CONTRIBUTIONS ON MEDICAL INFORMATION SYSTEMS INTEROPERABILITY DEMONSTRATED AT ELECTRONIC HEALTHCARE RECORDS SYSTEMS

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Contributions on medical information systems interoperability demonstrated at Electronic Healthcare Records systems

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Rezumat, There is a constant need for medical information systems that are easy to develop, flexible, reusable and mainly in the present times ready to a high degree of interoperability. This means a serious analysis of complex processes associated with the system and building the model that ensures all the previously mentioned requirements. The solution defended by this thesis creates a modern technological support in tools and methodologies for modeling, designing and implementing of complex medical information systems that are ready to communicate with other similar systems having as benefits the improvement of medical services for patients. After defining the requirements for information communication between EHR systems a generic model of medical information system was built. A methodological framework for validating the compliance with these requirements and to assess the quality of interoperability of electronic health records is proposed. New software tools and components to ensure interoperability were designed, developed and implemented based on the model. The quality of the developed model and tools has been discussed using proper metrics and validation of solutions was done on real clinical data from Bega Clinic Timişoara.

Contents

LIST OF ACRONYMS

AHIMA	American Health Information Management Association
ANSI	American National Standard Institute
ASTM	American Society for Testing and Materials
BPMN	Business Process Modeling and Notation
CCD	Continuity of Care Document
CCR	Continuity of Care Record
CDS	Concept Data Service
CEN	Comity European de Normalization
CIM	Computation Independent Models
CORBA	*Common Object Request Broker Architecture*
EDI	Electronic Data Interchange
EHR	Electronic Health Record
EHR systems	Electronic Health Record systems
EMR	Electronic Medical Record
GCM	Generic Component Model
GP	General Practitioner
HIT	Medical information technology
HL7	Health Level Seven
HL7 CDA	Health Level 7 Clinical Document Architecture
HTML	HyperText Markup Language
ICT	Information and Communication Technologies
IHE	Integrating the Healthcare Enterprise
IOM	Institute of Medicine
ISO	International Standards Organization
LOINC	Logical Observation Identifiers Names and Codes
MDA	Model-Driven Architecture
MDD	Model-Driven Development
MI	Myocardial Infarction
MML	Medical Markup Language
MOF	Meta-Object Facility
MPI	Master Patient Index
MRN	Medical Record Number
OGD IS	Obstetrics-Gynecology Department Information System
OMG	Object Management Group
ONC	Office of the National Coordinator for Health Information Technology
PDF	Portable Document Format
PDS	Patient Data Service
PHR	Personal Health Record
PIM	Platform Independent Models
PSM	Platform Specific Models
RADT	Registration-Admission-Discharge-Transfer
RID	Retrieve Information for Display
RIM	Reference Information Model
RM-ODP	ISO 10746 “Information Technology”–Open Distributed

	Process.Part 2: Reference Model
RUP	Rational Unified Process
SNOMED - CT	Systematized Nomenclature of Medicine Clinical Terms
TC	Technical Committee
TDS	Template Data Service
UML	Unified Modeling Language
UP	Unified Process
XDS	Cross Enterprise Document Sharing
XHTML	Extensible HyperText Markup Language
XMI	XML Metadata Interchange
XML	eXtensible Markup Lanhuage

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1. INTRODUCTION

1.1. Introduction into the topic

Information Technology is inherently multi-disciplinary and frontier research on different domains, healthcare being one vitally important and modern. Shared information is the foundation for seamless care with main strategic targets: high professional quality of care, shorter waiting time, less errors, high level of user satisfaction, better information about service and efficient use of resources. Achieving these outcomes depends on the ability of two or more systems or components to exchange information and to use the information that has been exchanged that defines by their interoperability [1]. Interoperability in healthcare involves communication between medical information systems as a basis for continuous care by creating an electronic health record for the patient making available information for physicians in real time and regardless of location.

Population over 65 years in Europe (EU-27) is currently 80 million people; this value is expected to double until 2050. Life expectancy is already growing by an average of 2.5 years per decade and the number of people over 80 years is expected to increase by 180% until 2050 [Eurostat, 2010]. In this context, ICT has premises to reduce costs and to support quality care. The European Union is moving towards "European e-Health Area", coordinating and promoting synergies between related policies and stakeholders in order to develop better solutions to prevent market fragmentation and disseminate best practices [2], [3].

The healthcare system in Romania is supported by ICT through computers and Internet connection, but regarding communication, there is a lack of interoperability. Solving this problem will result in achieving social and economic benefits, a better patient care, less medical errors, and reduced medical staff workload.

Communication between different systems and their components in a complex and highly dynamic environment must fulfill some requirements: openness, scalability, flexibility, portability, distribution at Internet level, standard conformance, business process orientation, consideration of timing aspects of exchanged data and information, user acceptance, lawfulness, and appropriate security and privacy services. [4]

Interoperability of different medical information systems facilitates access to information and enhances the safety and quality of patient care despite of its location, because information about a patient is available much easier electronically and at the same time provides patients and medical professionals with updated and relevant information about a patient provided to patients and health professionals is easier available when delivered electronically, thereby ensuring security and privacy of personal data.

Medical information systems need to communicate based on standards, facilitating the exchange of messages. There are several available standards, such as: HL7, EVN 13606, and DICOM. Building messages based on standards does not depend on particular technology, (e.g. C #, Visual Basic, PHP), and the data transfer between the systems can be made using the XML technology.

To meet the challenge for efficient, high quality, safe and sustainable care in developing countries, there is a need to extend and improve communication and cooperation between all actors participating in better patients' care by creating interoperable health information systems.

Developing a healthcare information system is a challenging task. It is important to create a medical information system that can be developed in less time and with less effort and be characterized by: flexibility, reusability and especially to be prepared for a higher degree of interoperability. Achieving this means a serious analysis of the complex processes associated with the system and creating a model which ensures all requirements.

Starting from the general frame prepared by the Generic Component Model, the thesis creates a model for the medical information system in a Department of Obstetrics-Gynecology with an original development and contribution on the interoperability feature, implements it using advanced technology and standards, adds useful IT tools and evaluates the results from a quality point of view and from the interoperability readiness point of view.

1.2. Objectives of the PhD thesis

The main objective of the PhD thesis is the investigation of advanced interoperability of distributed medical information system for a better collaboration between Electronic Health Record Systems with a study made on an information system serving a department of Obstetrics-Gynecology. In order to achieve this, six specific objectives have been defined:

1. Analysis of interoperability between systems and between EHR systems taking into consideration definitions, interoperability levels, system architectures and their representation using ontologies, terminologies and coding systems related to EHR.
2. Describing the possibility to model medical information systems and their interoperability using the GCM and other methodologies.
3. Study of the Electronic Health Record and its properties in relation with the interoperability concept.
4. Model the information and activity workflow in an Obstetrics-Gynecology department to be ready for high interoperability degree using GCM, and design and implement the related application.
5. Designing and implementing a web service as a support for flexible development of interoperable medical information systems.
6. Evaluate the developed solutions from a quality point of view and assessment of the potential interoperability degree.

1.3. Structure of the thesis

The Chapters of this thesis have been organized as in the following:

- Chapter 2 focuses on objective 1 analyzing the interoperability between systems taking into consideration definitions, systems and systems' architecture, interoperability characteristics, ontologies for system' representation and interoperability levels.

- Chapter 3 deals with objective 2 describing the possibility to model medical information systems and their interoperability using the GCM and other methodologies (UP, RUP, MDD and MDA).
- Chapter 4 focuses on objectives 1 and 3 where EHR architectures, advantages, models and systems are presented.
- Chapter 5 focuses on objectives 1 and 3 seen from the interoperability between EHR systems point of view and taking into consideration interoperability standards related to EHR, concentrating on interoperability examples, and presenting ontologies, terminologies and coding systems for EHR.
- Chapter 6 is the core of the thesis presenting a solution related to objective 4, creating and developing the informational framework for an Obstetrics-Gynecology department application using GCM seen from an interoperability point of view and presenting the design, implementation and use of the application.
- Chapter 7 is related to objective 6 designing and implementing a service supporting medical information system interoperability, making the process more flexible and integrated.
- Chapter 8 solves the objective 5, evaluating the developed solutions from a quality point of view and assessing the degree of potential interoperability.
- Chapter 9 concludes the thesis and gives a description of future directions.

Figure 1.1 reflects the coherence of the presented subjects as seen from the chapter's sequence.

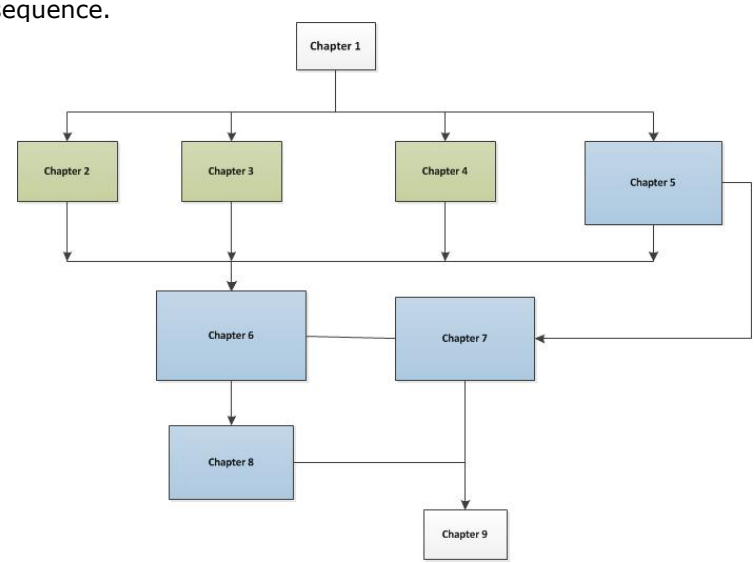


Figure 1.1. Structure of PhD Thesis

Green: theoretical developments
Blue: scientific contributions and applications
Gray: introduction and conclusions.

2. INTEROPERABILITY BETWEEN SYSTEMS

This chapter gives an overview of the importance to achieve interoperability between systems, deals with concepts as system and systems' architectures, describes interoperability characteristics, ontologies for systems' representation and interoperability level

2.1. Interoperability, systems and systems architecture

In [1], the interoperability is defined as: the ability of two or more systems or components to exchange information and to use the information that has been exchanged.

Communication between different systems and their components in a complex and highly dynamic environment must fulfill some requirements [4]:

- openness, scalability, flexibility, portability
- distribution at internet level
- standard conformance
- business process orientation
- consideration of timing aspects of data and information exchanged
- user acceptance
- lawfulness
- appropriate security and privacy services.

After [5], a system is defined as: „a collection of components organized to accomplish a specific function or set of functions, can be distinguished from its environment which may influence that system by setting constraints".

All the aspects and properties of systems presented from here up to the end of this Section 2.1 have been described in papers published earlier and referenced in this thesis. Usually, the content of referenced papers is fully interpreted and other references are used to confirm those statements.

A system architecture is defined after [6] as „a generic discipline to handle objects (existing or to be created) called systems, in a way that supports reasoning about the structural properties of these objects."

The system architecture can be referred in different contexts [6]:

- the architecture of a system (e.g., a model to describe or analyze a system)
- architecting a system (e.g., a method to build the architecture of a system)
- a body of knowledge for architecting systems while meeting business needs (e.g., a discipline to master system design).

System architecture is a global model and contains: a structure, properties, relationships, behavior and dynamics, multiple views of the system [6].

Using a system architecture results in describing consistently and design efficiently complex systems such as [6]:

- an industrial system (the original meaning of Systems Architecture)
- an IT infrastructure (Enterprise Architecture)

- an organization (Organizational Architecture)
- a business (Business Architecture)
- a project

After [6], the system architecture is based on 9 fundamentals principles:

- the object of the reality are modeled as systems
- a system could be separate in more subsystems
- a system had to be considered from interaction with other systems
- a system had to be considered through its whole lifecycle
- a system could be accessed from another with the help of an interface
- a system could be considered at various abstraction levels
- a system could be viewed according to several layers
- a system could be described through interrelated models
- a system could be described through different viewpoint

2.2. Interoperability characteristics

After [7], the definition of interoperability implies the multi-faceted nature of interoperability in e-Health. These different facets of the interoperability are the interoperability characteristics. The interoperability characteristics are: reuse, evolution, and standards adoption, explicit specification of business context, business services, and separation of specification from implementation.

The first interoperability characteristic is reuse, which relies on reuse of virtual worlds and virtual entities rather than developing new ones, but this cannot be achieved with an empirical process design, but modeling methods are needed [8].

The second interoperability characteristic is evolution. One of the evolution definitions after [9] is: „any change in the quality, functionality, or implementation of the services offered by a system." The most two relevant Lehman's laws [10] regarding to the evolution is first and sixth laws, which are described as:

- Systems must be continually adapted else they become progressively less satisfactory
- The functional content of systems must be continually increased to maintain user satisfaction over their lifetime.

The third interoperability characteristic is standard adaptation. Using standards in system integration is very important. It is generally agreed that the development and implementation of specifications and standards is not a simple process. There were identified some issues and barriers which made difficult the development and adaptation of specifications and standards and these are [11]:

- Complex and inflexible standardization processes;
- Lack of inclusiveness in the process of developing and adopting specifications and standards;
- Lack of consistent approach to allow multi-stakeholder collaboration and participation;
- Lack of early implementation of specifications;
- Lack of ability to create derivative works.

The fourth interoperability characteristic is explicit specification of business context. After [12], the business viewpoint identifies the business context and the scope of specification and contains the following artifacts:

- The use case and scenarios which will help the work.
- A set of well performed requirements – informational, functional and non-functional that can be extract from the use case and scenarios and driven out from subsequent analysis.
- A business object model that identifies objectives and business entities, including the roles that those entities have in executing processes to achieve the stated objectives.

Starting from Nehta's definition and browsing through literature I found that there are several important types of interoperability characteristics: reuse, evolution, and standards adoption, explicit specification of business context, business services, and separation of specification from implementation. It is important to identify the interoperability characteristics and I did so for each of them during the work at the thesis.

- the reuse characteristic - is used at the classes describing the system, the system classes are done in the reusable manner, it is described in Chapter 6.3.1.
- the evolution characteristic - the OGD IS is capable to be updated to new requirements in a flexible manner, as it is described in Chapter 6.4.
- standard adaptation - the communication between OGD IS with other EHR systems is using standards (HL7 CDA and CCD), reflected in Chapter 6.6 and Chapter 6.7.
- explicit specification of business context, business services and separation of specification from implementation characteristics - is done using Generic Component Model, because the system is decomposed to the fine grained level, and the three RM-ODP views (Enterprise, Information, Computational) are platform independent and the other two (Engineering and Technology) views are platform dependent, as described in Chapter 6.3.2.

2.3. Ontologies for systems representation

The paragraph concerns the ontologies that will be used future in the work related to SNOMED-CT (Systematized Nomenclature of Medicine Clinical Terms) and LOINC (Logical Observation Identifiers Names and Codes).

A commonly accepted definition of ontology in computer science is given by Gruber [13], which defines the ontology as „a specification of conceptualization, used to help programs and humans share knowledge".

From knowledge point of view ontologies are composed by the following components: concepts, attributes, relations and instances [14]:

- Concepts represent a set or a class of entities (e.g., peoples, products);
- Attributes represent the features of a class(e.g., shape, color);
- Relations represent the interaction between classes;
- Instances represent the actual entities.

In literature have been proposed numerous upper ontologies, but [15] identifies five successive levels of ontology hierarchy, including general or philosophical ontology, top level (reference) ontology, domain ontology, application ontology, all of them separated from ICT ontology

2.4. Interoperability levels

In order to improve the communication between systems, interoperability between these systems has to be ensured. For this reason, there were defined five interoperability levels depending on the objectives and requirements of the actors involved in communication and cooperation described in Table 2.1.

Table 2.1 Interoperability levels (after [16])

Interoperability Level	**Instances**
Technical interoperability	Technical plug&play, signal and protocol compatibility
Structural interoperability	Simple electronic data exchange
Syntactic interoperability	Messages, clinical documents, agreed vocabulary
Semantic interoperability	Advanced messaging, common information models and terminology
Organizations/service interoperability	Common business process

After [16], the interoperability levels are described as in the following:

- Technical interoperability is a prerequisite of ICT. It concerns with the information exchange and use, but information is not understood, it is an exchange of bits and bytes.
- Structural interoperability (data level interoperability) after Shannon's definition is information in mathematical terms, describing the grammar (codes, symbols, and alphabet) for exchange. In this type of environment, the knowledge for interpreting data and deriving the actions must be available at both ends.
- Syntactic interoperability supports interoperability by providing a grammar.
- Semantic interoperability concerns with communicating using formally modeled information. In health domain, it is define after [17] as: "Health system interoperability is the ability, defined by ICT applications and systems, to exchange, understand and act in citizens/patients and other health-related information and knowledge, among linguistically and culturally disparate health professionals, patients and other actors and organizations within and across health system jurisdictions in a collaborative manner".
- Organization/Service interoperability concerns with the service invocation according to the pragmatic aspect of the information.

In order to provide the business objectives, the system mediator has to provide all missing functionalities needed to successfully finishing collaboration. Communication and cooperation is based on common views on reality provided through observation resulting in data about the system/environment in question. The data have to be interpreted based on the business domain's knowledge and have to respect the business requirements. The information resulted is used to take the right action, and in this way the information cycle loop is closed. Information cycle and interoperability levels of communication and collaborating systems are directly interconnected [16].

Interoperability ontologies facilitate the integration of data from different sources and their interference [16]

2.4. Conclusions

The objective of this chapter is analyzing the interoperability between systems and between EHR systems taking into consideration definitions, interoperability levels, system architectures and their representation for ontologies, terminologies and coding systems related to EHR. Following aspects were analyzed in detail:

- importance of interoperability between systems giving the definition of the interoperability and basic requirements
- the systems' architecture definitions and principles
- the interoperability characteristics
- the ontologies for systems' representation related to the collaboration between concepts, as any interoperability depends on the knowledge shared between them
- the levels of interoperability depending on the objectives and requirements of the actors involved in communication and cooperation.

