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Implementation of Nationwide Electronic Health Record in Albania: A Case Study

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Abstract. Background: This paper presents a case study of the nationwide implementation of an Electronic Health Record system based on industry standards. Objectives: To critically review the finalized nationwide EHR implementation in Albania, pointing out the achievements and the shortcomings, gained knowledge and sharing lessons learned. Methods: This paper reports on our analysis of the project's documentation, first-hand experience working with healthcare professionals during and after project implementation. The initial system uptake analysis has been made using EHR usage statistics. Results: Despite very poor initial ICT infrastructure, minimal or non-existing medical nomenclature and a rather challenging project schedule, the nationwide implementation of the EHR system was successfully completed in less than two years. Conclusion: Although the system is already in use by 79 healthcare providers and is covering secondary and tertiary care, the majority of clinical data still remains in paper format; the access for clinicians to the system is limited due to insufficient ICT infrastructure.

Keywords. Electronic Health Record; Health Information, public health services, implementation EHR

1. Introduction

In 2012 the government of the Republic of Albania made a strategic decision to adopt industry standards for the emerging domain of eHealth in the country. With the support of the Austrian government, the Ministry of Health of Albania (MOH) launched a nationwide Electronic Health Record implementation project at the end of 2014, which was successfully completed in 2016.

This article provides a case study of the nationwide Electronic Health Record implementation project and outlines the lessons learned, focusing on the area of application of global healthcare information exchange (HIE) standards in Albania. The main objectives of this paper are: EHR implementation results assessment, identification and analysis of the key project implementation components, shortcomings, and factors that contributed to the successful implementation.

1.1. The Electronic Health Record and its Architecture

The term EHR is ambiguous and requires an explicit definition in the scope of this paper. The EU commission has defined an Electronic Health Record as a comprehensive

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medical record or a similar documentation of the past and present physical and mental state of health of an individual in electronic form and provides an ubiquitous availability of these data for medical treatment and other closely related purposes [1]. According to the World Health Organization, an EHR shall contain all personal health information which belongs to an individual [2]. This information shall be entered and accessed by healthcare providers.

Noteworthy, in this paper we omit the WHO imperative that data shall be entered and accessed primarily by healthcare professionals. One of the strategic goals of the Albanian government is the possibility for a patient to access his personal clinical data which is stored in the EHR system. Another valuable source for integrated medical care is the utilization and connection of data collected by medical devices for home use. Finally, the topics of the inclusion of Personal Health Records (PHR) and the possibility of merging these records with the EHR is intended for the future.

According to a HIMMS study [3], there are four major architectural models for a national EHR system. In a **fully federated** architecture model, patient data resides in a local facility. There is no central clinical data repository (CDR). The patient data always remains in the source systems of facilities. The EHR system front-end pulls data from the systems of health care providers. In a **federated** architecture model, patient data resides in a local facility. Patient data is consolidated in local CDRs. The EHR system pulls from a local CDR for updates to a central CDR as needed. In a s**ervice oriented** model**,** patient data is sent to the EHR system by a message at the end of a care event. Local systems are message enabled. The CDR holds care events within a patient record. Finally, an **integrated Electronic Patient Record (**centralized architecture**)** model represents a single integrated system. There are also hybrid models. For instance, France has an architecture model that falls in the category model Nr. 2 and 3. Sweden has an architecture that falls in the category model Nr.1 and 2.

The selection of the EHR architecture model is of fundamental importance. First, it shall meet major non-functional requirements for the information system. Second, it shall be robust enough to support not only the growth of the EHR system but also to accommodate the natural evolution of a country's e-Health ecosystem. Third, the shortcomings and limitations of the selected model shall be accepted and justified for the specific use case. The selected architecture model of the Albanian EHR system is presented in Section 2.2.

1.2. Initial ICT setting and eHealth landscape in Albania before project start

The existing Health Information System in Albania before the project was fragmented [4], of poor quality and in most cases not relevant for clinical and administrative decision-making. Lack of national standards and agreed data exchange protocols and terminology for Health Information Systems resulted in severe shortcomings and limitations of some ICT projects implemented in that time.

The ICT infrastructure in Albanian Healthcare System was underdeveloped and only islands of local area networks of different quality and standards were in place. In smaller Healthcare Provider Organizations (HPO) there was no networks infrastructure deployed. Larger HPOs had a few computers in administration department and statistical back office. In the largest hospitals computers were partially utilized in the admissions.

