

# The Legal and Public Health Implications Of Digital Health Technologies

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## KEYWORDS

Public Health, Law,  
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## ABSTRACT

To reduce the negative effects of digitization, normative advice in international human rights legislation incorporates digital health into ethical and human rights frameworks. The use of digital health technology for universal health coverage (UHC) is acknowledged to have benefits, but its implementation must be based on respect for human rights, equity, and ethics, as well as upholding norms of acceptable quality, safety, and morality. The WHA acknowledged the necessity to use digital health technologies in the wake of the COVID-19 pandemic in 2020, but stressed that in doing so, they must "pay particular attention to digital inclusion, patient empowerment, data privacy and security, legal and ethical issues, and the protection of personal data." This paper's goal is to critically assess the proposed legislative framework and policy that regulate digital health technologies in India, as well as the implementation of digital health.

## 1. Introduction

The word "ehealth" is new in India and has been defined differently by different organisations. The seventh telemedicine conference was held by Telemedicine and Telecare in 1999. When telehealth is utilised as a component of ICT in the health domain, cost effectiveness is increased. Eysenbach claims that marketing executives coined the phrase initially before 1999 [1]. In order to convey its promises, the tenets of e-commerce, and the prospects for internet and ICT growth in the health sector, the leaders promoted the word "e" for a variety of terms, including e-business, e-marketing, and e-commerce. The interface serves as a conduit for health service providers and patients through eHealth. Distance has a role in the data transmission process to other organisations. the use of electronics for telemedicine services, health network maintenance, prescription writing, and health database upkeep [2]. The wearable and portable modes, utilising health portals for medical care and research that aid in illness treatment, diagnosis, and lifestyle factor and disease monitoring.



Figure 1: Digital Health Technologies

The term "health" refers to an umbrella term that includes telemedicine, telehealth, health telematics, and health informatics [16]. It is used to describe the electronic healthcare services that professionals, paramedics, and IT technicians with minimal domain knowledge provide using the internet and

electronic devices to provide informational, healthcare, and educational services [21]. Health is the use of computer-related technologies and telecommunication to provide healthcare services to remote areas [3]. Alternatively, it refers to the application of contemporary information, electronics, and telecommunication technology to provide quick healthcare services to those in need by transmitting electronic diagnostic data from a geographically dispersed location to a physician seated in a higher centre in order to enhance managerial and patient care [15]. It achieves a balance between spending, cost-effectiveness, and organisational efficiency [4]. Transferring information rather than patients is another way of looking at health. Additionally, it exchanges medical data using information and communication technologies to provide healthcare services remotely.

In this case, the introduction is examined in section 1 of the article while the pertinent literature is examined in section 2. Section 3 explains the goal of the work, Section 4 shows the discussion of the work, and Section 5 concludes the project.

## **Literature Review**

To solve the issue raised by the use of e-health, a multilayered policy must be developed [5]. The long-term sustainability and integration of eHealth advancements are taken into consideration while developing a financial strategy for the public health sector [17]. For e-health to be better integrated and protected, an e-health policy needs to be created. A final plan can only be developed after all aspects of the eHealth project have been considered. The financial aspect of eHealth deployment is not addressed by public health policy [12].

According to [17], the experimental test revealed that the experimental group's intake of fat reduced significantly more than that of the control group. The trend indicated that the experimental group's attitude had changed and their intake of vegetables had grown while their intake of fat had decreased [6]. The experimental group developed the habit of altering their diet due to the information provided by the computerised database. The study came to the conclusion that individualised nutrition information encourages people to modify their eating habits in accordance with dietary recommendations. According to [7], consumers' expectations and demands have been enhanced by mobile eHealth services, and policymakers are optimistic about this development for the health care system. The development of broadband connections and telephone technology in rural areas has boosted the eHealth industry. A smartphone app that can improve healthcare quality can offer prompt and promising medical care. MHealth has the potential to be a more cost-effective option than traditional healthcare. Users can also subscribe to mHealth on a monthly basis, which enhances their quality of life. It encourages accessibility and lessens inequality. A few individuals are willing to pay for an extra service in order to receive a premium service [18].

