



**Patient Information and Electronic Health Records: A Legal Appraisal with Reference to European Health Data Space**

\*<sup>1</sup>Ayodhya Prabhashini Rathnayake

<sup>1</sup>Faculty of Law, General Sir John Kotelawala Defence University, Ratmalana

Email address of the corresponding author: \*ayodhya.rathnayake@kdu.ac.lk

---

**ARTICLE INFO**

**Article History:**

**Received: 10 September 2023**

**Accepted: 01 November 2023**

**Keywords:**

**Medicine; Information technology; Digitalization; Privacy**

**Citation:**

**Ayodhya Prabhashini Rathnayake. (2023). Patient Information and Electronic Health Records: A Legal Appraisal with Reference to European Health Data Space. Proceedings of SLIIT International Conference on Advancements in Sciences and Humanities, 1-2 December, Colombo, pages 170-175.**

---

**ABSTRACT**

The field of medicine deals with personally identifiable health information regarding individuals. Traditionally, individual records have been stored manually. However, the increased application of information technology and digitalization caused the use of electronic health information to make the provision of healthcare. 'Personal health information' is unique because, it deserves legal protection. The disclosure and leakage of such information in an unauthorized way can lead to embarrassing and discriminatory circumstances. The digitalization of healthcare services has earned a reputation for enhancing quality and efficiency. The involvement of personal health information and the advent of Electronic Health Record (EHR) create a conflict on the base of privacy. The paper deals with three main objectives namely to analyse the purview of patient rights and medical information, to analyse the concept of EHR and the emergence of digital health privacy, and to study the legal aspects with reference to the regulations of the European Union and 'Electronic Health Data Space'. Further, it extends to analyse the drawbacks in the Sri Lankan jurisdiction as well. The methodology adapted by the author in the research paper is qualitative in nature. The paper is involved with the analysis of literature pertaining to the subject of law

and in addition to the desk review, the doctrinal methodology supported in the study of domestic and national legislations. In conclusion, the author has recognized the balancing of rights between the patients and clinicians in handling EHR. The author proposes a framework for Sri Lanka by setting EU Recommendation on European Health Record Exchange Format as an example to facilitate the digitalization of health data.

## 1. INTRODUCTION

The digitalization of medical / health information is a popular mechanism adapted by the field of medicine. The imperative advantage of the increased use of digital health technologies is the management of patient information.<sup>1</sup> Among the identified digital solutions, Electronic Health Record (EHR) is of important concern as it constitutes a repository of information relevant to the status of health of an individual.<sup>2</sup> The information is in a computer processable form.<sup>3</sup> EHR has become a challenging and persistent technology in the purview of healthcare with both positives and negatives. The 'improved quality of care' is considered as one of the imperative positive points regarding the EHR. Thus, the use of EHR facilitates the storage of medical information including the different types of medications, protection of such information which enables the retrieval in necessary circumstances and the information is easily available in the context of emergencies where the patients are not able to communicate.<sup>4</sup> In addition to this, the EHR is a technology that signifies convenience and

1 Numair, T. et al. (2021a) 'Barriers to the digitization of health information: A qualitative and quantitative study in Kenya and Lao PDR using a cloud-based maternal and child registration system', *International Journal of Environmental Research and Public Health*, 18(12), p. 6196. doi: 10.3390/ijerph18126196.

2 Al-Shorbaji, N. (2022) 'Improving Healthcare Access through Digital Health: The use of Information and Communication Technologies', *Healthcare Access* [Preprint]. doi:10.5772/intechopen.99607.

