Contributions to the continuity of care: Integration of telemetry data into the Patient’s Electronic Health Records through the concurrent use of open standards.

Postgraduate Program in Cross Engineering
Biomedical Engineering
Mention of Excellence
PhD Dissertation

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Acknowledgements

Sitting in front of my computer, after writing this Thesis, I find myself struggling about how approaching this document’s last page. Finally, I have decided to dispense with the most of the formalism these pages are usually written because I want this “Thank you!!!!” really sounds like a real “Thank you!!!” and real “Thank you!!!!”s do not know about formalities.

However, and although it is kind of formality, my firsts thoughts are for you Nacho (Professor Ignacio Martínez Ruiz) and Adolfo (Dr. Adolfo Muñoz Carrero). It has been a long way since this “roller coaster” began to run and I hope “the end of this story that I started to tell would be as wonderful” for you as it is for me. It has not been always easy but I think I have finally “arranged all this information in order to look like knowledge”. And, of course, my gratitude to Catalina and Dionisio, who gently accepted to be external reviewers of this document.

I also want to thank people from CHIME for their gentle welcome and for letting me share some of their time and expertise. It was an incredible experience that make me test myself in an, until this moment, unexplored area. Although not seeming too chatty, I am not even in my mother tongue, you knew how to excuse me including in those moments that I thought that would be easier to teach you all Spanish (excepting Dionisio who commands the language) than explain myself in English.

To my colleagues, witnesses of this path and spoilers of this outcome. For their help and understanding. And for all this extra-pressure to make me continue writing in this last stage.

To my friends, because I don’t know what I have done to deserve your friendship. Because through your eyes I seem better than I really am. To have more deltas, and more teas, in our lives.

To my family. I am who I am because you are who you are. Because you tried to get involved, this is yours too (but only from page 88 to 103. :-P The rest is all mine... the Permanent head Damage is all mine).

To my angels. I miss you. I wish this would have made you feel proud, not because of the degree, but for having the courage to finishing it.
“It doesn’t matter how slowly you go as long as you do not stop.”

“When it is obvious that the goals cannot be reached, don’t adjust the goals, adjust the action steps.”

“There are three methods to gaining wisdom: The first is reflection, which is the highest. The second is imitation, which is the easiest. The third is experience, which is the bitterest.”
To the stones in my path:

The ones in which I tripped over (sometimes more than once) because they taught me some lessons

and, especially,

the ones I was able to use to lean on and which helped me to get back on my feet and be myself again.
Abstract

The society in which we are living is a changing organism that has been evolving as time goes by. The undergone changes (in the demographic structures, population habits, mobility patterns, etc.) have been consequences of technological improvements or discoverings and have caused changes in the heath care system’s user profile. So dramatic changes (i.e. more patients, who live longer and who suffer from different types of diseases) need of a change in the paradigm of the patient’s care process. Health care system has to know how to adapt itself to handle these changes.

During its development, this Thesis has been presented as a proposal for the improvement in the patient’s care process, through a technological viewpoint, based on the reuse of telemonitoring measurements and their proper integration in the patient’s Electronic Health Record (EHR) trying to harmonize two worlds which have traditionally been apart from each other: the medical device world and the clinical environment. To accomplish this, and using the standard-based design as premise, the main standards in the medical device environment have been enumerated and briefly described. A similar effort has been carried out in the EHR environment in which, besides of considering additional helpful mechanisms for the transmitted information’s semantic integrity, a similar set of EHR standards has been compiled. In this compendium, EHR communication standards have been specially considered and, particularly, their Information Models. In this analysis it has not been obviated either the influence of different organizations that promote one or the other standards.

Moreover, it has been reasoned about the general system’s architecture using as basis both the architecture of different telemonitoring systems, the needed infrastructure in the use of medical device’s interoperability standards and the various interactions that might be established among the different care services. All of this was done with the purpose of reusing existing telemonitoring modules, thereby avoiding the developing costs of building a system from the ground. This way, not only new systems would have the needed architectural support but developed systems might be re-used, somehow, for this purpose. After that, based on this infrastructure, various standards were selected in base of reaching the most of the medical device environment and, at the same time, a great flexibility and simplicity in the EHR communication.

The integration proposal has mainly been supported by the use of knowledge models to define, not telemonitoring reports but, each element contained in them. Archetypes suit this premise as they are both domain concept definitions and formal elements suiting the Archetype Model which is able to constrain an Information Model.
The integration process which was firstly outlined to harmonize a specific couple of standards, each of them belonging to different environments, evolved to acquire a more generic approach: based on a ISO/EN 13606 - ISO/IEEE 11073 Personal Health Device (PHD) standards compatibility study, the minimum criteria to allow the telemonitoring information acquisition would not be subordinated to a specific standard were obtained. At the same time, in relation to the EHR communication, the various initiatives to transform clinical content according a specific standard into others also justified considering the design from the selected standard viewpoint.

The proposed architecture allows the problem to be staged in two steps: firstly, the telemonitoring information integration in an EHR server and, after that, the EHR generation process to be communicated to other Health Centre Information System (HCIS). Data integration has been based on an acquisition methodology and the definition of those mechanisms which solve the communication gap among medical devices and the EHR environment. This gap is proposed to be solved through the definition of an Information Model, the definition of coding schemes in each of the acquiring systems and the use of a standard interface. On the other side, the reports’ generator system has been mainly based on the recursive hierarchy of the clinical report model and the analysis of the various parameters in the standardized EHR request interface. The whole system was deployed as a proof-of-concept and the various processes were tested both by internal procedures and third parties unconnected to the system deployment process.

Using this system implementation, security in the EHR communication has been considered in base of the jointly application of ISO/EN 13606-4 and ISO/TS 22600 standards. This way, in the system development, all the ISO/EN 13606 standard parts have been taken into account. The requirements’ analysis to apply the security normative led to design the EHR provider system blueprint. Moreover, in the parameters’ analysis, various inconsistencies were detected which led to propose a series of modifications in this document which would provide greater internal coherence among the standard parts. These modifications were also implemented and tested.

Finally, various future lines are suggested as conclusion.
Resumen

La sociedad en la que vivimos es un organismo cambiante que ha ido evolucionando con el transcurso del tiempo. Los cambios experimentados (en la demografía, en los hábitos de la población, patrones de movilidad, etc.) han sido el fruto de avances o descubrimientos tecnológicos y han causado cambios en el perfil de usuario del sistema sanitario. Cambios tan drásticos (más pacientes, que viven durante más años y están afectados de diferente tipo de enfermedades) necesitan de un cambio de paradigma en el proceso de atención al paciente. El sistema sanitario ha de saber cómo adaptarse a estos cambios.

En esta tesis se ha presentado una propuesta para la mejora del proceso de atención al paciente, desde un punto de vista tecnológico, basada en el aprovechamiento de medidas de telemonitorización y su integración en la Historia Clínica Electrónica (HCE) del paciente, intentando armonizar dos mundos que tradicionalmente se encontraban separados como son el de los dispositivos médicos y el entorno sanitario. Para ello, y utilizando como premisa inicial el diseño basado en normas, se han enumerado y descrito brevemente las principales normas en el entorno de dispositivos médicos. Un trabajo similar se ha realizado en torno a la HCE, donde además de contemplar otros mecanismos que ayuden a la integridad semántica de la información transmitida, se ha profundizado en cuanto a normas aplicables, especialmente en aquellas relacionadas con la comunicación de la HCE y, en particular, en sus modelos de información. En dicho análisis, no se ha omitido la influencia de las diferentes organizaciones que promueven unas normas u otras.

Por otro lado, se ha realizado un razonamiento sobre la arquitectura general del sistema, tomando como base tanto las arquitecturas de diferentes sistemas de telemonitorización como la infraestructura necesaria para el uso de normas de interoperabilidad en el ámbito de dispositivos y las diferentes interacciones que se pueden establecer entre los diferentes servicios de atención. Todo ello con el propósito de reutilizar diferentes módulos ya existentes, evitando los costes que acarrearía un desarrollo desde cero. De esta forma se consigue no sólo dar cobertura a nuevos sistemas implantados, sino reapprovechar en cierta medida los sistemas de seguimiento ya implementados. Posteriormente, a partir de ese esquema, se seleccionaron varias normas siguiendo un criterio por el cual se maximizara el alcance en el ámbito de los dispositivos y que ofreciese gran flexibilidad y sencillez en la comunicación de la HCE.

La propuesta de integración fue basada principalmente en el uso de modelos de conocimiento para la definición, no de informes de telemonitorización, sino de cada uno
de los elementos que los contienen. Como medio de expresar el conocimiento se usan arquetipos, definiciones de conceptos del dominio que a su vez son elementos formales que se corresponden con el modelo de arquetipos y que son capaces de establecer restricciones sobre un modelo de información.

El proceso de integración, que en principio fue planteado para armonizar una pareja específica de normas, una en cada entorno, terminó adquiriendo un carácter más genérico: a partir de un estudio de compatibilidad entre las normas ISO/EN 13606 e ISO/IEEE 11073 Personal Health Device (PHD) se obtuvieron los criterios mínimos que permitan, en aras de una mayor generalidad, que la aquisición de la información de telemonitorización no dependa de una norma concreta. A su vez, en cuanto a la comunicación de la HCE, los diferentes esfuerzos para convertir la información clínica transmitida según una norma a su equivalente en otra justificó considerar el diseño desde el punto de vista de la norma seleccionada.

El diseño de la arquitectura necesaria permite la división del problema en dos fases: por un lado, la integración de la información en un servidor de HCE y, por otro, la generación de extractos de HCE para su comunicación a otro sistema sanitario. La integración de los datos de telemonitorización se ha basado en una metodología de adquisición y en la definición de los mecanismos que solventan el gap entre el entorno de los dispositivos médicos y la HCE a través de la definición de un modelo de información, la definición de una codificación por cada sistema de adquisición y el uso de una interfaz normalizada. Por otro lado, el proceso de generación de informes se ha basado, principalmente, en la jerarquía recursiva del modelo de informe clínico y en el análisis de los distintos parámetros de la interfaz normalizada de petición de la HCE. El sistema completo fue implementado como prueba de concepto y los diferentes procesos fueron testeados tanto por procedimientos internos como mediante terceras partes ajenas al proceso de desarrollo.

Sobre esa implementación, se ha considerado la seguridad en la transmisión de la HCE mediante la aplicación conjunta de las normas ISO/EN 13606-4 e ISO/TS 22600. De este modo, en la construcción del sistema se han tenido en cuenta todas las partes de la norma ISO/EN 13606. El análisis de los diferentes requerimientos para la aplicación de la normativa de seguridad condujo a desarrollar un esquema de implementación del sistema provisor de la HCE. Además, debido al análisis de los parámetros necesarios se detectaron una serie de inconsistencias que llevaron a la propuesta de un conjunto de modificaciones en esta parte de la norma que proporcionarían una mayor coherencia interna entre las partes de la misma. Dichas modificaciones fueron, a su vez, implementadas y testeadas.

Finalmente, se señalan líneas de investigación futuras a modo de conclusión.
Conclusiones

Como John Milton una vez dijo: “Largo y arduo es el camino que conduce del infierno a la luz”. Sin embargo, “Un viaje de mil millas comienza con un simple paso” (Lao Tzu). Esto es lo que esta tesis ha intentado ser. Un pequeño paso.

La continuidad de cuidado, en la actual situación social, requiere cambios más complejos que el mero soporte tecnológico del proceso de cuidado sanitario que, de cualquier modo, debería ser transparente al profesional médico. Los centros sanitarios no están preparados para proveer una continuidad de cuidado proactiva dado que están más orientados al tratamiento de episodios agudos. Sin embargo, y dado que existe gran preocupación en esta situación, también hay un interés creciente en plataformas/sistemas de telemonitorización.

El uso de los sistemas de telemonitorización para mejorar el proceso de atención al paciente no es ninguna novedad. Sin embargo, estos sistemas tampoco proporcionan una solución válida si la información recogida no es incorporada a la HCE y transmitida de forma que no pierda integridad semántica. En esta línea de trabajo, esta tesis ha realizado varias contribuciones tras presentar el actual paradigma de la continuidad de cuidado, resaltando tanto la importancia de la atención de pacientes crónicos y la heterogeneidad tanto de dispositivos médicos como de tecnologías de transporte usadas en la implementación de sistemas de telemonitorización. Partiendo de esa heterogeneidad, se plantea el uso de un diseño basado en normas. Entre esas contribuciones se pueden encontrar:

- El estudio del ecosistema de normas de telemonitorización se llevó a cabo listando, tanto las iniciativas propietarias y las normas abiertas, como el trabajo de organismos de normalización relevantes.

- En el ámbito de la HCE se han estudiado recursos semánticos (clasificaciones, terminologías y nomenclaturas) y de normalización, especialmente a las normas de comunicación de la HCE y sus modelos de información. Posteriormente, a partir de este análisis se hace hincapié en las tendencias de harmonización entre ellos y sus respectivos modelos de información.

- Se han descrito varios escenarios en los que el punto de cuidado se encuentra de forma remota al centro sanitario y una de esas configuraciones es elegida siguiendo un criterio de una mayor configurabilidad. Sobre este escenario se identificaron los diferentes tipos de comunicación en una versión simplificada, lo que permitiría establecer a posteriori cualquier configuración de elementos en la arquitectura. En función de esa versión simplificada, se seleccionaron varias normas y, para asegurar
la integridad semántica de los datos adquiridos, se tomaron arquetipos como modelos de conocimiento porque a su vez son capaces de establecer restricciones sobre un modelo de información. Para expresar esos arquetipos se utilizó Archetype Definition Language (ADL) y, por lo tanto, se ha explicado en profundidad.

- A partir de las normas seleccionadas, ISO/EN 13606 y ISO/IEEE 11073 PHD, se confeccionó un estudio de compatibilidad de acuerdo a sus modelos de información y que incluye diversas soluciones para suplir las incompatibilidades que hay entre ellos. Además, ese mismo estudio permite la identificación de aquellos requisitos que permitirían abstraer la norma de adquisición de datos para trabajar con la norma ISO/EN 13606.

- Se ha definido una arquitectura capaz de incorporar los datos de telemonitorización en la HCE y para ello se ha diseñado una metodología de integración basada en el uso de arquetipos y un mecanismo que solventara el gap de comunicación entre los dispositivos médicos y la HCE que se basa en los mismos principios que la transmisión semanticamente interoperable de la HCE. Además se propone el diseño de un servidor de HCE usando un esquema de almacenamiento genérico y un proceso de generación de extractos orientada a tipo de dato. La arquitectura y la lógica de negocio se ha diseñado de una forma modular, teniendo en cuenta las particularidades del entorno de telemonitorización pero que permiten una fácil generalización del sistema.

- Se han realizado contribuciones a la seguridad en la comunicación de la HCE mediante el uso combinado del ISO/EN13606-4 y el ISO/TS 22600 mediante un estudio de requerimientos, que se materializa en el diseño de un esquema de implementación del sistema provisor de la HCE. Además, se proponen unas modificaciones a la norma que proporcionarán una mayor coherencia entre las partes de esta.

- Además, todo este sistema ha sido implementado como prueba de concepto. La metodología de integración se ha validado comprobando la correcta incorporación de datos enviados desde distintos dispositivos. Los extractos generados fueron comprobados tanto por tests internos como por terceras partes no relacionadas con el desarrollo del servidor de HCE. Relativo a la parte de seguridad, el servidor de HCE se complementa con un provisor de HCE, implementado con las modificaciones propuestas, y se testea con arreglo a la definición de una política de seguridad y la diferencia de respuesta de ese sistema con respecto al sistema compuesto solamente por el servidor de HCE.
Publications

The methodology and the results that appear in this Thesis are based on the following publications, as well as on publication under revision/in progress.

Publications in international Journals:


Book chapters:


Selected international conference proceedings:


Selected national conference proceedings:


## Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>AAL</td>
<td>Ambient Assisted Living</td>
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<td>ACSE</td>
<td>Action Control Service Elements</td>
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<td>ADA</td>
<td>American Dental Association</td>
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<td>ADH</td>
<td>Application Host Devices</td>
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<td>ADL</td>
<td>Archetype Description Language</td>
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<td>AMA</td>
<td>American Medical Association</td>
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<td>ANSI</td>
<td>American National Standards Institute</td>
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<td>AORN</td>
<td>Association of periOperative Registered Nurses</td>
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<td>APA</td>
<td>American Psychiatric Association</td>
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<td>APDU</td>
<td>Application Protocol Data Unit</td>
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<td>ASN.1</td>
<td>Abstract Syntax Notation One</td>
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<td>ASTM</td>
<td>American Society for Testing Materials</td>
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<tr>
<td>ATC</td>
<td>Anatomical, Therapeutic, Chemical classification system</td>
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<td>BER</td>
<td>Basic ER</td>
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<td>BT</td>
<td>Bluetooth Health Device Profile</td>
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<td>BTLE</td>
<td>Bluetooth Low Energy</td>
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<tr>
<td>cADL</td>
<td>constraint definition form of ADL</td>
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<tr>
<td>CAN</td>
<td>Controller Area Network</td>
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<td>CAT</td>
<td>Computed Axial Tomography</td>
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<td>CBIIT</td>
<td>NCI Center for Biomedical Informatics and Information Technology</td>
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<td>CCD</td>
<td>Continuity of Care Document</td>
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<td>CCR</td>
<td>Continuity of Care Record</td>
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<td>CCOW</td>
<td>Clinical Context Object Workgroup</td>
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<td>CD</td>
<td>Controlling Device</td>
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<td>CD.CV</td>
<td>Coded Data . Coded Value</td>
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<td>CDA</td>
<td>Clinical Document Architecture</td>
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<td>CDT</td>
<td>Current Dental Terminology</td>
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<td>CE</td>
<td>Compute Engine</td>
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<td>CEN</td>
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<td>CENELEC</td>
<td>European Committee for Electrotechnical Standardisation</td>
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<td>CHA</td>
<td>Continua Health Alliance</td>
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<td>CMISE</td>
<td>Common Management Information Service Elements</td>
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<td>COSTART</td>
<td>Coding Symbols Thesaurus of Adverse Reaction Terms</td>
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<td>CS</td>
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<td>CPT</td>
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<td>CTCAE</td>
<td>Common Terminology Criteria for Adverse Events</td>
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<td>CTS</td>
<td>Common Terminology Service</td>
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<td>dADL</td>
<td>data definition form of ADL</td>
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<td>DEC</td>
<td>Device Enterprise Communication</td>
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<td>DICOM</td>
<td>Digital Imaging and COmmunication in Medicine</td>
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<td>DIM</td>
<td>Domain Information Model</td>
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<td>D-MIM</td>
<td>Domain - Modeling Information Model</td>
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<td>DSM</td>
<td>Diagnostic and Statistical Manual of Mental Disorders</td>
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<td>ECG</td>
<td>Electrocardiogram</td>
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<td>EEG</td>
<td>Electroencephalography</td>
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<td>Electronic Health Record</td>
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<td>EMR</td>
<td>Electronic Medical Record</td>
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<td>ePHI</td>
<td>electronic Personal Health Information</td>
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<td>ER</td>
<td>Encoding Rules</td>
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<td>ETSI</td>
<td>European Telecommunications Standards Institute</td>
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<td>FDA</td>
<td>Food and Drug Administration</td>
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<td>FOPL</td>
<td>First-Order Predicate Logic</td>
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<td>FTP</td>
<td>File Transfer Profile</td>
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<td>FTP</td>
<td>File Transfer Protocol</td>
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<td>FSM</td>
<td>Finite State Machine</td>
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<td>FDB</td>
<td>First DataBank</td>
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<td>GDP</td>
<td>Gross Domestic Product</td>
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<td>GWT</td>
<td>Google Web Toolkit</td>
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<td>GHTF</td>
<td>Global Harmonization Task Force</td>
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<td>HCIS</td>
<td>Health Care Information System</td>
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<td>HeCo</td>
<td>Hearts Corporation</td>
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<td>HGNC</td>
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<td>HID</td>
<td>Human Device Interface</td>
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<td>HIMSS</td>
<td>Healthcare Information and Management Systems Society</td>
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<td>HL7 PHMR</td>
<td>HL7 Personal Healthcare Monitoring Report</td>
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<td>HMD</td>
<td>Hierarchical Message Description</td>
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<td>HTTP</td>
<td>Hyper Text Transfer Protocol</td>
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<td>HUGO</td>
<td>Human Genome Organisation database</td>
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<td>HUPH</td>
<td>Puerta de Hierro University Hospital</td>
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<td>ICD</td>
<td>International Classification of Diseases and Health Problems</td>
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<td>ICD0</td>
<td>Implantable Device Cardiac Observation</td>
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<td>ICH</td>
<td>International Conference on Harmonisation</td>
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<td>ICHI</td>
<td>International Classification of Health Interventions</td>
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<td>ICPC</td>
<td>International Classification of Primary Care</td>
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<td>Acronym</td>
<td>Full Form</td>
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<td>ICT</td>
<td>Information and Communication Technology</td>
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<td>ICU</td>
<td>Intensive Care Unit</td>
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<td>IEC</td>
<td>International Electrotechnical Commission</td>
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<td>IEEE</td>
<td>Institute of Electrical and Electronics Engineers</td>
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<td>IEEE 1451 NCAP</td>
<td>IEEE 1451 Network Capable Application Processor</td>
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<td>IHC</td>
<td>OASIS International Health Consortium</td>
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<td>IHE</td>
<td>Integrating the Healthcare Enterprise</td>
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<td>IHE DEC</td>
<td>IHE Device Enterprise Communication</td>
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<td>IHE IDCO</td>
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<td>IHE Patient Care Coordination</td>
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<td>IHE PIV</td>
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<td>II</td>
<td>Instance Identifier</td>
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<td>IIS</td>
<td>Internet Information Server</td>
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<td>INR</td>
<td>International normalized ratio</td>
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<td>ISCIII</td>
<td>Carlos III Health Institute</td>
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<td>ISM</td>
<td>Industrial Scientific Medical</td>
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<td>ISO</td>
<td>International Standards Organization</td>
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<td>IT</td>
<td>Information Technology</td>
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<td>ITU</td>
<td>International Telecommunication Union</td>
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<td>ITU-T</td>
<td>ITU Telecommunication Standardization Sector</td>
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<tr>
<td>IU</td>
<td>Iowa University</td>
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<tr>
<td>IVL&lt; TS &gt;</td>
<td>Time Interval</td>
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<tr>
<td>LIM</td>
<td>Logical Information Model</td>
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<tr>
<td>LIS</td>
<td>Laboratory Information System</td>
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<tr>
<td>LOINC</td>
<td>Logical Observation Identifiers Names and Codes</td>
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<tr>
<td>MCAP</td>
<td>Multi-Channel Adaptation Protocol</td>
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<tr>
<td>MD</td>
<td>Medical Device</td>
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<td>MD PnP</td>
<td>Medical Device Plug-and-Play</td>
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<td>MDER</td>
<td>Medical Device Encoding Rules</td>
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<td>MDAP</td>
<td>Medical Device Application Profile</td>
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<td>MDDL</td>
<td>Medical Device Data Language</td>
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<td>MDS</td>
<td>Medical Device System</td>
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<td>MedRA</td>
<td>Medical Dictionary for Regulatory Activities</td>
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<td>MIF</td>
<td>Model Interchange Format</td>
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<td>MIME</td>
<td>Multimedia Internet Mail Extensions</td>
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<td>MLM</td>
<td>Medical Logic Module</td>
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<td>MITyC</td>
<td>Ministerio de Industria, Turismo y Comercio</td>
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<tr>
<td>NANDA</td>
<td>North American Nursing Diagnosis Association</td>
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</table>
NCI  National Cancer Institute
NEHTA National EHealth Transition Authority
NEMA National Electrical Manufacturers Association
NHS National Health Service
NIC Nursing Interventions Classification
NIS Nursing Information System
NLM National Library of Medicine
NOC Nursing Outcomes Classification
OASIS Organization for the Advancement of Structured Information Standards
OMG Object Management Group
OMIM Online Mendelian Inheritance in Man
OPCS Office of Population, Censuses and Surveys Classification
OSI Open Systems Interconnection
OWL Web Ontology Language
PACS Picture Archiving and Communication System
PCIS Primary Care Information System
PDQ Physician Data Query
PDU Protocol Data Unit
PER Packet ER
PHD Personal Health Device
PHIS Pharmacy Information System
PIV Point of Care Infusion Verification
PKI Public Key Infrastructure
PM Persistent Metric
PNDS Perioperative Nursing Data Set
PoC Point-of-Care
PQ Physical Quantity
QMR Quick Medical Reference
RBAC Role-Based Access Control
RI Regenstrief Institute
RIM Reference Information Model
RIS Radiology Information System
R-MIM Refined - Message Information Model
ROSE Remote Operation Service Elements
RPC Remote Procedure Call
RTM Rosetta Terminology Mapping
RT-SA Real Time - Sample Array
SDO Standard Development Organization
SE Service Elements
SNOMED-CT Systematized Nomenclature of Medicine - Clinical Terms
SOAP Simple Object Access Protocol
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>SPL</td>
<td>Structured Product Labeling</td>
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<tr>
<td>SPP</td>
<td>Serial Port Profile</td>
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<tr>
<td>TS</td>
<td>Time Stamps</td>
</tr>
<tr>
<td>UCUM</td>
<td>UniFied Code for Units of Measure</td>
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<tr>
<td>UMLS</td>
<td>Unified Medical Language System</td>
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<tr>
<td>UN/CEFACT</td>
<td>United Nations Centre for Trade Facilitation and Electronic Business</td>
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<td>URI</td>
<td>Uniform Resource Identifier</td>
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<td>USB</td>
<td>Universal Serial Bus</td>
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<td>USB IF</td>
<td>USB Implementers Forum</td>
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<td>USB PHDC</td>
<td>USB Personal Health Device Class</td>
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<td>UWB</td>
<td>Ultra WideBand</td>
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<td>VNA</td>
<td>Visiting Nursing Association</td>
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<td>W3C</td>
<td>World Wide Web Consortium</td>
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<td>WHO</td>
<td>World Health Organization</td>
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<td>WDSL</td>
<td>Web Services Description Language</td>
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<td>WPAN</td>
<td>Wireless PAN</td>
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<td>WS</td>
<td>Web Services</td>
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<tr>
<td>WSN</td>
<td>Wireless Sensor Network</td>
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<tr>
<td>X73</td>
<td>ISO/IEEE 11073</td>
</tr>
<tr>
<td>XML</td>
<td>eXtensible Markup Language</td>
</tr>
<tr>
<td>ZHC</td>
<td>ZigBee Health Care Profile</td>
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Chapter 1

Introduction

1.1 Continuity of care between telemonitoring data and Electronic Health Records

Over the time many tribes have sought to locate the disease to expel it by removing whatever which makes the body to ill. So Shamans, who date back to the Upper Paleolithic era, enter into a trance state during a ritual to practice healing. Nevertheless, the first known medical record, or health record, is the one developed by Hippocrates in the fifth century B.C. [1]. Hippocrates stated that medical records should accurately reflect the course of disease and indicate its probable cause. So, in these documents, a profuse description of symptoms and their evolution over time is performed trying to relate the disease with the environment in which it was originated.

After that, in the medieval consillia, it can be analyzed the galen doctrine [2], which was principally influenced by the then-current theory of humorism [3]. In those documents some reasoning about the disease (i.e. pathogeny, ethiology and treatment) can be found as galens insist that the sole diagnosis that can be made is the one based on the reasoning.

With the Renaissance came an increase in experimental investigation, principally in the field of dissection and body examination [4] (a new autopsy procedure appeared), thus advancing our knowledge of human anatomy (e.g. differentiating between normal and altered organs). As an example of those advances in medicine Andreas Vesalius, a central figure of Renaissance medicine, wrote the first comprehensive book on anatomy pointing out Galen mistakes.
1.1. Continuity of care between telemonitoring data and Electronic Health Records

During the XVII century there was a break-up with the galen doctrine which preferred to rely on treatments of observed clinical effectiveness without inquiring into the mechanisms sought by therapeutic theory [5]. Clinicians, as Sydenham, taught that each patient was a unique dynamic entity in whom a disease could vary from person to person but, unlike Hippocrates, he did concern himself with classifying diseases in which can be considered a new nosology. The main contributions to this century are medical empiricism and the specify (i.e. diseases where described individually but they were related with typical cases in a morbid specie).

It is during the XVIII century when a model for medical records appears that is considered canonic and, with variations, it is the one used nowadays. This way, Boerhaave established the classic form for a morbid history (anamnesis, physical examination, diagnosis, history of the disease and autopsy findings) [6].

During the XIX century, three different mentalities about the way data are obtained appeared, i.e. the anatomo-clinical perspective, the pathophysiological perspective and the etiological perspective:

- The anatomo-clinical perspective is focused on classifying diseases by the lesions they produce.
- The pathophysiological perspective is focused on the function alterations a disease produces in the organism.
- The etiological perspective is focused in relating the family and personal background with the course and the status of the disease.

This differentiation gave greater internal coherence, descriptive accuracy and richness to the medical records because each of these approaches was offering partial images of the same disease. This mentality division is still used nowadays [7, 8, 9].

From Hippocrates to the actual date, medical records have not only preserved their application in the patient care but they have also incorporated other different features or applications, as described in [10], like the evaluation in the care quality (i.e. analyzing the effectiveness of the care provided to the patient) or its application to the teaching or researching field areas. Moreover, nowadays, medical records have embedded the administrative side of the care process, being an essential key in the health centre management tasks. Medical records are also considered legal documents as they set if the care process was required, if the health problem was correctly identified or if the appropriate action was prescribed.
Independently of those features/applications of medical records, a patient’s medical record is the systematic documentation of this patient’s medical history and care across time within one particular health care provider’s jurisdiction and it includes a variety of types of “notes” entered over time by health care professionals, recording observations of orders for drugs’ administration and therapies, test results, X-rays, reports, etc. as described in [11].

Due to different issues (i.e. changes in the demographics of the population or major impact index of chronic diseases) the amount of paper to deal with has been increasing significantly in the lasts decades. Moreover, the new medical tests (e.g. Computed Axial Tomographies, CATs) brought new different formats of recording information (e.g. X-ray) which turned the medical records into a mixture of different types of paper reports and multimedia files that could be printed and included in the paper amalgam. The inability of easily manage all this volume of information, especially considering the citizens’ new mobility needs who might live in a different city in which they might work, led, thanks to the Information and Communication Technology (ICT) development, to an attempt to harmonize that amalgam of papers and tests by means of removing the “physical support” in which data was recorded. A way of doing that was by mean of the paper-documents scanning [12], which facilitated the access to the medical records (among others benefits) but it did not necessarily allow to access the data in them contained, only their display. This is what in literature has been called Electronic Medical Record (EMR) or Electronic Health Record (EHR), as both terms are usually used indistinctly. However, in some papers distinctions between EHRs and EMRs are done, according to different features (i.e. ownership, within a single or multiple care delivery organizations, etc.) [13] or specific requirements an EHR meets that not are necessarily met by EMRs [14]. An EMR’s Adoption Model description can also be found in [13], which identifies the levels of EMR capabilities ranging from the initial Clinical Data Repository environment through a paperless EMR environment.

In any case, one of the most commonly accepted EHR definition comes from the Health Information Management Systems Society (HIMSS) [15]: “The Electronic Health Record (EHR) is a longitudinal electronic record of patient health information generated by one or more encounters in any care delivery setting. Included in this information are patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data and radiology reports. The EHR automates and streamlines the clinician’s workflow. The EHR has the ability to generate a complete record of a clinical patient encounter - as well as supporting other care-related activities directly or indirectly via interface - including evidence-based decision support, quality management, and outcomes reporting”.

1.1. Continuity of care between telemonitoring data and Electronic Health Records

The development of EHR systems has meant an evolutionary leap forward over paper-based systems, presenting the following advantages over them [16]:

- provides the opportunity for healthcare organizations to improve quality of care and patient safety,
- represents a huge potential for cost savings and decreasing workplace inefficiencies,
- there is an increasing storage capabilities for longer periods of time,
- it is accessible from remote sites to many people at the same time,
- the information retrieval is almost immediate and it can be continuously updated,
- can also provide medical alerts and reminders,
- allows for customized views of information relevant to the needs of various specialties,
- can provide information to improve risk management and assessment outcomes,
- can decrease charting time and charting errors and, therefore, increase the productivity of healthcare workers and decrease medical errors due to illegible notes.

