Interoperable infrastructure and implementation of a health data model for remote monitoring of chronic diseases with comorbidities

P. Finet ^{1, 2,3}, B. Gibaud ^{2,3}, O. Dameron ⁴ and R. Le Bouquin Jeannès ^{2,3}

¹ Centre Hospitalier Intercommunal Alençon-Mamers, Alençon, F-61000 France

² INSERM, U 1099, Rennes, F-35000 France

³ Université de Rennes 1, LTSI, Rennes, F-35000, France

⁴ IRISA, Université de Rennes 1, F-35042 Rennes, France

phfinet@ch-alencon.fr

Abstract - The future increase of chronic diseases justifies the development of telemedicine for following up patients outside of the hospital. However, current telemedicine applications are disease-specific whereas chronic diseases are often associated with comorbidities. We show that the use of interoperability standards for telemedicine systems makes it possible to build a telemedicine platform (with several medical devices) that can be shared between several diseases workflows. To remotely follow up the patient's vital signs, health professionals need to access to the context description and the relevant background information. The implementation of an health data model that meets the needs of practitioners seems to be an appropriate solution to this problem.

Keywords: Telemedicine, interoperability, Health data model.

I. INTRODUCTION

The ageing of the population is associated with the development of chronic diseases [1], which were responsible for 36 of the 57 million deaths worldwide in 2008 [2]. The United Nations estimated that this category is expected to reach 406 million by 2050 [3]. The aging of the population will result in an increase of the number of chronic diseases with comorbidity factors [4]. For example, compared with people who do not have diabetes, the diabetic patients have a higher risk of cardiovascular morbidity. Type 2 diabetes increases the risk of coronary artery disease by a factor of two to four, and the risk of heart failure by a factor of two to eight [5]. The use of telemedicine facilitates patient follow-up outside of the hospital. Telemedicine applications can contribute to reduce healthcare costs by reducing the number of hospital consultations and transports. However, most existing telemedicine projects focus on a single chronic disease and few actors. In such cases, comorbidities are usually not explicitly considered. In fact, taking comorbidities into account requires the ability to share medical data among health care information systems. To have access to care anywhere and anytime with telemedicine, it is necessary to create a fully interoperable infrastructure [6]. The benefits of such architecture are twofold: first, to avoid the redundancy of medical information systems as isolated islands, and second, to enable the chronic disease telemedicine application to take into account parameters from the comorbidities. The first part of this article consists in identifying a model of data structure that meets the medical needs of remote monitoring for several chronic diseases with various medical devices. This led us to propose in a second part a new implementation of interoperable telemedicine systems which allow healthcare professionals to share patient information.

II. THE PROPOSED TELEMEDICINE SYSTEM

A. Conception of the health data model

1) The telemedicine systems constraints

To analyse patient's data, health professionals need to access to the context description (e.g. information about the type of examination), the important background information (e.g. the type of collected measurements from medical devices and the date and the time date of the measurements) and the acquisition context (e.g. sensor characteristics). Furthermore, if exchanged information is limited to raw data captured by patients, it is not possible to interpret it meaningfully. Indeed, for example, the results of the measures do not have the same meaning according to the time and date of measurements. Patient's data are context-dependent [7]. They cannot be properly interpreted by a remote medical staff without specific contextual information.

For chronic diseases, the function of telemedicine systems is to monitor patients' vital signs. Patients with chronic diseases usually follow established care protocols to enable monitoring vital signs with the introduction of according to some alert thresholds. With this infrastructure, simultaneous monitoring of a chronic disease and its potentially chronic comorbidities can be performed, and two different physiological alerts could be treated at the same time. For this purpose, an environment should be implemented to share and exchange patient's data and to facilitate cooperation between healthcare professionals. In this case, the telemedicine systems must be fully interoperable from technical (between two different technology systems), syntactic (between two different communication systems) and semantic points of view.

In order to solve the two problems mentioned above, we propose an integrated solution addressing both previous issues.

A conceptual health data model that meets the medical needs of remote monitoring of patients addresses to first problem. The use of standard data exchange formats, interoperable services and standard transport protocols to send structured data to a remote location addresses the second.

