

## Safeguarding Patient Privacy: Exploring Data Protection in E-Health Laws: A Cross-Country Analysis

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### Abstract

**INTRODUCTION:** Health information amassed during the treatment of a medical condition is termed health data. This data encompasses information gathered about a patient and their family, forming a patient history. The internet has progressively transformed communication, commerce, and information acquisition. Among the diverse domains it has influenced, the healthcare sector stands out as one of the most intricate and unique realms of integration. Big data are the results of normal online transactions and interactions that take place online, the detectors that are implanted in devices and actual locations, as well as the generation of digital contents by individuals whenever they submit data over internet.

**OBJECTIVES:** The need of protection of health data and methods of safeguarding patient privacy. The study also helps understand and appreciate the best practices which will help India in implementing the law more effectively.

**METHODS:** A doctrinal method of research was employed to analyse the laws and regulations. A comparative approach of different countries gives us the understanding of the gaps and issues. The efficacy of the laws was tested as the paper explores the laws of Canada & Indonesia regarding data protection.

**RESULTS:** In this study, we understood the generation, processing, and interchange of these massive amounts of data can now be facilitated by cloud computing technology. As India, recently enacted '*The Digital Data Protection Act 2023*' which might be a ray of hope for protection of sensitive health data of individuals from misuse.

**CONCLUSION:** The journey towards optimal data protection is ongoing, requiring continuous adaptation to the dynamic nature of technology and the ever-changing healthcare environment.

**Keywords:** Artificial Intelligence, E-Health, Data Protection, Legal, Technology

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### 1. Introduction

In this modern era, digital technology has rapidly become more pervasive across the board of all social organizations. The proliferation of mobile electronic devices such as smartphones, tablet, and wearable technology, as well as media portals, the gathering of huge digital sets of data, and the monitoring of people's behaviour in shared environment using new technologies have all led to the digitization of social relationships, the creation and dissemination of information, corporate entities, and government entities and practices [1]. Such advancements in digital technology have had a significant impact on health care as well as global health, and this is true for both members of the public and those who are engaged in these

fields. The phrase "digital health" is gaining popularity as an umbrella term that may be used to describe a wide variety of technologies that are relevant to health and medicine.

The huge data collections that are produced by new technologies are yet another technological phenomenon that has evolved in recent times. These massive data sets are commonly referred to as "big data," and they are a relatively new concept. Concurrently, a rising digital economy has formed, where this information has taken on the value of a commercial good or service [2].

Electronic Health Records (EHRs) encompass digital documentation containing patients' medical past, test outcomes, prescriptions, and additional clinical data. These records are stored electronically and exchanged between healthcare practitioners [3]. In contemporary healthcare

setups, EHRs are crucial, as they grant medical experts rapid and secure entry to extensive patient details. EHRs hold the promise to transform healthcare administration, enhance patient results, and mitigate medical mistakes. Conventionally, healthcare involves the skilful application of healthcare professionals' knowledge to enhance and sustain health by diagnosing, treating, and preventing illnesses. With the advancement of digital technologies, healthcare provision has become more precise and efficient, eliminating the need for direct involvement of a healthcare expert and ensuring more accurate delivery.

EHR implementation in India is at an early stage, and only a minor fraction of healthcare providers presently employs EHR systems. Nevertheless, the Indian government has acknowledged the advantageous aspects of EHR integration and has initiated various efforts to encourage their adoption. India possesses a distinct healthcare structure with specific difficulties, including a scarcity of medical personnel, limited health awareness, and uneven healthcare resource allocation. Thus, introducing EHRs in India demands a meticulous examination of the nation's exceptional prospects and challenges[4].

In general, the legal and legislative environment in India for the use of AI in healthcare is complicated and in a state of constant change. Even though there are rules and regulations in place to make sure that artificial intelligence is used in a way that is both secure and responsible, there are still significant difficulties and unknowns that need to be resolved. Overall, it is anticipated that the application of AI in medical care will continue to expand in India over the next few years. Because of this, it will be essential for regulators, healthcare providers, and other stakeholders to collaborate in order to ensure that the technology is applied in a way that is safe, efficient, and ethical[5].

## 2. Legal Protection of Health Data in Indonesia

The protection of personal data in the health sector in Indonesia is governed by several laws and regulations, including the Law No. 36 of 2009 on Health, the Law No. 11 of 2008 on Electronic Information and Transactions, and the Government Regulation No. 82 of 2012 on the Implementation of Electronic Systems and Transactions in the Health Sector [6].