The contributions for this chapter are:

- A thorough review related to interoperability between systems, definition, basic requirements, and systems' architecture definitions and principles that prepared the support for the entire work.
- Defining interoperability characteristics selected from literature corresponding to the actual system.
- A review of the levels of interoperability for the actors involved in communication and cooperation, depending on related objectives and requirements.

3. MODELING MEDICAL INFORMATION SYSTEMS

3.1. Definitions

After [5] a model is defined as: „partial representation of the reality. It is restricted to those attributes the modeler is interested in. The interest in the model depends on the addressed audience, the reason and the purpose of the modeling exercise as well as the use of the resulting model for certain objectives and time instead of real world. Therefore, the model as a result of an interpretation must be interpreted itself"

After [5] a system is defined as: „a collection of components organized to accomplish a specific function or set of functions can be distinguished from its environment which may influence that system by setting constraints".

After [16] architecture is defined as: "the sum of a system's components, their functions and their interrelations, has to be described by the representation of related concepts at corresponding level of granularity and their aggregations to another level".

3.2. The Generic Component Model

For preparing a solid and flexible development process when implementing a medical information system it is important working with a model-driven system architecture. A proper model for start is the Generic Component Model (GCM) which analysis the desired system from many perspectives.

The GCM started to be developed by Professor Bernd Blobel from the University of Regensburg Medical Center, eHealth Competence Center. The GCM definition after [16] is: "an architecture framework that enables the representation of any real or virtual system including both the system architecture from its business perspective and the system's development process for the ICT solution supporting or enabling that business". The GCM can be used to model systems by reducing their complexity and it is possible to separate the phase of their design, specification, implementation and deployment by representing and interrelating different views [18].

It is possible to design advanced Electronic Health Record systems using GCM because this provides and architectural framework, also it can be used to design other domains (e.g., biomedical engineering domain, bioinformatics domain, legislation domain, ethic domain). This ensures the computation independent and ICT specific aspects of interoperability [9], [16]. The GCM is presented in Figure 3.1 [19].

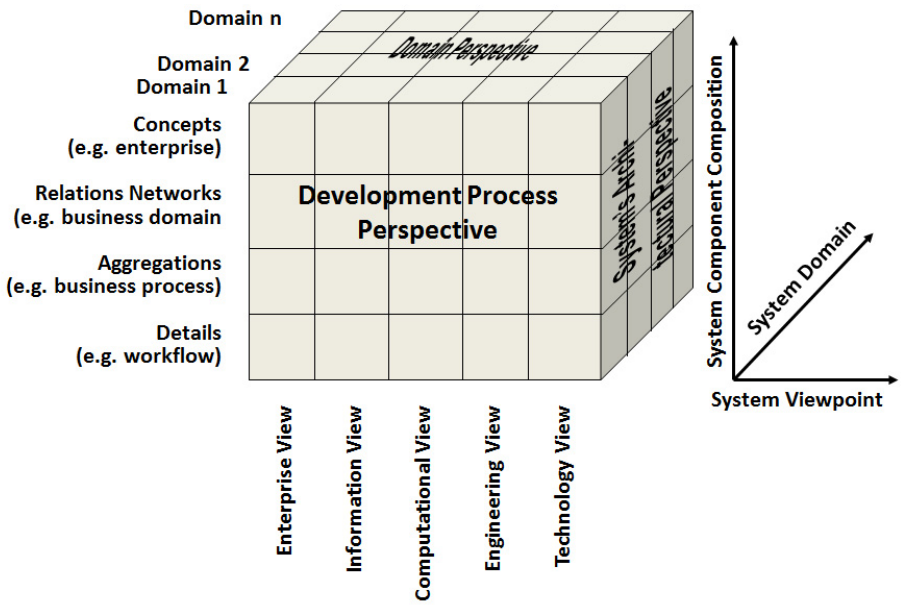


Figure 3.1 Generic Component Model (after [19].)

The GCM considers the system in three dimensions, as in Figure 3.1. [19]:

- Dimension 1 reduces the complexity of interrelated domains by separating them.
- Dimension 2 reduces the structural complexity of systems by decomposing them.
- Dimension 3 reflects the viewpoints of ISO 10746 “”Information Technology – Open Distributed Processing. Part 2: Reference Model” (RM-ODP) and has 5 views: Enterprise, Information, Computational, Engineering and Technology.

From an architectural perspective, GCM is the compositional character of any component-based system’s structure and behavior, considering the essential, unifying concepts and principles of its components and their relationships and so it is reduced the structural complexity of the system by decomposing the components [5]. An example is presented in the following lines, after [5], and the granularity model will be:

- The business domain’s high level objectives (enterprise level);
- The interrelations between the business domain’s systems (business domain level);
- The department-specific services (business process level);
- The procedure (workflow steps).

From a domain’s perspective the system in consideration represents the different domains associated with a system. Several examples are: medical, financial, technical, or administrative domains, domains or different policies and

security, different protocols layers domains, but also ontology-driven terminologies. It is considered domains also the sub-domains or combined to super-domains. The inter-domain relations, including the combination of domains are performed by ontology bridging [5].

The viewpoints of ISO 10746 "Information Technology – Open Distributed Part 2: Reference Model" (RM-ODP) are: Enterprise, Information, Computational, Engineering and Technology. From perspective point of view this is the development process consisting of the following steps: requirement analysis, design, implementation, evaluation, use and maintenance, which are reflecting the Rational Unified Process (RUP). The Enterprise, Information, and Computational views are platform-independent modeling and Engineering and Technology views are platform-dependent modeling [5].

In particular, the OGD is a system that can be modeled using GCM. According to RM-ODP viewpoints I decided to use the following:

- the Enterprise view modeled using Business Process Modeling and Notation,
- the IT perspective modeled using UML.

The core application OGD Information System is developed based on that model and it is described in detail in Chapter 6.3.

3.3. Unified Process and Rational Unified Process

The OGD Information System is developed on a model-driven basis, using the ISO 10746 RM-ODP views and appropriate tools according to the Unified Process, and it is described in Chapter 6.3.

The Unified Software Development Process, commonly known as the Unified Process (UP), is a generic software engineering process [20]. An instance of a UP is the Rational Unified Process, which is extensively used today.

Rational Unified Process is a software engineering process, is a process product and a process framework that can be adapted and extended to fulfill the needs of an organization [21].

The process structure has two dimensions [21]:

- The horizontal axis which represents the time as well as shows the lifecycle aspects of the process;
- The vertical axis represents core process disciplines, which group activities logically by nature.

The first dimension represents the dynamic aspect of the process and it is express in terms like: cycles, phases, iterations and milestones. In the RUP, a software product is design and builds in a succession of incremental iterations. Because of this, the design ideas can be tested and validated [21].

The second dimension represents the static aspect of the process, which is expressed in terms like: activities, disciplines, artifacts and roles [21]. Figure 3.2 presents a process structure in two dimensions.

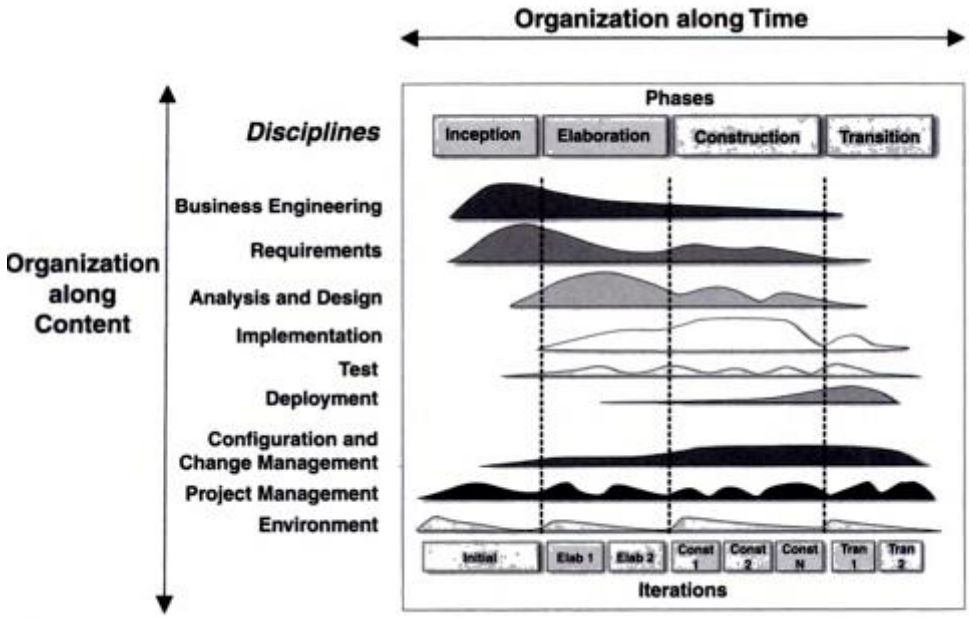


Figure 3.2. Process structure – two dimensions (after [21])

The RUP has six core workflows from technical workflows: business modeling, requirements, analysis, design, implementation, test and deployment.

The RUP facilitates the flexibility, scalability and reusability of the methodology because it provides tooling which delivers the methodology through exportable Web pages and XML Metadata Interchange (XMI) documents. The advantages of using the RUP is that the process's documentation can be viewed as HTML pages and shared as XML files to the software development teams and this will enforce them to design consistent models and use of the same guidelines [19].

3.4. Model-Driven Development and Model-Driven Architecture

After [22], the Model-Driven Development (MDD) is described as: "a software – engineering approach consisting of the application of models and model technologies to raise the level of abstraction at which developers create and evolve software, with the goal of both simplifying and formalizing (standardizing, so that the automation is possible) the various activities and tasks that comprise the software life cycle."

MDD assigns structure and common vocabularies, and by that way the artifacts are useful in different stage in the life cycle (e.g., describing an architecture), for underlying need to link with related artifacts and to provide a medium communication between participants in the project [22].

The Object Management Group (OMG) formalized the MDD approach and offers the Model-Driven Architecture (MDA) as a development process, which uses models and provides mechanism to automatic transformation between the models [23].

After [24], the Model-Driven Architecture is described as: "a software design approach for the development of software systems. It provides a set of guidelines for the structuring of specifications, which are expressed as models. Model-Driven Architecture is a kind of domain engineering of software systems. It was launched by the Object Management Group (OMG) in 2001".

After [25],"the Model-Driven Architecture provides an open, vendor-neutral approach to the challenge of business and technology change. Also, MDA separates business and application logic for underlying platform technology". Three main goals of MDA are: portability, interoperability and reusability by separating the architectural views.

It is platform-independent model of an application or integrated system's business functionality and behavior, using for this the OMG (Object Management Group) modeling standards, as UML and after, can be developed virtually on any platform (e.g., Web Services, .NET, Corba, J2EE), and it is shown in Figure 3.3 [25].

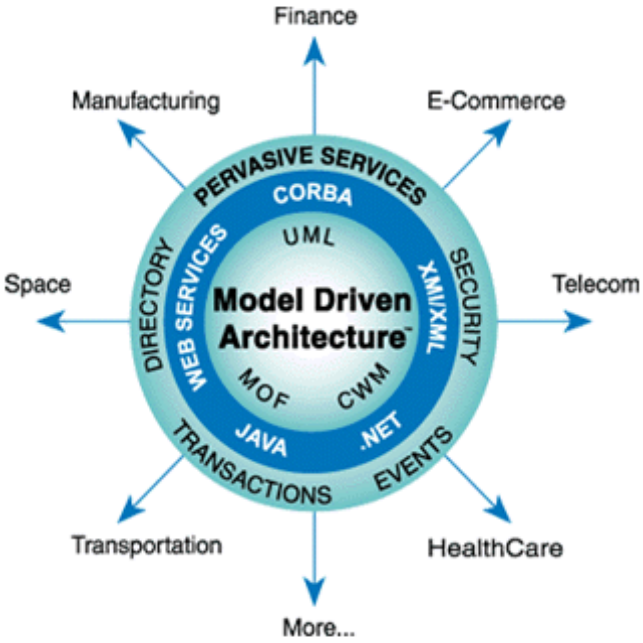


Figure 3.3. Model-Driven Architecture (after [25])

The Model-Driven Architecture is based on two things:

- A four layer meta-modeling architecture;
- Set of complementary OMG standards (Meta-Object Facility – MOF, Unified Modeling Language – UML, XML Metadata Interchange)

The four layer meta-modeling architecture is presented in Figure 3.4, where is presented an instance of the generic architecture model [26], [27].

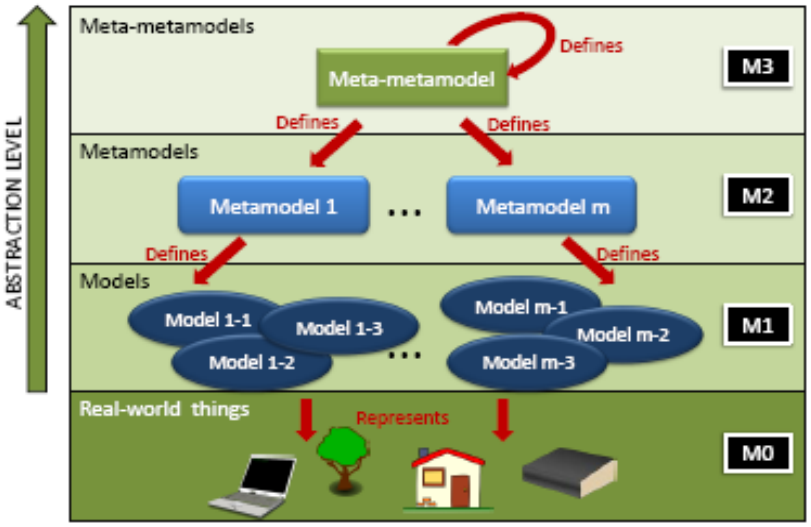


Figure 3.4. MDA four-layer MOF-based architecture (after [26])

MDA approach and standards help to [23]:

- Specifying a system which is independent of the platform that supports it;
- Specifying platforms;
- Choosing a particular platform to the system;
- Transforming the system specification into one for a particular platform.

The model transformation is based on the platform and a set of transformation rules and can be identified three model types [23]:

- Computation Independent Models (CIM);
- Platform Independent Models (PIM);
- Platform Specific Models (PSM).

The MDA and MDA-based architecture it can be easily developed using the RUP workflow description, where the MDA transformation can be comparable for example (example given in [28]) with different models described in the RUP: transformation of the Business Model and Requirement (CIM) into the Analysis Model (PIM); transformation of the Analysis Model (PIM) into the Design Model (PSM); and transformation of the Design Model (PSM) into the Implementation Model (Code).

3.5. Business Process Modeling and Notation

Business Process Modeling is used to model the real workflow in OGD. This real world model represents the Enterprise view, from RM-ODP views, using GCM. In Chapter 6.4 is presented the OGD model.

The definition of the Business Process Modeling and Notation (BPMN) after [29] is "a graphical notation that describes the logic of steps in a business process". Also, this graphical notation is designed to coordinate the sequences of processes and messages that flow between participants in different activities.

BPMN is used to communicate with a wide variety of information to a wide variety of audiences [30].

It is important to model using BPMN because [29]:

- is an internationally accepted process modeling standard
- is independent of any process modeling methodology
- creates a standardized bridge which reduces the gap between business processes and their implementation
- enables you to model processes in a unified and standardized way so that everyone in an organization can understand each other

The structural elements have the advantages that allow the viewer to differentiate the sections in a BPMN diagram. It was identified three basic sub-models within an end-to-end BPMN model [30]:

- Process (Orchestration):
  - Private non-executable (internal) Business Processes
  - Private executable (internal) Business Processes
  - Public Processes
- Choreographies
- Collaborations, which can included Processes and/or Choreographies
  - A view of Conversations

The BPMN diagrams are composed of five main categories of elements:

- Flow Objects
- Data Objects
- Connecting Objects
- Swim Lanes
- Artifacts

In the following are presented the main elements for each BPMN element categories studied after [31].

BPMN Flow objects

The *Event element* that happened during the course of a process or choreography is presented Figure 3.5.

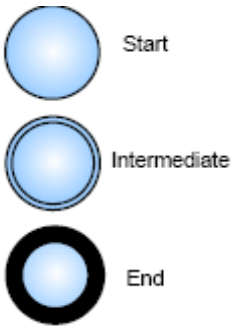


Figure 3.5. Event elements

An *Activity* represents the work to be performed in a Process. It can be a task, a subprocess, or choreography which represents a set of one or more message exchanges and involves two participants, and it is represented in Figure 3.6.

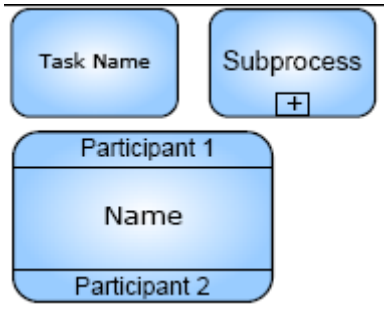


Figure 3.6. Activity elements

A *Gateway* is used to control the divergence and convergence of Sequence Flows in a Process and in Choreography and it is represented in Figure 3.7.

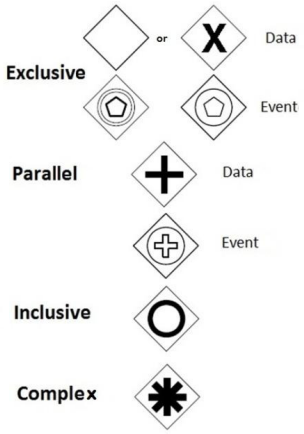


Figure 3.7. Gateways elements

BPMN: Data Objects

Data objects provide information about what Activities require to be performed and/or what they produce and it is shown in Figure 3.8.

