



A Framework for the Consistent Management of eHealth Interoperability in Greece

Dimitrios G. Katehakis¹^a and Angelina Kouroubali¹^b

¹*Institute of Computer Science, Foundation for Research and Technology - Hellas (FORTH), Heraklion, Greece*

{katehaki, kouroub}@ics.forth.gr

Keywords: Interoperability, Electronic Health Record, Public Health, Models and Frameworks, Enterprise Architecture Adoption and Governance

Abstract: This work presents an approach for the organized development of a countrywide framework to address the ever-growing demand for acquiring, exchanging and exploiting patient information to support high quality and cost-effective healthcare delivery. The national electronic health (eHealth) landscape in Greece is examined within the context of the recent recommendation on a European electronic health record (EHR) exchange format. Improving quality of life and well-being, in a secure and safe manner that respects the patients' privacy, is the key challenge. Interoperability of information and communication technology (ICT) systems is central for reliable and efficient collaboration between the involved stakeholders, including the patient and associated caretakers. In order to accelerate transformation towards citizen empowerment and a more sustainable health system, national authorities need to address issues relevant to mutually beneficial goals in a coherent manner. Practical implications are related to the sustainability of the underlying national infrastructure required to support reliable and secure exchange of meaningful EHR data, for both primary and secondary use, and by defining technical specifications for well-defined use cases, in a legitimate and standardized manner, under a highly regulated environment.

1 INTRODUCTION


Electronic health records (EHRs) have the potential to improve significantly the quality of healthcare outcomes and as such, they are an important tool for coordinated care. They aim at improving health outcomes through the delivery of healthcare services from multiple providers by ensuring that care is not delivered in silos (McDonald, et al., 2007). As stated in (Katehakis, et al., 2018), prerequisites for enabling data reuse and workflow automation include well-defined use cases, agreed terminology, and reliable clinical content. Effective coordination of care requires collaboration, goal oriented care planning, tracking care activities and interventions, as well as continuous assessment and review.


Increased healthcare needs will require a more resilient healthcare system. This is due to population

ageing, the rising occurrence of chronic conditions, and an increase in demand for long-term care (OECD/EU, 2018).

In order to use and interpret EHR information in a clinical relevant context, certain requirements are considered to be of great priority, including contextual information related to medical encounters and decisions, privacy and confidentiality of information, and disclosure law (Katehakis and Tsiknakis, 2006).

The widespread adoption of mobile technologies facilitates the introduction of new and innovative ways to improve healthcare delivery. Citizens can now use them to manage their own health and promote healthy living and active ageing by accessing useful information and linking to useful resources when needed; healthcare professionals and patients included (Kouroubali, et al., 2019). Mobile devices are becoming an integral part of the healthcare

^a <https://orcid.org/0000-0002-3763-191X>

^b <https://orcid.org/0000-0002-3023-8242>

industry, changing how care is delivered and received. The use of electronic medical records (EMRs) and electronic prescription is growing across the European Union (EU) countries, and growing numbers of EU residents use the Internet to obtain health information and access health services. Despite the fact that citizens have the right to access their personal data, including their health data, as provided for by (European Union, 2016) most citizens cannot yet access (nor securely share) their health data seamlessly across the units of their national healthcare system.

In spite of the fact that large amounts of health data are generated and stored electronically, during and between citizen encounters with national and regional health systems across Europe, they continue to reside in data silos. Opportunities to reuse data for better healthcare are often missed, due to the limited interoperability among digital health solutions (Beerenwinkel, et al., 2018). A framework to provide for the specific set of standards, protocols, procedures, best practices and policies to help professionals and patients improve the cost-effectiveness of the eHealth solutions they design, implement, and use is considered to be essential (Barbarella, et al., 2017; Lamine, et al., 2017).

A recent study by the Healthcare Information and Management Systems Society (HIMSS) Europe³ points out the fact that eHealth professionals should pay more attention to the patient over the next years, mainly due to the patient-generated data (through wearables or other tools and gadgets made for “consumers”) as well as health records that are owned and managed by patients/citizens. Once a country has reached a certain level of Electronic Medical Record (EMR) maturity - the priorities shift towards patient empowerment. Successful digital transformation is a team play.

