31st Annual International Conference of the IEEE EMBS
Minneapolis, Minnesota, USA, September 2-6, 2009

Integration Proposal through Standard-Based Design of an End-to-End Platform for p-Health Environments

I. Martínez, J.D. Trigo, M. Martínez-Espronceda, J. Escayola,
P. Muñoz, L. Serrano, *Senior Member IEEE*, and J. García, *Member IEEE*

Abstract— **Interoperability among medical devices and compute engines in the personal environment of the patient, and with healthcare information systems in the remote monitoring and management process is a key need that requires developments supported on standard-based design. Even though there have been some international initiatives to combine different standards, the vision of an entire end-to-end standard-based system is the next challenge. This paper presents the implementation guidelines of a ubiquitous platform for Personal Health (p-Health). It is standard-based using the two main medical norms in this context: ISO/IEEE11073 in the patient environment for medical device interoperability, and EN13606 to allow the interoperable communication of the Electronic Healthcare Record of the patient. Furthermore, the proposal of a new protocol for End-to-End Standard Harmonization (E2ESHP) is presented in order to make possible the end-to-end standard integration. The platform has been designed to comply with the last ISO/IEEE11073 and EN13606 available versions, and tested in a laboratory environment as a proof-of-concept to illustrate its feasibility as an end-to-end standard-based solution.**

I. Introduction

Last decade has implied a total evolution in healthcare applications due to the advances in the information technologies. The application environment has been extended from hospital-located healthcare services to the patient/user's context. This new approach brings recently elaborated concepts like Personal Area Network (PAN) and Body Area Network (BAN). Moreover, the user's ability to get around while being followed-up will bring the ubiquitous Personal Health (p-Health) into scene. All of these scenarios rely on specific medical devices based on sensors to acquire the user's biosignals (blood pressure, pulse, weight, temperature, ECG, among others) so they can be evaluated later either by the same user or the professional healthcare service providers.

This research work has been partially supported by projects TIN2008-00933/TSI and TSI2005-07068-C02-01 from *Comisión Interministerial de Ciencia y Tecnología* (CICYT) and European Regional Development Fund (ERDF), TSI-020302-2008-35/*Plan Avanza I+D* from *Ministerio de Industria, Turismo y Comercio*, a FPI grant to M. Martínez-Espronceda (Res. 1342/2006 from Public University of Navarre), and a research visit grant to J.D. Trigo awarded by DGA/CONAID/CAI (ref. IT7/08).

I. Martínez, J.D. Trigo, J. Escayola, P. Muñoz and J. García are with the Communications Technologies Group (GTC), Aragon Institute for Engineering Research (I3A), University of Zaragoza (UZ), c/ María de Luna, 3, 50018 Zaragoza, Spain (e-mail: jtrigo@unizar.es). M. Martínez-Espronceda and L. Serrano are with the Electrical and Electronics Engineering Dep., Public University of Navarre, Campus de Arrosadía s/n, 31006 Pamplona, Spain (e-mail: miguel.martinezde espronceda@unavarra.es).

Devices manufacturers all around the world have been fighting for a place in the market by creating their own protocols to transmit and manage biomedical signals. This fact causes an obvious lack of interoperability, specially suffered by end-users and healthcare system managers. Thus, standardization is being promoted to fill this interoperability gap from several organizations (in Europe, the main organization in this field is the Committee European of Normalization (CEN), within its Committee CEN/TC251, to which our research group belongs) [1]. Of all the standards for medical information interoperability that are being developed (DICOM, HL7, SCP-ECG), there are two protocols called to solve the interoperability leak in the European context: ISO/IEEE11073 (X73) [2] for medical devices interoperability, and EN13606 [3] for Electronic Healthcare Record (EHR) exchange.

X73 is a family of standards that describes all the features of the entire communication between a Medical Device (MD) and a Compute Engine (CE) by defining the device specializations, the data exchange/representation and terminology, the information profile, and the transport technologies including both in the protocol stack and the communication model. In parallel, EN13606 represents any information included in EHR, as well as its communication between EHR systems, managing semantic interoperability of the transmitted data. Its main is to normalize the way in that EHR (the whole EHR or a part (extract) of it) is interchanged to make them interoperable. Thus, EN13606 is not intended to specify the internal architecture of EHR system or the way data are stored or consulted, but the way the clinical information must be transmitted.