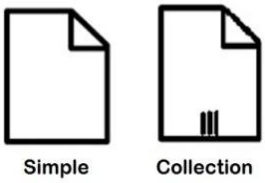


Figure 3.8. Data objects

Data Inputs, Outputs represents the necessary data (input) to adequately perform the activities and processes, and the produced data (output), and it is represented in Figure 3.9.

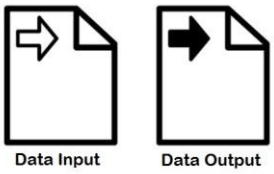


Figure 3.9. Data Inputs, Outputs

Data Store provides activities with a mechanism to retrieve or to store data which persist beyond the scope of the, process and it is represented in Figure 3.10.

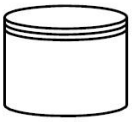


Figure 3.10. Data store

BPMN: Connecting Objects

Sequence Flow is used to show the order in which the activities are performed in a process and choreography. It can be: normal, conditional or default. These three types are presented in Figure 3.11.

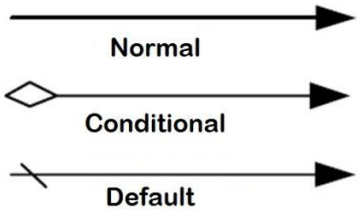


Figure 3.11. Sequence Flow

Message Flow is used to show the communication flow between two participants. Also, can include messages which represent the content of the participant's communication and it is represented in Figure 3.12.

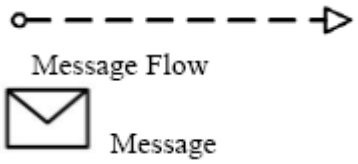


Figure 3.12. Message Flow

Association is used to link Artifacts and Text Annotations with other graphical BPMN elements and it is represented in Figure 3.13.

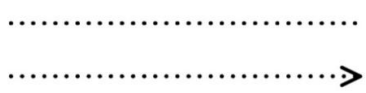


Figure 3.13. Association

Pool represents a Participant or Collaboration and acts like a graphical container for partitioning a set of Activities from other Pools, usually in the context of Business to Business situations and it is presented in Figure 3.14.

Figure 3.14. Pool element

A *Lane* is a sup-partition, which can be horizontal or vertical within a Pool. It is used to organize and categorize activities and it is shown in Figure 3.15.

Figure 3.15. Lane element

Groups represent a grouping of graphical elements that are within the same category. The scope of them is of documentation or analysis purposes, and it is represented in Figure 3.16.

Figure 3.16. Groups element

Text annotations are used by the modelers to provide additional text information for the reader of a BPMN Diagram and it is represented in Figure 3.17.

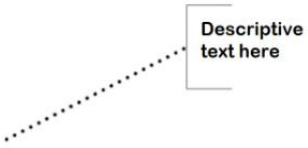


Figure 3.17. Text annotations element

In the following, there will be presented the sub-models within an end-to-end BPMN model:

Private (Internal) Business Processes which are internal to a specific organization and they are called workflow or BPMN Processes. There are two types of private Processes: executable and non-executable. An example is shown in Figure 3.18. The private Business Process will contain within a single Pool. The workflow can contain only one Pool and cannot cross the boundaries of the Pool [30].

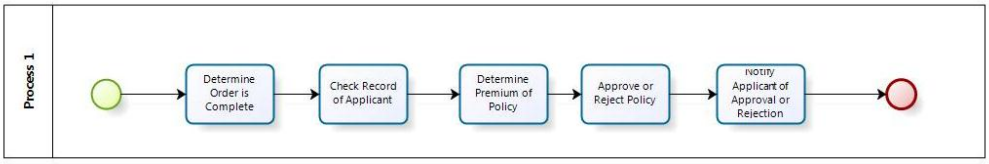


Figure 3.18. Example of a private Business Processes (after [30])

Public Processes represent the interaction between a private Business Process and another Process or Participant. The activities which are inside the private Business Process will not be shown in the public Process. The public Process shows to the outside world the Message Flow and the order of those Message Flows that are needed to interact with that Process. In Figure 3.19, an example of Public Processes is presented [30].

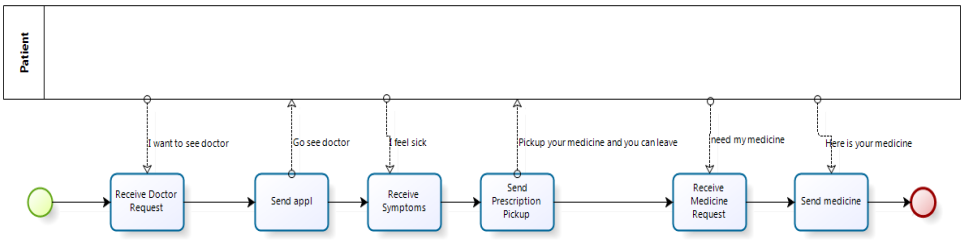


Figure 3.19. Example of public Process

Collaboration diagrams depict the interactions between two or more business entities and contain two or more Pools, which represents the Participants in the Collaboration. In the Figure 3.20, an example of a Collaborative Process is presented [30].

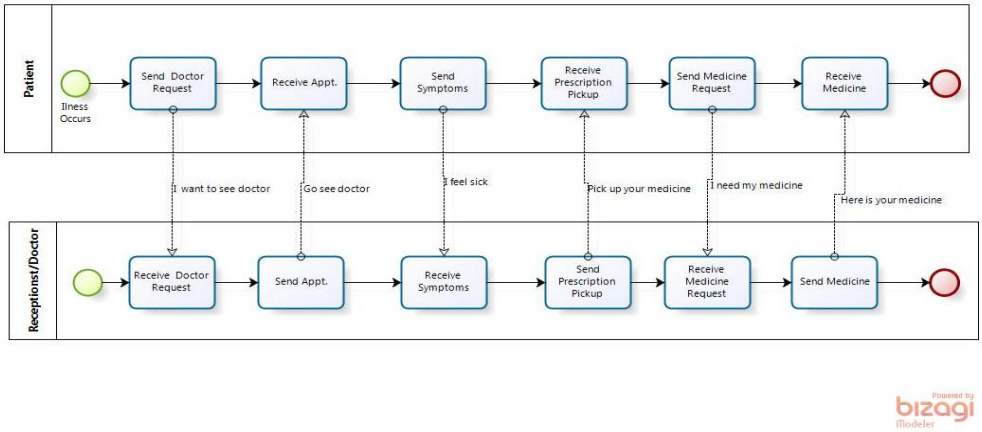


Figure 3.20. Example of a Collaborative Process

Choreography represents the expected behavior, basically a procedural contract, between interacting Participants, and an example is represented in Figure 3.21 [30].

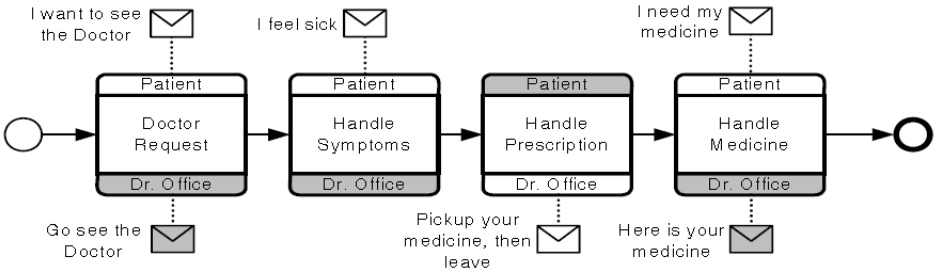


Figure 3.21. Example of Choreography

All the presented elements were used in &6.3.1 for modeling the real workflow in OGD.

3.6. Unified Modeling Language (UML)

Unified Modeling Language (UML) is used in this work to model the real workflow in OGD from an IT perspective. This real model represents a component of the Enterprise View and makes the relation to the Information view, this relating the real world and ICT world, detailed in Chapter 6.4.

UML is a standardized general-purpose modeling language which is used in object-oriented software engineering field. The OMG (Object Management Group) created and manage this standard and becomes the industry standard for modeling software-intensive systems [32].

The UML views are [32]:

- Use case view shows the functionality of the system from the external actors point of view;
- Logical View which describe the functionality of the system;
- The component view describes the organization of the code components;
- The process view shows the component behavior;
- The currency view shows the concurrency in the system, treats with the communication issues and synchronizations which can occur in the system;
- The deployment view shows the deployment of the system in the physical architecture with computers and devices called nodes.

Figure 3.22 shows how this views are interrelated [32].

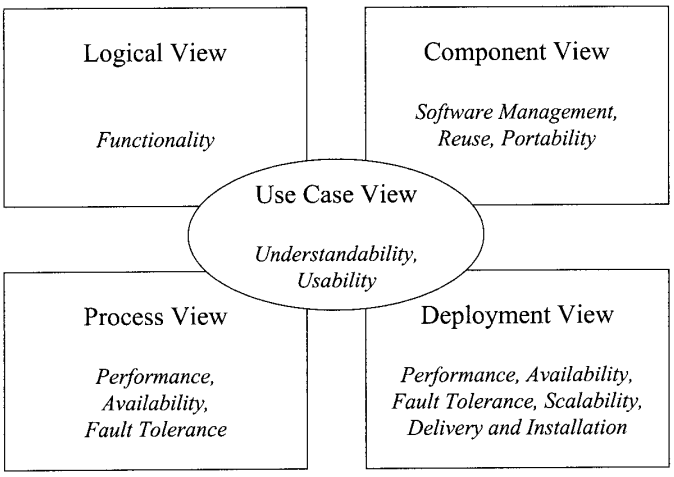


Figure 3.22. The UML view of architecture (after [32])

UML 2.2 has 14 types of diagrams divided into two categories [32]. Seven diagram types represent structural information, and the other seven represent general types of behavior, including four that represent different aspects of interactions. These diagrams can be categorized hierarchically as shown in the following class diagram [32] presented in Figure 3.23.

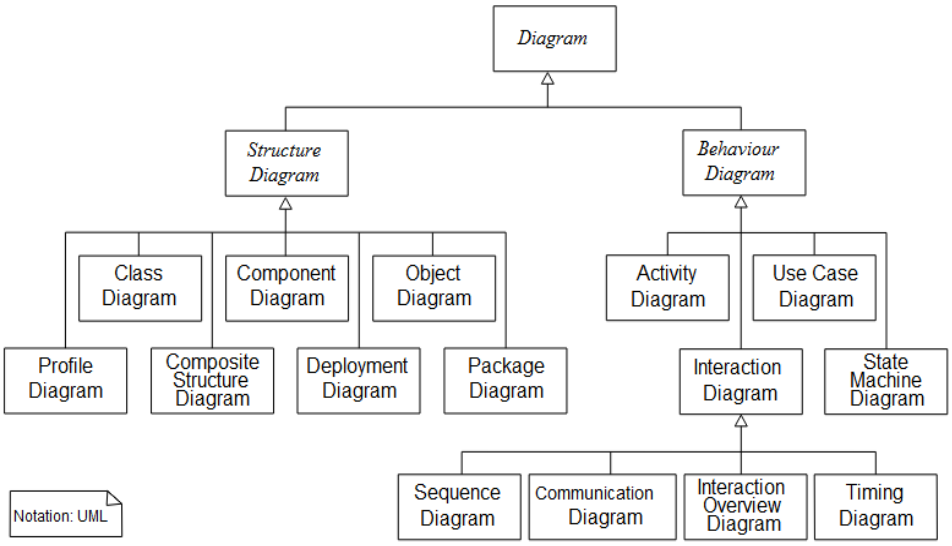


Figure 3.23. UML types diagrams (after [32])

Since structure diagrams represent the structure, they are used extensively in documenting the software architecture of software systems. In the following lines, diagram types from the structure diagram are described [32]:

- Class diagram: describes the structure of a system by showing the system's classes, their attributes, and the relationships among the classes.
- Component diagram: shows the software components and the dependencies between them
- Composite structure diagram: describes the internal structure of a class and the collaborations between them
- Deployment diagram: describes the hardware used in system implementations and the execution environments and artifacts deployed on the hardware.
- Object diagram: shows a complete or partial view of the structure of an example modeled system at a specific time.
- Package diagram: describes how a system is composed by logical groupings and shows the dependencies between them
- Profile diagram: operates at the metamodel level to show stereotypes as classes with the <<stereotype>> stereotype, and profiles as packages with the <<profile>> stereotype.

Behavior diagrams from the Figure 2.23 represent what must happen in the system being modeled. Since behavior diagrams illustrate the behavior of a system, they are used extensively to describe the functionality of software systems. The diagram types from the behavior diagram are described in the following [32]:

- Activity diagram: describes the business and operational step-by-step workflows of components in a system.

- UML state machine diagram: describes the states and state transitions of the system.
- Use Case Diagram: describes the functionality provided by a system in terms of actors, their goals represented as use cases, and any dependencies between them.

Interaction diagrams from Figure 2.23 are a subset of behavior diagrams, and represent the flow of control and data among the things in the system being modeled [32]:

- Communication diagram: shows the interactions between objects or parts in terms of sequenced messages. They are a combination of information taken from Class, Sequence, and Use Case Diagrams and describe both the static structure and dynamic behavior of a system.
- Interaction overview diagram: provides an overview in which the nodes represent communication diagrams.
- Sequence diagram: shows how objects communicate with each other in terms of a sequence of messages. Also shows how the objects are relative to those messages.
- Timing diagrams: are specific types of interaction diagrams where the focus is on timing constraints.

3.7. Conclusions

The objective of this chapter was to describe the support for modeling medical information systems and their interoperability using the GCM and other methodologies. There, the methodologies were analyzed which I used later in modeling and developing the Obstetrics-Gynecology Department Information System. The technologies and methodologies used during the work at the PhD thesis were described:

- The GCM which used in Chapter 6 to model the OGD IS
- UP, RUP, Model-Driven Development and Model-Driven Architecture for creating a model-driven architecture which support the OGD Information System development to be a model-driven basis.
- The ISO 10746 RM-ODP views and appropriate tools according to the Unified Process BPMN are used for modeling the real workflow from OGD, according to GCM.
- BPMN is described as support for modeling the real workflow in OGD.
- UML is described because it is used to model the real workflow of OGD from the IT perspective.

The contributions of this chapter are:

- An extensive review study related to system modeling applied in healthcare that resulted in selecting the Generic Component Model (GCM) due to his generic power for modeling the OGD IS.
- A vast synthesis of UP, RUP, MDD and MDA for creating a model-driven architecture for the development of the OGD Information System. Also one related to the modeling tools, BPMN and UML that were further used for the actual modeling.

4. ELECTRONIC HEALTH RECORD

This chapter presents the Electronic Health Record, its advantages and solutions for achieving interoperability. It is shown how important it is for the patient and also for the medical staff to have the medical patient information in real time and from many sources, available from different locations.

4.1. Definitions

After [33], Electronic Health Record (EHR) is defined as: "a longitudinal electronic record of patient health information generated by one or more encounters in any care delivery setting. Included in this information are patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data and radiology reports".

In Section 3.1 is defined what the system is, and for using an EHR, EHR systems must be developed. EHR system don't have an universally accepted definition but include: longitudinal collection of electronic health information for and about a patient, immediate electronic access to person and population by authorized people, provision of knowledge and decision-support that enhance the quality, safety and efficiency of patient care and support of efficient processes for health care delivery [34].

In 2003, the Institute of Medicine (IOM) identified the elements of "core EHR functionalities" and that are [35]:

- health information and data
- result management
- order management
- decision support
- electronic communication and connectivity
- patient support
- administrative processes and reporting
- reporting and population health.

Sometimes EHR is attributed "personally controlled Electronic Health Records" and it can contain standardized data collected from different information systems such as, health providers, pharmacies, clinical laboratories, and hospitals. With the data collected it is possible to create the patient medical history. It is important to include in these records the entire medical history from patient birth, this can include biometric and genetically derived information, doctor and hospital visits, immunization records, clinical observations, treatments and diagnoses, records of procedures performed, diagnostic images, allergies, drugs administered and other medical information [36].

The terms "EHR" and "EMR" (electronic medical record) are often used interchangeably, there is a difference between them, but the Office of the National Coordinator for Health Information Technology (ONC) makes the distinction. The EMR is the legal patient record that is created in hospitals and ambulatory environments and is the data source for the EHR [37].

In the next lines, the difference between EMR and EHR will be better described.

EMR is a digital version of the paper charts in the clinician's office. An EMR contains the medical and treatment history of the patient in one practice [38]. The advantages of using EMR over paper records are [38]:

- track data over time
- easily identify the patient
- check how the patient are doing in certain parameters
- monitor and improve overall quality of care within the practice

The information which is in EMR doesn't travel out easily from the practice. The patient's record sometimes is printed and delivered via mail to other persons. In this point of view EMR is not much better than a paper record [38].

EHR focus on all the patient health information, going beyond standard clinical data collected in the provider's office and inclusive of a boarder view on a patient's care. The EHR is design to collect and compiles the information. The scope of this is to share information with other healthcare providers, such as laboratories or specialists, so EHR contains information from all the clinicians involved in the patients' care. The National Alliance for Health Information Technology stated that EHR data "can be created, managed, and consulted by authorized clinicians and staff across more than one healthcare organization" [38].

The Electronic Health Record can improve the quality of healthcare, because it provides timely access to patient information, tracking the health status of the patients and can offer decision support mechanism to reduce medical errors [39].

The quality and the benefits of using EHR can be seen after a period of time of using it, possible it can take years after implementation [39].

