

The integration of e-health into the clinical workflow – Electronic Health Record and standardization efforts

Roberta Gazzarata¹, Fabio Vergari², Jan-Marc Verlinden³, Simone Naso⁴, Viola Parodi⁴, Tullio Salmon Cinotti² and Mauro Giacomini¹,

¹ Department of Communication, Computer and System Sciences (DIST), University of Genoa, Via Opera Pia 13,
16145 Genoa, Italy

{roberta.gazzarata, mauro.giacomini}@dist.unige.it

² Advanced Research Center on Electronic Systems for Information and Communication Technologies E. De Castro (ARCES), University of Bologna, Via Toffano 2, 40125 Bologna, Italy {fvergari, tsalmon}@arces.unibo.it

³ ZorgGemak BV, Papelaan 85F, 2252 EG te Voorschoten, the Netherlands
jan-marc@zorggemak.com

⁴ Infinity Tecnology Solutions (IST), Via Dino Col 4,
16149 Genoa, Italy
{simone.naso, viola.parodi}@itsinfinity.com

Abstract. The continuous increase in the number of different devices within medical information systems, produces a large amount of heterogenic clinical information which must be integrated and correctly stored in order to improve patient's health and decrease healthcare cost. The use of the universally recognized standards for the information and knowledge transmission and storage can be an excellent instrument to develop innovative eHealth solution. A EN13606 compliant telemonitoring solution is described in this paper; it is based on a collection and a semantic organization of sensor data, a standardized information transmission and storage within an internal repository during the monitoring period. This solution represents an example of care continuum concretization completely integrated with European Health System directives.

Keywords: semantic interoperability, eHealth, standardization, Smart Space.

1 Introduction

Recent studies [1] showed the impact of eHealth to healthcare and healthcare cost. The NHS (National Health Service) performed world largest study on eHealth with 6.000 patients involved. This study stated that, by using eHealth: the number of acute admissions decreased by 20%, the number of acute hospitalization went down by 14%, the number of patient-days in hospitals also went down by 14%, costs decreased by eight percent. And to top of it all, the mortality in this study were 45% lower than in usual care.

The European Commission provides us an insight on innovation barriers for eHealth [2]. In barrier 12 “*Lack of standards*”, they judged that there is a huge lack of understanding the standards for better semantic and functional interoperability in healthcare systems. This paper describes eHealth as the continuity of care that can be

supported by several tools, that can follow each patient in any aspect of his/her normal life. In cases of severe chronic diseases, as in cardiovascular condition, the permanent monitoring of the status of the patient can be a life saving tool [3].

At present, the continuous increase in the number of different devices, based on heterogenic technologies, within medical information systems, produces a large amount of clinical information about patients in all kinds of proprietary formats. Moreover, state-of-the art technologies provide instruments to design and develop innovative solutions which are able to enlarge the actual boundaries of healthcare beyond the hospital environment. This means that data sources can gather quality information independently from the site of measurements [4]. Consequently, in many developed countries health authorities are planning the creation of a life long health record diary which aims to contain all relevant clinical information which is organized in a structured environment; referred to as the Electronic Health Record (EHR) [5-6].

The concept of the EHR is defined by Iakovidis as “digitally stored health care information about an individual's lifetime with the purpose of supporting continuity of care, education and research, and ensuring confidentiality at all times” [7]. The EHR can collect varying types of information (observations, laboratory tests, diagnostic imaging, etc.) which are typically stored in different proprietary formats. Typical formats are for example, relational database tables, structured document-based storage and unstructured document storage (digitized hardcopies maintained in a common document management system) [8]. Among some implementations of the EHR, the one developed at Muenster University Hospital called *akteonline.de* is worthwhile describing briefly. The aims of this EHR are:

- to give citizens the possibility to be in charge of their own health record electronically;
- to provide access to this record through the internet independent of place and time;
- to present personalized health information online;
- to serve as a medium for sharing selected areas of health information with caregivers (which can be used as a communication between medical professionals, but under control of the concerned patient) [9].

