

Uncovering the Indian Digital Health System and Its Regulatory Framework

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Abstract

Historically, India has strived to ensure access to high-quality healthcare. Since the beginning of the flagship initiative, "Digital India Campaign," in 2015, India has been focusing on e-health. The Information Technology Enactments primarily regulate digital healthcare applications and service providers would be required to observe certain rules as an intermediary, to protect the sensitive personal information of patients. On the other hand, legislation has continued to lag behind technical improvements and is unable to address several crucial challenges. The ultimate authorities and their policies identified a more significant opportunity for strengthening the digital health ecosystem by launching the step forwarding initiatives. Through setting guidelines, the healthcare department has taken the proactive initiative of using the efficient integration of ICTs with the present health infrastructure. Indian health technologies are being provided protection under patent, copyright and trade laws. Barriers to providing healthcare remotely are being lowered all across the country. The focus of COVID-19 has moved from a thoughtful debate over whether to employ digital technologies towards an immediate need to reform practice.

1. Introduction

Digital technologies are increasingly ubiquitous, and the world's population has never been more connected. Innovation is occurring at an unparalleled rate, particularly within the digital arena. Nonetheless, its application to improving population health remains largely untapped, and there is enormous potential for using digital healthcare offerings [1].

In India, the term "digital health" is not specifically defined. However, it is generally understood to refer to health care services that use information and telecommunication technologies for purposes such as illness prevention, diagnosis, treatment, monitoring, and management. [2]. Both hardware and software solutions are part of these technologies

[3]. India is home to a large and diverse population, with over 1.3 billion people living in the country. Due to its size, it can be difficult for the government to provide high-quality health care to everyone. This is especially true in rural and remote areas, where access to healthcare services can be limited due to a lack of infrastructure and trained healthcare workers. In addition, India has traditionally struggled with a lack of digital infrastructure, which has made it difficult to deliver healthcare services using digital technologies. This has been a major challenge, as the use of digital technologies can greatly improve access to health care and the quality of care. As a result of these challenges, a significant portion of healthcare needs in India goes unmet. [4].

Since the launch of the "Digital India Campaign" in 2015, India has made significant progress in the field

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of e-health. The campaign, which is a flagship program of the Indian government, aims to increase the use of digital technologies in various sectors, including health care. As part of the campaign, the Indian government has implemented a number of initiatives to improve access to healthcare services through the use of digital technologies. These initiatives include the development of electronic health records, the expansion of telemedicine services, and the creation of digital health portals and platforms.

These efforts have led to significant improvements in the delivery of healthcare services in India. For example, the use of electronic health records has made it easier for doctors to access and share patient information, which has improved the accuracy and efficiency of healthcare services. Telemedicine services have also expanded, allowing patients in remote and rural areas to access care from specialists who may not be available locally [5,6].

The use of digital techniques and interventions in primary healthcare has had positive results in programs to help people quit smoking, educate women about maternal health, deal with mental health issues, and maintain vaccine supply chains, making the digitalization of public health in India essential. India's accomplishments in the e-health domain have received recognition worldwide [7].

2. Understanding the Legal Framework for Digital Health in India

The concepts "digital medications" and "digital health" are not well specified in India. Several regulations cover digital health services in general. Data sharing between the patient and the service provider is an element of digital healthcare. Personal information about the patient, like as medical records and clinical problems, is considered confidential personalised data or knowledge under data protection laws. Consent is the most important requirement under the Data Protection Regulations and must be produced in writing [3].

The Information Technology Enactment of 2000 has implications for e-health services in India, but these implications are somewhat varied. This is because e-

health services often function as intermediaries, connecting patients with health care providers but not directly providing health care services themselves. In this role, they are subject to the Information Technology (Sensitive personal data or information) (SPDI) Rules, 2011 ("Data Protection Rules") and the Intermediaries Rules of Information Technology, 2011 ("Intermediary Guidelines"). These rules and guidelines outline the responsibilities of intermediaries in protecting sensitive personal data and information, and service providers must comply with them in order to operate legally in India [3]. The SPDI Rules define sensitive personalised data relating to a person's physical and physiological health state and health history. As of, the collector of this data is obligated to follow particular procedures throughout data compilation and processing to safeguard the confidentiality of the data source [8].