3 Ibid [2]

4 *Privacy, security, and Electronic Health Records - HHS.gov*. Available at: <https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/consumers/privacy-security-electronic-records.pdf> (Accessed: 30 March 2023).

efficiency. The paper-based documentation proved the ineffectiveness by causing numerous data errors and delays and ultimately necessitated the digital medical records.<sup>5</sup>

All the technologies, including the EHR, deal with the 'Protected Health Information' which includes the particulars relating to the status of health, provision of healthcare and payment of healthcare. Thus, in such a purview privacy plays a major role.<sup>6</sup> 'Privacy' is a right entitled to by individuals to determine for themselves and simultaneously to determine the extent to which the personal information is accessed and shared.<sup>7</sup> 'Security' is an instance where the restrictions are imposed on the accessing of information.<sup>8</sup> Does the technology of EHR ensure the privacy and security of the personal health information of patients? The objectives of the research are three-fold where the paper involves the analysis of medical information and the patient rights, and it further analyses the purview of digital information systems including EHR and digital health privacy. The European Union (EU) directives have been discussed to study the nature of laws which address and balance the patient rights with the newly developed technology (EHR).

## 2. MATERIALS AND METHODS

The methodology adopted in this research is purely qualitative in nature. The author has done a literature review throughout the research with content analysis. This involves the analysis of both primary and secondary sources of law. Primary sources of law include the proposals of the European Commission including the European Health Data Space. Secondary sources of law include texts, academic publications, web articles,

5 Ibid [1]

6 Smail Keshta a et al. (2020) *Security and privacy of Electronic Health Records: Concerns and challenges, Egyptian Informatics Journal*. Available at: <https://www.sciencedirect.com/science/article/pii/S1110866520301365> (Accessed: 28 February 2023).

7 Ibid [6]

8 Ibid [6]

and other literature on medical law, information technology law, and ethics. The significance of the research is the adaptation of both desk review and doctrinal methodology.

### 3. RESULTS AND DISCUSSION

In the global sense, maintaining the privacy and confidentiality of health-related information is a challenging process.<sup>9</sup> People interact with healthcare providers and share data that are personal in nature. The advent of digital health information systems plays a predominant role in the modern era where such information is stored.<sup>10</sup> The significance of health data is that such data are sensitive in nature. Simultaneously, health data digitalization is conspicuous in the current context which facilitates the capture and storage of data by electronic means and opposed the paper-based health documentation.<sup>11</sup> Among the health information systems invented in the world, 'EHR takes a prominent place. The inception of the technology is the 'Electronic Medical Record' (EMR). EMR constitutes the paper charts in digital version.<sup>12</sup> EHR constitutes the electronic record of patient information. Patient health information includes the patient demographics, problems, medications, progress notes, past medical history, immunizations and radiology reports.<sup>13</sup>

EHR technology has pros and cons on its own. However, clinicians have both rights and responsibilities relating to the handling of EHR.<sup>14</sup> The patient care will be impeded by

the excessive outages of EHR.<sup>15</sup> Thus, they are entitled to establish a system which ensures the continuous access through a secured network.<sup>16</sup> A simultaneous responsibility is vested with the clinicians to protect the passwords to the electronic records, and the access is limited to the records of the patients who are under the care or the purview of them.<sup>17</sup> The safety hazards of EHR are connected to software errors and the usability issues which ultimately result in harm to the patients.<sup>18</sup> Thus, clinicians have the right to report and to have such matters investigated and resolved promptly. Further, there is a reciprocal responsibility on the part of such clinicians to take hasty steps to report and support the process of investigation of the security hazards of EHR.<sup>19</sup>

The societal institutions are dependent on the trust, and it has been considered as an important component in the event of accessing the personal information.<sup>20</sup> With the rapid increase in electronic health (e-health) and digital solutions, patients and society benefit greatly. However, simultaneously, there are privacy concerns as well.<sup>21</sup> Privacy predominantly deals with secrecy and confidentiality.<sup>22</sup> Article 8 of the European Convention on Human Rights (ECHR) defines privacy as the right an individual possesses, and it deals with respect to his private and family life, home, and correspondence.<sup>23</sup> Healthcare and treatment are also included under the purview of privacy as specified by the Article 8 of the ECHR.

---

9 Privacy and confidentiality of Personal Health Data Jan 2022. Available at: [https://www.data4impactproject.org/wp-content/uploads/2022/01/Privacy-and-confidentiality-of-personal-health-data\\_Jan-2022.pdf](https://www.data4impactproject.org/wp-content/uploads/2022/01/Privacy-and-confidentiality-of-personal-health-data_Jan-2022.pdf) (Accessed: 25 March 2023).