To the date, only a few information systems have been implemented in public HPOs. The cost accounting application "Kosto Spitali" had been introduced in 2011 [5]. The application has been used to collect statistical and financial data. However, the

application was standalone and relied on a manual data import/export or email communication. By that time, four hospitals have started the implementations of hospital information systems. An open source HIS was partially implemented and deployed. In addition, a specialized clinical information system for the obstetrics and gynecology was partially implemented in two national obstetric gynecological hospitals.

None of these hospitals had an integrated Hospital Information System, they didn't share common code systems or classifiers and thus were not ready for data exchange.

2. Methods

This study employs a single explanatory/exploratory case study design. All authors have in depth knowledge and first-hand experience in the subject of the study and hence are able to analyze and evaluate the technological, governance and change management impact of the EHR implementation. The assessment of the system uptake, user satisfaction and subsequent conclusions have been drawn relying on the extracted statistical data of the system usage and the performed survey of the end-users.

2.1. Project setup and definition of Albanian EHR system.

Prior to the implementation of the nationwide EHR solution, the Albanian government with support of the Austrian government conducted a feasibility study. The study investigated AS-IS situation of the ICT penetration in the Albanian public healthcare sector and has proposed, based on Austrian and EU experiences, a prioritized approach for the informatization of healthcare in Albania.

The study has shown that the majority of public hospitals are lacking network infrastructure. Out of 40 public hospitals only a handful had LAN networks and deployed medical information systems. The fundamental outcome of the study was an outlined prioritization of the necessary ICT activities in the healthcare sector of Albania. Two subsequent major steps were proposed: the implementation of a nationwide EHR system and the subsequent implementation of hospital information systems. Considering the "greenfield" ICT status in Albanian public HPOs, the study suggested to establish an industry standard EHR backbone, which would provide main building blocks for the eHealth infrastructure, as well as to establish well defined data exchange protocols for transport and semantic interoperability. Aiming to address the internet connectivity issues in remote areas, the study recommended the application of a federated architecture for the nationwide EHR, which would enable the operation of local facilities' systems in offline mode. Addressing the limited number of existing information systems and ICT infrastructure, it was suggested that the EHR solution shall include a front-end solution for healthcare providers as well as the necessary ICT hardware required to partially computerize public HPOs.

2.2. Nationwide EHR architecture

The Ministry of Health of Albania (MOH) has decided to implement the Austrian EHR COTS[2] solution, which is based on industry standards and is conformant with IHE

[2] COTS - commercially available off-the-shelf software

profiles recommended by the EU commission [6]. This strategic decision aimed to ensure an interoperable healthcare information exchange, predictable project results and future possibility of connectivity and data exchange with other EU countries through the epSOS/EXPAND project [7, 8].

Based on the outcomes of the feasibility study, a hybrid architecture model was proposed. By the year 2015, the internet connectivity has considerably improved, although limited bandwidth and low quality of service prevailed in remote areas. Considering this development, the hybrid model, combining federated architecture with service oriented architecture was adopted.

The selected architectural model has the following building blocks and features:

1. Local master patient index, XDS[3] register and repository are deployed for each healthcare facility;
2. National master patient index, national XDS register and a copy of all repositories are deployed in a central node;
3. Asynchronous communication of local nodes and central node enables the operation in unstable or none-connectivity mode;
4. Duplication of the MPI and clinical data repositories provide an extra layer of data loss protection.

The foreseen challenges of the selected architecture model were as follows:

1. Mandatory duplication of master data and the consequential necessity to synchronize it;
2. Possible loss or duplication of messages due to asynchronous communication;
3. Higher cost of implementation and maintenance in comparison to a fully centralized model.

The logical scheme of the EHR solution has two major layers – a central node (data center) and local facilities nodes. The central node includes the global master patient index (eMPI), copies of the XDS repositories and registers, the HPO organizations and personnel catalogue, components for auditing, access control, patient policy handling, interface adapters and the reporting module. Each local node is comprised of the front-end portal, a local MPI, a local XDS registry and repository, a HPO organizations and personnel catalogue, components for auditing, access control and asynchronous communication component. The following IHE profiles has been utilized in the system: ATNA, BPPC, CT, XCA, XDR, XDS, XUA, PDQv3, PIXv3, RFD, XPID, XDW, MS, EDPN, TN, and IC.

