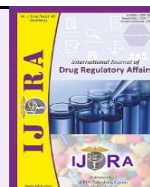


Available online on 15 Dec, 2024 at <https://ijdra.com/index.php/journal>**International Journal of Drug Regulatory Affairs**Published by Diva Enterprises Pvt. Ltd., New Delhi
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Review Article

**Current Regulatory framework of Digital Health in India**Ridhima Sandal^a, Sonal Setya^{b,*}^a Centre of Excellence in Pharmaceutical Sciences, Guru Gobind Singh Indraprastha University, Dwarka, New Delhi 110078, India^b Department of Pharmacy Practice, SGT College of Pharmacy, SGT University, Gurugram, Haryana 122505, India**Abstract**

India's healthcare system is experiencing a significant transformation with the increasing adoption of digital technologies. The rise of digital health has brought remarkable improvements in the availability, affordability, and patient-centeredness of healthcare services. This article reviews the evolving regulatory landscape governing digital health in India, highlighting existing frameworks, significant initiatives, and ongoing challenges such as fragmented regulations and data protection concerns. It emphasizes the importance of establishing robust regulatory structures to safeguard patient rights and data privacy, thereby fostering sustainable growth in the digital healthcare sector. Additionally, global perspectives on digital health regulations from organizations could provide a context for India's efforts. A balanced approach to regulation will be crucial for the sustainable growth of digital health in India. By strategically addressing digital health challenges, India has the potential to enhance healthcare delivery and achieve universal health coverage, underscoring the necessity of collaboration and innovation in the digital health domain. This article aims to offer meaningful perspectives for policymakers, healthcare providers, and technology developers, delivering a comprehensive overview of the existing landscape and potential future developments in the regulation of digital healthcare in India.

Keywords: Telemedicine; regulatory framework; digital therapeutics; electronic health records; mobile health; medical devices; NDHM; CDSO; digital health

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1. Introduction

Digital healthcare signifies a significant evolution in the intersection of technology and health, integrating digital tools with the medical field for providing improved healthcare services. The World Health Organization (WHO) defines digital health as a comprehensive concept that includes e-health and extends into innovative areas like big data analytics, genomics, and artificial intelligence (AI). (1) Essentially, digital healthcare leverages information and communication technologies (ICT) to achieve health-related goals, focusing on better treatment outcomes, improved diagnostic accuracy, and enhanced management of chronic health issues. (2) Digital health encompasses mobile health apps, telemedicine, wearable devices, electronic health records, and digital therapeutics. The key components of digital health are illustrated in Figure 1. By enabling data tracking, patient engagement, and personalized treatment, digital health supports improved outcomes and more efficient healthcare delivery across diverse settings.

In India, the healthcare landscape is experiencing a transformative shift, particularly accelerated by the COVID-19 pandemic. This digital health revolution aims

to enhance the accessibility, affordability, and patient-centric nature of healthcare services. By leveraging digital tools, healthcare providers can offer more efficient care, while patients are encouraged to take an active role in managing their health. This collaborative approach facilitates proactive engagement, allowing individuals to adopt new strategies for prevention, early diagnosis, and effective management of serious illnesses alongside chronic conditions. (3)

As India embraces the potential of digital health, establishing robust regulatory frameworks becomes essential to protect patient rights, ensure data privacy, and maintain high standards of care. Although the Indian government has introduced various laws and guidelines to regulate the use of digital health technologies, significant challenges remain. This review explores the current regulatory landscape governing digital health in India, emphasizing the need for continued refinement of regulations to address the emerging challenges and support for sustainable growth in the digital healthcare sector. This article is intended to provide valuable insights for policymakers, healthcare professionals, and technology developers, offering a clear understanding of both the

current state and future possibilities in the regulation of digital healthcare in India.

