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A Prototype of the National EHR system for Cyprus *

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***Abstract*— The aim of this paper is to present Cyprus' initiative for the design and the implementation of the prototype of the integrated electronic health record at a national level that will establish the foundations of the country's broader eHealth ecosystem. The latter, requires an interdisciplinary approach and scientific collaboration among various fields, including medicine, information and communication technologies, management, and finance, among others. The objective, is to design the system architecture, specify the requirements in terms of clinical content as well as the hardware infrastructure, but also implement European and national legislation with respect to privacy and security that govern sensitive medical data manipulation. The present study summarizes the outcomes of the 1st phase of this initiative, which comprises of the healthcare as well as the administrative requirements, user stories, data-flows and associated functionality. Moreover, leveraging the HL7 Fast Healthcare Interoperability Resources (FHIR) standard we highlight the concluded interoperability framework that allows genuine cross-system communication and defines third-party systems connectivity.**

***Clinical Relevance*— This work is strongly correlated with medicine since it describes the system requirements and the architecture of a national integrated electronic health records system.**

I. Introduction

In the era of technology, data collection, storage and processing are crucial and unavoidable. This helps in understanding the knowledge that is stored and many times hidden in the data. In medicine, keeping the data of a patient is vital. To strengthen this argument, an informed diagnosis can only be achieved by obtaining and interpreting the full medical history of a patient. Notably, clinical examinations generate an enormous amount of (big) data, including temporal signals, longitudinal high-quality images and video, -omics data, laboratory results, etc. These data carry invaluable information and the only way to process and extract new knowledge is to store them in a structured manner, in the form of an integrated electronic health record (EHR). Importantly, a key aspect towards materializing the full potential of an EHR, is to use a citizen centric philosophy. In other words, designed and oriented towards the needs of the citizens and not necessarily those of health institutions.

The complexity of such systems arises from the need of different systems and organizations to communicate to each other. For example, if we take a simple scenario of a citizen visiting a doctor, this requires organizational processes such as booking an interview, consent approvals from both parties, authorization and security issues, medical data entries, request for lab examinations, diagnosis reports, medicine requests, communication with pharmacies and others. To take it one step further, it is desirable that national EHRs can communicate data to each other so that doctors in different countries will be able to browse health information of foreign citizens. This procedure is called interoperability and there has been a major effort from the community towards achieving it. This is done by using the same protocols for communication, such as the "Fast Healthcare Interoperability Resources" (FHIR) by HL7 and the same coding for the entries such as the SNOMED and the LOINC. Recently, HL7 FHIR has been selected by several countries from all over the world, including USA, Australia, Canada, India, Netherlands, Belgium and UK, for the representation of the International Patient Summary (IPS) [1].

Currently in Cyprus, there is not an integrated EHR solution such as the one described above, however the development of such a system is an ongoing national priority. In this context, the eHealth4U research project undertakes the challenge of defining the structure and the content of the national integrated EHR system and developing the prototype implementation. The objective is to create a thorough EHR system which meets all the legislative obligations at a national level defined in the Electronic Health Law of Cyprus (eHealth law of Cyprus) [2] and at a European level using the General Data Protection Regulation (GDPR) [3]. At the same time, the eHealth4U is designed to satisfy the features of the proposed eHealth-based ecosystem serving national healthcare considering interoperability, patient-centered healthcare, citizen-ownership of the EHR, standardization and confidentiality and security [4]. In this paper, we present the progress of this work, as defined and explained above.

II. System Requirements

A. Legislation

The storage, processing, analysis and use of personal data are protected by the GDPR, which is a European directive set by the European Parliament and the Council in 2016. It describes the protocols in which personal data can be used and it also defines precisely how sensitive data such as medical data can be treated. Further on that, on a national level, Cyprus has adopted the eHealth law of Cyprus which sets the directions not only for managing data, but also other more generic issues pertaining to electronic health. According to the eHealth law of Cyprus, an Authority is established under the name "National e-Health Authority" (NeHA), which is a legal entity. Among a number of responsibilities, NEHA is also