The presented architecture was designed, implemented and deployed at the national e-government data center (central node) and 79 HPOs in the country (local nodes).

2.3. Semantic Standardization

In the early phase of the project, it was decided to rely on the HL7 CDA[4] level 3 document architecture. However, at the time when the project started, Albania had no

[3] XDS – Cross Enterprise Document Sharing is a defined set of standards and implementation rules for cataloging and sharing patient records across health institutions.

[4] HL7 CDA – Clinical Document Architecture

organizational capacity to manage a healthcare information system standardization. T*he only classifier and nomenclature in use was a local version of ICD9.* Therefore the implementation team faced the challenge of bringing existing or creating new localized classifiers, nomenclatures and standardized clinical documents.

This major project risk was addressed by the MOH by establishing a clinical documentation and standardization working group with appropriate decisive powers which agreed to benefit from existing industry standards and EU recommendations.

The final content and structure of the Electronic Health Record solution is still a work in progress. The current structure which is based on a well-defined semantic data model, framed in HL7 CDA level 3 documents, already promotes a shared understanding of patient data, information exchange between information systems and health care organizations, data retrieval from the EHR system and reuse of data for administrative purposes, statistical analysis or clinical research.

2.4. Technical Implementation Aspects

In this section, we address the critical EHR solution building blocks, related issues and relevant implementation decisions.

2.4.1. Providing ICT Infrastructure for Provider Organizations

Aiming to achieve feasible results within two years and considering the close to non-existing network infrastructure and computerization in healthcare facilities in the country, only a partial computerization was feasible. Furthermore, budget limitations and computer literacy would not allow a fully-fledged computerization of 79 facilities in the project scope. The agreed solution was to support the perimeter workflow, which entails the computerization of the patient entry point (reception/admission/emergency) and the patient exit point (discharge). This approach allows the entry of patient data in the initial and final steps of patient encounter. Patient reception and admission points become computerized hubs where clerks, nurses and doctors can access the EHR system, view or print documents. The deployed network infrastructure includes wireless access points, which give more degrees of freedom when work places need to be rearranged or end users start using laptops or mobile devices.

2.4.2. National Master Patient Index

The universal patient identification was missing in Albania. The existing systems used the patient insurance code, issued by the National Insurance Fund, or citizen's national ID. Obviously, both solutions have their limitations and do not support all typical use cases in the healthcare setting.

The National Master Patient Index has been established, following IHE PIX v3 profile, where a national unique patient ID is assigned and bound with the subsequent patient IDs issued by a local facility node, HIS, Civil Register or National Insurance Fund. It is of key importance that the Patient Index allows querying of all possible patient IDs, which especially simplifies the interoperability with legacy and proprietary systems.

2.4.3. Catalogue of Healthcare Organizations and Healthcare Professionals

Another hindering shortcoming was the absence of a register or regularly updated catalogue of the healthcare professionals and providers'. To address this issue, it was

decided to structure and provide an identity to all Albanian provider organizations, their hierarchical sub-organizations, their IT systems and their personnel using HL7 OID schemes.

The Ministry of Health officially registered the root HL7 OID for Albania eHealth and adopted the structure of the Austrian OID tree to the local requirements.

2.4.4. Patient Data Privacy

Patient data privacy is the cornerstone of an EHR system. Many layers address this issue, starting from physical access control to servers and computers, network protection and isolation and definition and management of end-users access control levels. Furthermore, all activities in the local and central nodes of the EHR are audited according to the IHE ATNA profile requirements.

Finally, a patient is entitled to explicitly decide if he or she is willing to share clinical data and if these data are made accessible in other public healthcare facilities through the EHR platform.

The patient consent management and policy enforcement is based on various international standards like IHE XDS, BPPC and OASIS SAML and XACML.

The patient can decide to allow remote access to documents stored in other communities with an OPT-OUT/OPT-IN policy. If no consent document exists for a patient the default consent is denying data exchange among healthcare facilities. In the case a patient wants to participate, he must OPT-IN to the healthcare information exchange. Changing the consent is possible at any time at any healthcare facility or through the citizen e-government portal.

3. Results

The nationwide EHR solution is deployed in 79 public HPO in Albania: 4 university hospitals, 11 regional hospitals, 25 district hospitals and 39 specialist out-patient clinics. All facilities are equipped with network infrastructure, a local EHR node and computerized workstations.

