IMPLEMENTATION OF THE NATIONWIDE ELECTRONIC HEALTH RECORD SYSTEM IN SERBIA: CHALLENGES, LESSONS LEARNED, AND EARLY OUTCOMES

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SUMMARY – Objectives: Many countries around the world have recognized the need for using an electronic health record (EHR) system. However, there is limited literature that could serve as a guide during a lengthy and challenging process of planning, development, and implementation of the e-Health system. Since the EHR system was recently introduced in Serbia, the purpose of this communication is to describe our experience and lessons learned along the way. Methods: The key personnel involved in the implementation of the EHR system in Serbia that began in 2015 conducted in 2019 a retrospective narrative review of the process and early outcomes. Results: An incremental approach in the planning, development, and implementation of the nationwide EHR system was taken. The process was split into phases with the gradual introduction of different regions of the country. The gradual shift from the existing to a new workflow for the prospective users was also implemented. The significant milestones were the achievement of quick legislative changes, the hiring of a professional team of experts in the field, the provision of timely and appropriate information and training to prospective users, the close collaboration between the implementation team and the Ministry of Health and mutual understanding of the aims and expectations, and the flexibility in accepting the evolving nature of the process, goals, and the system model. Conclusions: A successful implementation of the nationwide EHR system is feasible providing careful planning, the assembly of a multi-disciplinary team, the use of a stepwise approach, the early and continued involvement of the intended users, and the willingness to make adjustments along the way. The end-result sets the stage for the reform of the health care system itself.

Key words: *Electronic Health Record (EHR) system, E-health system, Electronic Medical Records (EMR), development and implementation, Serbia*

Introduction

The technology has an important role in interactions between medical doctors, nurses, and patients. It enables reducing the number of errors, increasing the provision of more appropriate evidence-based treatments, and higher efficiency. Many countries worldwide recognized the need for implementing an electronic health record (EHR) system. Different countries have chosen one of the many existing models of the EHR system and different pathways of implementation[1].

An EHR is a database of the patient's digital health characteristics[2]. The EHR is a tool for improving the quality, safety, and efficiency of the health system. Patients' data are constantly added to the EHR

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system during each encounter with health care professionals. Therefore, such an E-health system enables continuous improvements in the process and quality of services provided and better performance of a management system[3]. The benefits of EHR are recognized in both developed and developing countries[4]. However, the developing countries have been comparatively slower in their adoption due to high acquisition costs. On the other hand, and notwithstanding the benefits, the experience from England indicates that software systems may have some difficulty in fulfilling organizational and user needs [5].

The World Health Organization data show that many countries across Europe have already implemented EHR systems[6]. However, different countries developed and applied the EHR system at various levels of health care, which are performing sometimes only limited functions. So far, only a few countries have implemented EHR across all levels of health care and have seen many benefits. Many countries experienced difficulties in the implementation of such a system and some chose to temporarily or permanently discontinue the implementation process. In general, barriers for implementing EHR system in about half cases were high cost[6], problems with defining the scope of the system[1, 7, 8], problems with the development team, adoption of the implementation process put forth by the 2017 International Conference e-Health, limited timeframe, and regulatory and legislative issues.

Objectives

We conducted a retrospective narrative review of the process and outcomes associated with the development and implementation of the nationwide e-Health system, which was initiated in 2015 and brought to completion in 2019, to describe challenges, lessons learned along the way, and early outcomes. The lead author of this communication was directly involved in the process and was one of the key team leaders.

Electronic health record system in Serbia

In the Republic of Serbia, the project for the development and application of a national e-Health system was initiated in 2015. Before starting the project, and based on the awareness of the problems in other countries, a comprehensive analysis was made concerning the health system in our country and the prerequisites for the development and application of the EHR system were identified. The intent was to avoid factors that could adversely influence the development and application of the EMR system in Serbia. Some of the anticipated challenges included resistance to change caused by the introduction of a new system, lack of knowledge and competencies of some participants in the process, complexity of the system and perhaps unrealistic expectations from some participants.

To overcome the challenges from previous projects that involved the limited application of the e-Health system in our country, as well as to learn from experiences of other countries, the project team obtained strong political support from the Ministry of Health. The project team needed operational support for introducing changes in a routine health care environment. It included not only regulatory changes but also the definition of organizational and personal needs to create a new electronic health model. A model of an adapted centralized system was applied, which included the central national system connected with already existing local systems in healthcare institutions. However, it was also necessary to create a functional interface for users in healthcare facilities that did not have an electronic system already in place. Therefore, the first steps were to describe the envisioned system, define project management and the timeline, and address experience during the startup and application of the project.