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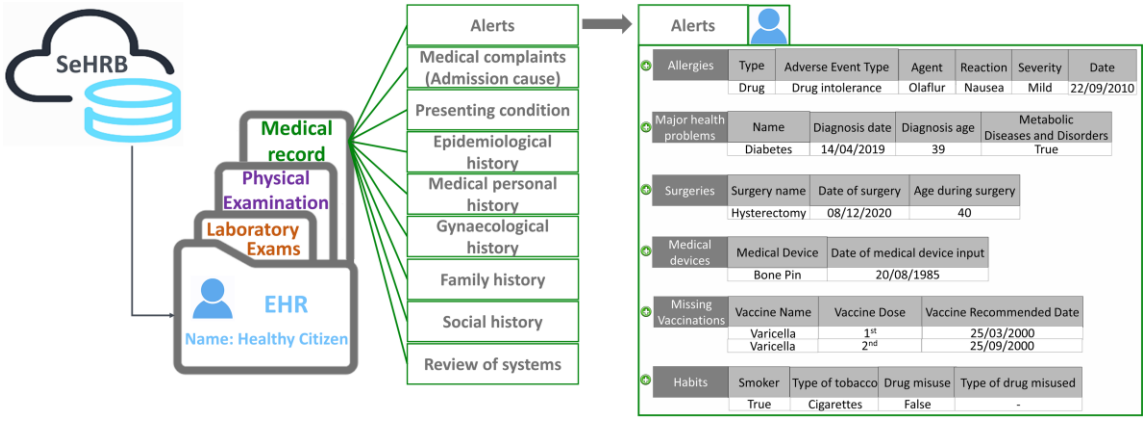

Figure 1: An example on how a patient's national EHR is structured in the eHealth4U system.

regulating the national integrated EHR system which will be kept in a universal health data bank called Single eHealth Records Bank (SeHRB). In eHealth4U we use the above two directions to draw up the Data Privacy Framework, as well as consent forms compliances.

B. Data Privacy and Security

The engagement of best practices and techniques for successful security engineering is required for the security and infrastructure services of any national eHealth system. In this framework, eHealth4U adopts certain technologies to guarantee that all its services are designed and developed considering secure engineering principles. To obtain enhanced security, scalability, high availability and data redundancy, eHealth4U uses cloud technology while it leverages a microservices software architecture solution using the Google Kubernetes engine. Furthermore, all actions that take place in the platform are logged for auditing purposes while for authorization and authentication the RFC6749 OAUTH2 open standard is used with claims based on the RFC7519 JSON Web Token (JWT) open standard.

Access to the EHR data by authorized healthcare providers may be carried out only when the owner of the data (i.e., the citizen) provides them with a consent. This derives as an obligation from the GDPR and the eHealth Law of Cyprus.

C. System requirements

The system requirements of the eHealth4U were gathered under the guidance of experienced medical doctors. A series of productive workshops were organized between the eHealth4U business analysists and the medical experts, discussing topics like: everyday medical practice, inpatient and outpatient medicine, proper capturing and storing of a medical history, and more broadly the type of the information needed for a complete EHR.

In eHealth4U, we are focusing in implementing the primary care specialties, being the general internal medicine, the general paediatrics and the family medicine. According to Zhong et al, primary care is the backbone of a national healthcare system [5]. It meets population needs, it improves the citizens' health while at the same time it reduces costs and it lowers inequality. As long as these specialties are implemented, other specialties can be easily adopted and incorporated into the system.

From the analysis of the requirements, we are separating the general components of the EHR system into two main categories, being (a) the healthcare related and (b) the administrative related requirements. The healthcare related requirements are further split into 3 main sub-categories which reflects how the healthcare providers use this information in their routine workflows. Aided by the medical team, these are the Medical History, the Clinical Examination and the Laboratory Results. One example of such a scheme is shown in Fig. 1. The Medical History includes the total set of a citizen's personal and health data which are captured during an interview between the citizen and the doctor. These data are further analyzed into the following sub-categories: Demographics, Family History, Vaccinations, History, Personal History, Epidemiological History, Gynaecological History, Social History and Systems Review (see Fig. 1). The clinical examination sub-category defines most of the possible clinical findings that might be observed by a doctor through a visit with a citizen. These data are extracted by two medical books [6-7] and are further analyzed and enriched by the medical team of the eHealth4U project. This category contains many sub-categories related to health, including vital signs, level of consciousness, the cardiovascular system, the musculoskeletal system, among others. In the laboratory exams sub-category we define findings from laboratory tests (e.g. chemistry, toxicology, etc.) [8], imaging tests (e.g. MRI) and other instrumental diagnostic techniques.