MoHFW launches e-Gov programmes in the healthcare industry to promote digital India [8]. The eHealth division was founded with the purpose of utilising ICT in the healthcare industry. Additionally, mhealth is expanding quickly and having an impact. Since information systems account for over 8% of GDP in India, they have a significant impact on the country's economy. With eHealth improving the quality of healthcare, services are becoming more affordable and accessible. The burden of disease is also lessened by appropriate monitoring of individuals' health rights. Patients can now obtain medical treatments day and night thanks to mobile and web services [9]. Patients could afford the service thanks to the call centres as well. Electronic medical records provide patient information that can be accessed to obtain online consultations and prescription medications [10]. According to the analysis, e-health has potential, especially in developing nations, but it also has drawbacks. The eHealth sector will implement e-Governance in order to change the infrastructure and architecture of eHealth. Adopting an appropriate entrepreneurial business model for eHealth is crucial. The public health care system ought to implement health care informatics. Measuring patient satisfaction can help improve the standard of service and system effectiveness.

## **2. Methodology**

To fully realise the enormous promise that digital healthcare has, a robust legal and regulatory framework must support the digitization initiative without undermining the rights-based approach to healthcare access. As mentioned above, because of the numerous fragmented laws and regulations, India's legislative and regulatory structure now has a great deal of gaps and lack of clarity [19].

### ***Competition Law***

Governments throughout the globe, including those in the UK, Australia, South Korea, EU, and UK, are debating passing new legislation to limit the dominance of a small number of major internet platforms in the market. Six bills "focusing on the anticompetitive impacts of self-preferencing, mergers and acquisitions, data accumulation, and network effects related to digital platforms" were advanced in June 2021 as a result of recommendations made by a US Congress committee report. The recommendations included breaking up tech giants and regulating them better and more proactively. The Competition Commission of India (CCI) has begun investigating Google and Apple for allegedly abusing the application industry. Google was fined INR 936.44 crore by the CCI earlier in 2022 for abusing its dominant position with regard to Play Store policies. Apple may be subject to severe financial penalties for the related matter of requiring the usage of an internal billing system. A package of suggestions to control anti-competitive behaviour on Big Tech platforms, including stringent guidelines for data usage for advertising, have been put out by the Parliamentary Standing Committee on Finance. The committee proposed that the firms be prohibited from employing third-party services that leverage their core services to process customer data.

Health data can greatly benefit from this. Big Tech businesses' access to and use of personal health data can be regulated with the help of competition law. To guarantee that the use of patient data complies with competition laws and does not result in anti-competitive effects, for example, competition authorities have the authority to place restrictions on mergers and acquisitions. In addition to fostering data portability and interoperability, competition law can also stop Big Tech businesses from establishing data silos and limiting customer choice and competition.

### ***Data Protection Law***

Data access regulations must be strictly enforced in data protection legislation in order to safeguard individuals' autonomy and privacy rights while also fostering a competitive economy. Controlling data access and technology provider usage should receive extra attention. A careful balance must be struck between giving platforms the freedom to bring their data-driven innovations to new markets and outlining exactly what kinds of data they can access, combine, and use. They also need to specify the extra responsibilities they must fulfil when doing business in the health sector. ***Law must address monetisation of health data***

As was previously said, the monetization of personal data can undermine informational and decisional autonomy and have negative consequences on the protection of rights at the individual and community levels. As a result, the need to control data monetisation is becoming more and more apparent. "Considering that data protection is a fundamental right... and that one of the main purposes of the GDPR is to provide data subjects with control over information relating to them, personal data cannot be considered as a tradeable commodity," the European Data Protection Board (EDPB) writes in its Guidelines on the processing of personal data in the context of online services. The EDPB made it clear that "personal data processing differs from monetary payments for multiple reasons, including the possibility that control over personal data may not always be regained once it has been lost." In their Joint Opinion 02/2022 on the proposed Data Act, the European Data Protection Board (EDPB) and the European Data Protection Supervisor (EDPS) reaffirmed this stance: "Data subjects can consent to the processing of their personal data, but they still cannot waive their fundamental rights." After announcing in August 2022 that it is "exploring rules to crack down on harmful commercial surveillance and lax data security," the US Federal Trade Commission is asking the public for feedback on the matter, particularly on "whether it should implement new trade regulation rules or other regulatory alternatives concerning the ways in which companies.