- Law No. 36 of 2009 on Health: This law governs the Indonesian health industry and contains clauses regarding the privacy of medical records.
- Regulation No. 20 of 2016 on the Protection of Personal Data in Electronic Systems, issued by the Minister of Communication and Information Technology: The rules for protecting personal data in electronic systems, particularly those used in the healthcare industry, are established by this legislation.
- The implementation of electronic systems and transactions is governed by Government Regulation No. 71 of 2019: The use of electronic health records is covered

under this regulation's provisions on electronic systems and transactions.

- Guidelines for Implementing the Electronic Medical Record, Regulation of the Director-General of Health Services No. HK.02.02/I/379/2017: This law offers rules for the use of electronic medical records, along with protections for sensitive patient information.
- Ministry of Health Regulation No. 24 of 2022 on Medical Records: sets out detailed provisions on implementing the new electronic medical records provisions for healthcare facilities. The regulation aims to serve as a new legal framework for digital-based and integrated medical records.

Apart from the above regulations cited, the adoption of Law No. 11 of 2020 on Job Creation, which contains regulations on the protection of personal data in electronic systems, particularly in the health sector, is the most recent development in Indonesian law pertaining to data protection in the healthcare industry. According to Article 118 of the law, Companies must adopt data protection measures in compliance with the terms of the Personal Data Protection Law and its implementing regulations. Companies must also get customers' permission before collecting, using, or disclosing their personal information. Additionally, on November 17, 2020, the Personal Data Protection Law was passed, and it contains extensive provisions for the protection of personal data, including health data. The law lays forth guidelines for how personal data should be processed, including the rights of data subjects, the responsibilities of data controllers and processors, and the specifications for data transfers [7]. In addition, the Personal Data Protection Law creates the Personal Data Protection Authority (PDPA) as the primary oversight agency for the law's implementation, particularly in the healthcare industry. The PDPA is in charge of making regulations, performing inspections, and upholding the law [8].

Overall, these initiatives demonstrate the Indonesian government's dedication to safeguarding personal information, including health information, and to developing a thorough legal framework to ensure the right handling and processing of such information in the health sector [9].

### A. Personal Data Protection Law (PDPA) In Relation to Healthcare Industry in Indonesia:

A comprehensive data protection law that covers all industries in Indonesia, including the health sector, is the Personal Data Protection Law (PDPA). The PDPA, which replaced the prior data protection law, was passed in 2016 and went into force in November 2020.

The PDPA governs how healthcare practitioners may gather, use, and disclose personal data, including information about a patient's health. Before collecting, using, or disclosing a patient's personal information, including their health information, healthcare professionals

are mandated by law to get the patient's consent. The security and confidentiality of patients' personal information must also be ensured by healthcare providers by means of appropriate safeguards [10].

Patients have the right to view and update their personal data, including their health information, under the PDPA. In some situations, patients have the right to request that their personal data be destroyed or anonymized.

The PDPA also creates a legal framework for Indonesian personal data protection in addition to these measures. To oversee the PDPA's implementation and enforcement, the law establishes the Personal Data Protection Commission as a data protection authority. Healthcare providers and other organisations who transgress the terms of the PDPA may be subject to investigations, penalties, and other enforcement actions by the commission [11].

Here are some takeaways as to how PDPA helps in protecting the healthcare industry in Indonesia:

- **Privacy protection for patients:** The PDPA offers a thorough framework for the protection of personal data, including information on health. By requiring healthcare providers to get patients' permission before collecting, using, or revealing their personal information, this can aid in protecting patients' privacy.
- **Promoting data sharing:** The PDPA can aid in promoting data sharing between healthcare providers and other system stakeholders. By enabling more precise and thorough medical records, this can result in better patient care and better health outcomes.
- **Increasing data security:** Under the PDPA, healthcare providers must put in place the proper security measures to guard against unauthorized access, use, or disclosure of personal information. This can lessen the possibility of data breaches and safeguard patients' private health information.
- **Promoting trust:** The PDPA can aid in fostering trust between patients and healthcare professionals by establishing a clear framework for the protection of personal data. Better health outcomes may result from more patient engagement and involvement in their own care.
- **Overall,** by promoting patient privacy, encouraging data sharing, improving data security, fostering trust between patients and healthcare providers and improving patient outcomes by establishing a clear legislative framework for data protection, the PDPA can significantly support Indonesia's healthcare sector.