Healthcare in Greece is provided by the national health system (NHS). It consists of a universal healthcare system provided through national health insurance, and private healthcare. During the past few years, a multitude of eHealth services has been introduced, in line with EU priorities, to control costs and improve services in a secure manner. These include electronic prescription (ePrescription), electronic dispensation (eDispensation) and electronic referral (eReferral) for primary care⁴, electronic confirmation (eConfirmation) for

insurance status verification⁵, electronic reimbursement (eReimbursement)⁶, electronic appointment (eAppointment) for booking doctors’ appointments for primary care⁷, and a business intelligence system (Bi-Health)⁸ that automates online retrieval of operational data for the Hellenic Ministry of Health (MoH).

Despite the fact that significant progress has been made to effectively link hospitals, regional health systems, and primary care (Katehakis, et al, 2012), still no uniform access to EHR is available nationwide (Katehakis, 2018).

Relevant challenges for the Greek NHS have to do with the non-optimal use of available data due to the lack of base registries (i.e. a trusted and authoritative source of information which can and should be digitally reused by others), within the context of an interoperability framework for the exchange and use of data across different organizations. For example, a number of organizations process information regarding drugs administered to patients. However, the lack of a consistent, good quality, complete, centralized drug registry creates a number of problems for doctors, nurses and pharmacists across the country that eventually affect patients.

The lack of a well-defined interoperability framework also affects other important patient care scenarios such as the management of available beds in public hospitals as well as providing medication for the chronically ill.

The development of services built upon international standards and best practices, under the provisions of national and EU legislation, turn out to be very important. The appropriate legal framework and governance, independently of the maturity of the technologies used, are key ingredients for establishing a successful framework for accessing and sharing EHR data at a national level, in line with the recently introduced recommendation on a European EHR exchange format (European Commission, 2019). The aim of interoperability with regard to EHR exchanges is to allow for the processing of information consistently in a way that the recipient can meaningfully interpret communicated information.

In the following section, the EU framework of cooperation towards the digital single market is presented together with interoperability guidelines and standards, including security and policy

³ <https://www.himss.eu/content/annual-european-ehealth-survey-2018>

⁴ <https://www.e-prescription.gr/>

⁵ <https://www.atlas.gov.gr/ATLAS/Pages/Home.aspx>

⁶ <http://www.eopyy.gov.gr>

⁷ <https://www.e-syntagografisi.gr/p-rv/p>

⁸ <http://portal.bi.moh.gov.gr/>

considerations. The road towards developing a national EHR, addressing relevant challenges for the Greek NHS, is subsequently described in section 3. Emphasis is paid on governance and sustainability towards the development of a national domain interoperability framework (DIF) for eHealth, highlighting critical research and practical issues. The paper concludes with some key recommendations.

2 EU FRAMEWORK OF COOPERATION

EU member states have to make their eHealth systems more interoperable to support citizens in gaining greater control over their health data, to improve clinical outcomes, and to manage the economic and social aspects of healthcare. Technical challenges for the implementation and adoption of EHRs and personal health records have mostly to do with issues relevant to interoperability, device connectivity, security, compliance with national and international legislation, as well as with local policies, usability and accessibility from different devices by users with different profiles (Katehakis, et al., 2017).

Data generated within an organization can be used in a different manner by another organization, while information exchange can occur within a small network or it can expand to regions, nations and cross-national initiatives (Sheikh et al., 2017). For example, in order to provide effective care, clinicians need comprehensive longitudinal data sets, while researchers and policy makers need quality data, in order to conduct research and support health planning. Deeper understanding and effective clinical interventions, as in the case of bioinformatics and personalized medicine, require innovative use of existing data. Standardization in medical informatics enables the interconnection and the interoperability between both care and research systems. Local clinical systems can be better aligned for easier data integration by preserving the meaning across information systems. Both transmitter and recipient interpret the shared information identically in different geographical locations, with possibly different local languages.