The administrative component involves services for scheduling and appointments. In this case, both managers are centralized systems, connecting all citizens with all healthcare providers, which facilitate the efficient coordination of the required actions (e.g. encounters with doctors, visits to laboratory centers, etc.) for the promotion of the citizen's well-being.

As the implementation of the platform is divided into short development cycles (called sprints), use cases and mockups are also used to apply a conformance test of the actual implementation with the functional requirements, at the end of each sprint. This task flow enhances the controlling of the gap between the expectations and the actual outcome of the system.

D. *Interoperability*

An interoperability framework specifies the tools for achieving the exchange of EHR data between healthcare

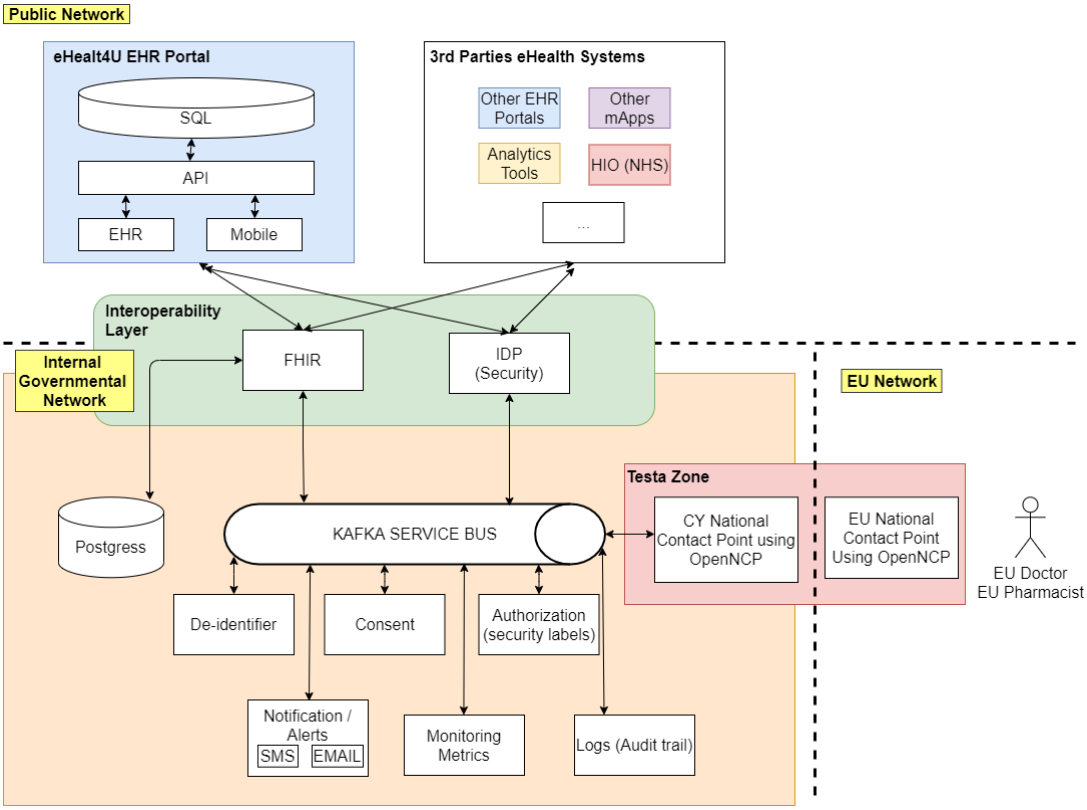

Figure 2: The eHealth4U software architecture diagram.

providers nationally or at a world-wide level. Following the European Commission (EC) recommendation announced in 2019 about the consideration of the possibility offered by resource driven information models (offered by HL7 FHIR) for the refinement of the exchange format of the EHRs [9], the FHIR standard was thoroughly studied, evaluated and selected for implementing interoperability in eHealth4U.

Another provision of the eHealth4U interoperability framework is the capture of citizens' health data in a structured form to facilitate its integration with various 3rd party systems in the national eHealth ecosystem (e.g. public health monitoring systems, etc.). FHIR implementations incorporate structured data allowing resources' elements to have coded values. In eHealth4U, priority is given in exploiting the fixed value sets provided by FHIR specification. The terminologies of SNOMED CT, ICD-11 and LOINC have been used to create value sets where FHIR specification did not fulfill the project's requirements. Finally, where none of the previous two solutions is applicable, a new code system is created based on the specific project's requirements [10]. In addition, a mapping between the EHR fields and the FHIR profiles' elements was made using SNOMED CT, ICD-11 and LOINC.