## B. Difficulties and Concerns Regarding Data Protection in the Indonesian Healthcare Sector:

Despite the regulations in place, there are several challenges and issues related to data protection in the health sector in Indonesia. Some of these challenges include:

- **Lack of knowledge:** Patients' and healthcare practitioners' ignorance of their rights and responsibilities regarding data protection is one of the major difficulties.

Healthcare providers could not completely comprehend their obligations to protect personal data, and many patients might not be aware of the risks and repercussions of data breaches. This can lead to non-compliance with regulations, mismanagement of personal data, and inadequate protection of sensitive information [13].

- **Lack of resources:** It is possible that many healthcare organisations lack the staff, infrastructure, and technology required to put in place comprehensive data protection procedures. Maintaining accurate and full records, preventing unauthorised access to personal data, and effectively handling data breaches may become difficult as a result. This can also leave personal data vulnerable to cyber-attacks and data breaches.
- **Limited regulatory enforcement:** Although Indonesia has laws in place to protect personal information in the health industry, their application may not always be guaranteed. For regulatory agencies to effectively monitor and enforce compliance with data protection requirements, there can be a shortage of resources or experience.
- **Cultural considerations:** In some circumstances, cultural considerations could make it more difficult to protect patient data. Due to cultural or religious views, patients may be reluctant to divulge sensitive medical information, which can make it difficult for healthcare providers to gather accurate and full data [12].

In general, overcoming these difficulties and problems with data privacy in the healthcare industry in Indonesia will call for a multifaceted strategy including participants from all facets of the healthcare system. This could involve stepping up awareness and education initiatives, allocating more funds, and stepping up regulatory enforcement.

## C. Analysis of Data Protection Law in Health Sector in Indonesia:

A thorough legal framework for the protection of personal data, including health data, in the healthcare industry is provided under Indonesia's Personal Data Protection Law. All data controllers and processors, including healthcare providers and other organisations that handle personal data in the medical field, are subject to the law.

The key principles of the Personal Data Protection Law in relation to the health sector include:

The requirement that data controllers and processors get consent from individuals before collecting, using, or disclosing their personal data, including health information, is one of the most crucial legal principles. This means that before collecting, using, or disclosing patients' health information, healthcare professionals must have their express consent.

- **Limitation on use:** Personal information, including health information, may only be handled for clear, acceptable, and legal objectives. Only those purposes that have been explicitly disclosed to patients and are

required for the delivery of healthcare services may be collected and used by healthcare professionals.

- **Data minimization:** Healthcare providers must make sure they only gather and use the bare minimum of personal information—including health information—to accomplish the particular goals for which the information is being gathered and processed.
- **Security:** Healthcare providers must put in place the proper security measures to guard against unauthorised access, use, or disclosure of personal data, including health data. The confidentiality, integrity, and availability of health data must always be maintained by healthcare practitioners.
- Healthcare providers must make sure that personal information, including health information, is not stored any longer than is required for the particular objectives for which it was gathered and processed.
- **Data subject rights:** The law outlines a number of data subject rights, including the right to access and update personal information, the right to object to the processing of personal information, and the right to request the deletion of personal information under specific conditions.
- **Accountability:** Healthcare providers are responsible for their data processing actions and are required to keep records of such actions. To make sure that their data processing activities comply with the law, they must also perform routine reviews [14].

Indonesia's health sector has significant challenges related to data privacy. A thorough legal framework for the protection of personal data, including health data, is provided under the Personal Data Protection Law. The law specifies unambiguous guidelines for the handling of personal data, protects data subjects' rights, and creates a supervisory authority to uphold the law. Concerns like knowledge, consent, security, data retention, data subject rights, data breach response, and supervision still need to be addressed in relation to data protection. Healthcare providers in Indonesia can enhance the privacy and security of personal data, including health data, and boost public confidence in the healthcare system by putting best practises and recommendations for data protection in the health sector into practice [15].

### 3. Health Data Protection in Canada

There are two federal laws in Canada regarding personal data protection, applicable to public and private sectors. “The Privacy Act, 1985”, which regulates a person’s right to access and correct information, only applies to federal government institutions. The “Personal Information Protection and Electronic Documents Act (PIPEDA), 2000”, regulating collection, usage and disclosure of personal information applies to private-sector organizations and federally-regulated businesses.