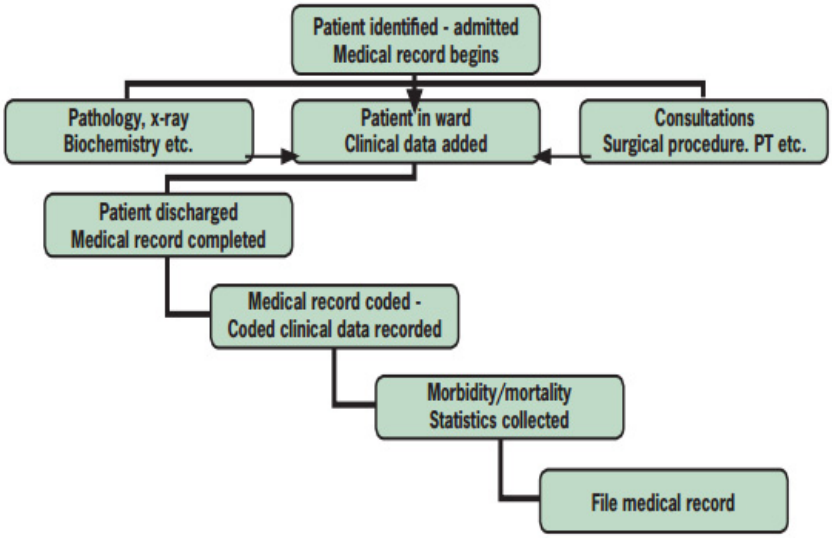


Figure 4.1. Manual medical record information flow (after [39])

In Figure 4.1, the manual medical record information flow is presented, which must be the same as an electronic health record information flow. The record commences on the admission of the patient with registration and identification data

verified. All healthcare data would then be entered electronically at the bedside or nurses' station via a terminal or other electronic device by attending healthcare practitioners [40].

An EHR can be created for every service a patient receives from a department (radiology, laboratory tests, pharmacy), or due to an administrative action. Also, some clinical systems allow electronic capture of physiological signals (e.g., electrocardiography), observations of care, and guidance of medical treatment. Often, these electronic records are not integrated; they are stored and remain stored in storage type systems, each with their users and their systems to identify patients. Figure 4.2 illustrates such a set of repositories. Every organization has a system for storing patient data specific scope. Healthcare provider must open each application to view specific data. The data may or may not be in compliance with the standard [41].

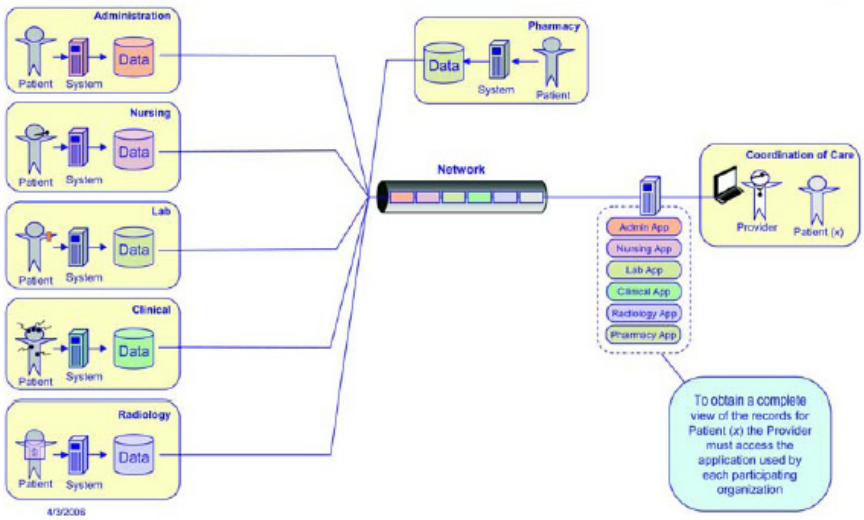


Figure 4.2. Electronic medical data before EHR (after [41])

Integrated architecture can be created to allow data sharing system. Each system in Figure 4.3 stored data locally. To share patient information, a system (or user of the system) should allow another system to access these files, or must submit a copy of the other system. Once the file is identified for sharing, it can be integrated with other files, depending on the level of interoperability of embedded systems [41].

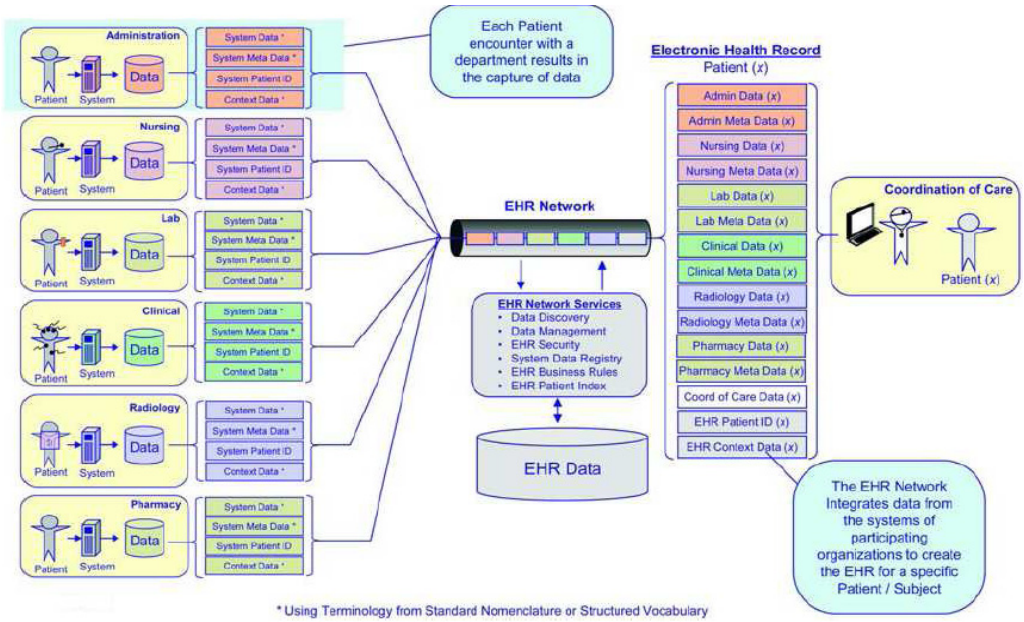


Figure 4.3. Overview of the EHR concept (after [41])

Figure 4.3 illustrates EHR integration of medical data from a set of systems. It is shown that EHR is a patient's medical data integration from multiple systems [41].

Most commercial EHR systems are designed to combine data from auxiliary services (pharmacy, laboratory tests or radiology) with various clinical care components (medical, medication administration records and treatment plans). Number of integrated components and features involved in a clinic depends on data structures and systems implemented by the technical teams. Clinics may have a number of auxiliary systems that are not necessarily integrated into EHR. Thus, EHR can import data from these auxiliary systems through a custom interface or interfaces provide access to allow doctors storage systems through a portal type. It can also incorporate the EHR few auxiliary systems [41].

The basic EHR components are [41]:

- administrative system components

Data regarding registration, admission, discharge and transfer (RADT: Registration-Admission-Discharge-Transfer) are key components of EHR. These data include information vital for identification and correct evaluation of the patient, including (but not necessarily limited to) name, demographics, family, employer data, complaints from superiors, etc. data on patient character [41]. The recording of patient data for EHR contains a unique patient identifier (typically a sequence of alphanumeric characters, unidentifiable outside institution). RADT data aggregation allows an individual's medical data to be used for clinical analysis and research [41].

This unique patient identifier is the core of an EHR and patient relates to all clinical observations, tests, procedures, medical problems, evaluations and

diagnoses. ID is often referred to as MRN (medical record number) or MPI (master patient index) [41].

- laboratory system components
  In general laboratory systems are independent systems that interface has with the EHR. Usually there are laboratory systems are used to integrate references, lab results, appointments, billing and other administrative services. Laboratory data are rarely fully integrated EHR. Some EHR systems are implemented so that the user is allowed access to laboratory information system through a link EHR interface [41].

- radiology system components
  Radiology information systems are used by radiology departments to bring together the patient radiological data (references, interpretations, patient identification information and pictures). A radiology information system typically includes patient tracking, scheduling, reporting of results and features from images. Radiology information systems are typically used with image archiving communication systems that manage digital radiographs. Although many clinics have a radiology information system, they are not always integrated with EHR systems [41].

- pharmacy system components
  Pharmacies are highly automated in clinics or large hospitals (to automatically take actions such as Automatic printing of prescriptions). However, usually, pharmacy information systems are not integrated with EHR systems. This can lead to the introduction several times a certain data regarding medication [41].

Despite the many potential benefits of EHR systems, using EHR systems can sometimes has some issues. Their design, implementation, use, and maintenance raise important concerns that must not be overlooked. EHR system failures can cause significant injury and cost lives and from this point of view it must take some measurements. The challenges of EHR System implementations are [42]:

- potential for errors
- privacy and security concerns
- expense time and burden
- legal issues

4.2. Advantages using EHRs

Some advantages of using EHR are:

- Facilitate the access of medical staff to patient's health information
  The interoperability between systems resulting in an EHR will allow the access for authorized persons (e.g., doctors, nurses) relevant information about the patients, including medical history, medications and allergies of the patients. This is important because if a patient arrives at the emergency unconscious, the medical staff will have the possibility to access the patient data. It can also significantly facilitate and help economically low-income patients [42].

In addition, one of the strengths of EHR is that there can be backup using servers or other storage units, thus being less vulnerable to loss or damage as paper records [43].

- Improving the care quality and reduce medical errors
  EHR systems can reduce errors and improve patient safety at the same time, with features for decision support [43]. EHR systems can contain reminders and can access medical literature to promote proper care, accurate, and responsible. Studies have shown that computerized reminders systems improve immunization rates, preventive care, adherence to practice guidelines and medical doctors detailing the patient's medical history. EHR systems also reduce costs recipe, recipe mistakes and unnecessary diagnostic tests. An example of such error is when the doctor prescribed a higher dose and EHR system announces that it is wrong.
  EHR systems can reduce the use of unnecessary antibiotics. One study showed that 70% of patients who went to the family doctor to treat sore throat were treated with antibiotics, although only 5% to 17% of adults with sore throat need antibiotics therapy [45]. Excessive use of antibiotics has led to resistance of bacteria to antibiotics [46]. This can lead to a less common health support systems intended to provide guidance for prescribing antibiotics.
  EHR systems can significantly improve the spread of knowledge in relation to effective new treatments through a decision support mechanism [47].
  In addition if it is allowed to doctors to look after electronic records of patients the information they need, when EHR systems can significantly reduce the time spent on searching information from the medical history of the patient [48].
  EHR systems also contribute to the improvement of public emergency. Persons responsible for EHR systems and public health officials can use functions from EHR decision support systems to warn doctor in an emergency. For example, national EHR systems can be quickly reconfigured to give recommendations for treating specific symptoms in patients with infectious disease emergencies.
- Reduces costs

Some commentators have estimated the net economic benefit of implementing EHR between the value of 8400$ and 140,000$ per physician for 5 years [49]. These cost reductions resulting from: fewer duplicate tests that result in administrative savings, a decrease medical errors and adverse events of medication to the patient uninteresting caused by allergies, medical history.

4.3. EHR models

Julius is a template based system that was integrated with existing EHR systems that allow the clinicians to define data items for recording and design of a template layout that guides the clinical user [50]. The system consists of three subsystems: the Concept Data Service (CDS), where the variables are defined, the Template Data Service (TDS) for defining data entry templates, and Patient Data Service (PDS), where the patient data is stored and managed [50]. These three subsystems are represented in the Figure 4.4. The Julius system is modeled using UML.

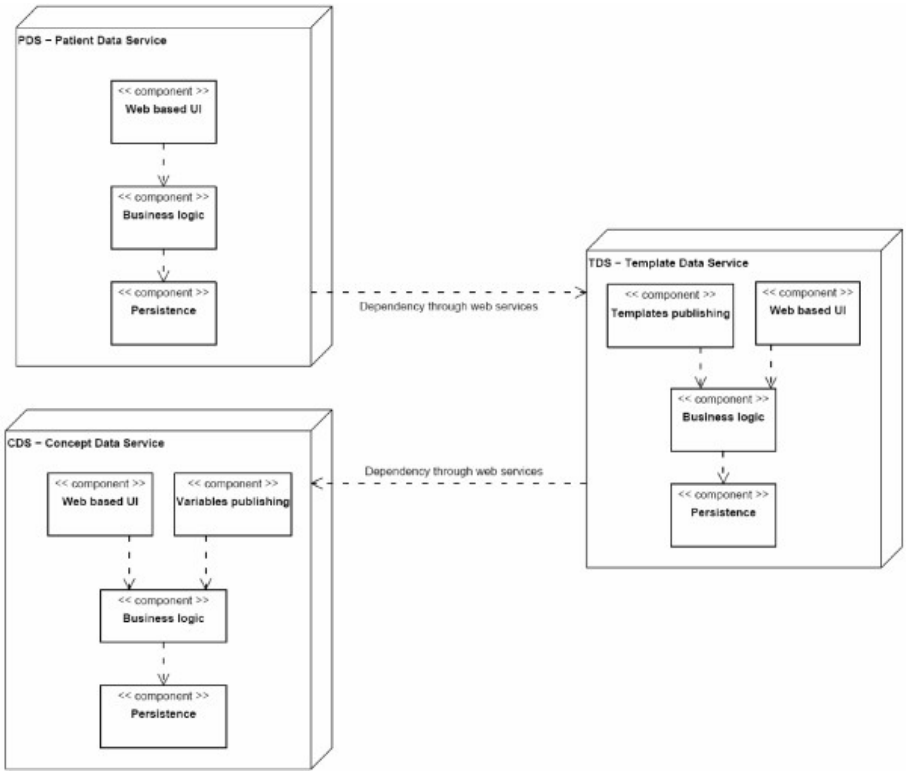


Figure 4.4. Figure System Architecture Overview (after [50])

In [51], the development of a reference functional model for electronic health record systems has been described. The methods used was firstly: they made some questionnaires and field interview survey was conducted in five hospitals in Japan and one in the USA, the scope of this was to collect data on EHR system function. Based on this survey results, a reference functional list was created, in which each EHR system function was listed and divided into 13 functional descriptive elements [51]. After this, it was built the meta-functional model and the functional model using UML class diagrams. In Figure 4.5, the following steps are shortly presented.

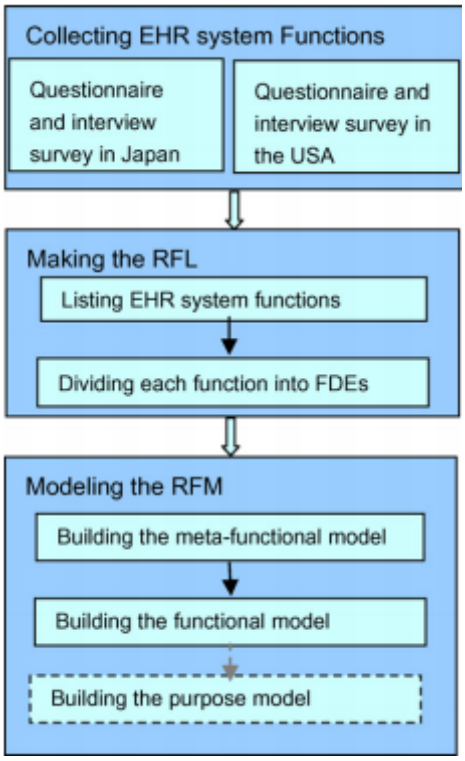


Figure 4.5. The presented methods with the steps (after [51])

In this subchapter, two models where presented which use UML for modeling the EHR systems. Modeling a complex system like the healthcare ones is not a very easy task as it results from these 2 examples.

The current thesis contains not only a model, but all the framework of the process that includes the OGD activities. That is why the OGD is modeled using GCM that can represent any real or virtual system, and all the actions and relationships are described in detail.

More, in the OGD model it is used the UML and BPMN to model the real workflow and to be a sound start for a flexible and correct implementation ready to be easy connected to other related systems, prepared for high interoperability.

4.4. EHR systems

This paragraph concerns with presenting several EHR systems, emphasizing the above mentioned benefits.

EHR is a longitudinal electronic health record which contains the patient information during patient life, for this is important to show that exists more EHR systems which participate to data collection.

Orion Health EHR described in [52] is an EHR system, which provides accessible EHR, and contains the medical history of the patient. The system architecture is presented in Figure 4.6.

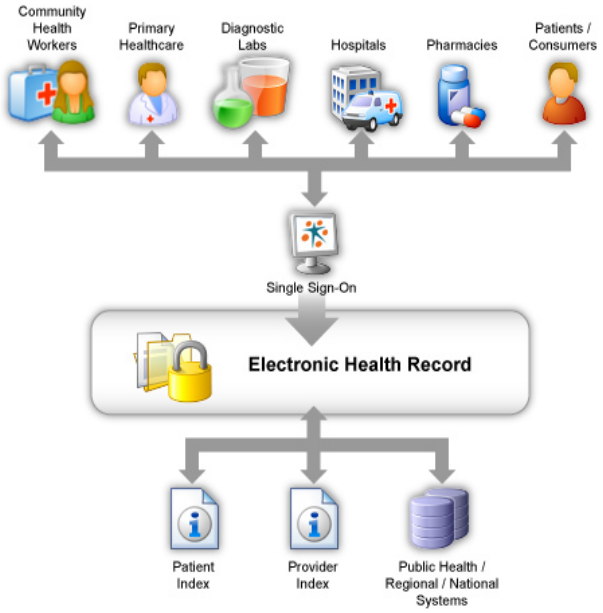


Figure 4.6. System architecture of Orion Health EHR ([52])

Answers Clinical (EHR) Solution described in [53], is an EHR system which connects the medical staff, medical residents, and the management part in real time and offers information about the patient. It provides a detailed EHR about the patient to resident doctor. It is specially developed for institutions which want to have continuity of care of the patient. Figure 4.7 presents the system architecture.

Figure 4.7. Architecture of Answers Clinical (EHR) Solutions (after [53])

Care360 EHR described in [54], is an EHR system which is simple, flexible, and reliable. It is performed for healthcare institutions, which will have access to the medical data without interruptions. Care360 EHR is the next generation which is based on Care360 Labs & Meds platform, provides the entire tool for creating and communicating the relevant patient information.