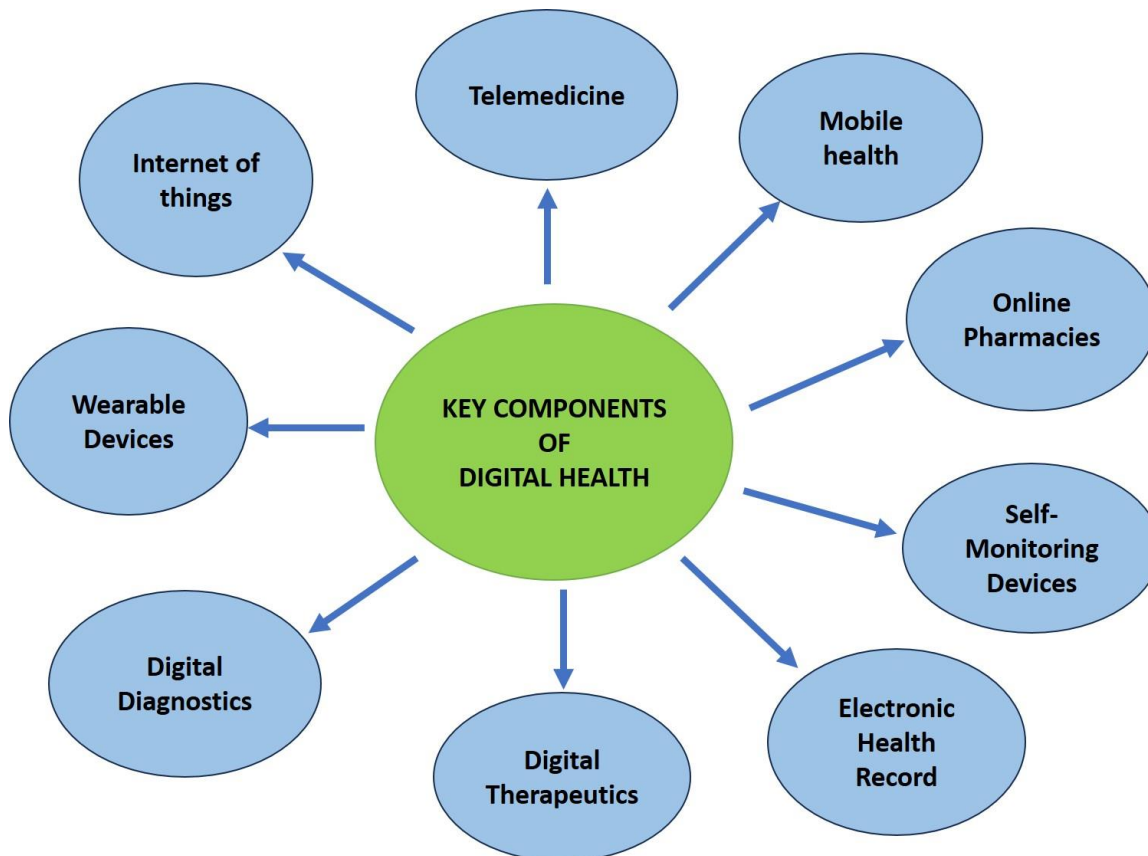


Figure 1. Components of digital health

2. Regulations for digital health in India

In India, digital health is governed by different rules, guidelines, and standards making it highly fragmented and unclear. The wide-ranging nature of digital health, which includes service delivery, data management, business

models, and technological advancements, adds to the complexity and disjointedness of the current system. (4) Figure 2 highlights the main regulatory bodies of India for managing digital healthcare.