2) Proposed health data model

To define an health data model suitable for telemedicine projects, we selected an appropriate modeling framework from the international standard HL7 Clinical Document Architecture (CDA) [8]. The aim of this standard is to share interoperable clinical documents between healthcare professionals. Theses models should support both qualitative and quantitative data captured during a medical consultation. Today, the CDA R2 version includes structured elements in the document header and in the document body [9]. This type of documents may include several sections that contain human readable narrative forms or codified structures for an automatic processing. Thus, it contains health data that can be easily integrated into databases of healthcare facilities [8]. With the last version of CDA, the body text sections include codified entries to recover external data (Fig. 1) [9]. The implementation of a CDA document requires to select an existing model that contains templates and rules sets. Templates are designed to create standardized clinical documents that are specifically intended to support clinical workflows in various use cases [10]. For our telemedicine project, we chose a CDA document which aims to get vital signs.

This type of document contains different templates and values. For each medical device used at the patient's home, the

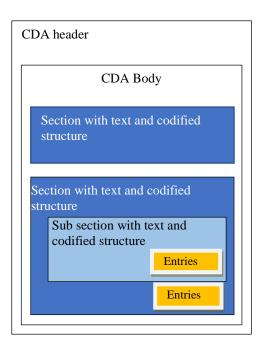


Figure 1. CDA structure

creation of the health context model consists of describing variables, constants and codes which are present in the CDA header, in a CDA section, in a CDA sub-section or in a predefined entry. As an illustration, we propose to describe the blood pressure monitor model [11] which is used in an experiment in progress. The operating principle of the pressure sensor is based on both the systolic and diastolic blood pressure measurements. For the blood pressure measurement codification, three medical nomenclature terms are required: Blood pressure code, diastolic blood pressure code and systolic blood pressure code. For the blood pressure monitor model, other data are required to provide contextual information: date and time of the data acquisition and sensor identification data. The health context model of blood pressure monitor is shown in Fig. 2.

At all stages of patient's data transfer, the variables, the constants and nomenclature codes of the health context model must be communicated to the different receivers of patient data.

3) Interoperability of the telemedicine systems

The aim of our project is to get an interoperable telemedicine system, suitable for monitoring a chronic disease and its potentially chronic comorbidities simultaneously. To guarantee quality and safety of patient's care, our telemedicine application combines three different systems: the patient

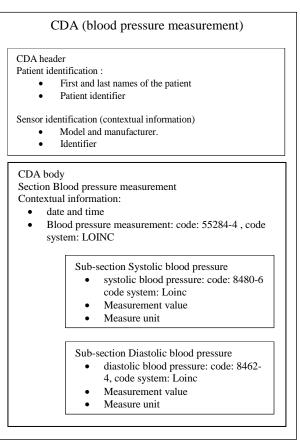


Figure 2: the health context model of blood pressure monitor

system for the medical monitoring and patient selfmeasurements, the data processing and archiving system, which is generally located in the hospital and the data transmission system between the two structures. These three systems describe the workflow of the patient's data from his home to the hospital and must be in teroperable.

Continua Health Alliance (CHA), a non-profit organization, promotes standard data exchange formats, integration profiles and standard transport protocols. The Guidelines of the CHA [12] help to develop interoperability between components of the three systems of our telemedicine architecture, based on international standards and Integrating the Healthcare Enterprise (IHE) technical frameworks. To guarantee plug & play capability, the CHA prescribes for the patient system the use of the ISO/IEEE 11073 standards family [12] for communication between medical devices and application hosting devices, such as mobile phones and set-top boxes. For the data transmission system, an IHE profile and the Health Level 7 (HL7) V2.6 [13] standard are used to transfer securely health data from patient's home to health professionals. The IHE DEC (Device Enterprise Communication) profile defined in the IHE PCD (Patient Care Device) technical framework allows a point-to-point communication between a hosting device and a remote server. A HL7 v2.6 message is transmitted to the remote server based on the information contained in the hosting device. For the data processing and archiving system, IHE has proposed the XDS (Cross-enterprise Document Sharing) profile [14], which comes from the IHE IT Infrastructure technical framework (ITI TF). This profile describes appropriate sharing of medical documents. It specifies the transactions supporting the registration, distribution and access to shared documents between healthcare facilities. Fig. 3 summarizes the different steps of data transport by the three interoperable systems with the use of communication standards, standard health data exchange formats and integration profiles.

