FACULDADE DE ENGENHARIA DA UNIVERSIDADE DO PORTO

FEUP

Information Systems Architecture Definition for the Portuguese Electronic Health Record

Eduardo Filipe Garcia Pinto

Mestrado Integrado em Engenharia Informática e Computação

Supervisor: António Carvalho Brito (PhD)

13th July, 2012

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Approved in oral examination by the committee:

Chair: Doctor Gabriel de Sousa Torcato David
External Examiner: Doctor Carlos Manuel Azevedo Costa
Supervisor: Doctor António Ernesto da Silva Carvalho Brito

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Abstract

The Information Technologies have revolutionized many areas of society. Since many years ago, the health area has been searching for solutions to improve existing processes, having as the main objective the improvement of healthcare services. In this sense, the availability of patient clinical data can be vital to a more effective diagnosis and treatment, by a health professional. This information should be accessible regardless of context, place, time or where it was collected. In order to share this type of data, many countries have initiated projects implementing Electronic Health Record (EHR), including Portugal in 2010.

The EHR complexity and scope makes it a high cost and risk project. In fact, the inherent difficulties of a project like this are as critical as its importance and the impact it has on societies. The implementation of a successful EHR implies, in most cases, the involvement of all stakeholders, from patient to health organizations, along with the professionals themselves, becoming a very long and continuous process.

In the context of this dissertation we propose an architecture for implementing the Portuguese EHR. The proposed architecture should serve as a platform for sharing information between multiple health entities, normalizing processes, applying conventions and chasing interoperability among agents. The ability of the system evolution on one hand, and ease of integration in international projects on the other, were two major concerns to be taken into account throughout the proposal definition process.

This dissertation project was developed in straight collaboration with the Ministry of Health. The architectural proposal results basically from the application of some ideas of Metropolis Model and Service-oriented Architectures. This proposal advocates the delimitation of the platform scope with the goal of promoting the creation of value by the stakeholders through well-defined and standardised data services.

Despite of the pressure to obtain quick results, the research work concludes that it is possible to do some strategic adjustments and, with that, be able to accomplish quick wins without precluding the future met of requirements. However, the creation of an EHR is a continuous and long process that will extend for several years.

Keywords: Electronic Health Record; Health Information Systems; Interoperability; Information Systems Architecture; Portugal

Resumo

As Tecnologias de Informação têm revolucionado as mais diversas áreas da sociedade. Desde há muitos anos atrás, a área da saúde tem procurado soluções tecnológicas que permitam melhorar os processos existentes, tendo como principal objetivo a melhoria dos cuidados de saúde que são prestados. Neste sentido, a disponibilidade da informação clínica sobre um paciente pode ser vital para um diagnóstico e tratamento mais eficazes, por parte de um profissional de saúde. Esta informação deve estar acessível independentemente do contexto, local ou data onde foi coletada. Com o objetivo de providenciar este tipo de dados, muitos países iniciaram projectos de implementação de Registo de Saúde Electrónico (RSE), entre os quais se inclui Portugal, em 2010.

A complexidade e abrangência faz do RSE um projecto de altos custo e risco. De facto, as dificuldades inerentes a um projecto deste género fazem juz à sua importância e ao impacto que tem nas sociedades. A implementação com sucesso de um RSE é um processo longo e implica, na maioria dos casos, o envolvimento de todos os agentes intervenientes no processo, desde o paciente à instituição de saúde, passando pelos próprios profissionais.

No contexto desta dissertação propõe-se uma arquitectura para implementação do RSE em Portugal. A arquitectura proposta deve servir como uma plataforma de partilha de informação entre as mais diversas entidades de saúde, normalizando os processos e codificações nesta área e promovendo a interoperabilidade entre os agentes. A capacidade de evolução do sistema por um lado, e a facilidade de integração em projectos internacionais por outro, são duas grandes preocupações a ter em conta ao longo do processo de definição da proposta.

Este projeto de dissertação foi desenvolvido em estreita colaboração com o Ministério da Saúde. A proposta de arquitectura resulta da aplicação de alguns principios do modelo de Metropolis e das Arquiteturas Orientadas a Serviços. A proposta elaborada defende a delimitação do âmbito da plataforma, tendo como objetivo a promoção do processo de criação de valor pelas partes interessadas, através de serviços de dados bem definidos e padronizados.

Apesar da pressão para obter resultados rápidos, este trabalho de pesquisa concluiu que é possível fazer alguns ajustes estratégicos e, com isso, ser capaz de realizar ganhos rápidos sem que tal afecte os futuros requisitos. No entanto, a criação de um RSE é um processo contínuo e extenso que durará vários anos.

Palavras-chave: Registo de Saúde Eletrónico; Sistema de Informação da Saúde; Interoperabilidade; Arquitectura de Sistemas de Informação; Portugal

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Eduardo Pinto

"Architecture is a verb, not a noun"

Christ J. Kamages

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Abbreviations

ACES	Agrupamentos de Centros de Saúde (Healthcare Primary Institutions Groups)
ADL	Archetype Definition Language
ADM	Architecture Development Method
ANSI	American National Standards Institute
ARS	Administração Regional de Saúde (Health Regional Administration)
ARSN	Administração Regional de Saúde do Norte (Health Regional Administration of North)
CBSS	Community-Based Service Systems
CDA	Clinical Document Architecture
CIC	Comissão para a Informatização Clínica (Commission for Clinical Informatics)
CNPD	Comissão Nacional de Proteção de Dados (National Committee for Data Protection)
CSP	Cuidados de Saúde Primários (Primary Healthcare Services)
DICOM	Digital Imaging and Communications in Medicine
ECS	Emergency Care Summary
EDA	Event-driven Architecture
EHR	Electronic Health Record
EMR	Electronic Medical Record
FEAF	Federal Enterprise Architecture Framework
FEUP	Faculty of Engineering of University of Porto
GP	General Practitioner
HIS	Health Information Systems
HL7	Health Level 7
ICD	International Classification of Diseases and Related Health Problems
IHE	Integrating Healthcare Enterprise
IHTSDO	International Health Terminology Standards Development Organisation
IS	Information Systems
ISO	International Standardisation Organization
IT	Information Technology
LOINC	Logical Observations Identifiers Names and Codes
NHS	National Health Service
OSS	Open-source Systems
PDS	Plataforma de Dados da Saúde (Healthcare Data Platform)
PS	Patient Summary
RIM	Reference Information Model
RIS	Rede de Informação da Saúde (Health Information Network)
RNU	Registo Nacional de Utentes (Patients National Record)
SCR	Summary Care Record

SINUS	Sistema de Informação de Unidades de Saúde (Information System for Health Institutions)
SNOMED	Systematized Nomenclature of Medicine
SOA	Service-oriented Architecture
SOAP	Simple Object Access Protocol
SONHO	Sistema Integrado de Informação Hospitalar (Integrated System for Hospital Information)
TOGAF	The Open Group Architecture Framework
WHO	World Health Organization
XACML	eXtensible Access Control Markup Language
XML	Extensible Markup Language
ZF	Zachman Framework

Chapter 1

Introduction

The revolution and advent of technology has been changing the way people interact with each other, forcing the companies to adopt new business strategies, improving life's quality and so forth. In the organizations' context, the Information Systems brought a new opportunity for improving and optimizing processes, helping to generate value and profits and making them more competitive [GW91].

The health context is one of the most complex and critical, compelling the organizations to support several business processes and interacting with multiple stakeholders from clinicians to laboratory technicians. With such a complex scenario it seems easy to understand the impact that the technology might have, automating processes or sharing information among all the interested parties. However, this complexity obviously raises the risks of failing for projects implementation, either because the products do not meet the requirements, the stakeholders' expectations or were built excessively monolithic what preclude future integration and evolution [Chu06].

1.1 Background

Despite of the healthcare arena largeness and the inherent difficulties of comprehensive Information Technology (IT) projects, several concepts and platforms started appearing [Hau06]. For instance, seems reasonable to say that the patient clinical information should be available to its consumers when needed, whatever the place or time of the occurrence. The Electronic Health Record (EHR) concept is described [GT05] as the "longitudinal collection of electronic health information about individual patients and populations". The main objective is to provide clinical information about a patient where it needs to be consulted, independently of its origin or location, helping to avoid clinical errors or duplication of efforts and resources. It is supposed to be a mechanism for integrating healthcare information for the purpose of improving care quality [Ors08] but obviously, these EHR systems are as complex as the implementations challenges they face.

1.2 Context

The benefits of an EHR seem consensual and undeniable. All around the world, several countries started expensive programmes trying to implement partial or total EHR solutions, some being more successful than others.

The Portuguese health information systems suffer from the same problems [Del11] that probably most of the countries: all over the years, the systems were being created essentially to solve local problems. These systems were developed without any kind of concern about interoperability — designing and building the systems following standards and not precluding future communications and data sharing. The consequence is quite predictable: the multiple existing systems, which have many purposes, use different codification standards and several interfaces to allow communication, do not have the capability to "talk" with each other. Plus, even if they could communicate, they would not be able to understand each other since they do not use the same language to express themselves. As final consequence, there is a huge amount of clinical data that cannot be shared.

In 2010, the Ministry of Health signed a protocol with the Faculty of Engineering of University of Porto (FEUP) establishing a partnership for delivering some recommendations about the design and implementation for the EHR. This dissertation appears under the scope of that protocol.

1.3 Motivation and Objectives

Clements, Kazman and Klein advocate [CKK01] that "architectures allow or preclude nearly all the system's quality attributes". In this sense, when it is pretended to create a system where the quality attributes are critical, the architecture is certainly one of the most relevant means to assure and facilitate them.

The purpose of this dissertation is to build an architecture proposal to the Portuguese EHR. This architecture must allow the integration of the existing multiple Health Information Systems, as well as providing an infrastructure for sharing data. The proposal must promote the interoperability between different healthcare organizations, either by forcing the utilization of international standards and conventions or by establishing well-defined interfaces. The future evolution of the system must also be taken into account when designing the architecture proposal.

Despite the deliverable is an architecture proposal, the final objectives can be pointed out as follows:

- deliver an architecture proposal, able to offer a complete and integrated vision from the healthcare organization level to the EHR level;
- development a set of recommendations that fosters interoperability and sharing of clinical information between different healthcare institutions;
- describe the necessary changes in the applications architecture in order to allow new services integration and facilitate the creation of an EHR system.

The thesis research was done through a straight collaboration with the Ministry of Health, allowing to work close to the EHR stakeholders. In this sense, the weekly meetings with the responsible entities were used to discuss the main architectural issues.

1.4 Document Structure

In the present chapter we described the context, motivation and goals of this dissertation. The document has more 5 chapters:

- Chapter 2, *Information Systems Models and Frameworks* – small introduction about the HIS and try to understand what kind of methodologies may be used to facilitate the implementation of such large systems, using Enterprise Architectures. Then, we briefly describe three Architectural Styles which stand as excellent solutions to solve some kind of architecture issues;
- Chapter 3, *International Practices and Conventions* – description of some of the health international standards trying to understand what advantages one has and where should each one be adopted. Next, we overview the implementation of two EHR case studies, in England and in Canada;
- Chapter 4, *Structural Concepts and Architecture* – clarification of some essential concepts to the research as well as to characterise the actual situation and organisation of the national healthcare public service;
- Chapter 5, *Architectural Contributions* – description of the contributions done in the scope of the thesis. It starts with the presentation of five principles followed by the detailed contribution to each project defined by the responsible entities;
- Chapter 6, *Conclusions* – state some final considerations about the work done. It reflects about the problems that appeared and the solutions adopted and perspectives the mid-term future for the Portuguese healthcare system.

Despite the document is written in English, there will be some concepts that shall not be translate since they represent entities or project names. In that case, the first time it appears its literal translation will be inserted as a footnote.

Chapter 2

Information Systems Models and Frameworks

In this chapter we present a general study about how is it possible to build ultra-large systems. The Information Systems (IS) are a kind of large dimension systems. The development methods used to implement these systems are an important source of experiences and techniques relevant to this dissertation. The first section describes some Enterprise Architecture Frameworks and in the second one we introduce three Architectural Models.

2.1 Enterprise Architecture Frameworks

The concept of Enterprise Architecture appeared more than 20 years ago. At that time, the systems' complexity was growing with an exponential velocity. However, most of the times, those systems were not able to fulfil the business needs and the problem was not lack of technology or knowledge but difficulties in understanding the business from those who were developing it. Thus, the software development was facing two problems at a time: in one hand, the systems were becoming huge and hugely complex; on the other hand, the systems were developed with few concerns about business orientation [Ses07].

Despite of being a problem with a considerable age and very studied also, it did not stop growing and there is not a quite clear solution. A lot of enterprise architecture models appeared and disappeared over the years. However, it is estimated that a considerably percentage of market is dominated by this three methodologies [Ses07]:

- The Zachman Framework;
- The Open Group Architecture Framework (TOGAF);
- The Federal Enterprise Architecture Framework (FEAF).

In the next subsections, we will slightly describe each one of them, trying to understand which the advantages and weak points of each one.

2.1.1 The Zachman Framework

The Zachman Framework [Zac87] aims to guarantee that all stakeholders' perspectives are being taken into account when developing a complex software system. In general terms, it is important to understand if all the artefacts are sufficiently focused and if the existing artefacts clarify all the players, from the business owner till the database designer, keeping all the visions aligned.

In the original article and in order to explain his methodology, John Zachman uses an analogy between building an information system and construct a building. Thus, when constructing a building, the architect starts with understanding the general requirements as how many divisions it is supposed to have and the general purpose of the building, usually by using bubble charts. In a second phase, the architect's drawings aims to represent the links between each room of the building and also its general structure. Finally, the architect presents the plans and they must represent and reflect the customer requirements and expectations. These plans already include several details about electrical system, masonry, wood structure, etc. After plans arrive the contractor, they suffer some adjustments either because of costs/price or because another kind of constructing limitations.

In general, we can say that there are three fundamental architectural representations, one for each player in this process: the owner, the designer and the builder. Through all this process, the project will be documented in many perspectives. The architect starts listening to the customer and building his own perspective of the project that is sent to the builder, which in turn builds another view that allows himself to clarify some aspects. Despite of all these documents refer and describe the same project, each one of them has different purposes. Each one of them is unique and independent, describes one area, one perspective, not being possible from one of those to conclude about the others.

Originally, the proposal of Zachman was based on a policy of three questions: What?, How? and Where?, used to describe the product. However, the model has evolved and now it is based in three more questions: Who?, When? and Why?.

Just as it is possible to see in Figure 2.1, Zachman claims a classification of the existing artefacts from multiple points of view, identifying:

- **Material description** — the data model of the system: "entity - relationship - entity";
- **Functional description** — the process model of the system: "input - process - output";
- **Location description** — the network model of the system: "node - line - node";
- **People description** — the organization units and roles within the system: "organization - reporting - organization";
- **Time description** — the events of the system: "event - cycle - event";

	DATA *What*	FUNCTION *How*	NETWORK *Where*	PEOPLE *Who*	TIME *When*	MOTIVATION *Why*
Objective/Scope (contextual) *Role: Planner*	List of things important in the business	List of Business Processes	List of Business Locations	List of important Organizations	List of Events	List of Business Goal & Strategies
Enterprise Model (conceptual) *Role: Owner*	Conceptual Data/ Object Model	Business Process Model	Business Logistics System	Work Flow Model	Master Schedule	Business Plan
System Model (logical) *Role:Designer*	Logical Data Model	System Architecture Model	Distributed Systems Architecture	Human Interface Architecture	Processing Structure	Business Rule Model
Technology Model (physical) *Role:Builder*	Physical Data/Class Model	Technology Design Model	Technology Architecture	Presentation Architecture	Control Structure	Rule Design
Detailed Reprentation (out of context) *Role: Programmer*	Data Definition	Program	Network Architecture	Security Architecture	Timing Definition	Rule Speculation
Functioning Enterprise *Role: User*	Usable Data	Working Function	Usable Network	Functioning Organization	Implemented Schedule	Working Strategy

Figure 2.1: Zachman Framework classification model[1]

- **Motivation description** — the high level organization goals of the system: "node - line - node".

Over the years, this model started to be considered more like a taxonomy model, helping to frame all the artefacts and state their value and meaning to the multiple stakeholders [Ses07].

2.1.2 The Open Group Architecture Framework

First developed in 1995, The Open Group Architecture Framework was based on the US Department of Defense Technical Architecture Framework for Information Management (TAFIM). From this sound foundation, The Open Group Architecture Forum has developed successive versions of TOGAF at regular intervals and published them on The Open Group public web site [Jos11].

TOGAF might be seen as a process for building an Enterprise Architecture. This framework states this building process as a continuous process of building multiple architectures from highly generic to highly specific ones, until reaching the organizational architecture level [Ses07].

This framework splits the EA in four categories:

- **Business Architecture** — describes processes used by business to meet own goals;

- **Application Architecture** — describes how to build applications from the framework and how to interact with the other ones;

[1] Source: http://upload.wikimedia.org/wikipedia/commons/d/da/Zachman_Framework_Detailed.jpg

- **Data Architecture** — describes how the information is stored, organized and accessed;
- **Technical Architecture** — describes the hardware and software supporting the applications and their interactions.

One of the most important concepts of this framework is the Architecture Development Method (ADM), which stands as a reliable and proven approach for building enterprise architecture descriptions, keeping the progress close to the business specific needs. Actually, it provides an overall process template for architecture development activity and a narrative of each architecture phase, describing each one in terms of objectives, approach, inputs, steps and outputs to the architects [LZ06].

