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THE MAIN DIRECTIONS OF STANDARDIZATION IN MEDICAL INFORMATICS

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SUMMARY

The application of the medical standard HL7 CDA for the tasks of creating clinical documents and digital signature means suitable for use in a single information space is described. A new specification (FHIR standard) is presented, based on the latest approaches in the field of e-health, but taking into account all the accumulated experience (real needs, successful solutions and typical difficulties). The structure of the electronic medical map (EMC), the conceptual, logical and physical model of the database for the needs of the cardiological service, which is the core of the unified information space of the RSSPMCC, is developed.

Keywords: *the electronic medical map (EMC), the unified information space of the RSSPMCC.*

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A flow of medical documents is a centerpiece for the IT penetration into healthcare facility activities. Over the past few decades, a lot of healthcare information systems (HIS) primarily targeting automation of the flow above called into existence. Wide spread of computer technologies helped (i) work the problem of "illegible doctors' handwriting", typical of a conventional paper medical history, (ii) use a digital signature technology to verify the authenticity of medical records and (iii) facilitate the Web technology-based remote data access [1].

There were some steps or evolutionary stages to be distinguished in the history of the IT penetration into the public healthcare system. Primarily, aiming to reduce the document flow the healthcare facilities turned to automation of information management. This included book-keeping operation, movement of the valuables, flow of internal documents and provision of patients with documents, that is, so-called administrative aspects. Improvement in performance of clinical and support units, including those of out-patient, in-patient and emergency care, as well as laboratory service and other specific units of the public healthcare system was focused at the next step.

Though the problems above have not been adequately resolved, active information systems capable of keeping track of hospital capacity, medical staff positions and clinical laboratories, and providing automation of registration, book-keeping records and function of

hospital pharmacies are not uncommon in the outpatient clinics and hospitals in major cities of Uzbekistan. Given the successes gained, there is a challenge in clinical information exchange between healthcare information systems at various health promoting facilities and their subunits. Thereby, as of current stage of the IT penetration into the medical branch, efforts of experts are focused on integration of the whole data set relevant to healthcare delivery to a patient throughout his/her life (electronic medical history recording).

As a consequence, realization of efficient communication between participants of the public health system appears to be the problem, and it is to be resolved by means of development of conventional standards for exchange of electronic medical documents and messages.

In this context, the "National Integrated Information System of Public Health of Uzbekistan" concept (2009) developed within a frame of "Health-2" project with pivotal characteristics and overt problems in medical assistance and the public health system in Uzbekistan, as a whole, taken into account became a milestone [2,3]. Within a scope of the concept, the extensive access is supposed to be provided to electronic medical histories devised in healthcare information systems of various healthcare facilities.

Analysis of research papers published at home and abroad (both close and far) demonstrated capability of current healthcare information systems to perform operations in information management within a public health system. However, as a rule, a health promoting facility develops its own healthcare information system stage-by-stage as possible, that is, by acquiring or developing specific modules for needs of its certain subunits. At this point, it is not financing but a need in gradual evolution of IT penetration into health promoting facilities instead of a leap-ahead that matters.

Even today, when the level of IT penetration into public health system countrywide is comparatively low, healthcare information systems in various health promoting facilities can be observed to turn into conglomerates of isolated systems. These systems are developed on the basis of specific situation-centered requirements, but not on those of information logical integrity, meant to be used in an isolated situation or finely acquiring rather freakish structures.

In these circumstances, it is important for both HIS produces and users not to face problems of supporting incompatible structures of communication and execution of transactions. The global experience indicates that the problems arise even at the level of interaction of isolated HIS components within isolated healthcare facilities, say nothing of the public health system integrated bus (support of integrated electronic medical records) on a national scale.

To avoid the problems above, a base to minimize the incompatibility and to maximize the information exchange between the systems. Health Level-7 or HL7 refers to a set of international standards for transfer of clinical and administrative data between software applications used by various healthcare providers [4]. It is a superstructure providing global integrity of specifications and methodology for development of healthcare information systems worldwide. Its specifications were developed in compliance with the predesignated goals, so its further extensions should comply with them as well.

It should be noted that the "National Integrated Information System of Public Health of Uzbekistan" concept (2009) is based upon generally accepted standards, including HL7 Version 3 Messaging Standard – an interoperability specification for health and medical transactions. However, the reality is that members of the medical community and those of operating systems community in Uzbekistan lack a clear idea of HL7, though the concept above was adopted almost 10 years ago.

