Implementation of the IHE XDS in Electronic Medical Data Interchange

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Abstract

A new integrated information system, based on electronic document, is to be implemented in the Polish Health Care System in 2017. Electronic medical records are the obligatory form of medical documentation in this system. Two crucial elements of this system are: EHR (Electronic Health Record), i.e. defining criteria and standards of electronic medical documentation and constructing a communication system allowing exchange of data and information between various institutions – stakeholders functioning in the healthcare system. IHE XDS (Integrating of Health Enterprise Cross Enterprise Document Sharing), developed specially for usage in healthcare systems, should be implemented in the Polish healthcare information system as both a local and global solution. European Union regulations dealing with electronic public service, openness and interoperability of information systems are important requirements and standards.

Key words: medical data, IHE XDS, electronic public service, interoperability, openness

Stowa kluczowe: dane medyczne, IHE XDS, elektroniczna usługa publiczna, interoperacyjność, otwartość

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Effective implementation and smooth functioning of the electronic workflow of medical records is crucial for the digitalization of healthcare in Poland. The transition to a higher level of information processing enabled by the use of digital data resources regarding medical events is dictated firstly by the need to adapt the current model of providing healthcare services to the needs of the aging population, and new organizational conditions where this care is provided. Secondly, as a member state of the European Union, Poland is committed to the consistent implementation of Community guidelines in the field of integrated healthcare system based on modern information and communications technologies [1]. The implementation of the Electronic Health Record and the construction of an integrated information system of healthcare based on electronic documentation and teletransmission has

been underway in Poland for several years now, and according to the already modified guidelines should start functioning in 2017. One of the basic elements of this system is the efficient exchange of data and information between the vast number of diverse companies operating in the healthcare system.

The solution enabling efficient digital data exchange also in the information system of healthcare are data transfer buses. The integration of electronically supplied services, in particular access to the data collected, for example, in data warehouses or in cloud computing, is enabled by data transfer buses. In this paper we present the concept of using IHE XDS (Integrating Healthcare Enterprise Cross Enterprise Document Sharing) telecommunications paths in the information system of healthcare being constructed. The possibility of processing electronic medical records (or, speaking more broadly, digital medical data concerning the patient) in the information system of healthcare has many benefits, which include [2]:

- improving the availability of medical services for patients (equal access for eligible beneficiaries, shortening the waiting time, rationalization of resource use);
- supporting the continuity of care (by improving the coordination of actions and information processing by medical entities);
- improving the safety of treatment (rationalization of clinical decisions, the emphasis on reducing the health risks associated with study drug);
- improvement of quality of care as perceived by the patient (in the context of the level of satisfaction, effectiveness and efficiency of healthcare provision).

Electronic public service

Modern IT solutions are becoming increasingly popular tools to support the provision of medical services in EU countries. Regulations contained in the European directives and introduced into the national legal system contribute to the formulation of the concept of 'electronic public service', meaning public service provided electronically [3]. The definition of electronic services included in the EU 'services' directive (77/388 / EEC), and implemented in the Polish act on electronic services, specifies that the service "is provided only using ICT, via the Internet or another digital network" [4, 5]. In force since January 2012, the Act on the information system in healthcare includes many advanced solutions and new medical functionalities of information systems that change the current model of health services [6]. Its aim is a multidimensional application of ICT and telecommunications integrating the processes of providing medical services in the healthcare system. Efforts in this area contribute at the same time to the development of information society, where a prompt and efficient processing of reliable information is becoming increasingly important [1].

On the other hand, transfer processes affecting such vast amounts of health data in a digital format (the socalled sensitive data) with an extremely broad semantic range and a diverse and intricate structure, is an extremely difficult organizational challenge for the present national information infrastructure understood as a series of complex, connected resources and information systems determining the functioning of the state as a whole, such as standards of information, information resources, information systems, information institutions as well as organizational structures and technical equipment used to support the collection, storage, processing and transmission of information in information processes and systems [3]. These difficulties are further complicated by the strategic importance of the healthcare information system as one of the key domain information systems of the state. According to the adopted premises of the healthcare information system in Poland, it fulfils the following roles: 1. shaping the information conditions for making long-

term, optimal decisions in health policy regardless of

the adopted organizational model of healthcare and the principles of its financing;

- 2. ensuring a stable information system, which, on the one hand, has a flexible approach to the organization of the system of healthcare (including the model of financing public funds benefits), on the other hand, remains resistant to disruptions in the collection and archiving of data due to system changes in healthcare, as well as
- 3. organizing the information infrastructure of the healthcare system by integrating all existing systems and registers and ensuring convenient exchange and analysis of collected data, based on the principles of openness and interoperability [7].