10 Ibid [9]

11 Ibid [9]

12 Ibid [9]

13 Ibid [9]

14 H. S.D. Rights and responsibilities of users of Electronic Health Records, CMAJ : Canadian Medical Association journal = journal de l'Association medicale canadienne. Available at: <https://pubmed.ncbi.nlm.nih.gov/22331971/> (Accessed: 15 April 2023).

---

15 Ibid [14]

16 Ibid [14]

17 Ibid [14]

18 Ibid [14]

19 Ibid [14]

20 Belfrage, S., Helgesson, G. and Lynøe, N. (2022) Trust and Digital Privacy in Healthcare: A cross-sectional descriptive study of trust and attitudes towards uses of electronic health data among the general public in Sweden - BMC Medical Ethics, BioMed Central. Available at: <https://bmcmedethics.biomedcentral.com/articles/10.1186/s12910-022-00758-z> (Accessed: 03 April 2023).

21 Ibid [20]

22 Ibid [20]

23 Guide on Article 8 of the European Convention on Human Rights. Available at: [https://www.echr.coe.int/Documents/Guide\\_Art\\_8\\_ENG.pdf](https://www.echr.coe.int/Documents/Guide_Art_8_ENG.pdf) (Accessed: 24 March 2023).

<sup>24</sup> The General Data Protection Regulation (GDPR) also values 'confidentiality' as a golden principle in the processes of data processing and regulating. The Recommendation on a European Health Record Exchange Format is primarily aiming at facilitating the cross border interoperability of EHRs within the EU jurisdiction. This is more supportive to the people in getting access and exchanging the data.

It is axiomatic that the patient information also constitutes a higher extent of privacy and such information should not be released to the outer society without the informed consent of the patient.<sup>25</sup> Patient information can be released only for treatment and administrative purposes without the permission of the relevant patient.<sup>26</sup> In addition to this, the patient has the freedom to have access to the information and to effect amendments.<sup>27</sup> The confidentiality expected from the clinicians and physicians in the context of handling EHR is at a higher extent.<sup>28</sup> Thus, it ensures that only the authorized persons have access to such information. Authorizing users have the effect of controlling access to such information.<sup>29</sup> It necessitates the standards of passwords to be changed in frequent intervals with a minimum number of characters and restrictions should be imposed on the re-use of such passwords.<sup>30</sup>

Throughout the research paper, the nature of EHR and the rights and responsibilities of the clinicians and the patients were discussed. The predominant necessity in the context of digitalization of health information is the protection of the privacy. To protect the health data, the European Commission

---

24 Ibid [ 23]

25 Harman, L.B., Flite, C.A. and Bond, K. (2012a) Electronic health records: Privacy, confidentiality, and security, *Journal of Ethics | American Medical Association*. Available at: <https://journalofethics.ama-assn.org/article/electronic-health-records-privacy-confidentiality-and-security/2012-09> (Accessed: 30 May 2023).

26 Ibid – [25]

27 Ibid [25]

28 Ibid [25]

29 Ibid [25]

30 Ibid [25]

presented a proposal for the regulation to set up the European Health Data Space.<sup>31</sup> This is supportive for the individuals to take control of their health data. In addition to this, the regulation opens the doorway to use health data for the purposes of promoting healthcare, research and innovation including policy making.<sup>32</sup> The foremost purpose of the regulation is to facilitate the safe and secure exchange of data while ensuring the use and reuse of such data.<sup>33</sup>

'European Health Data Space' reflects an ecosystem as it consists of all the rules, standards, practices, and a framework that governs the individuals and their access to the digital sphere. Thus, the individuals have been granted with the right to have access and control the electronic health data.<sup>34</sup> This is not confined to the jurisdiction of EU but still aims at the promotion of a single market for electronic health systems.<sup>35</sup> Additionally, European Health Data Space is directed to form a consistent, efficient environment for the purpose of using health data for the purposes of research, innovation and policymaking.<sup>36</sup>

Thus, the European Health Data Space is developed on three main pillars namely to establish a legal framework for the data access and exchange, ensuring the quality and interoperability of health data, and to develop a strong infrastructure.<sup>37</sup> The right granted to individuals to have access to personal electronic health data is significant and that includes the right of an individual to receive an electronic copy of the patient record

---

31 European Health Data Space & Public Health. Available at: [https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space\\_en](https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en) (Accessed: 30 May 2023).

