA would have the mandate to set up an agency to provide oversight, handholding, capacity building, etc.

Standards Development, release, and maintenance

- NeHA will oversee and actively work with all relevant stakeholders including SDOs for formulation and adoption of health informatics standards
- NeHA will act as a focal agency for participation or engagement with global SDOs in eHealth such as IHTSDO. It will undertake all activities leading to adoption and release of suitable standards and Indian profiles

Legal Aspects including Regulation

- NeHA will act as an enforcement agency with suitable mandate and powers
- NeHA will be responsible for enforcement of standards and ensuring security, confidentiality, and privacy of patient's health information and records

Setting up and Maintaining Health Repositories, Electronic Health Exchanges and National Health Information Network

- NeHA will prepare technical and policy documents relating to architecture, standards, policies, and guidelines for eHealth record repositories, HIEs and NHIN
- NeHA may also initiate Proof of Concept (PoCs), in close consultation with government - centre and states, industry, implementers and users
- NeHA would lay down operational guidelines and protocols, policies for sharing and exchange of data, audit guidelines and the like; these shall be guided by experience in operation and use of PoC, global best practices and consultations with stakeholders

(MoHFW, State governments and other public and private providers, academia, R&D labs, and others)

Capacity Building

- NeHA would co-work with academic institutions to spread awareness on Health Informatics and eHealth to health care delivery professionals. NeHA would provide inputs, in terms of areas of need / requirement of different courses according to the background of the learners, to academic institutions

Other Functions

- NeHA will collaborate and work with STQC, Department of Electronics and IT (DeitY) in creating a certification model for certification of HER products, STQC is envisaged to function as the certification body
- Incidental to the discharge of its functions or as assigned to NeHA by the government or parliament or as the situation warrants

Source: (Ministry of Health & Family Welfare, Government of India 2015; 2017a)

DISHA Act

The Ministry of Health and Family Welfare (MoHFW), GoI, plans to establish National eHealth Authority as a statutory body through a Parliament act called "**Digital Information Security in Healthcare, Act (DISHA)**" (Ministry of Health & Family Welfare, Government of India 2018).

"An Act to provide for establishment of National and State eHealth Authorities and Health Information Exchanges; to standardize and regulate the processes related to collection, storing, transmission and use of digital health data; and to ensure reliability, data privacy, confidentiality and security of digital health data and such other matters related and incidental thereto." (Ministry of Health & Family Welfare, Government of India 2018).

The proposed legislation "DISHA", will formally establish NeHA to ensure there is no duplication of efforts with regard to patients' digital records. The security of digital patient data and interoperability of the healthcare data have been longstanding issues in India and DISHA Act is an attempt by the Indian Government to overcome these hurdles. *"The purpose of the act is to provide for electronic health data privacy, confidentiality' security and standardization and provide for establishment of National Digital Health Authority and Health information Exchanges*

and such other matters related and incidental thereto”(Ministry of Health & Family Welfare, Government of India 2018).

DISHA Act was proposed by the Government of India in March, 2018 (Ministry of Health & Family Welfare, Government of India 2018). DISHA Act has three key objectives: first, to ensure security, confidentiality, privacy and standardization of the digital health data; second, to create central regulator, National Electronic Health Authority, and state regulators, state electronic health authorities; and third, to regulate the storage and exchange of electronic health data through Health Information exchanges. DISHA Act calls for creation of regulatory authorities at the central and state level to enforce the tasks as laid down in the legislation. The National Electronic Health Authority (NeHA) at the central level will be the apex body responsible for formulating standards, guidelines and protocols related to digital health data. The authority at the state level, State Electronic Health Authority (SeHA), will be responsible for ensuring the effective implementation of DISHA requirements in the states. This act will be applicable to whole of India except Jammu and Kashmir.

Governance of NeHA

Composition

The central government shall be responsible for the appointment of the members of NeHA. The composition of NeHA is given in Table 3.

