

Policy and Strategy for Interoperability of Digital Health in Europe

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Abstract

The development of electronic services for healthcare presents challenges related to the effective cooperation of systems and stakeholders in a highly regulated environment. In order to facilitate healthcare for all at the point of need it is important to establish the necessary conditions to guide the development and implementation of digital health solutions that are interoperable by design. Interoperability in eHealth is challenging for various reasons, including the fact that different products and solutions in the market do not follow well-known standards and interoperability guidelines. The paper draws upon the global, European and national policies, strategies, and implementation initiatives to offer an integrated approach towards interoperability in healthcare ecosystems. The authors provide guidelines and recommendations to support interoperability at legal, organizational, semantic, and technical levels.

Keywords:

Electronic Health Records, Health Information Exchange, Medical Informatics

Introduction

Digital healthcare, also known as electronic health or eHealth is a term incorporating different concepts, including health, technology, and business [1]. Technology provides the means to expand, to assist, and to improve human activities for the benefit of citizens, patients, healthcare professionals but also health organizations, businesses and public authorities [2]. Digital healthcare has taken a leap forward due to COVID-19. The pandemic has accelerated the adoption of digital solutions, telemedicine has been extensively used for consultations, and attitudes of health and social care professionals are shifting towards everyday technology use in healthcare [3]. The COVID-19 crisis, highlighted the importance of interoperability and digitalization in all aspects of daily life.

Digital healthcare, in the long term, holds enormous potential to ensure people live longer, healthier lives [4]. It can also bring economic benefits for those at the forefront of innovation. Despite the opportunities and benefits, major barriers hamper the wider uptake of eHealth. One of the major ones is the lack of interoperability between eHealth solutions, which encompass far more than just data exchange. Several hurdles include regulatory, technical and trust issues [5].

Interoperability in eHealth is about the delivery of contextually relevant understandings efficiently and securely to facilitate care coordination, irrespective of application, vendor or device [6; 7]. It is about improving healthcare. Also, interoperability is necessary for the implementation of personalized medicine, for coordinated care and research, for citizen empowerment and improved health outcomes [8].

Interoperable systems can make data sharable and reusable introducing many opportunities for growth and improvement.

Eliminating data silos and automating data integration supports the recognition of unseen patterns, offers opportunities to apply new intelligence to service patients and care-givers, creating value across the care continuum [9].

Interoperability in eHealth is challenging for various reasons, including the fact that different products and solutions in the market do not follow well-known standards and interoperability guidelines [10-12]. Healthcare digital services must interact with many other digital services within the health sector but also across different sectors. In addition, the need arises for cross-border sharing and utilization of services, data, and business processes [13]. To address these challenges, it is important to create the necessary conditions and frameworks to guide the market towards creating digital solutions that interoperate. Specifications should take into consideration the interaction with existing healthcare services and the necessary public services, integrated care pathways and shared workflows [14].

The vision of the World Health Organization Global strategy on digital health 2020-2025, is “to improve health for everyone, everywhere by accelerating the development and adoption of appropriate, accessible, affordable, scalable and sustainable person centric digital health solutions to prevent, detect and respond to epidemics and pandemics, developing the infrastructure and applications that enable countries to use health data to promote health and well-being” [15]. To achieve the vision of health for all and patient empowerment, health care systems need to be strengthened through the application of digital health technologies for consumers, health professionals, health care providers and industry. Health data sharing is a fundamental requirement in rendering this vision into reality and can only be achieved through digital interoperable information technology infrastructure across all care settings, public health authorities, universities and research institutions. An interoperable digital health ecosystem enables seamless and secure exchange of health data that is built on trust, is secure and protects privacy and confidentiality.

In Europe, citizens have the right to receive cross border healthcare, however, currently digital systems cannot support the unified access to patient information. As the world becomes more and more interconnected, healthcare information will need to be available beyond borders and beyond the traditional points of care in healthcare primary secondary tertiary facilities to social, community and home care. Europe is moving ahead with policy advances at the European Union (EU) and national levels, to enhance the interoperability of public services, taking into consideration the needs of different stakeholders as well as the role of emerging technologies. One of the EU priorities is to create a digital single market that aims, amongst others, to unlock the potential of a European data economy, helping citizens, public authorities, companies and researchers to make the most of new technologies by funding EU research in health and high-performance computing [3].