Interoperability is not possible without formal standards and specifications. Organizations such as Health Level Seven International (HL7⁹) and Personal Connected Health Alliance (PCHAlliance¹⁰) help towards the delivery of standards-based, open specifications that can support the flow of data from the point of capture into EHRs in the same format and coded content. Consensus on systems requirements is also important. Integrating the Healthcare Enterprise (IHE¹¹) describes how standards may be used effectively. Standard can be used with third party terminologies such as the Current Procedures Terminology (CPT¹²) code set, the Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT¹³), the Logical Observation Identifiers Names & Codes (LOINC¹⁴), and the International Classification of Diseases (ICD¹⁵) codes.

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 (European Commission, 2017). The new EIF provides guidance to public administrations, through a set of recommendations, on how to improve governance of their interoperability activities, streamline processes supporting end-to-end digital services, establish cross-organisational relationships, and ensure that existing and new legislation do not compromise interoperability efforts.

The eHealth domain in Europe uses the refined eHealth European Interoperability Framework (ReEIF) (eHealth Network, 2015) as the common framework for managing interoperability in the context of the eHealth Digital Services Infrastructure¹⁶ supported under the Connecting Europe Facility Programme¹⁷. Member States have taken important steps to foster interoperability with the support of the Commission, through the activities of the eHealth Network established under Article 14 of Directive 2011/24/EU of the European Parliament and of the Council (also known as the cross border healthcare directive).

The ReEIF and the new EIF provide the tools to support the creation of a national DIF for eHealth. According to (European Commission, 2017) four layers of interoperability form the basis for the interoperability framework, as presented in Figure 1.

⁹ <http://www.hl7.org/>

¹⁰ <http://www.pchalliance.org/>

¹¹ <http://www.ihe.net/>

¹² <https://www.ama-assn.org/practice-management/cpt-current-procedural-terminology>

¹³ <https://www.snomed.org/snomed-ct>

¹⁴ <https://loinc.org/>

¹⁵ <http://www.who.int/classifications/icd/en/>

¹⁶

<https://ec.europa.eu/cefdigital/wiki/display/EHOPERA/TIONS/eHealth+DSI+Operations+Home>

¹⁷ <https://ec.europa.eu/inea/en/connecting-europe-facility>

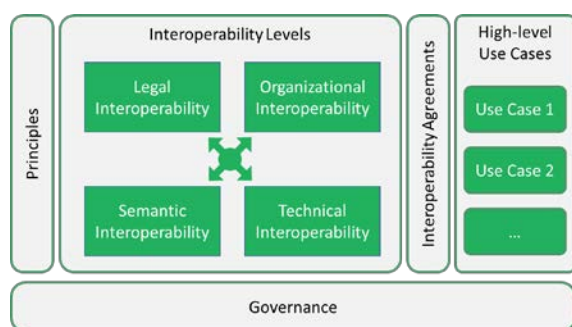


Figure 1: From EIF model to the ReEIF one (eHealth Network, 2015).

Legal interoperability ensures that organizations operating under different policies, legal frameworks and strategies are able to work together. Organizational interoperability refers to the way in which public administrations align their responsibilities, business processes and expectations to achieve mutually beneficial goals. Semantic interoperability refers to both the meaning of data and the exact format of the information to be exchanged. Technical interoperability covers the applications and infrastructures linking systems and services, including interface specifications, data presentation and secure communication protocols.

Citizens across Europe want to access and share their health data (European Commission, 2018). They also want to be able to provide feedback on quality of treatments. The slow deployment of interoperable digital health solutions across European countries remains a barrier for scaling-up integrated care (COCIR and IHE-Europe, 2017).