4) The different models and structure data of the communication standards

To represent data and to define data access, the ISO/IEEE 11073 family of standards provides some models which contain objects and attributes. They will help us to describe the data receipt and the data transfer process from one system to another. The system model of the IEEE standard 11073-20601

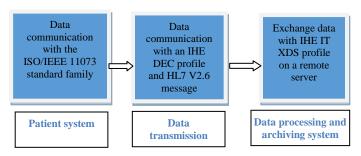


Figure n°3: The data communication

is divided into three principal components: the domain information model (DIM), the service model, and the communication model [15]. These objects and their attributes represent the elements that control the behavior of the device and the data transferred to a hosting device. The IHE DEC Integration Profile describes a HL7 v2.6 message which is used to communicate the information contained in the hosting device [16].

5) The DIM model

For the patient system interoperability and the transport of our data structure model, it is necessary to describe the DIM in order to analyse its objects and attributes which contain detailed information on the device, on the data type, on the number of physiological measurements to exchange and on the device status at the host device [17]. These components are essential items of the communication protocol between the sensor and the hosting device. The most important object is the Medical Device System (MDS). It represents the properties and services of the medical device. The attributes of the MDS object allow to identify the device, to describe its technical and the state data. Besides the MDS object, there are Persistent Metric Store (PM-store) object and other objects (zero or more per object type) which are derived from the metric class. These different objects are numeric objects which represent episodic measurements, Real Time Sample Array (RT-SA) objects which represent continuous samples or wave forms, enumeration objects which represent event annotations and PM-store which provides a persistent storage mechanism [17].

For simple medical devices (as a blood pressure monitor) which only deliver episodic measurements, the DIM consists only of MDS and numeric objects (see Fig. 4) [18]

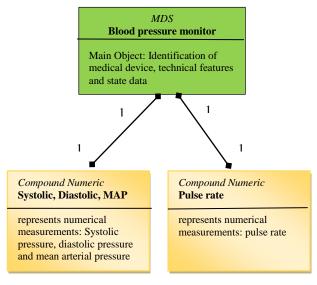


Figure n°4: The blood pressure monitor DIM

the health context model of blood pressure monitor	DIM Model	
Item in the model of blood pressure monitor	Variable or constant name	Item and location field in the blood pressure monitor DIM
SENSOR DESCRIPTION		
Model and manufacturer	MDC_ATTR_ID_MO DEL	Attributes included in MDS object
Identifier	MDC_ATTR_SYS_I D	
MEASUREMENT DESCRIPTION		
Date and time	Absolute-Time- Stamp	Attribute included in systolic/diastolic/MAP numeric object
Blood pressure measurement	MDC_PRESS_BLD_ NONINV	Code included in Numeric object (with another nomenclature: ISO/IEEE 11073-10101 Vital Signs Nomenclature ¹
Systolic blood pressure	MDC_PRESS_BLD_ NONINV_SYS	Code included in Numeric object (with another nomenclature: ISO/IEEE 11073-10101 Vital Signs Nomenclature
Measurement value	MDC_ATTR_NU_C MPD_VAL_OBS_BA SIC	Attribute included in systolic/diastolic/MAP numeric object
Diastolic blood pressure	MDC_PRESS_BLD_ NONINV_DIA	Code included in Numeric object (with another nomenclature: ISO/IEEE 11073-10101 Vital Signs Nomenclature
Measurement value	MDC_ATTR_NU_C MPD_VAL_OBS_BA SIC	Attribute included in systolic/diastolic/MAP numeric object.
Measurement unit	MDC_DIM_MMHG	Attribute « Unit-Code » included in systolic/diastolic/MAP numeric object. The unit is mmHg

B. The health data model communication

1) Comparison between the two models

To verify the first step of transport of all structured data of a blood pressure monitor (data transport with the ISO/IEEE standards), we analyzed the relation between the DIM data model and the health context model. The aim of this study was to verify the good mapping of all components between the two models (see TABLE I). The only difference between these models was the use of different nomenclature systems for medical terms. To obtain a semantic interoperability of the telemedicine application, it was required to elaborate a mapping between the ISO/IEEE 11073-10101 numeric codes and the equivalent LOINC term(s) [17].