Health Level Seven International (HL7) is a standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services. HL7 allows excluding or massively simplifying the development and realization of specific software interfaces of access to healthcare data.

Let's be clear, that HL7 neither includes a priori speculations about healthcare information system's architecture nor deals with a problem of architectural differences of the systems. HL7 cannot be considered as a PnP (plug-and-play) standard. The Reference Information Model (RIM) is the cornerstone of the HL7 Version 3 development process and an essential part of the HL7 V3 development methodology. RIM expresses the data content needed in a specific clinical or administrative context and provides an explicit representation of the semantic and lexical connections that exist between the information carried in the fields of HL7 messages [4,5]. Actually, HL7 RIM is the abstract representations of notions and their relationships in medicine.

The structure of classes and their connections is a result of prolonged meticulous work of many experts. HL7 RIM is based upon a speculation that the healthcare information can be described as a participation of some entities playing some parts in some acts (Fig.1).

Due to the very nature of many-sided activity in the public health system, development of universal model both of a process and the data to provide a description of the target environment in HL7 standard is impossible. In other words, it is impossible to build a healthcare information system for the isolated health promoting facility on the basis of HL7 RIM, as it is a maximal common model covering all areas of IT penetration into the public health system.

Though the HL7 standard was deeply and conceptually worked theoretically, the RIM specialization for the subject areas takes a good deal of time. After 10 years, many work groups failed to attain the stage of message development; on the stage of realization, complexity of the standard turned out to be higher than a pain threshold in the industry causing the criticism and a number of attempts to simplify the standard.

Fast Healthcare Interoperability Resources (FHIR), a draft standard describing data formats and elements (known as «resources») and an application programming interface (API) for exchanging electronic health records, is a most successful initiative. FHIR uses current information and communication technologies, to name XML, JSON, Web 2.0, HTTP и REST [6]. FHIR standard is meant to simplify realization of health information system without damaging information integrity. It uses current logical and theoretical models to make an unambiguous, easy to realize and rigorous mechanism for exchange of data between healthcare application programs. The built-in mechanisms of HL7 RIM tracking in FHIR ensure its conformity to the predesignated frameworks and models and top-of-the-line standard practice, while also relieving a developer of necessity to understand HL7 RIM in detail.

FHIR supports various versions of information system interactions, to name:

- online interactions (e.g. for mobile applications),
- exchange of messages (similarly to HL7 v2 and HL7 v3),
- electronic document communication (similarly to HL7 CDA) and
- Web service-based interaction (HTTP protocol, REST style)

The interoperability is ensured at all levels of information exchange in the public health system, to name the exchange between healthcare information subsystems in a health promoting facility and the exchange between healthcare information systems of various health promoting facilities, both at the regional and global scales.

All above makes it clear that the integration of health information rests on universal adherence to genesis of RIM classes, types of data, software requirements and other fundamentals of HL7 standards. Indeed, it is a basic condition but hardly the only one, as mechanisms for integration of data and interoperability of health information systems are considerably more complicated.

The templates of medical records, messages and their structural elements are one of the mechanisms in question. Thorough analysis of the HL7 Clinical Document Architecture (CDA), an XML-based markup standard intended to specify the encoding, structure and semantics of clinical documents for exchange, helps understand the essence of the templates [4,5]. As CDA is an excessively flexible and multifunctional specification, the next level of limitations for CDA is