Table 3: Composition of the National electronic Health Authority (NeHA)

a.	A Chairperson (Full-time)
b.	A member-secretary (equivalent to the rank of Joint Secretary to the Government of India)
c.	Four Full-time members <ul style="list-style-type: none">• One from Health informatics• One from Public Health• One from Law• One from Public Policy
d.	Four ex-officio members (not less than the rank of Joint Secretary to the Government of India) <ul style="list-style-type: none">• One from Ministry of Electronics and Information Technology;• One from Ministry of Panchayati Raj/ Ministry of Women & Child Development;• One from Directorate General of Health Services; and• One from Ministry of Law and Justice

Source: (Ministry of Health & Family Welfare, Government of India 2018)

Power and Functions

Table 4 enlists the power and functions of National electronic Health Authority (NeHA).

Table 4: Power and Functions of National electronic Health Authority (NeHA)

a.	Formulate standards, operational guidelines and protocols for the generation, collection, storage and transmission of the digital health data for the purposes of this Act, applicable to: <ul style="list-style-type: none"> • Clinical establishments generating and collecting digital health data for their own use or for further transmission to the health information exchanges; • Health information exchanges storing and transmitting digital health data to clinical establishments, or to other health information exchanges, or to State Electronic Health Authority, or the National Electronic Health Authority; • Any other entity having custody of any digital health data; • State Electronic health Authority and the National Electronic Health Authority
b.	To ensure data protection and prevent breach or theft of digital health data, establish data security measures for all stages of generation, collection, storage and transmission of digital health data, which shall at the minimum include access controls, encrypting and audit trails
c.	Conduct periodical investigations to ensure compliance with the provisions of this Act and any rules, regulations, standards or protocols hereunder by health information exchanges
d.	Notify and mandate the health information exchanges, in case of failure to comply with the provisions of this Act
e.	To lay down protocol for transmission of digital health data to and receiving it from other countries
f.	Collaborate and work with Standardization Testing and Quality Certification of digital health care system, by establishing necessary norms and institutions, including collaborating with existing institutions;
g.	Carry out all such incidental activities in consonance with all above powers and functions enumerated in sub-section Perform such other functions and exercise such other powers as may be prescribed

Source: (Ministry of Health & Family Welfare, Government of India 2018)

National Executive Committee

Composition

The central government shall be responsible for the formation of National Executive Committee to assist the National eHealth Authority in performing its functions as laid down in the DISHA Act. Table 5 gives the composition of National Executive committee.

Table 5: Composition of National Executive Committee

a.	Additional Secretary/Joint Secretary, eHealth as Chairperson
b.	Deputy Commissioner/Assistant Commissioners as members
c.	Director/Deputy Secretary as member
d.	Support by consultants and eHealth section

Source: (Ministry of Health & Family Welfare, Government of India 2018)

The power and functions of National Executive Committee shall be prescribed by the central government in consultation with the National eHealth Authority.

State Electronic Health Authorities

Composition

The state government shall be responsible for the appointment of members of the State Electronic Health Authority. Table 6 gives the composition of State Electronic Health Authority.

Table 6: Composition of State electronic Health Authority

a.	A Chairperson (Full-time)
b.	Secretary in-charge of State Health Department or equivalent as member-secretary
c.	Three Full-time members <ul style="list-style-type: none">• One from Health informatics• One from Public Health• One from Law
c.	Three ex-officio members <ul style="list-style-type: none">• Director, State Health Services• One from State Information Technology department• One from State Law department

Source: (Ministry of Health & Family Welfare, Government of India 2018)

Power and Functions

The power and functions of State Electronic Health Authority are given in Table 7.