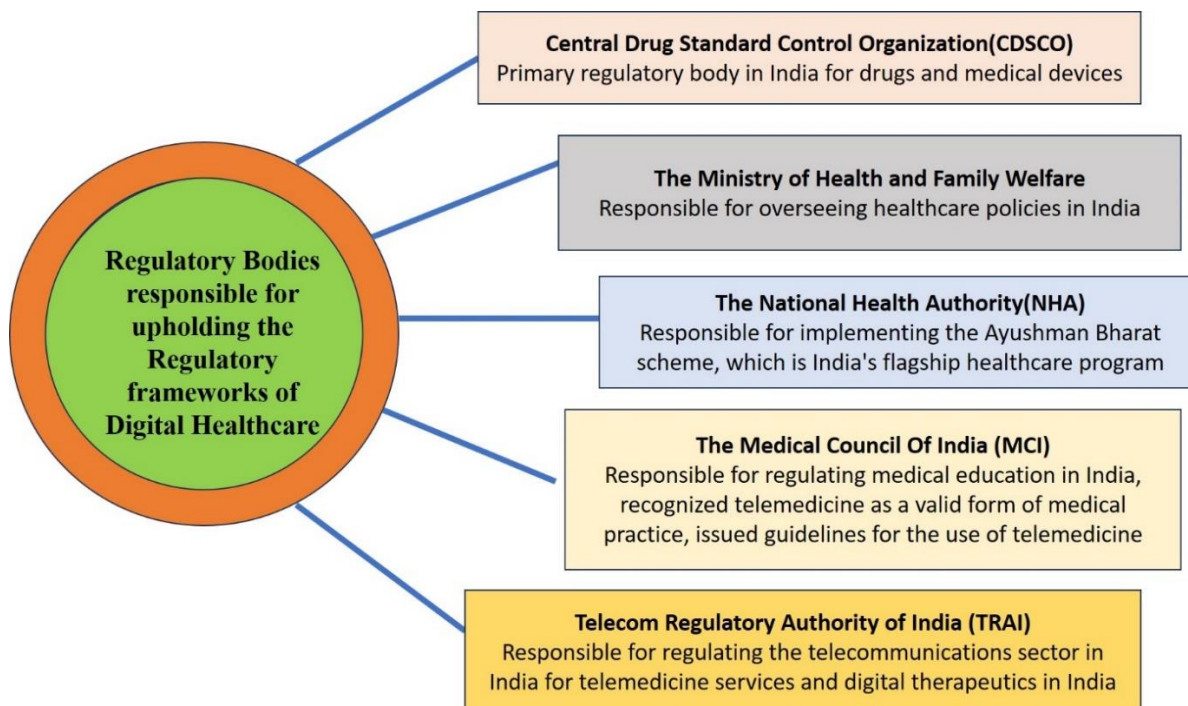


Figure 2. Regulatory bodies governing digital health in India

While there are no dedicated legislations specifically addressing digital health, several existing laws and regulations encompass the broader digital health landscape. In addition, the Indian government has launched numerous initiatives to strengthen and regulate

digital health, aiming to modernize healthcare access and management across the country (Table 1). The salient features of these regulations and initiatives are described in the following section.

Table 1. Timeline of digital health regulations and initiatives in India

Year	Regulation and Initiatives	Description
1940 and 1945	Drugs and Cosmetics Act and Rules	Governs the manufacture, distribution, and sale of drugs and cosmetics, including those sold through online platforms. Provides detailed regulations for the approval and sale of drugs, pertinent to e-pharmacy operations.
2013	Draft Telemedicine Practice Guidelines	Introduced an initial framework for telemedicine practices, covering protocols for remote consultations.
2015	Digital India Initiative	A nationwide initiative aimed at digital transformation across sectors, including healthcare, focusing on telemedicine and digital healthcare services.
2017	Medical Devices Rules	Specifies regulations for medical devices, encompassing Software as a Medical Device (SaMD), ensuring safety and effectiveness.
2018	National Health Stack	A framework designed to create a digital health infrastructure for India, facilitating electronic health records (EHR) and integrating health insurance schemes.
2018	National Digital Health Blueprint (NDHB)	A comprehensive plan to develop a seamless digital health ecosystem, promoting interoperability of health systems and adoption of EHRs.
2019	National Medical Commission Act	Formulates the National Medical Commission (NMC) to regulate medical education and practices, including digital health guidelines.
2020	Telemedicine Practice Guidelines	Finalized guidelines providing a structured approach for telemedicine practices, including ethical considerations.
2020	Clinical Trials Registry (CTRI) Guidelines	Sets forth standards for conducting clinical trials using digital methods, ensuring transparency and compliance.
2020	E-Sanjeevani Telemedicine Platform	A government-supported telemedicine platform offering online medical consultations, helping bridge the healthcare gap in rural and semi-urban areas.
2021	Draft Digital Health Data Management Policy	Aims to oversee the handling, storage, and sharing of health data in digital formats, ensuring privacy and security measures.
2021	National Digital Health Mission (NDHM)	A mission aimed at establishing a unified digital health ecosystem, providing every individual with a unique health ID to facilitate easy access to digital health records and services.
2022	Ayushman Bharat Digital Health Mission (ABDHM)	Expands upon the NDHM by integrating digital health records, telemedicine services, and insurance schemes into a unified national health infrastructure.
2023	Ayushman Bharat Digital Health Account (ABHA)	Introduces personal digital health IDs to citizens, enabling secure and convenient access to their health records through a unified digital system.

