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Digitalization of Health Data: Interoperability of the Proposed European Health Data Space

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Abstract. On May 3rd, 2022, the European Commission published its legislative proposal to create a European Health Data Space (EHDS) enabling citizens of the European Union to gain secure access to their electronic health data by establishing a market for digital health. This market will feature the primary and secondary use of electronic health records by digital products and services. The articles of the proposal address many aspects of ensuring health data interoperability. That includes the creation of a European Electronic Health Record Exchange Format for defined data categories including patient summaries and electronic prescriptions, the development of a central platform to provide a cross-border digital infrastructure and that each Member State institutes a digital health authority and a national point of contact. In addition, the Commission will define common specifications that electronic health record systems and medical devices will have to meet as interoperability requirements. In its current form, the proposal does not stipulate specific standards that need to be universally adopted to ensure semantic and syntactical interoperability. Considering that many datasets are not internationally harmonized and lack standardization, these specifications will need to be provided for example by existing standards like the International Patient Summary.

Keywords. European Health Data Space, digital health data, interoperability, electronic health records

1. Introduction

The COVID-19 pandemic has revealed how important electronic health data is in fighting health emergencies and has also fostered the rapid development of many digital health solutions. With an intent to harmonize and standardize digital health data in the EU, the European Commission has presented a legislating proposal on May 3rd, 2022, aimed at creating "a genuine single market for digital health". The European Health Data Space (EHDS) will provide EU citizens with greater control over and access to their electronic health data and ensuring that they can reap the benefits promised by innovative digital health services and products through use of their data. Since this will include the primary and secondary use of health data, the European Commission is making stipulations about interoperability requirements for national electronic health system

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infrastructures used within the EHDS and related products and services that could be provided by third parties from the industry or academia [1].

A key feature of this proposal is ensuring health data interoperability. Technical interoperability is defined by the presence of infrastructure that can support the exchange of structured data using appropriate ports and interface points. Semantical interoperability describes the unambiguous representation of clinical concepts by use of international standard reference systems and ontologies. On the other hand, syntactical interoperability is achieved when health data is kept in standardized data formats (such as XML or JSON). The most prominent exchange format for health data is Health Level Seven (HL7) Fast Healthcare Interoperability Resources (FHIR) exchange format. On the organizational level, interoperability is achieved when processes, user roles and access rights are harmonized and clearly defined [2,3].

2. Methods

We reviewed the European Commission's legislative proposal for the development of the EHDS along with supporting documents (such as the Communication from the Commission and the Impact Assessment) in terms of specification on interoperability of the EHDS that are outlined.

3. Results

The proposal for the EHDS is structured in eight chapters covering 72 articles, framed among others by an explanatory memorandum and a financial statement and supplemented by ten annexes. The articles cover several aspects of interoperability, which include specifications of an exchange format, infrastructure, governance, interoperability requirements for EHR systems and related products as well as semantic interoperability.

3.1. Exchange format (Syntactical interoperability)

The European Commission will follow recommendations to create a European Electronic Health Record Exchange Format (short EEHRxF) which will include electronic health data in the following priority categories (according to Article 5): patient summaries, electronic prescriptions, electronic dispensations, laboratory results, medical images and reports, and hospital discharge reports [1,4]. Article 6 of the proposal specifies that the exchange format will comprise of structured health data sets which will use coding systems and values as well as technical specifications for standardized data exchange [5].

3.2. Infrastructure and governance (Technical interoperability)

The main private and public stakeholders that are put into the foreground are natural persons/citizens, public health /research institutions, national digital health bodies, data protection authorities, health professionals and providers and patient associations.

In order to exchange health data between Member States, the EHDS will further develop a cross-border digital infrastructure in form of a central platform, referred to as the eHealth Digital Service Infrastructure (short MyHealth@EU, Art.12) [1].

Access rules for the use and re-use of data in the EHDS will be governed by the proposed Data Governance Act. In addition, the legislative proposal provides for the creation of a European Health Data Space board. Selected representatives from Member states, the Commission and digital health authorities along with observers will sit on the board.

It also states that a digital health authority is to be established by each Member State tasked with making sure that citizens' data rights are protected through the implementation of adequate mechanisms (Art.10). One aspect of that is the implementation of measures for identification and authentication of natural persons and healthcare professionals (Art.9).