The standard integration into end-to-end solutions is still an intricate work. In this context, some private initiatives such as Integrating the Healthcare Enterprise (IHE) and Continua Health Alliance have emerged and are willing to collaborate with the aforementioned organizations to encourage standardization [4]. This paper presents a proposal for an end-to-end integration of a standard-based platform oriented to p-Health solutions, developed through X73 and EN13606. In Section II the platform architecture is described by detailing its technical features as X73 evolution, integration with EN13606, and inclusion of a new proposed protocol for End-to-End Standard Harmonization (E2ESHP). In Section III the proposed standard-based design and implementation guidelines are analyzed by distinguishing the specific requirements for both standards. The future trends related to standard integration and its implantation into new protocol are discussed in Section IV.

II. Integration Proposal of an End-to-End Platform

One of the main challenges in the research lines for standard development and integration is its real implementation in a telemedicine solution, transferable to the healthcare system. Previous contributions have been developed for studying the viability of applying X73 in sanitary environments by implementing solutions to monitor patients in the Point-of-Care (X73PoC) [5], by testing in a laboratory environment the new approaches for Personal Health Devices (PHDs) as proof-of-concept to illustrate the standard evolution to X73PHD [6], or by applying EN13606 in healthcare systems [7]. Nevertheless, there are not antecedents about end-to-end solutions that integrate X73PHD and EN13606 oriented to p-Health, as this proposal.

The platform architecture (see Fig. 1) is based in a CE that collects the information acquired by different patient's MDs in the p-Health environment. This CE communicates, through the communication networks, with a Monitoring Server (MS) that manages the different CEs and gathers all the information arriving from each patient monitoring scenario to update the EHR. The characteristics of these different elements that comprise the system architecture are:

- MDs. The original medical data acquisition follows the vendor format (the majority of the MDs available in the market are not X73-compliant; so far, only one X73-compliant MD, a pulse-oximeter, has been developed [8]). Thus, the platform includes several X73-adapters in order to create the particular MD specifications following the X73PHD conformances. It generates the associate Domain Information Model (DIM) and establishes the Finite State Machine (FSM) to allow MDs to act as agents of the X73PHD communication model.
- CEs. Compute Engine is an interconnection element designed as an X73PHD-manager that recollects medical data from MDs through FSM. The stored information, with the specific *Configuration Profile*, is the data input to the frame creation process for the new proposed protocol for End-to-End Standard Harmonization (E2ESHP). This proposal of E2ESHP will allow CE (as client) and MS (as server) to guarantee the harmonized communication because of its design not only is X73PHD-compliant but includes as frame overhead with the patient information (that is not indispensable from the X73PHD point-of-view but it is mandatory for its inclusion in the patient EHR). Furthermore, E2ESHP will cover all the required functionalities of a p-Health service that are not usually included in the standards: supervision and remote control, platform updating and management, database access and user monitoring, network status, system intelligence, etc.
- MS. Monitoring server is composed by two entities. The first one acts as E2ESHP server because it is in charge of receiving data from X73PHD, decoding E2ESHP frames and extracting the appropriate X73PHD data (distinguishing of the associated user' information) in order to store them in the database. The second one acts as EN13606 client/server because it implements a double function: acceptation of EN13606 queries for further translation into mandatory fields to be searched in the database, and generation of EN13606 extracts following the EN13606 Archetype Model.

From this proposed platform architecture, the design guidelines and the implementation process have to guarantee several technical specifications regarding to the specific requirements for both X73PHD and EN13606 standards, as it is detailed in the next section of this paper.