- (1) collect, aggregate, protect, use, analyze, and retain consumer data, as well as
- (2) transfer, share, sell, or otherwise monetize that data in ways that are unfair or deceptive.”

According to The NDHM Strategy Overview in India, "even if the data was provided with consent, certain types of use of personal health data are expected to be prohibited -- for example, usage of data for commercial promotions." NDHM will finalise a list of these use-cases after consulting with MoHFW and other relevant parties. The data protection legislation for both personal and non-personal data must address this quickly. Regulating non-personal data is a topic that is unfortunately avoided by both the Digital Personal Data Protection Bill 2022 and the proposed framework. The government's development of the Digital India Bill is expected to tackle the matter of Big Tech's monetization of personal data.

### **The impact on rights and laws implicated**

Permission, confidentiality, and privacy risks It is unclear if pharmaceutical corporations' access to the massive volumes of personal health data they are gathering from many sources constitutes consenting. People rarely know when their data is being mined, and when it is sold, consent is typically lacking because the data was originally given for another purpose. Violations of privacy and confidentiality can also arise from the unintentional finding of humiliating information about an individual during data processing. Pharmaceutical firms are more at risk of experiencing a data breach the more specific categories of personal data they handle [11].

### **Targeted marketing to consumers undermines consumer choice In India**

Direct-to-consumer (DTC) advertising is mostly used to promote social marketing goals such knowledge of illnesses, family planning, hygiene, and health. Patented Ayurvedic medicines and homoeopathic medicines are permitted to be promoted as DTC products. The pharmaceuticals and Cosmetics Act forbids the promotion of such products for pharmaceuticals classified as Schedule H and Schedule X. Nevertheless, despite legislative restrictions, the public is increasingly exposed to advertisements for prescription pharmaceuticals because of the internet's nature and greater interconnection. This is harmful to people's health since it can result in improper antidepressant use, improper consumption without adequate consultation, an overemphasis on potential benefits, and a lack of knowledge about associated hazards. False information has the potential to create an overmedicated culture in which common ailments, cosmetic concerns, and natural disorders are all seen as medical emergencies [22].

### **Direct-to-physician advertising to influence prescribing decisions**

With less access to doctors for traditional sales representatives, DTP via EHRs is the new marketing tactic. Advertising to physicians in electronic health records (EHRs) is an obvious way for pharmaceutical companies to support and encourage their prescribing decisions. They collaborate even with EHR suppliers. For example, practice fusion, an EHR vendor, provides physicians with pertinent pharmaceutical business marketing regarding new treatments, goods, and services. Throughout the previous year, it has sold two sponsored EHR advisories: one for immunisations from Merck (\$MRK) and another for asthma and COPD from AstraZeneca (\$AZN). Practice Fusion was ordered to pay a penalty of USD 145 million in January 2020, in the first criminal action against an EHR vendor. Practice Fusion had used its EHR software to influence physician prescriptions of opioid medication, and had solicited and received kickbacks from a major opioid company in exchange. "The companies illegally conspired to allow the drug company to have its thumb on the scale at precisely the moment a doctor was making incredibly intimate, personal, and important decisions about a patient's medical care, including the need for pain medication and prescription amount," the US Justice Department said in a press release to that effect [20]. The same worries exist regarding EHR ads: that doctors may underprescribe less heavily advertised pharmaceuticals that are more effective and/or less expensive, and that patients may receive subpar care if their doctor is swayed by EHR advertisements [13]. Studies reveal that exposure to information supplied by pharmaceutical companies results in more frequent and



expensive prescriptions, and that exposure to physician-directed advertising is linked to less efficient and lower-quality prescribing decisions. It is illegal in India to use financial inducements, gifts, sponsorships, or donations for doctor-centric advertising. It is also against the law to pay chemists to promote a particular medication to patients. However, there is no requirement to have advertising content authorised beforehand by an organisation representing the business or government.