System characteristics:

- Management of the general patient information about the patient and his insurance
- Request of laboratory results and receiving them in electronic format
- ePrescribing
- Offers the possibility to send a secure message in Care360 network directly or fax.
- Complete clinic documentation, including vital signs, using different techniques of introducing data
- Possibility to access the information using Care360 Mobile and Care360 HD
- Requesting and receiving the radiography in electronic format
- Clinical decision support

In Figure 4.8, the interface is presented where the medical staff can introduce data about a patient.

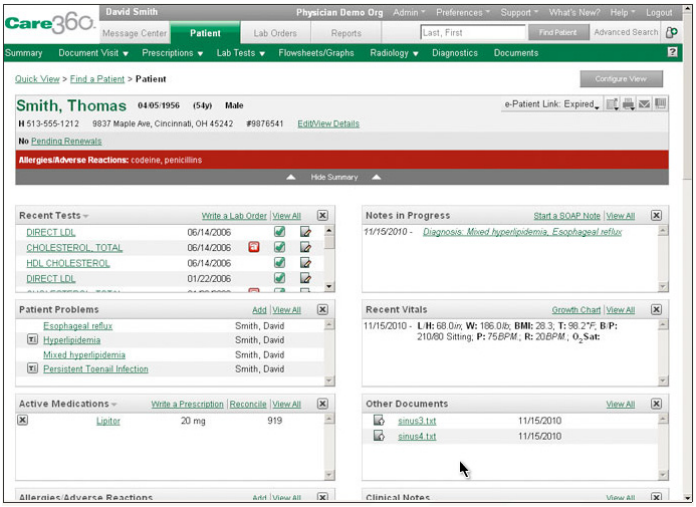


Figure 4.8. Interface from Care360 EHR (after [54])

eClinicalWorks Comprehensive Electronic Health Records (EHR) Solution described in [55], is an EHR system which offers more than computerization. This integrated solution represents the next generation of IT medical assistance, improving the health care. Using eClinical Works will improve the medical workflow and this will lead to a better care of the patient. In Figure 4.9 are presented the eClinical components.

Figure 4.9. eClinicalWorks (after [55])

In [56] is described an application for Obstetrics-Gynecology department in Northern Ireland. In Figure 4.6 shows a screenshot of the main maternity menu allowing access to obstetric component.

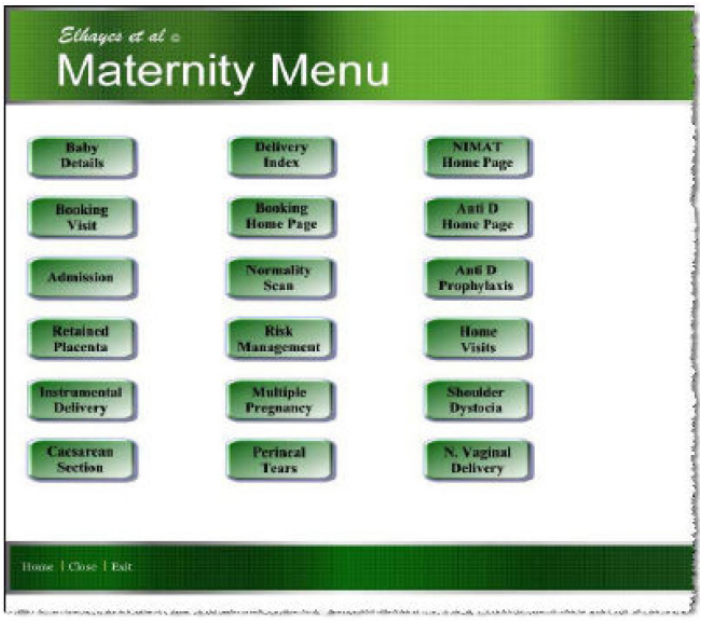


Figure 4.10.Screenshot of main maternity menu allowing access to obstetric components (after [56])

Pregnancy Risk Assessment Monitoring System (PRAMS) is a surveillance project of the Center for Disease Control and Prevention (CDC) and the State Health Department of USA. It is described in more detail in [57] which is a surveillance project of the Centers for Disease Control and Prevention (CDC) and state health department in USA. PRAMS collect state-specific, population-based data on maternal attitudes and experiences before, during and shortly after pregnancy.

PRAMS provide data not available from other sources about pregnancy and the first few months after birth. This data is used for preventing women with health problems, to monitor changes in health status, and to measure progress towards goals in improving the health of mothers and children [57].

PRAMS data are used by [57]:

- Researcher which can investigate issues in the field of maternal and child health
- State and local governments to plan and review programs and policies
- State agencies to identify other agencies that can have important contributions.

4.5. Conclusions

The objective of this chapter is the analysis of the Electronic Health Record and its properties:

- Study of the importance of using EHR and how it can be adapted to Romanian health systems
- Presentation of the advantages of using EHRs
- EHR models and the difference between them and the OGD IS model
- EHR systems that can help seeing what is important in developing an EHR system

After searching and studying the solutions for models and EHRs I identified what it is important in the development of the OGD.

The contributions of this chapter are:

- A review study representing the need of using EHR, presenting its advantages, EHR models, comparisons between solutions, as a basis to create an easy to develop and ready to interoperability OGD IS model

5. EHR SYSTEMS INTEROPERABILITY

In this chapter, the concept of interoperability between EHR systems is presented. The interoperability can be improved by using standards. The standards which are used for demonstration in this PhD thesis are: HL7 CDA (Clinical Document Architecture) and CCD (Continuity of Care Document). Several scenarios will be presented for using the two standards.

5.1. Interoperability standards related to EHR

This paragraph presents the main international standards used in medical informatics, focusing on two: HL7 Clinical Document Architecture (CDA) and Continuity of Care Document (CCD). These standards will be used for a standardized communication between hospital departments (e.g. Obstetrics-Gynecology Department and Pediatrics Department) or other medical applications (e.g. data transmission to Egadss system). It is important for the OGD IS to send the data in a standardized way to other medical information systems for ensuring continuity of care and being the basis for a sound EHR. The continuity of care means that the patient care starts during mother pregnancy, before the person is born, and continues during all patients' life, and when an institution of care is ending, others have access to previous data and take responsibility.

5.1.1. Standards related to EHRs

In Europe, the medical informatics standard is CEN/TC 251 [58]. This standard has the power and the responsibility for organizing, coordinating and monitoring development activities in medical informatics standards and promulgation of these standards. CEN published and makes available various materials called European standards (European Standards - EN), pre – European standards (European Pre-Standards - EVN) and reports CEN (CEN Reports - CR).

Electronic Data Interchange (EDI) is defined in many ways. The definition adopted by the International Data Exchange is „structured and coded data transfer standards agreed message from computer to computer by electronic means". The data are used primarily for processing the computer applications and not for direct interpretation by human users [58].

The standard development in the medical field has raised the interest of many organizations for a long time in the world, which is beneficial in the first instance but resulted in a lack of consistent and strong enough dispersion. Worldwide, the main organization involved in standardization is ISO (International Standards Organization), healthcare is the responsibility of the Technical Committee TC 215. In Europe the standardization work is within CEN (Comity European de Normalization), founded in 1991 as a technical committee for medical informatics – TC251. In December 1995 was approved „Directory of the European Standardization Requirements for Healthcare Informatics and Telematics. Programmed for the Development of Standard" – that constitutes the work program of CEN/TC 251 [58].

Figure 5.1 presents the Standards Developing Organization (SDOs) in the medical informatics domain.

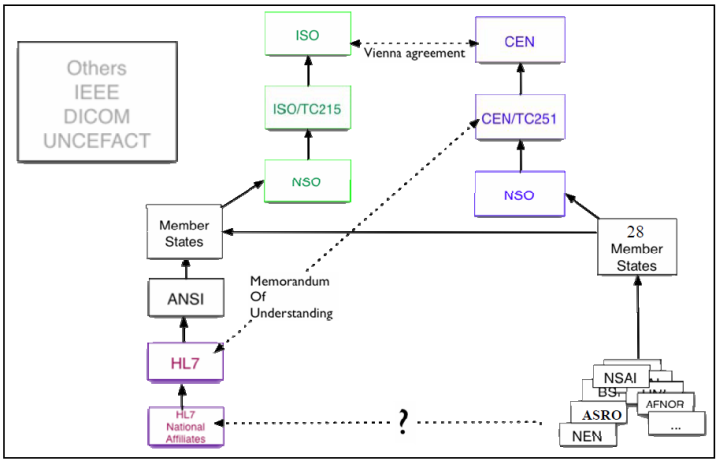


Figure 5.1 Implied organization in medical informatics domain (after [58])

The main organizations implied in medical informatics standardization are:

- ISO – International Organization for Standardization [59]
  - ISO/TC 215 – Health Informatics with the following working groups:
    - ISO/TC 215/WG1 – Health Records and Information Modeling Coordination
    - ISO/TC 215/WG2 – Messaging and Communications
    - ISO/TC 215/WG3 – Health Concept Representation
    - ISO/TC 215/WG4 – Security
    - ISO/TC 215/WG6 – Pharmacy and medication business
- CEN – European Committee for Standardization, TC251
- ASTM – American Society for Testing and Materials, Committee E – 31
- OpenEHR – (Open Electronic Health Record Foundation)
- HL7 – Health Level 7
- EHTO – European Health Telematics Observatory
- ETSI – European Telecommunication Standards Institute
- IEC – International Electrotechnical Commission
- IMIA – International Medical Informatics Association
- UN/EDIFACT – United Nations directories for Electronic Data Interchange for Administration, Commerce and Transport.

Worldwide is a great concern for developing standards for the medical informatics domain. These standards cover some more general issues such as the definition and purpose of EHR systems, data types and encoding information systems, up to specifying the detailed computer models to store data like documents and procedures for the exchange of medical information. The most relevant standards for the deployment of EHR are:

- ISO DTR 20514 – EHR definition and scope
- ISO TS 18308 – EHR Requirements
- CEN TS 14796 – Data Types
- CEN/TC 251 EN 13606 – EHR Communications
- HL7 – EHR Functional Specification
- HL7 – Templates specification
- DICOM – Digital Imaging and Communication in Medicine
- HL7 Clinical Document Architecture (HL7 CDA)
- Continuity of Care Document - CCD

A. ISO/TC 215

Medical Informatics Technical Committee of the ISO was founded in 1998 with the participation of the 25 member states and 14 observers. By 2004, a total of 14 standards important for EHR development and implementation have been produced under direct responsibility of ISO TC 215 [59]:

- **TR 20514:2005** – Technical report on electronic health record-definition, scope and context. Includes a pragmatic classification of EHR providing definitions of the main categories of EHR systems and descriptions of their characteristics. The report makes a clear distinction between EHR content and structure, the so – called „basic – generic EHR" defining a generic structure able to ensure wide applicability to all users and current and future EHR systems. Definitions cover a range of legislative requirements and access control system applicable to a wide variety of EHR.
- **TS 18308:2004** – Technical specification for medical and technical requirements for EHR architecture. The purpose of this standard is to make a collection of clinical requirements and technical architecture to establish the use, sharing and exchange of electronic medical records among different healthcare sectors, different countries and different models of health care delivery. This standard lists only EHR architecture requirements without specifying the architecture itself, so the main target group is the standards developers on EHR architecture.
- **TR 18307:2001** – Technical Report on Interoperability and Compatibility standards for communication and messaging. Describes a set of key features for achieving interoperability and compatibility of health information exchange between systems. The goal is to provide standards developer and those who implement these standards a set of criteria for messaging and communication in the medical field. The report contains a number of fundamental principles and objectives which is able to ensure the safety of health information exchange.
- **ISO 21731:2006 –** Standard Reference Information Model (RIM) – taken from HL7 v3 standard
- **ISO 17432:2004** – Messaging and communication. Web access to DICOM persistent objects.
- **ISO 20301**:**2006** – Healthcare cards. General characteristics.

- **ISO 20302:2006** – Healthcare cards. Numbering systems and procedures for the registration of personal identifiers.

B. CEN/TC 251

Since 1990, when it was founded, until now, CEN/TC 251 developed over 50 documents (standards, pre-standards, and reports). In the first phase, based on the documents provided in European research projects were developed aiming at pre-standards on some vocabulary used in medical informatics, electronic health sheet architecture, architecture of health information systems and the information in the care of health. In the second stage, starting in 1999 CEN began to publish a series of standards based on a review of previous stage pre-standards [58]. An important contribution to this process had EHRcom Task Force team of experts working on the revision of EVN 13606:2000 pre-standards to develop a standard (EN) thoroughly and completely adapted to the new needs to incorporate a solid vision for the application of generic models to specific clinical areas [59]. CEN/TC 251 relevant to EHR include [59]:

- **EN 13606** – Electronic healthcare standard communication – is based on the openEHR design specifications and is divided into 5 chapters
  - EN 13606 – 1 Reference models – adopted in 2007
  - prEN 13606 – 2 Archetypes
  - prEN 13606 – 3 References archetypes and terminologies
  - prEN 13606 – 4 Security
  - prEN 13606 – 5 Models for data exchange
- **EN 1068:2005** – Inventory coding systems
- **CEN/TS 14796:2005 –** Technical specification of data types
- **prEN 12967:2006** – Medical Information Systems Architecture (HISA)
- **CEN/TS 14463:2003** – Syntax to represent the content of medical classification systems (CIaML).

Other CEN standards:

- **EN 12052:2004** – Health informatics – Digital imaging – Communication, workflow and data management
- **EN 12251:2004** – Secure User Identification for Health Care – Management and Security of Authentication by Passwords
- **EN 12264:2005 –** Categorical structures for systems of concept
- **EN 12381 - 2005** – Time standards for healthcare specific problems
- **EN 14822** – **1:2005** – General purpose information components. Overview
- **EN 14822 – 2:2005 –** General purpose information components. Non-clinical
- **EN 14822 – 3:2005 –** General purpose information components. Clinical
- **EN 1064:2005** – Standard communication protocol – Computer – assisted electrocardiography

C. Health Level7 – HL7

One of the most commonly used standards in medical communication and information structuring is Health Level 7 (HL7). Developed under a public - private partnership, the standard is widely accepted by American companies, and is also supported by affiliated organizations in meanwhile 36 countries, including European countries [60].

HL7 has established itself as the standard for electronic exchange of information on health, both in both clinic and in administration. The major objective of HL7 standard is to facilitate the exchange of messages between applications that manage medical data. HL7 methodology is based on the acceptance that an event - trigger event - causes an exchange of messages between two or more applications. For example, a patient admitted determines collecting information and sending it to other systems [60].

The standard describes a Reference Information Model (RMI) – a basic model from which all HL7 messages have been derived. It consists of generic classes that can generate specific classes. From these models can be developed classes of messages [60].

In 2000, as part of RIM, CDA has been approved (medical document architecture) - a set of XML-based specification for exchanging structured clinical documents [60].

DICOM

DICOM – acronym for Digital Imaging and Communication in Medicine - is the industry standard for medical image transfer and communication between medical electronics. The standard was jointly developed jointly by the American College of Radiology (ACR) - responsible for technical supervision and care - and the National Electrical Manufacturers Association (NEMA) - responsible for overseeing the legal aspects and the publication of the standard [61].

All the storage and transmission of medical images (PACS) must comply with the DICOM standard, which currently remains a challenge, due to the high costs involved [61].

DICOM Structured Reporting

DICOM Structured Reporting (SR) is an extension of the DICOM (Digital Imaging and Communication in Medicine) standard which converts medical records and other clinical data. Structured reports are a general model for coded medical reports and are structured in a basic format to standard DICOM format. SR can use existing DICOM network infrastructure to archive and communicate, encryption and digital pattern reports small changes to existing systems [62].

DICOM SR provides a very flexible design for almost any type of data stored in plain text reports on complex documents with measurable numeric values and codes [62].

IHE Retrieve Information for Display (RID)

Retrieve Information for Display (RID) [63] is a technical specification published by the Integrating the Healthcare Enterprise initiative (IHE), and it provides quick and easy access to information about patients who are located outside the current application. Supports access to documents with well-known presentation formats. It also supports access to specific information such as allergies, current medication, summary reports for presentation to a clinician.

Patient care requires that health care providers and patients are able to create, manage, and access to comprehensive electronic health records (EHR) effectively

and safely. Its purpose is to improve the quality, effectiveness and safety of clinical care by making relevant medical information more accessible, easier for patients to access and authorized healthcare providers.

IHE brings together users and developers of medical information technology (HIT) in a recurring annual four-step process [63]:

- Doctors and technical experts define critical use cases for information exchange
- Technical experts create specifications for communication across the system to transmit cases, the selection and optimization of the standards.
- IHE test vendors systems at well planned events and supervised called Connectathons.

Figure 5.2 is presents the IHE organization and his connections [63].

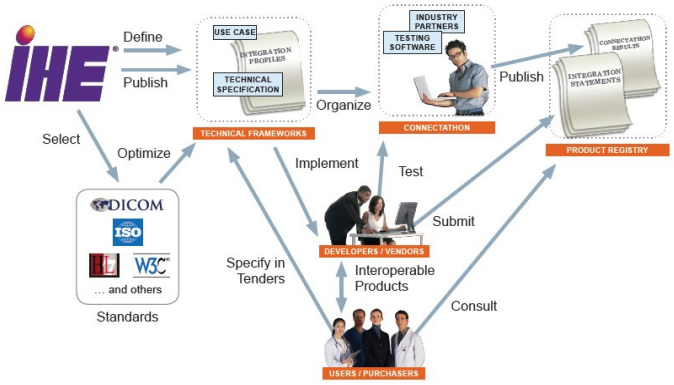


Figure 5.2 IHE organization and his connections (after [63])

IHE committees follow four steps for annually recursive process for transmitting with the interoperability help in different clinical domains [63]

- Surgical Pathology
- Eye Care
- IT Infrastructure
- Laboratories
- Coordination of patient care
- Devices for Patient Care
- Quality, Search and Public Health
- Radiography

IHE Cross – Enterprise Document Sharing (XDS)

Cross Enterprise Document Sharing (XDS) [63] is another IHE specifications aimed at providing a longitudinal archived document, cross-institutional health records [63]. XDS is document-centric and agnostic to content meaning that any

document can be stored in an XSD archive, provided that the metadata for the document (which has XDS detailed specifications) are available.