Openness and interoperability

In the context of the exchange of electronic medical data, the function of 'organization through integration' seems to be of key importance for the currently executed stage of computerization of the healthcare system. However, in order for the organizational function of the healthcare information system to be effectively put in practice, exchange and analysis of collected data should be based on the criteria of openness and interoperability. The importance of the first term refers to the definition of the so-called open standard, which - in order to gain the status of 'openness' - must meet the following conditions: (1) provide the opportunity to participate in the development of specifications for any person concerned (2) the standard itself is subject to public verification, (3) standard specification is available for free for everyone, and (4) the specification can be implemented using a variety of software development models [2].

The use of open standards is characterized by a large measure of discretion for the user – as a rule, their use cannot be subject to any legal or technical restrictions. The attribute of 'open' standards is consistent with the growing popularity of the so-called 'technological neutrality' principle, under which open standards should be used wherever available [8]. On the other hand, the use of open standards in the exchange of electronic medical data is held within the framework of the so-called 'interoperability principles' - the second element which determines efficient processing of information in the information system of healthcare. In the literature, interoperability has acquired different definitions, whose form and scope vary depending on the adopted perspective of the user. According to standardizing organizations dealing with the unification of standards and protocols used in the exchange and processing of information, this term means "the ability of two or more systems or components to exchange information and to use it" [9] or "the capacity of various functional elements of information systems to communicate, run programmes, or transfer data between one another in a manner not requiring any knowledge of the user, or requiring minimal knowledge of the unique properties of these elements" [10].

A slightly different interpretation of interoperability is assumed by the companies and market organizations

working in the field of information and communication technologies. For those entities, it mainly means "the ability of two or more entities to exchange information and to use the information exchanged between one another. Interoperability includes in particular interconnectedness (the capacity of two or more computer systems to exchange data and to use the data exchanged between one another - authors' note)" [11] or "the possibility of an efficient, effective and consistent communication and information exchange between different systems, applications, and computer networks, and the use of the resulting information" [12]. Some sources, apart from defining interoperability, also distinguish the levels at which the capability of exchanging information may be implemented [13, 14]. In the four-level model of interoperability, the first one provides the integration of the application using technical specifications, making possible the application-to-application integration type. The second level is conditioned by the possibility of accessing information and replacing it using the technical specifications for the exchange of files, character sets, encoding, etc. The third tier allowing the exchange of information using interoperability principles are the technical specifications ensuring safety of the transfer of the information exchanged.

The fourth level of interoperability is assumed to be the capability of communicating (within the afore-mentioned interconnectedness) using technical specifications for communication between the systems [13].

Some authors distinguish a three-level model of interoperability, where the capability of effective mutual cooperation covers three areas, i.e. business processes, information exchange and technical capacity to ensure safe and effective co-operation of different systems [14]. The above illustrated distinctive definitions and interpretations of the concept of interoperability by various entities and organizations, share a common definition proposed by the European Commission, where interoperability is "the capacity of fundamentally disparate, diverse organizations to interact in order to achieve mutually beneficial and agreed objectives, including the sharing of information and knowledge between organizations as part of business processes they realize, implemented through the exchange of data using these organizations' IT systems" [15]. An almost identical wording of the definition of interoperability could be found in the Polish act on the computerization of activities of public entities¹ [16]. Standardization and adaptation of the European legislative framework in the area of interoperability norms to the dynamic development of the information and communication technologies market is a necessity, indicated, among others, by the Digital Agenda for Europe [17]. This document prepared by the European Commission is one of the most important pillars of the Europe 2020 Strategy, aiming to define a way out of the European economic crisis and programming EU growth in the coming decades [18]. As a necessary condition for building a fully digital society, the Digital Agenda for Europe mentions, i.a. effective interoperability between IT products and services, including those operating in the health sector, enabling a secure storage of data on the health

status of patients in the healthcare system available online [17]. These criteria are met by the XML format, which is already used in recording systems, especially in the exchange of electronic documents based on the HL7 standard. The implementation of the principles of interoperability at the European level and their adaptation by healthcare service providers representing diverse profiles and scopes of activity brings many practical challenges which make such an undertaking considerably difficult. These include: (1) different legal environments in individual member states, which often makes it difficult or even impossible to cross-border exchange of information between public organizations, (2) problems with adapting different types of business processes realized by various public organizations, (3) lack of agreements and guidelines concerning the meaning and the format of information exchanged between member states, (4) the need to support multilingual communication, and (5) problems with the provision of uniform technical guidelines to support the exchange of medical records in an electronic form [14]. However, for each member state the primary problem is the efficient running of the process of development and harmonization of rules of interoperability between systems of domestic medical institutions. The effectiveness of the mutual co-operation of information systems regarding the exchange of electronic medical data throughout the Community depends on the results obtained at the level of individual member states.