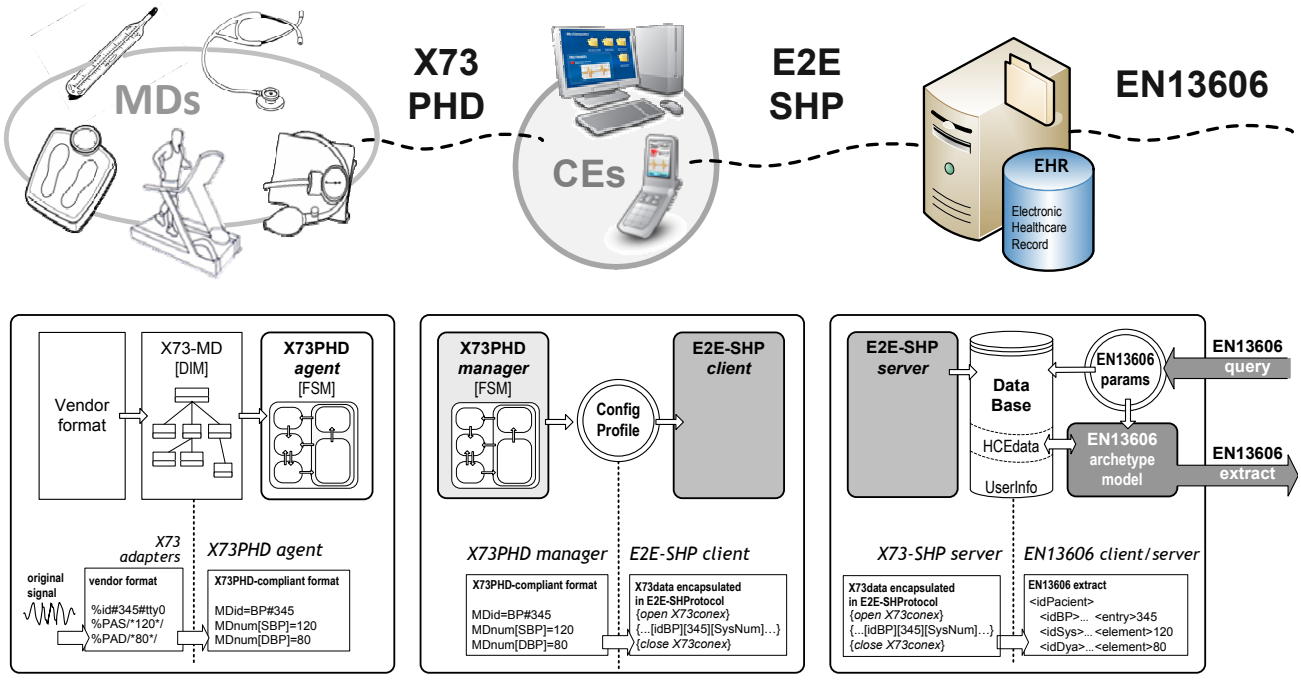

Fig. 1. Implementation proposal for end-to-end standard integration in a p-Health platform

III. Implementation Results from X73 and EN13606 Evolutions and Standard-Based Design

The X73 family of standards has undergone an evolutionary process from its firsts versions focused on the Point-of-Care of the patient (X73PoC) to the most recent version for personal healthcare environments (X73PHD). Thus, X73PHD has thoroughly simplified the architecture of the protocol for communication between *agents*/MDs and *managers*/CEs into three models (see Fig. 2): the Domain Information Model (DIM) that typifies the information inside the agent as a set of objects; the Service Model that provides methods to access the data that are sent between both systems to establish the interchange of DIM's data; and the Communication Model that describes the network architecture in which the agent communicate with the manager via point-to-point connection.

X73PHD evolves from X73PoC with a new protocol stack that is divided into three levels (see Fig. 2): Device Specializations as a set of model descriptions which collects the total of objects and attributes related to the MD components to make possible adding new agents, Optimized Exchange Protocol as the main part of the standard consisting of a medical and technical terminology framework (DIM) which will be encapsulated inside the protocol data units, and Transport Layer, allowing several transport technologies as USB, Bluetooth or ZigBee to be implemented (X73PoC established higher dependency between transport and upper and lower layers).

Thus, the main characteristics of X73PHD that enhance X73PoC are also the key points in the guidelines of the standard-based platform:

- Since the manager knows the standard specifications, the agent does not have to send its configuration unless it uses a different one. In that case, the manager will ask for that configuration in order to be able to work with that agent and to store this configuration for following reconnections. This often prevents the configuration procedure which can be a high time-consuming task in the case of multi-specialized MDs (such as multi-parametric monitor with blood pressure, pulsioximeter and glucometer).
- It defines different transport profiles, taking into account conditions of communication channel (application level).
- It is independent of the transport layer. This significantly reduces the implementation problems. The protocol assumes functionalities that the selected technology should fulfill. If that would not be possible, it admits the definition of functionalities through a shim layer.
- It reduces the complexity of the objects tree of the DIM, removing redundant classes and adding new ones such as permanent metric that allows storing measurements that can be sent when the manager requires them.
- A much more complete FSM is thoroughly described and tested to prevent any potential error during the operation of the protocol. The design of the FSM is more versatile since it has added new functionalities such as to have the agent configuration at manager's disposal.