32 Ibid [31]

33 Ibid [31]

34 Ibid [31]

35 Ibid [31]

36 Ibid [31]

37 A European Health Data Space – EU Commission publishes draft regulation (2022) Taylor Wessing. Available at: <https://www.taylorwessing.com/en/insights-and-events/insights/2022/07/a-european-health-data-space> (Accessed: 04 April 2023).

which consists of prioritized data.<sup>38</sup> Further, the right of an individual is extended to have access and to effect changes.<sup>39</sup> There is a simultaneous right established to impose restrictions by the individuals on the health professionals on having access to their health records and if they have access, the individuals can obtain information of such people.<sup>40</sup> Another facet which is under the concern of 'European Health Data Space' is the data quality. Data quality is signified with the EU quality certification label and further insists on the comprehensive exchange of personal electronic health data between different health systems.<sup>41</sup> Most of the Asian Jurisdictions have adapted EHR in their health care systems and in 2013, India introduced EHR standards within their territory. This is not the same in Sri Lanka, EHR is an emerging trend, and however, there are certain drawbacks recognized within the system itself. The predominant drawback is related to the issues of the trust and confidence of the people on digitalization of medical information. The recently enacted Personal Data Protection Act 2022 acts as an umbrella legislation to cover the private and government health institutions.

#### 4. CONCLUSION

Electronic Health (e-health) is an emerging trend in the world which is involved in the process of promoting healthcare. At present, the paper-based documentation is replaced by the digitalization of health records which is commonly known as EHR. EHR increases the efficiency in the purview of healthcare. However, there are challenges to the privacy of the patient information. European Union (EU) has recognized the 'Electronic Health Data Space' which creates an eco-system consisting of rules and procedures, defining the right of the individuals to protect the digital health records and impose restrictions on access to such

information. Simultaneously, it concerns about the improvement of the quality of data. Thus, it clearly shows the fact electronic health records particularly involve with the balancing of rights and responsibilities of patients and clinicians. Sri Lanka is blessed with a developed health system, and EHR is also recognized. However, the patients' apprehension on the digitalization of healthcare information is a main barrier to the successful implementation of the process. The Personal Data Protection Act 2022 does not sufficiently address the issues on EHR. This necessitates a separate policy framework to ensure that, digitalization of health data should go on par with the data protection and security in line with the international standards on cyber security.

#### BIBLIOGRAPHY

- A European Health Data Space – EU Commission publishes draft regulation (2022) Taylor Wessing.
- Al-Shorbaji, N. (2022) 'Improving Healthcare Access through Digital Health: The use of Information and Communication Technologies', Healthcare AccessBelfrage, S., Helgesson, G. and Lynøe, N. (2022) Trust and Digital Privacy in Healthcare: A cross-sectional descriptive study of trust and attitudes towards uses of electronic health data among the general public in Sweden - BMC Medical Ethics, BioMed Central.
- Harman, L.B. Flite, C.A. and Bond, K. (2012a) Electronic health records: Privacy, confidentiality, and security, Journal of Ethics | American Medical Association
- H.S.D. Rights and responsibilities of users of Electronic Health Records, CMAJ : Canadian Medical Association journal.
- Numair, T. et al. (2021a) 'Barriers to the digitization

38 Ibid [37]

39 Ibid [37]

40 Ibid [37]

41 Ibid [37]

of health information: A qualitative and quantitative study in Kenya and Lao PDR using a cloud-based maternal and child registration system', International Journal of Environmental Research and Public Health

Smail Keshta a *et al.* (2020) Security and privacy of Electronic Health Records: Concerns and challenges, Egyptian Informatics Journal.