In order to secure the citizen's access to and sharing of health data the EU is moving towards the development of specifications for a European EHR exchange format, based on open standards, taking into consideration the potential use of data for research and other purposes. The recommendation on a European EHR exchange format sets out a framework (European Commission, 2019) to achieve secure, interoperable, cross-border access to, and exchange of, electronic health data in the EU. The framework includes:

- a set of principles that should govern access to and exchange of EHRs across borders in the EU;
- a set of common technical specifications for the cross-border exchange of data in certain health information domains;

- a process to take forward the further elaboration of a European EHR exchange format.

The aim is to deliver the right data, at the right time, for citizens and healthcare providers, and allow for the secure access, sharing and exchange of EHRs. The baseline includes patient summaries, ePrescription/ eDispensations, laboratory reports, medical images and reports, and hospital discharge reports, in alignment with established priorities at a European level.

The General Data Protection Regulation (GDPR) (European Union, 2016) requires patient data to be protected and properly secured so that its confidentiality, integrity and availability are ensured. In addition, citizens and their healthcare professionals must have online access to their EHRs using secure electronic identification means (eIDAS Regulation) (European Union, 2014), while EHR systems rely on secure networks and information systems in order to avoid data breaches and minimise the risk of security incidents (Directive on security of network and information systems - NIS Directive) (European Union, 2016b).

The EU Agency for Network and Information Security has published several documents on strategies and ways of implementing privacy by design (European Union Agency for Network and Information Security, 2018).

3 TOWARDS A NATIONAL EHR

The development of national EHR in Greece implies a vision for the provision of healthcare in the country and significant technical knowledge. It has to follow best international practices and be combined with the existence of a national strategy. It is a long term, evolutionary process that requires the gradual integration and deployment of EHR information domains over time. Already the majority of EHR system components, within the information and communication technology (ICT) infrastructure of healthcare organizations, are operational in the country (Katehakis, 2018). Key EHR information exchange providers in Greece include:

- IDIKA (e-Government Center for Social Security Services¹⁸) for eConfirmation (for insurance status verification), ePrescription/ eDispensation, eRDV (for appointment booking – directly accessible to citizens), AHFY (citizen EHR focused on primary care –

¹⁸ <http://www.idika.gr>

aiming to become the backbone of the national EHR system, under development), and NCPeH (cross border services for ePrescription and patientssummary).

- EOPYY (National Organization for Health Care Services¹⁹) for eReimbursement (e-ΔΑΠΥ) and also registries for Hepatitis C and Chronic Myelogenous Leukemia.
- Hospitals.
- Healthcare Professionals.

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. An outstanding example is the fact that many organizations are directly involved in the management of pharmaceutical products without the existence of a common registry of medicinal products to serve as a common point of reference (Katehakis, et al., 2018). Synthesis of information required about medicinal products is fragmented within the above-mentioned entities. Communication between them, in the context of handling their business processes related to drug administration, is done by means of email exchanges and spreadsheet files. Data used by each entity is incomplete and not always up to date. Safety rules do not usually apply on the roles and responsibilities of data controllers involved in data management.

The Bi-Health system of the MoH²⁰ supports the automated extraction of certain data sets from public hospitals, related to patients, the cost of care per hospital, the use of consumables, and others. Bi-Health aims towards supporting documented decisions for the improvement of public health by extracting hidden knowledge through big data analytics. Initial data sets, collected online, included inpatient and outpatient data (admission, discharge and transfer notes, charging, etc.), materials, human resource and financial management data, as well as appointment booking data. Still not all points of care in the country are linked with Bi-Health.

Digitising 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. This is because

- Solution providers propose implementations without consulting each other.
- Interoperability agreements are too generic or non-existent.
- No national semantic authority, responsible and accountable for the provision of national terminology services, is in place.
- Interoperability standards, such as HL7, are not used in a consistent manner.

The key issue is that no national framework is in place to manage consistently interoperability in the country. Since the use case-driven approach is the foundational methodology for documenting user needs, the practical approach for achieving interoperability can be summarized in the following steps:

- identify use cases from an end-user perspective;
- select profiles and standards that support the use case;
- refine data content, including master files, and terminology;
- prepare implementation guides;
- organize component interoperability and cross-implementer connectivity testing;
- educate end-users;
- support communities of practice to promote sustainable standards-based implementation.