Table 7: Power and Functions of State electronic Health Authority

a.	Ensure that the clinical establishments and other entities in the state collect, store, transmit and use digital health data as per the provisions of this Act and the standards, protocols and operational guidelines issued by the National Electronic Health Authority, from time to time
b.	Conduct investigations to ensure compliance with the provisions of this Act
c.	Notify and mandate the clinical establishments and other entities, in case of failure to comply with the provisions of this Act
d.	Carry out all such incidental activities in consonance with all above powers and functions enumerated in sub-section (a) to(c) above Perform such other functions and exercise such other powers as may be prescribed by the Central Government

Source: (Ministry of Health & Family Welfare, Government of India 2018)

On 21st March 2018, the draft of DISHA act was placed by the MoHFW, Gol in the public domain for comments and suggestions(Ministry of Health & Family Welfare, Government of India 2018). The MoHFW, Gol also submitted the draft legislation to the Ministry of Electronics and Information Technology (MeitY), Gol for their suggestions. In response, it was informed that 'DISHA' Act will be subsumed under the upcoming 'Data Protection Framework on Digital Information, privacy, security & confidentiality' Act, which would be applicable to all domains including health(Ministry of Health & Family Welfare, Government of India 2019a).

Challenges

Undoubtedly, National eHealth Authority will be the foundation to streamline the work of developing national digital health architecture. However, the way is paved with numerous challenges. The regulations governing digital health need to be adapted rapidly to the technological advancements. Healthcare sector is in the crucial stages of innovating digitally and if it is not adapted as per the new digital technologies the system may become obsolete. New skills and capabilities should be imparted in the workforce to cope with the technological advancements and the unforeseen changes. The healthcare system should be able to cope up with the ever changing needs and expectations of the citizens at the same time. Streamlining funding for the establishment of national digital architecture would be a challenge especially in the Indian scenario where the existing public health system is already in shambles. Further, the healthcare sector in India is fragmented in public and private sector and the reliance of the citizens on private sector for healthcare needs is immense. Geographic, socio-economic and political factors put forward a host of challenges for this digital transition to succeed. Building and implementing a model for establishing electronic records for 1.35 billion people will not be an easy task.

International Lessons

Many countries have taken initiatives to set up nationwide e-health architecture in their countries. Many jurisdictions have set up an independent authority similar to National electronic Health Authority to further digital health initiatives. The progress and outlook of various countries' digital authorities regulating digital health initiatives are discussed below.

Canada is pioneer in this front and has set up Canada Health Infoway in the year 2001(Canada Health Infoway 2020a). Canada Health Infoway is a not for profit organization funded by the government of Canada to lead digital health initiatives across Canada(Ministry of Health & Family Welfare, Government of India 2015). It works in collaboration with provinces and territories for efficient implementation of digital health initiatives across the country. It has two strategic goals: first, "Providing safer access to medications, starting with PrescribeIT, a multi-jurisdiction e-prescribing service" and second, "Providing Canadians and their health care providers with access to personal health information and digital health services"(Wikipedia 2019b). Canada Health Infoway is in the process of establishing a single comprehensive national health record system in Canada(Canada Health Infoway 2020c). In November 2018, Canada Health Infoway launched a new initiative 'ACCESS 2022' which will provide all the Canadians access to their own health information(Canada Health Infoway 2020b). As per Independent Performance Evaluation by Bell Browne Molnar & Delicate Consulting Inc. (BBMD) of Infoway's performance in March 2018 (under its 2010 funding agreement with the Canadian federal government) "Infoway has greatly contributed to more timely delivery of health care, increased productivity and interoperability, improved access to, and sharing of information. The 2010 Funding Agreement has led to economic stimulus and the creation of many knowledge-based jobs"(Molnar 2018).

In United States of America, Office of National Coordinator for Health Information Technology (ONC) was established in the year 2004 to lead national health IT initiatives(Ministry of Health & Family Welfare, Government of India 2015). Its mission is to "Improve the health and well-being of individuals and communities through the use of technology and health information that is accessible when and where it matters most"(HealthIT.gov. 2019). In the year 2009, Health Information Technology for Economic and Clinical Health (HITECH) Act was passed(Ministry of Health & Family Welfare, Government of India 2015). Under this act, the Office of National Coordinator for Health Information Technology was given the task of building a national health information system. As a requirement, Office of National Coordinator for Health Information Technology submits annual report to the congress to update on the progress made on the adoption of nationwide system for electronic use and exchange of health information. The 2018 report to the congress mentions "As of 2015, 96 percent of nonfederal acute care hospitals and 78 percent of office-based physicians adopted certified health IT"("2018 Report to Congress - Annual Update on the Adoption of a Nationwide System for the Electronic Use and Exchange of Health Information" 2018). The report provides recommendations such as collaboration, innovation, upgradation of technical capabilities, improved transparency etc. to accelerate the progress of adoption of national wide health information system.