The results to date of the implementation work related to the development and introduction of unified standards for interoperability in the Polish healthcare information system can raise a lot of doubts. This fact was noted in the report of the Supreme Chamber of Control (in Polish abbreviated to NIK) from the controls carried out in 2012 checking the degree of preparation of service providers for the implementation of the Medical Information System and the actions of government related to the construction of healthcare information system as part of the 'Healthcare Computerization Programme' [19]. Among the weaknesses identified in its implementation were problems with ensuring interoperability in the exchange of medical data between the surveyed institutions. The results of the study showed i.a. that approximately a third of them have distributed ICT systems, which not only *do not* provide interoperable collaboration in the area of data exchange with other health entities, but only slightly facilitate communication between patients and the healthcare provider. The NIK audit confirmed that even if a selected region (hypothetically) established cooperation between the institutions with regard to the required interoperability principles, this fact would most probably be omitted by the Ministry of Health. According to NIK controllers, the Minister of Health did not have the full knowledge about the state of computerization of healthcare units in different voivodeships, in particular in the area of interoperability of the implemented solutions with the central project coordinated by the Centre for Health Information Systems (Polish: CSIOZ). Until the completion of the audit there was also a failed attempt to develop and implements solutions aimed at ensuring interoperability across borders, especially in the area of the planned integration with the epSOS project (European Patients Smart Open Services; this project will launch initiatives to develop modern communication technologies and integrated electronic services in the field of health in European Union countries, especially in terms of ensuring secure access to patient health information and electronic prescriptions available between the health systems of the member states – authors' note). Due to lack of national legislation sanctioning interoperability as a standard for data exchange in healthcare, it was not possible to implement policies ensuring consistency between medical information systems developed in different regions and those realized by CSIOZ. Delays and difficulties in the implementation of interoperability standards, required by the information system of the Polish healthcare, are above all due to there not being an agreed, responsible approach both of the decision-makers and suppliers of IT solutions that would enable the electronic exchange of medical data within and between computerized healthcare entities.

This problem requires particular attention as the system of electronic medical records is planned to have been implemented by 2017, allowing a full-range exchange of digital medical data in the Polish healthcare facilities for the first time on such a large scale and enabling efficient and secure cooperation of many different institutions for the optimal coordination of patient care. It will only be possible, however, if healthcare entities meet the deadline for launching the digital documentation system based on the framework principles of interoperability of computerized healthcare systems. They are to be implemented using the so-called profiles of integration describing the collection of necessary clinical information or data flows and the use of standards for the exchange of information in order to ensure interoperability of information systems functioning in healthcare [20].

The IHE XDS Model

Implemented on the basis of integration profiles, the interoperability model, rather than created in our country for the purpose of the computerization of the Polish healthcare system, is a concept developed by the international organization called IHE (Integrating of Healthcare Enterprise), representing an initiative to develop global standards for interoperability in the health sector [21]. Its national adaptation includes i.a. the use of IHE XDS profiles (Cross Enterprise Document Sharing) as an open standard for communication between service-oriented applications and their user. The concept of profile integration can be understood as a coherent mechanism for effective communication (and, more broadly, interoperability) between digital systems of healthcare providers, where the primary carrier of information about medical events related to the patient are electronic medical records providing current knowledge about the patient, available at the right time and for the right addresser [21]. A block diagram presenting the exchange of information between two medical entities (hospitals) using IHE XDS is shown

in Figure 1. Taking into account the process of communication between healthcare entities based on the model of IHE XDS, the primary task of a system of electronic medical data exchange thus organized, is maintaining the central register of documents and central management of permissions for their users. The medical facility included in the system, by creating and storing the medical records of the patient becomes responsible for the repository of documents, registering documents, accepting requests and sharing documents, keeping the history of document releases and further development of central dictionaries. The interoperability framework for the efficient transfer of data between institutions is determined, in turn, by the regional system of hospital network, which keeps the database of regional users, enables the integration of information systems, can maintain regional data repositories and on the basis of separate agreements operate entities outside the home network of hospitals (e.g. county hospitals, individual medical offices, etc.) [20].