This EHR solution is well structured, in order to provide citizens with a tool to insert and store parts of their medical data manually; instead it encounters difficulties in integration with solutions which transfer information automatically and independently from the site of the patient, as in common telemonitoring. This aspect is highly significant as one of the prominent research directions in the medical field is based on developing frameworks to improve health knowledge and processes for prevention and treatment of acute episodes. A smart and innovative solution, which is able to provide both personalized telemonitoring and the management of patient's health status, must ensure: the interoperability between heterogeneous devices and services, a reliable and secure patient data management and a seamless integration with the clinical standardized workflow.

This paper presents a specific implementation of this concept for people suffering from Congestive Heart Failure (CHF) class III [10]

2 Material and Methods

The material utilized in this work is related to clinical data obtained from patients affected by CHF; this data must follow a particular workflow. According to the specific medical guidelines, these patients have already been hospitalized and the large amount of data, collected during this period, is accessible through the institutional EHR. Due to their critical health condition, after the hospitalization, these patients must be continuously telemonitored and the information collected is of high importance : it be possible that these patients could have to be readmitted and, in this case, it is useful that the information is again available to the institutional EHR.

In order to efficiently implement this workflow, the following section should be included into the proposed system:

1. A Virtual Data Repository (VDR) internal to the system which maintains the same features of institutional EHR for all telemonitoring period;
2. Standardized interfaces to allow a bidirectional relationship between the institutional EHR and the internal VDR;
3. A collector to harmonize extremely fragmented signals coming from sensors placed on the field (Smart Space).

The system architecture followed the indications provided in the CEN/ISO 13606 (also called EHR.com). Specifically, during the implementation of interfaces two different, but equivalent approaches were used: the openEHR and the HL7 version 3 Clinical Document Architecture Release 2 (CDA R2). In both cases it was decided to use an information transmission based on the HL7 v3 message. Finally, Smart Spaces were used for the collection and semantic organization of information coming from the sensor network.

2.1 Different reference models

EN13606, openEHR and HL7-CDA are based on different Reference Models. These Reference Models are in fact more or less generic class-structures and datatype-definitions which are able to describe the health related objects (for example, medical condition).

One health related object can thus be described inside more different Reference Models. And there are more ways to describe a health related object inside the chosen Reference Model.

The main EU standard for a HER: the approved CEN/ISO 13606 (EHR.com).

CEN13606 leaves considerable space to adapt the implementation of the standard to local circumstances and organization maturity. The archetype model combines the deterministic view with the possibility to make a trade off toward local habits and peculiarities.

The main architectural features are; to act as discrete systems or as middleware components; to access, transfer, add or modify health record entries; to operate via electronic messages or distributed objects; to preserve the original clinical meaning

intended by the author; to reflect the confidentiality of that data as intended by the author and patient.

In enfacing this challenge, the goal has been to specify the information architecture required for communications interoperability between systems and services that might request or provide EHR data. This standard is neither intended to specify the internal architecture or database design of such systems, no to prescribe the kinds of clinical applications that might request or contribute EHR data in particular settings, domains or specialist fields. For this reason, the information model might be used to define a message, an XML document or schema, or an object interface as described in CEN/TC 251/N04-012 published on Health Informatics in 2004.

The ISO/NEN13606 parts:

- Part 1: Reference Model
- Part 2: Archetype interchange specification
- Part 3: Reference Archetypes and term lists
- Part 4: Security requirements and distribution rules
- Part 5: Interface Specifications

In this project we used two different approaches (reference architectures) to meet the EN13606; the openEHR approach is submitted to the VDR, the HL7 CDA approach is submitted to Smart Space. External messaging for both approaches is HL7 v3 (SOAP).

Virtual Data Repository (VDR).

The VDR Kernel is build on the scientific approach from the openEHR specifications. The Interface of the Kernel is SOAP, whereas middleware on top of the SOAP layer separates GUI from the Kernel by REST services. This transparent approach guaranties safety and ability to add services (like local regulations) without changing the architecture.

OpenEHR describes a two-level modeling methodology and two sets of specifications - an information part and a knowledge part. The first one defines a stable reference model that describes the EHR as a container that holds compositions (documents) which in turn may have entries (observations, evaluations, instructions, etc.). Although the selection of entries is based on a certain model of decision making in healthcare, the model itself does not attempt to represent clinical knowledge. It comes from a variety of sources - terminologies, ontologies, classifications, measurement systems, etc. - and the application of computable knowledge representation to the information model is how data acquires its context-specific meaning. The full computable data models of clinical concepts are called archetypes: blood pressure is an archetype, so is a synoptic report, pathology lab result, etc.