The TOGAF ADM also provides several guidelines and techniques:

- **Architecture Content Framework** — detailed model for architectural work products, including deliverables and artefacts;
- **Enterprise Continuum** — a model for structuring a virtual repository and classify architecture and solution artefacts, tracking how the artefacts evolve and how they can be re-used;
- **TOGAF Reference Models** — two reference models: Technical Reference Model (TRM) and Integrated Information Infrastructure Model (III-RM);
- **Architecture Capability Framework** — a set of templates, guidelines, resources that aim to help the architect establishing some practices within an organization.

In overall terms, TOGAF ADM recommends an iterative process for architecture development, not being prescriptive on breadth of coverage, level of details or time horizons. The architect determines those details to fit one specific project. One of the most important characteristics of TOGAF ADM is that, despite of having well-defined phases, it enough flexible to be adapted to the organization and to let architects build the best approach to implement TOGAF [TH04].

2.1.3 Federal Enterprise Architecture Framework

The Federal Enterprise Architecture Framework appeared with the objective of serving as a platform for sharing processes, information and documentation among the U.S. Federal Agencies and other government agencies. This framework gathers two main characteristics of the two previous: in on hand, it defines a taxonomy – similar to the Zachman Framework (Section 2.1.1) – for artefacts classification; on the other hand, it suggests a process for building and implementing the architecture like TOGAF (Section 2.1.2) does.

The FEAF partitions a given ‘platform’ into business, data, applications and technologies architectures, aiming to take those into account when applying the process of implementing the new architecture. Furthermore, the framework is organized in four levels [TH04]:

- Level I — the highest level which deals with the architecture drivers or external stimulus fetching the strategic direction of the architecture. It facilitates the transformation from the

original architecture to the new one by applying architecture standards and managing the process;

- Level II — an analyses of the business goals, direction, principles, strategies and priorities;
- Level III — expression of architecture in more detailed view by using business data, applications and technology views to model it;
- Level IV — representation of Data Architecture, Application Architecture and Technology Architecture using a combination of Zachman Framework and Spewak's Enterprise Architecture Planning methods.

FEAF also suggests a measurement process, being able to evaluate the maturity the inner organizations are adopting and implementing the enterprise architecture. This evaluation classifies the agencies measuring three essential attributes:

- Architectural completion — the maturity of the architecture itself;
- Architectural use — how is the architecture being used to improve efficiency of decision-making;
- Architectural results — the benefits brought by the use of the architecture.

Based on the analysis of this three attributes, the agencies are then rated in one of three categories: green, yellow and red.

2.2 Architectural Styles

An Architectural Style is a particular pattern that organizes components and connectors in a particularly form, providing a well-known reliable solution when facing a specific kind of problem [Kaz]. Each architectural style principle influences some quality attributes in a positive and some other in a negative way. Zheng Qin *et al* define it as "a solution to solve a certain class of problems which have common quality attributes requirements", stating also that "there is no architecture style that is proper for all systems, because every system have different quality attributes requirements" [QZX08]. Kim and Garlan advocate [KG10] that these concepts bring a number of significant benefits as they promote design reuse.

2.2.1 The Metropolis Model

Over the last years, two important trends are changing business and society: in one hand, the growing use of shared knowledge to create high-value services and projects; on the other hand, the growing preponderance of services. The businesses are evolving from a product-oriented perspective to a relation-oriented one. This change of paradigm brought the client to the middle of the business, helping to create value. The greatest examples of this new philosophy are the systems

based in communities as Wikipedia or Facebook, that are able to generate profit and value directly from its users.

The Metropolis Model [KC09] appears as an attempt of describing really huge complex systems built from two basilar concepts: Open-source Software (OSS) and Community-Based Service Systems (CBSS). Despite the growing importance of OSS and CBSS, there will always be some systems that cannot be developed by crowds, either because of the business criticality or for demanding unquestionable security guarantees. The Metropolis Model does not really apply to those systems.

We will start with an explanation of the "crowdsourced systems" and then briefly describe the principles of the Metropolis Model, always following the original article wrote by Rick Kazman and Hong-Mei Chen [KC09].

2.2.1.1 Crowdsourced Systems

The Metropolis Model identify its target as the "crowdsourced systems". This concept includes the kind of systems with some special characteristics:

- open teams — meaning that the assumption of having a closed and dedicated team of programmers should be abandoned;
- "mashability" — as the capacity of composing and integrating different systems and functionalities since that the consumption of software by one person or project does not make it less available for consumption by another;
- conflicting, not knowable requirements — the requirements emerge from the contributors and the users, making them highly unpredictable and often being in conflict between each other;
- continuous evolution — as a consequence of constant changing requirements and distributed resources, these type of systems are never finished nor stable, introducing the "perpetual beta" concept. The development of the project is done through multiple iterations empowering the users with the responsibility of testing and assuring its quality;
- focus on operations — the availability of its operations are, most of the times, as critical as their utility and, in that sense, it is not accepted any kind of system downtime (Amazon, eBay or Google are good examples);
- sufficient correctness — the notion of 'perpetual beta' expresses the idea of acceptance some incompleteness in software (e.g. Wikipedia);
- unstable resources — one of the most interesting facts is that, despite of the volatility of people, information and other resources that individually would be useless, when massive congregated are able to create reliable, stable and impressive computational powered systems;

- emergent behaviours — frequently, there are behaviours and tendencies that emerge from the system that are completely unexpected. In these systems, unlike the traditional ones, the crowds take the rudder and bring to the system unpredicted kinds of utilization or interaction.

2.2.1.2 The principles

The Metropolis Model presents a new unified vision between the CBSS and the OSS, focusing deliberately in the crowd value generation. This model suggests the creation of two levels: the kernel services and the periphery services. It states that the application's kernel may be developed using traditional methods.

The Metropolis Model is supported by the application of some principles:

- **Crowd engagement and egalitarian management of open teams** — the management must focus the people and the crowds, engaging the users for value co-creation. The engagement is not just a system-level issue, but a question of business strategy. These kind of system resort to crowd-sourcing chasing "potential for cost reduction, increased innovation, and quicker development time for delivering products and services that meet customer needs" as the authors explain;
- **Bifurcated requirements** — the requirements must be distinguished into kernel or periphery ones. The kernel should "deliver little or no end-user value" (e.g. Linux kernel, Wikipedia wiki or Facebook application platform). On the other hand, from the periphery appears most of the end-user value, as it happens with Wikipedia articles or Facebook applications;
- **Bifurcated architecture** — the architecture of these systems are composed by the kernel infrastructure and the peripheral services. Since the kernel must be designed and implemented to be stable and promote the integration of several components, it must not emerge from the use of the system;
- **Fragmented implementation** — the crowd-sourced philosophy must be applied only to the peripheral services. The kernel implementation shall be done by an "close-knit, highly motivated, coordinated team", ensuring its high quality.
- **Distributed testing** — while the kernel must be highly reliable and constantly tested, in the peripheral services it is only necessary the sufficient correctness;
- **Distributed delivery/maintenance** — at the kernel level, it is important to preserve backwards compatibility when deploying a new version. At periphery the release mechanisms are uncoordinated and form a constant stream;
- **Ubiquitous operations** — these systems are "always on" even when they are being upgraded. Also, they should monitor self state and create control mechanisms not allowing peripheral problems to affect the system's core.

2.2.2 Service-oriented Architectures

A Service-oriented Architecture (SOA) is "an architectural style that emphasizes implementation of components as modular services that can be discovered and used by clients" and that "emphasis on loose coupling between interacting services" [ST05]. However, as Thomas Erl stated [Erl05] there is no single definition of SOA. Instead, there are many opinions about what constitutes service-orientation. Erl advocates that the service-orientation paradigm has it "roots in a software engineering theory known as separation of concerns". Obviously, this concept has been applied in many contexts and to many platforms, from object-oriented programming till component-based programming approaches.

The service-orientation paradigm has no official principles. Although, there are "a common set of principles most associated with service-orientation" [Erl05]:

- **Services are reusable** — the services are designed to promote and support their reuse, regardless of whether immediate reuse opportunities exist;
- **Services share a formal contract** — in order to be possible to share, there is a necessity for stablish the terms of information exchange;
- **Services are loosely coupled** — services must be designed to avoid dependency outside itself;
- **Services abstract underlying logic** — the only part visible to the outside is the interface and the requirements that need to be met to obtain the service, and that are clarified in the contract's description;
- **Services are "composable"** — services might be aggregated with the finality of creating larger services, obtaining different abstraction levels and promoting re-utilization;
- **Services are autonomous** — the service is governed within an explicit boundary not being dependent to perform its operations;
- **Services are stateless** — services should not be required to manage state information as that might preclude their ability to stay independent and not coupled. The concerning about maximizing the statelessness must be central.

To conclude, as Srinivasan and Treadwell advocates [ST05] "service-orientation reinforces general software architecture principles such as encapsulation, modularization and separation of the interfaces from their implementations".

2.2.3 Event-driven Architectures

The Event-driven Architectures (EDA) are based in the event concept. An event [Mic06] is a notable thing that starts inside or outside the system and may consist in a problem, an opportunity and so forth. The event meaning should be defined in the business context. In an EDA, when an

event is triggered it is immediately disseminated to every interested parties [QZX08]. Then, these parties evaluate the event and might either call a service, trigger another component or simply take no action.

This architectural pattern promote loosely coupled and highly distributed systems. In fact, the creator of the event only has the task of dispatching it. From that point on, the creator loses track of the event, not knowing nothing about the post processing or even who are the interested parties. Usually, these architectures are defined by three main concepts:

- event trigger — triggers the event sending it to the event collector;
- event collector — redirects the received events to the interested parties;
- interested party — receives the event information and proceeds in accordance, calling another component or service;

This basic structure might be scaled, allowing to organize and build much complex systems.

To conclude, it is important to say that these architectures are advisable to be used for asynchronous flows of work and information. Also, these architectural styles easily combine for creating robuster solutions [Mar06, LC08].

Chapter 3

International Practices and Conventions

In this chapter, the objective is to present the main Health International Standards for interoperability, helping us to understand which options there are to allow the systems to properly share, interpret and store data. In addition, we analyse two EHR implementations case studies, from Canada and England.

3.1 Health International Standards

The pursuit of interoperability is not possible without the clearly definition of common languages and communication channels. These common languages are called standards and are usually created and managed by independent organizations.

3.1.1 Health Level Seven International

Health Level Seven International (HL7) is one of several accredited organizations of American National Standards Institute (ANSI), operating in the healthcare area. HL7 provides a set of standards towards interoperability, aiming to facilitate knowledge transfer among several stakeholders: healthcare providers, government agencies, patients and so forth [Sev].

3.1.1.1 HL7 Messaging Standard

One of the most used standards is the messaging one. The HL7 Messaging Standard appeared several years ago and had been evolving along the last two decades. Several institutions adopted and implemented it all over the world, most of the times investing lots of time and money to achieve it. Dave Shaver stated some interesting numbers [Sha10] about the utilization of the different standard versions, which are resumed in Figure 3.1. By observing the Figure 3.1, we can easily conclude that "the vast majority of HL7 messaging is done using messages that approximate

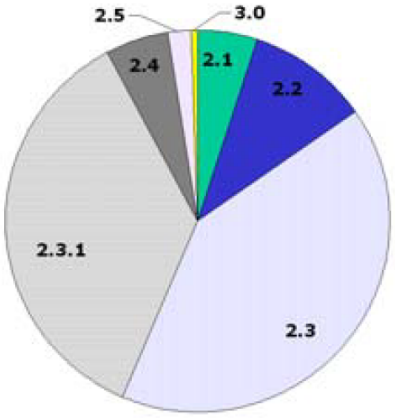

Figure 3.1: Approximate real-world usage of HL7 messaging standards [Sha10]

HL7 2.3 or HL7 2.3.1" unlike the newer ones (2.5 or greater and 3.0) that represent a "very small portion of real-world interfaces" [Sha10].

3.1.1.2 HL7 Messaging Standard Version 2

The HL7 v2 is a standard created several years ago. Nevertheless, it had evolving into some new versions. Currently, HL7 v2 is at version 2.7. However, as it was designed as backwards compatible, the version is not so relevant. In fact, what is often more important is how the system which is sending the message is populating the fields and segments the standard defines.

The HL7 v2 stands as a simple protocol for exchanging clinical data and it stands as the most widely used healthcare information standard [EAR+05]. Certainly, one reason for that is that the referred messages are plain text, with several fields split by the vertical slash character '|' as it is possible to observe in Figure 3.2.

However, some authors advocate that "the messages lack a formal underlying reference model, and feature considerable optionality in addition to permitting user-defined elements". In fact, that excessive flexibility obliges to establish a prior agreement structure and interpretation that might be called "negotiated interoperability" [AKPW10]. Obviously, this vagueness "provides great flexibility but necessitates detailed bilateral agreements among the healthcare systems to achieve interoperability" as state Eichelberg *et al* [EAR+05].

In this context, it is important to clearly identify the main advantages of using HL7 v2, which we point out next [AKPW10]:

- richly expressive data types;
- support for arbitrary structured objects;
- easy to adopt and use with low cost.

As expected, there are some arguments against also, which are:

[1]Source: http://www.interfaceware.com/images/ACKMessageAnatomy.png

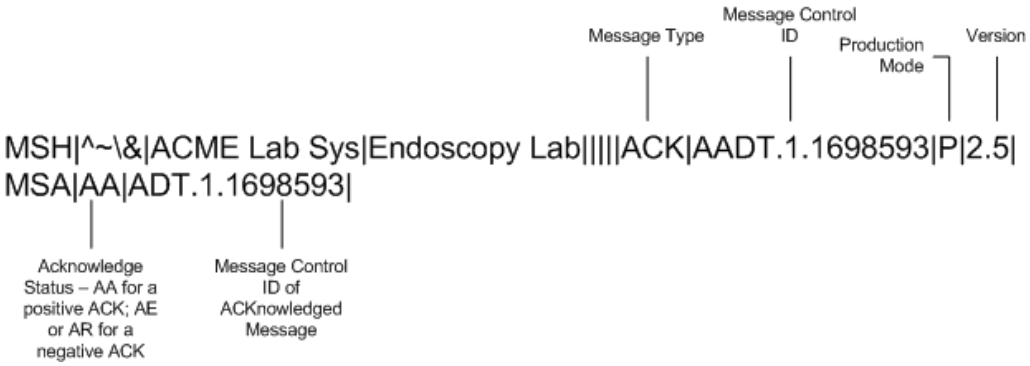

Figure 3.2: Example of an HL7 v2 acknowledgement message[1]

- excessive flexibility and optionally in message interpretation implies a "negotiated interoperability";
- lack of privacy and consent guarantees;
- growing tendency to abandon v2 in favour of v3.

To conclude, despite of being an exceeded standard it is still very relevant, being used world wide.

3.1.1.3 HL7 Messaging Standard Version 3

The HL7 v3 appeared as a natural evolution of HL7 v2, trying to solve some problems that the previous version had. Its first version was launched in 2005. Despite of being just a new release, this update means significant standard modifications as the main objective was to "establish semantic interoperability in loosely coupled systems" [AKPW10]. In this sense, at the core of this standard just appeared the Reference Information Model (RIM).

The RIM is an object model created as part of the Version 3 methodology, serving as a context provider to the multiple healthcare concepts. For instance, a WBC (white blood count) may refer to an order (intent) or a result (observation). In that case, the RIM structures "implement the context by binding the coded vocabulary term from the ontology to a specific place in the model" [Sha04].

With HL7 v3, the messages are no longer plain text but XML files (as we can see in Figure 3.3) which turns the message more human-readable but also more structured and rigid.

There are some advantages that should be credited to this Version 3, which are important to summarize [AKPW10, Sha10]:

- rich in clinical semantics;
- address many of the practical difficulties such as incomplete information, uncertainty, duplicate records and so forth;
- dynamic model no more complex than v2;

```
<identifiedPerson>
   <!-- Primary id as used/known by this registry -->
   <id extension="000197245" root="2.16.840.1.113883.19.3"/>
   <addr use="H">
     <streetName>Randomroad</streetName>
     <houseNumber>25a</houseNumber>
     <postalCode>1200</postalCode>
     <city>Anytown</city>
   </addr>
   <telecom use="H" value="tel:555 3542557"/>
   <statusCode code="active"/>
   <identifiedPerson>
     <name use="L">
       <given>Patricia</given>
       <family>Patient</family>
     </name>
     <administrativeGenderCode code="F" codeSystem="2.16.840.1.113883.5.1"/>
     <birthTime value="19750103"/>
     <maritalStatusCode code="F" codeSystem="2.16.840.1.113883.5.2"/>
   </identifiedPerson>
   <assigningOrganization>
       <!-- Scoper, the registering organisation -->
       <id extension="1002777" root="2.16.840.1.113883.19.200"/>
       <contactParty nullFlavor="UNK"/>
   </assigningOrganization>
</identifiedPerson>
```

Figure 3.3: Example of an HL7 v3 message [Spr07]

- “less expensive to build and maintain mid-to-long term interfaces”;
- “more of a ‘true standard’ and less ‘framework for negotiation”’;
- the long journey of maturing and reflecting about the standard.

Notwithstanding of the several advantages, there are some drawbacks that can be identified [AKPW10, Sha10]:

- not clear where the return of investment is since it does not offers substantial advantages over v2 for some areas (simple alerting, drug interaction checking, recall systems, best practice guidelines, clinical pathways, and so forth);
- message structures complex and difficult to understand;
- “inconsistencies between an Information Model (objects document things) interpretation and a Reference Ontology (objects are things) interpretation”;
- not suitable as a model for storage EHR information and does not specify and EHR Architecture neither;
- unclear how is it possible to query a v3 messages repository;
- absence of compatibility with HL7 v2;
- expensive and slow adoption.