However disadvantages associated with the EHR systems are also found, which are barriers and obstacles in their implementation [16]:

- the startup costs, which can be excessive,
- the substantial learning curve,
- confidentiality and security: although it is an issue than can be associated with both the EHR and the paper health record, there seems to be a greater concern of that issue around EHR despite the different security technologies available (i.e. firewalls or passwords),
- difficulties of EHR adaptation to workflows changes after the EHR system implementation,
- the lack of a common vision/definition of the EHR, that leads to different EHR requirements,
- the lack of a standardized common elements (i.e. terminology, system architecture, etc.),
- the inability to share medical data due to the existence of not accurate or dependable interfaces or the unsolved identification issue (i.e. unique health identifiers).
Moreover, the fact that electronic records might be created in any ancillary department (e.g. radiology, laboratory or pharmacy) or as a result of an administrative action (e.g. creating a claim) has to be taken into account. These EHRs are usually generated and maintained within this institution (i.e. a hospital, an integrated delivery network, a clinic, etc.) [1] and, therefore, they are usually separated in different systems. To effectively retrieving the whole longitudinal record of care it is needed to integrate the medical records of all care services provided over the patient’s lifetime. However, in certain situations, these electronic records are not integrated: medical data is captured, and remains, in silo systems which have their own user logins and their own patient identification systems. The lack of common criteria (e.g. architecture design, internal workflow, programming language, etc.) while developing these systems has hampered efforts to achieve a satisfactory exchange of clinical information, which is the ultimate goal of an EHR.

The sharing of information has been empirically proved to be a way of decreasing sanitary costs, as it has achieved savings [17] or savings are predicted to be accomplish [18] in different health systems. This is of great importance due to the large amount of changes nowadays our society is going through: the sharing of information among health care centers is not only needed because of patients’ mobility [19], which should carry with them all their medical records, but also because of the higher prevalence of chronic diseases and the aging of the population.

The underlying global population’s aging is a process known as the “demographic transition” in which mortality and then fertility decline from higher to lower levels. Decreasing fertility along with lengthening life expectancy has reshaped the population’s age structure in most regions of the planet by shifting relative weight from younger to older groups [20] and where the role of international migration has been far less important than the one caused by fertility and mortality. In Europe, the life expectancy gains at older ages are of 4-5 years over a period of last 40 years in the majority of developed countries and these gains are larger for women than for men [21].

This population aging has a direct relation to the economic perspective, as it creates two potentially major pressures on healthcare finances: increased utilization of health services and decreased revenues (as a declining share of the population is economically active). Old-age dependency ratios are projected to increase in the EU25, from four people of working age for every elderly person (old-age dependency ratio of 25%) to two (old-age dependency ratio of %50) by 2050. Furthermore, age-related public spending related to pensions, health and services for elderly people is projected to rise in the EU by 3-4 Gross Domestic Product (GDP) points between 2004 and 2050 [22].
However, a study [23] points that longevity per se does not raise health-cost issues: ageing populations account for only a small increase in health spending each year and it puts the cost at 0.5% annually. In this study it is also stated that the most significant healthcare impact of ageing will be the increasing number of people with multiple chronic conditions. This way, 40% of Europeans over 50 have more than one chronic disease and over-85s British people have, on average, five chronic diseases. Hence, although the longevity increasement is a triumph for public health and the result of social and economic development, many individuals will additionally face, as they age, the risk of having at least one chronic disease, such as hypertension, diabetes and osteo-muscular conditions.

Chronic diseases are defined as “diseases of long duration and generally slow progression” by the World Health Organization (WHO) [24] and they used to be considered as a problem of the rich and elderly population. Nevertheless, within high-income countries, poor as well as young and middle-aged people are affected by chronic conditions. In Europe, chronic diseases are the leading cause of mortality and morbidity and research suggests that complex conditions, such as diabetes and depression, will impose an even larger burden in the future. Therefore, as expenditure on chronic care rises across Europe, it would take up increasingly greater proportions of public and private budgets [25].

Summarizing, the implications of ageing for health care expenditure are very difficult to establish. Most of them will depend on how people age. Successful promotion of healthy ageing may mitigate the impact of ageing on healthcare expenditure, although expenditure on long-term care is certain to increase as both the utilization and costs of long-term care for older people have grown dramatically across Europe and they are projected to substantially grow in the future. As an example, a study of the Finnish population [26] found that although only 7% of the population over 65 years was receiving long-term care, they accounted for 55% of total expenditure. Hence, the problem of a new strategy in healthcare sector is being handle by the European Commission in documents like [27] in which different specific objectives are settled:

- fostering good health in an ageing Europe,
- protecting citizens from health threats,
- supporting dynamic health systems and new technologies.

Thus, all countries need to be prepared to address the consequences of demographic trends which means dealing with the increasing burden of chronic diseases through health promotion, disease prevention intervention at community level and disease management strategies within their health care systems [21, 28].
Chapter 1. Introduction

In this line, as stated in [29], there is evidence that cost-effective interventions exist to address chronic disease in developing countries as tobacco cessation programmes, mass-media education campaigns to improve diet or community-based physical activity programmes. But it is also needed, as reflected in [22], to build adequate systems of long-term care by combining formal and informal care (e.g. self-care and home-based services) and to ensure appropriate settings of care which will require to integrate long-term care throughout different levels of provision (i.e. primary care, specialized care, hospital care, etc.) and across the social and long-term care sectors. The technological implantation to stimulate an increment in the older people’s autonomy, like the use of telemedicine systems, would avoid health services to overcrowd and, moreover, would improve their efficiency. The coordination between healthcare services, on the other hand, can be accomplished through the appropriate EHR sharing.

The fact that telemedicine systems can be very helpful to the provision of care services has not gone unnoticed: Various teledermatology [30], teleophthalmology [31] or teleradiology [32] services have been deployed. These types of systems, although effective in their purpose, are very specific of their own respective areas. The development of other generic telemedicine systems, as they need to acquire less complex information (i.e. weight or blood pressure) and where the target patient profile is more general, is needing of simpler and less expensive infrastructure. The acquired measurements, as part of the patient’s disease routine care, could not only be consulted by the general practitioner in the primary care level but also by a specialized practitioner in the specialized care level. And similarly to telemonitoring systems, this kind of approach could be extended to the health&wellness area or the Ambient Assistant Living (AAL) area to track the patient’s habits that could be interesting from a medical perspective [33].

The above mentioned action areas (chronic patient’s monitoring, health&wellness and AAL) are being developed and strengthened due to the personal devices ecosystem proliferation. The image of a physician listening to the Korotkoff sounds to determine the patient’s blood pressure is now part of the medical history as, in the market, there are plenty of affordable personal devices capable of such action by just pushing a button.

These kinds of milestones have enabled the translation of the patient’s Point-of-Care (PoC) from a health center environment to a personal environment, acquiring ubiquitous characteristics, so the act of taking a measure is no longer tied to a particular place or a particular device: it can be accomplished within the range that encompasses a particular place with multiple different devices to one device at different locations or multiple different devices in different locations.
1.1. Continuity of care between telemonitoring data and Electronic Health Records

Personal Health Devices (PHDs) have also evolved and they not only show the acquired data in a display, but they have also developed different interfaces to transmit the medical data to other device which has superior capabilities (i.e. storage capacity, information processing for visualization or statistics, etc.) and which is associated with the former one. That communication can be performed by various transport technologies [34] (i.e. Bluethooth, Universal Serial Bus (USB), ZigBee, etc.) although the protocol governing communication is often proprietary by the manufacturer. This is a limiting design condition if a transparent communication between medical devices and the health care center would be needed to be established: ad-hoc solutions should be implemented for each possible combination of medical devices and health care centres.

To effectively take advantage of the proliferation of the PHDs it is necessary to study and define methods for the integration of the medical data in the EHR of the patient in a transparent way, i.e. independently of the medical device which was used to acquire the medical data or the technology used for its communication, by the use of a standard-based design. The standard-based design is a key factor that would ensure the scalability and modularity for any system deployment and, in the telemonitoring environment, it should be handled in both the “device-side” and the “health centre-side” of the architecture. This way, the measures acquired in the personal device environment, although bounded to the ones which can be acquired by the MDs, should reflect their respective domain concepts in the EHR environment regardless the syntax used in their later transmission. On the other hand, the clinical information transmission options between different services or heath care centers should be studied considering the various implementation paths, both commercial and academic proposals, additionally to other type of approaches like the modeling of domain concepts through the use of archetypes.

So, in order to achieve the harmonized integration of telemonitoring data into a Health Care Information System (HCIS), syntactic and semantic mechanisms should be applied through a standard-based design, as can be seen in Figure 1.1. Only, fulfilling these requirements it would be possible to guarantee an improvement in the continuity of care of the patient without increasing health costs in an increasingly overcrowded system.

This Thesis contributes to this paradigm of the continuity of care of the patient, researching about the harmonized integration of telemonitoring data into the patient’s EHR through the concurrent use of open standards.
Figure 1.1: Generic platform scheme for the harmonized integration of telemonitoring data into a HCIS with communication capabilities

1.2 Research Context

This Thesis is being performed in the framework of the Telemedicine and e-Health research line of the Communications Technology Group (GTC) and the Aragón Institute of Engineering Research (I3A), within the Biomedical Engineering Doctoral program of the University of Zaragoza, Spain. Regarding its research context, this Thesis is being developed mostly within wider projects of the Telemedicine and e-Health research line, such as:


- TSI-020100-2010-277: “PATIENT 2.0: Plataforma Accesible e inTeroperable de servicios Integrados de e-Salud para seguimiento y autocontrol de pacientes con ENfermedades crónicas basada en Web 2.0” from Ministerio de Industria, Turismo y Comercio (MITyC).


1.3 Hypothesis and objectives

The general approach of this Thesis is to research and make contributions to the ICT and Health Informatics (HI) fields applied to the e-Health area. Nowadays, research results in ICT and Information Society are considered strategic. Moreover, the application of these technologies to the health area through the proposal of new teledmedicine services facilitates the citizens’ access to the health system. Therefore, investigations in this area are highly relevant thanks to the benefits that patients, doctors and the whole health system enjoy. Specifically, the focal aim of this Thesis is to investigate on the field of medical informatics, through two fundamental pillars, on which this Thesis rests: (a) contributions on the harmonized integration of remotely acquired measures into the EHR of the patient, and (b) contributions on the interoperable exchange of EHR through the use open standards. This approach suggests the two foremost underlying hypotheses:

• TSI-020302-2008-35: “Historia de salud electrónica basada en estándares de información clínica bajo software libre” from Ministerio de Industria, Turismo y Comercio (MITyC).

Among these projects, it can be highlighted the active role this Thesis’ outcomes have played in several projects with a service provider and canarian software developer company primarily focused in the ICT field, highly specialized in health, public sector and enterprise solutions. Moreover, several collaborative relationships have been developed with the Carlos III Health Institute (ISCIII) and the Puerta de Hierro University Hospital (HUPH), both in Madrid. ISCIII is a leading public research organization which funds, manages and executes biomedical research in Spain. The HUPH’s main function, since 1964, is not only being a care centre but it is an institution with research and educational functions.

Finally, it can also be highlighted the research stay in the Centre for Health Informatics and Multiprofessional Education (CHIME) belonging to University College London (UCL), in London, United Kingdom (UK). The UCL CHIME is an internationally well recognized group for its contribution to the understanding of requirements, information models, clinical models and architectures of interoperable health records. They have worked for almost 20 years internationally in this field, are co-founders of the openEHR Foundation [35] and have led the development of key international standards such as ISO/EN 13606 [36] (EHR communication) and ISO 18308 (EHR architecture requirements). They are also active in specific areas such as EHR architectures, clinical modelling and confidentiality protection.
• The harmonized incorporation of telemonitoring measures into the patient’s EHR would enhance the continuity of care without raising the healthcare costs.

• The use of open standards for the interoperable EHR communication would ease the reuse of clinical data for the medical practice or any other medical application, like clinical research.

Thus, the major aim of the Thesis, together with the above mentioned hypothesis, leads us to the overall objectives:

1. To present the actual situation of the patient’s continuity of care paradigm through a comprehensive state-of-the-art of the e-Health sector, in the specific field of interoperable communication of EHR and among medical devices.

2. To deeply study the ecosystem of telemonitoring standards, remarking the main initiatives both proprietary (CANopen, ANT, Sensium, DICOM) and standards (HL7 and ISO/IEEE 11073).

3. To analyze the interoperability mechanisms by distinguishing and defining both semantic and standardization mechanisms.

4. To deeply study the ecosystem of EHR communication standards, remarking the main standards initiatives (openEHR, HL7 and ISO/EN 13606), comparing their Information Models and the different data types used by them.

5. To describe the different scenarios according to the remote location the Point-of-Care of the patient in relation to the HCIS and to reasonably select the different interoperability mechanisms according to the previously described scenarios of this study.

6. To review the security implications of the EHR standard election.

7. To discuss the concept of archetype as interoperability paradigm.

8. To contribute with a detailed compatibility study between the EHR and MD interoperability standards focused in their Information Models and to discuss any identified inconsistency between them and any implications for their joint use.

9. To argue about the implications of these standards’ election and the scalability of acquiring standards.

10. To define a generic architecture capable of embodying the telemonitoring data into the EHR of the patient according to the previously considered scenarios and to interoperable communicate the patient’s EHR. This would imply:

(a) To contribute with a methodology for data integration from patient telemonitoring measurements in EHR.
1.4. Organization and structure

(b) To contribute with an EHR server design for the interoperable communication of telemonitoring data.

(c) To contribute with the design of those mechanisms (i.e. access control and privilege management systems) through which the security features might be applied.

11. To implement the proposed designs as a proof-of-concept. The EHR Extract validation will be checked with unrelated parties to that server development.

12. To reasonably discuss about the forthcoming challenges for the EHR, stressing in the future evolution of the present work, like the fine-grained semantic integrity in telemonitoring data and its application to relevant medical conditions for the improvement of the continuity of care.

1.4 Organization and structure

In order to accomplish the overall objectives, the present Thesis is organized as follows:

• Chapter 2 presents a detailed state-of-the-art about standard-based interoperability focused on interoperable communication of EHR and among medical devices for patient telemonitoring. The ecosystem of telemonitoring standards will be studied, remarking not only the main proprietary initiatives (CANopen [37], ANT [38], Sensium [39], Digital Imaging and COmmunication in Medicine (DICOM) [40]) but the standard initiatives (HL7 and ISO/IEEE 11073 [41]). Finally, the main interoperability mechanisms will be presented from a semantic point-of-view (through a revision of the main medical encodings and the existing mappings that exist between each other) and from other standardization mechanisms (through a revision of the different types of standards that would be considered in the EHR server implementation). The ecosystem of EHR communication standards will be deeply studied, remarking the main initiatives (openEHR [35], HL7 [42] and ISO/EN 13606 [36]), comparing their Information Models and over-viewing the differences in each initiative’s DATA_TYPE subset.

• Chapter 3 describes different considered scenarios by distinguishing between a direct integration in a HCIS and the integration through an adapter element (in case the integration can not be accomplish in a direct way or it can be exploited for different health care centres). Based on the mentioned scenarios, the general architecture of the solution and the described standards, the election of different interoperability mechanisms will be justified as well as the security issues which imply this decision.
Finally, the concept of archetype is discussed as interoperability paradigm [43] (as two of the three studied EHR communication options, openEHR and ISO/EN 13606, are based on a dual approach and HL7 v3 uses a similar approach, the domain concept modeling through the use of archetypes is justified)[44].

• Chapter 4 contributes with a detailed compatibility study between the ISO/EN 13606 and ISO/IEEE 11073 focused in their Information Models. Regarding the identified issues in the compatibility study, inconsistencies between ISO/IEEE 11073 PHD and ISO/EN 13606 standards will be discussed. From this study, a generic architecture capable of embodying the telemonitoring data into the EHR of the patient according to the previously considered scenarios will be defined and designed. Following, a methodology for data integration from patient telemonitoring measurements in EHR will be contributed to design an ISO/EN 13606 EHR server for the interoperable communication of telemonitoring data. Finally, several contributions about the design and implementation for the access control and privilege management systems following the standard-based design paradigm, and using the ISO/TS 22600 will be accomplished. As a proof-of-concept, the proposed design will be implemented with ISO/IEEE 11073 PHD telemonitoring acquisition system, by developing an EHR server and validating the EHR extract.

• Chapter 5 presents the overall conclusions of this Thesis and main reflections about the forthcoming challenges for the EHR, stressing in the evolution of the present work, like the fine-grained semantic integrity in telemonitoring data, its application to relevant medical conditions or analyzing the use of EHR in different present projects, like the Spanish one.
Chapter 2

State of the Art

Some of the healthcare’s key business trends are the cost reductions and the efficiency improvement. The same way, one of the key ICT trends in healthcare is to increase access both to internal and external information or to support customer/consumer-focused initiatives [45]. Therefore, based on these pillars, the standard based design is considered a cornerstone in the current healthcare industry.

In the standard development, or promotion, processes different Standard Development Organizations (SDO) are involved, as organizations of other kind. These organizations work independently of each other but, sometimes, it is possible to establish symbiotic relationships among them, joining efforts in the development or promotion of these documents. The properly integration of telemonitoring data into the patient’s EHR will require the overview of both the standardization landscapes in the medical device and the EHR environments. In this section, a descriptive overview of the two studied scenarios will be performed.

2.1 Medical devices’ landscape

The development of any science is related to the tools it owns: the better tools, the bigger development. In medicine, these tools are the medical devices. The concept of medical device (MD) can be highly scattered: from simple tongue depressors to complex programmable pacemakers with micro-chip technology or laser surgical devices, including in vitro diagnostic products (i.e. general purpose lab equipment, reagents, test kits, etc) or certain electronic radiation emitting products with medical application (i.e. diagnostic ultrasound products, X-ray machines and medical lasers). According to the definition in section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act [46], enforced by the U.S. Food and Drug Administration (FDA) [47], a MD is: “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
• recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,

• intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

• intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of it’s primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.”

This one is a well accepted definition because it comes from a well-known SDO. However, there are others definitions in literature, like the one approved by the Global Harmonization Task Force (GHTF). GHTF is a voluntary international group of representatives from MD regulatory authorities and trade associations from Europe, the United States of America (USA), Canada, Japan and Australia, which in 2005 defined MD like [48]: “any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:

• intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:
  – diagnosis, prevention, monitoring, treatment or alleviation of disease,
  – diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
  – investigation, replacement, modification, or support of the anatomy or of a physiological process,
  – supporting or sustaining life,
  – control of conception,
  – disinfection of medical devices,
  – providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and

• which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

Both definitions are relatively close to each other although the last one comes from a more specialized environment and, accordingly, it appears to be a more specific one.
What it is true is that medical devices have dramatically evolved thanks to the Information Technology (IT) application since ancient Egyptians started making incisions for embalming with scalpels of sharpened obsidian around 7000 B.C. From the use of these primitive MDs, the apparition of the first modern stethoscopes, laryngoscopes or ophthalmoscopes between 1800 and 1850, the X ray discovering in 1895 or other achievements [49] have led the way to the apparition of new devices in the market. However, it was not until the 1980’s decade when there was a large increase number of MDs used in the patient’s care, specially those based on imaging technologies (i.e. CATs, magnetic resonances, etc.) and those used for the continuous monitoring of cardiac variables. The commoditization of consumer electronics also involved a surge in the number of electronic devices available at low price points and small sizes. This revolution affected the health-care industry, making patients able to buy low-cost digital health monitoring devices at many pharmacies and supermarkets [50].

The natural technological evolution in the MD manufacturing industry led to incorporate new features in the newer device designs, like the ability to communicate the acquired measurements by other means apart from showing them in a digital display: proprietary protocols and systems appeared [51]. Solutions to independently operate were designed, using proprietary protocols and interfaces for system or device integration. However, in the increasing complexity of the healthcare environment, stand-alone proprietary devices and systems were no longer providing an acceptable solution. MDs and systems must easily integrate with other vendors equipments, software or systems in order to improve patient safety and clinical efficiency as it is pointed in [52, 53].

But the lack of standardization in the device communication design is not the only obstacle for the seamless integration with other manufacturer’s equipment. There is a wide spectrum of technologies and interfaces to support the communication of the acquired measure, as pointed in [34], where different technologies for the e-Health environment are listed and compared to each other in terms of data rate, distance, frequency band, etc. Some of these technologies are also proprietary. Among these wired or wireless technologies and interfaces, different examples can be stressed like the Recommended Standard 232 (RS-232), Universal Serial Bus (USB), Bluetooth, Zigbee, Wireless LAN, Ultra WideBand (UWB), etc.

In this high-dispersion scenario different institutions which were promoting the use of standards in the MD field began to appear. Due to their specially active role, the following institutions can be highlighted, particularly the two firsts:
• Integrating the Healthcare Enterprise (IHE) [54], an initiative by healthcare professionals and industry to improve the way information is shared through the coordinated use of established standards, addressing specific clinical needs in support of patient care. In the MD context, the IHE Patient Care Device Domain [55] can be found, which includes different profiles like the Device Enterprise Communication Profile to transmit information from MDs at the point of care to enterprise applications, the Point of Care Infusion Verification Profile to communicate medication orders to an infusion pump or pump management system or the Rosetta Terminology Mapping to harmonize the use of existing nomenclature terms defined by the ISO/IEEE 11073-10101 nomenclature standard.

• Continua Health Alliance (CHA) [56], a non-profit, open industry organization of healthcare and technology companies joining together in collaboration to improve the quality of personal healthcare. CHA is working to provide interoperable devices and services for three categories of use cases: Health and Wellness, Chronic Disease Management and Aging Independently.

• Health Level 7 (HL7) International [42] which, although being more popular due to its promotion of other standards, it has developed another documents for the patient care like the HL7 Implementation Guide for CDA Release 2 - Personal Healthcare Monitoring Report (HL7 PHMR) [57].

• Healthcare Information Technology Standards Panel (HITSP) [58] which has developed documents like [59] to provide the context and background for the use of the HL7 PHMR Implementation Guide in the construction of Remote Monitoring Observation Documents.

• Medical Device Plug-and-Play (MD PnP) [60] Interoperability Program, which works to accelerate the adoption of medical device interoperability by providing interoperability building blocks like [52] whose latest version [61] has been released in May 2012.

• Global Harmonization Task Force (GHTF) [62] which encourages convergence in regulatory practices related to ensuring the safety, effectiveness/performance and MDs quality, promoting technological innovation and facilitating international trade through the publication of harmonized guidance documents on basic regulatory practices, like [48].

• Healthcare Information and Management Systems Society (HIMSS) [63] which its Medical Device Security Work Group works has created the Manufacturer Disclosure Statement for Medical Device Security [64], which intention is to supply health care providers with important information to assess the vulnerabilities and risks associated with electronic Protected Health Information (ePHI) transmitted or maintained by MDs.
In case of standards for communicating the information, different proposals have appeared across the time like:

- **CANopen** [37, 65], a Controller Area Network (CAN) higher layer protocol, which allows to apply the automatic control features into complex environments (like Intensive Care Units (ICUs)) or devices such as X-ray machines, magnetic resonators, angiographs or computer tomographs. It is also a European standard (i.e. EN 50325-4:2002 [66])

- **ANT+** [38], a wireless proprietary protocol based on the ANT protocol, which has developed device profiles for wireless sensor monitoring in the sport, wellness or home health areas such as heart rate monitor, bike speed and cadence sensors or temperature sensors.

- **Sensium** [39], a proprietary technology which offers a wide range of health and fitness out-of-hospital applications for non intrusive wireless monitoring of vital signs (i.e. power wireless sensor nodes, circuitry and sensors for continuous heart rate monitoring, temperature or single lead electrocardiograms (ECGs)).

- **Digital Imaging and COmmunication in Medicine (DICOM)** [40], which includes a file format definition and a network communication protocol, is the most widely adopted tool for handling, storing, printing, and transmitting information in medical imaging, enabling the integration of scanners, servers, workstations, printers, and network hardware from multiple manufacturers into a Picture Archiving and Communication System (PACS).

- **the IEEE 1451 standard** [67] which describes a set of open, common, network-independent communication interfaces for connecting transducers (sensors or actuators) to microprocessors, instrumentation systems or control/field networks.

- **the HL7 messaging** developed by the HL7 Health Care Devices Committee [68] which aims to facilitate the integration of health care device information at the enterprise level establishing standardized content as base for the messages.

- **the ISO/IEEE 11073 family** of standards, which aims to provide real-time plug-and-play interoperability for citizen-related medical, healthcare and wellness devices and to facilitate efficient exchange of care device data, acquired at the point-of-care, in all care environments.

These initiatives’ success has depended on different conditionings among which the open access to the technical documentation is unquestionably included. A compulsory condition to allow the widely adoption of an standard is for it to be open and, therefore, closed solutions like Sensium or ANT+ cannot aspire to reach the most of the market.
Among the open proposals, particular drawbacks should be analyzed: CANopen, among other disadvantages, presents a limited network length (depending on baud rate) [69] which can make it unsuitable for some purposes; some papers (e.g. [70]) various defects about the IEEE 1451 standard implementation are exposed, like the complicate required structure to be implemented for a distributed system based on this standard; DICOM standard is only focused on imaging and HL7 solutions might inherit the problems of the HL7 specifications.

However, if the DICOM case is studied, a categorical conclusion can be obtained: the more acceptance of the device manufacturers, the more of the market can be reached. Some times, industry acceptance is enough to create what is considered a de facto standard as it has occurred in other technological environments. This way, the Bluetooth specification was the outcome of a consortium established in 1998 by Intel and Microsoft that included IBM, Toshiba, Ericsson, Nokia and Puma Technology, but nowadays is widely used in all types of mobile devices by the majority of manufacturers.

Regarding the industry support, it is the ISO/IEEE 11073 (X73) family of standards the most relevant one as its development is being fostered by CHA and, therefore, it has the support of the main device manufacturers. Besides, they are supported by relevant international SDOs, like ISO and IEEE. ISO/IEEE 11073 was initially designed in 2004 (by absorbing three previous standards: ENV13734/VITAL, ENV13735/INTERMED and IEEE1073/MIB) to address intensive care unit scenarios focused on covering MD interoperable communication at the Point-of-Care of the patient (X73PoC). With the emergence of new transmission technologies (USB, Bluetooth or ZigBee) and wearable devices with new features and capabilities, the existing protocol was regarded as complex and in need of revision, leading to a more lightweight version. This evolution resulted in the creation of the most recent version for PHDs (X73PHD) and its architecture, which evolves by thoroughly simplifying the X73PoC model, is divided into the following three models (see Figure 2.1):

- Domain Information Model (DIM). This typifies the information inside the agent by describing an abstract model composed of a set of object classes which are instanced and can be referenced in an ISO/IEEE 11073 PHD-based communication. Each object class has one or more attributes which describe measurement data and agent’s control elements. The DIM includes the methods and actions that can be executed on each of the attributes and elements. The DIM covers the definition of the Medical Device System (MDS) object (root object in the PHD modelling), scanner objects (for MD data reporting), different metrics (numeric, real time sample array (RT-SA) and enumeration objects) and Persistent Metric (PM) store and segments (for data storing).
- Service Model. This provides methods to access data that are sent between agent and manager to establish the interchange of the DIM data. Thus, it defines the means by which the manager can interact with the agent. Two different types of services are distinguished: association and object access. Association services provide methods to negotiate and agree upon a common configuration (association request and response), release associations and abort connections. Object access services provide methods that allow a manager to interact with an agent by, remotely, executing actions and allowing access object attributes, through the link established. These services include event reports (often implemented by scanner objects and the MDS object) that are initiated by the agent and used to send its configuration (during the association procedure) or medical or personal health data (once the association has been established), get and set methods that allow the manager to access to object attributes, and actions that allow the manager to execute Remote Procedure Calls (RPCs) over the agent’s objects. While event reports are initiated by the agent objects, get, set and action reports are executed over them and initiated by the manager.

- Communication Model. This describes the network architecture in which one or more agents communicate with a single manager via point-to-point connections. Thus, it defines a Finite State machine (FSM), both for agent and manager, that controls the link state and transport mechanisms. All the transitions in the FSM are well defined and they involve the execution of some actions internally in the agent or the manager, the reception or the sending of a message, etc. The FSM determines the sequence diagrams in any ISO/IEEE 11073 PHD-based communication. It is transport-independent, which means that implementations of the stack can be shared among different transport technologies. It also defines different Encoding Rules (ER), Service Elements (SE) and the algorithms responsible for transforming the abstract model given by the DIM into a stream of bytes through a protocol.
2.1. Medical devices’ landscape

This main architecture implies a translation in a protocol stack for the intercommunication between agents and manager. The protocol stack has been simplified in ISO/IEEE 11073 PHD evolving from ISO/IEEE 11073 PoC with a new stack that is divided into three levels (see Figure 2.1):

- **Device Specializations.** Similarly as in the previous ISO/IEEE 11073 PoC, the Device Specializations are a DIM configuration modeling a specific device, adopting the hierarchy of elements based on the information and behaviour of the device. This set of model descriptions gathers the total of objects and attributes related to the DIM, such as an overall system configuration (MDS), PM-Store and Segments or Metric Specifications. For instance, a blood pressure monitor has up to four numeric elements implemented (i.e. Systolic, Diastolic and Average Components, and Heart Rate), but more complex devices, such as ECG signal monitors, will implement objects such as Real-Time Sample Array (IEEE 11073-20601, 2008). At the time of this writing, a release of ISO/IEEE 11073 PHD along with 18 associated device specifications (indexed as 11073-104XX) have already been published by the IEEE (13 of them with Standard category, 7 more by the ISO as well, while 4 more are in drafting process), as shown in Table 2.1.

- **20601 Optimized Exchange Protocol.** The main part of the standard consists of a medical and technical terminology framework (DIM) which will be encapsulated inside the Application Protocol Data Unit (APDU) through services. This protocol corresponds to both Communication and Service Models. Firstly, the Communication Model describes a point-to-point connection based on agent-manager architecture through the FSM, as shown in Figure 2.2. ISO/IEEE 11073 PoC defined these concepts in its Part 1 as MD Data Language (MDDL), which includes the DIM, and in its Part 2 as MD Application Profile (MDAP) for the ISO/IEEE 11073 Communication Model. Secondly, the Service Model defines a set of messages and instructions to retrieve data from the agent based on the DIM. These messages have to be coded for its further implementation using Abstract Syntax Notation One (ASN.1). It also provides data conversion from the ASN.1 notation to transfer syntax, using optimized MD Encoding Rules (MDER), as well as standard Basic ER (BER) and Packet ER (PER) support. Furthermore, ISO/IEEE 11073 PHD maintains the SE from ISO/IEEE 11073 PoC (i.e. Remote Operation (ROSE, optimized for MDER) between call requests and responses, Association Control (ACSE) and Common Management Information (CMISE)), including algorithms for the encapsulation of the messages generated by the DIM in order to transform the abstract model into the corresponding Protocol Data Unit (PDU) defined in ISO/IEEE 11073 PHD.
Chapter 2. State of the Art

Figure 2.2: Finite State Machine (FSM) for the X73PHD model

-10404 TM_2010 Pulse oximeter
-10406 TM_2011 Basic ECG (3-leads)
-10407 TM_2010 Blood pressure monitor
-10408 TM_2010 Thermometer
-10415 TM_2010 Weighing scale
-10417 TM_2011 Glucose meter
-10418 TM_2011 INR-blood coagulation
-10420 TM_2010 Body composition analyzer
-10421 TM_2010 Peak expiratory flow monitor
-10419 TM_2008 Cardio fitness/activity monitor
-10422 TM_2010 Medication monitor
-10423 TM_2010 Independent living activity hub
-10424 TM_2010 Body composition analyzer
-10425 TM_2010 Peak expiratory flow monitor
-10426 TM_2008 Medication monitor
-10427 TM_2008 Independent living activity hub
-10428 TM_2008 Body composition analyzer
-10429 TM_2008 Peak expiratory flow monitor

Table 2.1: ISO/IEEE 11073 Specializations

<table>
<thead>
<tr>
<th>Specialization</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>-10404 TM_2010</td>
<td>Pulse oximeter</td>
</tr>
<tr>
<td>-10406 TM_2011</td>
<td>Basic ECG (3-leads)</td>
</tr>
<tr>
<td>-10407 TM_2010</td>
<td>Blood pressure monitor</td>
</tr>
<tr>
<td>-10408 TM_2010</td>
<td>Thermometer</td>
</tr>
<tr>
<td>-10415 TM_2010</td>
<td>Weighing scale</td>
</tr>
<tr>
<td>-10417 TM_2011</td>
<td>Glucose meter</td>
</tr>
<tr>
<td>-10418 TM_2011</td>
<td>INR-blood coagulation</td>
</tr>
<tr>
<td>-10420 TM_2010</td>
<td>Body composition analyzer</td>
</tr>
<tr>
<td>-10421 TM_2010</td>
<td>Peak expiratory flow monitor</td>
</tr>
<tr>
<td>-10422 TM_2010</td>
<td>Medication monitor</td>
</tr>
<tr>
<td>-10423 TM_2010</td>
<td>Independent living activity hub</td>
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<td>Body composition analyzer</td>
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<td>-10441 TM_2008</td>
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<td>P11073-10419</td>
<td>Insulin pump</td>
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<tr>
<td>P11073-10422</td>
<td>Urine analyzer</td>
</tr>
<tr>
<td>P11073-10443</td>
<td>Physical activity monitor</td>
</tr>
</tbody>
</table>

expected Spiro meter
expected Fetal monitor
2.1. Medical devices’ landscape

- Transport Technologies. In this layer resides one of the most notable improvements within ISO/IEEE 11073 PHD, compared to ISO/IEEE 11073 PoC. The transport layer has to meet some security and quality conditions to be adopted by the standard. Transport and lower layers’ specifications are out of the current scope of ISO/IEEE 11073 PHD although other Special Interest Groups are working towards providing new profile definitions for both wired (RJ-45 and USB) and wireless technologies (Bluetooth and ZigBee) not included in ISO/IEEE 11073 PoC that only adopted IrDA, cabled Ethernet and RS-232 interfaces. ISO/IEEE 11073 PHD defines the concept of “type of communication profile” to classify different features offered by available transport technologies. These types are:

  - **Type 1:** Profiles that offer both “reliable” and “best-effort” transport services, where there shall be one or more virtual channels of reliable transport services and zero or more virtual channels of best-effort transport services.
  - **Type 2** Profiles that contain only a unidirectional transport service
  - **Type 3** Profiles that contain only a best-effort transport service, where there shall be one or more virtual channels of best-effort transport services

Some exchange services depend on the type of transport profile, such as confirmed service mechanism. In consequence, ISO/IEEE 11073 PHD is defined for use exclusively with Type 1 transport profiles. In case that the transport profile does not meet the Type 1 features, a shim layer which implements the additional features allocated before the upper layer is added if the technology allows it.