In this paper, the authors discuss the importance of establishing an interoperability framework to guide the design, development and implementation of digital health in order to facilitate healthcare for all at the point of need. The paper draws upon the European and national policies, strategies, and implementation initiatives to offer an integrated approach towards interoperability in healthcare ecosystems. They provide guidelines and recommendations to support interoperability at legal, organizational, semantic, and technical levels.

Methods

Secondary research is a research method that involves using already existing data that is summarized and collated to support the effectiveness of research. Secondary research has been conducted to gather and analyze global, European and regional policies and trends in digital health interoperability implementation. The relevant policy and strategy documents about digital health of the World Health Organization, the European Commission, and other relevant interoperability research & implementation documents have been gathered and analyzed. Interoperability barriers and implementation gaps have been identified. The interoperability trends and infrastructure have also been studied. The authors having analyzed the existing literature and drawing upon their extensive experience in research and development in the fields of medical informatics and digital health and their participation in technical and policy committees and working groups about interoperability in Europe and Greece, propose a general interoperability framework that can be adapted for healthcare digital services. They discuss interoperability principles and guidelines that can help to stir the healthcare digital ecosystem towards interoperability by design. The European policy and strategy foundations about interoperability in public administration services is presented followed by the new European Interoperability Framework and other relevant initiatives that guide interoperability in European member states. in the healthcare domain. The authors propose the adoption of this framework for the healthcare domain. The way forward is described taking into consideration the case of Greece.

Results

In recent years, in order to enhance and strengthen the design and testing of new healthcare products, and improve diagnosis and treatment, the EU is investing in the incorporation of emerging information and communication technologies, such as those of artificial intelligence, cybersecurity, and high-performance computing. Sizeable amounts of high-quality data are needed to realize the potential of these technologies. In addition, appropriate regulatory frameworks need to be established to safeguard the rights of the individual and society as well as stimulating innovation. However, the use of patient-centered health data is still under-developed across member states [16]. The EU digital strategy aims to support digital transformation for people and business strengthening digital sovereignty, setting standards and focusing clearly on technology, data, and infrastructure. [17]. It has put in action several initiatives and regulations towards advancing the interoperability of services in member states. This section will go through the relevant initiatives for advancing interoperability in healthcare. These include the new European interoperability framework, the digital transformation in Health and care act, the health data space, and the security and privacy regulations. The Greek National healthcare system is used as an example to illustrate some of these initiatives.

The New European Interoperability Framework

An interoperability framework sets the appropriate guidelines and establishes the context in which digital health applications can be designed and implemented in support of disease specific solutions, such as chronic non-malignant pain, diabetes and cancer.

The EU, having recognized the need for interoperability among member states, has created the Interoperability Solutions for Public Administrations, Businesses and Citizens programme (ISA²) to enable the creation and interoperability of cross-border and cross-sector eGovernment services for the benefit of European public administrations, businesses and citizens [18].

In an effort to guarantee the secure and free flow of data within the EU, the new European Interoperability Framework (EIF) was announced in 2017 [19]. The new EIF provides guidance on the design and update of national interoperability frameworks, and on national policies, strategies and guidelines promoting interoperability. It was adopted in the context of the digital single market strategy in Europe, to support interoperability within the public sector. The public sector plays a key role in the digital single market as a regulator, services provider and employer [10]. The new EIF offers recommendations, models and guidance that have the potential to improve the quality of European public services. Four layers of interoperability form the basis for the interoperability framework:

- Legal interoperability to ensure that organizations operating under different policies, legal frameworks and strategies are able to work together.
- Organizational interoperability for the alignment of public administrations responsibilities, business processes and expectations to achieve mutually beneficial goals.
- Semantic interoperability to ensure that when parties exchange data and information they preserve and understand their precise format and meaning.
- Technical interoperability covers the applications and infrastructures linking systems and services, including interface specifications, data presentation and secure communication protocols.

The twelve underlying EIF principles are fundamental behavioral aspects to drive interoperability actions and include core interoperability principles such as openness, transparency and reusability, principles related to generic user needs and expectations such as user centricity, inclusion, security and privacy, and foundation principles for cooperation among public administrations such as administrative simplification, preservation of information and others [20].