The IT Act 2000 and Rules 2011 provide some protections for the collection, disclosure, and processing of sensitive personal data, such as medical records and clinical histories. However, these laws have not kept up with technological advancements and do not address some critical issues related to data security in the digital healthcare sector. To address these gaps, the Indian government has endorsed the Digital Information Security in Healthcare Act (DISHA) 2018 and the Personal Data Protection Act 2019. These laws provide more comprehensive protections for personal data in the digital healthcare sector, including specific provisions for the handling of sensitive medical information. By implementing these laws, the government aims to ensure that the personal data of patients is kept secure and protected [9]. The Personal Data Protection Bill, 2019 (PDP Bill) is the main legislation in India that addresses the protection of personal data. The PDP Bill was introduced in Parliament and reviewed by a Joint Parliamentary Committee before being enacted into law. The Electronic Health Record Standards (EHR) for India were first issued in 2013 by the e-Health Division under the MoHFW and then revised in 2016 and are now implemented [4]. As part of PDP legislation, the Clinical Establishment (Registration and Regulation) Enactment of 2010 requires all clinical institutions to maintain electronic medical

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records (EMR) for each patient. This means that every clinical institution must register and maintain EMR for every patient in order to comply with the law. By implementing this requirement, the government aims to ensure that patients' medical records are securely stored and can be easily accessed by healthcare providers [9].

The Ministry of Health and Family Welfare (MoHFW) is the highest authority for health care in India at the national level. At the state level, each state has a Health and Family Welfare Department, which is led by a minister and also has a secretariat that reports to the Indian Administrative Service (IAS) framework. Below the state level, the health care system is organized into regional and zonal setups, which include three to five districts and report to the State Health Services Directorate. At the district level, the health services structure serves as a mid-level management organization that connects the state and regional levels on the one hand and the primary health centres and sub-centres on the other. This hierarchical structure ensures that healthcare services are delivered efficiently and effectively at all levels of the system [3], which together contribute to the functioning of the digital health ecosystem. In order to digitize the entire healthcare ecosystem in India, the MoHFW has announced the Health Data Management Policy, 2020 (HDM). The HDM includes the concept of "Security and Privacy by Design" as a guiding principle for the National Digital Health Eco-system (NDHE). This means that security and privacy will be built into the design of the NDHE from the beginning, ensuring that personal data is protected at all times (FIG.1) [4,6].

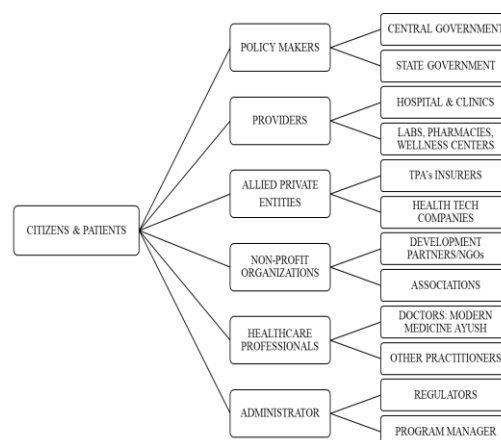


Figure 1 National Digital Health Ecosystem

In 2017, the National Health Policy identified the potential for developing a digital health ecosystem in India in order to achieve universal healthcare goals. This led to the introduction of the National Digital Health Mission (NDHM) in August 2020 as a pilot initiative in six union territories. The NDHM seeks to implement interventions that address health issues at the primary, secondary, and tertiary levels through prevention, promotion, and outpatient care. The NDHM consists of three main components: a patient-specific personalized health identification, a registry for health care providers, and a registry for medical facilities. The goal of the NDHM is to create a unified digital healthcare system.