XDS uses an ebXML registry by one or more file systems attached to implement EHR records.

Figure 5.3 is presents the IHE XSD participants and transactions [63].

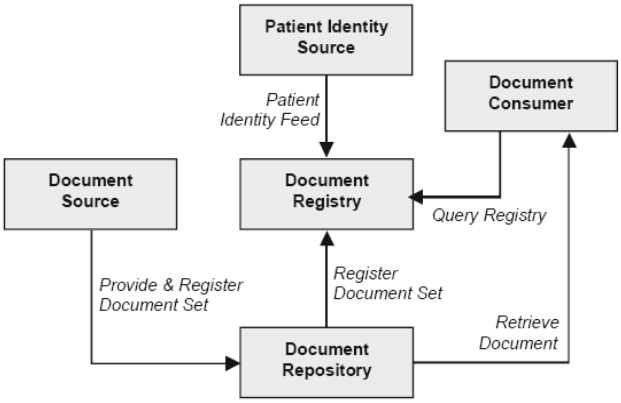


Figure 5.3 IHE XDS participants and transactions (after [63])

Medical Markup Language (MML)

Medical Markup Language (MML) was developed in the mid-1990s by EHR Research Group of the Japanese Ministry of Health and Welfare. The goal was to provide a way to standardize the exchange of medical records and other clinical data [64]. The current version 3.0 uses the XML Clinical Document Architecture Release One (CDA) format with a local extension header to store specific header fields and store the specific content of the MML markup community [64].

MML documents can be exchanged as HL7 messages or by any other electronic means of communication. It seems that MML is used quite often and therefore are commercial products on the market that supports MML [64].

5.1.2. HL7 Clinical Document Architecture standard

In the following, the HL7 CDA (Clinical Document Architecture) standard is described. It is the basis for developing the HL7 CDA component for the OGD system in Chapter 6, which will extract data from different databases and use them to create XMLs documents in CDA format.

The HL7 CDA is a document markup standard that specifies the structure and semantics of "clinical documents" for the purpose of data exchange and it is a complete information object which can include text, images, sounds, and other multimedia data and could be any of the following: discharge summary, referral, clinical summary, history/physical examination, diagnostic report, prescription, or public health report. This can be transmitted like a message, or it can exist independently, within the transferred message, like a document [65].

Clinical Document Architecture, Release 1 (CDA R1) becomes an American National Standard Institute (ANSI). CDA Release 1 is approved by Health Level 7

(HL7) standard in November 2000 and represents the first specification which is derived from HL7 Reference Information Model (RIM) [66]. CDA, Release 2 (CDA R2) became an ANSI standard when was approved by HL7 standard in May 2005.

A CDA is composed from a header and a body. The header contains information from identifiers and document classification and provides information about authentication, consultations, patients and implied provider. The body contains clinical reports, which is organized in section with narrative parts and it can be codified using standards vocabulary. The most important thing is that the CDA is derivate from RIM (Reference Information Model) [65].

The CDA R2 is used on international level. In United States of America, the CDA is used for prescription exchange in the emergency case and it is based on HIPAA (Health Insurance Portability and Accountability Act). CDA was implemented at the Mayo Clinic and the observation numbers is 50.000 per week [67].

CDA R2 developed very quickly and this leads the medical units to want to create CDA from the clinical reports. A barrier is that CDA is not fully semantically interoperable.

CDA has three levels of document definition: Level 1 (root hierarchy, and the most unconstrained version of the document), Level 2 (additional constrains on the document via templates at the "Section" level), Level 3 (additional constrains on the document at the "Entry" level, and optional additional constrains at the "Section" level) [68].

The CDA is encoded into Extensible Markup Language (XML). Also, it is derived from RIM and uses HL7 v3 datatypes. RIM and HL7 v3 datatypes provides a strong mechanism which allows using concepts from standardized code system such as SNOMED CT (Systemized Nomenclature of Medicine Clinical Terms) and LOINC (Logical Observation Identifiers Names and Codes).

CDA specifications are expressive and flexible and are designed to be large to cover the clinical document domain. Using templates and implementations guides will assure the validity of rules sets.

The major components of a CDA are shown in Figure 5.4. This XML document in CDA format contains a few components because of simplifying the example [67].

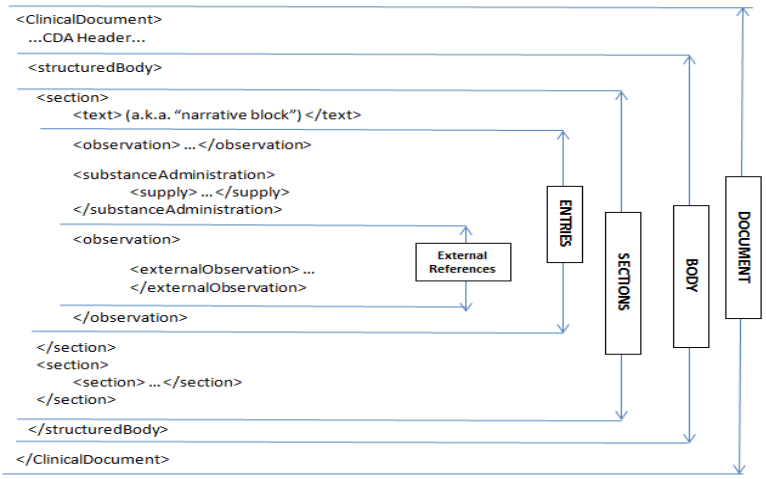


Figure 5.4 Major components of Clinical Document Architecture (CDA) (after [67])

A CDA document contains a principal tag named <ClinicalDocument> which is split into two parts: a header and a body. The header is between <ClinicalDocument> and <structuredBody> elements and identify and classified the document and provides information about authentications, consultations, patients and implied [67].

A CDA section begins with <section> tag. Each sections can contains only one narrative block, CDA entries and external references. The narrative block is a critical component of a CDA and must contains elements which can be easily read. This starts with <text> tag in <section> tag and is represented in XML, which is similar to XHTML. The initiator (defined as the role responsible for creating a document which is in conformance with the CDA requirements) must assure that the portion mentioned from the document body to be transmitted into the narrative block as sender, the compatibility to the sender render that in the final the document render to be realized into a correct way. This process assures human visibility and allows the sender to receive a CDA document from everybody and to see the exact content using only one style sheet.

From a section of the document, the narrative block represents the content which follows to be rendered, while the CDA entries represent the structured content for computer processing (e.g., support decision support). CDA entries typically present encoded content and narrative block in the same section.

The Figure 5.4 shows the <observation> and <substanceAdministration> CDA entries, which contains a partial overlapping of <supply> entries, although more CDA entries are defined. These entries are derived from RIM classes and allow a formal representation of clinical narrative situations.

While the narrative blocks must be always present, CDA entries are optional. A CDA document „initiator" is not forced to fully encode all CDA narrative entries inside the body, and also a sender is not forced to analyze and interprets the complete set of entries contained the CDA body. In implementation, the trading partners can assign additional „initiators" the creation of different entries with different return addresses and create various templates and/or implementation guidelines requiring the use of different inputs. As results, the CDA R2 can be put in application in a simple manner (e.g., only narrative blocks) or can be more detailed (e.g., more rich and expressive entries) and offers a good way to improve the content for a better computer processing.

CDA entries can be combined and can make references to external objects. CDA references always appear in an CDA entry, like other images, other procedures, or other observations (which begins with <externalObservation> tags, presented in Figure 5.4)

CDA specifies the structure and the semantics of clinical documents for exchange purpose. The scope of CDA application it continuously extending (e.g., some implementations use CDA to exchange laboratory reports or prescriptions), and a common question is the distinction of HL7 documents and HL7 messages as well as their appropriate use. Although there are gray zones, messages tend to be transient, trigger based and no persistent, whereas clinical documents have persistence, integrity and are authenticated by clinician and are easily readable by humans.

CDA documents can be transformed into HL7 messages and adapted to other transportation solutions. The exact method used is outside of the standards scope, but a number of requirements must be taken into consideration: all documents of CDA document that are integrated into CDA documents (e.g., multimedia content)

can be exchanged as unit, the content must be rendered or CDA files associated with a document can be included for exchange (e.g., style sheets). There is no need to change any of the references (e.g., a reference to the media who are in a separate file) in the CDA document basic package when creating or extracting parts (indeed, they can be changed). There are no restrictions on the directory structure used by receivers which can place the CDA document components in what folder they want, the critical metadata about the instantiated CDA required to manage documents must be included in the exchanged document.

At the local level, other elements can be used that can be used to extend the CDA when local semantics have no corresponding representation in the CDA specifications. To support the local needs, it is allowed to include additional XML elements and attributes that are not included in the CDA scheme. These extensions should not change the meaning of standard data elements, and receivers must be able to ignore these elements. Document recipients must be able to reproduce faithfully CDA documents while ignoring extensions.

CDA schema is derived from CDA R2 object model for implementation specification of HL7 XML technology, which defines the XML conventions used by HL7 specifications and algorithmically binds the object model to an XML Schema [69].

The CDA R2 object model is a technical specification CDA diagram. It is represented using the conventions and notations developed by HL7 to represent specific semantics built in RIM. Although it can be represented using Unified Modeling Language (UML), for presenting the RIM, HL7 offers more details about the specific constraints and provides with more class refinements when using the HL7 Visio diagrams.

By convention, HL7 diagrams simplify some relationships, enabling diagrams to be smaller and more concise and to convey more information visually.

A portion of the CDA R2 model is represented in Figure 5.5 and Figure 5.6 [66]. Figure 5.5 shows a portion from the CDA header and the connection to the CDA body and document sections. Figure 5.6 shows the connection from the document sections to the CDA entries. In Figure 5.7 presents the whole CDA from [65], and in this figure it, all classes and all relationships between the different classes can be seen.131

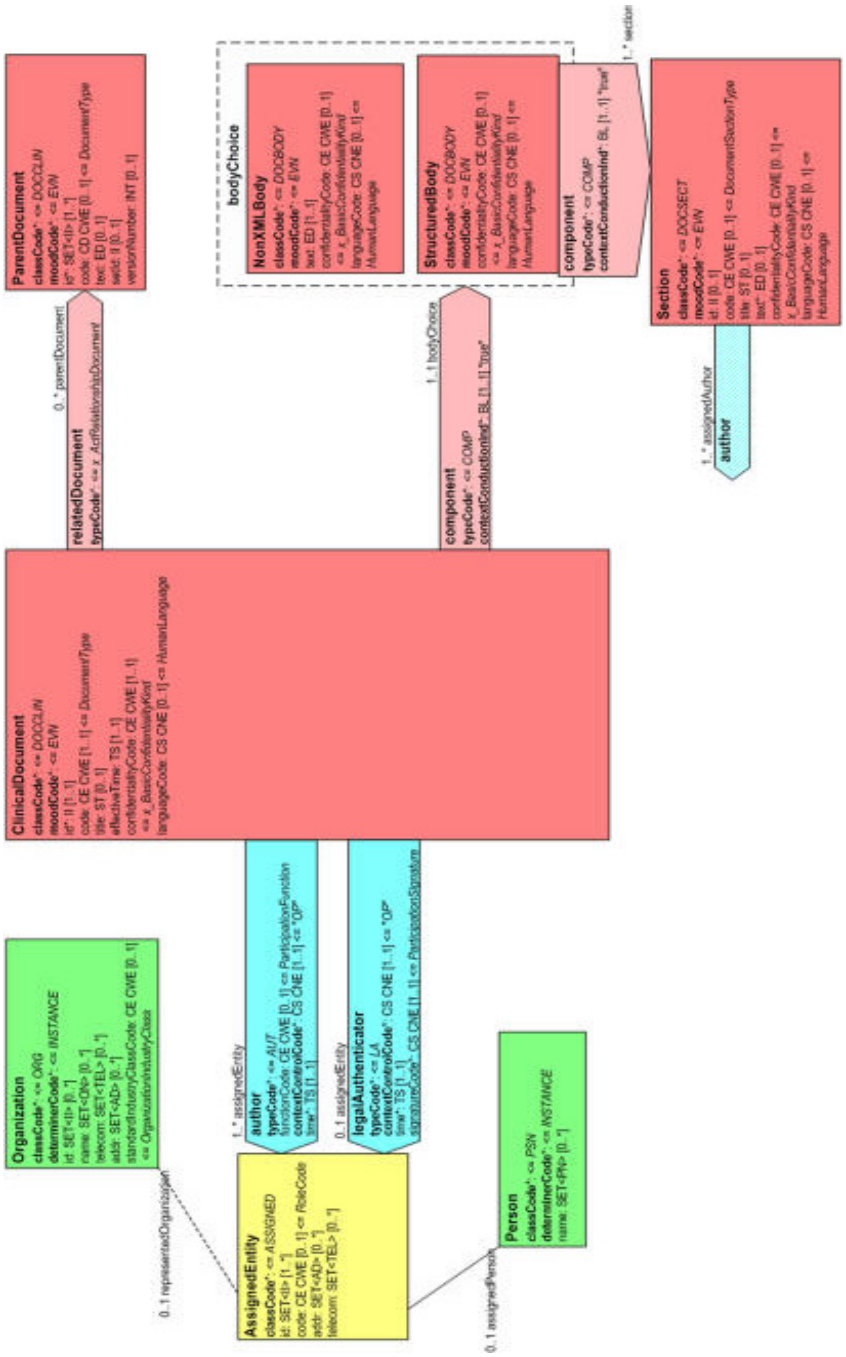


Figure 5.5 Clinical Document Architecture (CDA) model which shows a header portion and the connections with document body (after [66])

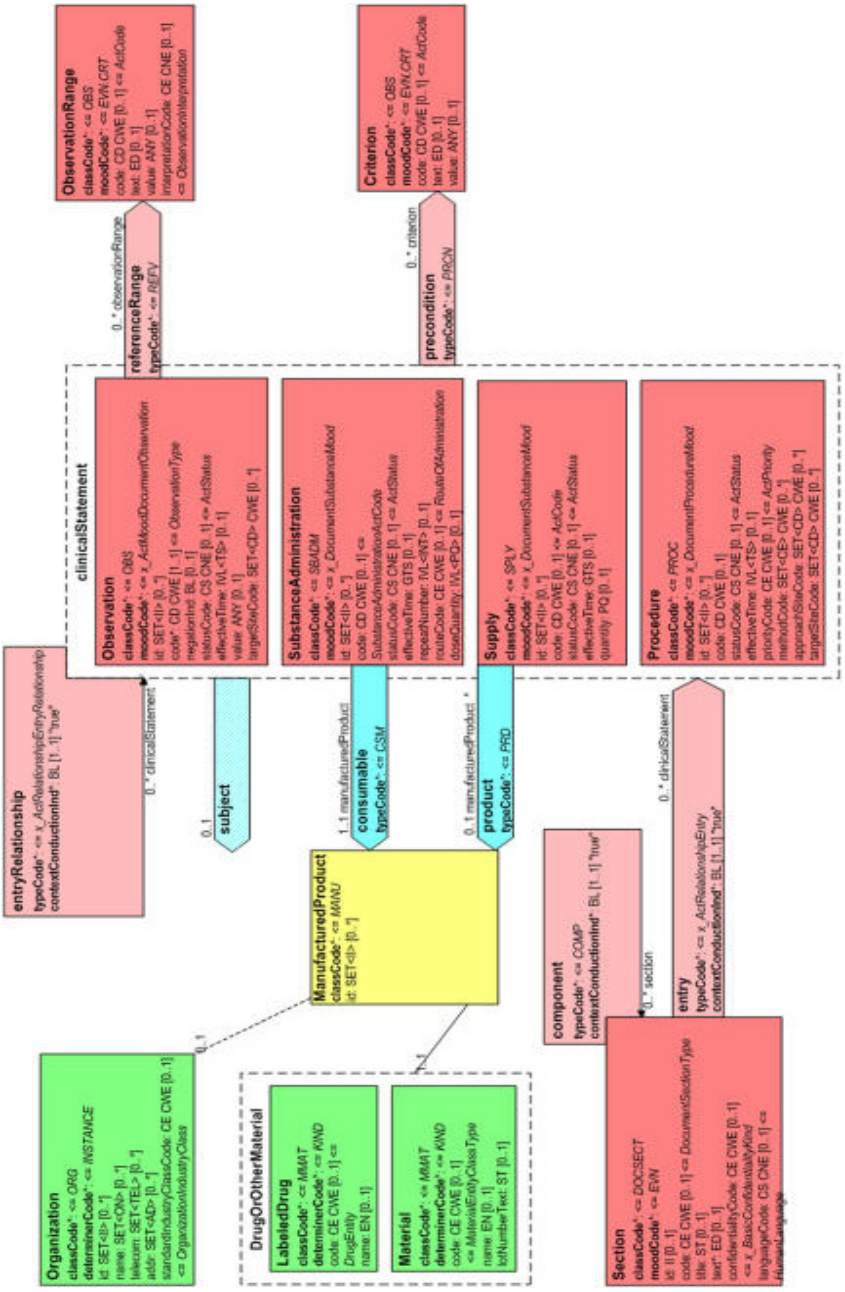


Figure 5.6 Clinical Document Architecture (CDA) model which shows the connection from document section with a portion of the clinical CDA model (after [66])