Prerequisites for the development of the e-Health system and its application in Serbia

Implementation of EMR system in the health care institutions in Serbia has been a continuous process dating back to late '80 although only a few primary care facilities and hospitals had their own Hospital Information System in place. One of the major prerequisites for the nationwide initiative described here was a successful implementation of computers and related software in the primary healthcare system (2006-2013) thanks to the support from the World Bank. In many Southeastern European countries, similar projects were formally completed and considered successful although the implementation into a routine practice did not practically take place. Accordingly, the World Bank report concerning these projects stated: "Many public sector digital technology projects fail"[10].

Learning from failures in other countries, a pilot EHR project was designed and implemented first. The proposed model of EHR was decentralized, but it included standards for interoperability and infrastructure

that allowed mutually connected institutions. We recognized that national regulations should be adjusted to accommodate the implementation of the EHR system into the institutions, including the way it is functioning as well as the necessary software and hardware[11]. As a result, the Health Care Law of the Republic of Serbia and the Law on Health Records of the Republic of Serbia were updated to regulate the development and implementation of the e-Health system[12, 13]. However, unlike in Northern Macedonia, which had the same e-Health system, the approved legislation allowed for greater flexibility and provided options for future changes without involving the National Assembly.

These changes had to be done timely and in close connections with an ongoing broader reform of the health care sector as defined by the 2017 International Conference e-Health. Therefore, the need for careful consideration and timely legislative updates is one of the valuable experiences of the Serbian Healthcare Authorities in the preparation for the implementation of the e-Health system.

The model of the national e-health systems in Serbia

The model for the national e-Health system and EHR system was selected based on the experience from other countries in the region and the likelihood of developing a specific technical solution we needed. The national system was envisioned as an operational ecosystem that connects functionally all health care facilities and central government institutions of public healthcare. This system should not only be operational for integration at the national level but also as a tool for future planning of strategic initiatives concerning reforms in public health.

Integration of the whole system includes, for example, primary health care that uses modules for e-booking appointments and e-referrals to other physicians, while at the level of secondary and tertiary healthcare, the module for hospitalization is obligatory. This structure also enables the bidirectional exchange of data between these levels of care. Moreover, the chosen model is also able to integrate other relevant systems, such as The Republic Health Insurance Fund, the Medicines and Medical Devices Agency, the Institute of Public Health, etc. Therefore, it was planned from the outset that the Institute of Public Health has access to the Business Intelligence module through a bidirectional web interface. This approach had several advantages:

1. Reliance on already existing software in health care and government institutions with the possibility of performing upgrades without interrupting the data flow.
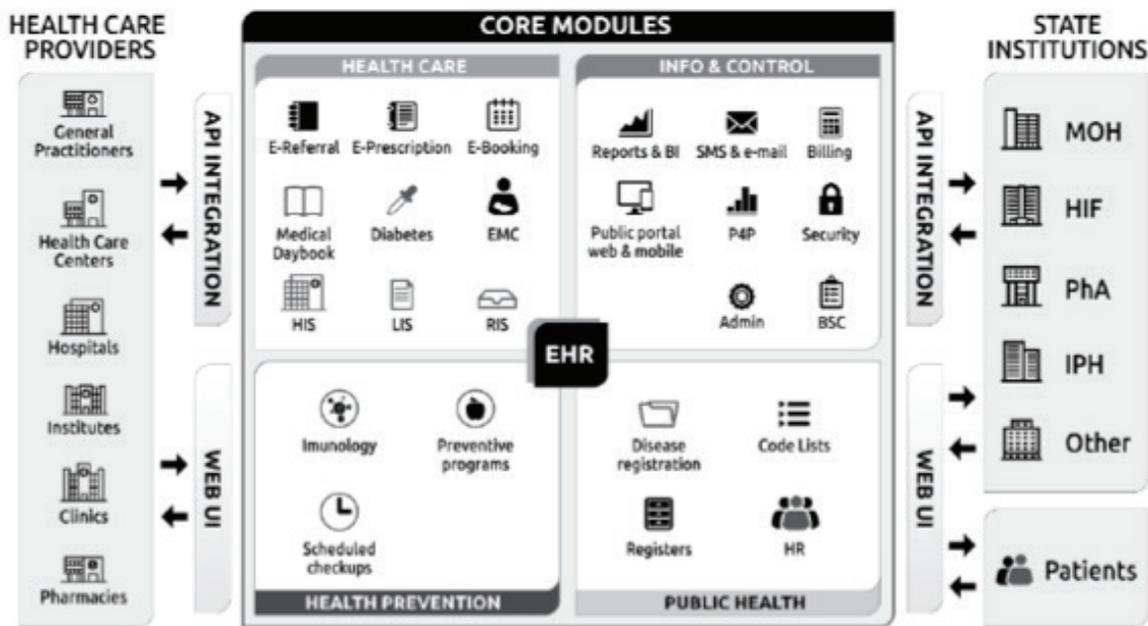

Fig. 1. Architecture of the national e-health system

2. The approach proved valuable for overcoming the resistance to learning new software.

3. The users not previously exposed to e-Health technology could quickly become accustomed to a new interface thanks to simply defined procedures.