In an interesting research by Gartner in 2006, Rishel predicted that "the HL7 V3 messages will fail to achieve critical mass, being replaced by ever-more-elaborate use of V2, a series of dialects of V3 chosen by individual countries and large enterprises, or the work of other standards organizations that may achieve less semantic interoperability while being easier to implement" [Ris06].

To complete, the HL7 v3 seems the natural evolution for the applications using the previous versions. Although, that migration will take many years and it might not be so pacific as would be desirable.

3.1.1.4 Clinical Document Architecture (CDA)

Clinical Document Architecture (CDA) is an ANSI-certified standard from HL7 organization. The first version (Release 1.0) was released in November, 2000 and the second (Release 2.0) was published with the HL7 2005 Normative Edition. [Sev] CDA defines the semantic and structure of clinical documents aiming to allow its exchanging. The CDA documents are actually XML documents. That concept is derived from the fact that these documents "derive their meaning from the HL7 Reference Information Model (RIM) and use the HL7 Version 3 Data Types which are part of the HL7 RIM" [AKPW10].

The CDA document is constituted by two parts, an header and a body. The header is used to unambiguously state the semantics of each entry in the document. The body "contains the clinical document content and can be either an unstructured text, or comprised of nested containers" [EAR+05].

It is important to distinguish the two versions of this standard, since there are many applications that still use the first version. The main characteristic of CDA standard is the documents classification into three different levels, although the interpretation of them is differentiated between the two versions.

The CDA Release One considers two levels [Sev, EAR+05]:

- Level One — basically it has a standardized header and additional information on the rest of the document;

- Level Two — allows to define and constraint both the structure and the content of the document, favouring the interoperability between systems since the receiver knows what to interpret;

The approximation of CDA Release Two is a little different. In fact, it provides an incremental approach, allowing and encouraging the documents to evolve and becoming more structured. One of the major additions is that the CDA body "uses RIM structures and controlled vocabulary to permit a much higher level of semantic interoperability" [Sev]. Atalag *et al* advocate that it is a "stable and flexible standard for developing communications with coded information" as well as "provides a pathway from narrative free text documents through incrementally coded data to fully coded and semantically interoperable clinical data" [AKPW10].

3.1.2 The openEHR

The openEHR standard is a standard owned by the openEHR Foundation, created in 2002. The Foundation is a non-for-profit organization with the founding partners being University College London and Ocean Informatics, an Australian company. The main objective is to research and develop interoperable electronic health records related topics, aiming to improve the care quality to patients [Les07].

Unlike other standards, openEHR develops specifications for implementing full EHR systems, pronouncing more in persistence as opposed to messaging. openEHR states that, in order to achieve lifelong, patient centred, secure and shareable EHR, the way cannot be the aggregation of messages [Bea02].

In order to provide an high level of interoperability, openEHR suggests the engaging of standardized clinical content models (called Archetypes), a stable reference model and semantically rich terminologies [AKPW10]. More in detail, Bale advocated a two-level methodology to model the EHR structure. In the first level, the existence of a generic reference model, specific to the healthcare domain but sufficiently general to be stable over the time (e.g. role, act, entity and so forth). In the second level, there were concepts mapped as archetypes, such as blood pressure, laboratory results and so on. The archetypes apply "constraint rules that specialize the generic data structures that can be implemented using the reference model" [Bea02].

Beyond the reference information model, the openEHR framework includes other resources that help the implementation following this standard, such as the ADL (Archetype Definition Language) language for expressing archetypes, an archetype library and a collection of open source implementations. As an example (Figure 3.4), we can restrict a generic Observation class to, for example, a Blood Pressure archetype.

3.1.2.1 Advantages and Disadvantages

There are some interesting characteristics about openEHR that might be useful to underline [AKPW10]:

- intuitive and understandable model for clinicians;
- approach based on recording and querying observations;
- extracts can be sent with HL7 v2 (see 3.1.1.2);
- likely stable reference model over the time;
- possibility to convert archetypes into CDA documents (see 3.1.1.4).

On the other hand, Atalag *et al* identified some arguments against either [AKPW10]:

- "lacks semantic rigour and does not contain a logically sound ontology";
- works well with simple scenarios, but does not easily handle complexity;
- no experiences with medium to large-scale systems;

```
OBSERVATION[at1000.1] matches {-- complete blood picture
 name matches {
     CODED_TEXT matches {
         code matches {[ac0001]}  -- complete blood count}}
 data matches {
     LIST_S[at1001] matches {-- battery
        items cardinality matches {0..*} \epsilon {
          ELEMENT[at1002.1] matches {-- haemaglobin
               name matches {
                 CODED_TEXT matches {
                     code matches {[ac0003]} -- haemaglobin}}
               value matches {
                  QUANTITY matches {
                     value matches {0..1000}
                     units matches {^g/l|g/dl|.+^}}}}
          ELEMENT[at1002.2] occurrences matches {0..1} matches
      {-- haematocrit
               name matches {
                  CODED_TEXT matches {
                      code matches {[ac0004]}-- haematocrit}}
               value matches {
                   QUANTITY matches {
                       value matches {0..100}
                       units matches {"%"}}}}
          ELEMENT[at1002.3] occurrences matches {0..1} matches
      {-- platelet count
               name matches {
                  CODED_TEXT matches {
                      code matches {[ac0005]} -- platelet count}}
               value matches {
                   QUANTITY matches {
                       value matches {0..100000}
                       units matches {"/cm^3"}
                      }}}}}}}
```

Figure 3.4: The ADL definition of Complete Blood Count archetype [EAR+05]

- weak governance of the openEHR Foundation.

To conclude, the interest with this standard is spreading worldwide. There is an increasing number of full or partial implementations of the openEHR specifications in several countries, like United Kingdom, Sweden, Australia, Denmark, The Netherlands, Singapore, USA, Japan, Brazil, Scotland or Turkey. However, there is not a really large-scale systems in neither of these countries and the use of the standard consists of using some of its concepts [AKPW10]. In another interesting article, Marta Silva and José Carvalho state that the "openEHR standard has original and sound fundamental concepts that definitely will influence future generations of health information systems" as long as note that "some openEHR core beliefs are highly debatable". Also, they raise some questions about the applicability of semantic interoperability "when the industry all over the world is struggling in exchanging basic unstructured demographic and clinical data through the complex network of health providers". [SC11]

3.1.3 Integrating Healthcare Enterprise

The Integrating Healthcare Enterprise (IHE) [Ent] is an initiative from healthcare professionals and industry that work to improve the way health care systems share information electronically.

The group was formed in 1998 as a cooperative venture by the Healthcare Information and Management Systems Society (HIMSS) and the Radiologic Society of North America (RSNA) with the goal to promote interoperability among imaging and health care information systems.

IHE is an international organization that focuses on the development of open and global IHE Integration Profiles and on the regional deployment of interoperable IT systems. IHE encourages the use of established interoperability standards such as HL7 and DICOM.

3.1.3.1 IHE Profiles

IHE strives to solve specific integration problems faced by its membership in the real world through Integration Profiles. These profiles define the systems involved (i.e., actors), the specific standards used, and the details needed to implement the solution. Each profile offers developers clear communication standards that have been reviewed and tested by industry partners. A group of systems that implement the same Integration Profile address the need/scenario in a mutually compatible way. Some examples of IHE Profiles are:

- Cross-enterprise Document Media Interchange (XDA) – transfers documents and meta-data using CDs, USB memory or email attachments;
- Cross-enterprise Document Reliable Interchange (XDR) – exchange of health documents between health enterprises using a web-based, point-to-point push network communication;
- Patient Identifier Cross Referencing (PIX) – cross-referencing multiple local patient IDs between hospitals, sites, health information exchange networks, etc.

3.1.4 Digital Imaging and Communications in Medicine

DICOM (Digital Imaging and Communications in Medicine) is an worldwide used standard for medical image communication. The standard provides data structures and services allowing the exchange of medical images and related information. In the actual structure, the standard is available since 1993, despite the creation remounts to 1983.

Unlike most of other EHR standards, the DICOM uses a binary encoding. Pianykh has an interesting point of view, saying that “contrary to popular belief, DICOM is not just an image or file format” but “an all-encompassing data transfer, storage, and display protocol built and designed to cover all functional aspects of digital medical imaging” [Pia08].

Other authors stated that “it has become a leading standard used by all major vendors of diagnostic medical equipment”, predicting also that “DICOM will soon be used in every medical branch that utilizes imaging, for example: cardiology, mammography, radiology, surgery, endoscopy, dentistry, pathology, etc” [MDG08].

3.1.5 Terminology and Ontology Standards

The need of data sharing between different healthcare institutions leverage the creation of multiple standards, attempting to allow, not only the data sharing, but also the easy interpretation of

the message's content. in fact, this kind of internationally endorsed classifications facilitate the storage, retrieval analysis and interpretation of data. In this sense, in the next subsections we will present some terminologies that were created with the aim of making the systems understand each other.

3.1.5.1 Systematized Nomenclature of Medicine - Clinical Terms

SNOMED CT (Systematized Nomenclature of Medicine - Clinical Terms) was created in 2006 by the International Health Terminology Standards Development Organisation (IHTSDO). This standard aims to provide a unique and embracing system with clinical terms. The objective is to have a repository, managed and updated centrally, available to all systems which adopted it and that can be used either to clinical purposes as to research projects. [ACS09]

Citing the official site, the SNOMED CT "provides the core general terminology for the electronic health record (EHR) and contains more than 311,000 active concepts with unique meanings and formal logic-based definitions organized into hierarchies" and "can be used to represent clinically relevant information consistently, reliably and comprehensively as an integral part of producing electronic health records" [IHT].

3.1.5.2 International Classification of Diseases

The International Classification of Diseases (ICD) [WHO] is "the international standard diagnostic classification for all general epidemiological, many health management purposes and clinical use". This standard is owned by the World Health Organization (WHO) and dates from 1850, being developed and reviewed every ten years. Although, every year new updated are release to the versions in use. The ICD provides an huge variety of codes to classify diseases, body signals, symptoms, abnormal aspects, complaints, social circumstances and external causes of injury or illness, beyond to having an additional classification used to classification of transplants and newborns and so forth.

ICD is a classification, and a essential one, as it define the universe of entities to be studied, and highlight the relevant aspects of the information that has been collected. Also, it allows their comparison in several contexts: within and between populations over time and the compilation of internationally consistent data.

3.2 International Case Studies

Several Electronic Health Record projects were initiated in multiple countries. The study of same of those might be fundamental in order to understand what can we learn with them. By doing that, it will help us to extend our horizons, retain the bad experiences and better evaluate some options that we might have to take.

In the next subsections, we will provide an overview by two EHR initiatives: the Canada Health Infoway and the National Health Service (from England).

3.2.1 Canada Health Infoway

Canada Health Infoway is an non-for-profit organization founded by Canada's First Ministers in 2001. It was specifically created to accelerate the process of development of Electronic Heath Record systems, promoting the adoption of standards that guide to communication facilitation between different healthcare organizations.

In order to guide the development of the systems in each different province, Infoway provided a national framework called EHR Blueprint. The EHR Blueprint is a set of principles, guides and components. It states "a comprehensive description of the components necessary for the interoperable EHR and describes, in broad terms, how the components are envisioned to work together" [Inf06].

3.2.1.1 Sharing EHR Information

In the process of building an EHR, there are several methods to allow sharing EHR information along several services, consumers and providers. EHRS Blueprint advocates that the best method (at least for their reality) is the creation of a shared reference information source that is populated by several health-care organizations around Canada. This reference is populated with clinical relevant data and is maintained externally from ever health-care organization (or Points of Service, as designated in EHRS Blueprint). The Points of Service (PoS) are able to reference or pull data from the shared repository.

The 'EHR Infostructure' is based on achieving full integration and interoperability between the EHR Solution and each PoS. In order to do so, EHRS Blueprint has a Health Information Access Layer that provides the interface which all the PoS communicate with. However, since EHRS Blueprint defines an unique interface for all PoS, most of these systems needed to adapt themselves to respect the standards and be able to stay connected to the system.

This shared reference presupposes the existence of peers along each different Canada's jurisdiction. These peers represent several copies of the EHRi in terms of structure, but dealing only with the local PoS. As the infrastructure is the same, the process of retrieving information from other peers, when needed, is relatively simple.

3.2.1.2 Architectural principles

The EHRS Blueprint states [Inf06] some architectural principles which guided the EHRs implementation. However, we will just point out the ones that might be more relevant and interesting at this point.

The fact of the EHR Infostructure information being stored as copy of the original one is a key characteristic, as it preserves independence between the EHRi and the PoS.

Another relevant principle is the controlled environment built around the system, defining one common interface and transforming EHRi into a black-box in which PoS can retrieve but also update clinical information for a specific patient.

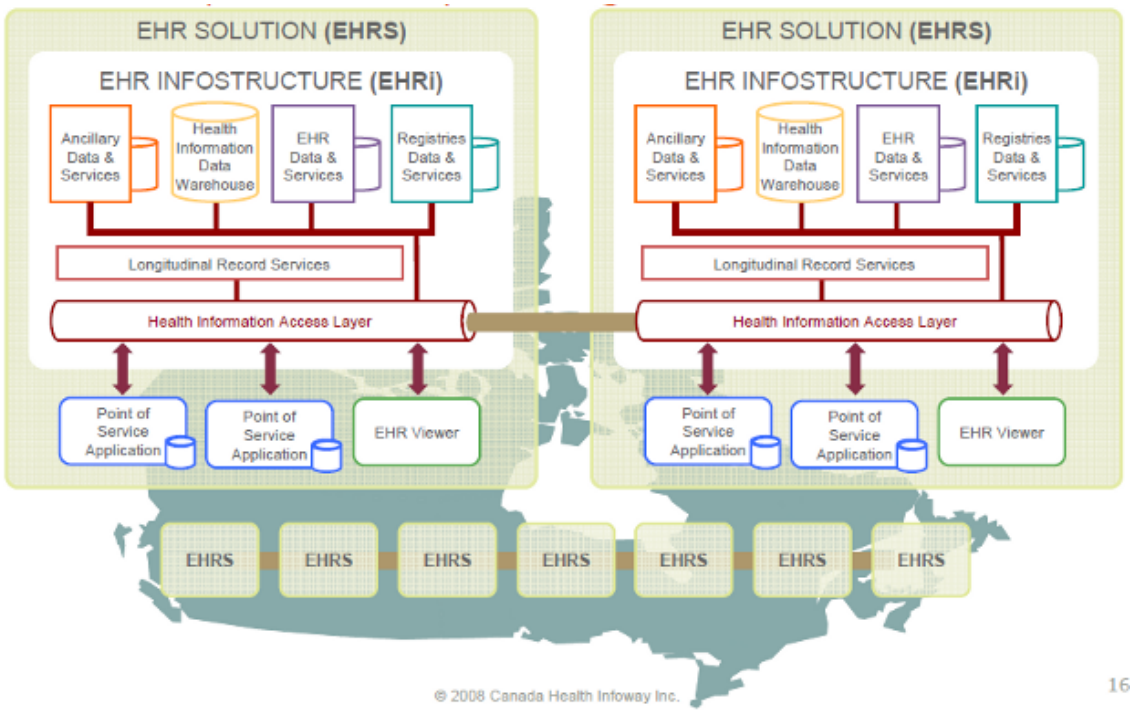

Figure 3.5: EHRS Blueprint Architecture overview [Inf]

The EHRS Blueprint was built following an Services Oriented Architecture, making the architecture more flexible and the components reusable.

Another interesting fact is that there is no single 'home' for the patient's electronic health record. Actually, each jurisdiction's EHRi holds and owns the data generated in health services from that jurisdiction.

3.2.1.3 Key elements

The EHR Blueprint has multiple components with certain characteristics. Although some of those had been already referred, it is useful to take a deeper look at them and point out some others also. Thus, the key elements are [Inf06]:

- **Point of Service Applications (PoS)** — these are software applications or information systems that provide clinical information to the EHR system, working as gateway for gathering critical patient data, absolutely fundamental to the system's purposes. It is important to notice that these systems are responsible for most collection of the patient's EHR data. Here, we refer to applications as an information system in hospital emergency department as well as an local pharmacy system and further so;

- **EHR Data Repositories** — sometimes, there is relevant clinical information that is no available in the PoS applications despite of being very relevant in a clinical decision making context. Instead, it is usually available through other systems. In this sense, the PoS applications are also responsible for pushing the data into these EHR Data Repositories – that

become responsible for storing it and keeping it available to the users that might need that. Four logical clinical domain repositories are identified by EHRS Blueprint: Shared Health Record, Drug Information, Diagnostic Imaging and Laboratory;

- **Registry Services** — there are the information linkers. There Registry Services provides the identification of patients, matching them with the required clinical data. In order to guarantee the match of required and retrieved information, these services offer: Client Registry, Provider Registry, Location Registry and Terminology Registry;

- **Longitudinal Record Services (LRS)** — as we saw in Subsection 3.2.1.1, the EHRS Blueprint is based on distributed data repositories. Thus, when it is needed to retrieve and show the information to the user (for instance, a physician), all the data must be gathered as if it was stored in the same place. These Longitudinal Record Services execute that task, bringing together data from different registries and sources, normalizing it for common understanding;

- **Health Information Access Layer (HIAL)** — it provides a single standardized way of sharing and retrieving data from EHRi. The fact of being unique and the single entry point obligates the PoS applications to adapt themselves to the interface but also to the information standards also.

3.2.2 England National Health Service

The National Health Service (NHS) Connecting for Health is part of the UK Department of Health. This organization was created on 1 April 2005 as the replacement for an older one (NHS Information Authority). It has the responsibility of managing and implementing the NHS National Programme for IT (NPfIT). The NPfIT was an initiative to upgrade the NHS to a centrally-mandated electronic health record for patients, connecting hundreds of hospitals and thousands of healthcare professionals and providing them relevant patient data by secure and certified means.