### **3. Result and Discussion**

Utilising more recent technology, eHealth can enhance healthcare. Using ICT allows for an improved process that minimises costs. Less patients are referred, which lowers costs, and older individuals don't put as much of a strain on consultants. The usage of ICT reduces the process and health tasks. By using this kind of technology, healthcare professionals spend a great deal less time on their tasks. The benefit that comes with using this kind of technology is the added health interventions. Numerous lives can be saved by eHealth because it facilitates quicker decision-making and efficient data management. Because of the use of ICT, health data are readily available. A consultant can act and make judgements more quickly as a result. Additionally, eHealth can yield significant benefits in managing increasingly complicated and large-scale caseloads with less additional workers and costs. Additionally, there are more patients, which medical staff can handle with ease. Improvements in ICT have an impact on our life. The development of the internet has brought about a major transformation in the world. Hardcopy medical data is exchanged in large quantities in a matter of seconds thanks to ICT. With the use of the internet, a button can be pressed to obtain new treatments and a diagnosis of the illness. Epidemics and pandemics can also be monitored. The internet can be used to evaluate medical records. In a split second, the prescription histories are accessible. It is possible to compare the effectiveness of pharmacies and physicians. The supply and demand of healthcare in India's rural areas fluctuate significantly. The rural health care in India is provided by modest government facilities or small nursing homes. The arrangements are insufficient to address rural India's needs. The impoverished relocate to other cities in search of better healthcare facilities with better infrastructure [14-15]. Despite its impoverished state, rural health systems have distinct benefits. The Indian healthcare sector offers several advantages that can be leveraged to enhance the quality of Indian rural healthcare services. These advantages include:

- The ability to offer affordable diagnostic facilities; information and technology can be leveraged to set new benchmarks for rural healthcare;
- The use of eHealth in semi-urban and rural settings has significantly reduced costs to the public purse;
- The Indian population is empowered to manage their own illnesses; and e-Health has improved primary healthcare in many ways.
- The pharmaceutical sector may be controlled to supply affordable generic medications, enabling high-quality, reasonably priced healthcare to reach every region of India..

Given the uncertainties and inadequacies in the legal frameworks surrounding the topic, maintaining privacy presents a significant obstacle to the digitization of health care, as the current structure may not be sufficient to control health data on a wide scale. Healthcare data protection is not specifically covered by the IT Act or the Data Protection Rules, which just provide a minimal level of protection by requiring the data owner to be notified about how their data is being used. The government and healthcare stakeholders should thoroughly assess the current legal and policy frameworks before focusing resources on large-scale efforts to digitise healthcare. This will help to ensure that digital health is approached under a "rights-based" framework that prioritises user control over data, access to high-quality healthcare, and the recognition of the rights to privacy and informed consent. The right to privacy is threatened by the lack of uniform standards requiring the implementation of data protection and security, particularly in light of the NDHB's proposals to associate SPDI with unprotected private companies like insurers, drug manufacturers, and device manufacturers

#### 4. Conclusion and future scope

The potential for increased accessibility to high-quality healthcare in India through digitization of healthcare might be extremely beneficial for underprivileged people and communities. But in addition to other structural issues, the implementation's legal and moral obstacles need to be addressed. Healthcare professionals that understand digital health are crucial when conducting tests or performing procedures, such as home health screenings, but the nation's infrastructure must also change to accommodate digital health solutions. However, the various issues mentioned above must be addressed by data protection laws in India. Further complicating the widespread adoption of digital healthcare is mistrust of public spaces and differences in access to healthcare. The digitalization of healthcare in India raises ethical questions in addition to legal ones. Informed consent is one of the main ethical concerns. This is a crucial issue that should be taken very seriously, especially for underprivileged people and communities who have a history of medical exploitation. A thorough framework for data protection and informed permission must be in place if the advantages of digital healthcare are to reach those who are most deprived of access to high-quality medical care. Implementing a rights-based framework for health is therefore essential in order to govern user data, prioritise informed consent, and advance the right to access healthcare that is specifically implemented in the context of the fundamental right to health in accordance with constitutional interpretation.

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