

Standards for Medical Information Interchange Design of Modern Mobile Devices and Solutions

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Abstract—In the area of medical information collection, transportation, presentation, and analysis there are a lot of standards. Many of them contradict each other. Mobile devices are a new domain of medical equipment. To enable their communication with different hospital information systems, standards have to be implemented. Standards selection and implementation is a hard process. The aim of this paper is to present the available standards concerning medical data exchange and how to transfer these standards and their applicability to the current mobile devices and remote applications oriented to medical and health care. A solution oriented to archetype data representation is presented, as a way to solve some information presentation problems.

Keywords—telemedicine; medical standards; conformance; electronic health record.

I. INTRODUCTION

The increasing use of mobile and individual healthcare devices is one of the major tendencies in out-of-hospital care. Many vendors provide extensive sets of those devices. Unfortunately, most of them cannot work outside their servers and service software. Transition of health data between hospitals, healthcare providers and health insurance companies is still very limited. Some of these limitations are defined by law restrictions, but many result from data format differences and general incompatibilities. The only way to solve these incompatibilities is to follow available standards and to maintain all new devices to be compatible with those standards. Common use and exchange of information between different actors in the healthcare process, in particular in clinical diagnostics process, is only possible if all partners adopt a common format, content, structure and meaning of exchanged messages.

This article targets some ideas and standards for their implementation in the area of health informatics and the correspondence between them and new generations of personal mobile healthcare devices.

This present paper is structured as follows: Section II presents the health care data exchange process and appropriate to it communication standards; Section III presents the archetypes as conceptual structures and their place in the medical data presentation process; Section IV briefly presents the design steps for mobile device software outlined in the archetype concept; Section V concludes the paper.

II. HEALTH DATA EXCHANGE AND COMMUNICATION STANDARDS

Exchange and interaction between the different actors can be discussed in terms of infrastructure or the application side.

A. Infrastructure level

This level corresponds to the interchange formats related to communication and transport protocols used from layer 1 (physical) to layer 6 (representative) of the OSI (Open System Interconnection) model [20] of the ISO (International Standard Organization). At this level, there are defined channels of communication (network connections, satellite communications, telephone systems, etc.).

B. Application level

This level corresponds to the content of the message, and it is divided into the layers of the syntax, semantics and pragmatic. According to the OSI model, that corresponds to the layer 7 (application layer).

Syntax layer describes the rules presenting how various phrases, signs and other may be combined into corresponding messages containing data or control information. These rules define the shape, consistency and physical representation of the messages.

Semantic layer (content layer) describes the content of the message and it requires an agreement on how to interpret the data unambiguously. An external system of terms representing medical concepts can explain the meaning. Many health organizations describe the data using their own conventions. As a result, in the process of data exchange, the receiving system cannot understand these codes if it does not have appropriate classification catalogue. Data exchange between many organizations is practically impossible. That is why standardized clinical nomenclatures are widely applied (clinical vocabularies, controlled medical terminology, etc.). A standardised clinical vocabulary provides a means of accurately, clearly, and reliably communicating medical information.

Context (pragmatic) layer describes the information and knowledge about the environment (context) where the message is generated. Together with semantic, the pragmatic level describes some of the content of the message.

At higher levels, it is much more difficult to achieve a common understanding of the content of the message elements.

Hereafter, we present the major existing and evolving standards in the field of medical informatics. The presentation is made from the lowest to higher levels of application level, i.e., the level of syntax to pragmatic level. By “standard”, we understand collection of specifications adopted by a standards organization or group. In the last two decades, many organizations have proposed standards for data exchange, but unfortunately most of them are defined at the level of syntax only.