In order to facilitate the interoperable feature of the standard and make use of the latest transmission technologies, new health profiles have been designed within Transport Working Groups to support ISO/IEEE 11073 PHD. These health profiles define the communication requirements that a health device must fulfill in order to be certified according to the CHA’s specifications. Currently, USB, Bluetooth and ZigBee technologies have a health profile specification already developed for ISO/IEEE 11073 PHD. The main technical features of each profile are following detailed:

- **USB Personal Health Device Class (USB PHDC)** [71]. USB is a specification for establishing a wired communication between a host and a range of client devices, which is why the USB system has an asymmetrical design master-slave. USB 2.0, released in April 2000 and standardized in late 2001 by USB Implementers Forum (USB IF), is the most common specification. It can theoretically reach a transfer speed of 480 Mbit/s. USB was the first technology that published a ISO/IEEE 11073 PHD compliant health profile. Before that, USB devices were required to implement proprietary methods to communicate information and use some of the defined classes. Typically
used Human Interface Device (HID), defined for computer peripherals like mouse and keyboard, or Vendor Specific Class, which required specific proprietary drivers for each device. In April 2007, the established USB Personal Healthcare Working Group published the USB PHDC specification, which is remaining the same to this day without any review.

– Bluetooth Health Device Profile (BT HDP) [72]. Bluetooth is a specification for Wireless PAN (WPAN) that allows data transfer between devices via a radio link in the Industrial Scientific Medical (ISM) band (2400-2500MHz) without a license while the power limitation is met. The specification defines a protocol stack and a series of profiles (i.e. guidelines that specify procedures by which Bluetooth devices communicate with each other for different types of use). There is a wide range of profiles like HID profile, File Transfer Profile (FTP), Serial Port Profile (SPP), etc. Each profile includes at least information on the specific characteristics of the Bluetooth stack used by the profile, as well as possible dependencies on other profiles and proposals of application-level format. Typically commercial MDs with Bluetooth technology made use of unpublished proprietary formats on the SPP. To solve these issues, Bluetooth SIG created in 2006 the Medical Working Group (MedWG) to design a profile for PHDs. The result of this work was the publication in June 2008 of Bluetooth HDP along with a new specific Multi-Channel Adaptation Protocol (MCAP) layer. In parallel with these profiles, a low power consuming version of Bluetooth Low Energy (BTLE) [73] will, together with the next technology described here, provide a considerable step towards battery efficiency.

– ZigBee Health Care Profile (ZHC) [74]. ZigBee, like Bluetooth, is a technology considered either as WPAN or LP LAN if applied to health applications. Defines a set of protocols that operate on the IEEE 802.15.4 standard, describing the physical layer and media access control. The result is a complete solution focused on applications requiring a low data rate, low cost, long battery life and encryption of data. It operates in several bands with different data rate ranges: 20kbits/s at 868MHz (used in Europe), 40kbits/s at 915MHz and 250kbits/s at 2.4GHz (recommended for e-Health environments). Thus, the maximum data rate of 250kbits/s is much lower than 1-3Mbits/s of Bluetooth, but the maximum number of nodes in the network is 65535, much higher than 8 in a Bluetooth piconet. The hardware is 90% more simple and has a much lower consumption allowing devices to work for several years mainly due to lighter memory requirements for the stack (ZigBee uses 28kBytes against the 100kBytes of Bluetooth) and the use of System on a Chip (SoC) [75] hardware integration technologies. ZigBee has been, for now, the latest transport technology to adopt a health profile (ZHC) approved by the ZigBee Alliance Board of Directors in March 2010.
2.2 Electronic Health Record’s landscape

The Electronic Health Records’ landscape is not simpler than the device situation. In fact, EHR systems have to deal with more complex information than the one provided by devices. If HIMSS EHR’s definition is recovered [15], an EHR would contain patient demographics, progress notes, problems, etc. Furthermore, an EHR system should possess some capabilities like the ones cited in [76]:

- Health information and data. Having immediate access to key information (e.g. such as patients’ diagnoses, allergies, lab test results, and medications) would improve caregivers’ ability to make clinical decisions in a timely manner.

- Result management. The ability for all providers participating in the patient’s care in multiple settings to quickly access new and past test results would increase patient safety and the effectiveness of care.

- Order management. The ability to enter and store orders for prescriptions, tests, and other services in a computer-based system should enhance legibility, reduce duplication, and improve the speed with which orders are executed.

- Decision support. Using reminders, prompts, and alerts, computerized decision-support systems would help improve compliance with best clinical practices, ensure regular screenings and other preventive practices, identify possible drug interactions, and facilitate diagnoses and treatments.

- Electronic communication and connectivity. Efficient, secure, and readily accessible communication among providers and patients would improve the continuity of care, increase the timeliness of diagnoses and treatments, and reduce the frequency of adverse events.

- Patient support. Tools that enable patients access to their health records, provide interactive patient education, and help them carry out home-monitoring and self-testing can improve control of chronic conditions, such as diabetes.

- Administrative processes. Computerized administrative tools, such as scheduling systems, would greatly improve hospitals’ and clinics’ efficiency and provide more timely service to patients.

- Reporting. Electronic data storage that employs uniform data standards will enable health care organizations to respond more quickly to federal, state, and private reporting requirements, including those that support patient safety and disease surveillance.

The majority of these EHR system capabilities, even the “electronic communication and connectivity” capability, can be succeeded using proprietary implementations.
Table 2.2: Main information systems in healthcare

<table>
<thead>
<tr>
<th>Service name</th>
<th>Information system</th>
<th>Acronym</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital</td>
<td>Hospital Information System</td>
<td>HIS</td>
</tr>
<tr>
<td>Nursing</td>
<td>Nursing Information System</td>
<td>NIS</td>
</tr>
<tr>
<td>Laboratory</td>
<td>Laboratory Information System</td>
<td>LIS</td>
</tr>
<tr>
<td></td>
<td>Picture Archiving and Communication System</td>
<td>PACS</td>
</tr>
<tr>
<td>Primary Care</td>
<td>Primary Care Information System</td>
<td>PCIS</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>Pharmacy Information System</td>
<td>PHIS</td>
</tr>
<tr>
<td>Radiology</td>
<td>Radiology Information System</td>
<td>RIS</td>
</tr>
</tbody>
</table>

The “electronic communication and connectivity” capability can be achieved based on pre-agreed semantic and syntax, although this would not be an easy, scalable task. Depending upon the complexity of the health care centre, one or various Health Care Information Systems (HCISs) can coexist within the same centre. Therefore, one patient’s EHR can be scattered in different information systems, having part of their data replicated. In the Table 2.2 a relation of the main information systems in a healthcare centre are listed, in which a high level division in various medicine specializations can be intuited. In this compendium, it can be highlighted the historical separation of Picture Archiving and Communication Systems (PACSs)(used to store, manipulate, and distribute patient radiological data and imagery). However, the PACS and RIS integration is commonly achieved through a broker, a software and hardware device that accepts HL7 messages from the RIS and translates, or maps, the data to produce DICOM messages for transmission to the PACS [77]. This example of integration can be achieved thanks to the standard-based design of both system’s interfaces. However, the connection of other type of HCIS has not been accomplished in such successful way, fragmenting the patient’s medical data in several HCIS and this fragmentation, in turn, results in errors, duplication, lack of coordination, and many other problems [78].

But not only the systems connection is required to avoid fragmentation, it is needed for the HCIS to inter-operate. Interoperability is usually defined as “the ability of two or more systems or components to exchange information and to use the information that has been exchanged” [79]. Standards provide a common language and set of expectations that enable interoperability between systems and/or devices [80]. These standards include, among others, vocabulary and communications and data exchange standards. In the next section, a descriptive overview of these interoperability mechanisms will be performed.
2.2.1 Interoperability resources

2.2.1.1 Semantic resources: vocabulary standards

Semantics is the study of both meaning in communication and the interpretation of signs as used by agents or communities within particular circumstances and contexts [81]. In every language, a series of linguistic phenomena appear (i.e. polysemy, synonymy and homonymy). In the medical language, this fact contradicts one of the most important features of specialized languages: univocity of meaning. The ideal situation should be that in which each specialized term would have a unique meaning, regardless of the context, in contrast with general language in which words may have several meanings depending on the context in which they appear [82].

For humans, the meaning of a given word is normally obtained by consulting a dictionary or by looking at the context where the word is being used. This not apply to computers which require a simpler and more precise semantic representation. The application of semantic technologies to the medical domain will provide IT systems with the ability to better understand terms and concepts as data is transmitted from one system to another, while preserving the meaning of the content.

One of the first efforts in applying semantic technologies to the healthcare systems are the investments made involving the classification of medical terms and their meanings. Tools in this area make use of coding and classification systems that produce controlled vocabularies, lexicons, taxonomies and ontologies. The term ‘coding’ is loosely used to include classifications, terminologies and nomenclatures, but they are not the same: a code is the representation applied to a term so that it can be more readily processed, a classification is the arrangement of all elements of a domain into groups according to established criteria, a terminology, which comprises all terms of a professional domain, is the language labeling attached to a concept while in a nomenclature codes are assigned to medical concepts and medical concepts can be combined according to specific rules to form more complex concepts [83].

A broad overview of the most important terminologies, nomenclatures, and classification can be seen in the Table 2.3, including Unified Medical Language System (UMLS) [84] and Systematized Nomenclature of Medicine–Clinical Terms (SNOMED-CT) [85], which aim to be general terminologies in contrast with the other encoding systems present in the Table 2.3 which focus on a concrete application area.

As these ‘codings’ have been developed by independent organizations, several ‘codings’ can appear in the same area. However, collaborative relationships can also appear, as the one between SNOMED-CT and Logical Observation Identifiers Names and
### Medical Terminologies Organization Application

<table>
<thead>
<tr>
<th>Medical Terminologies</th>
<th>Organization</th>
<th>Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anatomical, Therapeutic, Chemical classification system</td>
<td>World Health Organization (WHO)</td>
<td>Drugs</td>
</tr>
<tr>
<td>(ATC)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Common Terminology Criteria for Adverse Events (CTCAE)</td>
<td>National Cancer Institute (NCI)</td>
<td>Adverse Reactions</td>
</tr>
<tr>
<td>Coding Symbols Thesaurus of Adverse Reaction Terms (COSTART)</td>
<td>Food and Drug Administration (FDA)</td>
<td>Adverse Reactions</td>
</tr>
<tr>
<td>Current Dental Terminology (CDT)</td>
<td>American Dental Association (ADA)</td>
<td>Dentistry</td>
</tr>
<tr>
<td>Diagnostic and Statistical Manual of Mental Disorders (DSM)</td>
<td>American Psychiatric Association (APA)</td>
<td>Psychiatry</td>
</tr>
<tr>
<td>First DataBank (FDB)</td>
<td>Healthcare Corporation (HeCo)</td>
<td>Drugs</td>
</tr>
<tr>
<td>Grabeli</td>
<td>Computer-based Medicine, Inc</td>
<td>General</td>
</tr>
<tr>
<td>Human Genome Organisation database (HUGO)</td>
<td>HUGO Gene Nomenclature Committee (HGNC)</td>
<td>Genomics</td>
</tr>
<tr>
<td>International Classification of Diseases and Health Problems (ICD)</td>
<td>World Health Organization (WHO)</td>
<td>Diagnostic</td>
</tr>
<tr>
<td>International Classification of Functioning, Disability and Health (ICF)</td>
<td>World Health Organization (WHO)</td>
<td>health and health-related domains</td>
</tr>
<tr>
<td>International Classification of Health Interventions (ICH)</td>
<td>World Health Organization (WHO)</td>
<td>health interventions</td>
</tr>
<tr>
<td>International Classification of Primary Care (ICPC)</td>
<td>World Health Organization (WHO)</td>
<td>Primary Care</td>
</tr>
<tr>
<td>Logical Observation Identifiers Names and Codes (LOINC)</td>
<td>The Regenstrief Institute (RI)</td>
<td>Laboratory</td>
</tr>
<tr>
<td>Medical Dictionary for Regulatory Activities (MedRa)</td>
<td>International Conference on Harmonisation (ICH)</td>
<td>Adverse Reactions</td>
</tr>
<tr>
<td>MEDCIN</td>
<td>Medcomp Systems</td>
<td>Point-of-care</td>
</tr>
<tr>
<td>National Cancer Institute Thesaurus</td>
<td>National Cancer Institute (NCI)</td>
<td>Oncology</td>
</tr>
<tr>
<td>North American Nursing Diagnosis Association (NANDA)</td>
<td>North American Nursing Diagnosis Association (NANDA)</td>
<td>Nursing</td>
</tr>
<tr>
<td>Nursing Interventions Classification (NIC)</td>
<td>Iowa University (IU)</td>
<td>Nursing</td>
</tr>
<tr>
<td>Nursing Outcomes Classification (NOC)</td>
<td>Iowa University (IU)</td>
<td>Nursing</td>
</tr>
<tr>
<td>Omaha System (OMAHA)</td>
<td>Visiting Nursing Association (VNA)</td>
<td>Nursing</td>
</tr>
<tr>
<td>Online Mendelian Inheritance in Man (OMIM)</td>
<td>National Library of Medicine (NLM)</td>
<td>Genomics</td>
</tr>
<tr>
<td>Office of Population, Censuses and Surveys Classification</td>
<td>National Health Service (NHS)</td>
<td>Procedures</td>
</tr>
<tr>
<td>(OPCS-4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physician Data Query (PDQ)</td>
<td>National Cancer Institute (NCI)</td>
<td>Oncology</td>
</tr>
<tr>
<td>Perioperative Nursing Data Set (PNDS)</td>
<td>Association of PeriOperative Registered Nurses (AORN)</td>
<td>Nursing</td>
</tr>
<tr>
<td>Quick Medical Reference (QMR)</td>
<td>University of Pittsburgh</td>
<td>Diagnostic</td>
</tr>
<tr>
<td>RxNORM</td>
<td>National Library of Medicine (NLM)</td>
<td>Drugs</td>
</tr>
<tr>
<td>Systematized Nomenclature Medicine-Clinical Terms (SNOMED-CT)</td>
<td>International Health Terminology (IHTSDO)</td>
<td>General</td>
</tr>
<tr>
<td>Unified Medical Language System (UMLS)</td>
<td>National Library of Medicine (NLM)</td>
<td>General</td>
</tr>
</tbody>
</table>

### Table 2.3: Major medical terminologies for EHR interoperability

Codes (LOINC) under which SNOMED-CT adopts specific coding developed by LOINC within the laboratory encoding (SNOMED-CT takes over the LOINC’s laboratory procedure codes but keeps control over the terminology and coding of observation values [86]). Despite these isolated collaborative pieces of work which try to ensure a consistent unambiguous clinical reference terminology, the most habitual way of dealing with this “encoding overlapping” has been through bindings or cross-mappings, like the ones gather in [87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98], the most representative of whom are represented in Figure 2.3. The mapping between terminological resources is being addressed by documents like the ISO/DTR 12300 standard [99].
A fact that also supports this work methodology is that SNOMED-CT provides a Cross Mapping mechanism which ensures it could be used to effectively reference other terminologies and classifications [100].

![Figure 2.3: Main Medical Terminologies](image)
The controlled vocabulary provided by these encoding systems can be used during the data entry to provide a more precise and shareable expression that can be obtained using free text [101]. However, the use of clinical terminology systems is not the only mainstay upon with semantic interoperability solutions are based on. Semantic interoperability, as it was defined by [102], “means ensuring that the precise meaning of exchanged information is understandable by any other system or application not initially developed for this purpose” and it is the highest level of interoperability described in different works in the literature [103, 104]. Achieving semantic interoperability is not easy. Generic reference models for representing clinical data or agreed clinical data structures [105, 104] are also required, which strengthens the need for a standard-based design.

The EHR standardization arena is complex. In the next section an overview of this situation would be sketched.

### 2.2.1.2 Standardization mechanisms: other standards

EHR systems’ construction is not only related to the architectural issues, but security, identification management, EHR communication, etc. A sustainable EHR system construction needs these issues to be described and managed properly. Standards are definitions and specifications based on common knowledge and broad agreement. SDOs promote the use of standards and generally accepted terminologies to achieve semantic interoperability. An enumeration of the main SDOs for the EHR standardization can be found in the Table 2.4. Separate SDO can promote different standards, but coordination among them has generated synergies, such as The Vienna Agreement [106] between the International Organization for Standardization (ISO) and the European Committee of Normalization (CEN), or The Memorandum of Understanding [107] among Health Level 7 (HL7) International, Technical Committee CEN/TC251 and the Joint Initiative on SDO [108]. A relational map among those SDOs has been drawn in the Figure 2.4.

The different EHR standards can be categorized as shown in Figure 2.5. According to this classification, a labor-intense revision was performed in [131], and then partially reviewed in [132]. Over this revision, some changes have been detected:

- Some standards have been withdrawn like the EN 14720 or the EN 13607 standards.
- Some standards have superseded newer versions of the same standards, like the ISO/IEC 12052:2011 standard which has superseded the ISO/EN 12052:2004.
- There are other standards which have been recently released, like the ISO/EN 21090:2011 which has led to the withdrawal of the EN TS 14792 in April 2012.
### 2.2. Electronic Health Record’s landscape

**International**
- International Electrotechnical Commission (IEC)
- Institute of Electrical and Electronics Engineers (IEEE)
- International Organization for Standardization (ISO)
- ISO - Technical Committee 215 (ISO TC215)
- Digital Imaging and Communications in Medicine (DICOM)
- HL7 International (HL7)
- Integrating the Healthcare Enterprise (IHE)
- Organization for the Advancement of Structured Information Standards (OASIS)
- OASIS International Health Consortium (IHC)
- Object Management Group (OMG)
- United Nations Centre for Trade Facilitation and Electronic Business (UN/CEFACT)
- World Wide Web Consortium (W3C)
- International Telecommunication Union (ITU)
- ITU Telecommunication Standardization Sector (ITU-T)

**European**
- European Committee for Standardisation (CEN)
- Technical Committee of CEN for Health Informatics (CENTC 251)
- CEN Information Society Standardisation System (CEN/ISSS)
- CEN / ISSS e-Health Standardization Focus Group (CEN/ISSS e-Health)
- European Telecommunications Standards Institute (ETSI)
- IHE Europe

**American**
- American National Standards Institute (ANSI)
- American Society for Testing Materials (ASTM)
- National Electrical Manufacturers Association (NEMA)

### Table 2.4: Reference EHR SDOs

<table>
<thead>
<tr>
<th>International SDOs</th>
<th>European SDOs</th>
<th>American SDOs</th>
</tr>
</thead>
<tbody>
<tr>
<td>IEC</td>
<td>CEN</td>
<td>ANSI</td>
</tr>
<tr>
<td>IEEE</td>
<td>CEN/ISSS</td>
<td>ASTM</td>
</tr>
<tr>
<td>ISO</td>
<td>CEN/ISSS</td>
<td>NEMA</td>
</tr>
<tr>
<td>ISO TC215</td>
<td>CEN TC251</td>
<td>ETSI</td>
</tr>
<tr>
<td>DICOM</td>
<td>ISO TC215</td>
<td>OMG</td>
</tr>
<tr>
<td>HL7</td>
<td>ITU</td>
<td>UN/CEFACT</td>
</tr>
<tr>
<td>IHE</td>
<td>ITU-T</td>
<td>IHE Europe</td>
</tr>
</tbody>
</table>

**Figure 2.4: Relation between different SDOs**
Among this pile of specifications, EHR communication standards and how they model the clinical content have been mainly considered in the development of this dissertation, as one of its main purposes is to make contribution in the telemonitoring measures’ semantic interoperability. In the next section a description of the main EHR communication standards can be found.

2.2.2 EHR communication standards

Regarding medical data communication among different systems several approaches can be identified, from the most commercial to the most formal/academical ones. Among them, it can be highlighted:

- **HL7 suite of standards** in the clinical healthcare field, supported by HL7 International [42], an ANSI-accredited organization. Its name, referencing to the seventh layer of the ISO OSI Reference model (the application layer), points that its application is focused on the application layer, becoming protocols for the health care domain independent of lower layers which are considered as tools.

- **openEHR** [35], an open standard specification that describes the management, storage, retrieval and exchange of health data in EHRs. Its specifications are maintained by the openEHR Foundation, a not-for-profit organization.

- **ISO/EN 13606** [36], an international and European multipart standard which defines a rigorous and stable information architecture for communicating part or all of the EHR of a single subject of care (patient). It has been developed by CEN TC 251 and, subsequently it was adopted by ISO TC 215.

A more in-depth look at each of these options will help, among others, to identify what strategies are being followed by different agencies trying to achieve the interoperable communication of medical information.
2.2.2. HL7 Standards

Although HL7 suite of standards comprises more than messaging standards, as it is depicted in Figure 2.6, these ones are the most widely used and well-known specifications of the suite. The standard suite comprises, mainly:

- The Arden Syntax [133] for Medical Logic Modules is a language for encoding, representing and sharing medical knowledge among personnel, information systems and institutions. It is designed, or developed, for organizations that require systems that automatically assist physicians in decisions and alerts.

- The Clinical Context Object Workgroup (CCOW) [134] Management Specification serves, by synchronizing and coordinating applications so that they automatically follow the user’s context, as the basis for ensuring secure and consistent access to patient information from heterogeneous sources. This allows to simulate the users as they are only interacting with a single system when, in fact, they may be using multiple independent applications from many different systems, each via its native user interface.
Chapter 2. State of the Art

- The Reference Information Model (RIM) [135], a static model of health and healthcare information as viewed within the scope of HL7 standards development activities. It is the cornerstone of the HL7 Version 3 development process. It includes classes and state-machine diagrams and it is accompanied by use case models, interaction models, data type models, terminology models, and other types of models to provide a complete view of the requirements and design of HL7 standards (see Figure 2.7). The classes, attributes, statemachines, and relationships in the RIM are used to derive domain-specific information models. These are then transformed through a series of constraining refinement processes to eventually yield a static model for the information content of an HL7 standard.

- The Clinical Document Architecture (CDA) [136], which leverages the use of eXtensible Markup Language (XML), HL7 RIM and coded vocabularies. A CDA document consists of a header (patient information, author, creation date, document type, provider, etc.) and a body (includes admission details, diagnosis, patient details, medications, follow-up, etc. presented as free text in one or multiple sections, and may optionally also include coded entries.). CDA has three levels of document definition (as can be seen in Figure 2.8):
  - Level One, the most unconstrained version of the document. Level One supports full CDA semantics, and has limited coding ability for the contents. An example of a level one constraint on document type would be “Discharge Summary”.
  - Level Two - additional constraints on the document via templates at the “Section” (free text) level. An example of a level two constraint on document type would be “Emergency Department Discharge Summary”.
  - Level Three - additional constraints on the document at the “Entry” (encoded content) level, and optional additional constraints at the “Section” level.

CDA, by itself, does not specify a transport mechanism and can be utilized within a messaging environment or outside of it. Some of the transport methods include HL7 V2, HL7 V3, DICOM, Multimedia Internet Mail Extensions (MIME)-encoded attachments, Hyper Text Transfer Protocol (HTTP) or File Transfer Protocol (FTP) [137].

- Continuity of Care Document (CCD) [137, 138]. It is a joint effort of HL7 and ASTM to foster clinical data interoperability. The CCD is a CDA implementation of ASTM’s Continuity of Care Record (CCR) (ASTM E2369 - 05e2) [139]. CCD establishes a set of templates representing the typical sections of a summary record, and expresses these templates as constraints on CDA. CCD has been selected by IHE for Patient Care Coordination (IHE PCC) in seven of its profiles [140] and in the IHE’s Cross-enterprise Document Sharing (IHE XDS) Medical Summary for referral and discharge [141].
2.2. Electronic Health Record’s landscape

Figure 2.7: HL7 Reference Information Model, extracted from [135]
Chapter 2. State of the Art

Figure 2.8: Clinical Document Architecture (CDA) structure, reproduced from [136]

It also includes other standards like the HL7’s Common Terminology Services (CTS) [142] which was developed as an alternative to a common data structure by means of identifying the common functional characteristics that an external terminology must be able to provide, Structured Product Labeling (SPL) standard [143] which is a document markup standard that specifies the structure and semantics for the regulatory requirements and content of product labeling or various functional standards, like the HL7’s Electronic Health Record System Functional Model (HL7 EHR-S FM) [144] or the HL7’s Personal Health Record System Functional Model Draft Standard for Trial Use (HL7 PHR-S FM DSTU)[145].

Regarding messaging, there are 2 available options: HL7 v2 Messaging standard and HL7 v3 Messaging standard.

HL7’s version 2.x (HL7 v2.x) messaging standard [146] defines a series of electronic messages to support administrative, logistical, financial as well as clinical processes. It uses a human-readable (ASCII), non-XML encoding syntax based on segments (lines) and one-character delimiters although an XML encoding Syntax was approved by the ANSI as an American National Standard in June 2003 [147]. In HL7 v2.x, a message is a hierarchical structure associated with a trigger event. This trigger event is an event in the healthcare world which creates the need for data to flow among systems [148]. Each trigger event is associated with an abstract message that defines the type of data that the message needs to support. Recently, HL7 v2.7 was released [149].
2.2. Electronic Health Record’s landscape

<table>
<thead>
<tr>
<th>Name</th>
<th>Multiplicity</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>MSH</td>
<td>1</td>
<td>Message Header</td>
</tr>
<tr>
<td>EVN</td>
<td>1</td>
<td>Event Type</td>
</tr>
<tr>
<td>PID</td>
<td>1</td>
<td>Patient Identification</td>
</tr>
<tr>
<td>PD1</td>
<td>0..1</td>
<td>Patient Additional Demographic</td>
</tr>
<tr>
<td>ROL</td>
<td>0..N</td>
<td>Role</td>
</tr>
<tr>
<td>NK1</td>
<td>0..N</td>
<td>Next of Kin / Associated Parties</td>
</tr>
<tr>
<td>PV1</td>
<td>1</td>
<td>Patient Visit</td>
</tr>
<tr>
<td>PV2</td>
<td>0..1</td>
<td>Patient Visit - Additional Information</td>
</tr>
<tr>
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<td>Role</td>
</tr>
<tr>
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<td>0..N</td>
<td>Disability Information</td>
</tr>
<tr>
<td>OBX</td>
<td>0..N</td>
<td>Observation/Result</td>
</tr>
<tr>
<td>AL1</td>
<td>0..N</td>
<td>Patient Allergy Information</td>
</tr>
<tr>
<td>DG1</td>
<td>0..N</td>
<td>Diagnosis Information</td>
</tr>
<tr>
<td>DRG</td>
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<td>Diagnosis Related Group</td>
</tr>
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<td></td>
</tr>
<tr>
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<td>1</td>
<td>Procedures</td>
</tr>
<tr>
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<td>0..N</td>
<td>Role</td>
</tr>
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</tr>
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<td></td>
<td></td>
</tr>
<tr>
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<td>1</td>
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</tr>
<tr>
<td>IN2</td>
<td>0..1</td>
<td>Insurance Additional Information</td>
</tr>
<tr>
<td>IN3</td>
<td>0..N</td>
<td>Insurance Additional Information - Cert.</td>
</tr>
<tr>
<td>ROL</td>
<td>0..N</td>
<td>Role</td>
</tr>
<tr>
<td>ACC</td>
<td>0..1</td>
<td>Accident Information</td>
</tr>
<tr>
<td>UB1</td>
<td>0..1</td>
<td>Universal Bill Information</td>
</tr>
<tr>
<td>UB2</td>
<td>0..1</td>
<td>Universal Bill 92 Information</td>
</tr>
<tr>
<td>PDA</td>
<td>0..1</td>
<td>Patient Death and Autopsy</td>
</tr>
</tbody>
</table>

Table 2.5: HL7 Message structure associated with the trigger event AO4

The abstract message consist of a collection of segments that also includes the rules of repetition and inclusion for those segments. An example of message has been represented in Table 2.5. Segments are also composed by fields, fields composed by components and components by subcomponents. These entities are delimited in the message by separator characters, which can be seen in Table 2.6.

<table>
<thead>
<tr>
<th>Separator</th>
<th>ASCII</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; CR &gt;</td>
<td>13</td>
<td>Segment separator</td>
</tr>
<tr>
<td></td>
<td>124</td>
<td>Field separator, aka pipe</td>
</tr>
<tr>
<td>`</td>
<td>94</td>
<td>Component separator, aka hat</td>
</tr>
<tr>
<td>&amp;</td>
<td>38</td>
<td>Sub-component separator</td>
</tr>
<tr>
<td>`</td>
<td>126</td>
<td>Field repeat separator</td>
</tr>
<tr>
<td>\</td>
<td>92</td>
<td>Escape character</td>
</tr>
</tbody>
</table>

Table 2.6: HL7 v2.x separator characters
Actually, the segment separator is the only non-negotiable one: the rest of the delimiters are only suggested values. However, they are usually used as Table 2.6 indicates [150].

Although being a market success, HL7 v2.x presents different weaknesses like the lacks of a consistent application data model, formal methodologies to model data elements and messages, well-defined application and user roles or precision in the standard [151]. To address these challenges, a new standard was developed within the HL7 community. This new standard was decided to be not compatible with the HL7 v2.x to avoid the above mentioned legacy issues. In contrast to this decision, HL7 v2.x is drawback compatible with its prior versions.

HL7 v3 [152], according to [153], implies a higher level of interoperability in the conceptual framework devised in [154] than HL7 v2.x which is an example of level 3 interoperability (Machine-organizable data) while HL7 v3 is presented as a level 4 interoperability example (Machine-interoperable data). The HL7 v3 philosophy bases the methodology of the HL7's abstract message definition on the HL7 RIM, which can be seen in Figure 2.7: After a Committee agrees on the data and relationships that are relevant within an area of clinical or administrative knowledge, that knowledge is represented in a Domain Model, the Domain Message Information Model (D-MIM). Each D-MIM has to be expressed in RIM modeling terms, which means that all D-MIMs must be a constraint of the HL7 RIM. D-MIMs are not intended to be serializable as Refined-Message Information Models (R-MIM) are. R-MIMs are constraints on a D-MIM and represent the information contents for a set of messages. This R-MIM is restricted by the Hierarchical Message Description (HMD) (or the Model Interchange Format (MIF) file format). HMD specifies the order and constraints of particular set of attributes and relationships of the R-MIM, obtaining Messages Types. This Messages Types can specify different patterns of constraints for the same set of attributes as long as the constraints are, at least, as strict as those prescribed in the common message for the HMD, allowing a single HMD to satisfy the needs of a number of related interactions. Illustrative documents of this process can be found in [155, 156].