3. The Drugs and Cosmetics Act of 1940 (DCA) and the Drugs and Cosmetics Rules of 1945 (DCR).

In India, the regulation of manufacturing, import, sale, and distribution of pharmaceuticals and medical equipment falls under the Drugs and Cosmetics Act (DCA) and its associated rules, enforced by the Central Drugs Standard Control Organization (CDSCO). From April 1, 2020, these regulations have also encompassed medical device software, mandating approval for their clinical use. (5) Digital tools have become essential for healthcare professionals to diagnose, monitor, and treat patients. Software is classified as a medical device if it is used for diagnosis, treatment, prevention, or support of a disease or physical condition. Software intended as Software as a

Medical Device (SaMD) must meet specific regulations, including the Medical Device Rules, 2017, and follow ISO standards for quality (ISO 13485:2016) and risk management (ISO 14971:2019). Additionally, they must comply with international standards. In September 2021, CDSCO introduced guidelines that align with the International Medical Device Regulators Forum (IMDRF) to classify SaMD based on risk. These classifications include: Class A (low risk), which involves software that does not directly affect patient data (e.g., software that analyzes pre-recorded clinical data); Class B (low-moderate risk), which provides real-time patient information without clinical diagnosis (e.g., home-use ECG software); and Class C (moderate risk), which

includes software that helps diagnose conditions or analyze patient physiology (e.g., cardiovascular simulation tools). As of now, CDSCO has not identified any Class D (high risk) SaMDs. Each SaMD must follow a registration process according to its risk classification to meet safety and quality standards. Furthermore, online platforms such as e-pharmacies must follow the regulations stipulated by the DCA and DCR, ensuring safe and lawful digital healthcare operations in India.

4. National Health Policy

The National Health Policy of 2017 aimed to attain the highest possible level of health and well-being for all citizens in India while ensuring universal access to quality healthcare without causing financial burdens. It emphasized the importance of creating a robust Digital Health Technology Ecosystem to enhance healthcare delivery. Additionally, the policy recommended the establishment of a National Digital Health Authority to focus specifically on digital health initiatives. It also proposed the integration of Aadhaar with individual health data, facilitating better access and management of health information for improved patient care. (6)

4.1 Medical Devices Rules 2017 and Medical Device Policy 2023

The Medical Device Rules of 2017 introduced a phased licensing approach for medical devices in India. (7) Initially, from April 1, 2020, to September 30, 2021, there was no requirement for registration or licensing. This changed on October 1, 2021, when registration became mandatory, although licenses were not needed at that time. From October 1, 2022, a license was required for Class A and B devices, while Class C and D devices were exempt from licensing. However, starting October 1, 2023, all medical devices were required to obtain a license. Additionally, import licenses for Class A and B devices became necessary from October 1, 2022, with the remaining Class C and D devices needing import licenses by October 1, 2023, if they had not already been notified. The Medical Device Policy of 2023 was aimed to enhance the skills of professionals in the medical device sector through initiatives focused on skilling, upskilling, and reskilling. (8) This policy also sought to establish multi-disciplinary courses that addressed various aspects of medical devices. While there was no specific legislation in India to regulate technologies like AI and machine learning, it was important to note that telemedicine platforms utilizing these technologies were prohibited from providing patient counseling or prescribing medications.

4.2 Digital information security in healthcare act (DISHA)

The Digital Information Security in Healthcare Act 2018, introduced by the Ministry of Health and Family Welfare, establishes a new legal framework for data protection in the healthcare sector, aiming to ensure consistent electronic health standards across India. (9) In conjunction with this legislation, the National Institution for Transforming India (NITI Aayog) initiated the National Health Stack program to create digital health records for all citizens by 2022. The key objectives of the Act include

protecting the privacy, security, and standardization of digital health data, managing the processes for creating, collecting, storing, sharing, and using digital health information-particularly sensitive personal details. It also focuses on recording all health-related information, which encompasses both physical and mental health, services received, organ donations, medical tests, and any healthcare facilities accessed.

4.3 National Health Stack

In 2018, the National Institution for Technical Innovation (NITI Aayog) introduced the National Health Stack (NHS), a comprehensive digital healthcare framework designed to create centralized health records for all citizens. This initiative aligns with the government's major health program, Ayushman Bharat, and other public health efforts across India. The NHS aims to enhance transparency in the health insurance sector while enabling policymakers to forecast future healthcare needs, identify new services, and address existing gaps in the system. (10)

Key components of the NHS include the establishment of National Health Electronic Registries, serving as a single source for managing health data. It also features a Coverage and Claims platform, which supports large-scale health protection schemes and effectively detects fraud. The NHS proposes a Federated Personal Health Records (PHR) Framework to improve patient access to their health information and facilitate medical research. Additionally, a National Health Analytics Platform will integrate data from various health initiatives to inform policy decisions through advanced predictive analytics. Other essential elements, such as Digital Health IDs, Health Data Dictionaries, and Supply Chain Management for medications, will support the efficient management and portability of healthcare services across all health program