A. Syntax layer standards

These are generic standards, such as ASN.1 (Abstract Syntax Notation One) [21], EDIFACT (Electronic Data Interchange for Administration Commerce and Transport) [22], XML (Extensible Mark-up language) that are independent of the field of application. Specific to the field of health are standards of the HL7 organization (Health Level 7) [23], the DICOM (Digital Image and Communications in Medicine) [9] of the American College of Radiology (ACR) and the National Electrical Manufacturers Association (NEMA), representing a standard for the formatting, processing and storage of digital images and its associated data and the standard IEEE 1073 - MIB (Medical Information Bus). MIB is applicable to the exchange of data between devices located in intensive care, critical care and operating rooms (such as monitors, infusion pumps, ventilation devices). However, the DICOM was published back in 1993; so the standard precedes the development of the web technologies like XML and web services and uses binary en-coding for the graphical information. To overcome this problem, two additional supplementary standards were developed - Web Access to DICOM Persistent Objects (WADO) [10] and DICOM Structured Reporting (SR) [24].

Work on the specialization of the generic standards, such as XML, to answer service specific requirements of health applications, has started in the past few years.

B. Semantic layer standards

The following standards can be assigned to this level: LOINC (Logical Observation Identifiers, Names and Codes) [25], GALEN (Generalized Architecture for Languages, Encyclopaedias and Nomenclatures in medicine) [26], GRAIL Language (GALEN Representation And Integration Language) [26] and the multi-axial Systematized Nomenclature of Medicine-Clinical Terms SNOMED – CT [27]. The KIF (Knowledge Interchange Format) [28] is language for knowledge exchange and is characterized by declarative semantics, i.e., the meaning is straightforward and well defined.

C. Pragmatic layer standards

The list of these standards is presented by the model of the European Committee for Standardization (CEN, French: Comité Européen de Normalisation) - European Healthcare Record Architecture (EH CRA). In 2004, the ISO Technical Committee 215 published the specification TS 18308 – Requirements for an Electronic Health Record Architecture. It is extended with ISO/TR 20514 published 2005. This

report introduces the generic definition of the Electronic Health Record (EHR) – a repository of information regarding the health status of a subject of care, in computer processable form. Most of the novel developments like CEN EN 13606 and OpenEHR are based on this technical specification.

III. ARCHETYPES AS CONCEPTUAL STRUCTURES

When attempting to “plug-and-play” a new device from some vendor in an existing health network, the most important is the pragmatic layer.

The GEHR (Good European Health Record) initiative started at the beginning of the 90-s as European Union project. Currently, this initiative is maintained by an international online, non-profit organization, called the OpenEHR Foundation [29].

The most noteworthy concept of this initiative is a knowledge-based model, also known as the archetype modelling technique. It facilitates, on one hand, the specification of a generic clinical record structure, and on the other hand the specific semantic definitions of clinical contents. This model utilizes a dual-level methodology to define the EHR structure. More specifically, the first level is used to define a small, but constant in time, Reference Object Model (ROM) for an EHR, which typically contains only a few generic, concepts/classes (e.g., role, act, entity, participation, observation, etc.). In addition, at this level (the level of the ROM), additional methods on how to organize and group clinical information, capture contextual information, query and update the health record, and use of versioning to safely manage clinical information from a medico-legal point of view, are specified [4]. The second level is used to define constraining rules and mechanisms called archetypes. The archetypes role is to specify the common data structures, which have been created in the first level.

The OpenEHR initiative defines a formal language called ADL (Archetype Definition Language). The main purpose of this language is to describe the three main parts of each archetype: descriptive data, constraints and ontological definitions [7]. The descriptive data usually contains a unique identifier for the archetype; machine readable code, which describes the clinical concepts modelled by this archetype; different metadata, like version, author etc. The constraining rules describe the core of the archetype, define the possible constraints of a valid structure and also describe the contents of the component models for EHR. The ontological part defines controlled vocabulary, which can be used in specific parts in the archetype instance. Archetypes are chunks of declarative medical knowledge that are designed to capture maximally expressive and internationally reusable clinical information units. They encode knowledge about clinical observations, evaluations, actions and instructions regardless the context, in a coherent and holistic manner. Archetypes are based on conceptual structures of medical knowledge. Medical ontologies conceptualise domain objects, actions and relationships among them; the archetypes, representing the blueprints of defined medical domains, are focused on capturing clinical information about the patient.