So that all of the above utilities could become a functional part of the exchange of data in the electronic format, it is necessary to ensure compatibility (consistency) of the IHE XDS profile with existing standards of medical records workflow, especially in terms of the content of medical documents (e.g. HL7 CDA4 / CRS5, DICOM, PDF+) and the infrastructure of sharing medical records (including registries and repositories of electronic medical records) [21]. An additional potential of practical applications of the IHE XDS profile is also due to its participation in the representation of other profiles developed by the IHE organization, with which it forms a coherent whole (see Figure 2). The resulting family groups profiles into two main categories relating to semantics and content of medical records and the integration of their exchange. A detailed specification of this issue is as follows [21]:

1. The areas of semantics and content of medical records:

1.1. XDS-SD (*Scanned Documents*) – profile that describes the mechanisms of storing and sharing documents in the scanned form;

1.2. BPPC (*Basic Patient Privacy Consents*) – profile that describes the mechanisms of storing and sharing documents on the patient's consent;

1.3. EDR (*Emergency Department Referral*) – profile that describes the mechanisms of referrals relating to emergency departments;

1.4. PPHP (*Pre-procedure History and Physical*) – profile that contains information about the patient relating to surgical and invasive treatment;

1.5. XDS-I (*Cross Enterprise Document Sharing for Imaging*) – profile that describes the mechanisms of distribution of diagnostic images and reports, and contains information associated with them;

1.6. XD-LAB (*Sharing Laboratory Reports*) – profile that describes the mechanisms of exchange of laboratory test results between shareholders of the IHE XDS profile; 1.7. XDS-MS (*Cross-Enterprise Sharing of Medical Summaries*) – profile that describes the mechanisms of exchanging medical history reports and extracts;





Source: Kulesza K., Sokołowski M., Pośpiech A., Elektroniczna dokumentacja medyczna – doświadczenia światowe a polska rzeczywistość, Oracle Polska, http://www.slideshare.net/wydzial_ds_ezdrowia/elektroniczna-dokumentacja-medyczna-krzysztof-kulesza--marek-sokoowski-adam-popiech; accessed: 08.06.2015 [20].

Figure 2. Position of IHE XDS in the representation of IHE profiles



Source: Bliźniuk G., Profile IHE XDS i IHE XDW w zapewnieniu współdziałania instytucji medycznych, "Collegium of Economic Analysis Annals" 2014; 35: 9–23 [21].

1.8. XPHR (*Exchange of Personal Health Record Content*) – profile that describes the content and format of the two-way exchange of patient medical data between systems of healthcare entities.

2. The area of medical records integration:

2.1. XDS – profile that describes the mechanisms of integrating the exchange of data stored in electronic health records;

2.2. XDR (*Cross-enterprise Reliable Document Interchange*) – profile that describes the optimization mechanisms in the exchange of medical records, i.a. when there is no access to the registry of XDS documents and repository; 2.3. XDM (*Cross-enterprise Document Media Interchange*) – profile describing the mechanism of exchanging data containing media content by way of sharing files and catalogues.

The data flow may be more complex in the process of communication between the patient and healthcare facility using the IHE XDS profile (see **Figure 3**). In the example below, the beneficiary of the patient's medical data is the

hospital. As an institution where the patient is currently receiving treatment, it can access data from the computer systems of the doctor's office and the clinic. Exchange of hospital data with other profile users is carried out with the use of data repository, maintained by every institution, and the central register of documents XDS.

The following example shows that when exchanging certain types of medical data, you can skip the repository and registry nodes, e.g. the laboratory system used at the clinic can exchange data containing patient's laboratory results with the hospital without the mediation of the repository and the registry of documents. All profile stakeholders use the time server, which ensures that operations are performed in a unified real-time.

Enterprise Service Bus (ESB) and integration platform

The target model of integrating central ICT platforms with systems of healthcare facilities in accordance with the rules of interoperability is to be consistent with the requirements of the so-called *Service-Oriented Architecture*

Figure 3. A possible scheme of communication between users of the IHE XDS profile regarding patient data



EHR – Electronic Healthcare Records PACS – Picture Archiving and Communication System LIS – Laboratory Information System ATNA – Audit Trail and Node Authentication CT – Coordinated Time XDS – Repository of Documents

Source: Kulesza K., Sokołowski M., Pośpiech A., Elektroniczna dokumentacja medyczna – doświadczenia światowe a polska rzeczywistość, Oracle Polska, http://www.slideshare.net/wydzial_ds_ezdrowia/elektroniczna-dokumentacja-medyczna-krzysztof-kulesza--marek-sokoowski-adam-popiech; accessed: 08.06.2015 [20]. (SOA). Its basic idea boils down to designing a system depending on the way the services to be performed by it are defined [22]. A key component for the realization of the SOA concept is the so-called *Enterprise Service Bus* (ESB) or specialized software performing a fundamental role in the attribution characteristics of efficiency and standardization of electronic exchange of medical data among cooperating IT systems.