3.2.2.1 Architecture overview

The NPfIT has born as the world's largest civil information technology project, committing £12.4 billion over 10 years in order to improve the quality of healthcare in England. As expected, such a big project could not be just a single standalone implementation. In fact, the NPfIT is made of eight separated systems, which are [Bre05]:

- **One National Application Service Provider (NASP)** — designed to support the 'National Data Spine', which was destined to keep the patients' electronic data;

- **A New National Network (N3)** — a network connecting all the hospitals, applications and other healthcare providers, characterized by the need of being a really broadband one. It would be an essential infrastructure supporting and linking all the other services providers;

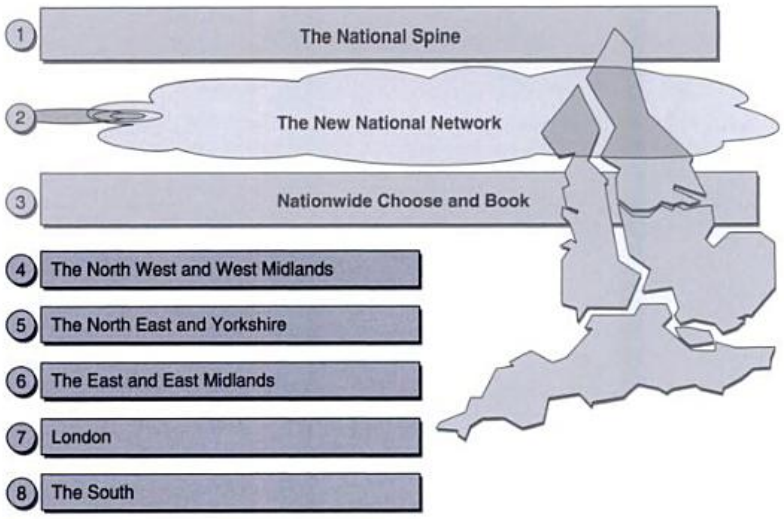

Figure 3.6: The England's National Programme for IT [Bre05]

- **One Electronic Appointment Booking (eB)** — a service (now called 'Choose and Book') that would give the possibility of the patients to choose the place, date and time for their appointments in a hospital or clinic;

- **Five Local Service Provider (LSP)** — five physically distributed providers, hosting the NHS Care Records Service (NHS-CRS) at a local level, covering all England's territory.

The Figure 3.6 briefly describes the kind of interaction between the different components of the system. It is important to notice that, in order to implement the five local clusters, five providers were contracted and made responsible for delivering the local services. The idea was that, in one hand, the providers would be challenged to compete between each other, speeding up the process of implementation. On the other hand, the risk would be lower since there was different suppliers implementing similar systems in parallel. CSC Alliance, BT Health London, Accenture and The Fujitsu Alliance were the contracted LSP's for the main body of the programme.

3.2.2.2 NHS Interoperability Toolkit (ITK)

The NHS Interoperability Toolkit is a set of standards, frameworks and implementation guides to support and favour the interoperability between local systems and across them. The NHS ITK aims to support flexibility and local innovation and also removing barriers to entry. It also wants to be an enabler of evolution and reusing of solutions that already proved to be valuable, connecting all the peers by standardization in order to ensure that there are no silos being created.

One of the key concepts of ITK is the use of a maturity-based approach, allowing the organizations to evolve through small steps, particularly for CDA documents. The step-by-step maturity model allows the organization to incrementally progress from sharing binary data to sharing fully-coded CDA documents.

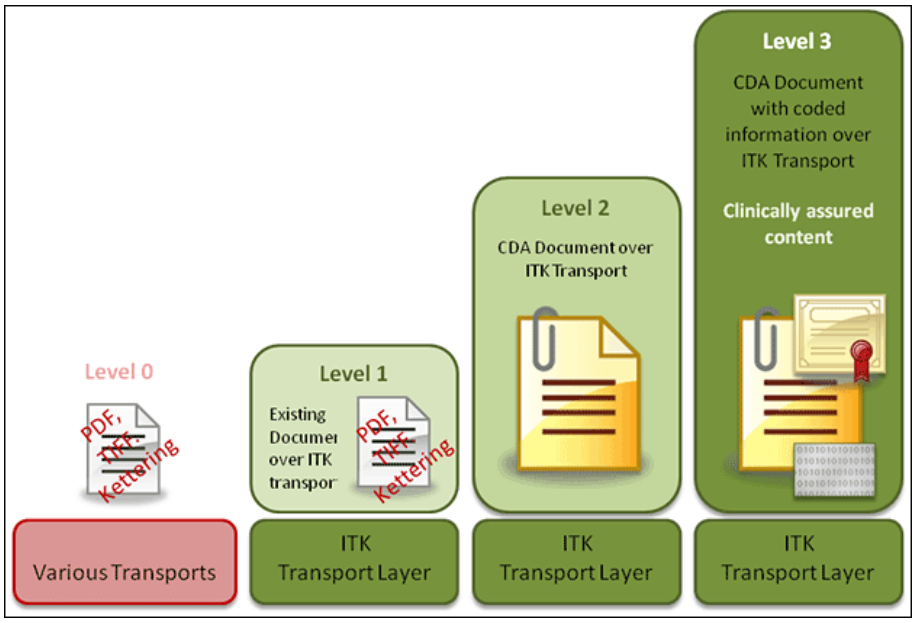

Figure 3.7: The NHS ITK Maturity Model [fH12]

As it is possible to observe in Figure 3.7, there are four possible levels in the model. The lowest one – Level 0 – is applied to any organization, when even the sharing itself is made out of the ITK Transport Layer. When one organization becomes to use the ITK Transport Layer it reaches the Level 1. Then, the Level 3 is assigned when an organization is able to share CDA documents. Finally, when the data is passed through CDA documents one organization has reached the highest level – Level 4. In Section 3.1.1.4 we explain the CDA standard more in detail.

3.2.2.3 NHS Care Records

The NHS Care Records is one of the NPfIT's components. This component is what we usually call an Electronic Health Record system, aiming to provide personal clinical information to the healthcare providers, increasing the quality and efficiency of the treatments.

The NHS Care Records considers two different types of records:

- **Summary Care Records** — records held nationally. A Summary Care Record – usually called Patient Summary – stores essential information about a person, available in emergency situations, informing the health professionals about what medicines are one taking, the allergies that might suffer from or any known bad reactions to other medicines;

- **Detailed Care Records** — records held locally. The Detailed Care Record is a more comprehensive record which might store data from past exams and details, avoiding the necessity for repeating them, for example.

3.2.2.4 The fall and the failure

The NPfIT started in October 2002 and since then it always been the target of some criticises. However, in April 2006, a set of 23 academics, wrote an open letter[2] raising several questions and concerns about the programme. A report by the King's Fund in 2007 also criticised the government's "apparent reluctance to audit and evaluate the programme", questioning their failure to develop a capable strategy [WAH07].

The next years were very troubled as long as several reports raising doubts about the feasibility of the project were made public [Pow04, Coi07, Bre07, CS07, Bre09]. One of those, by the Public Accounts Committee, stated in 2009 that the risks for the programme deployment were "as serious as ever", bringing up serious uncertainty about the capacity of the systems to meet expectations of clinical staff. [3] The over-and-over delays to deliver the fundamental services and the overrun of the programme's cost started to being unsupportable. In September 2011, the NPfIT has been dismantled following the conclusions of a new review by the Cabinet Office's Major Projects Authority (MPA) [oH].

[2] Details: http://editthis.info/nhs_it_info/The_Open_Letter_to_the_Health_Select_Committee

[3] Details: http://news.bbc.co.uk/2/hi/health/7850619.stm

Chapter 4

Structural Concepts and Architecture

An Electronic Health Record can be defined as the set of some essential healthcare services. In this section, the authors will describe the services which they consider the most important ones. The Patient Summary is the first concept to be analysed, being followed by the Personal Health Record. Both concepts are world wide known having an important when talking about the EHR implementation effort. Finally, there will be presented a small overview about the epSOS project, trying to evidence the most important architectural factors that might difficult the integration with the others countries.

4.1 Patient Summary

The Patient Summary (PS) [epSa] is a set of information that allows an healthcare professional to have a quick and easy overview over a patient, used in the epSOS project. A similar concept is used in the England's National Health Service, called Summary Care Records. Although the name may vary, the concept is practically the same and stands as an electronic record that will give healthcare staff faster and easier access to essential information about a patient. For instance, it is very helpful to provide safe treatment in an emergency [Ser10].

The epSOS Patient Summary contains the following data:

- Demographic information (e.g. name, birth date, gender);
- Most important clinical patient data (e.g. allergies, current medical problems, or major surgical procedures during the last six months);
- Current medication including all prescribed medicines;
- Meta-data about the Patient Summary itself (e.g. when and by whom was created or modified).

The clinical data included may vary but, in general terms, is very similar to the set stated above.

The benefits of the existence of a Patient Summary are not very consensual. In general terms, the advantages announced are:

- Improved information flow between patient and staff;
- Better and more accurate treatment in emergency situations;
- Quicker and easier access to essential information;
- Easier to allow the patient to check its own PS.

In fact, it is possible to point out two completely different case studies, in terms of acceptance and success: England and Scotland.

In England, several articles [And10, Coi11, GSB+10] had been written expressing concerns and doubts about the concept, arguing that the Summary Care Record (in England) should be abandoned "for reasons of safety, functionality, clinical autonomy, patient privacy, and human rights" [And10], stated Ross Anderson. Anderson justifies his critical saying that the data coming from multiple sources, for which there is no responsible, will create a poor and dangerously incomplete summary. Moreover, a final report [SBB+10] of an independent evaluation of the Summary Care Record programme concluded that there is limited evidence that the SCR programme had so far achieved the benefits set out. Despite of stating an evidence of improved quality in some consultations, particularly those which involved medication decisions and a probably reduce of rare but important medication errors, the commission was not able neither to find evidence of reduction in onward referral nor to evaluate the impact on the satisfaction of patients. Although, the report defends that the SCR was particularly useful in patients unable to communicate or advocate for themselves. On the other hand, Mark Walport advocates [Wal10] that "good information technology has the capacity to be transformational" insisting on the idea of quicker access to more reliable information that should help the treatment.

The Scottish case appears to gather more consensus and positive feedback. A study of Gartner Industry Research stated [Res07] that the Emergency Care Summary (ECS), how it is called in Scotland, is a success because it met a specific business need. Also, it advocates that the clinician buy-in was achieved by involving the clinicians in the definition of ECS data and designing the security and access protocol for it as well as there was "training out-of-hours staff to use ECS appropriately" which was identified as a critical factor too. Another study [JDS+08] on the ECS reported an estimated volume of 5.1 million patient records created from the general practitioner practices and 1.3 million of accesses to them, in 2008.

4.2 Personal Health Record

A Personal Health Record is a system whereby individuals can "access, manage and share their health information, and that of others for whom they are authorized, in a private, secure, and

confidential environment" [fH03]. As it is reported by some articles [TAB+06, TL09], the approach of the system might differ from being a totally isolated one till being integrated with the national healthcare system. Also, there is a lot of studies [TL09, PDS07, DBRT08, FD08] about the benefits that those systems can bring:

- quality, completeness, depth, and accessibility of health information provided by patients;
- self management support - e.g. care plans, graphing of symptoms, passive biofeedback, tailored instructive or motivational feedback, decision aids, or reminders;
- communication between patients and providers;
- access to patients' health knowledge;
- portability of clinical records and other personal health information;
- links to static or interactive information about illness, treatments, or self care;
- capture of symptom or health behaviour data by self report or objective monitoring through electronic devices.

There are some studies [KP08, Gea07] advocate the positive economic impact that a system like this may have. Also, this kind of system represents a new paradigm in which the patients have the central power over the information about themselves [BSB07]. Also, some new visions appeared, extracting the maximum value of the information inserted by the individual. For instance, how that information can be used in a mobile context [Bri10].

4.3 European Patients - Smart open Services (epSOS)

The epSOS (European Patients - Smart open Services) is the main European electronic Health (eHealth) project created by European Commission and partners. The main objective is to improve the health assistance to citizens who are abroad their own country. It aims to do so by implementing an interoperability platform, allowing different countries to exchange vital information. In that context, one health professional could access patient data from another country improving and précising the medical treatment [epSb].

4.3.1 Services and Standards

The epSOS is based on a Services-oriented Architecture. It states that all services are passive, implemented with traditional Web Services with their interfaces based on the Web Service Description Language [W3C WSDL 1.1]. When we say that the services are passive, it means that every transaction must be initiated by the consumer of the information. The key element of epSOS is the National Contact Point (NCP) and it stands as the only peer of contact for one determined country. In this sense, an NCP can serve both as a content provider when the request is made

from other countries or as a gateway for an information request from that country, conveying that request to the target one.

The NCP is based on a set of Common Components and when connecting those components to the national infrastructure it is possible to offer the following end-user services: Consent Service, Patient and Order Services, eDispensation Service, Auditing Service.

4.3.1.1 Consent Service

epSOS states that the patient must consent and allow the sharing of his information between peers of the epSOS network. This consent is realized through the IHE Basic Patient Privacy Consents (BPPC) profile[1] and the patient's consent is given in the origin country.

4.3.1.2 Patient and Order Services

The Patient and Order Services are used to retrieve medical information when abroad of the patient's home country. The medical data is returned in the epSOS common format and is realized by the IHE Profile XCA[2] Cross Gateway Query and Cross Gateway Retrieve. These documents are transmitted by web services exchanges and are complaints with the HL7 CDA Release 2.0 standard (see 3.1.1.4).

There are two type of documents to be exchanged: the 'ePrescrition' and the 'Patient Summary', both using epSOS specific CDA Level 1 and Level 3, respectively.

4.3.1.3 eDispensation Service

The eDispensation Service is required whenever it is necessary to update some medical data with some new information. In this context, one 'eDispensation' document is dispatched from the actual country to the patient's home country, being formatted with HL7 CDA Level 3.

4.3.1.4 Auditing Services

The Auditing Services aim to guarantee that all that sensible information is only accessible by those who have that right. Thus, it defines some rules about how to achieve Auditing and Authentication using the IHE Profile Audit Trail and Node Authentication[3].

4.3.2 Security Aspects

In terms of security, epSOS states some basic non-functional security requirements in order to guarantee that all transactions and data are reliable. Thus, epSOS must ensure: Identification, Authentication, Access Control, Non-repudiation, Data confidentiality, Data availability and Logging activities that impact security. Beyond these generic requirements, epSOS establishes some specific security requirements to be used in each country, dividing those into three levels:

[1]Details: http://wiki.ihe.net/index.php?title=Basic_Patient_Privacy_Consents
[2]Details: http://wiki.ihe.net/index.php?title=Cross-Community_Access
[3]Details: http://wiki.ihe.net/index.php?title=Audit_Trail_and_Node_Authentication

- First level — general epSOS as a whole (16 requirements);
- Second level — general NCP (34 requirements);
- Third level — national information infrastructure (9 requirements).

4.3.3 Identification and Authentication

The epSOS directives define three essential identification services:

- Service Entry Point Discovery — the discovery point returns single entry point for a NCP of a country;
- Patient Identification (and Authentication) — is realized through the IHE XCPD Integration Profile;
- Health Professional Authentication and Authorisation — is authenticated in the health professional's home country and have to generate an OASIS XACML (eXtensible Access Control Markup Language) file to declare it.

4.3.4 Semantic Issues

epSOS is obviously an huge and complex project, presenting several challenges to manage and resolve. We know that each country has its own policy, classification tables, ontologies and so on. So, one of the most interesting challenges is how to handle this diversity, finding a common language which enables the communication and transcription of several local classifications and taxonomies, not to mention the country language itself. In order to address this problem, epSOS defines a set of semantic services which we describe next.

4.3.4.1 CDA's PPC in epSOS

The CDA's PPC (Patient Care Coordination[4]) was integrated in epSOS, creating a significant amount of data elements.

4.3.4.2 epSOS Master Value Sets Catalogue

The epSOS Master Value Sets Catalogue (MVC) contains all value sets used within epSOS system and CDA framework. The value sets were built based on several well-known code systems, like SNOMED CT, ICD-9, ICD-10, LOINC, ATC, HL7 and so forth. The epSOS MVC is distributed as an Excel file.

[4]Details: http://wiki.ihe.net/index.php?title=Patient_Care_Coordination

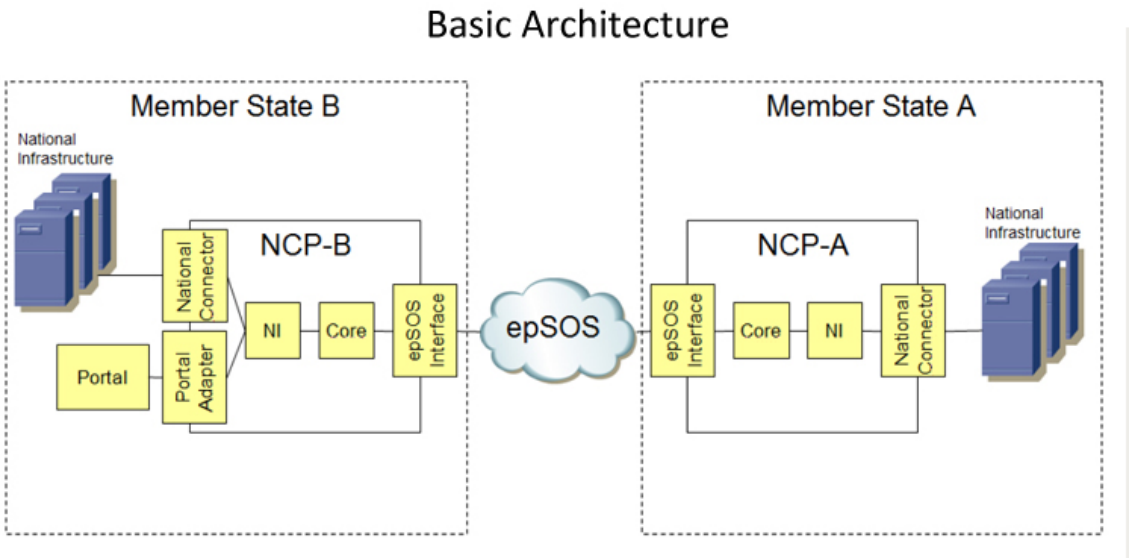

Figure 4.1: Basic Architecture of epSOS [epSb]

4.3.4.3 epSOS Master Translation/Transcoding Catalogue

The epSOS Master Translation/Transcoding Catalogue (MTC) is based on the epSOS MVC. It is made to fit the specific needs of a country and it is managed and updated its representatives. It is also provided as an Excel file.