For each of the proposed use cases, rules need to apply in order to determine how to accomplish interoperability at each of the following levels:

- Legal: for providing a thorough check of how public services will be established in regards to consistency with relevant legislation and corresponding data protection requirements, when drafting legislation.
- Organizational: for documenting and integrating, or aligning, business processes and relevant information exchanged, while at the same time aiming to meet the requirements of the user community by making services available, easily identifiable, accessible and user-focused.
- Semantic: to make sure, through the development and use of standardized vocabularies and formats, that the meaning of exchanged data and information is well understood by the different parties, resolving any possible ambiguities regarding the notions in the healthcare domain.

¹⁹ <https://www.eopyy.gov.gr/>

²⁰ <http://www.moh.gov.gr/>

- Technical: in order to ensure the use of formal technical specifications and widely accepted and used standards.

A national EHR will only become available when the EMRs generated and maintained by physicians and healthcare providers apply internationally recognized interoperability standards (Aanestad, et al., 2017) in a regulated manner. Interoperability should be guaranteed in a sustainable way and not as a one-off target or project.

In order to achieve this vision within the Greek NHS, the following need to be in place:

- a roadmap for the development and maintenance of national specifications, re-usable services and other assets;
- national, reusable interoperability specifications, compatible with the corresponding European ones, developed through open and transparent processes;
- mechanism and tools for compliance control, testing and certification;
- a national semantic authority.

The introduction of a conformity assessment scheme, considering ISO, IHE CAS²¹ and other successfully deployed in member states is expected to promote the adoption and take-up of interoperability testing of eHealth solutions and products against identified eHealth standards and profiles. This will require the establishment of a test and compliance control centre in the country.

Foreseen benefits include less effort in the introduction of new services, lower cost for the application of new solutions, a solid ground to support better research, less red tape, and more empowered patients in control of their diseases.

4 CONCLUSIONS

A key and essential pillar to establish a National EHR in Greece is the design and implementation of an interoperability framework that, with the appropriate open governance, will enable the systematic implementation of the necessary user cases that will populate the EHR with valid and quality elements. Transparency will allow other public administrations, citizens and businesses to view and understand administrative rules, processes, data, services and decision-making

Appropriate governance and legislation will guarantee that consistent management of eHealth interoperability in Greece will be applied and that all

involved parties, including health organizations and ICT solution providers, will comply with it. For that to happen, a thorough research is required of relevant best practices and corresponding level of maturity reached, in regards to eHealth interoperability and governance, in other countries sharing a similar profile to that of Greece.

Digitising health records and enabling their exchange could support the creation of large health data structures, which combined with the use of new technologies, such as big data analytics, and artificial intelligence can support the search for new scientific discoveries.

ACKNOWLEDGEMENTS

This work has been funded, in part, by the Center for eHealth Applications and Services, and was implemented in co-operation with the Computational Biomedicine Laboratory of the Institute of Computer Science, of the Foundation for Research and Technology – Hellas. Any opinions, results, conclusions, and recommendations expressed in this work are those of the authors and do not necessarily reflect the views of the Hellenic Ministry of Health or the European Commission.

REFERENCES

- McDonald, K. M., Sundaram, V., Bravata, D., M., et al, 2007. Definitions of Care Coordination and Related Terms. *Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies (Vol. 7: Care Coordination)*. Rockville (MD): Agency for Healthcare Research and Quality (US); 2007 Jun. (Technical Reviews, No. 9.7.) 3.
- OECD/EU, 2018. Health at a Glance: Europe 2018: State of Health in the EU Cycle, OECD Publishing, Paris. https://doi.org/10.1787/health_glance_eur-2018-en
- Katehakis, D., G., Tsiknakis, M., 2006. Electronic Health Record (EHR). In *Wiley Encyclopedia of Biomedical Engineering, 6-Volume Set*, Metin Akay (Editor), John Wiley & Sons, Inc.
- Kouroubali, A., Koumakis, L., Kondylakis, H., Katehakis, D.G., 2019. An Integrated Approach Towards Developing Quality Mobile Health Apps for Cancer. In *Mobile Health Applications for Quality Healthcare Delivery*, IGI Global, Hershey PA, USA, pp. 46-71.
- European Union, 2016. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free