Systems and technologies designed based on these principles give the opportunity to citizens to increase the benefits they receive using technologies and tools either directly or indirectly. The new EIF may benefit the implementation of eHealth systems for the management of personal health information for citizens [8]. The new EIF provides a relevant framework to guide the implementation and adoption of digital health applications and services.

Digital Transformation in Health and Care

The EU Commission's Communication on the Transformation of Digital Health and Care of April 2018 [17] identifies three pillars to support activities relevant to the enhancement of the digitization of the healthcare sector through meaningful use of digital innovations. These require further actions in order to provide the citizens secure access to and sharing of their health data, standardization for the existence of better data to promote

research, disease prevention and personalized health and care, and digital tools for citizen empowerment and for person-centered care. These are expected to require significant efforts towards the provision of secure access to and protection of health data, managing the diversity of Electronic Health Records, coordinating the substantiation of technical interoperability through open exchange formats and provision of access to trustworthy digital health services. Cross-border exchanges started in the EU in 2019, and the current goal is to have all EU countries on board by 2025 [21]. In the longer term, the Commission is working towards establishing a European electronic health record exchange format [22] that is accessible to all EU citizens.

EU Health Data Space

Despite the fact that the majority of Europeans have a positive attitude towards the use of health data for multiple purposes, the positive attitudes are typically conditional. Concerns evolve around data security, their commercialization, as well as the use of data against the interests of the people providing them [23]. The COVID-19 crisis has demonstrated that the value of data increases when they can be accessed, combined and shared. A common European Health Data Space is expected to promote better exchange and access to different types of health data (electronic health records, genomics data, data from patient registries etc.) to support healthcare delivery, research and policy. The creation of a European Data Space [24] is expected to be built on top of: (i) a strong system of data governance and rules for data exchange, (ii) data quality, and (iii) strong infrastructure and interoperability, and is one of the current strategic priorities of the Commission, including the health sector [25].

Security and Privacy

As telehealth solutions migrate to the cloud in order to support flexible and rapid deployment, security concerns need to be addressed promptly. The COVID-19 pandemic has surfaced an increased need for efficient, reliable, and secure electronic health and care services. The complexity of legal systems and new technologies, as well as concerns over the security of sensitive patient data have slowed the healthcare sector in adopting cloud services. The report on cloud security for health services by the EU Agency for Cybersecurity [26] helps healthcare organizations securely adopt cloud services and prepare for cybersecurity challenges. To this direction certain legal requirements in respect to privacy & data protection, including the General Data Protection Regulation [27], the NIS Directive [28], and the European Cybersecurity Act [29], cloud security and health such as MDR [30] and the electronic cross-border health services directive [31], need to be established, aligned and enforced. Typical cloud security challenges that need to be addressed include the lack of trust, lack of security and technology expertise, lack of investments, as well as difficulties related to the integration of cloud with legacy systems [32-34]. Key data protection challenges relate to data management, deletion, portability, encryption, as well as privacy by design techniques [35; 36].

Healthcare in the public and private sectors

Healthcare in Greece is provided by the National Health System (NHS). As a public service, it does not exist in isolation but as part of the wider national public administration. In the healthcare sector the past years several digital services have been implemented for the entire public sector. These implementations were reinforced through the economic crisis and the need for better control of costs within the NHS. Base registries for the healthcare sector are supporting instruments

for public administrations [15].

Digital health applications in hospitals interact with digital services within and across the healthcare enterprise using interoperability services. They contribute to the improvement of organizational performance and cost savings by applying the *data entered-once* and *used-anywhere* key concepts [37].

The eHealth and telemedicine landscape in the country is filled by several EHR systems, including clinical and non-clinical ones (e.g. for clinical trials), communicating mostly application to application. Despite the wide availability of EHR systems, there exists large fragmentation of information, limited out of the box interoperability capabilities among them, and questionable data quality. Digitizing health records and creating systems so that citizens can access and securely share them within and between the different actors in the health system is an important step towards integrating digital technologies into healthcare. That integration requires EHRs, to be interoperable across the NHS whereas currently many of the formats and standards in EHR systems used across the country are incompatible. The key issue is that the Greek, national interoperability framework (eGIF, <http://www.e-gif.gov.gr/>), introduced in 2012, is outdated and not compatible with the new EIF. Data governance is key enabling factor and any new legislation would need to govern and enable distributed and decentralized models to support efficiently all the health and care needs of the citizens and visitors of country. It needs to encompass both state of the art trends and real-world requirements to better support the effective delivery of the appropriate information to all authorized users [14; 37]. Following the EU regulations, principles and trends, the national healthcare system can interact with the digital transformation occurring in other sectors in Greece to set the right conditions for procuring and acquiring interoperable digital solutions.

