Digital Health Uptake

Executive Digest

The interoperability of EHR systems and health apps in the European Health Data Space

Topic: The interoperability of EHR systems and health apps in the European Health Data Space

Relevance of this topic to Digital Health

The European Commission's programme to develop a European Health Data Space (EHDS) is ambitious. It seeks to develop a pair of networks connecting Member States across Europe. One (called MyHealth@EU) is to enable any European citizen to access their own health record in any EU or EEA Member State, and for the communication of health records for urgent or planned care to a healthcare provider in any EU or EEA Member State to enable safe continuity of care. The other network (called HealthData@EU) will establish a harmonised approach across Member States to make data sets available for research, public health and health services policy and strategy development purposes in a consistent and well-governed way.

The development of the EHDS is based on the proposed EHDS Regulation which is in the later stages of negotiation at the end of 2023, with adoption expected in the first half 2024. It is envisaged that some elements of the EHDS Regulation will become enforceable within 12 months, and others within 36 months of entry into force of the Regulation as a whole. This Regulation imposes legal, semantic and technical interoperability standards on EHR systems, to ensure that communication of identified patient-level health data via the MyHealth@EU network can occur and that patients are better enabled to exercise the right data portabilitythat is provided for the in General Data Protection Regulation (GDPR). The key technical standard addressing interoperability of Electronic Health Records is known as the European Electronic Health Record eXchange Format (EEHRxF), set out in a European Commission Recommendation.

Keywords

Interoperability, digital health data, European Health Data Space, European Electronic Health Record eXchange Format

Current focus of policy, legislation, standards, emerging practices in this landscape

The proposed EHDS Regulation will give an important status and boost to the adoption of the EEHRxF across the EU and EEA Member States. The EEHRxF is to be elevated from its current format in a Recommendation, which Member States can choose to follow, to secondary legislation which will be adopted after the EHDS Regulation enters into force. The EHDS Regulation requires that any EHR system placed on the market or put into service in the EU 3 years after entry into force of the EHDS Regulation will have to comply with that Regulation and its secondary legislation. The EEHRxF will therefore apply to both cross-border and within country interoperability between healthcare provider EHR systems and connection to national eHealth infrastructures. The Regulation sets out essential requirements for EHR systems in order to promote their interoperability and data portability. It further requires that manufacturers of EHR systems bringing products to market 3 years after the entry into force of the EHDS Regulation will be required to implement common specifications and prove compliance with essential requirements through self-certification and must show the CE mark of conformity. Relevant post market surveillance mechanisms are to be established in MS.

It will be a future obligation for Member States to impose a downstream conformance requirement on the EHR systems that they endorse/reimburse. The EHDS Regulation creates the right, that may not already exist in all Member States, for citizens to add data to the EHRs. This right extends also to people other than the patient who have legal access to the EHR, such as informal carers. Such patient or carer added data will be marked so that healthcare professionals can identify added data.
With respect to data coming from wellness apps, the EHDS Regulation foresees that where a developer claims their health and wellness product is interoperable with electronic health record systems, then it should be interoperable with the EHR systems as provided for in the Regulation, meaning EEHRxF conformant EHRs. To support citizens and patients using such apps, the Regulation provides for a voluntary certification for wellness apps that claim interoperability. It should be noted, however, that this requirement has been challenged both in the European Parliament and in the Council as being too burdensome and may therefore not be included in the final EHDS Regulation.

The EEHRxF as contained in the current Recommendation is limited to certain kinds of health data: content that would contribute to a standardised patient summary and electronic prescriptions. The EHDS Regulation provides for its use in EHRs, ePresciptions and eDispensation in the first 12 months after entry into force, with extension to laboratory and imaging reports and hospital discharge notes with 36 months. However, beyond the EHDS Regulation, plans are already in place to develop an updated version of the EEHRxF that is expected to cover most kinds of personal health data that could be found in an electronic health record.