²¹ <https://www.euro-cas.eu/>

- movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance).
- Beerenwinkel, N., Fröhlich, H., Murphy, S., A., 2018. Addressing the Computational Challenges of Personalized Medicine (Dagstuhl Seminar 17472). In *Dagstuhl Reports* (Vol. 7, No. 11). Schloss Dagstuhl-Leibniz-Zentrum fuer Informatik.
- Barbabella, F., Melchiorre, M. G., Quattrini, S., Papa, R., Lamura, G.: How can eHealth improve care for people with multimorbidity in Europe?. *World Health Organization*, Regional Office for Europe.
- Lamine, E., Guédria, W., Rius Soler, A., Ayza Graells, J., Fontanili, F., Janer-García, L., Pingaud, H., 2017. An Inventory of Interoperability in Healthcare Ecosystems: Characterization and Challenges. *Enterprise Interoperability: INTEROP-PGSO Vision*, 1, 167-198.
- Katehakis, D., G., Halkiotis, S., Kouroubali, A., 2012. Materialization of Regional Health Information Networks in Greece: Electronic Health Record Barriers & Enablers. In *Advances in Electronic Health Records*, Ming Chyu (editor), pp. 285-299, Multi-Science Publishing Company, Texas Tech University, Lubbock, Texas, USA.
- Katehakis, D., G., 2018. Electronic Medical Record Implementation Challenges for the National Health System in Greece. *International Journal of Reliable and Quality E-Healthcare (IJRQEH)* 7(1), 16–30.
- European Commission, 2019. Commission Recommendation of 6.2.2019 on a European Electronic Health Record exchange format (Text with EEA relevance), C(2019) 800 final.
- Katehakis, D., G., Kondylakis, H., Koumakis, L., Kouroubali, A., Marias, K., 2017. Integrated Care Solutions for the Citizen: Personal Health Record Functional Models to support Interoperability. *European Journal for Biomedical Informatics (EJBI)*, Volume 13, Issue 1, October 2017, pp. 51-58.
- Sheikh, A., Cresswell, K., Wright, A., Bates, D., 2017. *Key Advances in Clinical Informatics: Transforming Health Care through Health Information Technology*. Academic Press.
- European Commission, 2017. *New European Interoperability Framework, Promoting seamless services and data flows for European public administrations*, Belgium, European Union.
- European Commission, 2018. *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society*, COM(2018) 233 final {SWD(2018) 126 final.
- COCIR, IHE-Europe, 2017. The Personal Health Connected Alliance: We are all in this Together: Advancing eHealth Interoperability. http://www.cocir.org/fileadmin/Publications_2017/170_22_COC_Interoperability_web.pdf
- eHealth Network, 2015. Refined eHealth European Interoperability Framework. https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20151123_co03_en.pdf
- European Union, 2014. Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC.
- European Union, 2016b. Directive (EU) 2016/1148 of the European Parliament and of the Council of 6 July 2016 concerning measures for a high common level of security of network and information systems across the Union.
- European Union Agency for Network and Information Security, 2018. Handbook on security of personal data processing. <https://www.enisa.europa.eu/publications/handbook-on-security-of-personal-data-processing>
- Katehakis, D., G., Kouroubali, A., Fundulaki, I., 2018. Towards the Development of a National eHealth Interoperability Framework to Address Public Health Challenges in Greece. *SWH@ISWC*.
- Aanestad, M., Grisot, M., Hanseth, O., Vassilakopoulou P., 2017. Information Infrastructures for eHealth. In: Aanestad M., Grisot M., Hanseth O., Vassilakopoulou P. (eds.) *Information Infrastructures within European Healthcare. Health Informatics*. Springer, Cham. https://doi.org/10.1007/978-3-319-51020-0_2