Within one year of its launch, the NDHM was renamed the Ayushman Bharat Digital Health Mission (ABDM) and is now recognized nationwide. The ABDM uses a healthcare approach that consists of two interrelated components: the establishment of health and wellness centres, and the Pradhan Mantri Jan Arogya Yojana (PM-JAY), which contributes to the country's progress towards achieving the Sustainable Development Goals and universal health coverage.

The Central Drug Standards Control Organization (CDSCO) is the main regulatory authority for medical devices and diagnostics in India, and functions under the Directorate General of Health Services. The Drug Controller General of India is responsible for granting permission for the production of specific medical equipment, including

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e-health technology devices. The manufacturing, import, sale, and distribution of medical equipment are regulated under the Drugs & Cosmetic Act and Rules 1940 and the Indian Medical Council Act of 1956. The Medications and Magic Remedies (Objectionable Advertisements) Enactment, 1954 and its regulations govern the advertising of drugs and devices in India and specifically prohibit any claims of magical cures for drug use [4].

3. Evolving Digital Healthcare Technologies

3.1 Telemedicine

In recent years, cell phone and internet use have become nearly universal in India, and wireless broadband technology has advanced. This has made it possible to provide real-time voice and video consultations, as well as the transfer of medical images such as X-rays and scans, and patient education using pictures and videos. These developments have greatly improved the delivery of healthcare services [10].

Telemedicine refers to the use of telecommunication technology to provide medical care to individuals at a distance. This can be especially helpful in addressing the challenges of providing health care in rural and remote areas, and in maintaining continuity of care. In order to promote the use of telemedicine, the MoHFW has issued Telemedicine Practice Guidelines, which provide guidance on the efficient integration of information and communication technologies (ICTs) with the existing healthcare infrastructure. These guidelines are intended to support the use of telemedicine to improve access to healthcare services for all Indians [11]. In 2005, the Indian Health Ministry established the National Telemedicine Taskforce to promote the use of telemedicine in the country. This task force has led to the implementation of several initiatives, including the Indian Council of Medical Research (ICMR)-AROGYASREE, the National e-Health Authority (NeHA), and Virtual Rural Care Centers (VRCs). These initiatives have helped to expand access to telemedicine services, making it easier for patients to receive care from a distance. Doctors in India have also found telemedicine to be a useful tool. It allows them to provide care to patients who may not be able to travel to a healthcare facility and

can help to maintain continuity of care for patients with chronic conditions [3].

The development of a telemedicine framework in India will require several key components, including:

1. *Improved health care apps*: It will be important to improve the quality of the interaction between patients and health care providers, as well as the interface used by these apps. This will help to ensure that patients receive high-quality care and are able to easily access the services they need.
2. *Solidifying cyber security*: Protecting health care data is a critical priority, as the misuse of confidential data could lead to fraud or cybercrimes. Ensuring the security of data used by healthcare apps and software will be essential in order to prevent these types of incidents.

Other emerging technologies in digital health services include wearables, such as heart rate sensors, exercise trackers, and oximeters. Artificial intelligence and 3D printing are also being used in clinics to improve the delivery of health care services. However, these technologies face many challenges in terms of reaching the market and being adopted by healthcare providers and patients.

One of the main challenges is the lack of regulatory frameworks for these technologies. In many cases, the existing laws and regulations do not adequately address the unique challenges posed by these technologies, making it difficult for companies to bring them to market. In addition, there are often concerns about the safety and effectiveness of these technologies, which can make it difficult to gain the trust of healthcare providers and patients.

While there is great potential for the use of emerging technologies in digital health care, there are many challenges that must be addressed in order to realize this potential. It will be important for the Indian government to develop appropriate regulatory frameworks and to address concerns about the safety and effectiveness of these technologies in order to

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enable their wider adoption in the healthcare sector [3] (Table 1).

