

Archetypes and Standards for Medical Information Interchange

Dimitar Tcharaktchiev¹, Vesselin E. Gueorguiev², Ivan Evg. Ivanov³

¹ Medical University – Sofia, University Hospital of Endocrinology
Sofia, Bulgaria
dimitardt@orange.fr

² Technical University Sofia
Sofia, Bulgaria
veg@tu-sofia.bg

³ Technical University Sofia
Sofia, Bulgaria
iei@tu-sofia.bg

Abstract

The extensive usage of mobile devices for vital signs collection and the use of ordinary communication networks for data transportation enabled many new opportunities but opened many new problems. In the area of medical information collection, transportation, presentation, and analysis there are a lot of standards. Many of them contradict each other. The standardization in the area of data transfer between Hospital Information Systems and mobile devices is very complicated task. Standards selection and implementation is a hard process. This paper pretends to present some of the available standards concerning medical data exchange and how these standards can be followed and implemented in mobile solutions.

Keywords: *Electronic Health Record, mobile device, telemedicine; health informatics standards; conformance.*

1. Introduction

“Be careful about reading health books. You may die of a misprint”. Mark Twain

In the era of the information society a lot of medical processes implemented on-the-field before now are running remotely. The growing age of the population and the increased need of individual health support changed the stress of home and post-hospital care. The increasing use of mobile and individual healthcare devices is one of the major tendencies in out-of-hospital care. Most of these 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. One 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 2 presents the health care data exchange process and appropriate to it communication standards; Section 3 presents the archetypes as conceptual structures and their place in the medical data presentation process; Section 4 briefly presents the design steps for mobile device software outlined in the archetype concept; Section 5 concludes the paper.

2. Health data exchange and Communication standards

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

2.1 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 [1] of the ISO (International Standard Organization). At this level, there are defined channels of communication (network connections, satellite communications, telephone systems).

2.2 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 standardized 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) [2], EDIFACT (Electronic Data Interchange for Administration Commerce and Transport) [3], 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) [4][5], the DICOM (Digital Image and Communications in Medicine) [6] 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 encoding for the graphical information. To overcome this problem, two additional supplementary standards were developed - Web Access to DICOM Persistent Objects (WADO) [7][8] and DICOM Structured Reporting (SR) [9].

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) [10], GALEN (Generalized Architecture for Languages, Encyclopaedias and Nomenclatures in medicine) [11], GRAIL Language (GALEN Representation And Integration Language) [11] and the multi-axial Systematized Nomenclature of Medicine-Clinical Terms SNOMED-CT [12]. The KIF (Knowledge Interchange Format) [13] 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 (EHCRA). 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 EN ISO 13606 and OpenEHR are based on this technical specification.[14]

3. 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 [15]. The extensive works [16][17] gives more information about the process of archetypes usage.

The foundation of a key approach to the integration problem is the use of two kinds of archetypes [18]. Using “archetypes” we mean “designed” archetypes, generally clinical, demographic or administrative. The common factors for all such archetypes are:

- they are based on the main part of the reference model;
- they are consciously designed from scratch by groups of domain specialists, and integrated into the existing library of openEHR archetypes;
- there is one archetype per identifiable health “concept”, such as an observation type, person type etc.

A second category of archetypes is “integration” archetypes. These are characterized as follows:

- they are based on the same high-level types, but use the Entry subtype `GENERIC_ENTRY` (see [19]);
- they are designed to mimic the structure of legacy or existing data or messages; the design effort therefore is completely different, and is more likely to be done by IT or other technical staff who are familiar with the structures of the incoming data;
- there is one integration archetype per message type or identifiable source data that makes sense as a transaction to the EHR.

In the data integration environment, “designed” archetypes always define the target structures, coding and other semantics of data, while “integration” archetypes provide the means mapping of external data into the openEHR environment [20].

The most noteworthy concept of openEHR 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. 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 [21]. 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 [22]. 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 conceptualize 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.