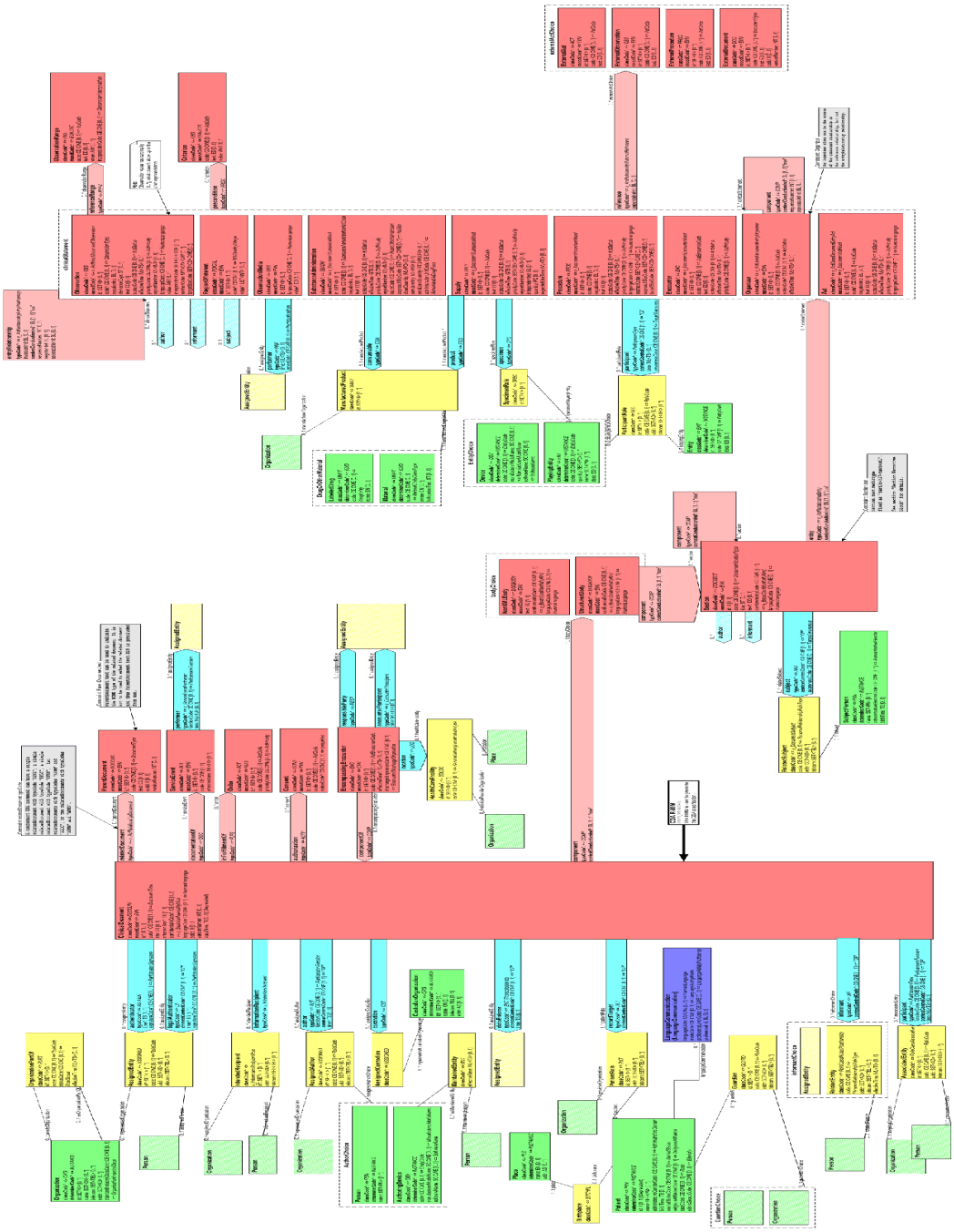


Figure 5.7 Clinical Document Architecture model (after [65])

Colors used in the figures correspond to RIM aria from where the class is derived. The RIM is a model which is based on agreed view on the domain of heath (care) domains and it is composed by six core classes (Act, Participation, Entity, Role, ActRelationship and RoleLink) and their specializations. Act class represents actions that are executed and must be documented as health care is managed and delivered (e.g., appendectomy, measure of the serum sodium); Participation class represents context of, or the functional role in an act, such as for what was realized, for what was done, for what was made (e.g., author, participant physician); Entity class represents physical things and beings which are of interest and take part in healthcare (e.g., personal, organization); Role class establishes roles that entities play in their participation in medical care (e.g., patient, member family); ActRelationship class is a relationship between different acts in a chains of activities, or two documents (e.g. causality, indication), and RoleLink class represents a dependency between the two roles (e.g. a role has authority over another role). Act class is colored in red, Participation class is colored in blue, Entity class is colored in green, Role class is colored in yellow and ActRelationship is colored in pink [65].

Each act has a mandatory moodCode attribute that distinguishes the act as a statement such as command, possibility or objective. The set value defined (CNE) HL7 for moodCode includes „EVN" (event) describing an Act class that took place, „DEF" (definition) meaning that Act class refers to a Master File description, „INT" (intent), where Act class describes a planned or requested action, „GOL" (goal), where is described a desired outcome, „EVN.CRT" (event criterion), which represents an event which must apply for an associated service to be taken into account.

An Act can have zero or more ActRelationship and can have (player) no participations, each played by an entity in different roles. A role is a relation between two entities (scopes), the entity which play a role (represented with a bold line between Role and Entity) and entity which is recognized as attribute role (represented with a dotted line between Role and Entity). So, in Figure 5.5 a „legalAuthenticator" is a participant of a „ClinicalDocument" Act and it is played by a „Person" entity into an „AssignedEntity" role which was organized by the „Organization" entity.

The CDA header's goal is to establish a framework for the document as a whole, to exchange documents between clinics and institutions to facilitate the clinical document management, and to facilitate the compilation of the individual documents in an electronic health record during his life.

The entry point into the CDA model is the ClinicalDocument class, corresponding to a <ClinicalDocument> tag which is root type from CDA schema. ClinicalDocument class contains different attributes, like ClinicalDocument.id, which specify the document into a unique mood; ClinicalDocument.code which specify the document type (e.g., patient hystory and physics) with the help of a code with a value set (CWE) which is composed by LOINC codes; ClinicalDocument.effectiveTime which represents when the document is created; ClinicalDocument.Confidentiality.Code which defines the general confidentiality degree of the document; and ClinicalDocument.languageCode, which specify which language is used.

Perhaps the most important change to CDA header from CDA R1 is made by RIM evolution since November 2000, which resulted in a significant reduction in ambiguity to allow a distinction between the various players. CDA R2 header defines many participants (e.g., authenticator, author, encounterParticipant,

legalAuthenticator, and performer). More information involved in the CDA header is done frequently by the same person, but this does not happen in every case, and CDA R2 header adds clarity to those less common scenarios. For example, if a doctor sees a patient as a consultant, dictates a note, and later signing doctor participates as author, encounterParticipant and legalAutheticator. On the other hand, if a resident sees a patient with another physician dictates a note and signs, and the note is reviewed by another doctor, resident is author and authenticator, both residents and medical staff are encounterParticipants, and second doctor is a legalAuthenticator.

The development model for CDA R2 was heavily influenced by the CEN ENV 13606, openEHR and DICOM models, in special to help determine the optimal level of abstraction and model validation. The CDA body contains the clinical report and can be unstructured, represented by NonXMLBody class which is shown in Figure 5.5, or can be composed of structure class parts represented by StructureBody class. NonXMLBody class is provided for those applications that are part from an existed non-XML document with CDA header. StructuredBody contains one or more section existing components.

Section class contains different attributes, such as Section.id, which uniquely identifies the section; Section.code, specifying the particular type of sections (e.g. allergies and adverse reactions, reviewing systems) through a LOINC code; Section.title represents the label which can be read by human; Section.text is a narrative block which was detailed above, which contains the section read by humans and document initiator which must be populate with content, and the receipt must render using the rules defined.

The branching from the right part of Section class represent the entry relation, which lead to the clinical statement model, part of which is shown in Figure 5.6. CDA entries are represented in a structured way for further computer processing (e.g., decision support applications). Usually, they encode portions of the narrative field of the section containing Section.text. The ClinicalStatement dotted box represents a structure, which contains specialization from Act class (such as Observation, SubstanceAdministration, Supply, and Procedure) that provides formal representation [67].

Figure 5.8 through Figure 5.12 represent different aspects of the clinical document model of CDA R2 type, including the mode in which the clinical declarations are partially overlapping within a document section. All the figures are valid fragments of a CDA R2 instance in some cases including optional components (e.g., codeSystemName and displayName), clarify the examples [67].

```
<section>
  <code code="8716-3" codeSystem="2.16.840.1.113883.6.1"
   codeSystemName="LOINC"/>
  <title>Vital Signs</title>
  <text>Temperature is 36.9 C</text>
  <entry>
    <observation classCode="OBS" moodCode="EVN">
      <code code="386725007" codeSystem="2.16.840.1.113883.6.96"
       codeSystemName="SNOMED CT" displayName="Body temperature"/>
      <statusCode code="completed"/>
      <effectiveTime value="200004071430"/>
      <value xsi:type="PQ" value="36.9" unit="Cel"/>
    </observation>
  </entry>
</section>
```

Figure 5.8 Simple observation CDA example (after [67])

```
<section>
  <code code="10164-2" codeSystem="2.16.840.1.113883.6.1"
   codeSystemName="LOINC"/>
  <title>History of Present Illness</title>
  <text>Henry Levin, the 7<sup>th</sup> is a 67 year old male
   complaining of disabling <content ID="SX1">osteoarthritis
   of the right knee</content>.
  </text>
  <entry>
    <observation classCode="OBS" moodCode="EVN">
      <code code="396275006" codeSystem="2.16.840.1.113883.6.96"
       codeSystemName="SNOMED CT" displayName="Osteoarthritis">
        <originalText><reference value="#SX1"/></originalText>
        <qualifier>
          <name code="363698007" codeSystem="2.16.840.1.113883.6.96"
           displayName="finding site"/>
          <value code="6757004" codeSystem="2.16.840.1.113883.6.96"
           displayName="right knee"/>
        </qualifier>
      </code>
    </observation>
  </entry>
</section>
```

Figure 5.9 A complex CDA example (after [67])

```
<section>
  <code code="10157-2" codeSystem="2.16.840.1.113883.6.1"
   codeSystemName="LOINC"/>
  <title>Family history</title>
  <text>
    <list>
      <item>Father had fatal MI in 1970.</item>
      <item>No cancer or diabetes.</item>
    </list>
  </text>
  <entry>
    <observation classCode="OBS" moodCode="EVN">
      <code code="22298006" codeSystem="2.16.840.1.113883.6.96"
       codeSystemName="SNOMED CT" displayName="Myocardial infarction"/>
      <effectiveTime value="1970"/>
      <subject>
        <relatedSubject classCode="PRS">
          <code code="FTH" codeSystem="2.16.840.1.113883.5.111"
           codeSystemName="PersonalRelationshipRoleType"
           displayName="Father"/>
        </relatedSubject>
      </subject>
      <entryRelationship typeCode="CAUS" contextConductionInd="true">
        <observation classCode="OBS" moodCode="EVN">
          <code code="399347008" codeSystem="2.16.840.1.113883.6.96"
           codeSystemName="SNOMED CT" displayName="death"/>
          <effectiveTime value="1970"/>
        </observation>
      </entryRelationship>
      </observation>
  </entry>
  <entry>
    <observation classCode="OBS" moodCode="EVN" negationInd="true">
      <code code="275937001" codeSystem="2.16.840.1.113883.6.96"
       codeSystemName="SNOMED CT"
       displayName="Family history of cancer"/>
    </observation>
  </entry>
  <entry>
    <observation classCode="OBS" moodCode="EVN">
     <code code="160274005" codeSystem="2.16.840.1.113883.6.96"
      codeSystemName="SNOMED CT"
      displayName="No family history of diabetes"/>
    </observation>
  </entry>
</section>
```

Figure 5.10 A medical history example (after [67])

```
<section>
  <code code="101155-0" codeSystem="2.16.840.1.113883.6.1"
   codeSystemName="LOINC"/>
  <title>Allergies and Adverse Reactions</title>
  <text>
    <list>
      <item>Penicillin - Hives</item>
      <item>Aspirin - Wheezing</item>
      <item>Codeine - Itching and nausea</item>
    </list>
  </text>
  <entry>
    <observation classCode="OBS" moodCode="EVN">
      <code code="247472004" codeSystem="2.16.840.1.113883.6.96"
       displayName="Hives"/>
      <entryRelationship typeCode="MFST">
        <observation classCode="OBS" moodCode="EVN">
          <code code="91936005" codeSystem="2.16.840.1.113883.6.96"
           codeSystemName="SNOMED CT" displayName="PCN Allergy"/>
        </observation>
      </entryRelationship>
    </observation>
  </entry>
</section>
```

Figure 5.11 An example of allergies and adverse reaction (after [67])

```
<section>
  <text>Take captopril 25mg PO every 12 hours.</text>
  <entry>
    <substanceAdministration classCode="SBADM" moodCode="RQO">
      <effectiveTime xsi:type="PIVL_TS">
        <period value="12" unit="h"/>
      </effectiveTime>
      <routeCode code="PO" codeSystem="2.16.840.1.113883.5.112"
       codeSystemName="RouteOfAdministration"/>
      <doseQuantity value="1"/>
      <consumable>
        <manufacturedProduct>
          <manufacturedLabeledDrug>
            <code code="318821008" codeSystem="2.16.840.1.113883.6.96"
             codeSystemName="SNOMED CT"
             displayName="Captopril 25mg tablet"/>
          </manufacturedLabeledDrug>
        </manufacturedProduct>
      </consumable>
    </substanceAdministration>
  </entry>
</section>
```

Figure 5.12 example of medication administration (after [67])

Observation class is used for representing codes and observations. Figure 5.8 represents a simple observation, the measurement of body temperature, which contained in the vital sign section. This demonstrates that a typical observation has Observation.code and an Observation.value. moodCode value is „EVN" (event), this means that this observation takes place. Furthermore, status (statusCode) and time

of realization (effectiveTime) are expressed. It is important that the nested observation is not based on Section.code value for correct interpretation and the observation of the body temperature can appear in another part of the document, in another section [67].

Figure 5.9 is represents a complex example, where a symptom is reported by the patient. The content is placed in the present history disease section. In Section.text exists a <content> tag from the nested entry as an observation. This mechanism can be used, for instance, by a natural language processing engine to associate a CDA entry with a narrative block. The figure also illustrates the use of a CD to insert a qualifier, enabling post-coordination of a SNOMED-CT concept to represent the right knee osteoarthritis [67].

The Figure 5.10 illustrates the use of entryRelationship class representing a set of observations for patient family history contained in the family history section. The first observation is about myocardial infarction (MI). The participation of „FHT" subject indicates that also the father suffered from MI. Crossing the entryRelationship class is a partially overlapping observation about decease. The participation subject propagates to this relationship, and with entry.Relationship.typeCode of „CAUS" indicates that MI was caused with reason of father's. The Figure also shows different representations of negation, one using negationID (because cancer is not present in the family history) and the other using a pre-coordination code (because in the family history is not present the diabetes) [67].

The Figure 5.11 represents allergies and adverse reactions. The narrative block contains three elements: one of them is represented as a nested observation. The patient has a history of hives registered as a separate observation, which is the linked to another observation of penicillin allergy through entryRelationship with „MSF" (is manifestation of) typecode [67]. SubstanceAdministration class is used to represent events related to drugs, such as medication history and medication administration orders. Participating as a consumer is a LabeledDrug or a Material entity in ManufacturedProduct role.

The Figure 5.12 illustrates the use of SubstanceAdministration class. „RQO" moodCode indicates that this is a request. The effectiveTime attribute uses PIVL_TS (a periodic time) datatype which indicates that the requested act must take place at each 12 hour. The „1" doseQuantity indicates that one is consumable and must be administrated at each act. The medicine is a 25 mg Captopril tablet [67].

The provisioning act is used to represent the material supply from one entity to another (e.g., to indicate a pharmacy request to give up of a certain amount of pills or a number of reserves), and can be coupled with SubstanceAdministration which can be used as a prescription [67].

The HL7 CDA standard is used for communication between different medical information systems, in our case the Obstetrics-Gynecology Department Information System with other systems (e.g., Pediatrics Department Information System, Clinical Decision Support System and General Practitioner Information System). It was also developed a CDA Component which can transmitted the information as XML document in CDA format.

Case studies of using the HL7 CDA and XML in CDA format are presented in detail in Chapter 6.6.

5.1.3. Continuity of Care Document (CCD) standard

In the following, a review of the CCD standard is presented because it supports the CCD Component that will help to extract data from different databases and using this data to create XML documents in CCD format for the OGD.

Continuity of Care Document (CCD – document which insures the continuity in healthcare) is a communication standard that provides summary information about the patient as a snapshot to share their medical data between providers and institutions. It summarizes the most common information required for the current and past health situation in a form that can be transmitted to other applications [70].

Specific clinical content and purpose of CCD is fixed by the ASTM Continuity of Care Record (CCR) specifications and XML representation specifications for patient data. CCD is based on the specifications of messages represented in XML for the exchange of clinical information. It has two restrictions: the design is derived from HL7 Reference Information Model (RIM) as expressed in Clinical Document Architecture Release 2 (CDA R2), and the exchanged information relates to any specific clinical information [70].

Besides the common constraints on data types, sources, roles, identifiers, and terminology constraints on language, creation date, patient, communication partner, and purpose as well as the CCD Footer are specified in CCD Header. The CCD body contains information about actors, functional status, problem, social and family history, allergies, medications, immunizations, vital sign, results, procedures, accounts, and care plans [70], [71].

In 2007, HL7 published two implementation guides: patient history as well as physics notes and consultation in 2007, which reuse the CCD templates. These guides were developed with the help of CDA for common document types (Common Document Types – CDA4CDT). These guidelines have been initiated by M*Modal, American Health Information Management Association (AHIMA) and Association for Healthcare Document Integrity (AHDI) [70].