HL7 v2.x messaging standard is arguably the most widely implemented healthcare standard in the world. The HL7 v3 messaging standard is used by U.S. government agencies, such as the FDA or the Department of Veterans Affairs. It is also widely used outside the U.S. in countries such as Canada, United Kingdom, the Netherlands, Germany and Mexico. There are large-scale CDA implementations in North and South America, Europe and Asia Pacific [157]. In Spain, HL7 CDA level 1 was chosen for document headers in the national EHR project [158] and extensions of HL7 CDA are being used in the “European patients - Smart open Services” (epSOS) project [159].
2.2.2.2 openEHR

openEHR [35] is an open standard specification that describes the management, storage, retrieval and exchange of health data in EHRs. Its specifications are maintained by the openEHR Foundation, a not-for-profit institution. Those specifications take the form of modular information models, service models and clinical information models, which will allow:

- to record any clinical information,
- to enable the use of archetypes and templates in any clinical system,
- to integrate with terminology systems as SNOMED-CT, LOINC, ICDx or ICPC classifications,
- to integrate with existing hospital information systems and other databases or applications via a published API,
- distributed versioning and merging of EHR,
- and, specially, to make the architecture componentised, adaptive and future-proof, so that it may be a reliable basis for managing 100 year+ health records [160].

The architecture is defined by abstract specifications. These specifications consist of the Reference Model (RM), the Service Model (SM) and the Archetype Model (AM)[161]. The first two correspond to the ISO RM/ODP information and computational viewpoints respectively. The latter formalizes the bridge between information models and knowledge resources.

openEHR Reference Model is composed by several sub-models or packages:

- Support Information Model [162], where the semantics for constants, terminology access, access to externally defined scientific units and conversion information are defined, in adition to assumed primitive types defined outside openEHR.
- Data Types Information Model [163], which describes the clinical/scientific data types used in other openEHR models.
- Data Structures Information Model [164], which describes common data structures used in openEHR Reference Model, including lists, tables, trees and history. It also contains a possible hierarchical data representation.
- Common Information Model [165], which describes common patterns used by other openEHR reference models.
- Security Information Model, which defines the semantics of access control and privacy setting for information in the EHR.
- EHR Information Model [166], which defines a logical EHR information architecture: the containment and context semantics of the concepts EHR, COMPOSITION, SECTION, and ENTRY.

- EHR Extract Information Model, which defines how an EHR extract is built from COMPOSITIONs, demographic, and access control information from the EHR.

- Integration Information Model [167], designed to be used in legacy, and other integration situations.

- Demographics Information Model [168].

  openEHR Archetype Model describes the semantics of archetypes and templates, and their use within openEHR. It includes the Archetype Definition Language (ADL) and various packages defining the object-oriented semantics of archetypes and templates.

  openEHR Service Model includes definitions of basic services in the health information environment centred around the EHR. Some of these services are:

  - Virtual EHR API, which defines the fine-grained interface to EHR data at the level of Compositions and below.

  - EHR Service Model, which defines the coarse-grained interface to electronic health record service.

  - Archetype Service Model, which defines the interface to online repositories of archetypes.

  - Terminology Interface Model, which provides the means for all other services to access any terminology available in the health information environment.

The openEHR approach, in order to model information, services and domain knowledge, is based on an ontological separation (between information models, domain content models, and terminologies), the separation of responsibilities (what it is called system of systems) and the separation of viewpoints (in the the ISO RM/ODP model [169], the openEHR Reference Model corresponds to the information viewpoint and the openEHR Service Model corresponds to the computational viewpoint). The application of these principles leads to a separation of the openEHR models, and consequently, a high level of componentisation and a better maintainability, extensibility, and flexible deployment.
2.2. Electronic Health Record’s landscape

Figure 2.9: High-level Structure of the openEHR EHR, reproduced from [166]

Figure 2.10: Elements of an openEHR Composition, reproduced from [164] [160]
In openEHR, the EHR is structured according to the model reproduced in Figure 2.9. A central EHR object, identified by an EHR id, specifies references to a number of types of structured, versioned information (EHR_access containing access control settings for the record, EHR_status containing various status and control information and optionally the identifier of the patient, Directory (an optional hierarchical structure of FOLDERs that can be used to logically organize COMPOSITIONs) and COMPOSITIONs containing all clinical and administrative content), plus a list of Contribution objects that act as audits for changes made to the EHR.

The logical structure of a typical COMPOSITION can be seen in Figure 2.10: A COMPOSITION contains ENTRYs, which can be grouped in SECTIONs. ENTRYs contain ELEMENTs, which may be grouped in CLUSTERs. ENTRYs are “clinical statements” and they are classified according to their type of information in ADMIN_ENTRY or CARE_ENTRYs (OBSERVATION, EVALUATION, INSTRUCTION and ACTION). The sub-classification of CARE_ENTRYs was due to the clinical problem-solving process.

openEHR is being used in various commercial, academic or non-profit organizations all over the world [170, 171, 172] like Ocean Informatics in Australia, P2D in Brazil, Code24 in the Netherlands, various universities in Spain, Brazil, Germany, Sweden, United Kingdom, Japan, New Zealand, etc. It is also used in the ClinicalTemplates.org or the openEHRgen Framework projects. openEHR has also aroused the interest of some governments like the Swedish or the Singapore ones [173].

2.2.2.3 ISO/EN 13606

The ISO/EN 13606 standard [36] is a multipart standard which main goal is to define a rigorous and stable information architecture for communicating part or all of the EHR. It is not intended to specify the internal architecture or database design of EHR systems or components. In order to achieve semantic interoperability, ISO/EN 13606 is based on a dual model: a Reference Model, which supports the information, and an Archetype Model, which it used to define the knowledge, i.e. the concepts of the clinical domain. This dual-model approach is shared with openEHR.

Archetypes are patterns, or models, that represent the specific characteristics of the clinical data. The cornerstone of this dual approach is that if knowledge changes (e.g. additional medical characteristics are required to be included), only the archetype under which data is modeled will change and information will remain unalterable.
For example, the following asseveration can be assimilated to knowledge: “A routine blood chemistry measures the following chemical substances in the blood: glucose, urea, creatinine, sodium and potassium”. On the other hand, information is the instantiation of that archetype for one patient in one specific point of time: “January 2nd, 2010 at 08:43 a.m. John Smith had: glucose = 80 mg/dL; urea = 11 mg/dL; creatinine = 0.77 mg/dL; sodium = 141 mmol/dL; potassium = 4.1 mmol/dL”. Eventually, due to new discoveries in medicine, it might become important to include additional measurements (for example, chlorine levels) in the routine blood chemistry tests. In such a case, only the archetype (knowledge) would change while information would remain unalterable.

The ISO/EN 13606 standard is divided into five different parts that are detailed below:

- Part 1: Reference Model. This part defines basic generic components that underpin information and the relationships between these components. Figure 2.11 shows a simplified scheme of these components. The EHR’s clinical data is comprised of the following logic blocks that can be seen in Figure 2.12:
  - Extract: The top-level container of part or all of the EHR of a single patient.
  - Folder: The high level organization within an EHR (i.e. episode of care, compartments of care, etc.).
  - Composition: Single clinical encounter or record documentation session (reports, test results, etc.).
  - Section: Clinical headings reflecting flow information (i.e. subjective symptoms, findings, treatment, etc.).
  - Entry: Clinical Statements.
  - Cluster: The mean to organize nested multi-part data structures (tables, time series, etc.).
  - Element: A container of a single data value. It is the leaf node of the hierarchy.

Additionally, the Reference Model sets hierarchical relationships between its components, achieving this way syntactic interoperability. A deeper analysis shows other relevant characteristics related to the use of the standard, like the ability of signing every single element by means of defining the ATTESTATION_INFO class. Moreover, the existing association relationship between this class and the RECORD_COMPONENT class is inherited by the rest of the elements, given that all of them derive from this abstract class. The separation of the demographic information allows transmitting clinical information anonymously, an essential factor due to security purposes. Each party composing the system (organization, devices, healthcare professional, patients, etc.) is identified by unique identifiers.
Chapter 2. State of the Art

Figure 2.11: ISO/EN 13606 Reference Model, reproduced from [36]

Figure 2.12: ISO/EN 13606 Blocks Relationship
Auditory capabilities are also present through the AUDIT_INFO class, which can be used to track what data has been introduced, when and by whom, and also the reason for that information to be modified. It allows recording every single request, whether accepted or not, additionally to the reason for the rejection.

- Part 2: Archetype Model. An archetype is used for modelling domain concepts, constraining the Reference Model at run-time by defining the structure of the instance and/or limiting the value range of an attribute. This part of the standard was adopted from openEHR: openEHR archetypes constraint openEHR Reference Model and ISO/EN 13606 archetypes constraint ISO/EN 13606 Reference Model. However, ISO/EN 13606 archetypes can be expressed in any formal language but openEHR archetypes are expressed in the Archetype Description Language (ADL). Figure 2.13 shows a simplified scheme of the Archetype Model, extracted from ISO/EN13606-2 standard.

Describing a well defined archetype is not a simple task. As seen in Figure 2.13, the ISO/EN 13606 standard offers different mechanisms to enable this modeling, such as the archetype_description, the ontology and the constraint_model. The archetype_description allows associating additional data (metadata) to the archetype, (e.g. a translation into a different language). The ontology is used to bind archetype nodes to specific medical terms. Finally, the constraint_model specifies a hierarchical schema that defines how an instance must be built.

Although the main feature in the ISO/EN 13606 standard is the dual model, described in the first two parts, it is also important to define other aspects in order to achieve interoperable EHR communication, such as nomenclature issues (part 3), security issues (part 4) or interfacing for querying (part 5).

- Part 3: Reference Archetypes and Term lists. This part mainly sets a normative set of coded terms, each one defining a controlled vocabulary for a Reference Model attribute contained in ISO/EN 13606-1 standard.

- Part 4: Security. This part describes a methodology for specifying the privileges necessary to access EHR data and, also, some other general security requirements that should apply to the EHR communications through a default mechanism (based on a double table input) or the specificity of particular policies.

- Part 5: Interface Specification. This part describes a set of interfaces to request access to the information and resolve the request. Three specific interfaces are defined (REQUEST_EHR_EXTRACT, to request part or the overall of one patient’s EHR, REQUEST_ARCHETYPES to request one or various archetypes and REQUEST_EHR_AUDIT_LOG_EXTRACT to request specific Audit Log data).
Figure 2.13: Simplified ISO/EN 13606 Archetype Model, reproduced from [36]
The ISO/EN13606 standard was completed on February 2010 when Part 5 was ratified. However, there are some examples of use in which it has been, or it is being, successfully applied like in the LinkEHR Editor [174] (an archetype editor), EHRFlex (a system that allows the interfaces) or Google Web Toolkit (GWT) [175] forms creation based on archetypes, etc. Moreover, it was selected for the EHR Swedish project and it was used in the clinical information repositories development in Minas Gerais (Brazil), NHS United Kingdom and Singapore, etc [176]. Moreover, it is being considered by the Spanish health ministry to be used in the Spanish project [177] due to the committee for the semantic interoperability’s recommendation. In the moment of the writing of this Thesis, the standard is being reviewed within the CEN and ISO committees.
Chapter 3

Materials and methods

Telemedicine is the use of telecommunication and information technologies in order to provide clinical health care at a distance. It can be broken into three main categories [178]:

• Store-and-forward telemedicine, which involves acquiring medical data (like medical images, biosignals, etc.) and then transmitting it to a doctor or medical specialist at a convenient time for offline assessment. Teledermatology or radiology are common examples of this category of telemedicine.

• Interactive telemedicine services, which provide real-time interactions between patient and provider. They include phone conversations, online communication and home visits.

• Remote monitoring, also known as self-monitoring/testing, which enables medical professionals to monitor a patient remotely using various technological devices. This method is primarily used for managing chronic diseases or specific conditions, such as heart disease, diabetes mellitus or asthma.

The same way medicine is transitioning to a more pro-active patient-centered model, so the telemedicine concept is evolving to telehealth. Telehealth is understood as an expansion of telemedicine, and unlike telemedicine (which more narrowly focuses on the curative aspect) it encompasses preventative, promotive and curative aspects.

Knowing that patient’s self-monitoring plays an important role in the chronic disease management and given that the high availability of PHDs in the domiciliary environment may provide useful information in the patient’s continuity of care, a way of harnessing this information for the betterment of the chronic diseases management has to be accomplished, specially for its proactive management.
3.1 Architecture

In literature there are continuous references to the ideal of how a health system should be: efficient, effective, integrated, informed and patient-center [23, 179]. However, health care centres are usually organized around an acute, episodic model of care that does not meet the needs of many patients, specially those with chronic conditions [180]. Moreover, as described in this Thesis’s introduction, information is segmented into several information systems that might not have the ability to share information with each other.

The required change in the healthcare model, which would help to improve the continuity of care, has to be accordingly supported by the technological support which would enable to take the appropriate actions in the patients’ care. However, current systems which were deployed under certain design premises are not always easy to change due to both technological and management issues: system’s maintenance or governance might not be performed within the same institution. Hence, although this factor is out of this Thesis’s scope, a realistic perspective has tried to be taken into account.

In this section, the bases of the above-mentioned architecture will be set on the basis of the standard-based design, possible technological limitations, market tendencies and academic works. Firstly, a description of various situations will be carried out and, over this description, a set of designing considerations will be performed. After that, a wider exposition would be made accordingly to the extracted conclusions.

3.1.1 Scenario descriptions

In literature, several telehealth/telemonitoring platforms have been presented. In [181] a review of proved medical conditions that have been successfully telemonitored is presented, which could be representative of the efforts in this area.

Measurement’s types are scattered in structure and complexity and range from single numbers, like the International Normalized Rate (INR), to complex multidimensional measurements, like a 12-lead ECG. These differences are not only related to the complexity of the measurements but the periodicity they should be acquired or how “reusable” these measurements are (e.g. a weight measurement is something that should be performed more often than an ECG and it is a measurement that might be more accessed by medicine practitioners (i.e. nurses, general practitioners, endocrinologists, etc.)). Other issues have to be considered like the needed device type for their acquisition or if help from a trained assistant is required because, although they are not completely restringing conditions, the inability to purchase a medical device or use it by one-self might mean these measures to be acquired through a parallel collecting system.
Other issue to take into consideration is how medical data are usually acquired in telemedicine platforms. Medical devices' technical features do not generally include the ability to send the acquired data to a remote health care information system. As shown in various examples [182, 183, 184, 185], a similar system structure can be found: a set of medical equipment is, somehow, bound to a gateway device or Controlling Device (CD) which is responsible for communicating the acquired information to a remote location (i.e. a remote information system).

In these documents, like [184], it is assumed that information remains in that location and it is no reference to the sharing of the acquired information, perhaps due to this information would be mainly used through the mentioned information system. This creates a new information silo, forcing a general practitioner to access various systems to get the complete picture of the patient’s health and hampering the information’s interpretation. However, the low reuse rate of certain tests, like the electroencephalographies (EEG), mitigates the effects of this lack of sharing and, from a security viewpoint, it can be a preventive action for the patient’s privacy as the record can not be inappropriately accessed for users not related to the acquiring system.

Finally, other types of considerations have to be taken into account like the population’s geographical distribution and its corresponding health care centre assignment. Chronic disease management, according to different models as Wagner’s Chronic Care Model or Kaiser Permanente Pyramid, is intended to be self-managed for the 70 - 80% of the population [179, 186]. Patients’ interaction with the healthcare system would increase if the subject of care is considered a high risk or a highly complex patient (patient with more than one chronic condition, co-morbidities). It is not until level 2 (high risk patient) where a multidisciplinary team is highly necessary, but it does not mean that professional care has to be only applied to this level and on: periodically acquired measurements can be sent to a care agent or healthcare professional in order to, for example, encompass preventive actions.

This last condition has to be extensible to the whole population, no matter how crowded the town the patient is living would be. Equity principle it is a criterion that should not be conditioned to the project’s economical viability, although the optimal use of resources should be considered. As an example, consider a small village in which a telemonitoring solution could improve the quality of care of its population but a dedicated resource assignation is not efficient (e.g. software licenses, servers, etc). In this situation, an easy way to reduce the project expenses might be gathering the telemonitoring data from various healthcare centres to be managed by a single entity (like the assignation of a specialized healthcare centre to various primary healthcare centres), as reducing or sharing medical devices among patients seems less reasonable.
In Figure 3.1 both approaches are depicted. Scenario B, which represents the suggested scenario, proposes that all the telemonitoring measurements of various healthcare centres would be collected in a central unit which could be requested by both primary care centres and specialized care centres. Scenario A represents the telemoting measurement’s inclusion in a reference health care centre. Although scenario B might seem more complex than scenario A, it presents certain advantages over the previous situation that might be interesting from a optimization use of healthcare resources.
Thus, in the case of very small populations, where would not be users enough to economically justify the project, they would be an addend to the total amount of users in a wider area. The same way, the use of this element in the architecture might be used to custom the area in which this service is deployed. This would help to guarantee the equality in the health care provision to all users. In the next sections the technological requirements to achieve semantic interoperability in the regular dataflow would be analyzed based on the standard-based design.

### 3.1.2 MD communication standard election

In the previous section, an architectural configuration has been proposed guided by the actual implementation trends and based on an optimal resources exploitation. In that simplification of integrated healthcare model, the sharing of additional information would be required among the different centres (not only the telemonitoring information but others like drug prescriptions), and consequently, these interactions were represented in both scenarios.

In this situation, the accomplishment of a seamless communication from MDs to any healthcare centre, and its HCIS, in which telemonitoring data could be requested is a complex task, even relaying on standards, due to the multiple types of communication involved in this process. The set of communications between elements in the generic telemonitoring platform shown in Figure 3.1, can be simplified and reduced to 3 different types of interactions: MD - CD, CD - HCIS and HCIS - HCIS. A graphical representation can be found in Figure 3.2. The MD - CD communication representation has been introduced from Figure 3.1 to Figure 3.2 in order to suit the requirements of the previously reviewed medical device interoperability standards, like in CANopen or the ISO/IEEE 11073 standards, or other initiatives where, at least, the network communication is handled by another device, like the Network Capable Application Processor (IEEE 1451 NCAP) in the IEEE 1451 standard.
In relation to the MD - CD communication, it cannot be ignored the leading role ISO/IEEE 11073 standard is running, not only because of the previously mentioned industry support but the orientation to the type of devices used in any eHealth platform. Both CANopen and IEEE 1451 standards obey to an excessively generic approach.

Hence, a special attention to ISO/IEEE 11073 standards would be given, specially to the PHD version as it might provide the greater of the informal care information. Whether the ISO/IEEE 11073 specializations or the ISO/IEEE 11073 DIM has to be the main focus depends on how generic the solution is aiming to be. As stated, specializations are nothing else than a DIM based model for a MD and, therefore, all the objects used in these models are a sub-set of the DIM ones. However, specializations cannot be disdained either due to the knowledge representation in them reflected: what measurements are mandatory, what are optional, how a measurement is arranged and which object is needed to access it, etc. Pro temp, no specifically decision will be taken.

3.1.3 EHR communication standard election

ISO/IEEE 11073 standards are being fostered by CHA and promoted by IHE (which also promotes HL7 standards), so the joint use of both standards are suggested in different documents [57, 187]. [57] also contains the Continua Design Guidelines in its data model, which has also been considered in this Thesis development. All these arguments led us to take HL7 standards into consideration for the HCIS - HCIS communication. However not only HL7 standards have been considered.

HL7 v2 messaging standards are the most spread option among the implemented ones. It, or they if the different versions are considered, is what can be called a dominating standard. However, the HL7 v2.x’s already-known interoperability problems have led to consider some transitioning towards other more formal proposals involving an information model. As an example, in the Valencia’s regional EHR project it was considered the use of HL7 v2 + CDA, HL7 v3 + CDA, HL7 v2 + openEHR/13606 or level 3 HL7 CDA to define OpenEHR/13606 archetypes [188]. This investment in the use of generic information models is due that they can be applied to draw specific domain information models [189], such as for care provision. These models are required to provide clean, consistent data in which business processes and applications rely on.

As seen in the description of current interoperability standards, about the definition of models, two different approaches can be found:

- HL7’s approach, which can be considered a top-down design methodology. HL7 CDA is one of its most well-known standards and the cornerstone in which other documents rely on, as they are based on greater level of specificity.
Chapter 3. Materials and methods

- openEHR and ISO/EN 13606 standard’s dual model approach. Archetypes are used to model domain concepts and they can be defined at any level of their hierarchical information model.

This would be a discriminatory basis upon which a reasoned decision can be performed, as there exist obvious similarities on how information is arranged (i.e. their hierarchical structure: documents, sections, entries, etc.). However, the archetype-based proposals offer a more flexible, scalable choice: A clinical document can be expressed as the aggregation of one or more entries, perfectly defined by their respective archetypes. The opportunity of reusing already defined clinical models is clear. Moreover, there are different levels of criticism about HL7 RIM [190, 191, 192, 193] and ISO/EN 13606 and openEHR have less complex information models.

Therefore, looking for an adaptable and scalable architecture, a dual model approach has been selected. The decision about if it should be an openEHR or an ISO/EN 13606 architecture was mainly based on a simplicity criteria: While openEHR specification describes the management, storage, retrieval and exchange of health data in EHR systems, the ISO/EN 13606 standard’s scope is the EHR communication for a single patient. Information systems have their own way to manage, store and retrieval information, so this part of their architecture is already working for data acquired within the institution the system belongs. The only thing missing is to fuse remotely acquired data with those which already are stored in the information system and for its proper integration the use of archetypes is proposed. Not to mention ISO/EN 13606 standard is an open specification while openEHR involves some intellectual property rights bounded to the openEHR foundation. Both options, nevertheless, are based on the same fundamentals as openEHR members collaborated in the ISO/EN 13606 redaction.

Moreover, the ISO/EN 13606 standard is immersed in an harmonization process with other standards, like the ISO/EN 13940 standard (i.e. System of Concepts for Continuity of Care or ContSys) or the ISO EN/12967 standard (i.e. Health Informatics Service Architecture or HISA)[194]. ContSys defines concepts around the topic of planned co-operation between various healthcare providers inside and outside of one jurisdiction, the patients and its surrounding. The clinical process and the concepts needed for all aspects, especially continuity of the clinical processes are its focus. HISA defines the information models, knowledge models and interfaces for the communication of electronic health record information between heterogeneous systems. The harmonization of the three standards would involve greater coherence for each of these standards, and more over that all the specifications are now within the ISO realm, which not only does widen their applicability, but makes explicit the wider market, opportunities and threats from such participation [195].
And finally, as was presented in the state of art section, despite of their relatively recent ratification it has already been, or it is being adopted by numerous EHR projects. Therefore, ISO/EN 13606 was selected to handle EHR communications among HCISs.

3.2 The security problem

The EHR standard election, which was mainly based on semantic interoperability criteria and scalability of the future implementation, does not collide with security issues. The same that some similarities can be found in how information is arranged among the previously sketched standards, other resemblances among them can be pointed out like a clinical content’s role-based access control policy. This way, the main EHR communication proposals use a similar approach to solve one of the most important concerns about any EHR implementation:

- ISO/EN 13606, as already mentioned, covers the security issue in its part 4 which assumes that another specification, the ISO/TS 22600 standard [196], is logically applied to govern access decisions in response to an EHR request.

- openEHR covers the EHR access control issue completely through the EHR_ACCESS object, which contains the rules and policies over which any access control has to be made [160].

- HL7 Int, in its version 3, includes its Role-based Access Control Healthcare Permission Catalog (RBAC) [197] which aims to provide the necessary content for among other, creating interoperable roles to facilitate interorganizational access control decisions and communications.

If the ISO/EN 13606 standard is selected, the implications about security need to be consulted in the part 4 of the standard. This sketches the communication process’ scenario description (differentiating between requester and recipient) which shows the needed interactions for including security features. Two different possibilities are offered to grant a heterogeneous access both to medical professionals and the various representatives the patient might have:

- The first one is through a double input table, as can be seen in Table 3.1. The access to each RECORD_COMPONENT is granted, or not, based on its sensibility and the access level of the recipient’s functional role. Functional roles are categories defined in the standard and they are used to describe the relationship among the professional healthcare and the EHR owner. Asterisks in Table 3.1 indicate special conditionings, as the record you are seeking to access must has been created in the same clinical setting or corresponds with the same specialty the EHR recipient belongs. This one sets a minimum conformance level with the standard requirements.
Table 3.1: Functional role and sensitivity mapping.

<table>
<thead>
<tr>
<th>Functional Role</th>
<th>Sensitivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject of care</td>
<td>✔</td>
</tr>
<tr>
<td>Subject of care agent</td>
<td>✔</td>
</tr>
<tr>
<td>Personal healthcare professional</td>
<td>✔</td>
</tr>
<tr>
<td>Privileged healthcare professional</td>
<td>✔</td>
</tr>
<tr>
<td>Healthcare professional</td>
<td>✔</td>
</tr>
<tr>
<td>Health-related professional</td>
<td>✔</td>
</tr>
<tr>
<td>Administrator</td>
<td>✔</td>
</tr>
</tbody>
</table>

- The second one is through an access policy model on which different customized policies might be defined based on functional and structural roles (Structural roles deal with relationships between entities expressed at a level of complex concepts and they are relatively static, often lasting for many years. However, functional roles are bound to the realization of actions and they are highly dynamic), clinical setting, specialty or specific identification of the recipient. Additionally, other characteristics might be expressed as filtering criteria although the way of expressing them is through plain text and, thereby, they should be expressed in a computational way. Content filtering areas also include the possibility of specifying if the record was created in a specific time interval, under an archetype or, reaching the highest level of specificity, if it is a specific EHR record. Meeting the minimum conformance and implementing this customized access policy model implies a normal conformance with the standard.

The standard also considers an extended conformance when an audit log view implementation is conforming a specific information model and the system was previously complying with a normal conformance level.

On the other hand, ISO/TS 22600 standard sketches a complex scenario description in which EHR requests are considered both from within and from outside the domain the EHR server is placed. A domain is the grouping (based on common organizational, logical or technical criteria) of the different manageable and operating components in an information system that supports shared care. The scenario description is done through the process model. ISO/EN 13606 assumes ISO/TS 22600 is logically applied. This standard is based on various elements on which the information exchange process is defined:

- Domain, as the previously mentioned grouping of components. Each domain might consist of sub-domains and domains might be extended into super-domains, by chaining a set of them.
3.2. The security problem

- Policies, as the framework including rules and regulations, the organizational and administrative framework, functionalities, claims and objectives, the parties involved, agreements, rights, duties and penalties defined as well as the technological solution implemented for collecting, recording, processing and communicating data in information systems.

- Roles, both functional and structural, as a set of connected behaviors, rights and obligations of the different entities. They require of actors’ authentication and identification.

- Directory, as a service providing information about entities.

- Authentication, to confirm the identity of a person or software program. Public Key Infrastructure (PKI) is the recommended method.

- Process, to describe the communication process. It is exemplified over the example of two domains, each of them having its authorization system with roles according to its needs and different rules for granting access to different information for the different roles. Whenever a user needs to use an application in their domain, the application has to check if he is authorized to do it and, if so, access is granted. If the user would need to use an application in another domain, a common policy repository needs to be consulted by both domains. This repository contains the pre-agreed rules on which inter-domain communications are performed. An inter-domain request, as stated in the ISO 22600-1, must contain “the identity and role of the requester and a reference to the relevant rule in the common policy repository”.

It is supposed that, if the EHR request runs counter to the agreed policies, the requesting system would prevent the EHR request to take place. However, the same check in the requested domain would be performed due to security issues although, if it is receiving an inter-domain request, it is supposed to be raised under the agreed rules.

It is in ISO/TS 22600-2 standard, in which can be found various models: for characterizing domains (the Domain model); to support multiple signatures in a document (the Document model) which is used, for example, in cases of delegation; a domain model for the policy definition (the Policy model); to manage relationships between the entities mediated by an activity (the Role model); to connect roles to policies (the Authorization model); to exert control over access to a sensitive object operation (the Control model); to model delegation (the Delegation model) and for access control management (the Access control model).
This way, the security issue is underpinned from a methodological basis. However, the adding of the security capabilities in this dissertation will be discussed after having accomplished other goals: the integration of telemonitoring data into the patient’s EHR and the generation of EHR Extracts fulfilling the semantic interoperability criteria.

### 3.3 The data type problem

As it may occur in other scenarios, an specific standard election might limit the ability of a system to interact with other systems which EHR communications would had been based on other competitive communication standard. From this standpoint, one system’s interoperability is limited to those systems which have compatible solutions with the prior one. Even having systems with the “tools” to provide semantic interoperability, these “tools” have to be compatible with each other.

Whenever different standards provide solutions for the same problem, a standard dominance can take place. Many factors are responsible for the dominance of one of them over the others like backward, forward or sidewalk compatibility, the timing of entry in the market, pricing strategies or the brand reputation of the “product” [198]: based on these premises it is understandable the predominance of HL7 v2.x messaging standards over the other available options as one of its versions was the first to be implemented in 1989, crowding out the most of the market.

To analyze these standards compatibility, specific studies have to be performed analyzing, among others, both the hierarchical block’s organization and the “pieces” that make up these blocks. The smallest pieces to consider in any standard are the data types used in their architecture. In the above considered standards:

- **HL7 v2.x**, considered as a unique piece of information in which different separators provide the ability to identify its segments, fields, etc, only needs of strings to be shaped. As an example, in [199] it can be seen, among other content, a compilation of HL7 v2.4’s data types.

- **openEHR** developed its own data types [163], which include 32 classes organized into different packets: basic, text, quantity, date time, time_specification, encapsulated and uri packages.

- **HL7 v3**, has its own set of data types. The HL7 RIM has various releases (4, to date [200]) and HL7 data types evolved from Release 1 to Release 2 [201].
• ISO/EN 13606 standard, which in its actual published specification stipulates its joint use with TS 14796 [202]. TS 14796 was composed by a set of primitive data types (atomical, not composed by simpler data types) and, based on them, 31 classes (including abstract classes), which inherit from the “DATA_VALUE” class (a root class), were described. However, this “partnership” is about to expire as, within the working committees, it was planned the replacement of this specification (which already has been withdrawn) for a new specification which would define a set of harmonized data types for information exchange: the ISO/EN 21090 standard [203]. This document would harmonize HL7’s, CEN’s and ISO’s data types. As ISO/EN 21090 standard was ratified in 2011 and ISO/EN 13606-1 standard dates from 2008, TS 14796 is apparently valid but this will be modified in the current standard review. Therefore, in this Thesis, ISO/EN 21090 will be considered as the data type set foreseeing its inclusion within the standard.

Some compatibilities studies have been performed like [163], where the compatibility between openEHR and HL7 v3 data types is performed, or [204] in which the transformability between HL7 v3, openEHR and ISO/EN 13606 is being questioned. In other cases, synergies between different SDOs have been sought like in the previously mentioned ISO/EN 21090 standard. This is already being used in different projects and implementations, like the Singapore Logical Information Model (LIM) or the Cancer Data Standards Registry and Repository (caDSR) Content [205], and being adopted by various organizations, like the Canada Health Infoway, the Australia’s National E-Health Transition Authority (NEHTA) or the NCI Center for Biomedical Informatics and Information Technology (CBIIT) [206]. However, although its considerable acceptance ratio, ISO/EN 21090 standard is receiving criticism for its complexity and its clear alignment with the HL7 data types [207, 208, 209, 210]. Thus, some publications consider this document to be, basically, HL7 data types Release 2 [211, 212].

In the standard’s compatibility workline other compatibility studies and initiatives can be highlighted like the [213] where the compatibility between openEHR and the joint use of ISO/EN 13606 and ISO/EN 21090 is discussed, [214] where a mapping from HL7’s data types and openEHR’s data types is performed, or [215] in which a strategy to automatically map HL7 v3 coded info into ISO/EN 13606 data structures using, whenever possible, the standard mechanisms. Furthermore, ISO/EN 13606 standard, in its actual revision process will again consider the alternative specifications and see how it should be harmonized with openEHR and CDA specifications [194]. There are also some guidelines to convert from HL7 v2.x to HL7 v3 [216, 217, 218, 219], although, theoretically, the latter specification presents no compatibility with the first one [151]. Hence, although the differences in the implantation level of the previous standards, it seems possible to partially/totally adapt the previous implementations to work with other standards and to contribute to a, hopefully, final standard harmonization.
Chapter 3. Materials and methods

3.4 Archetype, the interoperability paradigm

Archetypes, as above introduced, are models of clinical content. They are conform to a formal model, the archetype model, a simplified version of its main part is shown in Figure 3.3 (Figure 3.3 replicates Figure 2.13 for the reader’s convenience). Because of this, archetypes are machine interpretable. Archetype instances specify, and constraint, a particular hierarchy of RECORD_COMPONENT sub-classes, defining or constraining their names and other relevant attribute values, optionality and multiplicity, the data types and value ranges that ELEMENT’s data values may take, etc.