4.3.4.4 epSOS Ontology

The epSOS Ontology aims to unify different terminologies that might be used in the future, providing a linguistic reference of the terms in the epSOS value sets.

4.3.5 System Architecture

epSOS architecture (described in Figure 4.1) was built with the objective of being enough flexible to allow integration with all kind of services existing inside the boundaries of each member state. The Figure 4.1 presents the peer-to-peer connection between two countries. Also, it is possible to understand which components stay under the member state responsibility.

We will overview the main functions of each component in the next subsections, following a top-down approach.

4.3.5.1 epSOS Interface

The epSOS Interface is one of the common components, representing the higher layer of the system. This component might assume one of two roles: Income Protocol Terminator (IPT) when acting as NCP-A or Outbound Protocol Terminator (OPT) when acting as NCP-B.

When Member State B (the consumer of some required information) dispatches a request, the OPT transforms the objects into SOAP requests at the same time that signs and certifies that

request and send it to Member State A (the target NCP). At this point, the request arrives at the ICP of NCP-A. The ICP verifies the authenticity of the message and, if reliable, transcode the SOAP request into objects and convey them to a lower main component called Workflow Manager. On the other side, the NCP-B waits a response and when it arrives, it does exactly the same, returning the information to the respective Workflow Manager. The Workflow Manager is one of the core components and will be exposed later.

4.3.5.2 Core elements

The core elements serve as the business layer of the system. These are the components which are considered core elements:

- **Workflow Manager** — it is the entry point for the business layer of NCP, working like an orchestrator and being called both by IPT and the National Connector. The Workflow Manager is the controller of all the operations process, being able to call other services available by other components interfaces, usually returning that information to the OPT National Connector;
- **Security Manager** — it is the responsible for certifying and validating documents;
- **Transformation Manager** — it works as a data translator from the local language to the epSOS Reference Terminology and vice-versa;
- **Terminology Services Access Manager** — called by Transformation Manager. It is responsible for translating a local concept into a epSOS coded concept one, using the Terminology Repository, which represents the epSOS Reference Terminology, and is managed and updated by the country;
- **Audit Trail Writer** — it is the responsible for creating an event log of every transaction and sending it to the Audit Repository. Although, the audits are limited in terms of information.
- **Audit Repository** — it is the responsible element for storing the logs produced above. The logs are only accessible to the national infrastructure. Thus, these audit interfaces might be defined taking into account the national specific needs;
- **Routing Manager** — it stands as the pointer to the other countries, providing the routes to connect them. the routing tables are XML documents that might be stored locally or be fetched from a central repository either.

4.3.5.3 The National Interface and Connector

The National Interface represents the connection between the Workflow Manager and the National Connector. The National Connector is a collection of adapters that provide access and make use of the internal nation services, using the local protocols and formats. As it is the link for the national information systems, it can also invoke the Workflow Manager through the National Interface.

4.4 Portuguese Baseline Architecture

Before talking about where should we go, we must know the starting point. This section aims to provide a general overview about the current Portuguese Healthcare system, its information systems and the way they integrate or not with each other.

4.4.1 Organic Structure Summary

The Portuguese National Health Service is called *Serviço Nacional de Saúde*[5] (SNS) and supervises all the public healthcare services in the country [dS11c]. The institutions that constitute the SNS are every services or public healthcare providers, including:

- *Agrupamentos de Centros de Saúde*[6] (ACES) – these healthcare primary institutions groups are public health services with administrative autonomy, consisting of several functional units that combine one or more health units and whose mission is to ensure the provision of primary health care to the population of a given geographical area;
- *Unidades Locais de Saúde*[7] (ULS) – the health local units consisting of hospitals and health units, allow integration into a single public entity business, the various agencies and institutions of the SNS in a given municipality, providing health care to the population;
- *Hospitals*.

Moreover, the country is divided in five regions and exists one regional administration, *Administração Regional de Saúde* (ARS), for each one of them.

To the scope of this dissertation, is also interesting to present three entities inside the Ministry of Health:

- *Administração Central do Sistema de Saúde, I.P.*[8] (ACSS) – has the task of ensuring the financial management and human resources of the Ministry of Health and the SNS, and the facilities and equipment fostering the development and implementation, standardization, regulation and planning health policies [dS11c];
- *Serviços Partilhados do Ministério da Saude, E.P.E.*[9] (SPMS) – has the mission of provide shared services in the areas of purchasing and logistics, financial services, human resources and systems and information and communication technologies in order to "centralize, streamline and rationalize" procurement of goods and services in the SNS [dS10a];
- *Comissão para a Informatização Clínica*[10] (CIC) – was created with the goal that the clinical information, sparsely produced and stored, is available to the user and health professional who provides any service, regardless of the time and place of deliver [dS11d].

[5] National Health Service
[6] Health Centres Groups
[7] Health Local Units
[8] Central Administration of the Health System
[9] Shared Services of Ministry of Health
[10] Committee for Clinical Informatics

4.4.2 Information Architecture

In order to facilitate this characterization, we will divide the description in two main contexts: the primary healthcare data and the ambulatory healthcare data.

4.4.2.1 Primary Healthcare Data

This kind of data is gathered among the *Cuidados de Saúde Primários*[11] (CSP) institutions. The WHO defines the primary healthcare with five essential goals: "reducing exclusion and social disparities", "organizing health services around people's needs and expectations", "integrating health into all sectors", "pursuing collaborative models of policy dialogue" and "increasing stakeholder participation". In this sense, the information collected and managed at this level are:

- Allergies and intolerances;
- Vaccinations;
- Resolved, closed or inactive problems;
- Current problems and diagnosis;
- Current and past medicines;
- Eventually some information about the social historic of the patient.

As it is possible to observe, nowadays the major problem is not the lack of clinical information but the way that information is (or is not) shared and available when it could make the difference. In fact, this information is created, collected and consumed only in the institution where it belongs.

4.4.2.2 Ambulatory Healthcare Data

The ambulatory healthcare data is produced at the hospitals and contains data about:

- External consultation[12];
- Vaccinations;
- Resolved, closed or inactive problems;
- Current problems and diagnosis;
- Current and past medicines;
- Eventually some information about the social historic of the patient.

[11] Primary Healthcare Institutions

[12] External consultation - where the patients, with previous scheduling, are observed, diagnosed and receive therapeutics as well as simple surgical interventions or similar episodes

All the public hospitals use a system called *Grupos de Diagnósticos Homogéneos* (GDH), which are the translation of the Diagnosis Related Groups (DRG). The GDH is a classification system for hospitalized patients that defines coherent patient groups with a similar estimated cost. Through this system it is possible to state the set of goods and services that each patient receives having in count his needs and the pathology that brought him in. The GDH are used to calculate the financing level that a hospital receives [dS11a].

Moreover, the information is not directly collected or transformed in GDHs. In first place, the information is stored at the local information systems or, in some cases, in paper [TFS08]. Later, some specialized doctors transform the existing data into the GDH format so the hospital will be able to receive the state's support. Nowadays, the hospitals introduces the GDHs in a national central system called WebGDH. The information dispatch only occurs at the end of each month. The hospital diagnosis and procedures discharge letters are coded using the ICD-9-CM (see Section 3.1.5.2).

4.4.3 Application Architecture

In this section, it is pretended to characterise the main applications in the public healthcare institutions. The goal is to understand which applications support the key business processes and how they interact with each other.

4.4.3.1 SONHO

Sistema Integrado de Informação Hospitalar[13] (SONHO) is an information system for patient management created in 1988 and disseminated by the Portuguese hospitals, with no competitors at that time [TB05]. Nowadays, SONHO is the dominant system in Portuguese hospitals' being installed in about 90% of the Portuguese public hospitals. SONHO has as the main objective to control the flow of patients in the hospital, that mean to know who is in and who leaves, and what resources were spend with which patient, aiming to ensure some standardization of statistical data and billing. This system started with three modules: outpatient, inpatient and emergency but some new modules were added, like surgery operation room and day care modules [CcAC09]. The user interface is represented in Figure 4.2.

This application allows the registration of clinical data (e.g. history of an inpatient encounter, emergency summary report, referral letters, diagnosis and procedures), allowing the establishment of a bridge between the clinical data and the production of the DGHs with billing purposes [dS11b].

4.4.3.2 SINUS

Sistema de Informação de Unidades de Saúde[14] (SINUS) was created with the same intents of SONHO but for the primary healthcare institution contexts. The SINUS is widely disseminated

[13] Integrated System for Hospital Information
[14] Information System for Health Institutions

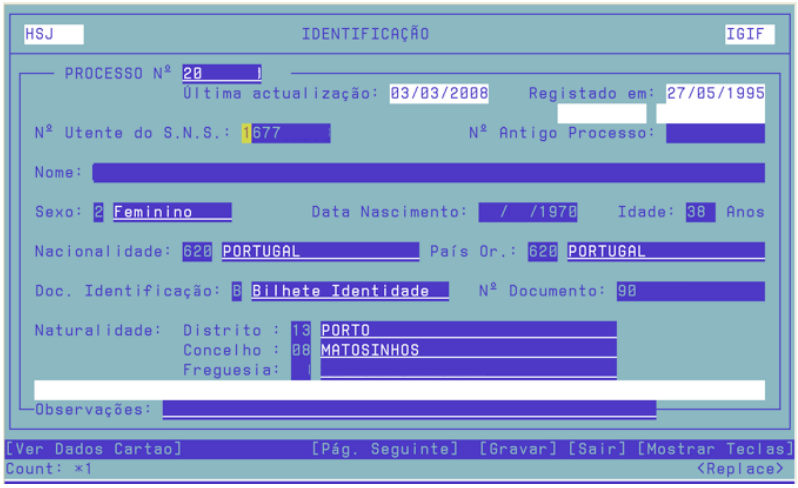

Figure 4.2: First screen of SONHO

over Portugal, being present in 3 hospitals and 72 primary health care institutions. Currently, SINUS is still supporting the healthcare unit management, mainly in terms of medical consultation scheduling and vaccination. Furthermore, until that functionalities are replaced, the system must keep operational, although the recommended abandonment of the module "Managing Users" [dS10b].

4.4.3.3 SAM

In 1999, the Ministry of Health decides to start developing a new system called *Sistema de Apoio ao Médico*[15] (SAM). The SAM was born as a web software layer, supported upon the SONHO and SINUS systems, aiming to serve as a platform where doctors could introduce information in SINUS and SONHO at the same time. SAM was designing with two essential guide lines [Cas05, CdSdS10b]:

- Provide some basic functionalities to the doctor daily activities and related with the data stored at SINUS and SONHO, like scheduling management, reports, few clinical data records, etc.
- Enable the implementation of some processes which interfere with the doctor activity.

4.4.3.4 SAPE

Sistema de Apoio à Prática de Enfermagem[16] (SAPE) is a software [CdSdS10a] directed to the nursing professionals, that allows the scheduling and recording of the healthcare activities at the health institutions. SAPE was built to address the nurse daily activities, trying to organize and facilitate the information consume. On the other hand, it was also created with the objective of

[15] Doctor Support System
[16] Nursing Practice Support System

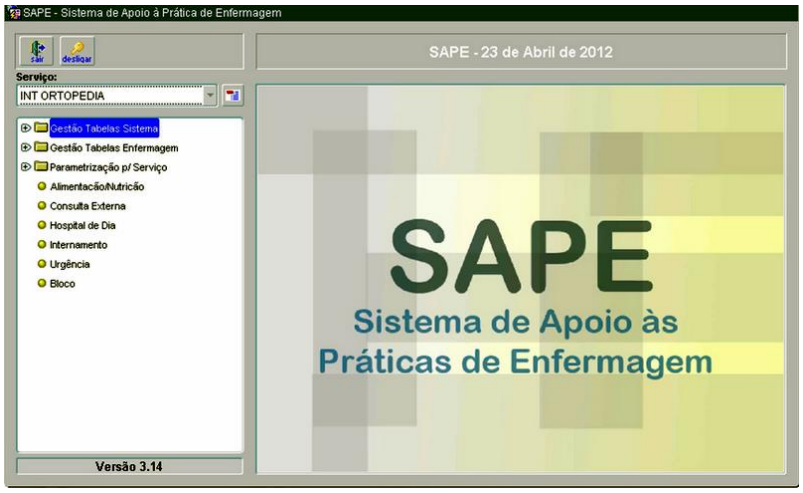

Figure 4.3: User interface of SAPE

normalizing the nursing records system. The collected data results from the nursing healthcare at the institutions where the system is implemented.

This system uses the *Classificação Internacional para a Prática de Enfermagem*[17] (CIPE) as a language reference. The Figure 4.3 presents the user interface of this system.

4.4.4 Technical Architecture

This section overviews the technical infrastructure that supports most of the public healthcare organizations nowadays, in both hospitals and primary healthcare institutions.

4.4.4.1 Hospitals

In the healthcare context, the hospitals are probably the most complex institutions. These institutions have several services to offer which means that their information systems have to support multiple processes and professionals from different specialities. In this sense, these institutions usually have each own information systems department, responsible for maintaining the hospital technical infrastructure and adjusting the systems to the existing processes.

The need for supporting several processes led the hospitals to successively buy and implement applications to solve specific problems creating a truly complex web of systems working as islands.

4.4.4.2 Primary Healthcare Institutions

In the case of the primary healthcare institutions the reality is very different. These kind of institutions are smaller and with much less complex processes. Also, they mainly use the systems developed and supported by the Ministry of Health [dS10b]. However, the technical infrastructure

[17] ICNP - International Classification for Nursing Practice of International Council of Nurses

where are installed those systems is, most of the times, very poor. Unlike the hospitals, these units neither have a support team to keep the servers up and running nor an appropriate room.

Chapter 5

Architectural Contributions

The objective of this section is to explain and state some suggestions about what is possible to do in the next two or three years, in order to achieve some kind of interoperability and sharing, with the aim of improving the healthcare services in Portugal. In this sense, the goal is not to predict the future about the health information systems or to propose intangible milestones but to point out some strategies that might help to create value in the mid-term future without precluding future requirements and evolutions.

This chapter is meant to explain the progresses that were made since this dissertation work was initiated by February. However, there was a previous work of studying architectures and standards and also understanding the new government's strategy that was done since November. The work was done in a close cooperation with CIC in terms of researching and discussing the best options to take. It will start explaining the work methodology between all the team, advancing then into the explanation of what was found to be more or less relevant. Finally, we explain for each project what were the contributions and what might be done in the future to help the Portuguese EHR to grow healthy and robust. Along the different sections, the authors explain the developments made under this collaboration and also the vision proposed to the mid-term future.

5.1 Methodology

The methodology was based on a relation of great cooperation between the team and the responsible entities, namely CIC, ACSS and SPMS. The meetings were in a weekly basis counting more than forty since November. The FEUP team's role was to support the design and implementation process, helping in the process of taking decisions, discussing the multiple options and bringing new solutions to the table.

5.2 Strategic vision

The CIC opted by a strategy based on several projects and new processes running at the same time, instead of one with long study, research phases and long implementations schedules. This agile strategy led to the creation of 4 projects, which has different goals but are strongly connected to the creation of an EHR:

- Personal Health Records – website that is supposed to has the functionalities of a normal PHR, letting the patient to introduce clinical information and give consent for it to be accessed by healthcare professionals. The Patient Portal already existed but was added to it a new module called ***As minhas notas***;
- epSOS integration – website to provide the integration with the epSOS project, providing the possibility of send a patient summary abroad or to receive clinical data about a foreign patient. The project was named ***Portal Internacional***;
- Patient Summaries – platform to support the existence of a single clinical summary for each patient, containing the most important information about him/her. The Portuguese project was called ***Resumo Clínico Único do Utente (RCU2)***;
- Information sharing among institutions – the ***Plataforma de Dados de Saúde (PDS)*** with the aim of connect the projects above and providing the access that the professionals need to the referred information.

5.3 Principles

The goal of defining some principles is to serve as guidelines for the architecture being developed. This concept is used in the TOGAF methodology [Jos09, Jos11]. These principles intent to give a premature vision of what might be the development process and the changes that the institutions will have to face.

5.3.1 Favour the quick-wins

5.3.1.1 Statement

The difficult times that Portugal are passing through imply the search for solutions with short-term results and value. In this sense, there is an emergent need for balancing the best solution and the reasonable solution with short-term benefits.

5.3.1.2 Rationale

The project's scope and complexity obliges the definition and search for solutions that might motivate all the stakeholders. Since there are an huge number of interested parties, the quick-wins are a big help in order to raise interest and contributions to the project. On the other hand, the

definition of short-term milestones help to keep control of the progress. Most of the healthcare institutions are big structures with several difficulties to respond to change in time and the others are not simply not used to do it.