2) The HL7 V2.6 message

To transfer the health context model data from the patient's home to a remote location, the IHE DEC profile advises the use of a HL7 v2.6 message which contains patient's information in encoding syntax based on segments [16].

This type of message has two main characteristics: it can be sent without solicitation from the remote location and its structured data cover all observations and results which come from the patient's home. The name of the message type is « ORU^R01^ORU_R01 » [16]. It consists of several optional or mandatory data segments. It is composed of three main components: the Message Header (MSH), The Observation/Result segment (OBX) and the observation Request segment (OBR). The MSH defines the identification of message, the sender and receiver, the message type, and some specifics of the syntax of a message [16]. The OBX is used to transmit a single observation or observation fragment [16]. All results of patient's measurements should be contained in OBX segments. The third component is the observation Request segment (OBR). It contains the request of the medical act (ordering information) and the context for observation (i.e., whether the request was done in-clinic or remote). When a set of observations is ordered, the order message contains an OBR segment [16]. Some fields in the OBR segment apply only to the ordering message.

For remote monitoring systems, the message structure of « ORU^OR01^ORU^R01 » is suitable to transmit data between the patient's home and a remote health care facility. In the message header, the patient's identification and contact information may be transmitted by the Patient Identification (PID) segment. All results of patient's measurements are contained in OBX segments. The identification of the device will be present in an OBX segment. In this case, the suffix of the OBX-3-observation identifier is DEV [15]. In the OBR-4 of the OBR segment, we have the identifier codes for the requested patient's measurements. For the transfer of the message, it is advised to use HTTPS or other secure standard protocols. The HL7 message sent from the patient's home allows the patient's data to be processed and stored on a

 $^{^{1}\,\}mathrm{A}$ mapping between the ISO/IEEE 11073-10101 numeric codes and the equivalent LOINC term(s) is required

remote server. When a patient's measurement threshold is exceeded, Data processing and archiving system must be able to generate and display alerts or to indicate the actions to be implemented in case of emergency. In this case, a CDA document can be created.

3) The CDA document

The CDA document is automatically generated and it is made accessible by medical professionals. The document sharing management system can be built with the XDS profile functional architecture [14]. This profile describes appropriate sharing of medical documents. It specifies the transactions supporting the registration, distribution and access to shared documents between healthcare facilities [14]. With the IHE XDS profile, sending and receiving clinical documents can be achieved with standard communication protocols as HTTP or HTTPS.

III. CONCLUSION AND PERSPECTIVES

Telemonitoring is a helpful tool for at home preventive care for vulnerable population with chronic health conditions. To be efficient, the data collected at the patient's domicile must be exhaustive to support adequate interpretation and follow up of vital signs. The guidelines of the CHA help building an interoperable solution for the three systems of telemedicine applications. This ecosystem promotes the use of the ISO/IEEE 11073 standards family for communication between medical devices and computer systems, and the use of HL7 standards and of IHE integration profiles for exchanging clinical data among information systems. Implementing a health context model data to collect vital signs should facilitate medical data exchange between healthcare professionals. CDA, a structured and standardized document, is an appropriate tool to the new conditions of information exchange.