4.4 National Digital Health Blue print

The National Digital Health Blueprint is an extension of the National Health Policy 2017, designed to ensure that every citizen in India can access healthcare through digital channels, enhancing the system's efficiency and effectiveness. This initiative envisions a comprehensive digital health system that prioritizes inclusivity, security, privacy, education, and the empowerment of citizens. (11) It includes foundational elements and various data registries to enable straightforward access to health information. This blueprint features essential components such as a unified framework, a set of architectural elements, and a five-tier structure of institutional components. It proposes a Unique Health ID (UHID) to enhance user control over privacy and consent, while also allowing health records to be shared seamlessly across the country. The plan stresses the importance of maintaining digital health records, following specific guidelines, and utilizing health analytics effectively.

5. National Medical Commission Act

The 2019 National Medical Commission Act, overseen by the National Medical Commission (NMC), regulates medical education and practice in India. (12) The Medical Council of India (MCI) Code encourages the digitization of medical records to facilitate quick access for healthcare providers. Physicians are required to adhere to the MCI

Code and must submit a statement confirming their compliance. The NMC Act and MCI Code encompass digital health apps that relate to the healthcare services doctors provide to patients in India.

6. Telemedicine Practice Guideline

The 2020 Telemedicine Guidelines of India aimed to provide a framework for standardizing and expanding teleconsultation services across the country. These guidelines apply to all types of communication, including text, audio, and video, and set rules for Registered Medical Practitioners (RMPs) under the Indian Medical Council Act, 1956. (13) Key aspects addressed include the consultation's context, proper identification of both the RMP and the patient, mode of communication, consent, type of consultation, and patient evaluation and management. RMPs can only prescribe medications when confident in the quality of patient information. Medications are classified into four groups: List O (over-the-counter drugs like paracetamol), List A (low-risk drugs such as skin creams and diabetes medication, requiring initial video consultation for new prescriptions), List B (medications added to existing treatment plans, such as enalapril for hypertension), and the prohibited list (including Schedule X drugs and those under the NDPS Act, like benzodiazepines). (14) The National Medical Commission (NMC) has issued guidelines for the Professional Conduct Regulations, 2023, which includes updated Telemedicine Practice Guidelines for Registered Medical Practitioners (RMPs). (15) The guidelines bring several new changes to telemedicine practices. These changes aim to enhance patient safety, ensure ethical standards, and align medical practice with digital advancements. RMPs must digitize patient records within three years and ensure compliance with existing laws. Consent procedures have been strengthened, requiring documented signatures from patients in various formats. Continuous professional development (CPD) for telemedicine practice is now essential, but the earlier requirement for certification within three years has been removed. Platforms hosting telemedicine services must establish protocols for emergency referrals and can no longer display RMP ratings, reviews, or advertisements. The responsibility for verifying RMP qualifications and maintaining accurate records lies with the platform administrators. AI-based counseling or prescriptions remain prohibited, ensuring direct communication between RMPs and patients. New rules also outline how RMPs should behave on social media and provide clearer guidance for follow-up consultations. These changes aim to enhance patient safety, ensure ethical standards, and align medical practice with digital advancements.

7. E- Sanjeevani Telemedicine Platform

E-Sanjeevani, India's National Telemedicine Service, aimed to promote digital health equity and support the goal of Universal Health Coverage (UHC). (16) This platform allowed users to quickly and easily connect with healthcare professionals and specialists using their mobile devices, enabling individuals to access quality healthcare remotely by visiting the nearest Ayushman Bharat Health & Wellness Centre. E-Sanjeevani operated in two main formats: the E-Sanjeevani AB-HWC, a provider-to-

provider telemedicine service that facilitated teleconsultations for patients at Health and Wellness Centres (HWCs), with community health officers assisting in connecting patients with doctors and specialists located at secondary and tertiary health facilities or medical universities in a Hub-and-Spoke model; and the E-Sanjeevani OPD, a patient-to-provider telemedicine service that allowed individuals to receive healthcare from the comfort of their homes using devices such as smartphones and laptops. In response to the COVID-19 pandemic, the Government of India released the Telemedicine Practice Guidelines, specifically designing E-Sanjeevani for teleconsultations between patients and healthcare providers. As a result, it became a vital resource for many individuals seeking medical advice for both COVID-19 and non-COVID-19 health issues from the safety of their homes.