Insufficiently clear legal provisions
High system development and maintenance costs
Lack of diagnostic accuracy
Less technology awareness
Scarcity of ethical implementation
Security and privacy issues
Battery life of gadgets
Reliance on technology
Connectivity problems
Compatibility of open standards in IoT products.

Table 1 Factors affecting the implementation of digital healthcare technologies

4. Intellectual Property Landscape In Indian Digital Healthcare

4.1 Trade secret protection

Conventions like the North Atlantic Free Trade Agreement (NAFTA) and the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) regulate trade secret laws in India. In the digital healthcare sector, companies often use mutual agreements, such as non-disclosure and confidentiality agreements, to protect sensitive information. These agreements are typically used to safeguard proprietary information, trade secrets, and other sensitive data.[9]

In addition, many companies include terms in their employment contracts that require employees to maintain the secrecy of the company's secrets not only during their employment but even after they are terminated. These provisions are intended to prevent employees from sharing sensitive information with competitors or others who may use it for their own gain. By implementing these measures, companies can help to protect their intellectual property and ensure that their sensitive data remains secure [12].

4.2 Patent protection

Under the Agreement on TRIPS, India is required to provide patent protection under the Patents Act of 1970. In order to qualify for patent protection, an invention must meet the patentability requirements of novelty, inventiveness, and industrial applicability. In addition, the invention must not fall under the purview of Sections 3 and 4 of the Act, which exclude certain subject matter from patentability.

One potential challenge for digital health applications is Section 3(k) of the Indian Patents Act, which prohibits the patentability of a computer program as a whole. Since digital health applications are based on software and computer programs, they may fall under this provision. However, recent rulings by the Delhi High Court have indicated that not all computer programs are prohibited by Section 3(k), and that when a computer program has a "technical impact" or makes a "technical contribution," it may be eligible for patent protection. This means that digital health applications that meet the requirements of novelty, inventiveness, and industrial applicability, and that have a technical impact or contribution, may be eligible for patent protection in India [2]. Under Section 3(i) of the Indian Patents Act, a patent may not be issued for a program or device that is intended for "a process for the medicinal, surgical, curative, prophylactic, or other treatment of human beings or any process for a similar treatment of animals to make them free from disease or to increase their economic value or that of their products." This means that digital health applications that are intended for the treatment of human beings or animals may not be eligible for patent protection.

However, the inclusion of an in vitro mechanism in a device or technique may be considered patentable. In vitro refers to experiments or processes that are conducted outside of a living organism. The inclusion of an in vitro mechanism in a digital health application may make it eligible for patent protection, even if it is intended for the treatment of human beings or animals. Overall, the patentability of digital health applications in India will depend on their specific features and intended use, and it may

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be necessary to seek legal advice in order to determine whether a particular application is eligible for patent protection [9].

4.3 Copyright protection

Indian copyright law protects "computer programs" such as digital health applications. This means that if someone creates a digital health application, they will automatically have the exclusive right to use and distribute it. While it is not mandatory to register a copyright for a digital health application, doing so can be beneficial.

When a copyright is registered, it serves as the first official proof that the creator of the work has the exclusive right to use and distribute it. This can be useful in the event that someone tries to steal or use the digital health application without permission. In such a case, the creator can use the registered copyright as evidence that they are the rightful owner of the work.

In addition, registering a copyright can also make it easier to enforce the creator's rights. For example, if someone tries to use the digital health application without permission, the creator can take legal action to stop them. This can be difficult to do if there is no official proof of ownership, but with a registered copyright, the creator can more easily defend their rights in court. [2].

5. Impact Of Covid-19 On Indian Digital Health Care

The COVID-19 pandemic has highlighted the need for digital innovations in the healthcare sector. The pandemic has put immense strain on healthcare systems, exposing gaps and weaknesses that must be addressed. The digitization of healthcare has been shown to be an effective way to improve the delivery of care and has enabled more efficient and timely responses to the pandemic.