This can be done at any level of the hierarchy and, as they can be reusable, an archetype-based concept definition allows the finest-grained definition level: while simple concepts are defined by simple archetypes, more complex concepts (defined by the aggregation of simpler concepts) might be defined by a more complex archetype which will include the archetypes of these simpler concepts. This does not mean this is the only way of defining complex concepts using archetypes as the building of complex concepts for the ground is, as well, allowed but it would require of a higher effort to reach the same level of specificity.

Consequently, archetypes provide the mechanisms to not only model the complexity of the clinical environment but any other possible scenario. An archetype can be mainly divided in 3 main blocks:

- Archetype description, which is considered the archetype’s metadata description. Author, date of creation, purpose, lifecycle status, etc. are specified using the ARCHETYPE_DESCRIPTION class, which is also based on the ARCHETYPE_DESCRIPTION_ITEM class. These parts are expressed in natural language and, therefore, if a translation to another language is performed that metadata should be also translated. The translations also have their own metadata, expressed in natural language, through the TRANSLATIONDETAIL class. The creation or modification (i.e. modification of descriptive information or adding a new language and/or term bindings) of the archetype in a repository is handled through the AUDITDETAILS class.

- Archetype ontology, where all linguistic entities are defined: term definitions and constraint definitions, which define the meanings of various terms and textual constraints which occur in the archetype, and term bindings and constraint bindings, which describe the mappings of terms used internally to external terminologies.
3.4. Archetype, the interoperability paradigm

Figure 3.3: Simplified ISO/EN 13606 Archetype Model, reproduced from [36]
• Archetype constraint model. Any archetype definition is an instance of a \texttt{C\_COMPLEX\_OBJECT}, which expresses constraints on a class in the underlying Reference Model. This Reference Model is recorded in the \texttt{rm\_type\_name} attribute. A \texttt{C\_COMPLEX\_OBJECT} consists of attributes of the type \texttt{C\_ATTRIBUTE} (\texttt{C\_SINGLE\_ATTRIBUTE}, for single-value attributes and \texttt{C\_MULTIPLE\_ATTRIBUTE} for Multiple-valued attributes), which are constraints on the attributes (i.e. any property, including relationships) of that Reference Model class. Accordingly, each \texttt{C\_ATTRIBUTE} records the name of the constrained attribute (in \texttt{rm\_attribute\_name}), the existence and cardinality expressed by the constraint (depending on whether the attribute it constrains is a multiple or single relationship), and the constraint on the object to which this \texttt{C\_ATTRIBUTE} refers via its children attribute (according to its reference model) in the form of further \texttt{C\_OBJECT}ts. The subtypes of \texttt{C\_OBJECT} are:

- \texttt{C\_COMPLEX\_OBJECT}, to represent constraints on instance of a non-primitive type.
- \texttt{C\_PRIMITIVE\_OBJECT}, to represent constraints on a primitive type node. Primitive type nodes can be constrained through the classes which inherit from \texttt{C\_PRIMITIVE} (\texttt{C\_STRING}, \texttt{C\_BOOLEAN}, \texttt{C\_INTEGER}, \texttt{C\_REAL}, \texttt{C\_DATE\_TIME}, \texttt{C\_TIME}, \texttt{C\_DATE} and \texttt{C\_DURATION})
- \texttt{ARCHETYPE\_SLOT}, to determine which other archetypes may appear at that point in the current archetype.
- \texttt{ARCHETYPE\_INTERNAL\_REF}, to reference, using a path, a previously defined object node in the same archetype.
- \texttt{CONSTRAINT\_REF}, to express constraints in terms of external resources, such as constraints on terminology value sets
- \texttt{C\_DOMAIN\_TYPE}, which enables the creation of specific "C," classes, inheriting from \texttt{C\_DOMAIN\_TYPE}, which represent custom semantics for particular reference model types.

This way, any type in the reference model can be archetyped through a cascade of \texttt{C\_COMPLEX\_OBJECT} / \texttt{C\_ATTRIBUTE} / \texttt{C\_PRIMITIVE\_OBJECT} objects. The \texttt{C\_ATTRIBUTE} and subtypes of \texttt{C\_OBJECT} enable constraints to be expressed in a structural fashion. In addition to this, any instance of a \texttt{C\_COMPLEX\_OBJECT} may include one or more invariants. Invariants are statements, in form of predicate logic, which may be used to state constraints on parts of an object. They are not needed to state constraints on a single attribute, but are necessary to state constraints on more than one attribute (e.g. “diastolic pressure should be \leq systolic pressure” in the blood pressure measurement archetype). Assertions are also used in \texttt{ARCHETYPE\_SLOT}s in order to express the “included” and “excluded” archetypes for the slot.
The effect of the model is to create archetype description structures that are a hierarchical alternation of object and attribute constraints. The repeated object/attribute hierarchical structure of an archetype provides the basis for using paths to reference any node in an archetype.

Archetypes may also be specialized: an archetype is considered a specialization of another archetype if it specifies that second archetype as its parent, and only makes changes to its definition such that its constraints are “narrower” than those of the parent. Any data created via the use of the specialized archetype shall be conform both to it and to its parent.

![Figure 3.4: ADL archetype structure, extracted from [220]](image)

Archetypes can be defined using any formal language like the Web Ontology Language (OWL) or the Archetype Definition Language (ADL). The later (in its version 1.4) is overviewed in the ISO/EN 13606-2 standard. However, since July 2010, openEHR released ADL v1.5 [220]. The improvements over version 1.4 of ADL have been focused on facilitating the representation of specialized archetypes, so they can express themselves only in terms of the changed or new elements in its definition rather than including a copy of unchanged elements. ADL follows the structure outlined in Figure 3.4 and, to establish such constrictions on any instance of the Reference Model, it is based on the definition of three other languages (First-Order Predicative Logic (FOPL), data definition form of ADL (dADL) and constraint definition form of ADL (cADL)), as are following detailed:
Chapter 3. Materials and methods

<table>
<thead>
<tr>
<th>Text</th>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>matches, is_in</td>
<td>∈</td>
<td>Sets membership</td>
</tr>
<tr>
<td>exists</td>
<td>∃</td>
<td>Existential quantifier</td>
</tr>
<tr>
<td>for_all</td>
<td>∀</td>
<td>Universal quantifier</td>
</tr>
<tr>
<td>implies</td>
<td>⊃, →</td>
<td>Material implication</td>
</tr>
<tr>
<td>and</td>
<td>⊓</td>
<td>Logical conjunction</td>
</tr>
<tr>
<td>or</td>
<td>⊔</td>
<td>Logical disjunction</td>
</tr>
<tr>
<td>xor</td>
<td>?</td>
<td>Exclusive or</td>
</tr>
<tr>
<td>not</td>
<td>̃ ¬</td>
<td>Negation</td>
</tr>
</tbody>
</table>

*Table 3.2: Telematic equivalent of the reserved word for First-Order Predicate Logic (FOPL).*

- First-Order Predicate Logic (FOPL). Used to define the content of the rules sections, as well as the “slot” clauses in the cADL definition section, by means of assertion statements. An archetype slot defines a compositional chaining point in an archetype at which other archetypes can be inserted, if they match the constraint defined by the slot. There are reserved words such as [exists, for_all], [and, or, xor, not, implies] or [true, false] which can be replaced by their mathematical equivalents. Table 3.2 shows a summary of the main reserved words (text), the equivalent mathematical symbols (symbol) and their meaning. In addition, the assertion statements may contain arithmetic operators, relational operators, boolean, quantifier operators (existential and universal), and support some functions such as min(), max(), sum() or mean(). The operands may be constants, references to objects, built-in variables or archetype-defined variables.

- Data definition form of ADL (dADL). Used to express the content of the language, description, ontology, annotation and revision history sections. An dADL document only contains objects of the same information model and, using dADL syntax, any block can be expressed as a serialized object. However, on certain occasions, it is preferable to express any block using an abstract syntax and dADL allows the value of any object to be expressed through a plug-in syntax. There are no reserved words in this language (all identifiers are assumed to come from the model) but there are a number of reserved characters, as indicated in Table 3.3. As a basic feature, all the data containing a dADL document are arranged in a hierarchical manner and can be uniquely identified. Thus, each node can be identified by a path that goes through all the nodes, from the root node to the current location. As for the data types that it contains, a dADL document is able to return several primitive types (character, string, integer, real, double, boolean), date and time instances in various ISO 8601 [221] formats, lists or ranges of all the above types and some special data types (Uniform Resource Identifier (URI) identifiers, coded terms, etc.).
3.4. Archetype, the interoperability paradigm

<table>
<thead>
<tr>
<th>Character</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td><code>&lt;</code></td>
<td>Open an object block</td>
</tr>
<tr>
<td><code>&gt;</code></td>
<td>Close an object block</td>
</tr>
<tr>
<td><code>'</code></td>
<td>Within <code>&lt;&gt;</code>, used to delimit single character values</td>
</tr>
<tr>
<td><code>&quot;</code></td>
<td>Within <code>&lt;&gt;</code>, used to delimit string values</td>
</tr>
<tr>
<td><code>=</code></td>
<td>Indicate attribute value = object block</td>
</tr>
<tr>
<td><code>(,)</code></td>
<td>Type name or plug-in syntax type delimiters</td>
</tr>
<tr>
<td>`</td>
<td></td>
</tr>
<tr>
<td><code>[]</code></td>
<td>Within <code>&lt;&gt;</code>, used to delimit coded terms</td>
</tr>
<tr>
<td><code>&lt;#</code></td>
<td>Open an object block expressed in a plug-in syntax</td>
</tr>
<tr>
<td><code>#&gt;</code></td>
<td>Close an object block expressed in a plug-in syntax</td>
</tr>
<tr>
<td><code>-</code></td>
<td>Used to indicate comments</td>
</tr>
<tr>
<td><code>;</code></td>
<td>Used to separate blocks (optional)</td>
</tr>
</tbody>
</table>

| UpperCase | First letter of type names |
| LowerCase | First letter of attribute names |

Table 3.3: Reserved characters list for Data definition form of ADL (dADL) with their corresponding meanings

- Constraint form of ADL (cADL). Used to express the definition section. The use of cADL syntax allows the setting of restrictions on any object defined by an object-oriented information model. Its primary role is the definition of allowable configurations of data whose instances conform to very general object models. These configurations are obtained by the nested sequence of restrictions on the types that contain restrictions on the attributes of these types, expressed as restrictions on the types of these attributes. For example, a type may be restricted by the restriction of any of its attributes. The way to constraint this attribute is to constraint the data type that the attribute is. If this attribute is a string, this attribute could be constrained preventing it from containing numbers. In cADL a set of reserved words can be identified, among which can be found: [matches, matches, is_in, is_in], [occurrences, existence], [cardinality, ordered, unordered, unique], [infinity], [use_node, allow_archetype] or [include, exclude]. Some of these words can be replaced by their mathematical equivalent as can be seen in Table 3.4. In other cases, this substitution is not possible as in: existence (determines if a given attribute is mandatory or not), cardinality (indicates that specific attribute is a container and contains a number of entities whose range is displayed by this keyword), and occurrences (indicates how many node instances may appear).

Although the major difficulty that involves the building of a system based on the archetype paradigm, archetypes are already being used in different projects to guarantee the semantically integrity of medical data communication:
Chapter 3. Materials and methods

Table 3.4: Equivalent of the reserved word for constraint ADL (cADL)

<table>
<thead>
<tr>
<th>Text</th>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>matches</td>
<td>is_in</td>
<td>Set membership</td>
</tr>
<tr>
<td>not</td>
<td>~</td>
<td>Negation</td>
</tr>
<tr>
<td>infinity</td>
<td>*</td>
<td>Infinity</td>
</tr>
</tbody>
</table>

- [222] which, within the ARTEMIS project, uses OWL representation of archetypes for achieving interoperability among different health care systems conforming to different EHR standards;

- [223] addresses the extraction of data from Entity-Attribute-Value (EAV) conformant databases and its representation in XML schemas derived from archetypes to get, what they call “archetyped EHR extract”;

- [224] in which the use of archetypes is suggested to avoid the interoperability gap between “electronic patient records” and “electronic data capture systems”, which are used in the clinical trials, to encourage the secondary use of medical routine data;

- [225] in which a bi-directional semantic conversion, from templates defined in a legacy EHR system to openEHR archetypes, is accomplished;

- [44] in which archetypes are considered clinical integration components which allows to upgrade already deployed systems in order to make them compatible with an EHR standard;

- [226] in which archetypes are proposed to express more specialized semantics, allowing to map concepts between HL7 CDA R-MIM and ISO/EN 13606 RM;

- [227] in which archetypes have been used in the improvement of the automatic semantic provisioning in data mediation services, or

- in [228] where the use of archetypes is proposed to be integrated within the HL7 v3 messages.

Therefore, archetypes have been found to be, not only powerful integration resources but, the linking element between different EHR communication standards and the base for achieving semantic interoperability.

In the next section, the application of archetypes to the telemonitoring data acquisition would be analyzed as a resource for the data integration and the later information transmission.
Chapter 4

Results

In these section, the main outcomes of this Thesis are exposed. The objective of providing a channel through which telemonitoring data might be fused with those measurements acquired in the patient’s healthcare centre, and recorded in its HCIS, was staged in 2 phases:

- The acquisition of telemonitoring measurements by an intermediate information system.
- The building of an ISO/EN 13606 server, as it was the previously selected standard, to guarantee the semantic integrity of the acquired information.

To accomplish these goals, a preliminary study has to be performed and different considerations have to be taken into account. The existence of open standards which, in a master-slave configuration, handles the MD communication it is, in turn, the first design conditioner in the global integration process. One of the first questions in mind is related to information and, more specifically, how the previously collected information in the MD suits with the medical requirements in the HCIS. In this regard, ISO/IEEE 11073 standard provides an information model (i.e. the DIM) which can be used in the preliminary study. It does not mean, or it is not intended, that the later conclusions would be only applicable to ISO/IEEE 11073 medical data because data would be treated as generically as possible.

Moreover, to accomplish the acquisition of the telemonitoring data, it is also needed to define how the communication between the CD (named as Compute Engine (CE) in the ISO/IEEE 11073 standard) and the ISO/EN 13606 server is going to be carried out. This issue is of crucial importance because this communication cannot be a bottleneck in the end-to-end communication process. Therefore, a scalable and generic communication process should be defined to fill the communication gap and which would allow meeting the requirements of both communication ends.
Finally, the implementation of the ISO/EN 13606 standard has to be accomplished. There have been various ISO/EN 13606 implementations in literature, like [229, 230], and although a new implementation might not be as innovative as other areas of this Thesis, it would be handled from the telemonitoring perspective insomuch as considerable design simplification can be performed. These design simplifications might allow to easily apply the whole set of ISO/EN 13606 specifications, including the security part which will be implemented after succeeding implemented a first EHR server prototype.

4.1 ISO/EN 13606 - ISO/IEEE 11073 PHD compatibility study

Information models are used to represent concepts, relationships, constraints, rules, and operations to specify data semantics for a chosen domain of discourse. They provide sharable, stable, and organized structure of information requirements for the domain context [231]. In this section a study of both information models is going to be performed to check their adequacy degree in order to ensure the properly translation from one to another: Within each EHR Extract, and the rest of container classes, there are various fields/attributes that need to be mandatorily covered and it is needed to determine which of these data are provided by the MD and which have to be provided by parallel sources of information. Moreover, this study will be useful in the later design of the EHR server as it will provide useful information to design a information storage schema.

4.1.1 Information Models comparison

This study has been performed using as basis the ISO/EN 13606 RM’s classes, as the medical data representation will have to conform this model. From Table 4.1 to 4.7 the details of each generic block defined in the ISO/EN 13606 [36] Reference Model are listed, distinguishing between their main attributes and attributes from association (marked with *). It has also been indicated what DATA_TYPE they correspond to, specifying in each case if they are mandatory in ISO/EN 13606 (marked as MND) and whether or not they can be linked to ISO/IEEE 11073 PHD standard (marked as X73).

At first sight, the two standards do not appear to have obvious similarities, although common structures can be identified. It might be possible to make a first approximation for the COMPOSITION generic block in ISO/EN 13606 standard to the ISO/IEEE 11073 PHD MDS, as MDS is the object on which relations are established with other numeric objects, while COMPOSITION is the container structure that finally contains clinical data. However, an ISO/EN 13606 COMPOSITION might have data from more than one MD, and that equivalence would be a very marked constraint in the final system design.
Chapter 4. Results

Figure 4.1: ISO/IEEE 11073 Domain Information Model

Trying to keep a generic design, all the main generic blocks in ISO/EN 13606 are described below, detailing their relationship with ISO/IEEE 11073 PHD:

- **EHR_EXTRACT.** (See Table 4.1) This is the container component with the highest hierarchical order. From its construction point of view, and for a specific EHR system, nearly all the information can be obtained in a deterministic manner except the patient this information belongs to. Patient identification in ISO/IEEE 11073 PHD is not obvious. Even though there is a field in the PM-segment class, or within the Event-Report message for measurement update, that indicates the person owning the acquired data by the MD and having with local significance between the CE and the MD, this information is not provided by the rest of the classes derived from the metric class (see Figure 4.1). In these cases it would be necessary to identify the patient by annexes to the pure ISO/IEEE 11073 communication.

<table>
<thead>
<tr>
<th>EHR_EXTRACT</th>
<th>DATA_TYPE</th>
<th>MND</th>
<th>X73</th>
</tr>
</thead>
<tbody>
<tr>
<td>authorising_party</td>
<td>II</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>ehr_id</td>
<td>II</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>ehr_system</td>
<td>II</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>rm_id</td>
<td>String</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>subject_of_care</td>
<td>II</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>time_created</td>
<td>TS</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>*all_compositions</td>
<td>Set &lt; COMPOSITION &gt;</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>*criteria</td>
<td>Set &lt; EXTRACT_CRITERIA &gt;</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>*folders</td>
<td>Set &lt; FOLDER &gt;</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>*demographic_extract</td>
<td>Set &lt; II &gt;</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

Table 4.1: Comparative study: EHR_EXTRACT Class
The rest of the container components in the ISO/EN 13606 EHR_EXTRACT are inherited from the RECORD_COMPONENT class and, therefore, they will have certain number of attributes in common. Among the RECORD_COMPONENT attributes highlights the sensitivity attribute which establishes a certain level of security, as this register is only accessible by particular professionals if the access level granted to his/her functional role is higher than this value. Similarly, archetype_id and meaning attributes can be highlighted as they enable to indicate if the record is structured under a particular archetype or if its significance is comparable to a clinical concept.

- FOLDER. (See Table 4.2) This is an optional classification by which a HCIS can organize every COMPOSITION according to a given criteria: all those COMPOSITIONs that coincide with an episode (e.g. a patient who feels weak and has an analysis, a patient who goes to the doctor or respiratory specialist, etc.), all those COMPOSITIONs falling within the same specialty (e.g. psychiatry, endocrinology, etc.), to name a few. The level of granularity in this classification can be enhanced through the use of FOLDERs within FOLDERs. As that level of organization is higher than the COMPOSITION level, and strictly a FOLDER only contains pointers to COMPOSITIONs, not the COMPOSITIONs themselves, no parallelism will be proposed.

<table>
<thead>
<tr>
<th>FOLDER</th>
<th>DATA_TYPE</th>
<th>MND</th>
<th>X73</th>
</tr>
</thead>
<tbody>
<tr>
<td>archetype_id</td>
<td>II</td>
<td></td>
<td></td>
</tr>
<tr>
<td>meaning</td>
<td>CV</td>
<td></td>
<td></td>
</tr>
<tr>
<td>name</td>
<td>TEXT</td>
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<td>✓</td>
</tr>
<tr>
<td>orig_parent_ref</td>
<td>II</td>
<td></td>
<td></td>
</tr>
<tr>
<td>policy_ids</td>
<td>Set &lt; II &gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>rc_id</td>
<td>II</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>sensitivity</td>
<td>Integer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>synthesised</td>
<td>Boolean</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

*links | Set < LINK > | ✓ | ✓ |
*feeder_audit | AUDIT_INFO | ✓ | ✓ |
*sub-folders | Set < FOLDER > | ✓ | ✓ |
*attestations | Set < ATTESTATION1NFO > | ✓ | ✓ |
*compositions | Set < COMPOSITION > | ✓ | ✓ |

Table 4.2: Comparative study: FOLDER Class
• COMPOSITION. (See Table 4.3) By formal definition, a COMPOSITION is the set of information resulting of a single clinical encounter or record documentation session and it can be structured in SECTIONs for easy reading or navigation within each COMPOSITION. This block includes a session_time attribute that is the time interval or date when the data was acquired, in this scenario, from the CE. The harmonization of this field with ISO/IEEE 11073 PHD standard might be done in various ways:

- Establishing temporary thresholds through the MDS object and performing calculations for date and time after the MD association (IVL_TS.low) and just before the MD disassociation (IVL_TS.high), according to the states defined in the ISO/IEEE 11073-20601 FSM. This approach would be applicable to transmissions in which there is no connectivity problem and medical data can be immediately sent after being acquired. At present ISO/IEEE 11073 PHD allows various possibilities for doing the calculation if these attributes are implemented: date-and-time (MDC_ATTR_TIME_ABS), base-offset-time (MDC_ATTR_TIME_BO), relative-time (MDC_ATTR_TIME_REL) or HiRes-relative-time (MDC_ATTR_TIME_REL_HI_RES). In the case there would be a temporal adjustment notification during the acquisition process, the start timestamp of data acquisition should be changed in the same direction as the finish timestamp to prevent temporal inconsistencies.
Through the timestamps of different measurements or notes transmitted during communication. This approach could be applicable to store-and-forward transmissions (or if there would be any sort of connectivity problems), in which the CE would keep the acquired measurements’ timestamps to maintain their integrity and the measurements, acquired in various sessions, would be jointly sent to the EHR server. ISO/IEEE 11073 PHD allows different ways of expressing time: absolute-time-stamp (MDC_ATTR_TIME_STAMP_ABS), base-offset-time-stamp (MDC_ATTR_TIME_STAMP_BO), relative-time-stamp (MDC_ATTR_TIME_STAMP_REL) and HiRes-time-stamp (MDC_ATTR_TIME_STAMP_REL_HIRES). The PM-segment class deserves special consideration because it allows the start time of the measurement to be obtained directly, with the following attributes: Segment-Start-Abs-Time (MDC_ATTR_TIME_START_SEG) or Segment-Start-BO-Time (MDC_ATTR_TIME_START_SEG_BO), and the finish time of the measurements, with the attributes: Segment-End-Abs-Time (MDC_ATTR_TIME_END_SEG) or Segment-End-BO-Time (MDC_ATTR_TIME_END_SEG_BO). In addition, the Date-and-Time-Adjustment attribute (MDC_ATTR_TIME_ABS_ADJUST) allows date/hour changes to be reported.

According to the COMPOSITION definition, all medical information that is transmitted in a single instance of communication to the EHR server has been considered as an only COMPOSITION. Various COMPOSITION attributes (i.e. committal and, optionally, composer which are responsible for structuring information and recording it correctly in the information system) can be statically fulfilled in the EHR server. However, it is worth noting the other participations attribute, through which it might be possible to identify the CE (or any other controller device if it is not an ISO/IEEE 11073 based acquiring system) which has made this medical data communication, playing the role of collector of medical information.

- **SECTION.** (See Table 4.4) This allows information to be structured within a single COMPOSITION to facilitate reading, or to reflect the information flow within a clinical encounter. As with FOLDER, the degree of granularity in this division may be increased by using SECTIONS within other SECTIONS, creating a nested structure in the COMPOSITION organization. As stated previously, the information organization in a COMPOSITION is a composer’s function and, therefore, it falls outside the CE functions and it is certainly out of scope of the ISO/IEEE 11073 standard.
Table 4.4: Comparative study: SECTION Class

- **ENTRY.** (See Table 4.5) This contains all information related to a single measurement or observation, or series of them. As they represent the smallest units which have clinical significance in the EHR_EXTRACT, ENTRYs are also called clinical statements. An ENTRY is composed by ITEMs (abstract class) that are made tangible through CLUSTERs and/or ELEMENTs. For each ENTRY it would be interesting to determine its meaning attribute (and by extension, the name attribute) through which these data is identified with a single concept. However, some concepts have singularities that prevent them from being directly identified (e.g. blood pressure consists of two values or body temperature would be needed to be complemented with information of the given context.). Therefore, some type of processing will be needed to map these concepts with any clinical terminology such as SNOMED-CT [85]. Moreover, meaning, in archetyted systems, will correspond to the archetype node name. If this is the case, no binding would be needed but the need of processing hierarchical-lower logic blocks to gather the required information to build this model of knowledge can also be intuited.

In any case, it may be interesting to record the MD which has provided each ENTRY through the info_provider attribute (FUNCTIONAL_ROLE type). This attribute is completed with the mandatory attribute performer fulfilled with the system-id field of the ISO/IEEE 11073 MDS object (MDC_ATTR_SYS_ID) and optional attributes obtained in a static manner: mode (MOD01), service_setting (which encodes the fact that the measurement was obtained outside the clinic) and function (which encodes that the role has been the measurement’ acquisition).
4.1. ISO/EN 13606 - ISO/IEEE 11073 PHD compatibility study

<table>
<thead>
<tr>
<th>ENTRY</th>
<th>DATA_TYPE</th>
<th>MND</th>
<th>X73</th>
</tr>
</thead>
<tbody>
<tr>
<td>archetype_id</td>
<td>II</td>
<td>×</td>
<td>×</td>
</tr>
<tr>
<td>meaning</td>
<td>CV</td>
<td>×</td>
<td>✓</td>
</tr>
<tr>
<td>name</td>
<td>TEXT</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>orig_parent_ref</td>
<td>II</td>
<td>×</td>
<td>×</td>
</tr>
<tr>
<td>policy_ids</td>
<td>Set &lt; II &gt;</td>
<td>×</td>
<td>×</td>
</tr>
<tr>
<td>rec_id</td>
<td>II</td>
<td>✓</td>
<td>×</td>
</tr>
<tr>
<td>sensitivity</td>
<td>Integer</td>
<td>×</td>
<td>×</td>
</tr>
<tr>
<td>synthesised</td>
<td>Boolean</td>
<td>✓</td>
<td>×</td>
</tr>
<tr>
<td>act_id</td>
<td>String</td>
<td>×</td>
<td>×</td>
</tr>
<tr>
<td>act_status</td>
<td>String</td>
<td>×</td>
<td>×</td>
</tr>
<tr>
<td>subject_of_info_category</td>
<td>CS</td>
<td>×</td>
<td>×</td>
</tr>
<tr>
<td>uncertainty_expressed</td>
<td>Boolean</td>
<td>✓</td>
<td>×</td>
</tr>
<tr>
<td>*links</td>
<td>Set &lt; LINK &gt;</td>
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<td>×</td>
</tr>
<tr>
<td>*feeder_audit</td>
<td>AUDIT_INFO</td>
<td>×</td>
<td>×</td>
</tr>
<tr>
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<td>Set &lt; ITEM &gt;</td>
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<td>✓</td>
</tr>
<tr>
<td>*info_provider</td>
<td>FUNCTIONAL_ROLE</td>
<td>×</td>
<td>✓</td>
</tr>
<tr>
<td>*other_participants</td>
<td>Set &lt; FUNCTIONAL_ROLE &gt;</td>
<td>×</td>
<td>×</td>
</tr>
<tr>
<td>*subject_of_information</td>
<td>RELATED_PARTY</td>
<td>×</td>
<td>×</td>
</tr>
</tbody>
</table>

Table 4.5: Comparative study: ENTRY Class

- ITEM. Although ITEM is an abstract entity, it has some attributes of great importance in telemonitoring environments that both CLUSTER and ELEMENT will inherit. It is worth noting obs_time (for collecting the exact date and time in which medical data were acquired. To do so, any of the previously mentioned timestamps can be used as the time of the measurement recording might not be necessarily the same as the instant data in which data was acquired by the MD) and item_category (for distinguishing, based on the model of medical knowledge, the core of the measurement from other types of related notes such as the followed protocol in its acquisition or other context information).

- CLUSTER. (See Table 4.6) This is a structure used to organize complex information. A CLUSTER can contain other CLUSTERS and/or ELEMENTs. As with ENTRY, its meaning attribute (or name) might not be obtained by direct mapping of ISO/IEEE 11073 standard although its representation structure is comparable with RT-SA (see Figure 4.1). Therefore, in some cases, a mapping between the type attribute (MDC_ATTR_ID_TYPE) and a clinical concept becomes obvious (e.g. plethysmographic curve).

- ELEMENT. (See Table 4.7) This is the lowest container unit that stores a single DATA_VALUE. In this case, the meaning (and name) attribute can be acquired directly from the ISO/IEEE 11073 type attribute (MDC_ATTR_ID_TYPE).
Table 4.6: Comparative study: CLUSTER Class

<table>
<thead>
<tr>
<th>ELEMENT</th>
<th>DATA_TYPE</th>
<th>MND</th>
<th>X73</th>
</tr>
</thead>
<tbody>
<tr>
<td>archetype_id</td>
<td>II</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>meaning</td>
<td>CV</td>
<td>x</td>
<td>✓</td>
</tr>
<tr>
<td>name</td>
<td>TEXT</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>orig_parent_ref</td>
<td>II</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>policy_ids</td>
<td>Set &lt; II &gt;</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>rc_id</td>
<td>II</td>
<td>✓</td>
<td>x</td>
</tr>
<tr>
<td>sensitivity</td>
<td>Integer</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>synthesised</td>
<td>Boolean</td>
<td>✓</td>
<td>x</td>
</tr>
<tr>
<td>emphasis</td>
<td>CV</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>item_category</td>
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<td>x</td>
<td>✓</td>
</tr>
<tr>
<td>obs_time</td>
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<td>✓</td>
</tr>
<tr>
<td>structure_type</td>
<td>CS</td>
<td>✓</td>
<td>x</td>
</tr>
</tbody>
</table>

*links Set < LINK > | x | x |
*feeder_audit AUDIT_INFO | x | x |
*parts Set < ITEM > | x | ✓ |

Table 4.7: Comparative study: ELEMENT Class

To complete this description, the rest of the generic blocks in ISO/EN 13606 standard are listed (See Table 4.8), indicating which attributes they include and their relationship (if any) to ISO/IEEE 11073 PHD:

- AUDIT_INFO. This mainly contains information about the time (when) and the person (who) responsible for the medical information committing, both for the initial medical data acquisition or successive versions (if any) of the RECORD_COMPONENT.
4.1. ISO/EN 13606 - ISO/IEEE 11073 PHD compatibility study

- **ATTESTATION_INFO.** This is used to support the attestations performed in a clinical encounter (e.g. when doing a scan, or similar test, in various countries it must be specified what image was being shown on the screen when the diagnosis was made).

- **FUNCTIONAL_ROLE.** This documents the participation of a third person, device or software component when medical information is obtained.

- **RELATED_PACTIVE.** This identifies the relation between the subject_of_information and the subject_of_care.

- **LINK.** This defines the relation between different RECORD_COMPONENTs (e.g. cause/effect relations).

To conclude this comparative study and, how it was pointed in previous sections, special considerations about the leaf nodes of the EHR_EXTRACT (i.e. data types, or alternatively ISO/EN 13606 ELEMENTS) should be emphasized, as a bottom-up methodology has been selected to maximize the generality of a further implementation. There are three basic considerations:

- In the first place, note the ISO/EN 13606 standard stipulates the use of TS14796 [202] to define the data type set for the health information exchange. However, as it has been withdrawn in favor of the ISO/EN 21090 standard [203] trying to solve this way the non-homogeneity problem with HL7 data types and foreseeing the jointly use of this specification, or part of it, with the ISO/EN 13606 RM, an ISO/EN 21090 - TS14796 comparative study was performed. Independently of the inheritance between types of data (both to establish a new branch of data types or to define a more specific type), the number of classes defined in ISO 21090 has increased significantly from TS14796. In addition, great efforts have been put in the definition of classes to underpin structured text in order to achieve support in the transmission of the various clinical documents that would have been stored as free plain text. Similarly, the DATA_TYPE class is not more derived from the abstract DATA_VALUE class but from ANY, from which the rest of the classes derive and that, in turn, derives from HTIX. Furthermore, it is in the ANY class where the null_flavour attribute is now found. This attribute is used to determine why a particular record is empty. Below, some of the changes the most representative DATA_TYPEs have undergone are detailed:

  - Instance Identifier (II), is essential for the unequivocal identification of records, devices, people, etc. The number of its attributes increases due to inheritance. It can be highlighted the fact that the time period for which the identifier is valid (<IVL_TS>) in this new document is divided into two different attributes: validTimeLow and validTimeHigh.
<table>
<thead>
<tr>
<th><strong>AUDIT_INFO</strong></th>
<th><strong>DATA_TYPE</strong></th>
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</thead>
<tbody>
<tr>
<td>commiter</td>
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<td>✘</td>
</tr>
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<td>✓</td>
<td>✘</td>
</tr>
<tr>
<td>previous_version</td>
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<td>✘</td>
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<td>✘</td>
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<td>✘</td>
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<td>✘</td>
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</thead>
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<td>✓</td>
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<table>
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<th><strong>X73</strong></th>
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<table>
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<th><strong>X73</strong></th>
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</tr>
<tr>
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<td>CS</td>
<td>✓</td>
<td>✘</td>
</tr>
<tr>
<td>role</td>
<td>CV</td>
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<td>✘</td>
</tr>
<tr>
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<td>✓</td>
<td>✘</td>
</tr>
</tbody>
</table>

**Table 4.8: Comparative study: Other Classes**
– Coded Value (CV), used for the representation of an encoded concept. The attributes remain unchanged, but it is now called Coded Description. Coded Value (CD.CV) and restricts CD instead of specializing Coded Simple Value (CS).