8. Draft Digital Health Data Management Policy

The Health Data Management Policy is a crucial initiative under the National Digital Health Mission (NDHM), aimed at ensuring "Security and Privacy by Design" for safeguarding individuals' digital health information. (17) This policy acts as a comprehensive guide within the National Digital Health Ecosystem (NDHE), setting the foundation for data privacy protection in compliance with relevant laws and standards. Its key objectives include the protection of digital personal information—such as personal health identifiers, electronic health records, and electronic medical records—through the implementation of suitable technical and organizational measures. The policy also seeks to create a voluntary digital health record system that is accessible to individuals and healthcare providers, emphasizing user consent and adherence to international standards for data interoperability and sharing.

A significant aspect of the policy is its consent framework, which empowers users by giving them control over their data. It introduces an electronic consent manager to facilitate user interactions for obtaining consent to access health information. The policy also safeguards the rights of data owners, providing guidelines for data access, portability, correction, and deletion. Additionally, it outlines the responsibilities of data fiduciaries, the entities responsible for determining the processing of personal data and imposes restrictions on data collection, usage, and storage.

9. National Digital Health Mission

The National Digital Health Mission (NDHM) aimed to create a national digital health ecosystem that would facilitate universal health coverage in an efficient, accessible, inclusive, affordable, timely, and safe manner. (18) It sought to provide a wide range of data, information, and infrastructure services by utilizing open, interoperable, standards-based digital systems, while ensuring the security, confidentiality, and privacy of personal health information. As a component of the Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (AB PM-JAY), the NDHM was guided by the philosophy of "Think Big, Start Small, Scale Fast."

A key feature of the NDHM was its operation as an opt-in program. This allowed individuals to create their Health ID using their Aadhaar number or mobile phone number, along with other personal information, although using Aadhaar was optional. Individuals retained control over their personal health records, which could only be accessed or shared with their consent. They could specify sharing durations ranging from a minimum of one hour to longer periods and had the option to revoke consent at any time. The NDHM operated within a framework of essential rights and various laws, including the Personal Data Protection Bill 2019, the IT Act 2008, and the Aadhaar Act. The initiative was underpinned by the National Digital Health Blueprint, which provided both the strategic and technical foundation for its implementation. In line with the principle of 'Sabka Saath, Sabka Vikaas,' the NDHM included specialized systems and offline components designed to connect with underserved, marginalized, remote, tribal, and digitally unaware communities. Local government networks, Accredited Social Health Activists (ASHAs), and Anganwadi workers (AWWs) played vital roles in empowering these individuals with digital technologies.

An important element of the NDHM was the Consent Manager and Gateway, which served as a portal for the exchange of health information. Health records could only be issued or viewed with explicit patient consent, ensuring individuals-maintained control over their personal data. Additionally, the NDHM proposed the creation of an Open Telemedicine and E-Pharmacy Network, establishing an open digital environment for market participants while allowing government oversight to ensure accountability and transparency.

10. Ayushman Bharat Digital Health Mission (ABDM)

Expanded upon NDHM, integrating digital health records, telemedicine services, and insurance schemes into a unified national health infrastructure. (19)

11. Ayushman Bharat Health Accounts (ABHA)

A vital aspect of the ABDM is the Ayushman Bharat Health Accounts (ABHA), which provides a 14-digit unique identifier for individuals. ABHA simplifies the access and transfer of digital health records by consolidating patient data, enabling efficient tracking of medical histories. (20) This system allows for seamless healthcare access across various services within the Ayushman Bharat program, promoting transparency and accountability in the healthcare sector through online transactions and digital records.