During the pandemic, there has been a significant increase in the use of telemedicine and mobile technology in the healthcare sector. For example, the Indian government launched the "AAROGYASETU" software application, which allows people to assess their risk of contracting

COVID-19 and to access information about vaccination. This has helped to provide support and assistance to the public during the pandemic. In addition, companies like "PRACTO" have seen a five-fold increase in the use of telemedicine consultations during the pandemic.

Looking forward, initiatives like the Ayushman Bharat Health & Wellness Centre are institutionalizing the use of telemedicine, paving the way for a more digital and connected health care system in the post-COVID era. The pandemic has shown the value and potential of digital health care, and has accelerated the adoption of these technologies in India [13].

The epidemic has improved India's healthcare system by investing in digital infrastructure, resources, and personnel. The way in which treatment is provided has also undergone substantial changes, moving from the acute setting to the community setting and from person-focused care to patient-centred care. However, this crisis has brought to light a critical gap in nations' contingency planning requirements for upgraded and nearly real-time access to reliable information. India has become a thriving market for health technology firms that target particular issues and develop cutting-edge technological solutions that can help close gaps in the Indian healthcare system. This is due to government efforts, incentives, and changing patient expectations. [14]

According to a 2020 Digital Health Consumer Survey conducted by Accenture, the COVID-19 pandemic has accelerated the adoption of digital health care services among consumers. Prior to the pandemic, the adoption of digital health services had stalled, but the global health crisis has led to an increased reliance on these technologies.

However, the survey also found that many of the issues that were identified in earlier research continue to be relevant. For example, consumers continue to have concerns about the security, privacy, and trustworthiness of digital health services. In addition, many consumers have encountered problems with the digital experience, which can turn them off from using these services in

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the future. Furthermore, there are challenges associated with incorporating new digital tools and services into clinical operations, which can make it difficult for health care providers to fully embrace these technologies [15].

6. Conclusion

The digital healthcare system in India has come a long way in recent years, with a growing number of hospitals and clinics offering services such as telemedicine and electronic health records. However, there is still a need for further enhancement in order to improve access to health care for all Indians.

One of the key challenges facing India's digital health care system is the lack of widespread internet connectivity. While internet access has improved in recent years, many rural and remote areas still lack reliable connectivity. This makes it difficult for patients in these areas to access health care services, particularly those that rely on the internet, such as telemedicine.

Another challenge is the lack of trained healthcare professionals who are able to use digital technologies effectively. Many healthcare workers are not familiar with the latest digital tools and technologies, and may not know how to use them to their full potential. This can limit the effectiveness of digital healthcare services, and can also make it difficult for patients to receive the care they need.

One potential solution to these challenges is to invest in training and education programs for healthcare workers. This could include training on the use of digital healthcare technologies, as well as education on the benefits of using these technologies in clinical practice. This would help to ensure that healthcare professionals are able to use digital technologies

effectively, and would also help to increase awareness of the benefits of these technologies among patients.

In addition to training and education, there is also a need for increased investment in infrastructure and technology. This could include investments in internet connectivity in rural and remote areas, as well as the development of new digital healthcare technologies that can improve access to care. By investing in these areas, India can ensure that its digital healthcare system is able to provide high-quality care to all of its citizens.

The COVID-19 phase highlighted the need for digitalization in the health sector, addressing the gaps in an existing system. India is coming up with incredible opportunities to become a digital health pioneer by launching multiple national public health initiatives like Ayushman Bharat, and NDHM. New health tech start-ups are being set up. Overall, the digital health care system in India has made great strides in recent years, but there is still a need for further enhancement in order to improve access to care for all Indians. By investing in training and education, infrastructure, and technology, India can ensure that its digital healthcare system is able to provide high-quality care to all of its citizens.

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