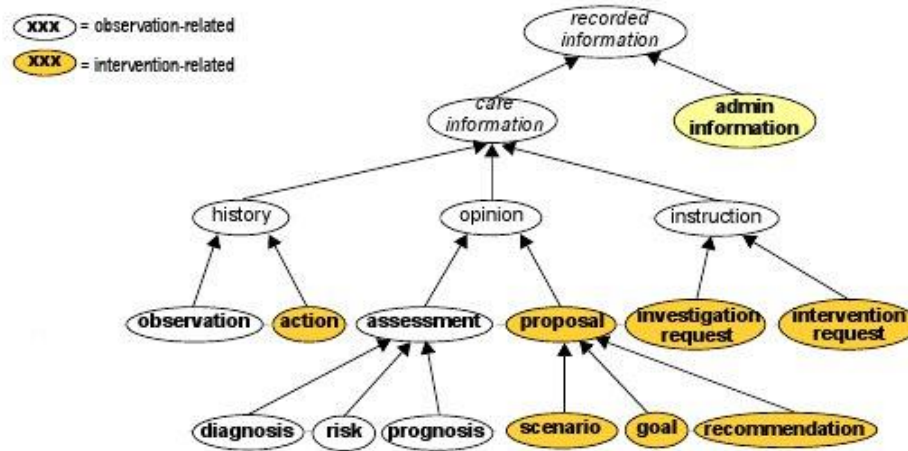


Figure 1. The Clinical Investigator Record Ontology [12]

Analysing the important types of information in the health care process, we select the Clinical Investigator Record Ontology, where the observations (evidences) and opinions (inferences) are different categories (see Figure 1). This taxonomy provides the categories in the Entry classes of the openEHR reference model [31].

In 2008, the archetype approach to structuring patient-related records became ISO standard 13606-2:2008, as a specification of the information architecture required for interoperable communications between systems and services dealing with EHR data [14]. This way, ISO 13606-2:2008 defines how to organise hierarchically the EHR content, how to define the individual data items and their aggregations, what types of values or measurement units are appropriate, and so on. Archetypes are viewed as a serialized representation, an exchange format for communicating individual archetypes between archetype libraries.

All this work makes archetypes as a platform for integration in future mobile device connectable to extended hospital or other health care networks.

IV. DESIGN STEPS OF SOFTWARE FOR MOBILE APPLICATIONS CONFORMING TO ARCHETYPE CONCEPT

To design a new mobile device which can be “plug-and-play”-ed the following steps are recommended (technical design is excluded):

- Definition of minimum clinical data set - the main goal of this step is to prepare appropriate data set for clinical data measurements. This involves the definition of the measurements to be performed. A specialized data set of clinical markers for patient’s status description has to be provided.
- Data standardization - the goal of this step is to prepare presentation of all registered markers and measurement results as clinical archetypes according CEN EN ISO 13606 standard. The possibility to integrate the obtained measurement and analysis results to available EHR has to be proposed.
- Design of infrastructure level communication depending on the exact communication environment.

This number of steps looks simple, but they offer several possibilities to design devices with standardised

interconnection interface. As an example, the archetype for blood pressure introduced in [19] will be discussed.

Minimal data set consists of the following elements:

- Blood pressure (BP)
 - systolic BP*
 - diastolic BP*
 - mean arterial BP*
 - pulse BP*
- State/ Position
 - Standing*
 - Sitting*
 - Reclining*
 - Lying*
 - Lying with the tilt on the left*
- Other - *cuff size, location of measurement, method, mean arterial pressure formula, diastolic endpoint, etc.*

Based on this data, we can obtain an extended archetype as presented in Figure 2.