4. Data security was considered important given the need for confidentiality of personal health information.

5. It was possible to integrate 57 already existing information systems at the national level. Application Programming Interface I was created enabling quick integration and synchronization processes, while minimizing technical errors, etc. Moreover, Extensible Markup Language (XML) based standard allowed data exchange enabling the integration based on interfaces. Built-in were also relevant international system, such as 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10) for diagnosis coding, Anatomical Therapeutic Chemical Classification System (ATC coding) developed for the classification of drugs and other medical products, as well as Diagnosis Related Groups (DRG) classification system [14] for healthcare services.

6. In the case of functions that are not handy for users, fast repair and improvement are possible.

The highest level of the system architecture was based on the Pinga Platform (Figure 1). Functional modules were grouped into 4 sections:
1. Healthcare consisting of system parts, Hospital Information Systems (HIS), Laboratory Information Systems (LIS), and Radiology Information Systems (RIS); Healthcare module are the following: e-Referral, e-Prescription, e-Booking, Medical Daybook, Diabetes, E-Mother Card.
2. Information, monitoring, and control: Reports and Business Intelligence (BI), SMS and E-Mail, Billing, Web & Mobile Public Portal, Payment for Performance (P4P), Security, Admin. Balanced ScoreCard (BSC).
3. Health prevention: Immunology, Prevention Programs, Scheduled Checkups.
4. Public health: Disease Registration, Code Lists, Registers, Human Resources (HR).

The web user interface is provided through modules. Integration with other systems is enabled via API, including e-Referral, e-Booking, e-Prescription, Medical Daybook, HIS, LIS, and RIS.

Implementation of e-Health system in Serbia- "Moj-Doktor"

Integrated Health Information System (IHIS), named "MojDoktor" (MyDoctor) was introduced in 2015. It consists of multiple modules, including e-Booking, e-Referral, e-Prescriptions, Medical daybook, Disease registers (for Birth, Cancer, Diabetes, Cardio-vascular diseases, death, etc.), Reports and Business Intelligence. The procedure for implementing the procurement lasted from June to August of 2015. Bidders had to develop a functional prototype by September 2015. After completing their evaluation in November 2015, the decision was made to proceed with the system based on the Pinga Platform, i.e. the e-Health system that was already being used in the Republic of Northern of Macedonia.

The first decision made was to develop a prototype model (methodology of Evolutionary prototyping)[15]. The developed prototype included completely functional modules and interfaces: web user interface and API for integration with the systems in health care facilities as well as central state institutions - the State Health Insurance Fund, the Institute of Public Health and the Medicines and Medical Devices Agency of Serbia. Simulation of the functioning of interfaces for the integration of the prototype with the other systems was made. The project for the development and implementation of the system was carried out in two major phases. Prince II and ITIL V3.0 technology guidance approaches were used and adapted to serve as a framework for the delivery of services envisioned.

The first phase was the development. This phase took place from November to December 2015. It was dedicated to the analysis of the health system in Serbia with emphasis on processes that should be automated with the central e-system and the analysis of the current equipment in the institutions - network infrastructure and connectivity to the Internet, workstations, medical information systems. As a result of the analysis, documents were prepared with recommendations for technical upgrades of health facilities and changes in laws and regulations, extending medical documentation, etc. For example, extending the content of the referrals with mandatory fields has been done: the exact time of the appointment, the name of the doctor, or the name of the institution where the

patient is referred to. Also, changes in workflow within and between health facilities were proposed. For example, all doctors were obliged to create calendars of planned activities for the following month, their managers had to provide approval and the administrators had to publicize the public part of the calendars. Another example is the change in a referral process for an episode of the treatment; all initial referrals are made by a general practitioner to the most appropriate specialist, who in turn could make further referrals as needed, thus eliminating the need for a patient to go back to his general practitioner for all subsequent referrals, as required before.

The second phase was dedicated to the dissemination of the system. This ran from January to June 2016. The goal was to disseminate the system to all institutions nationwide and begin to functionally use all modules. For this, two sub-phases were planned; first, the integration of the existing hospital information systems for users that will continue to use local systems and secondly, the inclusion of institutions lacking adequate hospital information systems for users that will directly use the put in place national system.