– Time Interval (IVL< TS >), for setting time intervals. Its attributes are increased by inheritance, and it is able to specify a validity period for the time period.

• In the second place, it is important to categorize what ISO/IEEE 11073 measurements that can be sent, and how these ISO/IEEE 11073 “leaf nodes” can be translated to ISO/EN 13606 “leaf nodes”. Table 4.9 shows a list of measurements that can be obtained from ISO/IEEE 11073-104xx™ specializations approved at the time of writing, within the ISO/IEEE 11073 class that represent them and their compliance criterion (mandatory, M, or optional, O). In parallel, other specializations are being worked on at the draft stage, such as the insulin pump or the urine analyzer. These measurements can be summarized as follows:

– Both simple numerical values (weight, temperature) and complex values (blood pressure composed by systolic and diastolic pressure) through the numeric class of ISO/IEEE 11073 that accurately indicates the type of medical concepts being sent.

– Waveforms (ECG, pulse oximetry) through ISO/IEEE 11073 RT-SA class, which is designed for continuous transmission of data waveforms.

– Context information related to the measurement acquisition process, through the enumeration or numeric classes of ISO/IEEE 11073. A particular example of this is the 11073-10408™ Thermometer specialization, where the context information would be implicit in the definition of the type attribute (MDC(Attribute_ID_TYPE)), which can take different values such as MDC_TEMP_BODY (generic), MDC_TEMP_AXILLA (axillary), MDC_TEMP_ORAL (mouth), MDC_TEMP_TYMP (ear), etc.

Table 4.9 also includes a possible proposed representation according to ISO 21090 DATA_TYPES. It has also been noted the existence of various ISO/IEEE 11073 non-clinical measurements, like the “Event Device Err” in the glucose meter specialization. Although it could be questionable the inclusion of these in the EHR of the patient, it was decided to not constraint any possible aggregate representation for the acquired information. Undoubtedly, they can be used as validation mechanism of the acquired clinical information which could be used before the recording, or after being recorded, to test the patients ability to acquire measurements by their own or for statistical purposes.
<table>
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<th>class</th>
<th>M/O</th>
<th>DATA_TYPE</th>
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</thead>
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<td>$Sp_{02}$</td>
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<td>M</td>
<td>PQ</td>
</tr>
<tr>
<td></td>
<td>Pulse</td>
<td>num</td>
<td>M</td>
<td>PQ</td>
</tr>
<tr>
<td></td>
<td>Pulse Amplitude</td>
<td>num</td>
<td>O</td>
<td>PQ</td>
</tr>
<tr>
<td></td>
<td>Plethysmogram</td>
<td>RT-SA</td>
<td>O</td>
<td>PQs/SLIST(PQ)</td>
</tr>
<tr>
<td></td>
<td>Streaming PCFGs</td>
<td>O</td>
<td>SET(num, enum, RT-SA)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Collection PM-S</td>
<td>O</td>
<td>SET(num, enum, RT-SA)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PulseEvent</td>
<td>enum</td>
<td>O</td>
<td>CD.CV</td>
</tr>
<tr>
<td></td>
<td>Pulse Character</td>
<td>enum</td>
<td>O</td>
<td>CD.CV</td>
</tr>
<tr>
<td></td>
<td>Physiological Limits</td>
<td>enum</td>
<td>O</td>
<td>CD.CV</td>
</tr>
<tr>
<td></td>
<td>Physiological Flags</td>
<td>enum</td>
<td>O</td>
<td>CD.CV</td>
</tr>
<tr>
<td></td>
<td>Device Annunciation</td>
<td>enum</td>
<td>O</td>
<td>CD.CV</td>
</tr>
<tr>
<td>-10407 Blood pressure monitor</td>
<td>Diastolic, Systolic, MAP</td>
<td>comp</td>
<td>M</td>
<td>PQs</td>
</tr>
<tr>
<td></td>
<td>- Diastolic</td>
<td>num</td>
<td>M</td>
<td>PQ</td>
</tr>
<tr>
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<td>- Systolic</td>
<td>num</td>
<td>M</td>
<td>PQ</td>
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<td></td>
<td>- MAP</td>
<td>num</td>
<td>M</td>
<td>PQ</td>
</tr>
<tr>
<td></td>
<td>Pulse</td>
<td>num</td>
<td>O</td>
<td>PQ</td>
</tr>
<tr>
<td>-10408 Thermometer</td>
<td>Body Temperature</td>
<td>num</td>
<td>M</td>
<td>PQ</td>
</tr>
<tr>
<td></td>
<td>MDC_ATTR_ID_TYPE</td>
<td>–</td>
<td>M</td>
<td>CD.CV</td>
</tr>
<tr>
<td>-10415 Weighing scale</td>
<td>Body Weight</td>
<td>num</td>
<td>M</td>
<td>PQ</td>
</tr>
<tr>
<td></td>
<td>Body Height</td>
<td>num</td>
<td>O</td>
<td>PQ</td>
</tr>
<tr>
<td></td>
<td>Body Mass Index</td>
<td>num</td>
<td>O</td>
<td>PQ</td>
</tr>
<tr>
<td>-10417 Glucose meter</td>
<td>Glucose</td>
<td>num</td>
<td>M</td>
<td>PQ</td>
</tr>
<tr>
<td></td>
<td>Context Exercise</td>
<td>num</td>
<td>O</td>
<td>PQ</td>
</tr>
<tr>
<td></td>
<td>Context Diet</td>
<td>num</td>
<td>O</td>
<td>PQ</td>
</tr>
<tr>
<td></td>
<td>Context Medication</td>
<td>num</td>
<td>O</td>
<td>PQ</td>
</tr>
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<td></td>
<td>Context HbA1C</td>
<td>num</td>
<td>O</td>
<td>PQ</td>
</tr>
<tr>
<td></td>
<td>Context Tester</td>
<td>enum</td>
<td>O</td>
<td>CD.CV</td>
</tr>
<tr>
<td></td>
<td>Context Sample Location</td>
<td>enum</td>
<td>O</td>
<td>CD.CV</td>
</tr>
<tr>
<td></td>
<td>Context Meal</td>
<td>enum</td>
<td>O</td>
<td>CD.CV</td>
</tr>
<tr>
<td></td>
<td>Event Device Err</td>
<td>enum</td>
<td>O</td>
<td>CD.CV</td>
</tr>
<tr>
<td></td>
<td>Context Health</td>
<td>enum</td>
<td>O</td>
<td>CD.CV</td>
</tr>
<tr>
<td></td>
<td>Observations</td>
<td>PM-S</td>
<td>O</td>
<td>SET(num, enum, num-num)</td>
</tr>
<tr>
<td>-10418 International Normalized Ratio (INR) monitor</td>
<td>INR</td>
<td>num</td>
<td>M</td>
<td>REAL</td>
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<td>Control calibration</td>
<td>num</td>
<td>O</td>
<td>REAL</td>
</tr>
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<td></td>
<td>Prothrombin time</td>
<td>num</td>
<td>O</td>
<td>PQ</td>
</tr>
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<td></td>
<td>Quick value</td>
<td>num</td>
<td>O</td>
<td>PQ</td>
</tr>
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<td>ISI</td>
<td>num</td>
<td>O</td>
<td>REAL</td>
</tr>
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<td>INR target level</td>
<td>num</td>
<td>O</td>
<td>REAL</td>
</tr>
<tr>
<td></td>
<td>Device and sensor status</td>
<td>enum</td>
<td>O</td>
<td>CD.CV</td>
</tr>
<tr>
<td></td>
<td>Device alarms</td>
<td>enum</td>
<td>O</td>
<td>CD.CV</td>
</tr>
<tr>
<td></td>
<td>Context tester</td>
<td>enum</td>
<td>O</td>
<td>CD.CV</td>
</tr>
<tr>
<td></td>
<td>Batch code</td>
<td>enum</td>
<td>O</td>
<td>CD.CV</td>
</tr>
<tr>
<td></td>
<td>Current medication level</td>
<td>num</td>
<td>O</td>
<td>PQ</td>
</tr>
<tr>
<td></td>
<td>New medication level</td>
<td>num</td>
<td>O</td>
<td>PQ</td>
</tr>
<tr>
<td></td>
<td>INR observations</td>
<td>PM-S</td>
<td>O</td>
<td>SET(num, enum, RT-SA)</td>
</tr>
<tr>
<td>-10420 Body composition</td>
<td>Body fat</td>
<td>num</td>
<td>M</td>
<td>PQ</td>
</tr>
<tr>
<td></td>
<td>Body height</td>
<td>num</td>
<td>M</td>
<td>PQ</td>
</tr>
<tr>
<td></td>
<td>Body weight</td>
<td>num</td>
<td>M</td>
<td>PQ</td>
</tr>
<tr>
<td></td>
<td>Body mass index</td>
<td>num</td>
<td>O</td>
<td>PQ</td>
</tr>
<tr>
<td></td>
<td>Body Water</td>
<td>num</td>
<td>O</td>
<td>PQ</td>
</tr>
<tr>
<td></td>
<td>Soft Lean Mass</td>
<td>num</td>
<td>O</td>
<td>PQ</td>
</tr>
<tr>
<td></td>
<td>Fat Free Mass</td>
<td>num</td>
<td>O</td>
<td>PQ</td>
</tr>
<tr>
<td>-10421 Peak flow</td>
<td>Forced Expiratory Volume in 1 second (FEV1)</td>
<td>num</td>
<td>M</td>
<td>PQ</td>
</tr>
<tr>
<td></td>
<td>Forced Expiratory Volume in 6 second (FEV6)</td>
<td>num</td>
<td>M</td>
<td>PQ</td>
</tr>
<tr>
<td></td>
<td>Peak Expiratory Flow</td>
<td>num</td>
<td>M</td>
<td>PQ</td>
</tr>
<tr>
<td></td>
<td>Personal best</td>
<td>num</td>
<td>M</td>
<td>PQ</td>
</tr>
<tr>
<td></td>
<td>Reading status</td>
<td>enum</td>
<td>M</td>
<td>CD.CV</td>
</tr>
</tbody>
</table>

Table 4.9: ISO/IEEE 11073-104xx specializations for telemonitoring measurements.
In the third and last place, and although it should not be in-depth considered in a generic compatibility study, considerations about these elements aggregation can be performed. In the ISO/IEEE 11073 specializations there is a certain “degree of freedom” about which classes can, or have to, be implemented to be compliant with the specification. As shown in Table 4.9 there are mandatory and optional measurements and it depends on the device capabilities to provide a more nurtured source of information. This way, a situation in which two different weighting scales, one providing body weight and the other one providing both body weight and body mass index, might occur and both would be complying with the ISO/IEEE 11073-10415 specialization. Therefore, a potential aggregation of these measurements to shape an higher-level concept model should have to take into consideration the mandatority/optionality of each measurement element. If only mandatory measurements are considered, it appears that all of them can be represented in ISO/EN 13606 with Physical Quantity (PQ) or real DATA_TYPEs, but the reading status attribute from 11073-10421^{TM}Peak flow which could be considered a Coded Value (CD.CV). In this case, reading status can have the possible encoding values: pefm-read-stat-post-medication (user had medication before taking reading), pefm-read-stat-cough (user coughed while taking reading), pefm-read-stat-short-effort (user effort was short while taking reading), pem-read-stat-long-time-to-peak (user took longer time than expected to reach maximum blow force). The CD.CV association strategy might be extrapolated to any other value listed, specially considering that the use MDER in the ISO/IEEE 11073 standard eases the establishment of term’s correspondence. Thus, the code attribute may be obtained from the possible reading status values. The code system attribute could be associated either with the coding system that would establish each specialization or a single general coding system that would encompass all the encoding rules used in the standard.

In relation to CD.CV, its main attributes are:

- code (which identifies a concept within a reference system).
- codeSystem (which identifies the reference system itself).
- displayName (which is optional and corresponds to translating the concept into an understandable language to the receiver).
- originalText (which is optional and corresponds to the translation of the name of a concept in the native language when the data is entered into system).

The same way, the main attributes of PQ and the relations with ISO/IEEE 11073 are:

- Value. This corresponds to nu observed value or compound basic in ISO/IEEE 11073, depending on whether it is transmitted over a single value or more than one value, respectively, within the same class.
– Unit. This corresponds to ISO/IEEE 11073 unit-code of the metric class.
– Precision (optional). This corresponds to ISO/IEEE 11073 accuracy of the numeric class.

Finally, in case of REAL, its main attributes are:

– Value. This corresponds to nu observed value.
– Precision. This corresponds to ISO/IEEE 11073 accuracy of the numeric class.

Once these very first considerations have been exposed, a more in-depth analysis would be performed, mainly to address those issues which will enable the joint use of both standards and to avoid the logical interoperability gaps result of the orthogonality in the standards’ scopes.

4.1.2 Discussion regarding identified issues and the implication of inconsistencies between ISO/IEEE 11073 and ISO/EN 13606 standards

As pointed in the last section, there are some gaps to be solved before succeeding in the exploitation of ISO/IEEE 11073 telemonitoring data for the improvement of the continuity of care of any patient. In this section, main obstacles to overcome will be set out and solution proposals will be suggested.

In this section only those concerns related to information models will be considered. It is obvious that the information acquired by the CE will be sent to an EHR System but no assumption about how that task would be performed has wanted to be done. This process, or communication structure, will be referred as ‘instance of communication”. This “instance of communication”, as the interoperable EHR transmission requires, would need of different mechanisms like a well-established syntax ruled by an information model. However, the earlier stages of this stepwise standard convergence require a more intensively focus in the “what” rather than the “how”. This way, the main problems to be solved, in this stage, are:

• Patient identification. This issue is still one of the main concerns in the interoperable EHR transmission. As the ISO/IEEE 11073 is device center, the top-level object of any health device is the MDS class and its identification attributes are focused in establishing manufacturer, model, type of agent, etc., regardless which patient is using that health device. However, patient identification is crucial in shared environments where different patients can use the same device (e.g. home environments with several family members).
This obstacle should be solved by the CE, which must build the “instance of communication” assigning each medical data to the right patient. Hence, the use of a higher level procedure which will coordinate the acquisition of measurements and the patient identification will be necessary. On the other hand, the HCIS would be responsible for mapping the patient identifier in the CE - HCIS communication with the one used in the healthcare center, if patient identification has local significance between CE and the HCIS.

- Timestamps. The ability to place in time a single measurement is a pre-condition to track how this measure is evolving in order to ensure that the previously taken actions are having the desired effect. Moreover, certain physiological measurements might need to be amended if they have been performed in the morning or in the afternoon, like body temperature. ISO/IEEE 11073 standard allows time-expression through different ways and/or attributes:

  - date-and-time (MDC_ATTR_TIME_ABS).
  - base-offset-time (MDC_ATTR_TIME_BO).
  - relative-time (MDC_ATTR_TIME_REL).
  - HiRes-relative-time (MDC_ATTR_TIME_REL_HI_RES).
  - absolute-time-stamp (MDC_ATTR_TIME_STAMP_ABS).
  - base-offset-time-stamp (MDC_ATTR_TIME_STAMP_BO).
  - relative-time-stamp (MDC_ATTR_TIME_STAMP_REL).
  - HiRes-time-stamp (MDC_ATTR_TIME_STAMP_REL_HI_RES).
  - Segment-Start-Abs-Time (MDC_ATTR_TIME_START_SEG).
  - Segment-Start-BO-Time (MDC_ATTR_TIME_START_SEG_BO).
  - Segment-End-Abs-Time (MDC_ATTR_TIME_END_SEG).
  - Segment-End-BO-Time (MDC_ATTR_TIME_END_SEG_BO).

In some point of the transmission, the way time is expressed should be translated towards an EHR compatible expression (i.e. TS class). As there are different ways of fixing the same instant in time, various conversion procedures should be implemented depending on the attribute source from which it had been obtained. The place in which this conversions have to be placed could be debatable:

  - In the CE, managed by a higher level procedure. In case of any date and time adjustment was reported, the amendment might be easier to be handled in this entity than in the HCIS. An eligible final unifying timestamp format could match with ISO 8601 pattern [221], the international standard for date and time representation, which is otherwise required in some EHR Extract attributes.
In the EHR system, which will involve the use of a more complex syntax to conform the “communication instance”. This could be affordable assuming the CE implementation would be considerably simplified and the EHR system presents higher processing capabilities than some portable devices (e.g. smartphones, PDAs) which could also perform this task.

- Filling the blanks. As it can be seen from Table 4.1 to 4.7, there are several mandatory ISO/EN 13606 attributes which cannot be filled directly from the provided ISO/IEEE 11073 information. Based on the premise that each communication instance must be addressed to an entity (system, procedure, etc.), each one would generate a COMPOSITION for each patient. In order to comply with ISO/EN 13606 standard, each RECORD_COMPONENT has to be identified with a name, an II and a statement defining if this RECORD_COMPONENT has been created within the EHR_EXTRACT for a specific purpose. Because of the information origin, the synthesized attribute can be considered invariably FALSE, but the name attribute depends on the complexity of the RECORD_COMPONENT. This way:

  - In COMPOSITIONs, name can be recorded statically using the same designation (e.g. “Telemedicine Report”).
  - In ELEMENTs and some type of CLUSTERs (e.g. plethysmogram), name can be obtained from ISO/IEEE 11073 type attribute.
  - In some types of CLUSTERs (e.g. blood pressure) and other higher level entities like ENTRYs, name can be obtained through some kind of information processing. In this particular situation, in which there is no direct matching, archetypes as model of concepts can be especially helpful.

Regarding IIs, these are mainly compound by extension (a unique identifier in a “namespace”) and root (the “namespace”). Root attribute does not necessarily correlate with the organization that manages the issuing of the identifiers (a given organization may manage multiple identifier namespaces). However, root attribute has to be a Distributed Computing Environment Universally Unique Identifier (DCE UUID), an Object Identifier (OID) or a special identifier taken from lists that may be published by ISO or HL7. In this context, root attribute can be considered as a constant. On the other hand, the creation of extension attributes can be globally managed within the EHR server or they can be built using as base unique identifiers, common in relational databases, which will simplify this task. Other types of simplifications can be:

  - Committal attribute, within COMPOSITION components, which identifies the entity responsible for the COMPOSITION recording which can also be obtained statically. This task might be performed by the same entity the communication instance was addressed to.
– Uncertainty_expressed attribute from ENTRY component, which can be bounded to FALSE as its default value.

– Structure_type attribute of CLUSTER component, which can take “STRC01” to indicate that its elements must be represented as a list.

• Concept mapping. As previously commented, ISO/IEEE 11073 standard uses its own codings (i.e. MDER). This codes, although might be used to identify which concepts are related to, are not those used to identify those terms in the HCIS. To properly integrate these terms, a terminological correspondence needs to be made between ISO/IEEE 11073 nomenclature terms and the appropriate terminology codes. Back again, the mapping can take place either in the CE or the HCIS but this last option has an important advantage over the first one: the system in charge of doing the mapping could be re-used for any telemonitoring system (proprietary or standard-based) and, if this process is centralized in a single unit, it would be easier to modify the mappings in case the HCIS terminology scheme would change. Furthermore, complex concept definition can be tailored from single concepts more easily in the EHR server.

4.1.3 Abstracting the acquiring standard

During all this Thesis’ development, the importance of using standards has been emphasized. Standards, among others, provide interoperability and vendor neutrality. These powerful arguments are incontestable. However, in the proposed architecture, is it mandatory to fulfill with and end-to-end standard based design from MD to the patient’s EHR? To answer this question, the architecture schema should be recovered (see Figure 3.1).

In this schema, there are three communication echelons to deal with:

• MD to CD.

• CD to HCIS.

• HCIS to HCIS.

Junction points between these echelons in the communication chain might be used as entry/access point to reach a final common destination:

• Data stored in the HCIS must to be properly communicated to other HCIS.

• Data acquired by MDs must be sent to the CD.

• Data in the CD must be sent to the HCIS.
ISO/IEEE 11073 was first considered because it can provide manufacturer independence, but it does not mean this architecture would be completely unsuitable for non ISO/IEEE 11073-compliant devices. In fact, in early stages in the development of the ISO/IEEE 11073 standard, the use of adapters was proposed to avoid the absence of ISO/IEEE 11073 devices, as it can be seen in [232]. In [232], a similar architecture scheme to the one described in this thesis is also proposed but, if it is thoroughly read, differences are clear: what is call “X73/EN13606 Monitoring server” acts as what could be called “standard translator”, transforming “ISO/IEEE 11073 data” into “EN13606 data”. This “EN13606 data” was not an ISO/EN 13606 EHR," but ISO/EN 13606 ENTRY compliant structures. Moreover, various of the highlighted inconsistencies between standards were not addressed (e.g. patient identification, timing, etc.) as both standards were still under development. However, the equivalence between ISO/IEEE 11073 compliant MD and the joint use of proprietary MD and ISO/IEEE 11073-adapters was proved.

Adapters were used to mimic an ISO/IEEE 11073-compliant device behavior or, in other words, to homogenize the communications between MD and CD (CE, in the ISO/IEEE 11073 standard). In the next chain echelon a similar methodology can be applied: If the ISO/IEEE 11073 standard is considered for the acquisition process, the CE should perform some computing in order to build the “instance of communication”. If other proprietary standards/protocols were used, their CDs should perform the accordingly computing tasks to build a similar “instance of communication”, which will obey the same rules, obtaining an homogeneous environment in the nearby of the EHR server, the same homogeneity a standard would provide. To clarify this idea, an analogy can be performed between the exposed situation and empiricism or Plato’s Cave myth, although philosophical teachings can feel uncorrelated to this Thesis’ purposes. If one of its axes is considered (i.e. “reality is perception”) and it is applied to the EHR server’s network perception, a clear rift is observed about MDs. The EHR server’s reality is only composed by those devices it has to exchange information with (i.e. HCISs and CDs, or only the CDs if the EHR server is not going to receive EHR," from other HCISs). It only will see what CDs allow it to see (i.e. “instances of communication”). These are the shadows of a farther reality.

This does not mean that the way data is acquired is not relevant, as an open standard is preferred to do so. It just means that proprietary protocols could be also used for the betterment of the patient’s continuity of care as long as acquired data would be communicated in an homogeneous way, independently of the device manufacturer. Doing that would imply a half-way solution between ad-hoc solution for vendor devices in the HCIS and the built-in of ISO/IEEE 11073 adapter for every non-compliant ISO/IEEE 11073 MD.
In any case, the ISO/IEEE 11073 standard has been of great help for establishing some basic design conditions the “instance of communication” should consider, among them it can be highlighted:

- **Patient identification.** In the CD to HCIS communication is essential to append a patient’s coding to discriminate which measurements should be embedded in which patient’s EHR. In this case, an identifier with local significance would be preferred over an identifier with global significance based on a simplicity criteria: Patients might, and surely will, have different patient identification codes in different healthcare services. The EHR server will have to implement a sub-system which allows to relate a patient with all their identification codes. The way to unambiguously identify an entity is through a similar scheme like II does: uniquely coding it in a system, which also would be unambiguously identified. However, within a system, only a unique coding is required to achieve unambiguous definition.

- **Time specification.** As previously commented, time plays an important role in the patient’s continuity of care. The identification of those points in time, in which a measurement was performed, is needed.

- **Coding elements.** The assignation of codes to certain names/concepts involves certain advantages, specially if that coding involves specific, fine-grained concepts. An important piece of this Thesis’s state-of-the-art was introducing the idea that, as some medical concepts can be applied to different areas of medicine, it is for sure that their corresponding codings will have overlapping codes. In addition it was shown up that mapping among these coding systems are the mechanism used to bound the same concept with various codes in various coding systems. ISO/IEEE 11073 provides its own encoding system and it is able to communicate fine-grained concepts (e.g. it encodes and transmit systolic and diastolic pressure codes but it does not have a code for blood pressure). If that coding strategy is used, it will no matter which coding system has been used as long as it would be known and the appropriate mappings among equivalent terms would had been performed.

And, chiefly, it has been of great importance to get a general knowledge of the device domain because, although final models need to be related to the EHR, to complete these models some pieces need to be obtained from the device domain. And, it cannot be used what it was not there in the first place.

In the next section, an in-depth explanation of the telemonitoring data acquisition will be performed, considering the use of generic structures.
4.2 Telemonitoring data acquisition

As previously stated, the CD to the HCIS communication problem is no more than a communication problem in which semantic interoperability is sought, as in any type of communication. This means that, although its background is not as broad as in other areas, there is a solid basis to start working. As starting point, the assumption that the CD is a special type of small HCIS will be considered. If this would have been the case, the problem to solve would be an EHR communication problem and this subject has been already addressed. Thus, to fulfill EHR semantic interoperability requirements four prerequisites, according to ISO/TR 20514 (Electronic Health Record – Definition, scope and context) [233], need to be accomplished:

- agreement on a standardized reference model,
- standardized service interface models,
- a standardized set of domain-specific concept models,
- standardized terminologies associated with controlled vocabularies.

Taking as premises the same tools used for the interoperable EHR communication among different HCIS, the design of a generic telemonitoring system capable of incorporating remote data in the patient EHR can be accomplished. Hence, this proposal is based in the data encoding, the use of a “Reference Model” (which defines the communication syntax) and the modeling of clinical concepts using archetypes.

In each of the EHR communication standards based on a Reference Model, there is obvious similarities among the paper-based medical report and their electronic representation (i.e. their organization in SECTIONs, ENTRYs, etc.). In case of telemonitoring data, there is not a model that might be used as reference but a paper sheet in which measurements are noted by hand. Therefore, the model that will be used will be one based on the telemonitoring scenario (see Figure 4.2):

![Figure 4.2: Telemonitoring problem model](image-url)
• A CD might be assigned to various patients.

• Each patient needs of certain types of MDs (i.e. thermometers, weighting scales, etc.) to track the evolution of certain physiological measurements.

• Measurements might need of context information to allow their correct interpretation.

• In a shared environment, various patients might use the same devices.

A Reference Model which would be able to reflect this organizational structure will suit our modeling requirements. When a physiological measurement is being tracked, it is kind of an “unwritten rule” to most of times use the same MD so there would not be calibration problems, different sensibilities, etc. which might skew the measurement process. It is true that, in various telemonitoring platforms, a device is provided to the patients. However, mobility conditions (in which the MD is not carried with the patient) or the MD breakup, also need to be considered because they would imply an unplanned change of device. Hence, it was decided to always append MD information to the measurement itself. MDs are used as classifying criteria due to the possibility of being an store-and-forward platform: In real-time platforms, measurements are sent to a server after being acquired while in a store-and-forward platforms information is stored, for a while, and then data is sent to a remote location. During this time, various measurements might have been performed by the same person and same device. Clustering the information by MD avoids constantly repeating the MD information in each measurement. The clustering of the measurements by MD has been thereby performed based on a simplicity criteria.

This high-level scenario description should be more detailed to provide the resources to, among other things, be able to represent the characteristics of the measurement acquisition process and to guarantee semantic integrity allowing the correct interpretation of the measurements (for example, a body temperature of 37.5 degrees has a different interpretation if it is taken in the morning or at night) and ensuring the information is not compromised by possible technological failures.

In the attribute concretion of each of this generic entities, the following considerations have been taken into account:

• About the CD, it only would be needed an identifier. In this case, to set up a telemonitoring platform, CDs would have to be previously configured, among other reasons, to define how data will be delivered to the HCIS. This identifier would have local significance. Plain text info could be recorded in the HCIS and retrieved in base of this identifier.
• About the patient, an identifier with local significance might be used. Mappings with another patient’s identifiers, and optionally demographic information, will be performed in the EHR server.

• About the MD, the identifier necessities have been already discussed. However, the MD ability to identify itself has to be questioned. In case of ISO/IEEE 11073-compliant devices, this information is available through the MDS class. If it is not the case, some selected parameters (i.e., Manufacturer, model and serial number, which will allow to uniquely identify the device) should be completed in the CD using the patient assistance.

• About the measurements and the context information, a different approach was taken. Their properly transmission and interpretation is the final target of the telemonitoring setup. The structure used to represent them should be expressed in an scalable format, enabling its easy translation in whatever the DATA_TYPE that concept was decided to be modeled.

A generic study of those measures that might be acquired through a telemonitoring system was performed to design a valid model for the acquired measurement. In this study, a distinction between two basic terms was set: measurement is everything that a device might provide and concept is anything owing significance (i.e., systolic pressure). Thus the concepts are always the same and any measurement would be composed of an aggregation of several concepts and, this way, the dependence on the device, or what it is capable to provide, becomes minimum.

Based on the previously performed compatibility study, telemonitoring measurements can be modeled like, at least, three different DATA_TYPES (i.e., PQ, REAL, CD.CV). If those DATA_TYPES are abstracted, they can be modeled as the aggregation of 3 “subconcepts”: What is transmitted, the value of what is being transmitted and the context of that value (e.g., units of the measurement or coding scheme the code belongs). Sometimes, that context subconcept is un-needed (e.g., unitless measurements as the INR).

However, dimensioning a concept as the aggregation of two or three sub-concepts might not be suitable to represent another concepts or if the patient would want to manually add notes. So, hypothetically, infinite sub-concepts within a concept would be allowed which would enable this model adaptation to a more complex one (having more sub-concepts). To discriminate one sub-concept to another, it was decided to encode these sub-concepts using 2 fields: “attribute” and “value”. This methodology will allow to reuse each of the coding systems used in the acquisition process, with no more than indicating it in higher levels of organization, like the MD.
4.2. Telemonitoring data acquisition

A representation of this Reference Model is shown in Figure 4.3, where device is an abstract class. According to that, the communication structure can be simplified to the concatenation of simple measurements jointly with the patient id and, optionally, some context information (e.g. device responsible for the acquisition, etc.). Each measurement will also include date and time of the acquisition in case the telemonitoring system would be store-and-forward.

The construction of a structure compliant with this Reference Model would require some processing capabilities and, at the same time, would be applicable if the interaction with a WSN, or other intelligent devices, would be feasible. The technological evolution leading to a cross-domain integration is reflected in papers like [234], and this integration paves the way to the collaboration among home devices in order to enrich the data quality provided to the EHR server, not only for their definition but also for their validation.

Regarding the use of terminologies and controlled vocabularies, as already stated, encoding would be the basis of the communication structure. Controlled vocabularies are expected to be used by the acquiring mechanism, like the MDER in ISO/IEEE 11073 standards. These various coding systems can be bounded to each other through a cross-mapping mechanism. This way, although the number of codes will be increasing with the use of different acquiring systems, they will be compacted for the HCIS - HCIS communication. In the CD to the HCIS communication, just remark that the aggregation of various controlled vocabularies, is still a controlled vocabulary.

Other point to consider is the interface through which the communication is going to be performed. Information will only flow in one direction, and it will correspond to a structure compliant with the model described in Figure 4.3. This “request” will have the accordingly “response”, in which it will be confirmed if the data has been correctly acquired by the HCIS. This confirmation will be used in the CD for managing if sent data can be erased from their internal memory or it has to be stored for later re-sending.
Finally, a telemonitoring system based on archetypes, as domain-specific concept models, is proposed. Figure 4.4 shows in detail the functional diagram by which the clinical data flow will have to pass from the moment of their remote acquisition until their storage on the EHR server, and moreover the structural scheme of a measurement. In this case, due to simplicity, only the three previously mentioned sub-concepts have been depicted.