5.3.1.3 Implications

This strategy obliges the organizations to gain some flexibility. Also, the search for quick-wins may fare worse then solutions without so much rapid benefits.

5.3.2 Normalize the data

5.3.2.1 Statement

The normalization path seems inevitable. Accordingly, this proposal should privilege and encourage the adoption and evolution of the systems, instead of creating several solutions according with each existing system.

5.3.2.2 Rationale

The advantages of normalizing data, processes or any other kind of action are recognized and consensual. In fact, with the systems growing up exponentially in number and complexity, the need for sharing data has increased as well, creating a context where a system should be able to communicate and exchange data with thousands of others. The definition of norms for representing the data allows an healthcare institution to much easily receive and interpret data from one other.

5.3.2.3 Implications

The change of information systems that are not prepared to be expanded might be very slow and complex, in most cases. Also, there is a need for changing the processes, unifying them, and that change might be more difficult than previous one. Moreover, there will be a necessity for defining national unified models for documents like discharge letters, analysis and so on.

5.3.3 Adopt international standards

5.3.3.1 Statement

There are numerous health standards ready to be used and facilitate sharing and exchanging of clinical information. The new services should adopt a standard and the old ones should be converted.

5.3.3.2 Rationale

Most of the times, the standards can not be directly applied to the Portuguese reality. That is, the national systems are using national codifications which simply can not be substituted. In that case, the solution might be to create ways of translate between the two codifications.

5.3.3.3 Implications

There will be necessary to define conversion tables or services between the national and international codifications. These kind of work should be supervised and controlled at the Ministry level in order to align all the institutions.

5.3.4 Search for flexible solutions

5.3.4.1 Statement

With such a long process, there are several decisions that have to be made late in the process of implementation. In that situations, the decisions should consider the solutions that will allow the system to evolute easily.

5.3.4.2 Rationale

Most of times, the search for flexible solutions have high costs in terms of implementation schedule. Certainly, there is a need for balancing the level of flexibility that the solution might search for. Usually, the better solutions take more time to be designed and adopted. Moreover, flexible solutions are often more complex and heavy than others. In this context, the key is always the capacity for balancing both perspectives.

5.3.4.3 Implications

The search for flexible solutions may require more resources and more time to implement the projects.

5.3.5 Fit without precluding

5.3.5.1 Statement

The strategy is not to replace the existing systems but to fit them trying not to compromise future requirements and developments.

5.3.5.2 Rationale

Most of the systems in use were created several years ago. That is, every healthcare professional is accustomed to the existing systems and that a sudden and unprepared change to the way they have to work and do their job might sentence the project's failure.

5.3.5.3 Implications

It will be necessary to understand which systems are fundamental to the business goals, meaning that might be some systems which does not worth to integrate with, either because they are too old and will be deprecated soon or because they simply have not enough audience.

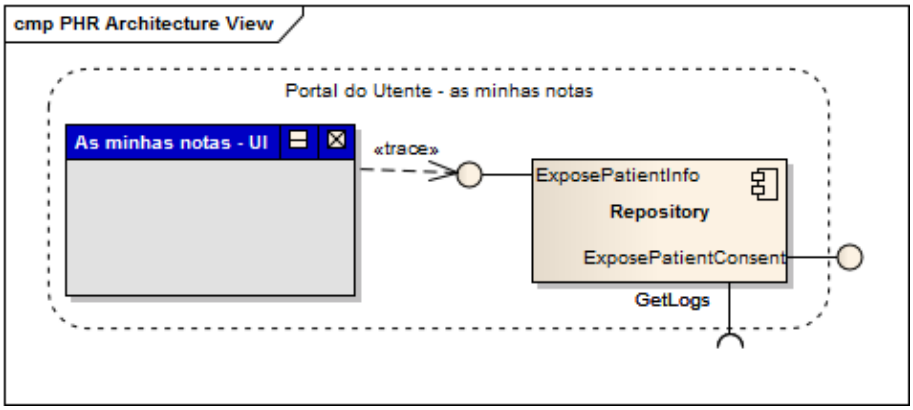

Figure 5.1: Overview of the Portuguese PHR system which was integrated with *Portal do Utente*. The system might stand alone as an repository providing some essential services as described in the figure.

5.4 The Portuguese Personal Health Record

As described at Section 4.2 the PHR system may be an important component to the successful implementation of an EHR. In the section, the goal is to state the recent developments made under this assumption but also to understand which are the next steps that need to be taken.

5.4.1 Recent developments

It is important to notice the introduction of the Patient Portal that centralizes all the patients' information across the country, in the same system.

To the existing Patient Portal was added a new section called "My Notes". This section pretends to be a PHR system. For now, the portal allows an individual to input the following information: emergency contacts, health information (height, weight, blood glucose, or blood pressure), lifestyle, health problems, allergies and medications. As stated at the service, the objective is to allow the citizen to have an active role in managing, promoting and improving its health state.

The system also allows the individual to give or withdraw the consent to share the information among the public healthcare institutions.

5.4.2 Future vision

This is the kind of system that can be built almost standalone (see Fig. 5.1). In fact, it was developed as a new peace of software, despite of the integration with the RNU login services. Actually, in addition to storing personal information and allowing the consent managing, it also allows the patient to access the professionals list who saw his/her notes.

Despite of having some interesting features already, the system still has a large margin to evolve. One of the features that should be improved is the patient consent. The actual consent only has to options:

1. give or not give access to the self-introduced records at the Patient Portal - My Notes by a healthcare professional;

2. give or not give access to the existing information stored at the several institutions of the Portuguese National Health Service by a healthcare professional.

Probably it will be necessary to have a more detailed consent, providing more options like, for instance: give consent only in case of an emergency or only to institutions within a determined country region.

In terms of information and new functionalities, there are several examples of what could also be included. The authors believe that the following are good examples:

- important events, dates and hereditary conditions in the family history;
- vaccines administrated and vaccines still to be administrated and their dates;
- organ donor authorization.

Last but not least, the information does not worth anything unless it can be shared and access by the professionals. In that sense, if the collected data is not saved in an appropriate format there will be necessary too much effort to share it. So, it is fundamental to use a standard to store the information as well as to implement the interfaces and services that will allow that exchange.

5.5 The Portuguese Patient Summary

The Patient Summary (see Sec. 4.1) stands as an essential concept of an EHR. In the next few sections, the authors describe the main developments recently done but also the work that is still to be done in order to improve the service quality.

5.5.1 Recent developments

The Portuguese Patient Summary (PS) project which was called the RCU2 - Resumo Clínico Único do Utente (Patient Single Clinical Summary) is certainly the most important component. In fact, as described in Section 4.1, the PS might turn into to the enabler necessary to mobilize the institutions and get them to adopt standards and normalize processes.

The development of the RCU2 raised several questions. Those are the issues that are described in the following subsections.

5.5.1.1 The repository

Where to store the information? Firstly, the question of the RCU2 physical location was a very complex one. As the clinical information is produced at healthcare institutions, there were some reservations about the possibility of gathering it and centralizing it. In fact, when consulting the CNPD – Comissão Nacional de Proteção de Dados (National Committee for Data Protection) – the

reservations were confirmed. The CNPD did not allow the creation of a national RCU2 repository and obliged it to be distributed at the primary healthcare institution, where the patient has its family doctor.

The problem is that the CSP – Cuidados de Saúde Primários (Primary Healthcare) – institutions are not equipped with the necessary infrastructure to support and provide the RCU2 service, either because the servers are just to old, not secure enough or the bandwidth is not adequate.

In that way, a possible solution is to store the data at each ACES – Agrupamentos de Centros de Saúde (Healthcare Primary Institutions Groups). The ACES are defined as groups of CSP institutions and thus they are a lot less, smoothing not only the implementation effort but also the support and upgrading processes. However, the ideal solution would be to create a repository for each of the five ARS – Administração Regional de Saúde (Regional Health Administration), bringing the following advantages:

- easiness of supporting and upgrading the systems;
- facility to secure and guarantee data confidentiality;
- still being a distributed system, despite of being much smaller;
- division of responsibilities among the ARS instead of centralizing them at the Ministry.

5.5.1.2 The required information

Which information and where to collect it from? The question about the information to be present in the RCU2 was another fundamental one. In this case, the work done by the CIC – Comissão para a Informatização Clínica (Commission for Clinical Informatics) – in cooperation with the FEUP team, was based on two concerns:

- involving the clinicians asking them to identify which information is more crucial and brings more value;
- trying to match the RCU2 data with the data required and suggested to the epSOS PS.

In the early stages, the data available will be restricted to the data available at the existing information systems. Notwithstanding, the data identified as useful, which is not available at the systems yet, must be considered to the next phases of the project.

Most of the information selected to be part of RCU2 is present in the CSP units. Although, the hospital episodes are also a relevant source of clinical data, specially regarding procedures, allergies and prescriptions. In the context, the discharges letters produced, which synthesize the events held indoors, are the easiest way to transfer the data to the RCU2. Nevertheless, to enable this exchange the hospitals need to produce the discharge letters:

1. in a digital format instead of using paper – something that still happens in some institutions;
2. using a model defined at national level in order to normalize them.

In a parallel work, there was the need of defining the new data model for the RCU2 (the Patient Summary system). In a team effort it has been defined a database model that is be able to store the RCU2 information. The model can be found at Appendix A.

The model was conceived with two main concerns:

- Approximate the data model to the existing representation in the healthcare primary care units in order to facilitate the data transfer;
- Build a RCU2 model based on the epSOS Patient Summary information recommendations and requirements in order to facilitate the data export and dispatch to other countries by epSOS platform.

The referenced model will be tried out at the primary healthcare institutions.

5.5.1.3 The synchronization process

How often is the data transferred between the healthcare institutions to the RCU2? Is it immediate? Daily? Weekly? Since we have defined which data will constitute the RCU2 and where it comes from, it is necessary to determine on which basis the RCU2 will be updated. That synchronization may occur immediately when the information arrives at the local information system or it may be exchanged with a determined frequency (e.g. daily, weekly, monthly, etc). The information has to flow between different institutions. Mainly, it has to be transferred between the hospitals or others CSP institutions to the CSP unit where the RCU2 to that specific patient is stored. The process could be described as it follows (see Fig. 5.2):

- the general practitioner introduces the discharge letter into the information system;
- the information system dispatches the data to a PDS receiver;
- the patient identification is checked against the RNU and is returned the correspondent CSP;
- the data is forwarded to the CSP institution;
- if requested, the data shall also be sent to another national institutions but not without making it anonymous.

In terms of the standard recommended to export the RCU2 to others institutions, the HL7 CDA (Section 3.1.1.4) appears to be the best option:

- sufficiently recent to be actual but sufficient old to be mature;
- standard used within the epSOS project;
- evolution of HL7 V2 which might be used to transfer the event data;
- international well-known standard.

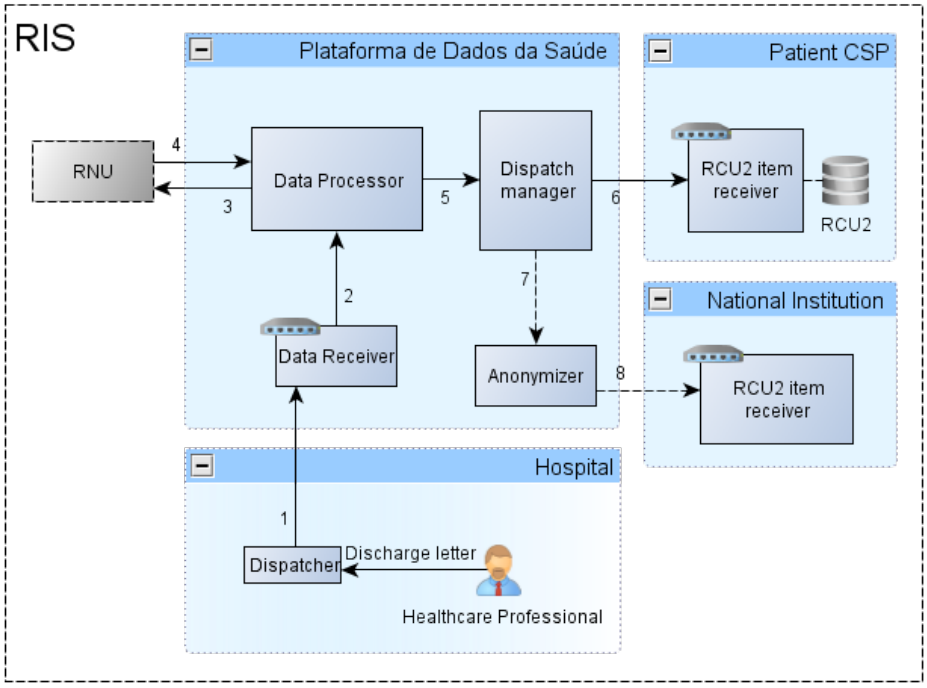

Figure 5.2: The flow of a discharge letter between the hospital and the CSP unit

5.5.1.4 The management process

Will it be automatically managed or will exist anyone responsible to manage it? If so, who will be that person? When describing the PS concept (Section 4.1) was possible to recognize the importance of being the doctors to manage the PS in the Scottish case study. In fact, a model completely automated to integrate and validate the information would bring two essential issues:

1. discredit and distrust about the information;

2. difficulties dealing with conflicting information from different institutions.

In this sense, it was defined that would be the family doctor to manage the RCU2. That means that each general practitioner is responsible to administer the registries of their patients, allowing them to hide deprecated information and accept or reject proposals for new data. Clearly, this strategy brings new liabilities and charges to the doctors that might have an huge impact in their daily work. In that sense, this approach has to be carefully communicated in order to get sufficient acceptance by the professionals.

5.5.2 Future Vision

The recommendations presented in the next subsections are centred in three fundamental questions: the location of the data; the codification of the data and the process that allows the data to

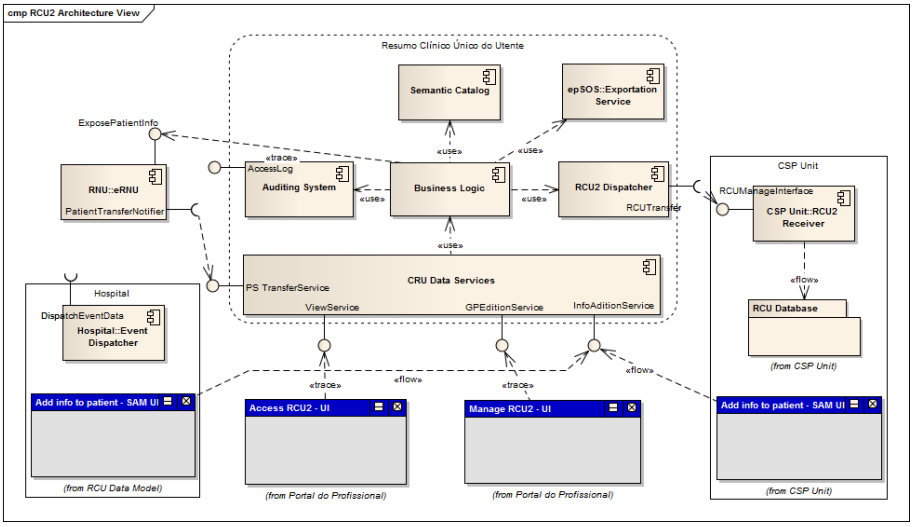

Figure 5.3: A summary of the future vision for the RCU2. This project will be interconnect with two kind of institutions: hospitals and CSP. Also, it will be constituted by the referred main components with well-defined services to retrieve data.

be uploaded from the local institutions to the repository above. A summary of the architecture can be found at Figure 5.3.

5.5.2.1 The repository

Regarding the RCU2, the natural tendency is to group the several institutions by regions and trying to have as few instances as possible. This policy of centralization has great advantages in terms of ease of troubleshooting, improvements, maintenance, etc.

5.5.2.2 The information

The use of a standard to store clinical information is often the first solution to evaluate. Even with respect to the RCU2, the possibility of migrating the data model to a standard like HL7 RIM, must not be discarded. However, it seems impossible in the medium-term future to completely apply a standard to it. There are several reasons to that, but the most prominent one is the effort that it would require to change the existing systems in order to exchange data like that. Also, since that the systems are not likely to be substituted in the mid-term future, it is a lot easier to store it in the original format at RCU2. Obviously, when sending that data abroad, it has to be transformed and transcoded to the international standards. Nevertheless, that is a different question of how the information is transferred between institutions, not how it is stored.

5.5.2.3 The synchronization process

The synchronization process has to be analysed in two different contexts: the hospitals and the CSP. About the hospitals, the GDH repository could be used to retrieve information from the

hospitals to the RCU2. However, as stated earlier in this document (Section 4.4.2.2), it could bring problems of confidence in the information. On the other hand, this system has the information codified which has a great advantage since it would allow to integrate that information much quicker and with fewer effort. The other alternative would be to modify the existing systems.

The situation of the CSP unit is quite different. In this case, it will be necessary to build a infrastructure to keep the temporary information and dispatch it daily.

5.6 The epSOS integration

The goal of this section is to describe the work realised under the epSOS integration process.

5.6.1 Recent developments

As described in Section 4.3, the epSOS project is based on two essential services (Patient Summary and ePrescription) but Portugal was integrated only with the PS sharing commitment. Since the epSOS integration is very dependent on the evolution of the other projects, particularly on the RCU2, there was no significant developments on it. Despite of the Portuguese NCP implementation process is at the responsibility of an external company, there was a close work between the company and the SPMS, in which the authors also have participated. The results of that close collaboration are described in the next section, helping to define the future vision.