The integration of the local systems took place in sub-stages by incorporating groups of the developed modules; e-Booking and e-Referrals (in March 2016) e-Prescriptions (April 2016), e-Daybook/Protocols (May 2016), and Registers/Business Intelligence, Admin (June 2017) In parallel, implementation in institutions was organized, with the first introduction in the regions that gravitate toward large tertiary care clinical centers (university hospitals in Nis, Kragujevac, Belgrade, and Novi Sad). The division of the territory in four regions that gravitate toward clinical centers was the most appropriate because very few patients are referred from one region to another.

An important step in the implementation was the system promotion, i.e. informing prospective users of the purpose and foreseen benefits of the system. The first step was to get the information to the managers and IT administrators at each health facility. Joint presentations were organized in each of the four regions to explain the system objectives and present the basic system functions. After these presentations, training sessions for the users were performed.

Within the development phase, five-day training was carried out in December 2015 for a group of 20 "super users" from the major health care facilities and the Ministry of Health. After that, "super-users"

trained facility administrators. From the previous experience, it was decided that each facility should have at least one person with technical education or high computer knowledge assume the role of a local system administrator with the highest account privileges and in charge of training and supporting end-users. Larger facilities were allowed to have more than one administrator. At the beginning of the dissemination phase, it was realized that the initial training was not sufficient and that it was necessary to directly train the administrators. Thus, two-day training for administrators of facilities was organized in all four regions. In facilities where the system introduction was difficult to realize, either the administrators were individually trained or the training was directly provided to medical doctors at those health care facilities. Some users attended more than 3 training session before beginning to use the system. The most common reasons for additional on-site training was insufficient knowledge of the work processes and the functioning of the health system or the lack of technical skills. Persons who could not carry out the training of end-users were considered inappropriate to have a role in further implementation of the system at their health care facilities.

In the phase of the system dissemination (January-June 2016), 18 two-day training sessions were held for facility administrators and over one thousand individual training sessions. In the Clinical Center of Serbia alone (the largest one in Serbia), 60 group sessions and additional presentations originally assigned to software companies were provided. The training and three additional presentations for employees in the call centers and those from the pharmaceutical chamber were also held. Nearly 6 thousand hours of training for various users of the system were given in this phase. Additional training and assistance were provided on-site to accommodate the evolving needs of the users along with the minor system revisions before the system warranty expiration on December 31, 2016.

The system began to be intensively used in a very short time. The total number of individual patients in the system grew very rapidly considering the population of Serbia just over 7 million according to the 2011 census. At the same time, the average waiting time from the appointment to the actual examination was shorter in comparison to the period preceding the implementation.

Discussion

For more than two decades, various electronic health record systems existed in the Serbian health care system[1]. The newly implemented e-Health system goes far beyond patient data and includes the Health Information System (HIS), Electronic Health Record (EHR), EHR applications, Personal Health Record (PHR), Electronic Health Card, and Electronic Prescription[18]. The created IT ecosystem encompasses many items concerning patients and enables more efficient interactions between medical doctors, pharmacists, laboratory staff, and governmental entities. The e-Health system implementation has already given excellent results affecting most of the segments of the Serbian healthcare system. It also received the recognition of the appropriate European professional bodies. Namely, the country was ranked high in the 2017 report of the European Healthcare Consumer Index[9]. In this report, Serbia was listed as "the climber of the year" for 2016 as it continued to implement the project successfully.

The integration of e-Health technologies in Europe was implemented to provide better health services for patients and the opportunity to control and analyze the economy and quality of the healthcare system. Depending on the socio-economic situation, each country sought to find the best way of dealing with health system management and control[16]. However, the implementation of e-Health systems is not a simple task. This is even more difficult in Balkan countries for many reasons, such as the lack of fully cooperative and constructive behavior by some of the central institutions, individual and collective resistance to change and the built-in skepticism that any change will lead to improvement, the opportunism of some persons involved. In such circumstances, the successful implementation of large systems is difficult. That is why previous attempts were not successful in our country even though the successful implementation of information systems is rare in the Balkan region.

In Serbia, however, similar to the situation in the Republic of Northern Macedonia[17], a "magic solution" was discovered through the identification of an appropriate technical solution, careful implementation strategy, and proper planning of activities. It involved gradual scaling of operation which allowed shortening the implementation deadlines and tightening of the way the system is being used. This collectively helped to rather successfully overcome many challenges.

