Implementation Status of the Proposal for a Regulation of the European Health Data Space in Portugal: Are We Ready for It?

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Abstract. The European Health Data Space (EHDS) proposal aims to establish a set of rules and governance frameworks to promote the use of electronic health data for both primary and secondary purposes. This study aims at analysing the implementation status of the EHDS proposal in Portugal, particularly the points concerning the primary use of health data. The proposal was scanned for the points that gave member states a direct responsibility to implement actions, and a literature review and interviews were conducted to assess the implementation status of these policies in Portugal This study found that Portugal is well advanced in the implementation of policies concerning the rights of natural persons in relation to the primary use of their personal health data, but also identified challenges, which include the lack of a common interoperability framework for the exchange of electronic health data.

Keywords. Data Protection, Electronic Health Data, European Health Data Space, Primary Use of Data, Portugal

1. Introduction

In May 2022, the European Commission (EC) launched the proposal for a Regulation on the European Health Data Space (EHDS) establishing a set of rules, infrastructures, and governance instruments, under a common governance framework, to promote both primary and secondary uses of electronic health data (EHD) [1].

This represents a crucial step in achieving seamless cross-border healthcare in the European Union (EU) and an important opportunity for using the extensive health data which is currently neglected by granting access to researchers and public health authorities to large international electronic health datasets [2]. The adoption of this ambitious project will accelerate the availability and quality of EHD, improve the diagnosis and treatment of patients and contribute to the continuity of care across borders. The EC aims at enforcing the Regulation by 2025 but this deadline depends on its approval and correct implementation, which relies on the engagement of a highly complex multi-stakeholder environment (e.g., member states, health providers, citizens, academia, regulators, as well as industry).

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In this context, it is essential to analyse to what extent member states are ready for the EHDS. It is well known that when it comes to the primary use of EHD, countries have different maturity levels - some have achieved high levels of digitalization and interoperability within their borders, while others are still lacking basic infrastructure. For example, the summaries of patient health records and electronic prescription services exist in two-thirds of EU countries, but only in a few can they be shared across borders.

This paper aims to analyse the implementation status of the EHDS Regulation proposal with regards the points encompassing the primary use of EHD in the Portuguese healthcare context.

2. Methods

The qualitative study was carried out between November and December 2022. First, there was an extensive analysis of the Regulation proposal and a filtering of the article points that gave member states a direct responsibility to implement one or more actions, resulting in the selection of eighteen points on the access to and transmission of personal EHD for primary use, for implementation across five different areas [1].

Secondly, the researchers conducted a detailed assessment of the status of implementation in Portugal of the policies listed in the proposed Regulation. Due to the extensive nature of this text, the project's scope was restricted to the primary use of EHD - patients' rights, access by health professionals and priority categories of data to be shared - to convey more detail to the final assessment, as depicted in Table 1.

This analysis was based primarily on the consultation of Portuguese governmental websites, websites of public and private Portuguese healthcare providers, and national regulatory entities. To complement this information, non-systematic literature consultations were conducted (although there is a scarcity research on this topic), as well as a semi-structured interview with a representative of the Shared Services for the Portuguese Ministry of Health.

Table 1. Adapted from the Regulation's Proposal on the EHDS on primary use of EHD (Chapter II, Section I) [1] - articles and respective points selected for analysis.

Article	Implementation
3 - Rights of natural persons in relation to the primary use of their personal EHD	5. Member States shall: a) establish one or more electronic health data access services at national, regional or local level enabling the exercise of rights referred to in paragraphs 1 and 2; b) establish one or more proxy services enabling a natural person to authorise other natural persons of their choice to access their electronic health data on their behalf.
	7. Member States shall ensure that, when exercising the right to rectification under Article 16 of Regulation (EU) 2016/679, natural persons can easily request rectification online through the electronic health data access services referred to in paragraph 5, point (a), of this Article.
	9. Notwithstanding Article 6(1), point (d), of Regulation (EU) 2016/679, natural persons shall have the right to restrict access of health professionals to all or part of their electronic health data. Member States shall establish the rules and specific safeguards regarding such restriction mechanisms.
4 - Access by health professionals to personal EHD	3. Member States shall ensure that access to at least the priority categories of electronic health data referred to in Article 5 is made available to health professionals through health professional access services. Health professionals who are in possession of recognised electronic identification means shall have the right to use those health professional access services, free of charge.

Article	Implementation
	4. Where access to electronic health data has been restricted by the natural person, the healthcare provider or health professionals shall not be informed of the content of the EHD without prior authorisation by the natural person, including where the provider or professional is informed of the existence and nature of the restricted electronic health data. In cases where processing is necessary in order to protect the vital interests of the data subject or of another natural person, the healthcare provider or health professional may get access to the restricted electronic health data. Following such access, the healthcare provider or health professional shall inform the data holder and the natural person concerned or his/her guardians that access to electronic health data had been granted. Member States law may add additional safeguards.
5 - Priority categories of personal EHD for primary use	1. Where data is processed in electronic format, Member States shall implement access to and exchange of personal electronic health data for primary use fully or partially falling under the following categories: (a) patient summaries; (b) electronic prescriptions; (c) electronic dispensations; (d) medical images and image reports; (e) laboratory results; (f) discharge reports.

3. Results

In Portugal, there is a government-funded web portal aiming to gather essential information from each citizen to improve the provision of healthcare, which comprises a Personal Area (for patients' access) [3]. Another government-funded web portal comprises a Professional Area (for healthcare providers), an International Area (for international access to data) and an Institutional Area [4].