Apart from the federal laws, Canada’s ten provinces and three territories also have separate legislation protecting

personal data and personal health data. Each of them has separate public-sector laws which apply to them, instead of the Privacy Act, 1983. PIPEDA, 2000 applies to 10 of the provinces and territories of Canada, while the other three have separate private-sector laws that are substantially similar to the federal law.

Before going into protection of health data in Canada, it is pertinent to put forward what is understood by personal information and personal health information. Both the federal laws define personal information in their own ways. However, in general, personal information may be considered to refer to any information of an ‘identifiable person’. Such information may be in the form of

- Race, Nationality or Ethnicity, Religion, Colour, Age, status of marriage
- Educational, Medical, Criminal or Employment history, financial information
- Any identifying number or symbol
- Address, Fingerprints, Blood type
- Personal opinions or views etc.

Office of the Privacy Commissioner of Canada provides advice and information for protection of personal information, while also enforcing the two federal laws in the country.

#### A. Protection of Health Data in Canada

PIPEDA, 2000 is all-encompassing inasmuch as it refers to ‘personal health information’ in Section 2 of the Act. Personal health information, according to PIPEDA, 2000, refers to

- Information of physical or mental health
- Information of any health service
- Information concerning donation or examination of body part or bodily substance
- Information collected in the course of providing health service
- Incidental information

Sub-clauses (d) and (e) to Section 2(1) also bring information collected in the course or incidentally, respectively for the provision of health services, into the scope of the Act. It can therefore, be inferred that the provisions of the Act for the protection of personal data also applies to protection of personal health data, except where it has been explicitly excluded [16].

Section 5(3) of PIPEDA, 2000 states that an organisation is only permitted to gather, utilise, or share personal data when it is considered as appropriate by a reasonable person. Section 6.1 of the same establishes the importance of valid consent regarding collection, use or disclosure of such information and Section 7 lists out the situations wherein information may be collected, use and disclosed without

valid knowledge or consent of the person. Section 9 also regulates access to information to a person if information regarding third person may be disclosed through that.

On breach of any provisions of the above Act, the court, upon investigation, may order the organisation to correct its practices, publish a notice in this regard and award damages to the aggrieved persons.

Furthermore, most of the provinces have their separate laws to regulate and protect health information. We shall consider them one by one.

- Alberta- Alberta’s separate legislation for the protection of health data is the “Health Information Act”.
- British Columbia- British Columbia protects health data via the “E-Health (Personal Health Information Access and Protection of Privacy) Act”.
- Manitoba- The separate legislation of Manitoba is the “Personal Health Information Act”.
- New Brunswick- New Brunswick protects health data through “Personal Health Information Privacy and Access Act”.
- Newfoundland and Labrador- The separate legislation is called “Personal Health Information Act”.
- Northwest Territories- The health data is protected by “Health Information Act”.
- Nova Scotia- Nova Scotia’s separate legislation to protect health data is “Personal Health Information Act”.
- Ontario- “Personal Health Information Protection Act” protects health data in Ontario.
- Saskatchewan- “Health Information Protection Act” protects health data in Saskatchewan.
- Yukon- Yukon’s separate legislation is “Health Information Privacy and Management Act”.

Each of the above laws regulate the collection, use and disclosure of health information and many of them are actually substantially similar to PIPEDA, 2000. Nunavut, Prince Edward Island and Quebec do not have a separate legislation dedicated to protection of health data [17].

Recently, e-health has developed into a major area of deliberations and discussions. Research by Richard C. Alvarez has shown that e-health can lead to collection, processing and maintenance of health information for various uses like providing health services. He has specifically mentioned Infoway, an independent, not-for-profit health corporation and its mission to facilitate the development and adoption of electronic health information systems which also, strictly incorporates standards of confidentiality and protection of health information. Several Health Information Networks have also been mandated by different provinces and territories like Newfoundland and Labrador, Saskatchewan and Alberta to connect provincial hospitals, nursing homes, physicians, pharmacists, and healthcare providers.