In a similar way, the EN13606 standard is in continuous evolution from lasts two decades and it is not completed yet. It is based on a dual model: Reference Model that supports information and Archetype Model that defines "knowledge" (an archetype is a pattern that represents the specific characteristic of the clinical data). EN13606 is divided into 5 parts: 1/Reference Model, 2/Archetype Specification, 3/Reference Archetypes and Term lists, 4/Security, y 5/Interface Specification. In the beginning of 2009, the fifth one of these five parts had not been ratified and the Reference Model of its dual model has several differences with the previous version (ENV13606) of 2004. These main differences, in order to adapt the concepts that are needed to transmit in an EHR query/extract are:

- Sensitivity is not a mandatory parameter, and now it is represented by an integer. If sensitivity is not transmitted, a default value is supposed to determinate who is allowed to access that information.
- Attribute used to group a set of COMPOSITIONs (*contribution_id*) goes from AUDIT_INFO class to COMPOSITION class, so its meaning is more related to clinical information rather than context information.
- CLINICAL_SESSION class and its attributes are now included by RECORD_COMPONENT and FUNTIONAL_ROLE classes; in this way, COMPOSITION class contains now optional attributes as *session_time* (time interval of the session) and *territory* (country where the extract was created), and FUNTIONAL_ROLE class contains *healthcare_facility* (organization at which the role was performed) and *service_setting* (type of service location at which the role was performed).
- Optional attribute *composer* is replaced by a mandatory association with *committal* belonging to AUDIT INFO class. Now context information is larger since it must be said who sends the information, when was it send and from which EHR system. In addition, it differentiates between who send it and who created it, since they can be different people indeed.
- Attribute *version_specific*, that makes reference to the target of a link was a RECORD_ COMPONENT or a version, is removed. Since every version of a record component has a unique identifier, it is logical to make reference to that identifier giving no importance to if it is a version or not.

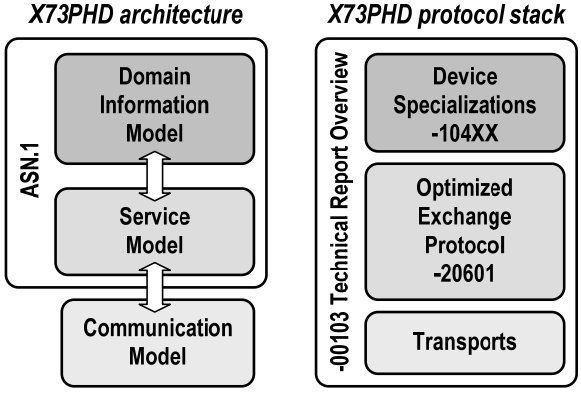

Fig.2. X73PHD architecture and protocol stack

After studying the evolution of these fields and the inheritance between classes, an EN13606 implementation would require a MS from which we would be able to generate a valid EHR extract, as shown in Fig. 3. As we can see, this example contains additional fields like *meaning* to bind the measurement meaning to a clinical terminology and *archetype_id* to identify the pattern data which is transmitted after. In this example, CEN Data types (TS14796) has been used meanwhile the definition of a new data type, common to ISO/IEEE, HL7 and CEN, would be carried out.

EHR_EXTRACT
ehr_system.extension = **Miguel Servet Hospital**
ehr_system.assigningAuthorityName = **Aragon Healthcare Service/AHS**
ehr_system.valid_time = **1/1/1900 – 1/1/3000**
ehr_id.extension = **EHRextract.120025022008**
ehr_id.assigningAuthorityName = **AHS**
ehr_id.valid_time = **1/1/1900 – 1/1/3000**
subject_of_care.extension = **441003686941**
subject_of_care.assigningAuthorityName = **AHS**
subject_of_care.valid_time = **1/1/1900 – 1/1/3000**
time_created.time = **15/02/2009 17:32**
rm_id = **EN13606-1.0**
COMPOSITION
rc_id.extension = **0003**
rc_id.assigningAuthorityName = **Miguel Servet / AHS**
rc_id.valid_time = **1/1/1900 – 1/1/3000**
name = **Telemedicine Data List**
sensitivity = **3**
committal.ehr_system.extension = **Miguel Servet Hospital**
committal.ehr_system.assigningAuthorityName = **AHS**
committal.ehr_system.valid_time = **1/1/1900 – 1/1/3000**
*committa*l.committer.extension = **Perez MD**
committal.committer.assigningAuthorityName = **AHS**
committal.committer.valid_time = **1/1/1900 – 1/1/3000**
committal.time_commited = **10/01/2009 17:32**
ENTRY
rc_id.extension = **0004**
rc_id.assigningAuthorityName = **Miguel Servet / AHS**
rc_id.valid_time = **1/1/1900 – 1/1/3000**
archetype_id.extension = **CENArch.Entry.TMWeightMeasure.v1**
archetype_id.assigningAuthorityName = **Miguel Servet**
archetype_id.valid_time = **1/1/1900 – 1/1/3000**
name = **Weight measurement**
meaning.codingScheme = **2.16.840.1.113883.6.96**
meaning.codingSchemeName = **SNOMED**
meaning.codingSchemeVersion = **7**
meaning.codeValue = **301333006**
meaning.displayName = **Body weight measurement**
synthesissed = **FALSE**
sensitivity = **3**
ELEMENT
rc_id.extension = **0005**
rc_id.assigningAuthorityName = **Miguel Servet / AHS**
rc_id.valid_time = **1/1/1900 – 1/1/3000**
name = **Weight measurement**
meaning.codingScheme = **2.16.840.1.113883.6.96**
meaning.codingSchemeName = **SNOMED**
meaning.codingSchemeVersion = **7**
meaning.codeValue = **301333006**
meaning.displayName = **Body weight measurement**
sensitivity = **Clinical**
synthesized = **FALSE**
value.PQ.value = **77**
value.PQ.units = **kg**
value.PQ.property = **Weight**