5.6.2 Future vision

The epSOS project may become an important catalyst to the introduction of standards and the normalization of data. As saw in Section 4.3, the integration within the epSOS context requires the use of specific standards, namely HL7 CDA v2 (Sec. 3.1.1.4). In that sense, it will be required that Portugal has the capability to send information in specific formats. The epSOS definition is based on two use cases:

- Case A – provide information about a Portuguese citizen who is at an European healthcare institution;
- Case B – receive information about a foreign citizen from its own country;

5.6.2.1 Case A

If we will be sending the RCU2 codified with HL7 CDA, it may be interesting to start sharing it the same way internally. In order to achieve that, it will be necessary to bring the National Connector (see Section 4.3.5.3) into the scope of PDS instead of staying as a service created only to epSOS. The next components seems to be fundamental:

- locate the National Connector, which could have the responsibility to transcode from RCU2 to HL7 CDA, within the PDS scope;

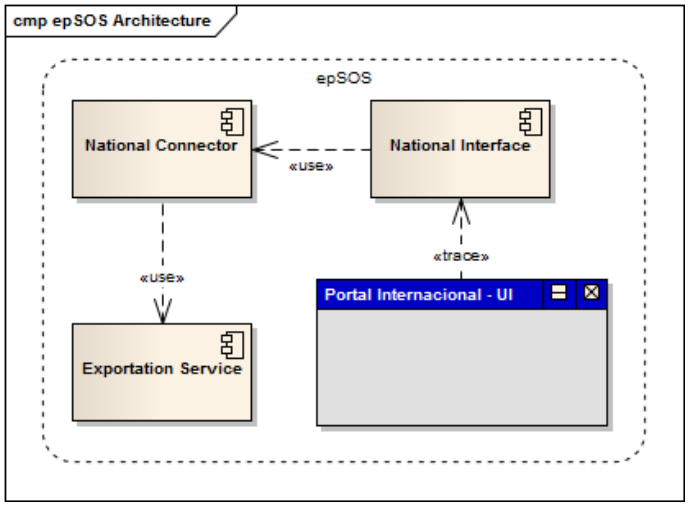

Figure 5.4: General view of the epSOS components. The components represented are only the ones that directly interact with the creation and dispatch of the PS

- define the services using the standards (e.g. IHE profiles, see Section 3.1.3).

This way, it will be possible to share the standardized RCU2 not only to other countries but to several institutions, namely the private ones. Another important note is the existing dependency between this case and the *Portal do Utente* in order to confirm the patient consents.

5.6.2.2 Case B

In order to access the clinical information of a foreign patient, the CIC decided to create a new project called *Portal Internacional*[1]. This website would allow every authenticated and authorized professional to access some PS in a Portuguese healthcare institution event context. However, there is a really big problem: the absence of a Nation Healthcare Professional Record and consequently of an Authentication Provider, which the authors explore more in detail at Section 5.7.2.4. A general view of the components is presented at Figure 5.4.

5.7 The Portuguese Electronic Health Record

The next subsections are intended to describe the way all the projects are supposed to be connected and to share clinical data. The section starts with the recent developments and then presents the vision that the authors built from the research done in the last months.

5.7.1 Recent Developments

Through the last months, some developments were done in order to integrate the several data and systems existing. This section aims to state the work done and the problems that were raised.

[1] International Portal

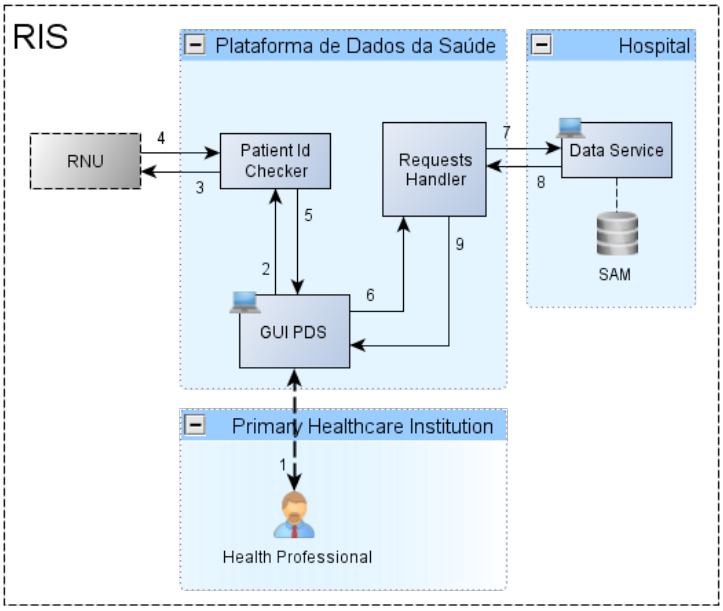

Figure 5.5: Control flow for the process of a clinician accessing information in other healthcare institution with SAM system

5.7.1.1 The Professional Portal

The Professional Portal aims to be the gate through which the doctors will be able to access the clinical information about a patient. In this system, it is intended to gather the information coming from the Patient Portal (introduced by the referenced patient) but also the information stored at other institutions like primary healthcare institutions and hospitals. In this sense, it was necessary to think how it would be possible to integrate the data from two different sources:

Since that the SAM application has a web interface, and it is installed in a significant percentage of the hospitals and primary care institutions, the quicker solution found was to allow the clinicians to directly access the system in order to consult the information. However, to accomplish that, it is necessary that each institutions publishes that service to the public health information network (RIS - Rede de Informação da Saúde). Basically, the work-flow (Fig. 5.5) would be something like this:

1. the clinician at local institution is using SAM to access the local episode and patient information;

2. the clinician clicks in link that takes him to the Professional Portal;

3. the clinician selects one institution accessing directly to the SAM of that institution to consult the information.

5.7.1.2 Discussion

In order to achieve this kind of work-flow is necessary to modify: first, the SAM application introducing the link to the Professional Portal; second, the institutions' infrastructure to allow external connections to their SAM system. Since SAM was developed within the Ministry of Health, the first part was relatively easy to accomplish. On the other hand, the second part is much more difficult than initially estimated:

- it is inconceivable to configure n-to-n permissions so that each institution is able to access all the others. So, the logical solution is to make the request pass through the PDS (Plataforma de Dados da Saúde). With this option, from the target institution point of view the request comes always from PDS, and that is the only external platform to have access to the system;
- the PDS has to provide a tunnelling service handling the request and the reply, something that can be very heavy when working country-wide.

5.7.2 Future vision

In the Section 2.2 we referred some architectural styles that could be interesting to this work. When working with complex projects like this, the solution is always an aggregate of smaller solutions. That means that is not possible to simple apply one model or one style but a composition of several. About the styles that we have studied, we can retain some guides and understand what problems they can solve and where we should use them.

A previous study [CPO+11] advocates the match between the Metropolis Model and the Portuguese healthcare national system. In fact, the authors believes the match is possible. However, the urgency for results prevents the try for a completely fit of the model. Nevertheless, there are several principles that it is possible to extract and apply to the current model. In the next few subsections, we will overview some principles that might be adopted from the studied models.

5.7.2.1 Definition of kernel's scope

The Portuguese EHR project was renamed to *Plataforma de Dados da Saúde*[2] (PDS). The recent developments under the sign of PDS has led to the releasing of two systems: the Patient Portal - My Notes and the Professional Portal. However, these two systems were developed almost as independent systems, with their own user interfaces, architecture, technologies and even implemented by different institutions (as represented at Fig. 5.6).

In order to became a real platform for sharing clinical data, the PDS should evolve with a well delimited scope. Following some principles of the Metropolis Model (see Sec. 2.2.1) it is possible to formulate the next suggestions:

- delimit the scope of PDS to a platform for sharing data;
- split the logical domain from the presentation one.

[2]Healthcare Data Platform

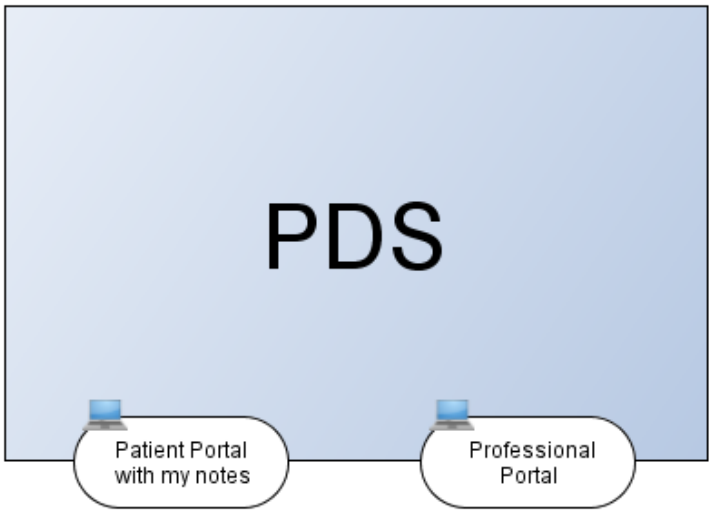

Figure 5.6: The actual situation with the two portals

The objective is to transform the two applications so that the two existing interfaces became only the official clients to the clinical information repository (PDS), in the case, the official ones. To achieve this, it is necessary to clearly separate the two domains, defining web services that are used to query and retrieve data, like represented at Fig. 5.7.

This strategy meets the Metropolis Model principles since we are trying to create a smaller but more robust kernel of clinical information. At the same time, it allows to transform those interfaces into open interfaces. By doing that, many stakeholders would have the opportunity (Fig. 5.8) to:

- develop new applications using the existing services provided directly by the Ministry;
- integrate the information in the work-flow of the existing information systems.

The most significant part is that, the power and investment of the companies would create significant value to the patients, even with the Ministry spending no money unless the effort to provide and define the services. Sometimes, when talking about crowd-sourced where the information is the fundamental, it is not necessary to do high investment but to provide the right tools to the interested parties.

5.7.2.2 Internal organization

The PDS is expected to became a really huge system. In that sense, the way it is internally organized is fundamental to allow the addition of new services to fit new requirements. The Service-oriented Architectures (Section 2.2.2) appear as an interesting solution to solve the scalability and complexity issues.

There are some PDS components that are easily identified as potential services, for instance:

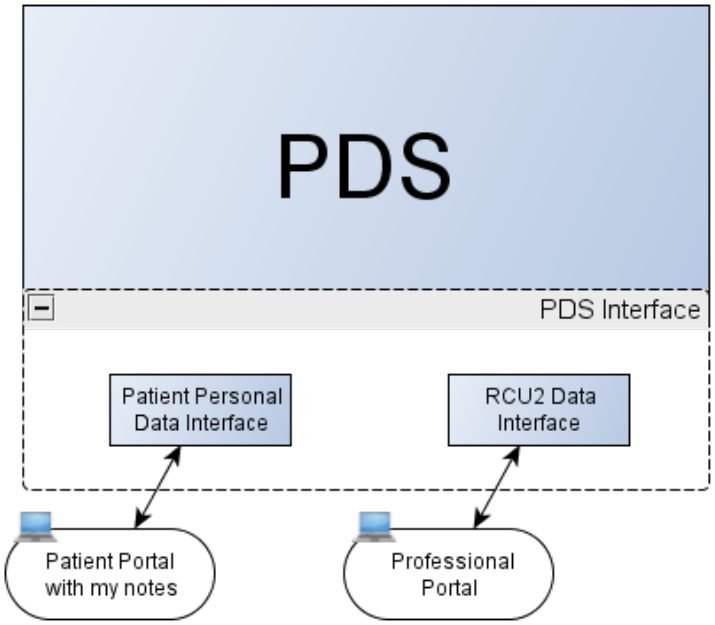

Figure 5.7: The recommended approach, creating well-separated logic and interface domains

- Data Anonymizer - receives some data and returns it without being possible to reveal the patient identity;
- Data Dispatch Manager - receives the data to be transferred to some institution and assures that it arrives the destination;
- RCU2 Manager - important component to manage all the actions performed that are related with RCU2. It might be an example of a service composed by internal services itself.

5.7.2.3 The event handling

In the Section 2.2.3 we have shortly described the Event-oriented Architectures and obviously, it was on purpose. The healthcare reality is a area characterized by several events, an emergency situation, a surgery, a complementary exam, etc. In fact, each episode is an event that has information attached and that is relevant to someone, either a patient, a doctor or even an institution. In this sense, it is important to understand how is it possible to fit this model in a very complex context. In terms of medium-term vision, the situations triggered as events are:

- the family doctor needs to get warned about new information of its patients, to include in the RCU2;
- some national institutions (e.g. *Instituto Nacional de Estatística*[3] (INE) or *Direção-Geral de Saúde*[4] (DGS)) are interested in receiving information.

[3]Statistical National Institute
[4]Overall Direction of Health

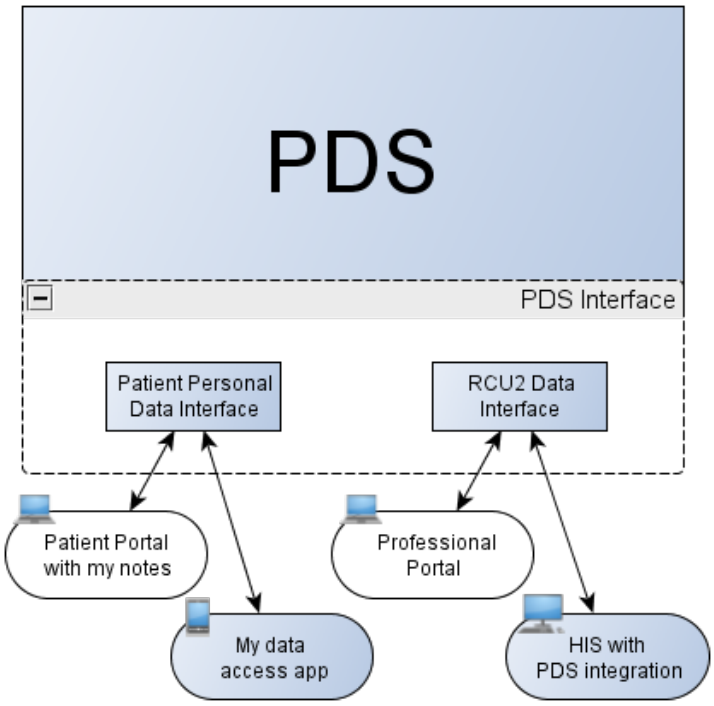

Figure 5.8: The possibilities created by opening the interfaces to other stakeholders

The use of an event-oriented architecture would be like (Fig. 5.9):

1. the national clients manifests interest in received some kind of information at PDS;
2. the subscription service registers the interested clients;
3. when an event arrives at PDS, the subscription service forwards it to the interested parties.

In summary, it consists in the creation of a specific service inside PDS, that would be responsible for managing the subscriptions that the institutions do. Moreover, the family doctors would also be automatically registered to receive notifications about the new proposals for the their patients RCU2.

Since we are talking about triggering and handling events, the use of HL7 V2 (Section 3.1.1.2) might facilitate the data transfer between the local institutions and the services above (e.g. Subscription Service). Such as described in the referred section, in addition of HL7 V2 being an event-oriented standard it is also an excellent way of sending small portions of data.

5.7.2.4 Healthcare Professional Identity Provider

An Healthcare Professional Identity Provider could help to solve some significant problems in the Portuguese health area. In fact, this problem must be divided in two different issues. The first and most important has to do with the creation of a health professionals national record as it exists to

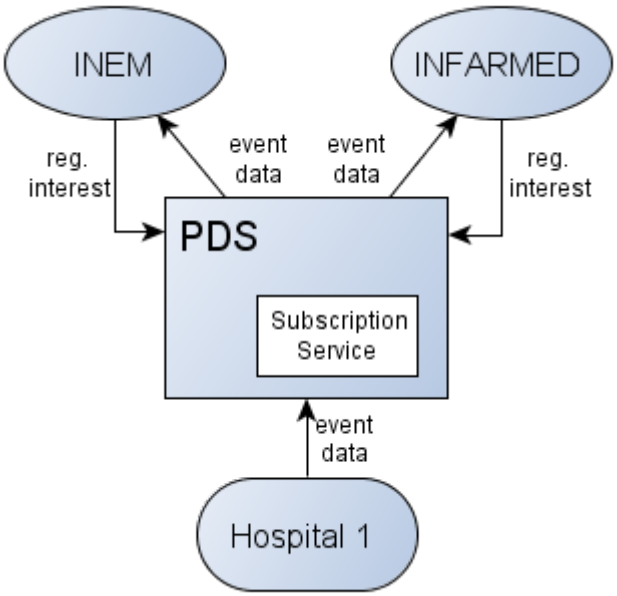

Figure 5.9: The application of an EDA in the context of PDS

the patients, the *Registo Nacional de Utentes*[5] (RNU). The aim of the system would be to store all the professionals working in the healthcare services, helping the Ministry and its information system particularly.

The second issue is the creation of an identity provider certifying that one individual is actually an authenticated and authorized healthcare professional and must be able to access some kind of information.

The urgency for this record is recognized amongst the professionals working in the Ministry's information systems. However, despite of the importance that that kind of record might bring to the systems development, it is not recognized by the superior instances since that it is not a project with enough visibility.

5.8 Architecture Overview

The overview is constituted by four essential modules. The entity responsible (CIC) for planning this change process defined the following projects:

- *Portal do Utente (as minhas notas)* – the Portuguese PHR;
- *Resumo Clínico Único do Utente* – the Portuguese Patient Summary;
- epSOS integration – *Portal Internacional* and the RCU2 availability abroad the country;
- *Portal do Profissional* – the portal where the professionals access the patient clinical data.