Research has also established how rapid technological change and advancement like Big Data and Artificial Intelligence is creating more and more information and thus, the protection of such information becomes important. Thus, revolutionizing technological advancements may threaten privacy of health data. While Canadian framework for data protection, especially health data protection is fairly open to data sharing for research and other appropriate use, there is pressure to strengthen laws. Thus, data protection laws in Canada must attempt to reach to a perfect balance of safeguards and engagement through data sharing, taking responsibility and accountability for the same. In 2022, the Digital Charter Implementation Act, also known as Bill C-27 was introduced in the Canadian Federal government which still is in the draft stage and awaits assent. If that bill is passed, it would bring the Consumer Privacy Protection Act (CPPA) which would replace PIPEDA, 2000 and would also bring a separate tribunal into existence for such matters.

#### 4. The New Framework of Data Protection in India

Earlier, India had introduced the Health Data Management Policy in 2020. The draft policy included creating a system of personal and medical records which would be voluntary and based on consent. However, it was criticized for allowing access of health data to private entities. The Government then released the revised version of Health Data Management Policy of 2022 which addressed these issues. A Personal Data Protection Bill was also introduced in 2019. This bill was highly criticized, with many raising concerns about privacy [18].

India has passed a comprehensive act on data protection- the Digital Personal Data Protection (DPDP) Act, 2023 which was notified in August 2023 but has not come into force yet. It shall be supplemented by rules to be issued by the central government in due course of time. A Data Protection Board of India shall also be established as an adjudicatory body. The DPDP Act is applicable to any data identifiable with the data principal. It also applies to all kinds of digital personal data and not only special categories. However, removing the distinction between sensitive personal data and other data may turn out to be disadvantageous and may create risks since health data is no longer considered sensitive data. Moreover, it also raises concerns of usage of artificial intelligence in the case of data management. For an illustration, Section 2(g) of the DPDP Act, 2023 mentions “consent manager” which can be any person registered with the above-mentioned Board. Also, Section 2(s) mentions that a person can be an “artificial juristic person” as well.

Article 22 of the Regulation Number 20 of 2016 on Personal Data Protection in Electronic Systems by Minister of Communication and Informatics of the Republic of

Indonesia provides certain requirements to be complied with for transferring data outside of the country. The parties must-

- a. Be in coordination with the Ministry or officials / institutions that are authorised to do so; and
- b. Implement the provisions of laws and regulations on cross-border Personal Data exchange.

Canada does not explicitly regulate or prohibit cross-border transfer of data. If the personal information is being used for the purpose it was originally collected for under the PIPEDA, 2000, then this personal information may be transferred to an organization outside of the jurisdiction [19].

On the transnational flow of data, the DPDP Act, 2023 in India gives unilateral powers to the Government to restrict flow of data.

## 6. Conclusion

The National Strategy on Artificial Intelligence that was published by the Government of India has been a major driver in artificial intelligence's continued expansion into digital health solutions, which have recently started to be implemented. Digital interventions open the door to the accumulation of enormous amounts of data, which artificial intelligence systems that employ mathematical algorithms can then use to attempt to make sense of these complicated and extensive datasets. Some algorithm-based mental health apps have been reported to use AI; however, the basic conflict between the significance of permission and data reduction as stated in Indian data protection frameworks like the Sri Krishna report makes this type of intervention ecology untenable. By acquiring significantly more information about an individual's private life from them, linking Aadhaar to these systems can make them more intrusive. The setting and features of both the person and the condition can cause health data points to differ, which can make it difficult for AI systems to draw meaningful relationships between the two. Because there is a lack of knowledge, education, and organization to perform the right to informed choice in the vast bulk of healthcare situations in India, obtaining meaningful consent is already difficult. As a result, obtaining consent can become even more difficult if medical evidence is instantaneously fed into an AI system. Even though data are often directly linked in ways which are not easily recognizable, or since the impacts are not completely understood, it's going to be challenging for people living with medical problems to perceive and/or exercise their own consent in these types of situations. This will also be the case for the family members of these individuals.

In conclusion, the examination of data protection regulations in the healthcare sectors of Indonesia and Canada underscores the critical importance of balancing technological advancements with robust privacy measures.

Both nations are navigating the complex landscape of digital health, aiming to harness its benefits while safeguarding patients' sensitive information. While Canada's well-established legal framework showcases a commitment to data security, Indonesia is actively adapting its regulations to keep pace with the evolving e-health landscape. As these countries work towards enhancing healthcare services through digital means, it is evident that comprehensive data protection measures are integral to fostering trust among patients, healthcare providers, and stakeholders. However, the journey towards optimal data protection is ongoing, requiring continuous adaptation to the dynamic nature of technology and the ever-changing healthcare environment.

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