The component of the enterprise service bus along with the IT systems of individual users connected to it forms the so-called integration platform. ESB enables integrated information exchange between applications based on different technologies and IT platforms using integration services, thus providing a secure, unified, fully flexible and collision-free (with respect to the information flow processes implemented earlier) configuration of the application, e.g. its expanding, moving or replacing [21]. An example of such a solution can be found in the Estonian EHR system, which uses a similar solution called X-ROAD. An additional functionality of the bus service is the management of information processes important from the perspective of continuity and monitoring of implemented information exchange. Although according to the accepted guidelines in healthcare computerization, the enterprise service bus will not be used as a direct provider of functionality for the end user, it will be critical to ensure interoperability and scalability. Only in rare cases will there be a possibility of direct links between some IT systems and specific resources and data registers without ESB [23]. The architectural design for ESB contained specific requirements for such a solution, which are given below. According to them, ESB must (1) carry out the translation (transposition) of communication, (2) enable integration of data registers implemented in a variety of different technologies, (3) implement redirection of communication depending on the context and content of the message, (4) have load-balancing mechanisms of communication between the nodes, (5) enable integration of applications and services implemented in different technologies, (6) ensure integrity, non-repudiation and confidentiality of communication, and (7) provide mechanisms for filtering and validating messages [23]. The expected functionalities of ESB include the capacity to connect old IT healthcare systems with implemented ICT platforms, supporting standards of cooperation and communication between IT systems, ease of configuration, and enabling mass flow data [24]. The balance of benefits and results of the implementation of the ESB architecture in the healthcare information system is shown in Table I.

 Table I. ESB – balance of selected benefits and results of implementation

Benefits	Results
faster and cheaper connection of information systems	enabling online registration for medical consultations
enabling easy communication and exchange of data between systems	providing patients with electronic medical history, performed serv- ices, referrals, prescriptions, vaccination plans, recommendations
minimizing data redundancy (possibility of transmitting certain data between systems)	enabling electronic implementation of prescriptions
flexibility and scalability of architecture	allowing electronic handling of sick leave
allowing for an easy expansion of information systems with addition- al modules and integration of the existing ones thanks to the relative independence of the technologies used, among other things	providing the medical staff with electronic health data of patients
ensuring communication security between systems	providing fast access to electronic medical records in an emergency
	providing information on health (prevention)
	allowing ongoing analysis of data on medical events
	enabling electronic invoicing
	improving electronic billing of medical services
	improving electronic handling of drug refunds
	providing information enabling ongoing monitoring and responding to threats
	ensuring homogenous and uniform rules for the collection of sharing of digital resources on medical events
	ensuring interoperability
	access to reliable data on medical events

Source: Elektroniczna Platforma Gromadzenia, Analizy i Udostępniania Zasobów Cyfrowych o Zdarzeniach Medycznych – studium wykonalności, Centrum Systemów Informacyjnych Ochrony Zdrowia, 2009, http://konfederacjalewiatan.pl/upload/File/2009_06/ Studium.pdf; accessed: 11.06.2015 [24].

Conclusions

In 2017 an integrated IT system based on electronic documentation is to be introduced in the Polish healthcare. An electronic document is to be a valid form of documentation. The two key elements of the system are: EHR (Electronic Health Record), i.e. defining the criteria and standards for electronic medical records system and the construction of an efficient exchange of data and information between a large number of various entities operating in the healthcare system. Data transfer buses are a solution enabling an efficient exchange of digital data also in the healthcare information system. IHE XDS data transfer buses (Integrating Healthcare Enterprise Cross Enterprise Document Sharing), specially developed for use in healthcare, systems should be introduced as a both local and global solution. The construction of the system should include European Union regulations for electronic public service, openness and interoperability. The component of ESB along with IT systems of individual users connected to it creates the so-called integration platform. The solution using data transfer buses enables an exchange of information between applications based on different technologies and computing platforms.

Note

¹ Note, however, that the provisions of the said act do not apply to state-owned companies, commercial companies or special services in the meaning of Art. 11 of the Act of 24 May 2002 on the Agency of Internal Security and Intelligence Agency (Journal of Laws, no. 74, item 676, as amended), The Sejm Chancellery, the Senate Chancellery, Office of the President of the Republic of Poland and the Polish National Bank except in cases where in connection with the execution of tasks by these entities there is an obligation to provide information to and from entities other than government administration.

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