Fig. 3. Example scheme of an EN13606-compliant EHR extract

IV. Conclusions and Future Trends

The lack of standard integration in biomedical environments requires efforts to develop harmonized healthcare applications like the proposed implementation of an end-to-end standard-based platform for a ubiquitous p-Health solution. The followed design guarantees the specific requirements for the two main standards in this context, ISO/IEEE11073 and EN13606 (both adopted as European way of medical information interoperability).

These results open new challenges currently under research from our group as the integration with managements systems and the implantation of the X73PHD communication model on microcontroller-based devices. The integration of X73PHD with management protocols (as SNMP or RMON) will contribute new functionalities as data security, dynamic and versatile monitoring, and remote configuration of MD features (battery control, patient advices, etc.). The microcontroller-based design will imply to MDs an autonomy increase and a weight and size decrease due to minimize the power consumption. From our know-how of X73PHD standard, a proposal of pattern-based design will make possible an X73-kernel implantation with all the standard features and functionalities supported by Real Time Operating System (RTOS) and ready for the inclusion of new wireless technologies as ZigBee.

Acknowledgments

The authors wish to thank PHDWG and Melvin Reynolds, *convenor* of the CEN/TC251 WGIV, for the contributions to this research. We also appreciate the contribution of Miguel Galarraga (UPNA associate professor and researcher) and Adolfo Muñoz (researcher of the *Instituto de Salud Carlos III*, AENOR/CTN139 general manager, and CEN/ TC251 member) to the excellent results carried out during the last years in this work.

References

[1] Comiteé European Normalisation/TechnComm251 (CEN/TC251). http://www.cen.eu – http://www.centc251.org [In Spain, Asociación Española de Normalización (AENOR/CTN139) http://www.aenor.es/ desarrollo/inicio/home/home.asp]. Accessed April 09.

[2] ISO/IEEE11073. X73PoC MD Communication standard. [Part 1. MD Data Language (MDDL)] [Part 2. MD Application Profiles (MDAP)] [Part 3. Transport and Physical Layers]. X73PHD standard. [P11073-00103. Technical report - Overview] [P11073-104xx.Device specializations] [P11073-20601.Application profile-Optimized exchange protocol]. http:// www.ieee1073.org/. Accessed April 09.

[3] EN13606 CEN/TC251. Electronic Healthcare Record Communication. Standard Parts 1, 2, 3, 4 and 5 (2006). http://www.medicaltech.org. Accessed April 09.

[4] Integrating the Healthcare Enterprise (IHE). http://www.ihe.net/. Continua Health Alliance. http://www.continuaalliance.org/home/. Accessed April 09.

[5] Martínez I. *et al*. Implementation Experience of a Patient Monitoring Solution based on End-to-End Standards. *Int Conf IEEE Eng in Medicine and Biology Society*, vol. 1-16, pp. 6426-6429, 2007.

[6] Martínez I. *et al*. Optimization Proposal of a Standard-based Patient Monitoring Platform for Ubiquitous Environments, *Int Conf IEEE Eng in Medicine and Biology Society*, pp. 1813-1816, 2008.

[7] Muñoz A. *et al*. Proof-of-concept Design and Development of an EN13606-based Electronic Healthcare Record Service, *J Am Med Inform Assoc*, vol. 14, pp. 118-129, 2007.

[8] Vena platform (X73-compliant pulsioximeter). *Cambridge Consultants (Altran Technologies)*. http://www.cambridgeconsultants .com/news_ pr204.html/. Accessed April 09.