An important feature of the openEHR environment is that the modeling of the data is not enforced by the openEHR environment but by archetypes. The base of all data-modeling is in the reference-model, which allows very flexible modeling. Although it is optimized for use for medical-orientated data.

The archetype is meant to represent all the clinical knowledge regarding a certain concept. However, in order to make a practical use of archetype libraries we combine them. For example a medical specialist may specify that he needs the systolic and

diastolic blood pressure, and the arterial, or the pulse, he might not be interested in discussing whether the patient was sitting, standing, etc.

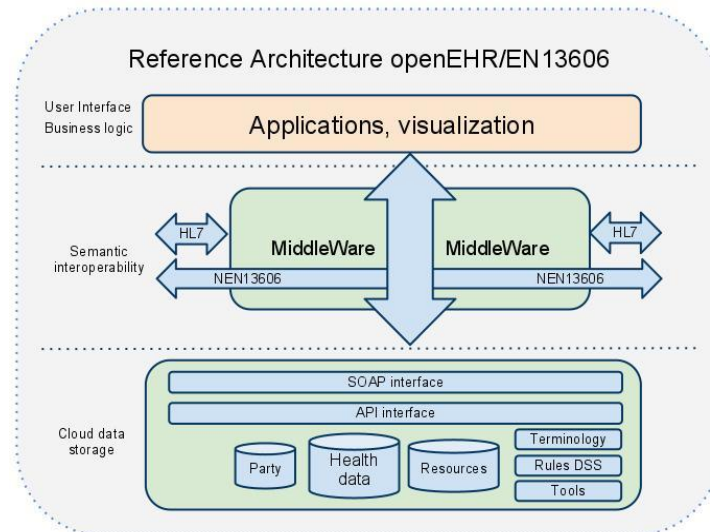


Fig.1. Reference Architecture openEHR/EN 13606

In different circumstances, e.g. in sports medicine we may want to have a baseline reading and then repeat it every 5,10mins. Archetypes allow for different constraints in different formats (GUI), so long as we use the same basic clinical models. Once we've selected the GUI we can further enhance the semantics by querying available terminologies (SNOMED, ICD) and producing bindings to the terminology subsets that should be used with particular archetypes. If our understanding of medicine is enriched, we can produce a new version of the archetypes, or in order to dig deeper, we can specialize them and so on.

HL7 v3 CDA R2.

The Clinical Document Architecture Release 2 is a document markup standard developed by HL7, encoded in markup languages as XML or RDF, that specifies the structure and semantics of a clinical document for the purpose of exchange. HL7 CDA R2 provides an object model in order to represent a technical diagram of the CDA specification and structure. The basic structure of CDA Release 2 is formed by two parts fully HL7 v3 RIM (Reference Information Model) derived: a *header* and a *body*. The *header's* purpose is to set the context for the document as a whole, to enable clinical document exchange across and within institutions, to facilitate clinical document management and to facilitate the compilation of an individual patient's clinical documents into a lifetime electronic patient record.

The *body*, contains the clinical report and it can be either an unstructured blob or can be comprised of structured markup. In the second case, the *body* is divided up into recursively nestable document *sections*. Each *section* contains a single "narrative block", any number of CDA *entries* and external references (such as some other

image, procedure, or clinical document). The “*narrative block*” represents the content to be rendered, which is expressed in human language. Every *section* can contain a *clinical statement* which could be one of the following: an *observation*, a *substance administration*, a *supply*, or a *procedure*. Each *clinical statement* in turn can relate to another one through a semantic relationship (e.g., cause, component, reason) [11].

2.2 Smart Space

The Smart Space (SS) platform is a solution able to share understanding of information significance in order to provide a semantic interoperability of information collected by heterogeneous devices and sensors. SS manage and store information about entities existing in the physical environment, that is, the users, the objects surrounding them, the devices they use, or about the environment itself. In its architecture Smart Space has two main actors: the semantic information broker (SIB) and the knowledge processor (KP). The SIB is a digital entity which stores and keeps up-to-date significant real-world information. The information model is a directed labeled graph corresponding to a set of Resource Description Framework (RDF a basic semantic web standard) triples. In order to specify information semantics, ontologies defined in OWL (Web Ontology Language) are used. The KPs are software components able to interact with the SIB, produce and/or consume data. The legacy adapters are KPs that enable legacy SS-unaware devices to exchange information with the SIB. To allow KP to exchange data an application layer protocol based on XML (eXtensible Markup Language), Smart Space Access Protocol (SSAP), is defined. It provides a simple set of messages (join, insert, remove, update, query, subscribe, and leave) that can be used over multiple connectivity mechanisms.