The eHealth4U is designed to address the requirements for deploying the eHealth services across all European countries, as directed by the eHealth Digital Service Infrastructure (eHDSI) initiative [11] and the European Directive 2011/24/EU [12] on patients' rights on cross border care. More specifically, the functional and non-functional requirements for the eHDSI Patient Summary (PS), ePrescription (and eDispensation) documents are collected and adopted for the eHealth4U. For the needs of the eHealth4U the eHDSI PS is implemented as a document which has the ability to be synthesized dynamically based on a subset of the total data that are contained in an EHR. In this regard, a mapping between the eHealth4U EHR fields and the Master Value Catalogue (MVC 4.1) [13] is done and is included in the FHIR terminology service.

Third Party Systems: Third-party service providers can integrate with the eHealth4U platform via a standardized RESTful interface as defined in the FHIR standard. Guidance on the integration processes will be provided by the Implementation Guide (IG) that will be delivered in the form of a website hosted on the official HL7 implementation guides registry. Currently, there are four ongoing projects that will be integrated as third-party systems with the eHealth4U platform: the electronic cross-border health services, the Digital Green Certificate (DGC), the Covid19-CY National eHealth platform and the CY-Biobank eHealth platform.

The electronic cross-border health services include the eHDSI Patient Summary and ePrescription (and eDispensation) which have been implemented for the needs of Cyprus. The National Contact Point (NCPeH) of Cyprus is responsible for their exchange to any other EU country which also supports cross-border services [14].

The DGC is a European-wide initiative aiming to provide a vital tool towards enabling the safe travelling of European citizens across Member States. A DGC is issued at a national level for citizens that have been vaccinated, recovered from Covid-19, or have a recent negative Covid-19 test result. At the same time, Europe maintains a trusted DGC gateway for the exchange of the necessary information needed to validate a DGC. As a part of the national eHealth ecosystem, a citizen and/ or a personal doctor, via the eHealth4U platform, will be

in position to request a DGC issuance that will be later stored to the citizen's EHR [15].

Covid-19 CY National eHealth platform was developed in response to the worldwide Covid-19 pandemic outbreak as a tool for effective administration of care in a timely fashion to hospitalized Covid-19 patients [16].

The CY-Biobank is a project under the Molecular Medicine Research Center of the University of Cyprus [27]. The main objective of the project is to support the building of a contemporary Biobank research infrastructure fully integrated with the eHealth4U (as the prototype the national integrated EHR system) allowing authorized access to the citizens' EHR data.

III. The eHealth4U Software Architecture

To accommodate the abovementioned requirements, a microservice system architecture has been selected as the most relevant and optimum architecture to facilitate the eHealth4U platform's objectives. The microservices approach facilitates further benefits in addition to the above-described characteristics, such as, data security, easier compliance with HIPPA and GDPR recommendations, flexibility to use different technologies, among others.

In Fig. 2, we illustrate a high-level representation of the software architecture. The eHealth4U ecosystem consists of two layers:

- Internal Governmental network, which can be only accessed by authorized and accredited personnel being responsible for the development, maintenance and monitoring of the eHealth4U platform.
- Public network, which can be accessed by the eHealth4U EHR Portal and other third-party systems.

The internal governmental network comprises of several services such as the KAFKA service, the Postgress database and others. It is responsible for implementing security mechanisms and citizen data management and manipulation processes, including storage. To facilitate communication with 3rd Party Systems Providers, it exposes an interoperability layer (denoted with green colour in Fig. 1). The eHealth4U Portal is a typical example of a third-party service provider residing in the public network that uses the interoperability layer to access and perform a set of operations on a citizen's EHR.

IV. Conclusions

The eHealth4U is a first attempt for creating an integrated EHR solution in a national level. So far, we have implemented the infrastructure which includes data privacy protection based on national and European legislations, the system requirements, several use cases and mocks. The interoperability framework was also defined including the terminologies based on HL7 FHIR standard and selected IHE profiles, which is considered a key point in development. In this frame, the FHIR server was also implemented. The development of the eHealth4U platform is still ongoing. The final product of the project will be tested and evaluated based on a first and early EHR adopters program in Cyprus healthcare using certain clinical showcases. The evaluation period will be split in cycles. By the end of each cycle, feedback from end-users will be received and exploited for the improvement and the fine-tuning of the required platform's functionality.

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