REFERENCES

- P. Finet, R. Le Bouquin Jeannès, O. Dameron, and B. Gibaud, "Review of current telemedicine applications for chronic diseases. Toward a more integrated system?", IRBM, March 2015, vol. 36, n° 3, pp. 133-157.
- [2] World Health Organization, "Global Status Report on Non communicable Diseases", 2011.
- [3] United Nations, "World Population Prospects: The 2006 Revision. New York: United Nations", Department of Economic and Social Affairs, Population Division; 2007, See: http://www.un.org/esa/population/publications/wpp2006/WPP2006_High lights_rev.pdf (last checked 8 November 2013).
- [4] C.D. Mathers, C. Bernard, K. Moesgaard et al, "Global Burden of Disease in 2002: data sources, methods and results", In Global Programme on Evidence for Health Policy Discussion Paper No. 54. Geneva: World Health Organization; 2003.
- [5] I. Martín-Timón, C. Sevillano-Collantes, A. Segura-Galindo, F. Javier del Cañizo-Gómez, "Type 2 diabetes and cardiovascular disease: Have all risk factors the same strength?", World J Diabetes 2014 August 15; vol. 5, no. 4, pp. 444-470.

- [6] R.L. Craft, "Toward technical interoperability in telemedicine", Telemed. J. E. Health, 2005, vol. 11, n° 3, pp. 384-404.
- [7].. M. Baas, S. Bernonville, N. Bricon-Souf, S. Hassler, C. Kolski, A.G. Boy, "Towards a context model for human-centered design of contextual data entry systems in healthcare domain", 16th International Conference on Human-Computer Interaction, Heraklion, Crete, Greece, June 22-27, pp. 223-233.
- [8] R.H. Dolin, L. Alschuler, C. Beebe, P.V. Biron, S.L. Boyer, D. Essin et al, "The HL7 Clinical Document Architecture", J. Am. Med. Inform. Assoc., 2001, Vol. 8, pp. 552–69.
- [9] J.M. Ferranti, R.C. Musser, K. Kawamoto, W.E. Hammond, "The Clinical Document Architecture and the Continuity of Care Record: A Critical Analysis", J Am Med Inform Assoc, May-Jun 2006, vol. 13, n° 3, pp. 245–252.
- [10] Health Level Seven, "L7 Implementation Guide: S&I Framework Transitions of Care Companion Guide to Consolidated-CDA for Meaningful Use Stage 2, Release 1 – US Realm", See: https://www.hl7.org/implement/standards/product_brief.cfm?product_id= 258 (last checked 7 November 2015).
- [11] R.H. Dolin, L. Alschuler, S. Boyer, C. Beebe, F.M. Behlen, P.V. et al, "HL7 Clinical Document Architecture, Release 2", J. Am. Med. Inform. Assoc., 2006 Jan-Feb;13(1): pp 30-9.
- [12] F. Wartena, L. Muskens-Schmitt, "Continua: The Impact of a Personal Telehealth Ecosystem", International Conference on eHealth, Telemedicine, and Social Medicine eTELEMED, pp. 13-18, 2009.
- [13] M. Frohner, P. Urbauer, M. Forjan, B. Pohn, F. Gerbovics, S. Sauermann et al, "Development of an Android App in Compliance with the Continua Health Alliance Design Guidelines for Medical Device Connectivity in mHealth", Biomed Tech (Berl), 2012 Sep 6, vol. 57 Suppl 1.
- [14] G. Duftschmid, C. Rinner, M. Kohler, G. Huebner-Bloder, S. Saboor, E. Ammenwerth, 'The EHR-ARCHE project: Satisfying clinical information needs in a Shared Electronic Health Record System based on IHE XDS and Archetypes", Int J Med Inform., Dec 2013, vol. 82, n° 12, pp. 1195-207.
- [15] I.N. Korsakov, S.M. Kuptsov, D.A. Raznometov, V.V. Feklistov, M.A. Sumskoy, "On Demand Plugins for X73-PHD Manager", International Journal of Advanced Trends in Computer Science and Engineering, 2013, vol. 5, pp. 35-40.
- [16] IHE, "IHE Patient Care Device (PCD) Technical Framework, Volume 1 PCD TF-1 Integration Profiles", 2013 October 11.
- [17] IEEE, "Std 11073-20601: 2010 Health Informatics Personal Health device Communication – part 206101: application profile - optimized exchange protocole", 2010 May 1.
- [18] IEEE, "Std 11073-10417: 2010 Health Informatics Personal Health device Communication - part 10407: device specialization - blood pressure monitor", 2008 December 10.