12. Challenges in the regulation of digital health care

India's healthcare sector has seen significant progress with the integration of digital technologies. However, several regulatory challenges continue to hinder its full potential. The regulatory landscape for digital health in India, as in many developing countries, is often fragmented. Various authorities, including the Central Drugs Standard Control Organization (CDSCO), the Ministry of Health and Family Welfare (MoHFW), and the Ministry of Electronics and Information Technology (MeitY), oversee different aspects, often without clearly defined roles. This lack of coordination can result in regulatory overlaps, delays, and

confusion, which may compromise patient safety and lead to market inefficiencies. (21) Additionally, limited digital infrastructure, such as poor internet connectivity and insufficient device access, particularly in rural areas, hampers the widespread adoption of digital health solutions and contributes to healthcare disparities. (22)

Low digital literacy is another challenge, with many individuals in rural regions and older demographics lacking basic digital skills, limiting their ability to effectively use digital health platforms and reducing the impact of such initiatives. Compliance with data protection laws and obtaining informed consent remain challenging, especially as telemedicine services expand rapidly. Ensuring that patients understand how their personal data is used and obtaining proper consent is essential but difficult to implement consistently. (23) Data protection and cybersecurity are paramount, yet enforcement guidelines for regulations such as the Information Technology Act 2000, the Intermediaries Directive 2011, and the Data Protection Rules 2011 remain insufficient. Although the Data Protection Act, 2023 (DPDP Act) represents progress, its stringent compliance demands create implementation challenges. (24) Healthcare providers, especially those with limited resources, often struggle to maintain robust cybersecurity measures, leaving them vulnerable to data breaches, misuse, and legal repercussions. Cybersecurity threats further exacerbate these issues, making organizations susceptible to cyberattacks that can result in privacy violations, identity theft, and reputational damage. (25) Addressing these challenges requires a cohesive approach, with clearer regulations, improved infrastructure, enhanced digital literacy programs, and stronger cybersecurity measures. A well-coordinated regulatory framework and collaboration among stakeholders will be essential for driving sustainable growth and innovation in India's digital health sector.

13. Global perspective on digital health regulations

Around the world, countries and organizations are increasingly adopting digital health technologies to improve access to healthcare and enhance the quality of services. The World Health Organization (WHO) has initiated its Digital Healthcare Strategy to boost public health through digital solutions. This approach highlights the critical need for interoperability, which allows different health systems to connect effectively. It also emphasizes the importance of strong data security and protecting patient privacy, along with encouraging active participation from stakeholders in developing user-friendly digital health solutions.

The European Union has its eHealth Action Plan, focusing on creating integrated electronic health records to improve system connectivity, promoting telehealth and mobile health (mHealth) for better patient care, and expanding telemedicine services to reach underserved areas. In the United States, the National Coordinator for Health Information Technology (ONC) has established a detailed framework for digital health that prioritizes interoperability of electronic health records, data privacy, and effective use of data analytics to enhance public health.

The International Telecommunication Union (ITU), in collaboration with WHO, also advocates for using broadband and mobile technologies in healthcare delivery, encouraging nations to develop comprehensive digital health plans.

For India to strengthen its digital health sector, it can learn from these global practices while considering its unique challenges. A more unified regulatory framework is essential, which could streamline oversight by coordinating the roles of key organizations like the Central Drugs Standard Control Organization (CDSCO), the Ministry of Health and Family Welfare (MoHFW), and the Ministry of Electronics and Information Technology (MeitY). This would help create clear regulations that reduce delays and confusion.

Investing in digital infrastructure is vital for improving connectivity and resource availability, especially in rural areas, to ensure broader access to digital health services. Additionally, enhancing digital literacy through targeted education programs is crucial for helping citizens, particularly in remote communities, gain the skills needed to use digital health tools effectively.

Strengthening laws on data protection and improving cybersecurity measures are necessary steps to safeguard patient information and build trust in digital health solutions. Moreover, fostering partnerships between the government, technology firms, and healthcare providers will encourage innovation and the development of effective digital health solutions. By implementing these strategies, India can better align its digital health regulations with international standards, making meaningful progress toward achieving universal healthcare and ensuring fair access to quality health services for all its citizens. (26)

14. Conclusion

India's regulatory framework for digital health is steadily evolving to meet both international benchmarks and the unique needs of its healthcare system. The rise of digital health tools has significantly expanded access to care, yet it also introduces regulatory hurdles, such as ensuring data privacy, achieving standardization, and bridging urban-rural divides in digital accessibility. Initiatives like the National Digital Health Mission (NDHM) and the implementation of telemedicine standards highlight India's proactive approach toward a cohesive digital health structure that values both data security and interoperability. Considering international regulatory models which prioritize secure data management, device categorization, and technology-driven innovation, India has the opportunity to build its regulatory approach in a way that nurtures innovation while safeguarding health data and public welfare. Continued public-private collaboration and a focus on inclusive digital infrastructure can enable India to create a secure and accessible digital health environment, meeting both domestic needs and global regulatory expectations.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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