In the biomedical context, this platform can be use as the core of this telemonitoring alarm system: every patient has his personal Smart Space that manages information collected from heterogeneous devices together with the user profile; thanks to its publish/subscribe mechanism, the solution is responsible also for event/notification [12].

3 Results

The EN13606 compliant telemonitoring solution which is proposed in this article is formed by:

- A Virtual Patient Repository, based on EHR.com specifications, to collect information and knowledge about the patient and present it via a semantic interoperable Web Service;
- A Body Sensor Network (Smart Space), based on HL7 CDA specifications, to collect and semantically organized information coming from monitoring sensors;
- A Web Service, based on the message broker HL7 v3 (SOAP), which provides a standardized interface to allows bidirectional communication between either SS-VPR and EHR-VPR.

3.1 Clinical Information Workflow

To allow a correct interpretation of clinical information workflow, now three different storyboards are presented (Figure 2).

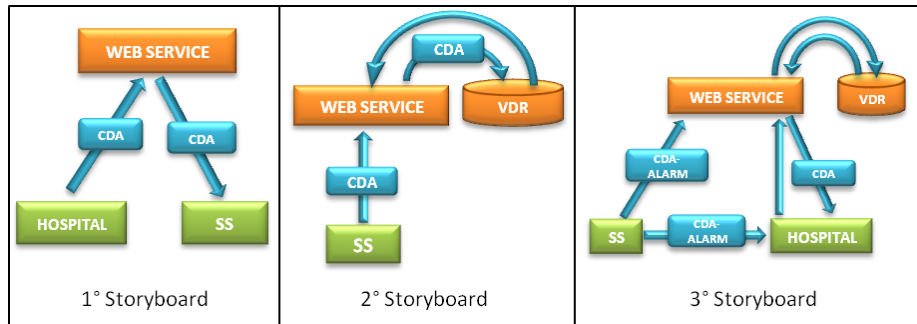


Fig.2. The clinical information workflow: the three storyboards

In the first storyboard, the patient is discharged from the Hospital and from now she/he will be monitored at home by the Smart Space platform; the care structure Information System uses a specific Web Service function to send the complete Clinical Document Architecture to SS system. This document contains the information necessary to enable a new registration on the patient's specific SS: the threshold values for the clinical observations for this patient, required to set the alarm criteria on SS. In the same time a new Virtual Data Repository is initialized.

The second storyboard describes a typical information update within Virtual Patient Repository. The Smart Space platform collects and semantically organized all information, coming from the patient's Body Sensor Network, within the Semantic Information Broker. Several times a day, a specific Knowledge Processor interacts with SIB and produces a CDA which contains, within the key elements Observations, the semantically organized information which are collected in that specific time interval. After that, the KP sends this CDA to Web Service which temporarily store these Observation until the VPR calls the specific service to be updated with the new information. In this way, the Web Service prepares a CDA which contains all the Observation temporarily stored within its local database and sends it to VDR.

In the third storyboard is represented the critical situation in which one or more vital sign measured are out of range, so the KP prepares and send a CDA broadcast alarm message either to Web Service and to Hospital Information System.

Thanks to this information, the Hospital Information System is informed about the critical health status so it can organize the relief and prepare the patient readmission. In fact, it can call the specific Web Service function to obtain a CDA which contains all the relevant information collected within the VDR on all telemonitoring period. Therefore it is able to update the EHR of the patient who is going to be readmitted.

4 Conclusions

In this paper a telemonitoring solution which ensures the integration of e-health into the clinical workflow is presented. This is possible thanks to the use of the universally recognized standards – EN13606 (EHR.com) with two different specifications; openEHR and HL7 v3 CDA R2 – for the information and knowledge transmission and storage. Both solutions communicate in the XML message defined by HL7 v3.

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