Medical data are received by the collector element, the CD, which is responsible for the fragmentation of the received information into simple elements and the generation of the communication instance conforming the model represented in Figure 4.3 for its sending to the receiver module. Once a structure complying this model is received in the HCIS from the CD, it is processed to methodically extract the acquired information. Firstly, and based on the syntax defined by the model, the information is segmented reaching the concept granularity level. Each of these concepts is firstly decoded based on the acquiring coding system (which is also specified in the communication instance), selecting each sub-concept through the attribute field. Among these sub-concepts, the one which designates “what” has been acquired is used as key element in a translation process, as it is used to establish the mapping to the code used in the HCIS. This mapping might be even performed on a local database where the concepts are arranged the same way that SNOMED-CT arrange its: for each concept a set of synonyms would be established, bounding each term to the equivalent concepts in various particular system (e.g. proprietary communication system).
4.2. Telemonitoring data acquisition

From here, a repository of simple archetypes (represented as Archetype Repository in Figure 4.3) that have links to the encoding used in the HCIS is checked. This allows to know under what conditions the information should be recorded. Thus, in the chosen archetype lays down the conditions under which a measurement should have been acquired (for example, we can have an archetype to indicate that the diastolic pressure has a specific code and its units have to be mmHg). Once the reception premises are known (i.e. the archetype is identified), data is processed in order to achieve the archetype adequacy.

Obviously, acquired data are diverted into different sub-process as different data types will need of different data processing which would provide data adequacy to the identified archetype. This way, for numeric data (which include both physical quantities and unit-less data types), a sequential validation has to be performed following these steps:

- Verification of the units, if any. Carrying out this kind of checking responds to the diversity of medical devices and the possibility of receiving measurements in different but equivalent units (e.g., blood pressure which, having units of pressure, can be expressed both in millimeters of mercury (mmHg) or kiloPascals (kPa)). In fact, and given that this knowledge is reflected in the definition of the archetype, this process would remain valid if it was discovered, for example, that the most appropriate units to define the blood pressure are atmospheres of pressure (atm).

- Scaling of value. This would be relevant in case the units of the received medical data do not correspond to the one dictated in the model. Obviously, it is needed to know the required operations to convert the value of the concept to make data coherent to the new units.

Finally, after performing this whole process (i.e. from the mapping of all the sub-concepts contained in a concept to the archetype adequacy of these data), the decoded data are sent to the data insertion logic, becoming then consistent with the internal structure of the HCIS storage scheme. However, this sending has to be performed bringing together all the needed pieces to make up full clinical-significance concepts and this is happening at the ENTRY level as ENTRYs are also known as clinical statements. Regarding this issue, archetypes also allow to set up complex concepts (e.g. blood pressure) from single concepts (i.e. systolic and diastolic pressure) in a modular way and thereby archetypes will be of great help to solve this issue: higher-level archetypes will be looked for until reaching an entry-level archetype.

This process has been analyzed for a situation involving a single concept. The decoding of an entire communication structure with multiple data would require reiterating the process as many times as needed.
4.3 Interoperable communication of EHR

The next stage, in the end-to-end communication definition, is to underpin the EHR_EXTRACT generation and communication. Therefore, for the design of an ISO/EN 13606 EHR server, parts 1 and 5 of the standard (which provide a Reference Model and an standardized interface) have been mainly considered. Furthermore, the use of archetypes is planned to be applied to define the clinical knowledge.

With regard to archetypes, it is needed to determine which of them use. Archetypes are already being used in various EHR systems and, therefore, it can be interesting to determine if previously defined models are suitable for telemonitoring purposes or it is needed to define new ones. This consideration was made in order to take advantage of their reutilization properties, avoiding the proliferation of what can be called “duplicate archetypes”. However, the proliferation of “duplicate archetypes” should not be major problem neither although archetype governance is one of the current issues in the ISO/EN 13606 standard development.

In the documentation process, the lack of a central archetype repository was made evident, one of the most common self-criticism within the ISO/EN 13606 community. However, it is not needed to find an specifically ISO/EN 13606 archetype but any archetype. Archetypes are used to represent knowledge and any knowledge representation is valid: only a way to translate its restrictions from one Reference Model to another is required, either manually or automatically. As an example, [235] presents a solution to translate ISO/EN 13606 to openEHR archetypes and vice versa.

Hence, the required knowledge was sought in an alternative knowledge repository, the openEHR clinical knowledge manager [236], in which various terms are already defined or are being defined (i.e. in a draft status). Among these terms, some specially useful for the continuity of care in chronic diseases were found, like the blood pressure term. Nevertheless, its direct application in the telemonitoring scenario was highly questioned although, in its description section, the “self-measurement with a home blood pressure machine” is considered as a valid scenario. The reasons for such considerations range from its high level of generality (e.g. the method of measurement is itemized and various possibilities will never be used if the measurement is acquired through a device, as palpation) to the optionality of all its components. This issues can be avoided specializing the archetype but the model definition, at the ENTRY level, collides with the proposed methodology to define knowledge according to a bottom-up approach.
In the mentioned repository there is also an archetype, in draft status, for modeling a MD. As occurred with other models, it is a very generic one and, as previously mentioned, the feasibility of automatically obtain some of these parameters has to be further analyzed, as it combines various description elements with management elements (i.e. Date of expiricy as the date the device is not longer fit for use). Physicians should determine what of this information would be useful for the appropriate interpretation of the measurement. Moreover, unlike the ISO/IEEE 11073 standard which allows the association of any ISO/IEEE 11073-compliant device with the CE (whatever if it was the previously assigned to the patient or not), it can not be assumed that the acquiring device would be registered in the EHR server.

Considering this, it was decided to use self-made archetypes, in some cases inspired on the above mentioned openEHR archetypes (e.g. the blood pressure term) but making them up for other non-archetyped terms (e.g. INR term). Archetypes were defined at the ELEMENT level and ENTRY archetypes were built from the previous ones. However, unlike the openEHR archetypes, some of the sub-ENTRY components were set as mandatory in order to establish a rudimentary hierarchy among the ENTRY components. In any case, studying these archetypes made evident the importance for reflecting/identifying which MD had been responsible for acquiring the measurement.

Another point to have in mind, not related to the modeling of information, are the security issues: ISO/EN 13606 has to be complemented with ISO/TS 22600 [196], the privilege management and access control standard. Security aspects will be later discussed.

Regarding the server design, ISO/EN 13606-1 standard does not impose any restrictions on how data should be stored and, thus, any storage system might be used. Obviously, the mechanisms to properly fill and complete all mandatory fields in the EHR_EXTRACT (the whole EHR or part of it) have to be implemented, either within the same storage scheme or by parallel mechanisms. Hence, there will be a complementary link-up between the storage scheme and the EHR Extract generation procedure. Thus, particular information organization within a specific HCIS will require a different interaction process than information organized in a distinct HCIS based on a different information scheme. Moreover, the identifying necessities involved in the acquiring process does not vanish within the EHR server as, in order to suitably manage records within the system, a procedure able to associate a unique identifier to each RECORD_COMPONENT has to be designed. This association should be generated at the time of data registration, so it may require some kind of interaction with the COMPOSITION’s composer/committer process.
While the committer is the party responsible for committing a RECORD_COMPONENT within the patient’s EHR, the composer is the agent (party, device or software) responsible for creating, synthesizing or organizing information that is committed to it. This distinction is made as not always the one who composes the reports is the one who records them. In our case, the composer should act to bring the received information (“communication instance”) to a clinical document schema in accordance with ISO/EN 13606 and ISO/EN 21090 standards, deciding which of the reported data are actually included in the patient’s EHR. The received information will be assigned a default sensitivity value (Clinical Care) and each one of the RECORD_COMPONENTs generated in this transformation will be bounded to a unique identifier in the system.

So, one of the first decisions to be taken is the design of a suitable storage system. Due to simplicity issues, it can be based on the ISO/EN 13606 Reference Model, although some classes/attributes might be dispensed with for several reasons (optional, senseless in this scenario, etc). The aim is to balance design simplicity and meaning integrity. To accomplish that goal, different simplifications and considerations will be performed. Moreover, jointly with this scheme, two different bounded-scheme procedures are required: one responsible for the arrangement of the information received from medical devices (the acquisition process) and another responsible for the EHR_EXTRACT generation from interrogations to that scheme. In the next subsections, a wider explanation will be exposed.

4.3.1 Storage system and acquisition process

In this subsection, both the storage system and the acquisition process will be jointly in-depth explained although, alike ISO/EN 13606 does not impose any storage system, this Thesis’ design philosophy intends to be as neutral as possible in the references to the storage system.

Besides, considerations and simplifications about the particularities of the telemonitoring scenario will be presented, although some of them also condition the EHR generation process (in which case they will be explicitly mentioned). Keeping in mind this system’s main function is the EHR_EXTRACT generation, the hierarchical structure of the different logic blocks might be reflected in the design of the storage system. However, as long as the system is designed only for sending extracts and not for receiving them, an ISO/EN 13606 Reference Model perfect reflection is not necessary to be implemented. Regarding the definition constraints, several aspects should be considered including the existence of non-mandatory fields and the separation between demographic and clinical data. Among them, some considerations about the data organizational criteria can be done:
• In the present situation, data is collected and noted by hand. When enough information is gathered, it is delivered to the healthcare centre. To maintain a similar approach as if data were delivered by hand in a health center, it was decided to consider all information submitted at once as a single COMPOSITION, regardless of the amount of communicated data. This initial consideration, although being the most correct interpretation of the standard, might lead to the proliferation of COMPOSITIONs containing one or small amount of medical data, moreover in real-time systems. Being aware of the potential overhead’s risks, due to later simplicity issues, this decision will be maintained.

• Assuming the complexity of the EHR_EXTRACTs generated from telemonitoring data is not excessive, it was decided to dispense with SECTION and FOLDER logic blocks, as their functions are organizational and navigational aids within a COMPOSITION. Avoiding the use of FOLDER and SECTION will simplify the EHR generation process.

• The implementation of an unsupervised acquisition system of telemonitoring measurements does not require the use of some Reference Model classes as the telemonitoring EHR server does not need to support some information a regular EHR server might support. Among them, the ATTESTATION_INFO class (for confirmation of any of the generated records) or the RELATED_PARTY class (to identify the person who is the subject of the information and that does not match the COMPOSITION’s subject_of_care) can be found.

In relation to the information that it is going to be stored, and based on the previously compatibility ISO/EN 13606 - ISO/IEEE 11073 study, it can be assumed that most of the information (at least, all information of mandatory implementation) that can be obtained could be associated to REAL, PQ or CD.CV instances defined as ISO/EN 21090. The rest depends on how they are defined. Thus a Collection Measurement retrieved from the ISO/IEEE 11073-10404 specifications (pulseoximeter device) can be defined for the joint transmission of pulse and SpO2 or pulse, pulse amplitude and plethysmogram, depending on how it was set up. In any case, the Collection Measurement has to be decomposed in order to identify each of the different measures that compose it. And it seems obvious that in the end, as occurs in the ISO/EN 13606 standard, the architecture leaf node would be a DATA_TYPE and, therefore, a DATA_TYPE oriented architecture design should be considered in this piece of work.

Moreover additional considerations, in relation of the data that is being acquired, can be performed like:

• The automatically recorded data in the system will not be later modified, so the RECORD_COMPONENTs’ versioning is meaningless.
Moreover, and considering one again the ISO/IEEE 11073 standard, the video transmission (or any other file format) is, for the moment, out of consideration. ISO/IEEE 11073 standard is not prepared for the video transmission and this feature is shared by most commercial MDs. Hence, the use of multimedia elements will be obviated.

Both of these considerations will impose design conditions in the EHR generation process as the EHR request interface includes these parameters (i.e. versioning, multimedia files) among those which might be used to perform an EHR request.

These considerations which, in a first place were determined for designing a suitable storage system, were also used for the acquisition process design which has to overcome the various gaps between ISO/EN 13606 and ISO/IEEE 11073 standards. Additionally, it will follow the data acquisition methodology described in the previous section. Its operating logic can be itemized as follows:

1. When an “instance of communication” arrives, the identity of the CD which sends the information is determined (allowing to record a description of the CD in plain text, if desired).

2. It would create a COMPOSITION entity for each of the patients contained in the “communication instance” and for each of them it will proceed as follows:

   (a) Following the functional diagram described in Figure 4.4, the acquiring process will recursively fragment that piece of “communication instance”. It will determine which protocol has been used for the acquisition of the medical information (i.e. ISO/IEEE 11073 standard or through any other mean) as this will be used in the posterior code mapping. Considering the standard used for the data acquisition, it will be established which concepts are being transmitted and which are their equivalents in the HCIS. In the acquisition process it was supposed that, from the CD, a unique time format would be sent to the EHR server. If not, the accordingly time transformations will have to be previously applied. In any case, the time and date format will be checked to ensure its feasibility and its adequacy to the local date format.
4.3. Interoperable communication of EHR

(b) In base of the acquiring standard, a mapping process will be triggered and, subsequently, an archetype repository will be requested in order to determine the model under which the information should be recorded. If there is any discrepancy, in the PQs elements for instance, an adequacy subprocess would be started. In this stage, the repository only contains archetypes at the ELEMENT level. Based on this pieces of information more complex structures would be composed: CLUSTER, and subsequently ENTRY, will be obtained from ELEMENT entities.

(c) Once the ENTRY or ENTRYs are determined and validated (e.g. a measurement whose bounded timestamp does not match with a real time and date will be discarded), the recording of all the data will be performed. In this recording, the assignation of unique identifiers will be carried out and, as previously designed in the compatibility study, “blanks will be filled” with static information or the information will be obtained from a database, etc. if needed.

In this case, composer’s and committer’s funtions are performed by the same entity.

4.3.2 EHR_EXTRACT generation process

As it was happening with the data acquisition process, the EHR_EXTRACT generation process depends on how the information was previously arranged. Therefore, as intended in the previous subsection, this matter would be dealt with as generically as possible. In order to accomplish this task, and recovering some of the previously stated conclusions, a “DATA_TYPE oriented” architecture will be considered. This means, basing the design on a conceptual framework, that it is proposed to be independent from any specific programming language or implementation technologies. A more colloquial way to express this idea is to hide the storage system after a set of data structures, which are basically made up of DATA_TYPES.

This storage system’s abstraction, in addition, paves the way towards an Object-Oriented Programming paradigm. Furthermore, a multi-layer architecture might be implemented to answer different EHR communication necessities.

Thus, a schematic outline of the proposed multi-layer architecture for the EHR_EXTRACT generation process is shown in Figure 4.5:

- The first layer corresponds to the level of data access (Data Access), in which the translation between the storage system and data representation (shaped like classes) is performed.
Chapter 4. Results

Figure 4.5: Multi-layer architecture for interoperable management of ISO/EN 13606 Electronic Health Records

- The second layer is based on the construction of classes (Class Based Core) and it represents the core process, in which the business logic is defined.

- A third layer (XML Interface) is defined to avoid the dependences with the implementation technology.

- The last layer (Customized Interface), is a conceptual set of interfaces, in which the problem of legacy system might be addressed.

To illustrate its functioning, it will be supposed that an EHR_EXTRACT request arrives to the requestEHR interface. From here, the server obtains the request parameters (Obtaining Parameters) and identifies the COMPOSITIONs that meet the requirements of the request (Obtaining Composition_id). Once determined, and after completing the header (GenerateEHRheader), these Compositions (GenerateComposition) are added to generate the EHR Extract (GenerateExtract). Finally, this EHR Extract will be returned to the requester.

A third layer is enabled to be invoked for the generation and exchange of XML files (XML Construction). This uses the application core and, by means of XML conversion, it is able to transform serialized ISO/EN 21090 DATA_TYPES and ISO/EN 13606 Reference Mode blocks into classes (Class Conversion) and vice versa. Thus, this layer offers genuine interoperability (through the requestEHRXML interface) since there is no dependence on technology.
A fourth layer has been implemented to facilitate data requests by legacy systems which do not implement this standard. This layer should be formally placed on the client side, although the server can provide this additional functionality. This way, through intermediate wrapping procedures, it would be possible to accommodate the request syntax of these heterogeneous systems (requestEHRparams) to suit the ISO/EN 13606 standard request interface.

Thus, the EHR_EXTRACT generation process is relying on the second layer of this architecture which business logic is triggered when an EHR request arrives to the EHR server. However, as defined in the ISO/EN 13606-5 standard, the request can have a variable number of parameters as most of them are optional. The possibility of having multiple allowed combinations of the request parameters has led to the development of a methodology for the REQUEST_EHR_EXTRACT interface to increasingly handle, in an orderly fashion, the potential request parameters.

Figure 4.6 shows the order and internal logic for the system initialization management. All input parameters, excluding subject_of_care that is mandatory, are first checked in order to determine if they have been specified as a parameter. This check is performed after making certain that the subject_of_care specified in the request is registered in the system. After that, max_sensitivity is used as input in a generic block to determine what records the applicant has permission to access. In this situation, where all the recorded data have the same level of sensitivity (clinical care), this check is important to be performed in the first place for computing reasons as a lower sensitivity value would return an error with code REAS01 (There are no accessible data that correspond to the request). If none is specified, the default sensitivity value is assumed to be specified.

Once verified the recipient has data access, other input parameters are processed along with the patient identifier, if these would have been specified (archetype_ids and meanings). The COMPOSITION identifiers which meet the EHR request requirements are stored. If archetype_ids or meanings parameters would have been specified, all COMPOSITION identifiers of that subject_of_care would be obtained. Subsequently, temporal filtering is performed, if this was a request condition. Finally, those COMPOSITION identifiers which contain specific records, if any, are added after ensuring that they belong to the right subject_of_care. This last parameter is considered independent of the temporal filtering. The multimedia_included and all_versions parameters specification, as previously argued, would make no difference on a server with these characteristics.
Figure 4.6: EHR_EXTRACT Request Logic

This procedure allows the homogeneous treatment of any EHR Request, regardless of the number of specified parameters.
4.3. Interoperable communication of EHR

The EHR_EXTRACT generation process takes advantage of the EHR_EXTRACT hierarchical features, as it follows the methodology shown in Figure 4.7 where any logical block construction is achieved by combining the generation of different DATA_TYPEs and other blocks contained in it. In order to mark off the number of DATA_TYPEs to be included in the EHR_EXTRACT, the previous analysis on what measures the ISO/IEEE 11073 standard is able to provide (real, PQ and CD.CV) was completed with the mandatory fields in the EHR_EXTRACT transmission: Time Stamps (TS), Time Intervals (IVL< TS >), Coded Simple (CS) and Instance Identifiers (II) (see Table 4.10). Having identified the main DATA_TYPEs and generic blocks, specific strategies can be designed to build them up and work with them. In the study extension the whole ISO/EN 13606 Reference Model has been considered to ensure the inclusion of all the needed DATA_TYPEs but, obviously, not all the fields have to be used.

In the design specification, one of the ISO/EN 13606 blocks (AUDIT_INFO) has been put on a level with ISO /EN 21090 DATA_TYPEs. In addition, both this and the TIME_INTERVAL classes are generated from the aggregation of different DATA_TYPEs. The main functions included in the EHR Extract generation process are listed below:

- **Generate “Generic Block”**. Creates the corresponding generic block (COMPOSITION, ENTRY, CLUSTER and ELEMENT) according to the ISO/EN 13606 standard.

- **IIConstructor**. Generates an II DATA_TYPE, an identifier that uniquely identifies a thing or object.

- **PQConstructor**. Generates a PQ DATA_TYPE, a dimensioned quantity expressing the result of measuring.
**Table 4.10: Mandatory, and some optional, EHR_EXTRACT fields**
4.4 Security in the EHR communication.

- CDCVCConstructor. Generates a CV DATA_TYPE, coded data consisting of a code in a code system.

- CSConstructor. Generates a CS DATA_TYPE, a coded data in which the code system is specified, by constraint, in the ISO/EN 13606-1 standard.

- TSConstructor. Generates a TS DATA_TYPE, a point in time conforming to ISO 8601 [221].

- RealConstructor. Generates a real DATA_TYPE, a dimensionless quantity expressing the result of a measurement.

- IVLTSConstructor. Generates IVL<TS> DATA_TYPE, a date or time interval.

- AUDIT_INFOConstructor. Generates an AUDIT_INFO class which represents the committal and revision data about a RECORD_COMPONENT.

This DATA_TYPE oriented methodology easily allows extending the type of data used in the data modeling. Thus, during this Thesis development, the ISO/IEEE 11073-10418 (INR Monitor) was completed and it was required to include INR, not as a PQ DATA_TYPE but as REAL DATA_TYPE, because INR is unit-less. Or, if this server would be upgraded to communicate encapsulated data (e.g. a video file), the multimedia included parameter in the EHR request would be included as input in a hypothetical EDConstructor function, which would generate an ED DATA_TYPE.

It also smooths the efforts needed to alter the EHR server, if its characteristics are decided to be modified. This way, if an EHR server is wanted to be implemented without some of the considered simplifications (all records have the same level of sensitivity, COMPOSITIONs are fully transmitted), the new EHR_EXTRACT generation process would only differ from the present one in a generic module, placed before the “Generate Logic Block” function. That module would make a fine filtering over the EHR_EXTRACT data using as parameters sensitivity, archetype_ids, meanings and re_ids. The boolean output of that block would enable the block’s creation.

4.4 Security in the EHR communication.

EHR systems are the cornerstone upon which the increase on the citizen’s quality care is being based and the tool which have led to empower the number of patients who can be attended. From a security standpoint, the patient’s EHR should be created, processed and managed in order to ensure the content’s confidentiality and to legitimate patient’s control about its use.
Ideally, each fine-grained entry in the patient’s EHR would be able to be linked with a certain number of people who have access to view this information. This listing should be generated, or at least approved, by the patient and should be able to dynamically reflect the range of people with the duty of care towards the patient. Similarly, it should also include those people outside the patient’s care (e.g. those related to consent research activities) granting them partial access to the EHR and denying access to those parts that were considered too personal or outside the research scope.

Thus, combining different EHR access policies, it is possible to grant a heterogeneous access both to medical professionals and the various representatives (i.e. caregivers or other family members) the patient might have. However, these requirements are difficult to fulfill due to several conditionings within the medical environment, as the difficulty in classifying in a standardized way the EHR records’ sensitivity, the need to review and manage access permissions as any other record in the EHR or to determine the appropriate access permissions into a real-time computing environment, which is probably distributed.

Regarding security issues, ISO/EN 13606-4 and ISO/TS 22600 standards are the references as ISO/EN 13606 has been selected for the EHR communication. Figure 4.8 sketches a generic representation of the scenario, mixing some of the generic components referred in both of the documents.

![Generic network architecture for the EHR request access control](image)

*Figure 4.8: Generic network architecture for the EHR request access control*
4.4. Security in the EHR communication.

<table>
<thead>
<tr>
<th>ISO/EN 13606-5 EHR_Request parameters</th>
<th>Minimum conformance</th>
<th>Normal conformance</th>
<th>Extended conformance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recipient’s functional role</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Recipient’s specialty</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Recipient’s clinical setting</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Recipient’s identity</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Recipient’s structural role</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Recipient’s organization</td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

Table 4.11: Parameters needed to apply the ISO/EN 13606-4 standard based on the conformance level

Once established the scenario, broadly speaking, it was necessary to define the ISO/EN 13606-4 compliance level of the requested system, in which the EHR server would be placed. Applying security features, according to the various conformance levels was staged in the following steps: a minimum compliance was originally considered and, afterwards it was planned, using scalable and generic methods and interfaces, to increase the architecture conformance level without, thereby, completely re-defining it in the subsequent developments. The sensitivity-based access policy model facilitates the transition from minimum to normal conformance.

After the standards’ analysis, relevant parameters have been identified in Table 4.11 and categorized based on the various conformance levels. Within this list some items have been explicitly omitted, those contained in the ISO/EN 13606-5 standard for the EHR request specification (the patient’s identification, the purpose of the request, the request time interval, a set of archetype identifiers, a set of coded values, a set of record component identifiers, the maximum sensitivity value and the requests that all versions of each COMPOSITION, or all the multimedia data, would be included in the EHR). Some of these, as it will be seen, have special relevance not only for the request itself but for the policies’ definition.

Regarding a specific patient’s EHR, any user in the system has been assigned a maximum access level through the specification of their functional role. The EHR requester system might, by mistake, request data using a sensitivity data above this top value. However, the EHR provider system might amend this error in the EHR request as it is the direct requester of the EHR server. This functionality can also be used in normal conformance level to deal with the possible defined policies by the patient. To achieve that, a fine-grained identification of the recipient is needed to be performed, i.e. a univocal identification of the general practitioner has to be provided (i.e. the one which uses performing a role in a specific clinical setting).
<table>
<thead>
<tr>
<th>Recipient’s functional role</th>
<th>Medicine-related professional: General practitioner, specialist, administrative, etc.</th>
<th>Single person: The patient, guardian, other person, etc.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recipient’s specialty</td>
<td>Querying HCIS</td>
<td>Querying HCIS</td>
</tr>
<tr>
<td>Recipient’s clinical setting</td>
<td>Based on the recipient’s identity</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Recipient’s structural role</td>
<td>Based on the recipient’s identity</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Recipient’s organization</td>
<td>Based on the recipient’s identity</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Request’s sensitivity</td>
<td>Based on the functional role, specialty, clinical setting and a possible special authorization.</td>
<td>Based on the recipient’s functional role.</td>
</tr>
</tbody>
</table>

*Table 4.12: Parameter obtention from the EHR recipient fine-grained identification.*

Recipient’s fine-grained identification might also allow the obtaining of some of these relevant parameters and, therefore, not all the previously listed parameters have to be sent to the EHR provider, as it should be able to get them from a user identification system. This system, in an intra-domain scenario, might be a demographic server. If the request is performed from outside the domain, they should be obtained through the Directory services. Therefore, if a high quality user identification system can be assumed, the root from which the rest of parameters can be obtained would be the only one to be specified.

In the Table 4.12, it can be seen how the needed parameters might be obtained from the fine-grained identification of the EHR recipient. In this table a discrimination between a non-medical and medical related recipients has been performed. The recipient’s parameters were selected in base to the minimum and the normal conformance with the ISO/EN 13606-4 standard. As ISO/TS 22600’s Policy Model is not an information model, but a domain model, no specific parameters can be obtained from it. However, rules defined in the policy agreement should have an equivalent formulation according to the access policy model defined in ISO/EN 13606 standard, even those which may be similar to the minimum conformance ones and were expressed through the Table 3.1. Because of this, ISO/EN 13606-4 standard has been specially considered.
4.4. Security in the EHR communication.

<table>
<thead>
<tr>
<th></th>
<th>ISO/EN 13606-4</th>
<th>ISO/EN 13606-5</th>
</tr>
</thead>
<tbody>
<tr>
<td>rec_ids</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>archetype_ids</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>time_period</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>max_sensitivity</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>meanings</td>
<td></td>
<td>✓</td>
</tr>
</tbody>
</table>

**Table 4.13: Target request parameters**

Users’ identification is, thereby, a cornerstone in the development of systems based on access policy models. A valuable input to the user identification, within the ISO/EN 13606 standard, is the demographic model described in its part 1. However, it lacks of a mechanism for relating PERSON entities to each other (e.g. IDENTIFIED_HEALTHCARE_PROFESSIONAL and SUBJECT_OF_CARE). openEHR Demographic Information Model [168] does includes this idea of relating parties and it assigns the relationship a validity time. This is of great importance in functional roles management as these relationships may vary in an agile way. This lack, within the ISO/EN 13606 demographic model, of a mechanism to relate different PERSON entities is surely be due to it is not a management standard, but a communication one. These lacks have to be overcame in the final implementation.

Other points to take into consideration are the restrictions about the EHR requested target content. Policies are defined for some entities (request_characteristics) about some content (EHR_target) using various parameters. An itemization of the EHR_target constraining parameter, is done in Table 4.13 which also presents the EHR request parameters. In this itemization, max_sensitivity is also used in ISO/EN 13606-4 standard but it can not be specified: it is fixed based on the actual relationship between the EHR recipient and the subject of care.

Having this information in mind (request_characteristics and EHR_target), a generic business model can be designed to be implemented in the EHR provider which would deal with both intra- and inter-domain requests, and which would be based in the fragmentation of the original EHR request into more specific EHR requests. This model can be seen in Figure 4.9, in which the parameter obtaining process has also been represented: As it has been commented, before the EHR querying, some parameters used for determining the existence of defined policies for the EHR recipient and the subject of care have to be obtained by interrogating the demographic server and/or the directory service depending if it is an intra- or inter- domain request. This distinction can be performed based on the existence of a reference to a relevant rule when invoking the EHR provider as sets ISO/TS 22600 in inter-domain requests.
To calculate the maximum allowed access level and suit the minimum conformance criteria, it is necessary to compare the specialty and the clinical setting of the recipient with those recorded in each clinical document. Based on an ISO/EN 13606-1 Reference Model study, the identity of the composer of the report can be obtained through the attribute performer of the COMPOSITION class and, once it is obtained, the specialty and the clinical setting can be known through the demographic model. However, the Reference Model states that the recording of the composition’s composer of a report is optional but, if it is made, it is mandatory to identify the person responsible for composing that report and it sets as optional other fields such as the role performed.

In any case, if the composer was not identified in the COMPOSITION recording, the committer (i.e. the party responsible for committing the COMPOSITION to the EHR) is a mandatory attribute in the committal of the EHR. Therefore, to increase the access level of a privileged healthcare professional from 3 (Clinical care) to 4 (Privileged care), it would be necessary that the COMPOSITION’s composer would be recorded. In its faulty, the committal might be consulted to check the specialty and clinical setting parameters although it is not granted that the committal would belong to, at least, the same specialty that the composer. In this case, the access level will remain as 3 (Clinical care). An access level of 5 (Personal) will only be guaranteed in a few cases as in “some health care settings, such as in the armed forces of some countries”.

Figure 4.9: Access control methodology
This initial calculation, used to accomplish a minimum conformance with ISO/EN 13606 standard, will be integrated in an algorithm (depicted in Figure 4.10) which allows the joint compliance of the specifications gathered in both documents. The high-level algorithm proposed to fulfill both documents’ requirements proposes the EHR provider to:

1. Identify if the request has two (i.e. information about the requester, and recipient if it is the case, and the EHR request) or three parameters (i.e. a reference to a relevant rule), in order to differentiate whether the request comes from the inside of the domain or from its outside.

2. If it comes from the domain, the demographic server would be queried about the EHR recipient. Otherwise, it would be the Directory Service which would be requested to get this information after ensuring the rule was applicable and the access to the requested information is allowed. In this phase, the maximum request access level would be established. In the case of the privileged healthcare professionals, it will be set to 4 or 5 (if there is evidence that has been authorized) and non-compliant records will be filtered a posteriori.
3. Once the EHR recipient is identified, the policies that apply to the patient would be obtained. If the request came from within the domain, a policy repository would be queried while if it comes from outside the domain, a common repository should be consulted to ensure compliance with the requirements of the policy agreement. These consults will be based on the request characteristics of the access policy model in the ISO/EN 13606 standard, querying by role (functional and structural), clinical setting, specialty and / or party (person, device or organization). In this stage, one should be aware that although a fine grained identification of the EHR extract recipient is required, a policy might be defined for someone whatever the role they play using a coarse grained identification (i.e. the policy might be defined for a person, which might involve several roles (identify him as both a single person and medicine related professional) or it might be defined for an institution).

4. Once known the request characteristic requirements, the EHR_target will be the focus of the business logic. Table 4.13 shows the content criteria according to ISO/EN 13606-4 and ISO/EN 13606-5 standards. From a practical standpoint the business logic should be defined, in part, based on ISO/EN 13606-4 standard and some additional considerations based on ISO/EN 13606-5 standard like not sharing information if the purpose is not the right one or if the multimedia information is allowed to be transmitted. In fact both of the presented examples could be encompassed in the “other_criteria” attribute, within the EHR_target specification although this attribute is defined as a set of strings. These strings should be interpretable by both humans and computers but no further explication is given about the semantic or syntax of this specification. Obviating the use of this attribute, the business logic would follow as:

(a) It is checked that the max_sensitivity request’s parameter would be less than, or equal to, the access level granted by the role. If not, the max_sensitivity parameter value would be overwritten.

(b) An ISO/EN 13606 request is performed considering all the parameters but the rc_ids and archetype_ids parameters, which will be later analyzed. If the meanings parameter was null and rc_ids and/or archetype_ids parameters were not specified, no request would be performed. If this first request is performed, and the sensitivity would have been previously increased (in the case of privileged healthcare professionals), a preliminary filtering would be performed to remove those records which do not suit the original criteria.