In the US, which healthcare accounts for about 20% of the gross domestic product, only 3.7% of the hospitals have fully instituted the EMR system according to the 2016 report[1] following the 2015 federal law. Jha et al. showed low levels of adoption of e-Health records in US hospitals, suggesting that policymakers faced substantial obstacles to the achievement of health care performance aims that depend on health information technology[2]. A policy strategy focused on financial support, interoperability, and training of technical support staff is necessary to spur the adoption of e-records systems.

One of the benefits of e-Health system implementation would be significant reduction of healthcare costs in Serbia[19]. Namely, the Serbian health system has difficulties in achieving an adequate financing[20, 21]. Based on latest data, current health expenditure (CHE) as percentage of gross domestic product (GDP) in Sebia is 8.4% (total GDP accounts for 50.597 billion US$)[22, 23]. Therefore, further successful implementation of e-Health system would enable redirection of funding to other health care services which could not be financed so far, including advanced technology in establishing precise diagnosis[24]. Moreover, in many clinical situations, like ischemic stroke, higher number of comorbidities is generally associated with worse functional outcomes of medical rehabilitation[25]. In situation like this, HER will probably enable more efficient and reliable source of information concerning patients like this one, which would enable better functional outcome after stroke.

Conclusions

An incremental way of development and implementation of the nationwide e-Health system in Serbia appears to be successfully implemented. It was organized in phases through a gradual introduction of regions. The gradual introduction was also implemented in the workflow of medical professionals and doctors as users by moving from the existing way of working towards the new ones.

Quick and appropriate legislative changes were made, before or during the process of the system implementation. It included changes to laws about the e-Health system with a detailed and precise definition of the e-Health system and the manner of its usage. The strategic commitment of the Serbian government and the involvement of the health minister provided strong support for the implementation of the e-Health system.

The important step was hiring a competent team of experts from different fields and the developers of the e-Health system. Collaborative work of the developer and implementation teams with the Ministry of Health on a clear understanding of the aims and expectations was also vital. Flexibility in accepting the change of objectives and appropriate adjustment of the system model as well as clear procedures for implementation were present all the time.

Of particular benefit for the implementation was timely and appropriately given information to the prospective users about the system operation and perceived benefits to the workflow across multiple points of care provision and most importantly to patients. Adequate training of system users at all levels was crucial as was the ongoing evaluation and adjustment in the training approach.

Conflict of Interest

The authors declare that they have no conflicts of interest in the research.

Protection of Human and Animal Subjects

The study was performed in compliance with the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects and it was reviewed by the Serbian Ethical Committee.

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Sažetak

UVOĐENJE NACIONALNOG ELEKTRONIČKOG SUSTAVA BILJEŽENJA ZDRAVSTVENIH PODATAKA U SRBIJI: TEŽAK PUT SA DOBRIM ZAVRŠETKOM

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Ciljevi: Mnoge su zemlje diljem svijete prihvatile potrebu za uvođenjem elektroničkog sustava bilježenja zdravstvenih podataka. Cilj je ovog rada opisati nužne uvjete za početak razvitka i uvođenja sustava za e-Zdravlje u Srbiji te opis projekta koji je uveden u našoj zemlji.

Metode: Opisali smo nužne uvjete za početak razvitka i uvođenja sustava e-Zdravlja i načina na koji je projekt uveden u našoj zemlji.

Rezultati: Uvedena je metoda za postupni razvitak i uvođenje nacionalnog sustava elektroničkog bilježenja zdravstvenih podataka u Srbiji. Uvođenje je organizirano u fazama, postupnim uvođenjem regija pomoću funkcionalnih modula. Postepene promjene su također uvedene u rad medicinskih liječnika kao korisnika, od postojećih metoda prema planiranima. Najvažnije faze razvoja i uvođenja bile su: brze legislative promjene, pravovremeno i primjereno pružanje informacija korisnicima sustava, trening za primjereno korištenje sustava za sve korisnike, kolaboracija timova za implementaciju sustava i timova Ministarstva zdravstva, jasno razumijevanje ciljeva i očekivanja i od strane Ministarstva zdravstva i uvoditelja sustava, fleksibilnost u prihvaćanju promjena u ciljevima i primjerenim podešavanjem modela sustave te zapošljavanje primjerenog profesionalnog tima stručnjaka u tom polju.

Zaključci: Elektronički sustav bilježenja zdravstvenih podataka smatrao se vrlo važnim alatom za uvođenje mnogih reformnih mjera u samom zdravstvenom sustavu.

Ključne riječi: *elektronični sustav bilježenja zdravstvenih podataka; e-zdravstveni sustav; razvoj i uvođenje; Srbija*