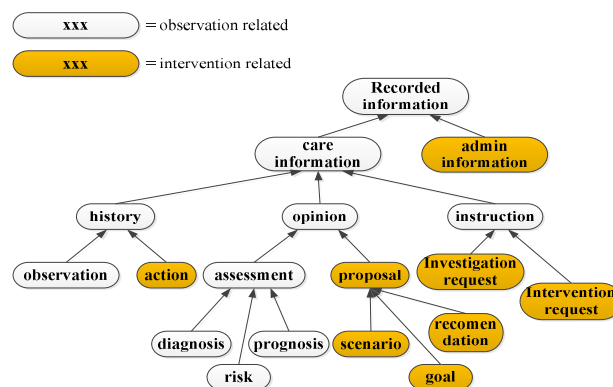


Fig. 1. The Clinical Investigator Record Ontology [23]

Analyzing the important types of information in the health care process, we selected 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 [20].

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 [24]. This way, ISO 13606-2:2008 defines how to organize 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 HIS and mobile device connectable together and to other health care networks.

4. 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 EN ISO 13606 standard. The possibility to integrate the obtained measurement and analysis results to available EHR has to be proposed. [25][26][27]
- 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 standardized interconnection interface. As an example, the archetype for blood glucose measurement [19] will be discussed.

The extended archetype is presented in Figure 2. The presented in Figure 2 archetype provide a basis for software development and extended presentation of obtained patient's data and its context. It gives a possibility to integrate the obtained information in a patient's electronic health record and to transfer them or part of them to the hospital information system.

The preliminary software design, based on the proposed archetype, was a subject of an inter-university project. Together with another implementation of a blood-pressure metering device they were a basic test-bed for archetype-based design of mobile vital-signs acquiring devices.

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 [28][29], 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 behavior. This did not degrade the validation process because its target was the archetype software representation not the real device control and precise measurements.

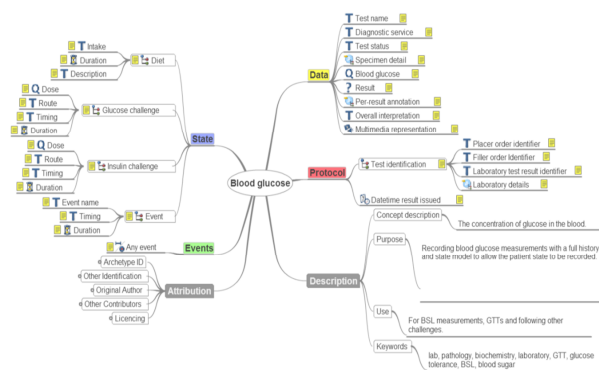


Fig. 2. Map View of the 'Blood Glucose measurement' archetype [19]

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.

5. 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, standardization 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 understanding enhances the computer-based and remote medicine. It will be based on a formally-proven well-designed structure, open and easily adaptable standard, possibility to combine inter-domain knowledge and to present virtual uni-platform services and systems.

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Dimitar Tcharaktchiev is an Associate Professor in Medical University - Sofia. He has a Ph.D. in Medical Informatics and acknowledged medical specialties in Internal diseases, Public Health and Health Management, specialisations in Geriatrics and Endocrinology. Dr. Tcharaktchiev is also member of Bulgarian Institute for Standardization, Bulgarian representative in the European Committee for Standardization – TC for Health Informatics – CEN/TC 251. He was invited scientist (2001-2004) to the University Paris 6, European University Hospital "Georges Pompidou", member of the team received the e-Health price 2003 of the European Commission. Dr. Tcharaktchiev is a chairman of Association PROREC Bulgaria, Member of EUROREC Institute.

Vesselin Gueorguiev – doctor on Computer Sciences. Assist.-Professor at the TU Sofia. Senior researcher at the Advanced Control Systems Lab at the TU Sofia.

Ivan Evg. Ivanov is a member of IEEE and IFAC, Assoc.-prof. at the TU Sofia and head of Advanced Control Systems Lab at the TU Sofia.