The presented in Figure 2 archetype gives a basis for software development and extended presentation of obtained patient’s data and environment of its obtaining for electronic health records and its transfer to hospital information system.

We did a preliminary software design, based on the proposed archetype. Simple implementation on a single-board-computer based on ARM processor is done, as well. The implementation is only for design validation. The design and testing environment includes a program generator for embedded devices and semi-natural simulator [30][31], which were used to build the software and to simulated operating environment. No real sensors, actuators and similar were installed. The module operated in a simulated space, connected to an external computer. This computer ran a simplified model of the blood-pressure measurement device physical hardware and communicated via physical signals to the embedded computer. Some of simulations were very simplified and only imitated some behaviour. This did not degraded the validation process because its target was the archetype software representation not the real device control and precise measurements. According to some previous work [32] and prototype of a Hospital Information System (HIS), implemented under Bulgarian National Science Fund Do02-113, some data transfer has been realized. All

activities were only test and validate the idea to use archetypes as software design paradigm for unified medical data transfer from mobile medical device to HIS.

It does not have any medical validity and only proves the possibility to implement the presented formal technology on a physical device.

Some lessons from this implementation are that software design has to be very precise and to follow the archetype design without variants and “adaptations”. The communication increases because more data are transferred. Data composition in the mobile device and its parsing in the HIS are simple. Here is one of the most useful elements of this design. Data can be recognized without some specific extra information because the archetype model is implemented both in the HIS and the mobile device. Every mobile device conforming this this archetype can exchange data to the HIS. Of course, the protocol can be unified also, but we discussed this in the previous sections.

V. CONCLUSION

In this paper, we presented a general overview about the available standards for medical information interchange and their usability for system-to-system and device-to-system connection. We discussed about availability of standard elements in clinical descriptions. It is evident that the conceptual structures, designed to capture patient-related clinical information in order to ensure its systematic representation, need a long period of development, standardisation and wide adoption in order to provide interoperability. First step in this direction is the presented way to generate a formal archetype and after that – to transfer it on a specific hardware, implementing all needed data acquisition and communication actions. Technically, this is not a problem. Today the problem is to achieve a common understanding of the exchanged content between systems and not a used data transfer technique. The proposed new type of thinking in terms of archetypes and conceptual structures solves many problems in this area and reduces standards contradictions.

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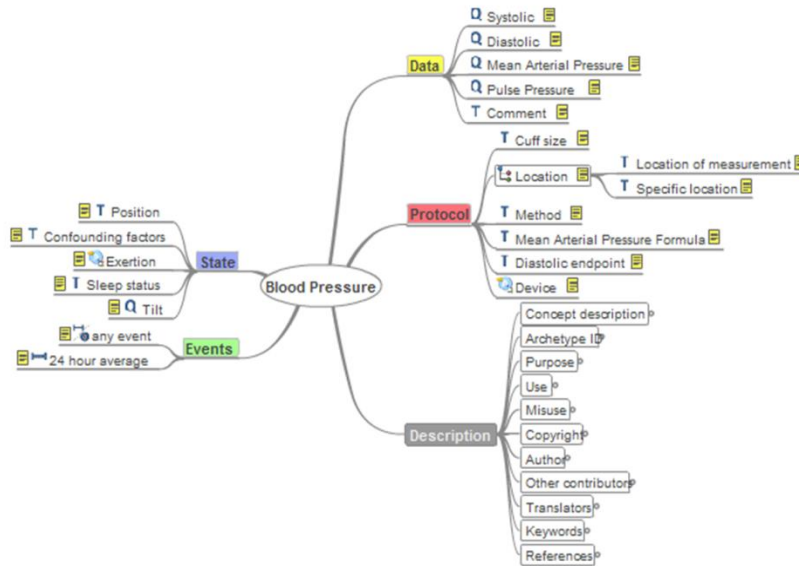


Figure 2. Map View of the 'Blood Pressure measurement' archetype [1]