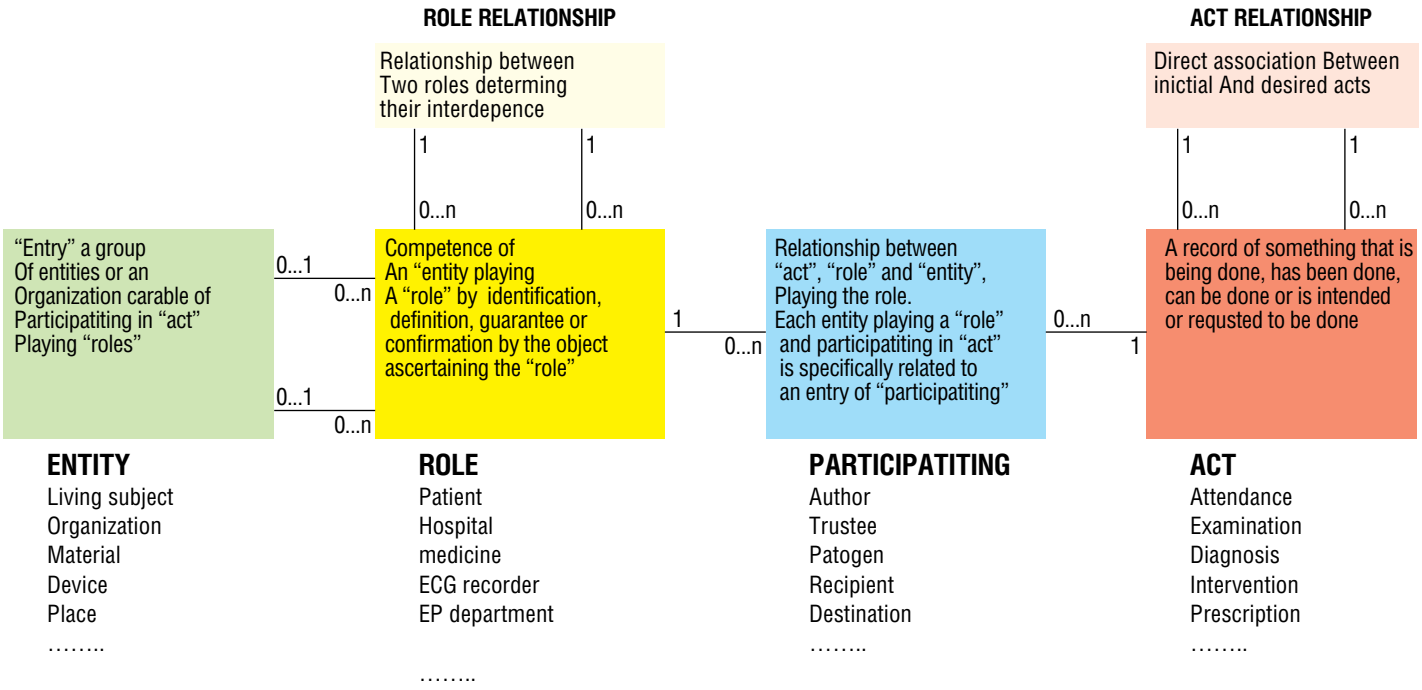

Figure 1. HL7 RIM basic classes

templates or patterns determined at the levels of documents, sections and records. The templates should be developed in conformity with HL7 requirements and contain the detailed description of the way the elements of a document are to be structured and presented for integration of clinical information to be preserved. CDA flexibility allows producing a great deal of various templates. Thus, for the moment, there are nine templates for medical records, to name Continuity of Care Document, Consultation Note, Diagnostic Imaging Report, Discharge Summary, History and Physical Note, Operative Note, Procedure Note, Progress Note and Unstructured Document.

Conversion of information contained in medical records in a natural language to the adapted computer representation (semantic representation of medical knowledge) is another mechanism underlying integration of various health information systems and clinical data.

The scientific field related to formalization and structuring of story-like clinical notes is of great current interest. Percent of the unstructured texts, even at the third level of CDA formalization of medical records, remains significant, especially in sections describing a patient's complaints, medical history, initial and physical examination. The conversion of information contained in a medical record in a natural language to the adapted computer representation could help automatize many clinical tasks, both of applied and academic character.

SNOMED CT or SNOMED Clinical Terms, a systematically organized computer processable collection of medical terms providing codes, terms, synonyms and definitions used in clinical documentation and reporting is the most widely used tool to the above problem solution. Available for more than 40 years, it is constantly upgraded and refined. Having been in progress by means of addition many terms to the logic-based public health terminology, SNOMED CT is recommended as the one with comprehensive coverage of diseases, clinical data, etiology, treatment, procedures and outcomes [7,8].

Of all CIS countries, the Russian Federation appears to take the most active and efficient actions in standardization of health information exchange; the results of the work are quite obvious. On its website nsi.rosminzdrav.ru, the Ministry of Health and Social Development of the Russian Federation presents a program complex as the unified register of the regulatory reference information (RRI) on the health and social development system of the country. RRI register is a basic service element for development and integration of information systems used by health promoting facilities. The program complex is intended for (i) RRI transfer, storage and updating, (ii) monitoring and management of RRI pool, tracking of object versioning, user's access granting and information support, and (iii) integration of information systems. Thus, "the Clinical Report" in the Russian Federation is set forth on 207 pages only, handling compound data structures and a dozens of directories [9,10].