In Australia, National e-Health Transition Authority (NEHTA) was established in July, 2005 conjointly by the federal, state and territory governments(Wikipedia 2019a; Ministry of Health & Family Welfare, Government of India 2015). The NEHTA aimed at exploring new ways of collecting and exchanging electronic information(Wikipedia 2019a). The purpose of NEHTA was “to lead the uptake of eHealth systems of national significance and to coordinate the progression and accelerate the adoption of eHealth by delivering urgently needed integration infrastructure and standards for health information”(Wikipedia 2019a). NEHTA led the work of establishing national e-health architecture and began the work of establishing Personally Controlled Electronic Health Record (PCEHR) system in the year 2010(Wikipedia 2019a). In the year 2012, NEHTA turned on the Personally Controlled Electronic Health Record (PCEHR) system(Wikipedia 2020a). However, in November 2013, Australian government undertook a review of Personally Controlled Electronic Health Record (PCEHR) system and it was suggested that NEHTA should be discontinued(Australian Government 2020). Subsequently, the 2015-2016 federal budget announced the establishment of a new entity called Australian Digital Health Agency(Australian Government 2020). From 1st July, 2016 Australian Digital Health Agency took over the work of NEHTA(Australian Government 2020). Australian Digital Health Agency further extended the work of establishing Personally Controlled Electronic Health Record (PCEHR) system which is now called as “My Health Record”(Wikipedia 2020a). “My Health Record” is a centralized system of patient electronic records in Australia. It allows patients to control their health information to be accessed by the doctors(Nishith Desai Associates 2020).

In United Kingdom, NHS Connecting for Health (CFH) Agency was established under the UK Department of Health in the year 2005(Wikipedia 2020b). The agency was established as a part of Department of Health Informatics Directorate with a role to develop a national IT infrastructure(Wikipedia 2020b). The agency undertook the responsibility of delivering “NHS National Programme for IT (NPfIT)” for NHS England under which a centralized NHS Care record system (NHS CRS) was needed to be developed(Wikipedia 2020b). However, in March 2013, NHS Connecting for Health (CFH) Agency stopped functioning and some of its work was taken over by the Health and Social Care Information Centre(Wikipedia 2020b). In August 2016, Health and Social Care Information Centre was given a new name “NHS Digital” for trading purposes(Wikipedia 2019c). Currently, NHS Digital provides a centralized system for patient records in England(Wikipedia 2019c). NHS Care record system (NHS CRS) enables access to patients’ electronic records to General Physicians across NHS England(Ministry of Health & Family Welfare, Government of India 2015). It allows patients to have control over their own records and can be used for booking hospital appointments(Ministry of Health & Family Welfare, Government of India 2015).

In Sweden, national e-health services are coordinated by a company called ‘Inera’(Lithner 2017). Inera is owned and financed by the Swedish Healthcare regions and municipalities(Lithner 2017). It is owned by 21 county councils and (soon) 290 local authorities(Zetterström and Marklund 2017). Inera is responsible for the development of national health information exchange infrastructure, development of standards and provision of national e-health services. As per

Sweden national e-health vision 2025 ““In 2025, Sweden will be the best country in the world in using digitizing and e-health services in order to support the citizens to achieve a good and equal health and welfare, and to develop and strengthen their own resources for increased independence and social participation”(Lithner 2017). Their focus is on three things: laws and regulations, terminology and technical standards.