Within the current EEHRxF, the European Patient Summary, electronic prescription and dispensation specifications are elaborated in the respective eHealth Network Guidelines; however, the rapid pace of evolution of the standards is creating a dynamic landscape. For example, Release 2 of the European patient summary on the electronic exchange of health data as provided for in the Cross-Border Directive (2011/24/EU) is now envisaged to align with the CEN-ISO International Patient Summary (CEN-ISO 27269:2021). This is very similar to the European Patient Summary, and covers similar headings: demographics, conditions, allergies, medications, family history, procedures, care directives, etc. The data items under each heading (e.g. what information is expected when communicating a health condition) are formally defined. There is now also a recognition that HL7 Fast Health Interoperability Resources (FHIR) is rapidly being adopted in place of the older HL7 CDA, and that technical interoperability for the IPS (and the other document types listed above) should utilise FHIR.

Implications for digital health uptake

The recognition of the need for wider adoption of standards is reflected in the XpanDH project, which seeks to support acceleration of adoption of interoperability standards, especially the EEHRxF, relevant to data flows, and to track the forward evolution of the EEHRxF specifications.
The XpanDH project addresses the full ecosystem of actors involved in providing access to health data, seeking ensure that each group of actors can:

Developers

- Become familiar with the EEHRxF and closely monitor plans for an updated version of it including extensions to its scope.
- Ensure the necessary skills to implement interoperability standards and to undergo conformance testing.
- Take functionality advantage of the increasing availability of interoperable data from EHR systems (e.g. patient summary, medications) that may contribute data into digital health tools, as well as receive data from digital health tools.

Enabling Actors

- Contribute to the evolution of the EEHRxF and ensure that existing standards and specifications (e.g. value sets) are updated.
- Prepare to widen educational activities to train other stakeholders in the EEHRxF.

Payers and procurers

- Look for national and regional health systems guidance on requirements for interoperability certification, to become part of future procurement contracts.
- Plan now within existing contracts for developers to meet future interoperability requirements.

Users

- Be ready to adapt care pathways to leverage the benefit of improved information sharing between digital health solutions and EHR systems.

Remaining gaps and issues

The EEHRxF is being promoted as an EHR representation, but it is in practice limited to a patient summary and continuity of care clinical documents. Digital health solutions may benefit from the ability to receive interoperable patient summary data, but the real impact of interoperability for digital health is likely to be greater when the EEHRxF is extended to include specifications supporting a wide range of clinically relevant use cases.
Decision makers will need to plan for and make investment provision for the wider use of digital health when its data is interoperable.

Date of creation or latest update

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Legislative, regulatory, policy or standardisation instrument, or good practice
Title
Commission Recommendations on a European Electronic Health Record exchange format
Instrument status
EC Recommendation, not enforced in in its own right as a Directive or Regulation, but proposed for mandatory adoption within the EHDS Regulation (see below).
Publisher or source
The European Commission
URL or reference
https://digital-strategy.ec.europa.eu/en/library/recommendation-european-electronic-health-record-exchange-format
Summary of the instrument
The drivers for the European Commission publishing this exchange format standard are: (i) to strengthen the rights of citizens to receive safe and effective healthcare across European borders throughout the EU; (ii) to uphold the rights of European citizens to have access to their own health data in a usable form; (iii) to tackle the slow pace of adoption of more comprehensive electronic health record interoperability standards within European Member States, by promoting a fast track subset of the total EHR. Many Member States have collaborated with the European Commission to establish the MyHealth@eu digital services infrastructure that can enable the secure communication of personal health information between European countries. This is being strengthened with mandatory Member State adoption via the EHDS regulation. The EEHRxF content covers the following types of electronic clinical document: • European Patient Summary • Electronic prescriptions • Electronic dispensations • Medical images and image reports • Laboratory results • Discharge reports The specification for each of these kinds of clinical document presently anticipate that they will be communicated using the HL7 Clinical Document Architecture (CDA) – but is being migrated to FHIR (see below).
Implication for digital health stakeholders
• EHR systems, and other digital health solutions that communicate with EHR systems, either to extract patient information from them or to communicate patient generated data to them, or bidirectionally, should consider alignment with the EEHRxF, especially to the IPS. • This alignment is today optional, but may become mandatory within a few years.