[5]Patients National Record

Table 5.1: Summary of *Portal do Utente - as minhas notas*

	Recent developments	**Future vision**
Application Architecture	completely new system (website) to be integrated with the existing ones	definition of services for retrieving the data
Information Architecture	centralized repository of clinical self-introduced information and patient consent	new types of consents; new functionalities allowing the introduction of more information; store the data using a standard
Technical Architecture	-	web services implementing IHE profiles

All these projects are supposed to be interconnected by a platform created with that goal and named *Plataforma de Dados de Saúde* (PDS). The future vision, represented by the Figure 5.10 is based on limiting the scope of PDS to the minimum, removing all the user interfaces clients from its scope. To do this, it is necessary to implement services that those clients interface can use to present the information. This way, it is possible in future to open that services to other stakeholders, letting them construct alternatives to the official clients and new ways of using that information. These future "investors" may be companies that build software to the healthcare arena as well as private healthcare institutions.

The obvious response to the problem of exchanging clinical information is using well-known standards. Although, in the chaotic context of several systems and applications not talking with each other that is not a reasonable answer. So, having this scenario into account it is possible to point out these guidelines:

- the systems in development process or the systems yet to come should be built under some existing international standard;
- the data that is sent out from the PDS should use standards and interfaces completely defined and clear;
- the data flow inside the PDS may not be using standards if that option clearly brings benefits;
- regarding the existing systems, a process for adopting some standard should be done with small accomplishments, step by step.

The next tables help to understand the state of the four essential components.

Table 5.2: Summary of RCU2

	Recent developments	**Future vision**
Application Architecture	new background system to provide access to the RCU2	well defined interfaces to retrieve and manage the RCU2
Information Architecture	selection of important information; definition of data model; to be implemented at a CSP level by CNPD imposition; document managed by the family doctor	group the RCU2 into real data warehouses by regions with reliable backup systems;
Technical Architecture	to be stored at the CSP servers	-

Table 5.3: Summary of epSOS project

	Recent developments	**Future vision**
Application Architecture	designing and discussing the new background system and the *Portal Internacional*	integrate the National Connector into the PDS
Information Architecture	completely dependent of other services like *Portal do Utente* or RCU2	-
Technical Architecture	-	define the services of NC using IHE profiles; necessity for an Healthcare Professional Identity Provider

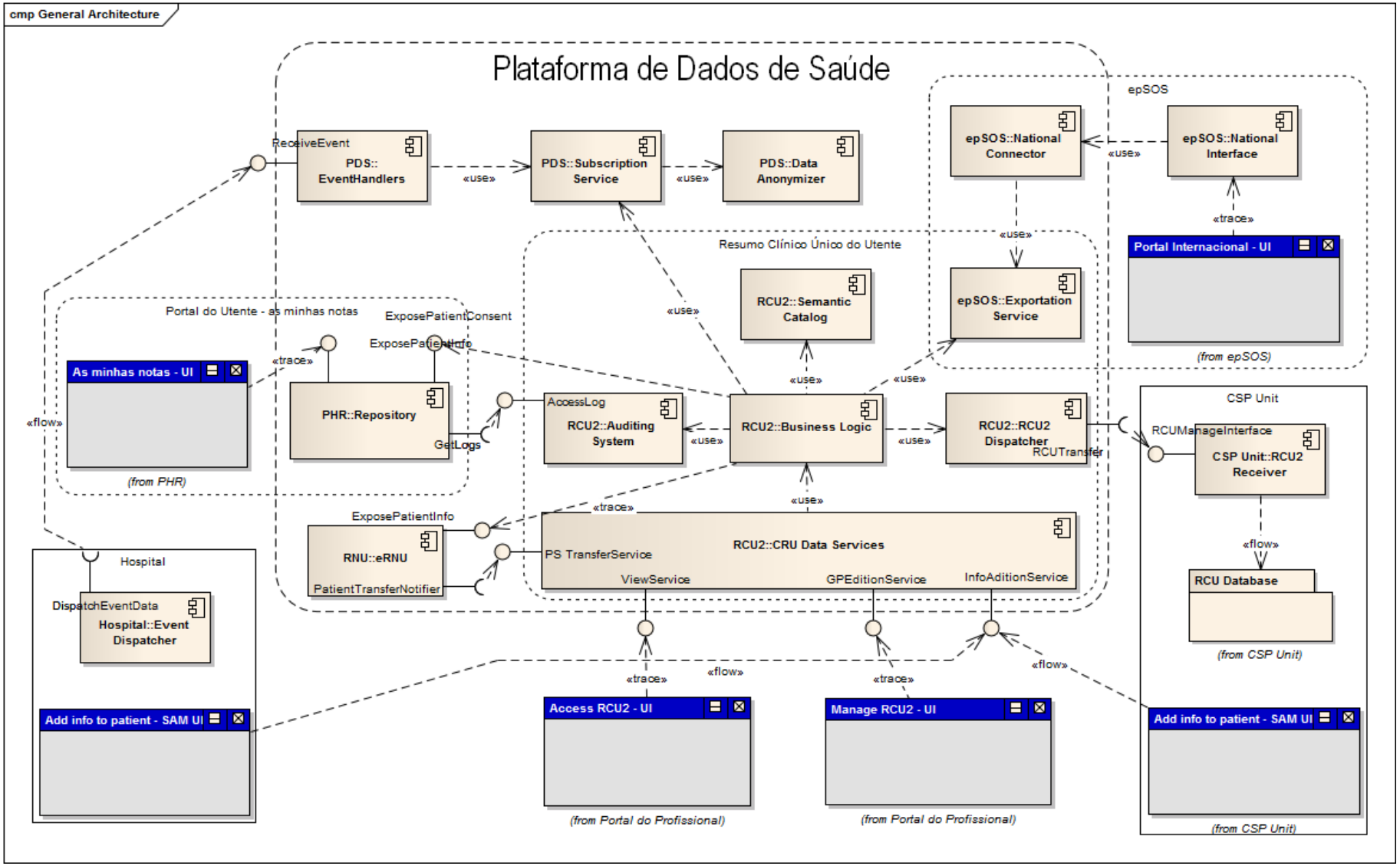

Figure 5.10: General view of the architecture future vision

Chapter 6

Conclusions

The importance of an Electronic Health Record system and its benefits in the healthcare services equals the difficulty that they face to be implemented. In fact, this kind of platform take many years to be implemented, always resulting in high costs. In this context, it was important that this architecture proposal could reflect the existing case studies, in order to avoid approaches that could led to implementation failures. However, the challenges are not only the size of such project. Most of the times, EHR implementations have to deal with and manage multiple external factors, either political, economical or social. These factors tend to limit and condition the execution progress.

6.1 General

The health area has several actors, multiple institutions and not less business processes. In this scenario, it was fundamental that the research for designing the proposal was done close to the main stakeholders, essentially the healthcare organizations IT directors. On the other hand, the Portugal economic situation demands these projects to obtain short-term results. In this dissertation work, the main objective was not the short-term perspective but the long-term evolution and vision of the system. However, it was also important that the architecture proposal allows to obtain some quick results, without precluding the future development, not only because of the economic situation but also because that might be the right way to engage all the EHR stakeholders, from patients to healthcare organizations.

Throughout this dissertation study, an important knowledge of healthcare arena was gained. This knowledge is fundamental to be able to work in a complex context like this, where there are several stakeholders from completely different backgrounds, multiple institutions involved and many underlying interests. The research work was done on a weekly basis and in straight collaboration with the SPMS team. The existence of this cooperation allowed this work to be realistic. Moreover, it validates the dissertation work since that the people involved have many years of experience in the area and have a deep knowledge about the health information systems panorama and health organizations.

6.2 Contributions

The work done under this dissertation project comprehended several IT engineering areas. Indeed, the contribution was from the analyses of the business to understand the main requirements and problems, passing through the study of the information and application architecture, till the definition of a database model for the RCU2, with specific requisites to work over Oracle 7.3.1 databases.

Due to the research done, it was possible to state the possibility of making some little adjustments in order to facilitate and enhance future developments. In fact, there was always a concern about designing the architecture the right way but also to provide paths to quick-wins. In this sense, the authors believe that the main platform created to allow the data sharing (PDS) should focus on allow that. That is, the PDS should clearly stablish its limits and scope and then offer a set of services to provide the clinical data sharing following some principles of the Metropolis Model. This way, the user interfaces would be implemented by the consumers of the data, either hospitals or independent software companies, for instance. The point is that each consumer would integrate the data the way it wants. In addition, the availability of certified and secure open services would instigate the stakeholders to develop under those services, removing the need for government's investment and increasing the quality by competition.

Another conclusion is that there is an urgent need for normalisation. That is, the organizations must make an effort to normalise not only the codification standards but also the processes. However, the initiative and the example has to come from the higher instances under penalty of not being successful. On the other hand, in terms of standards, it is possible to say that the adoption of a standard to store and share clinical data will not solve all the problems but might be a pivotal step to solve several of them. Thereby, and following an evolutionary strategy, every interface or service thought to be available outside PDS, should be built with international standards, either for defining the services available (e.g. IHE profiles) as for encapsulate the data (e.g. HL7 CDA).

Regarding PDS internal organisation, it is recommended to use a SOA approach in order to improve flexibility and reuse of the multiple components and services. In this case, the immediate use of standards should be applied to the new services.

To conclude, the authors believe that the objectives were met and that the research constitutes an important document to alert the responsible entities to possible issues and new solutions.

6.3 Future

Despite of the effort that has already been spent and some positive results that have been achieved, there is still many changes to be done and many requirements to be met before Portugal can claim to have an EHR. Anyway, the path to reach it is too long and demands the existence of side projects that serve as guides and milestones of the global project.

The implementation and availability of the RCU2 should be the priority in the near future because it has potential to have an enormous positive impact. The authors believe that only the

realization of this project is already a giant step to help the professionals increase of the healthcare services quality.

Apart from the conceptual and business challenges, the final purpose must guide all the future work: improving the patient healthcare services allowing the healthcare professionals to access relevant clinical information.

Appendix A

Specific Contributions

A.1 RCU2

A.1.1 Local Database Model

In the scope of the collaboration with Ministry of Health, it was developed the database model to held the RCU2 data. The data model was built in a team effort with Dr. Raquel Deveza[1], Eng. Miguel Oliveira[2], Dr. José Castanheira[3]. The model is divided in two layer:

- the bottom layer has the tables with all the data and logs of the operations (see Figure A.1);
- the top layer provides the views to be consulted and which use the structure above (see Figure A.2).

[1] Dr. Raquel Deveza - Coordinator of the RCU2 project at SPMS
[2] Eng. Miguel Oliveira - FEUP team member
[3] Dr. José Castanheira - Coordinator of Information Systems Unit of ARSN

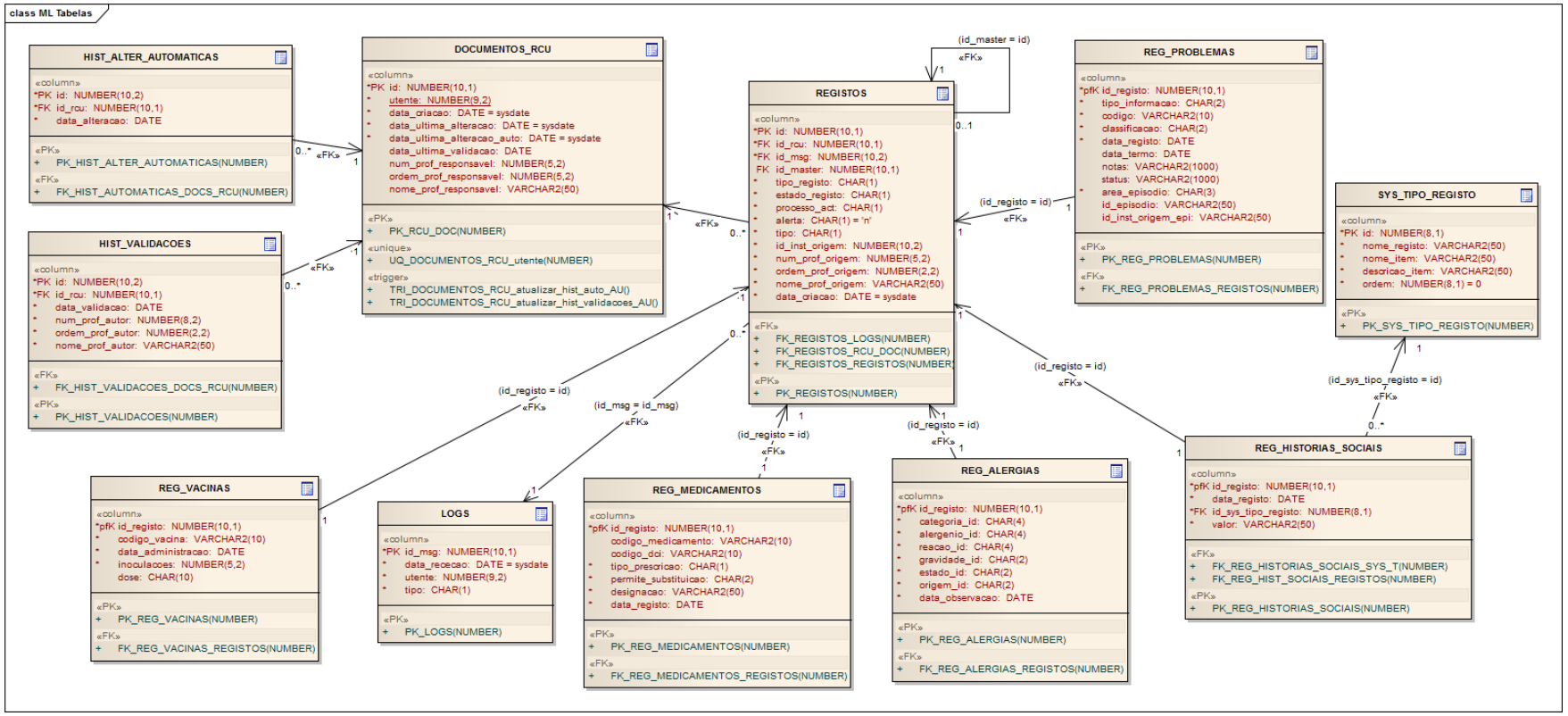

Figure A.1: Database model developed internally to support the RCU2 - bottom layer

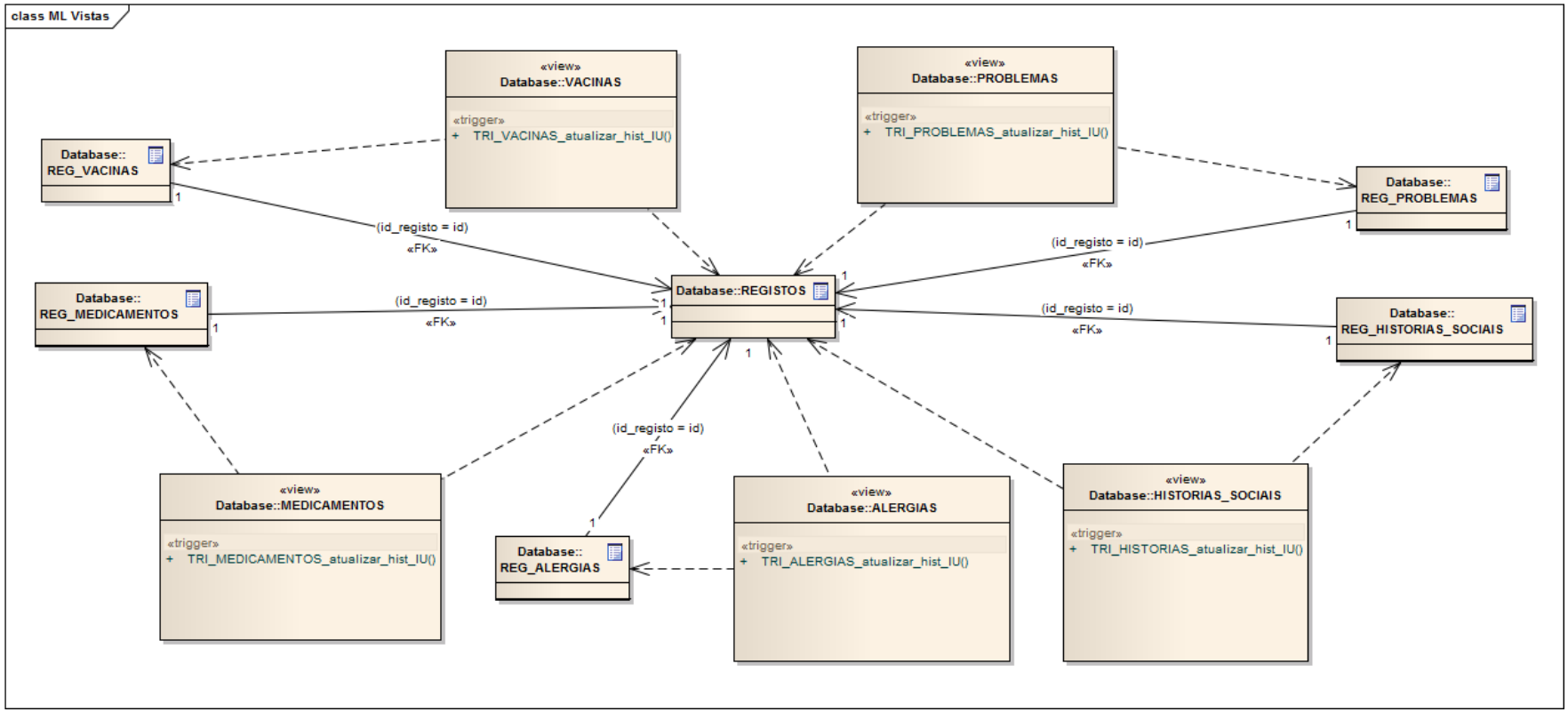

Figure A.2: Database model developed internally to support the RCU2 - top layer

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