National Digital Health Mission

In July 2018, NITI Aayog, Government of India proposed the development of digital architecture “National Health Stack (NHS)” with the aim to create a centralised health record for all the citizens by the year 2022(NITI Aayog, Government of India 2018). The National Health Stack will be built in line with the India’s flagship scheme “Pradhan Mantri-Rashtriya Swasthya Suraksha Mission (PM-RSSM)” and will also bring all the health verticals at the central and state levels under one roof(NITI Aayog, Government of India 2018). In July 2019, NITI Aayog came up with a report “National Digital Health Blueprint (NDHB)” as an action plan to realize the vision of building National Health Stack(Ministry of Health & Family Welfare, Government of India 2019b). The National Digital Health Blueprint keeps National Health Policy 2017 in perspective and forms the foundation on which the entire National digital health Eco-system can be built. National Digital Health Blueprint vision is *“To create a National Digital Health Eco-system that supports Universal Health Coverage in an efficient, accessible, inclusive, affordable, timely and safe manner, through provision of a wide-range of data, information and infrastructure services, duly leveraging open, interoperable, standards-based digital systems, and ensuring the security, confidentiality and privacy of health-related personal information”*(Ministry of Health & Family Welfare, Government of India 2019b). The report “National Digital Health Blueprint (NDHB)” recommends the establishment of “National Digital Health Mission”: the entity responsible for implementing National Digital Health Blueprint.

The National Digital Health Mission will be a government owned body with the vision “To be the best healthcare network globally” and the mission “To provide every Indian with access to digital health services”(Ministry of Health & Family Welfare, Government of India 2019b). The National Digital Health Mission institutional framework will be operational at two levels: the Governance level and the implementation level. The roles and responsibilities within the institutional framework of National Digital Health Mission are given in Table 8.

Table 8: Roles and responsibilities within National Digital Health Mission

Level	Roles	Responsibilities
Apex Level	<ul style="list-style-type: none">Policy formulation and regulation related to National Digital Health Mission	<ul style="list-style-type: none">Provide policy direction

	<ul style="list-style-type: none"> • Supervising the function of the entire National Digital Health Mission • Providing guidance to the National Digital Health Mission at the highest level 	
Board of Directors	<ul style="list-style-type: none"> • Administrative leadership to the National Digital Health Mission • Develop policy direction for National Digital Health Mission • Develop models for self-financing of National Digital Health Mission 	<ul style="list-style-type: none"> • Develop financing mechanism for sustainability of National Digital Health Mission
CEO Level	<ul style="list-style-type: none"> • Implement policies and decision approved by the Board of Governors at ground level • Identify models for funding Operation • Coordinate with MoHFW and the States/UTs • Engage with private sector to ensure their participation in the National Digital Health Mission • Resolve technical and operation issues at ground level • Policy administration 	<ul style="list-style-type: none"> • CEO to have overall execution responsibility of the National Digital Health Blueprint • Ensure private sector participation in National Digital Health Mission
Operations	<ul style="list-style-type: none"> • Manage Day to Day Operation at the ground level • Capacity building of Health Informatics • Ensure smooth implementation of 	<ul style="list-style-type: none"> • Overseeing all the activities of operation including implementation, training, support and modifications

	<ul style="list-style-type: none">• National Digital Health Infrastructure	
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Source: (Ministry of Health & Family Welfare, Government of India 2019b)

Interestingly, there are assumptions that ‘National Digital Health Mission (NDHM)’ might replace the proposed ‘National eHealth Authority (NeHA)’(Lakshmi Mittal and Family South Asia Institute, Harvard University 2019).

Conclusion

National electronic Health Authority (NeHA) will be the nodal authority enforcing laws and regulations to streamline all the efforts needed to develop integrated national health information architecture. Establishment of NeHA will give a fillip to all the efforts needed to create electronic health records for all the citizens of the country. State electronic Health authorities will also play a crucial role in this regard as health is a state subject in India. Multisectoral coordination should be sought to accelerate the work in this regard. New skills and capabilities should be imparted in the workforce to cope with the technological advancements. The regulations governing digital health need to be adapted rapidly to the technological advancements. Close partnership between various institutions and organizations is essential to drive a change. Experiences from other countries can guide orderly evolution of National electronic Health Authority in India.

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