In total, 2.300 ICT hardware items have been deployed, which include datacenter equipment, network infrastructure and computerized workplaces for each facility. In 79 institutions, we have computerized 296 work places.

During project implementation period 2740 end-users have been trained and have been provided with the access to the system according to their roles: 1200 receptionists and operators, 1500 nurses and doctors, 40 administrators for local facilities and centrally at MoH.

From June 2015 until December 2016 there are a total of 196.624 patient encounters registered in the national EHR. The system adoption trend for the last five months of 2016 is shown in Figure 1.

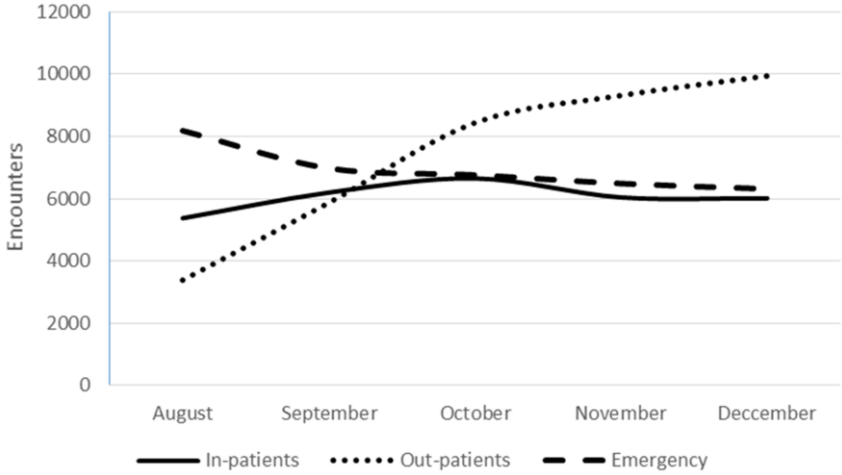

Figure 1. Nationwide EHR system in Albania uptake statistics

3.1. First EHR implementation outcomes

The most noticeable outcomes after completion of the system rollout are as follows:

- Integration with the e-government platform through e-government Electronic Service Bus, allowing to query and receive high quality patient demographic data.
- Improved patient flow control due to a better patient demographic data collection.
- Implemented front-end portal and BI component, allowing the minimization or complete elimination of paper journals for the registration of patients in the facilities.
- Creation of standardized electronic discharge summaries, emergency physician notes and out-patient visit summaries.
- Provision of direct access through the patient portal and of indirect access through an API to clinical data stored in clinical document repositories.
- Exchange of clinical documents and health information between 79 health care facilities and the possibility to connect a non-limited number of further public HPOs, e.g. GP offices.
- The Albanian Health Data Dictionary [11] was appended with the following coding systems and classifiers:
    - LOINC: CDA DocumentCode, CDA SectionsCode, CDA EntryCode;
    - HL7: PersonalRelationshipRoleType, RoleClass, TelecommunicationAddressUse, TimingEvent, URLScheme, ObservationInterpretation, ActSite,
    - EDQM: DoseForm, Package
    - ISO: ISO 639-1 (LanguageCode), ISO 3166-1 (CountryCode
    - UCUM: Units
    - Albanian classifiers: Allergy, AdverseReaction, ProblemCode, TargetSiteCode, Severity, SocialHistory, StatusCode

4. Discussion

Given the complexity of eHealth projects and high diversity of the healthcare sector environments, an objective assessment of eHealth initiatives has proven to be a challenging task. Nevertheless, we try to evaluate this EHR implementation project through the dimensions of the project goals achievement and the assessment of the main project deliverables.

We have identified various shortcomings and indispensable compromises, which have the potential to influence the decision-making process in other e-Health projects and may support the completion of e-Health environments in other countries.