(c) It is checked if any of the identified policies in 3. concerns to the archetypes which may be requested and different sub-requests are performed:

   i. If they are not concerned, it is used the same sensitivity level established in (a) and the other values used in the request (time interval, all_versions).
ii. If they are concerned, time interval from both the request and the policies would be checked. These intervals may overlap in different ways, as illustrated in Figure 4.11.

iii. It is checked if any of the identified policies in 3. concerns to the rc_ids which may be requested and 2 different requests are performed:

A. If they are not concerned, the sensitivity level and all_version parameters would be the same as established in (a).

B. If they are concerned, the sensitivity level and all_version parameters would be the same that the ones established in the policy.

A. If the time intervals (of the request and the policy) do not overlap, it would be considered that the policy does not affect and you would proceed according to i.

B. If the request time interval was fully contained in the policy time interval a query of that archetype with the time interval of the consultation and the sensitivity level and all versions value of the policy would be performed.

C. If there would be a partial overlap of the time intervals then several queries would be performed differentiating those which periods time periods don’t overlap (and proceeding according to A)) from those one which do (and proceeding according to B)).

5. The result of all those requests would be aggregated in a single response after checking that no duplicate data is found.

Once the methodology and other technical recommendation has been presented, in the next section a particular implementation, as a proof-of-concept, will be developed.
4.5 Architecture implementation and validation

In the following section, the implementation of the EHR server will be detailed, allowing the conceptual validation of the proposed methodology. This explanation is going to be carried out from two different viewpoints: the acquisition process and the EHR_EXTRACT generation process. After that, the security application outcomes of the implemented EHR server are displayed.

4.5.1 Proof-of-concept with ISO/IEEE 11073 PHDs. Telemonitoring acquisition system

ISO/IEEE 11073 standard, and specifically its PHD version, was selected for this proof-of-concept due to various reasons that have been repeated over the course of this Thesis dissertation: ISO/IEEE 11073 specializations, already enumerated in Table 2.1 and further expanded in Table 4.9, are clearly in line with the telemonitoring needs of physiological measurements. ISO/IEEE 11073 standard also owns its own coding system (MDER) which suits the unambiguous designation of the concepts. This will simplify the CD design, in particular, with those aspects related to the transmission of the medical data to the EHR server. Therefore, it is perfectly suitable for the proof-of-concept implementation.

For the implementation of actual testing, in the telemonitoring environment various fixed (PCs desktop, NetBooks and Tablet PCs) and mobile (mobile phones, PDAs and Smartphones) CEs were installed as the elements responsible for centralizing the acquisition and encoding of medical data in accordance with ISO/IEEE 11073 and constructing a connection instance in XML format according the model shown in Figure 4.3. The considered telemonitoring measurements correspond to certified MDs at the time of writing, indexed as ISO/IEEE 11073-104XX: glucose meter (10417\textsuperscript{TM}-2011), pulse oximeter (10404\textsuperscript{TM}-2010), blood pressure monitor (10407\textsuperscript{TM}-2010), thermometer (10408\textsuperscript{TM}-2010) and weighing scale (10415\textsuperscript{TM}-2010). Based on these specializations, various archetypes were defined at the ELEMENT level but the blood pressure concept which was defined as a CLUSTER as it is considered as the aggregation of systolic and diastolic pressure. Systolic and diastolic pressure were also archetyped as ELEMENTs. In the first stage of this implementation only mandatory measurements in the ISO/IEEE 11073 certified devices were archetyped.

These archetypes were designed using the LinkEHR Editor Lite [174]. A example of these simple archetypes can be seen in Figure 4.12, in which the definition section is shown. This telemonitoring archetype was designed to be able to preserve data acquisition time from the enrollment time in the system, through the field obs_time, and bounded to reference terminology through the meaning attribute.
4.5. Architecture implementation and validation

<table>
<thead>
<tr>
<th>Device type</th>
<th>Operating system</th>
<th>Technologies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Desktop PC</td>
<td>Linux</td>
<td>IrDA, RS-232</td>
</tr>
<tr>
<td></td>
<td>Windows</td>
<td>IrDA, RS-232, RJ-45</td>
</tr>
<tr>
<td>Netbook</td>
<td>Windows</td>
<td>USB, Bluetooth</td>
</tr>
<tr>
<td>PDA &amp; smartphones</td>
<td>Windows Mobile</td>
<td>Bluetooth</td>
</tr>
<tr>
<td></td>
<td>Andorid</td>
<td>Bluetooth</td>
</tr>
</tbody>
</table>

Table 4.14: Summary of CD Applications

<table>
<thead>
<tr>
<th>definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>ELEMENT[@a0908] occurrences matches (1..1) matches { -- TelemonitoringWeight</td>
</tr>
<tr>
<td>value existence matches (1..1) matches</td>
</tr>
<tr>
<td>PQ[@a0801] occurrences matches (1..1) matches { -- PQ</td>
</tr>
<tr>
<td>units existence matches (1..1) matches</td>
</tr>
<tr>
<td>CS[@a0907] occurrences matches (1..1) matches { -- CS</td>
</tr>
<tr>
<td>codeValue existence matches (0..1) matches (&quot;Kg&quot;)</td>
</tr>
<tr>
<td>codingScheme existence matches (0..1) matches</td>
</tr>
<tr>
<td>ID[@a07008] occurrences matches (0..1) matches { -- ID</td>
</tr>
<tr>
<td>cid existence matches (0..1) matches</td>
</tr>
<tr>
<td>{&quot;2.16.840.1.113883.6.89&quot;}</td>
</tr>
<tr>
<td>}</td>
</tr>
<tr>
<td>codingSchemeName existence matches (0..1) matches (&quot;UCUM Case</td>
</tr>
<tr>
<td>Sensitive&quot;)</td>
</tr>
<tr>
<td>}</td>
</tr>
<tr>
<td>value existence matches (1..1) matches ({0.0..500.0})</td>
</tr>
</tbody>
</table>
| }
| obs_time existence matches (1..1) matches { |
| IVLTS[@a0902] occurrences matches (0..1) matches { -- IVLTS |
| high existence matches (0..1) matches |
| TS[@a0906] occurrences matches (0..1) matches { -- TS |
| time existence matches (1..1) matches (yyyy-mm-ddhh:mm:ss) |
| }
| highClosed existence matches (0..1) matches (true: true) |
| }
| meaning existence matches (0..1) matches { |
| CD[@a0902] occurrences matches (0..1) matches { -- CD |
| codeValue existence matches (0..1) matches ("368038001") |
| codingSchemeName existence matches (0..1) matches ("NOMED CT") |
| codingScheme existence matches (0..1) matches |
| ID[@a07004] occurrences matches (0..1) matches { -- ID |
| cid existence matches (0..1) matches ("2.16.840.1.113883.6.8") |
| }
| }
| }

Figure 4.12: Definition section of the weight telemonitoring archetype

These archetypes were used to adequate the acquired information to a common format, as was shown in Figure 4.4. After the concept mapping is performed an additional processing about units was required for PQ concepts as, based on the MD configuration, some of the acquired measurements might be expressed in various scales. The transformation of the received measurements has been carried out based on a conversion table of the ISO/IEEE 11073 data to the Unified Code for Units of Measure (UCUM) units designed ad hoc for this work. As an example, Table 4.15 shows unit conversions for some certified medical devices.
In the left side of the Figure 4.13, the reference structure used to send acquired data to the EHR server can be seen as the representation of the validation data process. As a result of the tests carried out, the appropriate data inclusion in the system was observed, while irrelevant data was ignored. In addition, since the storage system in the EHR server was designed using as basis the Reference Model defined in ISO/EN 13606-1, archetypes defined for the information inclusion in the EHR server were useful when implementing the data insertion logic.

![Figure 4.13: Concept Identification](image)

<table>
<thead>
<tr>
<th>Concept</th>
<th>ISO/IEEE 11073 units</th>
<th>Conversion</th>
<th>UCUM units</th>
</tr>
</thead>
<tbody>
<tr>
<td>weight</td>
<td>Kg</td>
<td>*1</td>
<td>Kg</td>
</tr>
<tr>
<td></td>
<td>Lb</td>
<td>*0, 455</td>
<td></td>
</tr>
<tr>
<td>temperature</td>
<td>°C</td>
<td>*1</td>
<td>°C</td>
</tr>
<tr>
<td></td>
<td>°F</td>
<td>*1/1, 18 − 32/1, 8</td>
<td></td>
</tr>
<tr>
<td>glucose</td>
<td>mg/dL</td>
<td>*1</td>
<td>mg/dL</td>
</tr>
<tr>
<td></td>
<td>mmol/L</td>
<td>*18</td>
<td>mmol/L</td>
</tr>
<tr>
<td>blood pressure</td>
<td>mmHg</td>
<td>*1</td>
<td>mmHg</td>
</tr>
<tr>
<td></td>
<td>kPa</td>
<td>*7,50061683</td>
<td></td>
</tr>
<tr>
<td>oxygen saturation</td>
<td>%</td>
<td>*1</td>
<td>%</td>
</tr>
<tr>
<td>heart rate</td>
<td>beats/minute</td>
<td>*1</td>
<td>beats/minute</td>
</tr>
</tbody>
</table>

*Table 4.15: Conversion between units for ISO/IEEE 11073 data*
In the conversion process, various ISO/IEEE 11073 codes were found to have the same equivalent term (e.g. MDC_PULS_RATE_NON_INV and MDC_PULS_OXIM_PULS_RATE both correspond to pulse, the coding depends on the device which was used for its acquisition, a blood pressure monitor or a pulse oximeter). However, as there is a N:1 equivalence relationship, this fact does not mean an exception to the exposed methodology. If, at any point, it would be necessary to perform a reverse mapping, this could be achieved using the type of device as discriminant, but this situation seems unlikely to happen.

Other important decision to take was what to do with “non-relevant data” or “unexpected data”. The system operation is based on coding and the understanding that knowledge, or models if this expression is preferred, must and should be defined from the clinical environment. MDs might provide data which would not be included in the archetype requirements or data which can be disdained because they are self-calculated in the EHR server from others (e.g. pulse pressure is defined as the systolic pressure minus the diastolic pressure). In those cases it was decided to ignore them, although a log of each “communication instance” is performed.

In the next section, other aspects related to the EHR server implementation will be commented.

4.5.2 Proof-of-concept. EHR_EXTRACT generation system and EHR_EXTRACT validation.

The EHR_EXTRACT generation process has been implemented following the DATA_TYPE architecture design. All the defined functions or procedures were programmed to follow the business logic design. In this implementation an storage system was chosen to complete the server design. The hierarchical properties of the EHR_EXTRACT led us to consider the use of a relational database.

This decision, in addition to ease the translation from the storage system to the DATA_TYPE classes, enabled the creation of unique self managed identifiers within the system, through an strategy of combining different namespaces in the system with the primary key of certain tables within the designed scheme. The definition of the extension attribute through the combination of numbers and strings allowed the search criteria optimization, minimizing the number of queries to perform in the system.
The implementation of both processes has been based on Web Services technologies (WS) [237]. The technologies involved in this communication are the Simple Object Access Protocol (SOAP) [238], based on XML [239], and Web Services Description Language (WSDL) [240] that specifies syntax and mechanisms for the exchange of these messages. The WS development technology has been C# [241], taken from the dotNet framework, including an Internet Information Server (IIS) [242] for ASP.Net dynamic web pages. The storage system has been based on a MySQL server.

To evaluate the design, a series of tests has been carried out focused on the proposed multilayer architecture and using the ISO/EN 21090 DATA_TYPE set. In the first place, to ensure the correct behavior of the proposed implementation, a debugging process has been performed using both “black box” and “white box” testing.

To this end, an ad-hoc Web client application was implemented. This serves as proof-of-concept as it obtains information supplied by the WS and performs tester and demonstrator functions. Figure 4.14 shows different representative capture operations of the step-by-step application functioning:

- Secure access. To access the client application, a secure access procedure has been established/simulated using username and password. Through this functionality, the requester is identified and access rights are simulated. The main interface can then be accessed, which includes on the left side a constantly available menu to access each of the main features: EHR Extracts request, archetypes request and documentation related to the implementation.

- EHR request. The EHR Extracts request menu includes all possible parameters that can be specified as defined in ISO/EN 13606-5 standard. Since many parameters are optional, it was decided to use pull-down secondary interfaces to be only activated when desired. These sub-interfaces, as shown in Figure 4.14 (a), are adapted to the type of data that needs to be specified: boolean for all_versions parameter, integer for max_sensitivity, etc. Furthermore, additional support has been enabled to ensure the request is made as accurately as possible by messages indicating the default behavior with the use of these sub-interfaces and different types of valulators (some require a specific parameter to be introduced, others request that the introduced parameter be adapted to fit a certain pattern, etc.). On the other hand, as shown in Figure 4.14 (b), storage tables have been designed for those parameters in which more than one value can be specified. These tables allow any component in them contained to be edited or deleted and, as a rule, only the values contained in the tables are valid at the time of building up the request.
4.5. Architecture implementation and validation

Figure 4.14: EHR Client / Tester
• **EHR Extract.** Once the request is performed, the EHR Extract, generated according to ISO/EN 13606, is received. At this point, the client application is responsible for performing those actions considered appropriate with the received information (e.g. display it, store it, show it in an evolution graphic, etc). Figure 4.14 (c) shows, as an example of operation, part of an EHR Extract in XML format corresponding to the chronic patient’s telemonitoring report where several physiological measures are being controlled (weight, blood glucose, etc). The weight measurement is highlighted, represented by an ENTRY composed of a single ELEMENT. To facilitate both the display and data analysis, Figure 4.14 (d) displays the result of a small decoding routine which was implemented to show, in plain text, some information: time context (acquisition and recording dates), the concept of the measurement and its value, 70 kg).

• **Archetypes.** The screen of archetypes request has been designed with a sub-interface methodology similar to the previous one, and it is accessed by pressing “Archetypes Button”. As an example, Figure 4.12 shows part of one archetype for the weight.

In the second place, the validity of the generated EHR Extract was checked in collaboration with the Puerta de Hierro University Hospital (HUPH) and the Carlos III Health Institute (ISCIII), both in Madrid (Spain). Both institutions jointly developed an EHR server [229] according to the ISO/EN 13606 and ISO/EN 21090 standards. The server, among others, has an EHR Extract validation functionality which has been used to test the EHR extracts conformance. This module receives EHR extracts, analyzes them and sends a response message indicating whether the extract has successfully passed validation and, if not, its the cause. All EHR extracts generated by the proposed architecture and sent to the HUPH/ISCIII server were correctly validated. In addition, this collaboration has resulted in the production of a complete framework of 681 classes defined in C#, including listed classes, that would interact with any possible instance defined by the ISO/EN 13606 Reference Model and the ISO/EN 21090 specification. The class construction layer, in this implementation, has been completed to the required level but, due to its modular design, it can be easily supplemented in the hypothetical case that new features were needed.

In third and last place, integration with external systems has been tested in cooperation with a private Spanish company, which offers EHR consulting services and it is unrelated to the proposed development of the multilayer architecture. To this end, a custom-made interface has been developed in accordance with all the input parameters specified in ISO/EN 13606-5. Interoperable and scalable structures (such as string[], string[][][], among others) have been selected so that calls could be made through a generic library for different WS. The results of this integration were completely satisfactory, verifying the integrity of the proposed solution.
4.5.3 Proof-of-concept. Application of security features to the EHR communication

The security methodology was applied to a replica of the previously implemented EHR system. The replicated data were modified to get a greater dispersion in the data source, specifically in the sensitivity values, and have a suitable testing scenario: sensitivity was raised to privileged care for some records (weight and INR) and it was lowered for others (temperature).

For testing the designed algorithms an scenario comprising two systems has been set up: System 1, in which the EHR server intended to be consulted can be found, and the system 2 which acts as an external system to the first domain. Therefore, all requests coming from the system 1 will be intra-domain requests and those which come from the system 2 are considered as intra-domain requests. To simulate being logged in each of the two domains, two different interfaces were designed and implemented as Access Control Modules. Figure 4.15 shows an example of these interfaces through which the user authentication will be simulated in their respective domains and from which a univocous identification of the user can be obtained.

Besides, a policy agreement among the domain1 and the domain2 was defined which sets that the only exchange of medical data would be for the continuity of care but not for clinical research or other purposes. To that end, only general practitioners would be able to request the other’s domain EHR server. The medical data agreed to be exchange are weight, blood pressure and oximetry but, as in the two domains were different procedures about the INR measurement process, it was decided not to exchange these types of measurements.

![Access control system interface](image)
Within the system 1, these actors can be found:

- user1: This user is a doctor. She is the mother of the user2.
- user2: This user is an 18 years old patient. He suffers from anorexia and he does not want his mother to know his weight evolution. To that end, he defined a policy preventing her to look up these data.
- user3: This user is an endocrine specialist who controls the user2’s nutrition and needs to control weight gains or loses. To that end, it might be necessary to define a policy to ensure the data access. She also works as gynecologist and playing this role there is no need to know these data.
- user 4: This user is a medical researcher who wants to monitor the blood pressure raising in the actual society. Thus, policies were defined for the people involved in the research study which granted access to blood pressure information.

Within the system 2, only a user is found to simulate inter-domain requests. He is a general practitioner in the domain 2 and he has also started a PhD degree in Biomedical engineering in the research department of his University. Policies for those people who signed the patient’s consent were defined according the signed policy agreement.

The implementation was carried out using WS which suits the criteria of sending a response for every request, specially for the EHR provider. When a successful login is performed, each system presents the various roles this party is able to act. The EHR request is performed through a similar interface like the one shown in Figure 4.14. This also allows to get a fine-grained identification of the requester, and recipient if it is the case. This fine-grained identification is achieved consulting a demographic server, which it is not a perfect representation of the ISO/EN 13606 Demographic Model because it lacks of the mechanism for relating PERSON entities to each other (e.g. IDENTIFIED_HEALTHCARE_PROFESSIONAL and SUBJECT_OF_CARE) as previously mentioned. openEHR’s Demographic Model [168] was taken as reference to fulfill ISO/TS 22600 Role Model specification. These relationships were timestamped for audit issues. The Directory Service module was also based on the ISO/TS 22600 Domain Model.

Policies were represented in a local repository. The storage scheme used mostly followed the UML representation of the Access Policy Model. The set of strings of some attributes (other_criteria, in the EHR_target, and other_characteristics, in the request_characteristics) have not been considered for the implementation although they have been included in the local repository scheme. This was due to the dubiety they introduced in the business logic.
This casuistry is not comparable to the one in the ISO/EN 13606 interface implementation, where the number of parameters to deal with was variable but all of them were known. Knowing all of them allowed their sorted incorporation into the EHR server business logic after analyzing the possible interactions among them. Access policies do not require of an interface but, like in the interface business logic, it would be of great help to know all the possible parameters. In the access policy model, the number of parameters is neither known nor limited due to the previously mentioned fields. They allow to consider any devisable policy but they introduce vagueness in the system. Moreover, a “syntax and a semantic” should be defined to make them automatically processable.

In the proposed scenario it was specified that only EHR communication obeying a particular purpose in intra-domain requests were allowed. However, purpose can not be explicitly specified in the policy model. Although the scenario could have been previously changed, it was decided to keep it as it was the first example of policy proposed before studying the ISO/EN 13606-4 standard. If the standard is follow to the letter, this might be solved using the set of strings (i.e. the other_criteria attribute, in the EHR_target) but this would imply the definition of the mentioned “syntax and semantic”. In addition to this parameter, the missing of some ISO/EN 13606 request parameters was also noticed.

Based on these facts, and trying to enhance the coordination among ISO/EN 13606 parts, several modifications are proposed mainly focused in the inclusion of the missing parameters. The clustering of the purpose parameter within the EHR_target of the policy (through the other_criteria attribute) might be not appropriate because the purpose is not related to “what” but “for what”. However, unlike the purpose parameter, the multimedia_included parameter which is also missing in the ISO/EN 13606 policy model might better suit the “what” is requested. Based on these reflexions, and considering any policy should consider at least all the parameters that might be contained in an EHR request, it was proposed and implemented an extension of the access policy model. This extension includes the multimedia_included parameter (as optional) in the target section and to create a new optional section which includes the purpose (as an optional set of CD.CV) and other_context_variables (as an optional set of strings, to preserve the essence of the model definition). This last one should be, like the others sets of strings, interpretable by both humans and computers. For the purpose, it was considered the DD ISO/TS 14265 [243] which itemize a set of possible purposes for processing health information. This modification also led to modify the business logic: In the step 3. queries to determine the request_characteristics included the purpose, if it had been determined, and the EHR server queries will use as multimedia_included parameter the logic AND of the value specified in the policy (if any) and the parameter specified in the original request.
Chapter 4. Results

The standard neither specified another issue that was pointed previously to the implementation, like how to proceed when contradictory policies would have been defined. In this piece of work, it was decided to enjoin those which explicitly include the recipient (i.e. that name the recipient or any of the parties that have delegated over the recipient) over those which might be more generic. It was also decided, for this implementation, the subsequent degree in importance of the rest of the parameters: functional and structural role, clinical setting, specialty, and other party.

Based on these considerations and the proposed modifications, various tests were run for each user in the proposed scenario which included different combinations of EHR request parameters. Firstly, a first set of queries were run to test the minimum conformance criteria using the users in the domain1. The results were compared with the outcome of the same requests in the original server. Once accomplished, another set of tests was run including users in both domains and the defined polices. The resulting EHR Extracts obtained of those tests were compared with the ones obtained from the same requests to the EHR server which comply with the minimum conformance. It was observed how the defined access policies were skewing the communicated clinical content. Therefore, satisfactory results were obtained.

The study of this standard has raised other suggestions in the applicability or implementation of ISO/EN13606-4 standard, like the recording of the EHR requester in the extended conformance, as it is performed in other environments. Moreover, the logging of any delegation chain (if any) might be an interesting feature to introduce to track the systems’ appropriate behavior, just in case the EHR system would not preserve them in their management system.

Moreover, other questions were raised like the existence of a criteria for obtaining the EHR policies: if the EHR Request interface could be reused (as they are stored as COMPOSITIONs, and if the rc_id would match the policy_id) or an additional interface should be implemented, as example. These, and other questions, need to be deeply discussed in a future.
Chapter 5

Discussion & reflexions

In this section it will be recovered some of the conclusions that have been inferred during this Thesis, emphasizing them, although they have been previously presented as they were needed in the dissertation development. Similarly, a set of new challenges that might provide continuity to the work presented in this Thesis will be proposed.

5.1 Final conclusions

The use of telemonitoring services to improve the patient’s care process is no newness within the objectives of already presented dissertations or implemented platforms. In the first chapter of this Thesis, besides of describing and providing evidence of the already known demographics situation and its evolution trends, an introduction to EHRs has been sketched. EHRs are considered, within this Thesis, the cornerstone upon which the care process is carried out and the central piece around which this Thesis is developed. In this way, in this Thesis’s Chapter 1 a set of specific objectives were proposed to be reached which, in turn, will allow to make contributions to the harmonized integration of remotely acquired measures into the EHR of the patient and to the interoperable exchange of these EHRs through the use open standards.

These specific objectives have been covered along this Thesis. This way:

- The actual situation of the patient’s continuity of care paradigm in the specific field of interoperable EHR communication and among medical devices has been presented as proposed Objective 1. Regarding this initial objective, and based on the previously mentioned exposition of the current situation, a greater importance in the chronic diseases management than the aging population’s burden has been established for any health system. In this line, telemedicine systems are introduced as tools to improve the care provision. In relation to medical devices, their evolution has been described, remarking the high heterogeneity of devices
and transport technologies (if any) used in their implementation. An additional difficulty degree appears when the point of care location becomes variable. These facts led to the consideration of an standard based design to fulfill the integration requirements of both environments.

- The study of the telemonitoring standards’ ecosystem was carried out listing the best known and widespread initiatives, both proprietary (CANopen, ANT, Sensium, DICOM) and standards (HL7 and ISO/IEEE 11073), after introducing relevant SDO which work in the MD environment. The listing included references about the target subfield or application area (i.e. specific devices, specific environments, etc.) in which they are applied as proposed **Objective 2**. In this listing, due to its prevalence in industry and standardization organizations’ support and the PHD orientation, ISO/IEEE 11073 family of standards is specially considered and deeply explained.

- In the EHR environment, interoperability mechanisms have been studied differentiating semantic and standardization resources as proposed **Objective 3**. Relative to semantic resources, the study center has been relative to classifications, terminologies and nomenclatures and the way this encodings relate to each other. Regarding the standardization resources, the various types of standards available in the EHR context have been presented jointly with the main SDOs in the EHR arena and the relationships among them. Due to the high amount of EHR standards, a deeper analysis has been performed only considering the main EHR communication standards as proposed **Objective 4**, and more specifically their respective Informations Models.

- The description of the various scenarios in which the patient’s point of care is located remotely to the health care centre, as proposed **Objective 5** has been carried out, in Chapter 3, based on different considerations like the use of standards in the device environment, architecture of previous telemonitoring systems, equity principles among the patients and optimal use of resources. Over this general scenario, different types of communication were identified and a simplified architecture scheme was settled. This allowed to abstract any possible configuration of logic blocks. Over this simplified scheme, ISO/EN 13606 and ISO/IEEE 11073 PHD standards were pointed to underpin a seamless communication of information.

- The implications of the EHR standard election, as part of **Objective 9**, was exposed, and minimized, as a consequence of the convergence of the EHR communication standards. This way, and from the conflicting basis that different standards use different set of data types, various initiatives or studies which aim to translate one standard’s clinical content to another one as harmonizing efforts was listed.
• The security implications of the EHR communication (Objective 6) were explained, in base of the ISO/EN 13606 standard election and the needed access control’ and privilege management systems’ characteristics to carry on with a standard-based design paradigm. Accordingly, ISO/EN 13606-4 and and ISO/TS 22000 standards were explained.

• To ensure semantic interoperability, models of knowledge are considered as cornerstone both in the EHR integration and the EHR communication. Archetypes are both models of clinical content and set constraints on a Reference Model (or Information Model), so they were selected to ease the data integration with the EHR standard’s Information Model. Therefore, archetypes are thoroughly studied as proposed in Objective 7 so ADL as a language to define archetypes.

• A detailed compatibility study between the ISO/EN 13606 and ISO/IEEE 11073 PHD standards, specifically between their Information Models, was carried out due to the leader paper of ISO/IEEE 11073 PHD standard in the MD arena, as proposed in Objective 8. The study was performed using as base ISO/EN 13606 Reference Model and it sets which attributes can be obtained from ISO/IEEE 11073 PHD DIM, which can be obtained statically and which by other means. Thank to this study, various inconsistencies were identified and solutions were proposed to solve them. Moreover, this study was used as base to, abstracting the acquiring standard, establishing the minimum requirements to turning this architecture towards an acquiring standard neutrality, completing this way Objective 9.

• A generic architecture capable of embodying the telemonitoring data into the patient’s EHR according to the previously considered scenario and able to communicate the patient’s EHR was defined. The problem was split in various stages. Firstly, a methodology for data integration from patient telemonitoring measurements into the EHR was proposed using archetypes as cornerstone in the integration process, as proposed in Objective 10a. This methodology also involved the definition of the mechanisms which would bridge the communication gap between the MD and the EHR environments. This gap is proposed to be solved fulfilling the same requirements that the ones for the EHR semantic interoperability communication and which included a high level of codification to avoid the dependency of established data types. After that, an ISO/EN 13606 EHR server was designed for the interoperable communication of telemonitoring data, Objective 10b, which imply the design of an appropriate storage scheme and the EHR Extract generation process. This EHR_EXTRACT generation process was implemented according a DATA_TYPE oriented architecture and using the hierarchical properties of the EHR_EXTRACT document. To initialize the generation process, an EHR request is handled. The business logic was designed in
a modular way, considering the particularizations about the telemonitoring data but allowing the easy generalization of the system. Finally, the coordinated use of ISO/EN 13606 and ISO/TS 226000 standards was accomplished studying the requirements needed in terms of identification requirements and parameters of the request as proposed in Objective 10c. A blueprint for the implementation of the EHR provider was designed over this study.

- The proposed design was implemented as a proof-of-concept with ISO/IEEE 11073 PHD telemonitoring acquisition system as was proposing Objective 11. The acquiring system, and methodology was tested through the observation of the right integration of sent data from various fixed and mobile CDs, using different types of operating systems and through various transport technologies. The EHR Extract validation was firstly checked in a EHR demo client and, after that, with unrelated parties to the server development. The EHR communication security features were also tested but after various inconsistencies were detected, different modifications to the standard were proposed. These modification are believed to give greater internal coherence within the different parts of the ISO/EN 13606 standard. Tests, in the deployed system using the proposed modifications, were run and the validity of the EHR provider was based on the comparisons among the EHR responses provided by the EHR provider module and those provided by the EHR server to the same EHR request.

Finally, in this last Chapter, possible future lines will be proposed for this piece of work to continue as Objective 12 was proposing.

5.2 Future lines

As John Milton said: “Long is the way, and hard, that out of hell leads up to light”. However, “A journey of a thousand miles begins with a single step” (Lao Tzu). This is what this Thesis is intended to be. A small step.

Continuity of care, in the actual social situation, require of a change in various aspects more complex than the technological support of the health care process which, by the way, should be transparent to the physician. Health care centers are not prepared for addressing continuity of care in a proactive way, as they are more targeted to assist acute problems. However, as there is greater concern in this situation there is, therefore, a growing interest in the development of telemonitoring platforms. In this line of work, different possibilities can be suggested:
• The fine-grained semantic integrity in telemonitoring data. As pointed in Chapter 3, the features of the telemonitoring system which would acquire remote data (i.e. real-time, store-and-forward, etc.) must be taken into account for diverse considerations involving the integration process.

In this situation, the set-up of a unidirectional communication channel between patient and general practitioner is an important drawback in the health care process as there will not be a dialog, but a monologue, and therefore, all the answers of a possible question should be provided for the appropriate interpretation of the measurement (e.g. the temperature should be accompanied by a reference of where it was acquired: axillary, oral, etc.) or, even, for its validation. The number of elderly people who live on their own is increasing in the last decade and, consequently, it is needed to provide references of any information that indicates a fault in the acquiring process (e.g. you should be sat in a comfortable position when measuring your blood pressure and you should not have drunk coffee before acquiring it [244]). This might mean the interaction with non-medical devices: domotic devices, sensors, etc.

Although it is a clinical knowledge issue, different models can be provided using clinician’s assistance for these measurements, establishing which answers should be mandatory to provide and which “make extra points in the final score for the data quality”. The business logic bounded to all the possible answers would also need to be designed.

• Relevant medical conditions or those with a high prevalence in the society. Continuity of care is about medical conditions (i.e. diabetes, hypertension, heart failure, etc.) in which the monitoring of some physiological measurements are of great importance. Clinical guides for various medical conditions can be found in [245, 246]. In this context, the fine-grained semantic integrity of the telemonitoring measurements would be considered for the definition of their respective reports. These reports would also contain the information provided by other services and, therefore, a merge of various EHR_EXTRACTs followed by a selection of specific ENTRYs (or viceversa) would be required. In this type of report, a bottom-up methodology approach might be used as there are several physiological measurements common to various medical conditions.

Additionally, the relation among medical conditions should be questioned. Thus, suffering from diabetes increases the possibility to have an hypertensive disorder and, although is purely a medical criteria, in this more proactive shift the joint monitoring of some of the “side effect conditions” can be considered to preventively control their development. All of this considering each patient singularity.
• ISO/EN 13606 follow-up and contributions to its harmonizing process. Despite the unfamiliarity to security issues, some rifts in the cohesion among the ISO/EN 13606 parts were detected. These rifts should be corrected in the reviewing process that is being carried out to get a greater cohesion among the different documents.

In other lines of work, the system improvement might be pursued, looking for the technological improvement of the system features. Some of the test scenarios might include the comparison with other programming languages or, even, the application of mechanisms which are being used in different scenarios supporting a huge amount of data (e.g. facebook, tweeter, etc.) as the change to a noSQL database management system. It can also be questioned the use of ontologies to define domain concepts.

Furthermore, although out of the scope of these Thesis, a small reference to the EHR sharing projects needs to be done. Two main projects have to be considered: the Spanish project (i.e. el proyecto de Historia Clínica Digital del Ministerio de Sanidad, Servicios Sociales e Igualdad) and the european project (i.e. the epSOS project). The commissioning of high scale projects, like the ones presented, require of what is called “organizational interoperability” and as shown in [247] different barriers have to be downed. Both projects, which are in an advanced stage, have selected different standards to base the communication process as the aspired information to communicate was suiting a top-down approach. However, a study posing a bottom-up approach might be carried out. The utility of this study would be clear, at least in the Spanish project, where there is a highly similarity in the structure of the different reports and where various concepts are present in the most of them. Thus, defining this concepts as ENTRYs they could be re-used in various reports. Moreover, the way in which reports from both projects could be re-used in each other might be studied.
Bibliography


Bibliography