It goes without saying, that the development of standards requires significant inputs and resources which is in power of the government establishments, not private developers of health information systems. Under the circumstances, development of the standard-oriented architecture is the only feasible strategic solution. To target something that is not there, it is necessary to speculate or intuitively foresee the direction for standardization in the medical industry. To develop an integrated electronic medical record (IEMR) in the absence of accessible structured documents in guidance papers of Uzbekistan Public Health Ministry is quite a task.

Completeness and accuracy of the outpatient's medical record, a primary recording document, are of great consequence in the work of a medical practitioner. An outpatient department of the Republican Specialized Scientific-Practical Medical Center of Cardiology, Uzbekistan Public Health Ministry uses a reference form 025/U approved by Uzbekistan Public Health Ministry as the outpatient's medical record. The service in question is performed in compliance with the established practice to meet requirements to medical record maintenance.

The records of healthcare workers are known to be illegible and undescriptive, as to completeness of the data, considerable percent of the outpatient's medical record do not meet requirements to medical record maintenance. As a rule, it is the result of pressure on time a medical worker faces trying to meet the requirements in question. As a whole, medical workers find it difficult to memorize numerous standards and medical aid procedures; search for appropriate information in multi-page directories takes up much of their time in the process of attendance.

The electronic medical record used at the outpatient department of the Republican Specialized Scientific-Practical Medical Center of Cardiology, Uzbekistan Public Health Ministry, is generated with the aim of (i) making performance of its medical staff transparent,

(ii) developing the standard for information exchange between its separate units, and (iii) making statistical accounting of its patients' data. So far, the issue is a database mandatory for out-patient service provided by the Center.

Classically, the process of database development consists of conceptual, logical and physical design, and generation of internal data presentation to the users of various categories, to administrative and medical ones, in this context. As there is no generally accepted EMR standard in Uzbekistan, we decided to use not a classical approach but a cyclic round-robin scheduling which implies correction of the conceptual and logical models of data at the stages of the database physical design and development of web-interface access to the database. Luckily, Ruby programming language and Ruby on Rails, a server-side web application framework, we use allow implementing that by standard means.

The database developers and medical workers of the Center jointly tested, endorse and adapted current EMR templates based on clinical protocols and standards of diagnosis and treatment, and internal standards established at the Republican Specialized Scientific-Practical Medical Center of Cardiology, Uzbekistan Public Health Ministry to meet requirements of healthcare delivery.

The EMR database is intended for the entry, storage and view of data of the outpatients referring to the Republican Specialized Scientific-Practical Medical Center of Cardiology, Uzbekistan Public Health Ministry. Medical workers, to name, administrators, physicians, nurses and lab technicians, patients and their electronic medical records, as well as results of laboratory investigations are the entities constituting the basis of the database conceptual model. Each entity has its own set of attributes. The EMR currently in use contains 82 attributes.

The data about administrators are entered by the developers, medical workers register all by themselves at the database access interface, entering their attributes, including full name, E-mail, role (a physician, a lab technician, a nurse) and a password. By the web-interface the EMR is accessible to all medical workers through local area network, but according to each worker's role he/she may access only his/her EMR set of attributes. For example, nurses may generate a patient's EMR, enter his/her passport details and transfer the EMR to any physician registered.

A physician may not edit a patient's passport details, but he/she may entry the data of primary examination (medical history), transfer the EMR to a lab technician and assign a therapy only after all appropriate analyses, such as ECG, EchoCG, ultrasonography of brachiocephalic arteries, ultrasonography of inner organs, blood tests, a cycle ergometer test, daily monitoring of ECG, are completed by the lab technician. Accordingly, the lab technician may enter only results of laboratory investigation and return the EMR to the physician who transferred it. One of the EMR attributes saves a sequential list of all medical workers who saw the patient. On behalf of any entity, an administrator performs all acts above and promptly refreshes entries to the Drug Reference Book.

Today, the EMR generated for the outpatient department of the Republican Specialized Scientific-Practical Medical Center of Cardiology, Uzbekistan Public Health Ministry, is tested for integration into the diagnostic and treatment process. The electronic medical record is planned to be developed for the inpatient department of the Center. The data exchange between the outpatient and inpatient departments will be provided in compliance with FHIR standard. To put it into effect, "FHIR client" and FHIR server" applications are integrated into the outpatient EMR.

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