Discussion

Large amounts of health data of every citizen are stored in national and regional digital health systems. The majority of these data continue to be confined in data silos [14]. Reusing data is often not an option due to the limited interoperability among digital health solutions, rendering the vision for better healthcare largely unattainable. Data is stored in disparate data repositories using different information models, in different syntaxes, semantics, or formats. Data capture is often inconsistent or follows incompatible formats. Further uses of data for specific purposes are not formalized or readily available. Often, data are of variable quality and unstructured, as free text, posing greater challenges for automatic processing [38]. In addition, there is a huge gap between public and private sectors and interoperability tends to work only in high impact cases such as national registries. The following recommendations offer a guide towards national digital health initiatives in Greece and abroad.

Health Interoperability Framework: The framework gives specific guidance on how to set up interoperable digital public services. A framework can integrate the fundamentals and set the standards of healthcare services. The new EIF, in combination with the national interoperability framework, provide an appropriate guide for establishing a national interoperability framework to address specific use cases of high priority for the healthcare domain [14].

Security and Privacy: The implementation of specific legal, organizational and technical digital security measures requires careful planning, impact assessment and costs. Due to the cyber

security skills gap, it is expected that those who are less prepared will remain more vulnerable. Healthcare organizations will require additional support, as well as specific guidance, from appropriate national and other authorities (such as the EU), industry-level standards, clear guidelines from Data Protection Authorities and cooperation with technology service providers (e.g. cloud service providers), and manufacturers of medical devices. The provision of incentives for investments in cyber security measures will be required.

eHealth Governance: A holistic approach on interoperability can only be achieved through appropriate governance. Governance indicates fundamental guidelines in establishing the application of interoperability rules. Sustainability of interoperability across the care continuum can establish true coordinated care systems rather than one-off targets or project [39].

Digital Health Quality Assessment (testing and certification): To ensure that interoperability principles and guidelines are implemented and operational in the healthcare digital ecosystem it is important to define and establish interoperability and conformance testing and certification. It is very important that a compliance strategy is in place, as well as a roadmap for the development and maintenance of national specifications and interoperability principles, standard-related rather than self-defined. The creation of a mechanism for compliance control and certification of relevant software is considered critical.

Healthcare Process Modeling: It is important to incorporate process modeling in healthcare service delivery using international standards, such as the graphical representation for business process model and notation (BPMN), and the template of description of high level use cases and realization scenarios [14]. A standardized process modeling will facilitate the unified description of digital services for easier consumption and sharing.

Healthcare Service Vocabulary: EU Member States aim towards the provision of cross-border healthcare services. However, this process is quite complex, due to the heterogeneity of the actors, information and services of the different Member States. The complexity of exchanging data may lead to semantic interoperability conflicts. The core public service vocabularies can be extended and used, in healthcare as in all other areas, to reduce these semantic conflicts.

Interoperability Learning Programs: Education and training about interoperability, interoperability assessment, and sector specialized interoperability challenges for end users, policy makers and public employees, are essential. These learning courses provide the basic and advance understanding of interoperability challenges, needs and issues in the public sector.

Conclusions

Interoperability in healthcare is a complex societal issue because it involves various actors, dissimilar perspectives, norms and values. Existing systems, policies and governance structures are interrelated and in a continuous co-evolution within the broader societal dynamics. Addressing the existing structures and focusing on the emergent vision of citizen empowerment allows for an improved insight into the feasibility of change. The design and implementation of an interoperability framework with the appropriate open governance is an essential foundation towards citizen empowerment and a more sustainable health system.

Interoperability enhancement can contribute to cost reduction, and greater integration through reuse of available services and

orchestration of services in an effective manner to maximize service outcome and benefits for citizens and public administrations. An evaluation strategy needs to be closely linked with specific policies to support the continuation of the assessment, governance and implementation of digital public services nationally. There is a significant space for improvements towards the development and implementation of seamless interoperable services for citizens, administrations and business in the public sector across Europe. Further work is necessary to enable member states to harmonize with relevant EU directives and drive interoperability towards integrated services for citizens.

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