4.1. Assessment of achieved Results and Recommendations for other nationwide EHR Solutions

4.1.1. Management and governance aspects:

1. **Achieved level of informatization.** The initially planned partial computerization of 79 healthcare facilities has been fully achieved and exceeded. The risk buffer of 10% for main equipment components was sufficient. The critical success factor has been the strategic decision of the implementation team not to rely on the deliverables of third parties, i.e. infrastructural pre-installation efforts and to cover these activities in the scope of the project.
2. **System adoption trends**. Given the experience in other countries [12], the adoption rate of this EHR system is adequately growing. As shown in Fig. 3, the growth rate is uneven and differs depending on the respective healthcare process. The uptake for instance in emergency departments started to decline after the first months. The main reason has been that the computerized clinical documentation template did not match the workflow of the emergency departments. Another negative influence has been the shortage of ICT infrastructure in every hospital ward. The processes of auxiliary transcribing and required patient folders logistics are tedious and interfere with the system usage.
3. **E-Health governance.** Similar to the experience gained in other national EHR implementations [13], we have realized that an active participation of the main stakeholders (management of MOH and HPOs) as well as the involvement of the relevant entities such as legal departments and personal data privacy agency on at the early stage of the project is of key importance.
4. **Patient data privacy.** A patient data protection action plan has been developed and implemented to ensure a high level of patient data protection. Reflecting early obtained experiences of the system usage, we have identified two fields where the current situation shall be improved. First, more strict access level control shall be implemented, introducing the concept of the treatment relationship between patient and healthcare provider. Second, the patient data sharing consent policy shall be extended to provide more flexibility for the sharing of subsets of the patient's EHR data to certain HPOs or clinical specializations. Conversely, such advancements require thorough discussions and the acceptance of medical and patient communities.

4.1.2. Technical aspects:

5. **Hybrid EHR architecture** (federated and service oriented). The implemented architecture has proven to be able to provide a robust and reliable solution for remote

facilities with unstable internet connectivity. However, the maintenance of such infrastructure requires a highly skilled team and a professional and well attuned cooperation between the 1st, 2nd and 3rd level support.

6. **Achieved interoperability level.** During project implementation, two interfaces with HIS and two interfaces with national information systems (e-government platform, e-citizen portal) have been implemented. Noteworthy, the learning curve of the medical IT domain and the implementation of IHE transactions may be a challenging task for IT specialists from other domains. Therefore a simplified *proxy API* based on web services or a REST API can be a valuable tool for minimizing the integration effort.
7. **National clinical document repository (CDR) based on IHE XDS profile**. The implemented CDR completely fulfills the current needs. Currently, we are planning to extend its usage and to store electronic clinical documentation which is generated in other national systems, i.e. adult check-up, immunization and e-prescription.
8. **National master patient index based on IHE PIX and PDQ profiles.** The implemented MPI supports the matching and linking of patient records, based on Levenshtein [14] or weighted match algorithm [15]. Initially, the MPI has been deployed as a standalone register, which appeared to be a significant shortcoming of the whole EHR backbone and had the potential to negatively affect the entire e-Health ecosystem. In the final phase of the project, the interface to the national Civil Register (CR), which covers more than 98% of the patients, was deployed. The implemented interface to the CR minimizes data entry error rates and saves time by avoiding the manual entry of patients' demographic data. Most importantly, it prevents, otherwise unavoidable, numerous patient records duplicates.
9. **Healthcare providers and their personnel catalogue based on IHE HPD profile.** The implemented hierarchical healthcare provider catalog (directory) based on HPD profile was an important step, which has resolved the missing functionality required for the implementation of national EHR system. However, at the present moment, we can state that this component is insufficient and a full-fledge HPD register shall be developed as a separate project, which would fulfill all requirements for the management of healthcare professionals master data records.

4.2. Limitations

The authors of this paper have been directly involved in the implementation of the nationwide EHR project in Albania. Although our intention has been to remain neutral and constructive, possible bias in the assessment of the results and the overall evaluation may occur.

Moreover, the evaluation timeframe after completion of the project is still too short to draw a solid conclusion on the final results. Therefore further studies are required to examine the effects and impacts of a nationwide EHR on the healthcare landscape in Albania.

4.3. Future work

Several important activities are already in an implementation phase and others are in a planning stage. The integration with the Albania citizen portal is currently undergoing testing and is waiting for the final acceptance. The e-Health section of the portal will allow Albanian citizens to access their medical documents stored in the EHR system. It

will provide an auditing report and will allow the submission of consent for data exchange between health care institutions.

It is planned that all implemented national e-Health systems will be connected to the open and standard based EHR backbone. This will affect the recently implemented and deployed adult check-up system and the e-prescription solution.

Another important direction to be addressed is the further informatization of public hospitals. The Ministry of Health has started preparatory work for the implementation of hospital information systems in all regional hospitals in the country. All new IT systems for clinical information management, procured by the MoH, will be connected to EHR backbone.

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