Legislative, regulatory, policy or standardisation instrument, or good practice
Title
The EHDS (draft) Regulation requirements for interoperability
Instrument status
Draft EU Regulation, currently under review and revision by the European Parliament. It is expected to be adopted and enter into force in the first half of 2024.
Publisher or source
The European Commission
URL or reference

https://health.ec.europa.eu/publications/proposal-regulation-european-health-data-space_en

Summary of the instrument

The European Health Data Space (EHDS) Regulation is an ambitious legislative proposal, backed with a substantial multi-billion budget, to establish two infrastructures and corresponding data ecosystems. They are briefly summarised below, with an emphasis on those aspects relevant to this Digest.

a) A *primary use* network that expands the existing eHealth Digital Services Infrastructure which provides the basis for implementing MyHealth@EU. This targets enabling all European citizens to be able to access their own health record and to authorise any cross-border healthcare provider to access this information in order to deliver safe and effective care in a country other than the country in which the patient usually receives care (i.e. cross-border care). The provisions for MyHealth@EU include the required participation of all Member States and the requirement to utilise the EEHRxF. Compliant EHR systems must be self-certified by their manufacturers against essential requirements specified in the Regulation (to be further detailed in secondary legislation), and must be able to import/export using the EEHRxF. Data quality must be checked for completeness and accuracy. Digital health applications exchanging data with other systems must also conform to the EEHRxF. As provided for in the GDPR, citizens will have the right to access their EHR consolidated at Member State level, which must be portable. Persons may limit access to the EHR and know who has accessed it.
b) A *secondary use* network named Healthdata@EU is to be implemented across the Member States, to enable researchers, innovators, policy-makers and regulators at EU and Member State level to access relevant electronic health data to promote better diagnosis, treatment and well-being of natural persons, and lead to better and well- informed policies. Member States must establish Health Data Access Bodies, to grant and enable ethically approved access to data sets to requesting public and private entities at a proportionate cost, provided the data will be used for (specified) permitted purposes and not for prohibited purposes. They should provide data sets through a secure and audited processing environment. The EHDS Regulation provides that usually only anonymised data will be available for secondary use. Where access to pseudonymised data is necessary for the research endeavour, if the data user can show they have a legal basis in GDPR Article 6 for processing data, the EHDS will provide an EU level basis for meeting the requirement in Article 9(2)(j) for secondary processing of identifiable data for research. The EHDS therefore simplifies cross-border secondary use of health data which was very difficult to establish under GDPR.

Implication for digital health stakeholders

- The proposed EHDS Regulation enforces the role of, and compliance with, the EEHRxF. This includes EHR systems, and wellness applications claiming interoperability with them and it is therefore becoming an important requirement for digital health developers to include and procurers to insist on.
- Although the EHDS primary use network refers to cross-border information flows, it is expected that many Member States will reuse this capability internally.

Legislative, regulatory, policy or standardisation instrument, or good practice

Title

The XpanDH Project

Instrument status

A European Commission project

Publisher or source

The XpanDH project

URL or reference

https://xpandh-project.iscte-iul.pt

Summary of the instrument

XpanDH has the overall objective of preparing, supporting and empowering individuals and organisations to be ready and adopt the European EHR exchange format (EEHRxF) through the establishment of a network

of networks and a vibrant ecosystem. The XpanDH project aims at preparing and building capacity in individuals and organisations to be ready to use the European Electronic Health Records Exchange format (EEHRxF), by establishing a pan-European effort through a Network of Networks approach, that will ensure that the involved and multiple digital health actors are motivated, inspired and supported to advance to concrete adoption of the EEHRxF by guidance and real examples organised as an aggregation of interoperability assets - the X-bundle -, around the EEHRxF. The XpanDH project pursues the main goal of maturing and accelerating a sustainable and scalable interoperability environment in Europe for digital health innovations based on the EEHRxF, involving both the supply and demand aspects. The consortium is composed of several associations with the common goal to mature and accelerate a sustainable and scalable interoperability environment for EEHRxF-based digital health innovation among EU Member States.

XpanDH will develop and publish interoperability resource bundles for particular “adoption domains” using the EEHRxF, which may be used by future implementers needing to be interoperable to this format. This will be complemented by training materials, and support communities for different stakeholder groups.

Implication for digital health stakeholders

- This project may be a valuable source of practical specifications and guidance on how to adopt the EEHRxF