A national point of contact must also be designated by Member States to ensure that requirements and obligations are being enforced. The national point of contact is overseen by the digital health authority, which supervises the correct implementation of health-related datasets. This touches on ensuring that the European electronic health record exchange format, is implemented on a national level [5].

Overall, the proposed EHDS will build on the legal frameworks laid out by the General Data Protection Regulation (GDPR), the Regulation (EU) 2017/745 on medical devices (Medical Devices Regulation) and the Regulation (EU) 2017/746 on in vitro diagnostic medical devices (In Vitro Diagnostics Regulation), the proposed Artificial Intelligence Act, the proposed Data Governance Act and the draft Data Act, as well as the Directive 2016/1148 on security of network and information systems (NIS Directive) 15 and the CBHC Directive [5,6].

3.3. Interoperability requirements for EHR systems and related products

EHR systems are required to support common interoperable formats (ontologies and exchange formats). Consequently, an EHR system may not employ features that restrict or complicate authorized access to electronic health data (European Commission 2022a). In addition, EHR system providers must compose a technical documentation and an information sheet for users prior to placing their product on the market and in order to obtain an EU declaration of conformity and ultimately CE certification for their system.

Furthermore, the European Interoperability Framework (EIF) is named as a common reference to ensure organizational, semantic and syntactical interoperability. The EIF was adopted by the European Commission in March 2017 and provides specific direction for the development of interoperable data-based services [7]. The Commission will also develop common specifications (including technical specifications) for meeting interoperability requirements for medical devices. In addition, the legislative proposal accounts for the possibility of issuing data quality and utility labels for datasets that are made available through health data access bodies. These will attest quality and utility based on aspects that can be best described as compliance with the FAIR principles [8], such as available (meta) data documentation, data quality, coverage and enrichment, provenance as well as access.

3.4. Semantic Interoperability

Semantic interoperability is mentioned in the legislative proposal, however without providing specifics. Similarly, to information provided about syntactical interoperability, the EIF should be utilized as a common reference. The proposal further states that EHR system manufacturers should confer with the Commission to decide on common specifications, including the use of coding systems [5].

4. Discussion

In our review of the European Commission's legislative proposal, we found that articles and stipulations cover all aspects of health data interoperability, including provisions on organizational (with regards to governance and infrastructure)-level as well as technical (exchange format) and semantics-level interoperability. The language, however, is held general so that if the legislation is signed into law, more specific guidance would need to be provided. As many cross-border datasets are not harmonized, issues in terms of comparability might arise when data is used for research purposes. This problem is recognized as the proposal states, that harmonization of data is imperative. Thus, coding systems used for electronic health data for example will have to be harmonized. The EIF, which lays out six steps on managing specifications for interoperability, is referenced for consideration. These steps include the needs- and requirements-based identification of candidate standards and specifications, the assessment of the selected candidates based on standardized methods, followed by the implementation and monitoring of standards, as well as managing change procedures and documentation [9]. The recommendations set out in the EIT would need to be addressed by the European Commission in the future so that developers and providers of EHR systems, products and services can be given a catalogue of approved international interoperability standards for semantics and syntax that need to be adopted. The work to derive such a catalogue of standards will require the involvement of experts and existing initiatives in the field of standardization and interoperability and standards developing organizations (SDOs) such as the European Committee for Standardization (CEN) [10], HL7 and IHE International. One of the standards that is available is the International Patient Summary (IPS) which is the result of a collaboration between the leading SDOs and provides a standards-based minimal patient data set for use by clinicians [11,12]. The EHDS proposal also makes no reference of the ISO 23903 standard which was introduced in 2021. ISO 23903 provides a framework for representation of concepts on a semantic level by giving a model for harmonization of intended and existing systems, specifically ICT-supported systems. Ontology and knowledge harmonization is supported by the Interoperability and Integration Reference Architecture that underpins the fundamental approach and value of interoperability. Thus, this ISO standard could be considered a useful guide in terms of establishing semantic interoperability in the EHDS [13].

5. Conclusion

Interoperability of digital health data that are stored and managed in electronic health record (EHR) systems and are to be exchanged and (re)-used within primary and

secondary data usage markets is the main guardrail of the European Commission's proposal for a European Health Data Space. Overall, the proposal lays out clear specifications to establish organizational interoperability first and foremost, with a focus on increasing accessibility of electronic health data across borders in a secure and trustworthy fashion.

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