In their personal area, users take on an active role in maintaining, promoting and improving the documented data about their health status, consequently, providing more effective and safer care. This service provides free, immediate access (through authentication) to the patient's emergency contacts, medication, allergies, illnesses, documents and health reports (this data entries can be either registered by the patient or the healthcare professional), and this data can be accessed by other healthcare professionals (different from the ones that registered firstly the data and if the patient authorizes its accessibility) as long as they belong to the national health service (Serviço Nacional de Saúde - SNS). Additionally, patients have the right to request access to their health data (either electronically or on paper) to the health units where it is registered.

As custodians of health information, health units allow users to consult their local medical records; however, there is no access to the patient's centralized health records across all units. Patients can request access either in person or by email. If the patient cannot physically go to the health unit to require access, they can assign this right to a third party. This authorisation, signed by the user, should include the user's and the selected representative's complete identification (name, citizen card number and address) as well as the information to be consulted [5]. (Article 3, Point 5)

In the portal mentioned above, there are twelve items under the privacy settings, allowing its user to set who will have access to their personal health information. They can also be notified of who, when and where their health information was accessed. Should the patient not authorise the sharing of information, this is only reflected in the central data storage system - the local health units where data is registered will continue to have access to their medical history (e.g., consultations, prescriptions, etc.). Vaccination information is always available, as it is Public Health information. (Article 3, Point 9; Article 4, Point 4)

When it comes to the request for rectification of personal health data, the Portuguese legislation states that the data subject shall have the right to obtain from the controller without undue delay the rectification of inaccurate personal data concerning them, as well as the right to have incomplete personal data completed, including by means of an additional declaration [6]. However, changes to patient clinical records can only be performed by a family doctor and/or the attending physician in the professional area of the EHR platform. In the case of electronic prescriptions (ePrescriptions), it is not possible to change the data [7]. (Article 3, Point 7)

Regarding the "Professional Area" of the portal, it allows health professionals to access patients' medical data. The complete medical records are not made available through the portal, only summary data concerning the patient's appointments, treatments, diagnosis, and prescriptions. This service is available in all SNS primary and secondary care units, although efforts are in place to allow for the intake of data collected by private providers. (Article 4, Point 3)

The purpose of the "International Portal" is to give doctors from other EU countries the possibility to consult the patient's clinical information. This access is only possible with prior authorisation by the user, encompassing the Patient Health summary and the patient's ePrescriptions. The Health Summary details the patient's allergies, chronic medication, vaccinations, medical and nursing diagnoses, procedures, and medical devices. In the case of ePrescription, the data corresponds to the electronic medical prescription data: prescription number, prescribed drugs, prescription location and identification of the doctor [8]. In Portugal, this service is currently available to facilitate the sharing and reception of data with more than ten EU member states.

However, electronic dispensations, medical images and image reports, laboratory results and discharge reports cannot yet be shared. (Article 5, Point 1)

4. Discussion

It is essential to consider that this study is based on a Regulation Proposal yet to be approved, and it will likely be modified before it is turned into a law. However, the researchers believe that the current analysis still stands as valuable evidence concerning the status of the implementation of digital health policies in Portugal and can help in the definition of the Portuguese digital health roadmap of the next decade. This research has shown that Portugal is well advanced in collecting and sharing EHD within its borders.

In terms of cross-border EHD sharing, Portugal's technological development was, as in other countries, accelerated by the COVID-19 crisis. Similarly, it is expected that the implementation of the Regulation will proceed at different paces depending on the existing national infrastructure. If, on one hand, the lack of existing infrastructure may pose a challenge (e.g., the need to promote professionals' and users' eHealth literacy; to implement software solutions at the hospital level), on the other hand, it may also represent a competitive advantage, as it allows countries to implement processes from scratch, benefiting from the experience (and lessons learned) of countries leading the digital transformation. Having adopted Electronic Health Records (EHR) in the 1990s, Portugal will have to adapt to the new processes proposed in the Regulation once approved. This is no easy task since the provision of services must be continued, and the legacy systems should be interoperable with future solutions. The main challenge of this project was the scarcity of literature (academic or otherwise) on the implementation of digital health initiatives in Portugal. Although there are references to the use of European

funds (namely the Recovery and Resilience Plan) for digital health transformation, there is a need for more detailed information on the course of implementation and objectives of the financed projects. Only then will it be possible to assess the impact of these projects on the implementation of the EHDS in Portugal.

5. Conclusion

Due to the dynamic nature of digital health transformation, monitoring the trend in impacts arising from the EHDS will constitute a crucial part of the action in this domain.

To ensure that the selected policies deliver the intended results and to inform future revisions, it is necessary to monitor and evaluate their implementation. This can be achieved primarily through reporting by digital health authorities and health data access bodies.

This research shows that Portugal is ready for the EHDS Regulation's approval, and it is on a promising path towards its implementation, particularly regarding the primary use of EHD. However, the proposal is still being discussed, and its implementation depends on the regulation approved. This means that the proposal may still be substantially altered, in which case some aspects evaluated in this paper may be rendered inapplicable. In the opinion of the researchers, the proposal, as it stands, could be overly ambitious to be enforceable in all member states in a coordinated manner.

From the collected information and considering the limitations of this study, the researchers suggest that future in-depth studies on this topic should be conducted, with access to further information and expert opinions. Similarly, future research should also analyse the points on the proposed Regulation that refer to the secondary use of health data.

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