The Patient Care Coordination technical framework provides a library composed by 120 reusable templates for CDA entries and sections, including those for CCD implementation guideline. It also defines a specific number of profiles for CDA documents such as the exchange of personal health record content (Exchange of Personal Health Record Content - XPHR), which reuses the CCD sections and entries [70].

ANSI/HITPS defines some content specifications used in some specifications. The content component of registration and medication history (HITSP C32) describes content of the document summarizing customer registration and information about medication contained in the personal health record (PHR) to exchange information. The content component was revised in 2007 to be additionally included in CCD sections [70].

The CCD core model represents the clinical report model, which includes CDA entries, references and associated participations. Clinical reports are generally based on clinical content models by derived from the HL7 RIM. To improve these reports at a new level of specification used for exchanging information, CCD introduces sections in templates, clinical reports and entries to support a sublevel of clinical reports. These templates defined by CCD are reused by other specifications which are complying with CDA. They are built in block inside CCD [70].

CCD advantages are [70]:

- syntax and shared architecture

  Not all the information exchanged between health information systems is summarized. Clinicians use other specialized clinical documents, including medical history and physical examination, consultation note, pathology or radiology report, and discharge summary. Discharge summary is not specified in CCR, but in CCD.

  - easy to represent the information

    CCD uses a small and fixed XML tag set for each CCD. Therefore, it can easily be represented in any application, including a Web browser, without prior negotiation between the information exchange partners, using specialized style sheets or XML representation of a single static display. Tags such as <section>, <paragraph> and <title> are easily represented as HTML, PDF, or any type or display on a device, including EMR.

  - the shared model provides extensibility

    CDD uses an UML model, the RIM (Reference Information Model), with the full spectrum of new generation of HL7 specifications. While it is specific to the health system, RIM is abstract and general enough to provide requirements that go beyond healthcare establishment and support most of the international information exchange requirements in addition to these new areas:
    - public health: reports are a complete and accurate response on changing conditions required by the model of complete, general and shared information. The new reports on medication safety and infection based messaging using RIM and documents that are compatible with CCD and CDA.
    - clinical trial: reducing the number of papers for clinical benefits will reduce costs and can improve quality. Clinical data exchange standards provided by CDISC (Clinical Data Interchange Standards Consortium) are compatible with RIM, the model is shared by CCD and CDA.

  - a better monitoring

    The CCD specifications must meet the reporting requirements without redundant data entry. Mapping the report requirement to RIM addresses the medical data recording in electronic format (EMR/EHR) which must respect the reporting quality using data derived from CCD and CDA.

eDocument integration in patient electronic health record (EHR)

All electronic medical records (EMR) and electronic health records (EHR) import, manage, and export clinical documents. CCD and all CDA documents are designed for this type of exchange and integration. Thus, all types of documents imported as

conformant CDA documents contain data that can be readily integrated into document management systems, EMR-based patient charts, and record locator services [70].

CDA defines the minimum data set required to support any of these types of applications. It has been considerably used in producing each of these scenarios since 2000 [70].

Using CCD in healthcare in Romania

A CCD example has been developed which has been adapted to the Romanian healthcare actuality. In this case, the CCD standard is used for communication between hospital information system and general practitioner information system [72]. If a general practitioner information system doesn't have information about a patient, then it is necessary to send a CCD containing all the patient information.

The CCD header is presented in Figure 5.13.

```
<?xml version="1.0" encoding="ISO-8859-1"?>
- <ClinicalDocument xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd" xmlns="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
    <templareId root="2.16.840.1.113883.10.20.1"/>
    <id root="2b857fce-53b9-4cb7-8151-39d276db1ce7"/>
    <code displayName="Summarization of episode note" codeSystemName="LOINC" codeSystem="2.16.840.1.113883.6.1" code="34133-9"/>
    <effectiveTime value="20110613"/>
    <languageCode code="Ro"/>
  - <author>
      <time value="20110613"/>
    - <assignedAuthor>
        <id root="1.3.6.4.1.4.1.2835.1" extension="1"/>
        <code codeSystem="2.16.840.1.113883.5.11" code="SELF"/>
      - <assignedPerson>
          <name>EClinic</name>
        </assignedPerson>
      </assignedAuthor>
    </author>
  - <custodian>
    - <assignedCustodian>
      - <representedCustodianOrganization>
          <id root="1.3.6.4.1.4.1.2835.3" extension="1"/>
          <name>E-Care Management</name>
        </representedCustodianOrganization>
      </assignedCustodian>
    </custodian>
      <!--******************Demographics******************-->
  - <recordTarget>
    - <patient>
      - <name>
          <CNP>2343</CNP>
          <Nume>Popescu</Nume>
          <Prenume>Maria</Prenume>
        </name>
      </patient>
      <administrativeGenderCode codeSystem="2.16.840.1.113883.5.1" code="F"/>
      <birthTime value="15.05.1985"/>
      <maritalStatusCode codeSystem="2.16.840.1.113883.5.2" code="casatorit"/>
    - <documentationOf>
        <serviceEvent classCode="PCPR"/>
        <effectiveTime>20110515</effectiveTime>
      </documentationOf>
      <performer typecode="PRF"/>
    - <time>
        <low value="2010"/>
        <high value="2011"/>
      </time>
    - <assignedEntity>
        <id root="1.3.6.4.1.4.1.2835.1" extension="1"/>
        <code displayName="Physician" codeSystemName="LOINC" codeSystem="2.16.840.1.113883.6.96" code="22028-5"/>
      - <assignedPerson>
          <name>Ionescu Marian</name>
        </assignedPerson>
      </assignedEntity>
    </recordTarget>
```

Figure 5.13 CCD header example

Figure 5.14 presents an example of a CCD component.

```
- <component>
  - <observation classCode="OBS" moodCode="EVN">
      <templateID root="11"/>
      <code displayName="Eritrocite" codeSystem="2.16.840.1.113883.6.1" code="11273-0"/>
      <statusCode code="completed"/>
      <effectiveTime>20110515</effectiveTime>
      <value value="5.36" unit="x10^6/uL" xsi:type="PQ"/>
    - <methodeCode codeSystem="2.16.840.1.113883.5.84" code="460179">
      - <referenceRange>
        - <observationRange>
            <text>4.00-5.80 x10^6/uL</text>
          </observationRange>
        </referenceRange>
      </methodeCode>
    </observation>
</component>
```

Figure 5.14 CCD component example

Figure 5.13 shows a part of a CCD header containing the name of the physician which created the CCD, and Figure 5.14 presents a blood analysis, in this case erythrocytes and its value.

5.2. Interoperability examples - HL7 CDA Component

In the next three subchapters three examples of GCM instances are presented, using the HL7 CDA Component. These are, the result of personal and original work applied in real life practice. The HL7 CDA extracts data from different databases and sends them to other medical information systems (e.g. Clinical Decision Support, LabKey Server and other hospital departments such as Pediatrics). The third example introduces how standardized communication can be used related to cloud computing.

5.2.1. Transmission of patient data to Egadss system using HL7 CDA Component

The communication between databases and Egadss application is realized with the help of the HL7 CDA standard. [65] The Egadss application supports only XML in HL7 CDA format as data input [73]. Figure 5.15 represents the system architecture which is an instance of GCM. The application sends a data request. This request is provided as an attachment to the recommendation results.

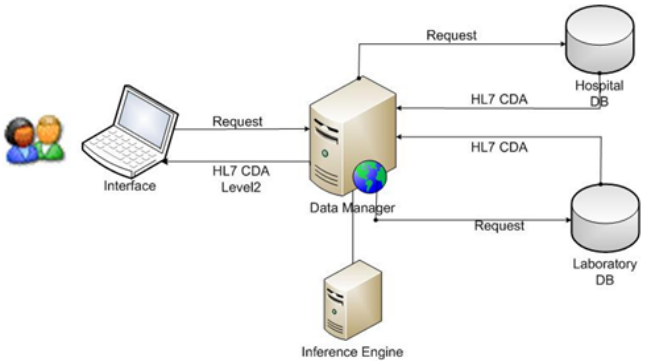


Figure 5.15 System architecture

Clinical Decision Support Systems are "active knowledge systems which use two or more items of patient data to generate case-specific advice" [75].

The components of the CDS (Clinical Decision Support) system architecture are: decision making system and the interface. There are based on Web Services. The inference engine is based on Egadss open source solution [73], [75]. In order to have a standardized communication interface between databases and "recommendation generator" - Egadss uses as inputs HL7 CDA (Level 3) standard messages as XML files, where the patient data is represented (XML retrieved from the HL7 CDA Component). Another standard used by Egadss is Arden Syntax, which is a clinical guideline formalism accepted as an official standard by the HL7 group, being used for the representation of medical knowledge. The result of the inference is a CDA Level 2 document, containing the medical recommendations [73], [75]. To manage the connection and the order in which the different web services are invoked, a Data Manager was developed. Data Manager has the role to respond on different requests that come from the main components of the system (interface, medical data source, inference engine). In order to realize this, three communication channels are opened and are represented in Figure 5.15 with: Interface, HL7 CDA Component, and inference engine (Egadss).The interface allows the medical staff and patients to visualize the steps of the protocols, medical information regarding a patient, different alarms, and they can insert feedback concerning the recommendations. The interface is implemented using the ASP.Net platform with C#. A more detailed description can be found in [76]. Beside the use of HL7 CDA documents, other sources can be added to the system through the Data Manager [77].

Egadss is a clinical decision support system that has as inputs HL7 CDA standard messages as XML files [73], [75]. This results in a standardized communication interface between databases and "recommendation generator". Egadss extracts the patient data from the XML representation and uses this information to generate new clinical recommendations, making the system very flexible and easy to be implemented in any medical unit. The recommendations resulted from Egadss are also structured as a CDA level 2 document.

The Arden Syntax is a clinical guideline formalism accepted as an official standard by HL7 [75]; it is a textual representation organized in frames, intuitive and without room for ambiguity. It is freely available, a mature and actively maintained open standard. This is the reason why Arden Syntax is used instead of other guideline formalisms as Proforma, GLIF (GELLO), Asbru, etc. [73], [75], [78], [79].

Egadss is running system, and value is added using multiple data sources based on HL7 standards [76].

The HL 7 CDA Component extracts the data from a local database and presents it using XML in HL7 CDA format [76]

The HL7 CDA Component implementation is developed in Visual Studio .net 2010, deploying the C# language. The databases are hold on SQL Server 2008, but it also is possible to use Oracle or MySQL. HL7 CDA can be implemented in Java. Egadss reads an XML file, and it does not matter in which language the XML in CDA format is developed [76].

Figure 5.16 demonstrates an example for an XML file presented below containing the data concerning the active problems section and the laboratory results in HL7 CDA format. This information is used by Egadss. The data is extracted from the database, and based on that an HL7 CDA document is prepared. The Active Problems section represents the patient's symptoms, in this case Urgency of

urination symptom, associated with an ICD9 code. The Laboratory section presents the result of a potassium test, which is needed for Egadss [76].

```
<!-- ******************Active Problems section******************  -->
- <component>
  - <section>
      <code code="11450-4" codeSystem="2.16.840.1.113883.6.1" />
      <title>Active Problems</title>
    - <entry>
      - <observation classCode="OBS" moodCode="EVN">
          <code code="788.63" codeSystem="2.16.840.1.113883.6.2" codeSystemName="ICD-9-CM" displayName="Urgency of urination" />
        </observation>
      </entry>
    </section>
  </component>



    <!-- ******************Labs section******************  -->
  - <component>
    - <section>
        <code code="11502-2" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" displayName="Labs" />
        <title>Urinalysis</title>
      - <entry>
        - <observation classCode="OBS" moodCode="EVN">
            <code code="2829-0" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" displayName="Potassium" />
            <effectiveTime value="20101002" />
          </observation>
          <value xsi:type="PQ" value="44" />
        </entry>
      </section>
    </component>
```

Figure 5.16 CDA example

5.2.2.Transmission of patient data to Labkey Server

5.2.2.1. General information about LabKey Server

The LabKey Server is an open source platform which supports: the submission of specimens' requests across collaborating organizations; graphically defining new experimental data types, metadata and wizards for data collection: transitioning experimental results for multiplicity of spreadsheets to custom tables in a shared database; securely organizing, integrating, analyzing, visualizing and sharing diverse data types, from clinical records to complex assays; interacting dynamically with external data sources; tracking study participants and cohorts over time; developing custom interfaces using client libraries; authoring visualizations in a built-in R scripting environment [80].

Other open source platforms are: CAISIS, which is a web – based cancer data management system that integrates research with patient care [81]; i2b2 (Informatics for Integrating Biology and the Bedside) is developing a scalable informatics framework that will enable clinical researchers to use existing clinical data for discovery research [82]; SIMBioMS (System for Information Management in Biomedical Studies), which is a multi-module solution for data management in biomedical studies [83]; ISA (Investigation/Study/Assay) infrastructure that is an general-purpose format and available desktop software suite targeted to experimentalists, curators and developers [84]; InterMine, which is a powerful data warehouse system, where it is possible to create databases of biological data accessed by sophisticated web query tools [85].

Unfortunately, these tools store only metadata in their databases, not results. Furthermore, they do not have a broad range of customizable, scientifically-relevant

properties for every column of data, built-in user interface for scripting in R and dynamic interaction with external data sources [80].

LabKey Server has core services and specialized modules which are autonomous and can be upgraded independently to add new functionalities, including data storage, file management and security, together with specialized modules and also support specific scientific scenarios by encapsulating application logic, user interfaces and data. The modules are presented in Figure 5.17 [80]:

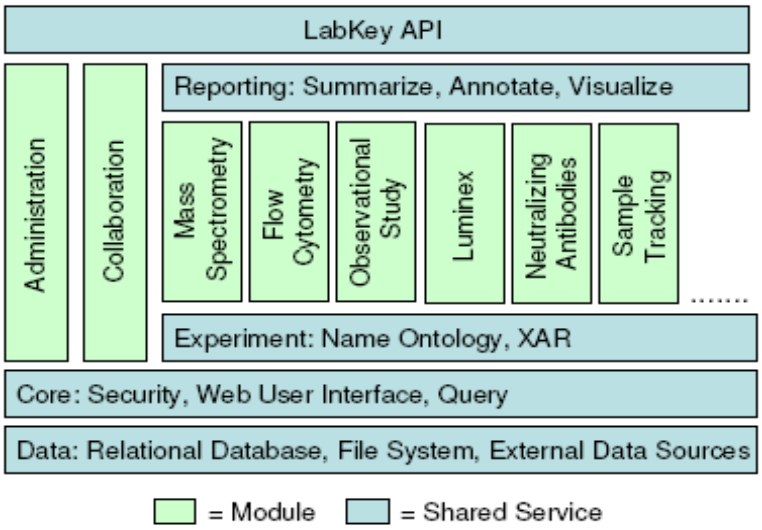


Figure 5.17 LabKey Server's modular architecture (after [80])

Observational Study is used for statistics, reports and charts. Dynamic access can be configured for PostgreSQL, MySQIL or Microsoft SQL Server databases, or for other data sources. In general, users can work on a LabKey Server with data from external source just like any other type of data. Authorized users can view shared sources using LabKey Server's familiar, accessible grid user interface.

A server can also be configured to display search results from external web sites. LabKey Server also provides a variety of web-based collaboration tools, including file management, Wikis, message boards and issues trackers [80].

5.2.2.2. System architecture using LabKey Server

Figure 5.18 presents the author's proposal for a system architecture using the LabKey Server which is an instance of Generic Component Model.

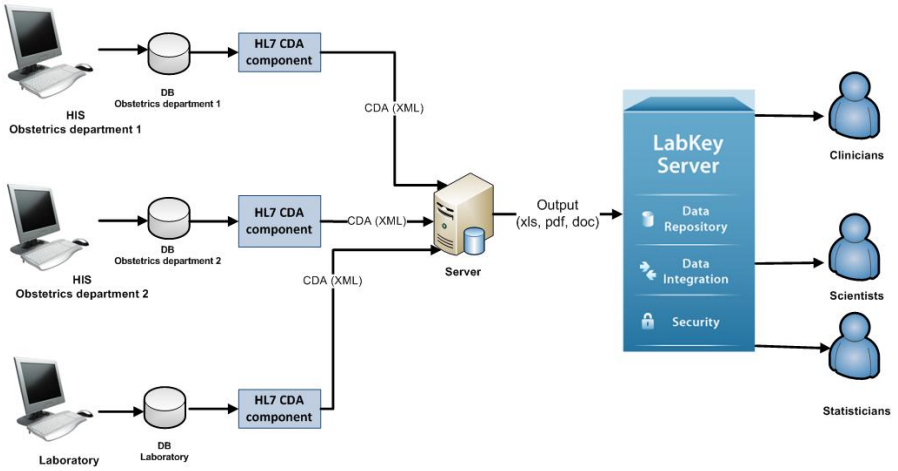


Figure 5.18 System architecture

The system includes 2 obstetrics departments and one laboratory that communicate information using HL7 CDA (Clinical Document Architecture), connected to a Server using Web Services to be stored in a database. Thereafter, the data will be send to the LabKey server in Excel format, or alternatively in Word or PDF format, to help the physicians, scientists or statisticians in their research and clinical activity.

5.2.2.3. The HL7 CDA Component

The CDA Component extracts the data needed and converts it into a CDA in XML format. Then the information is sent to the Server using a Web. The name, surname and the unique Romanian id are transmitted in an anonymous mode.

Figure 5.19 shows an example of a CDA laboratory section for a blood test which transmits the value of beta- HCG [86].

```
<!--*****************Labs Section*****************-->
<component>
  <section>
    <code code="11502-2" codeSystem="2.16.840.1.113883.6.1"
     codeSystemName="LOINC" displayName="Labs" />
    <title>Blood test</title>
    <entry>
      <observation classCode="OBS" moodCode="EVN">
        <code code="19180-9" codeSystem="2.16.840.1.113883.6.1"
         codeSystemName="LOINC" displayName="beta-HCG" />
        <effectiveTime value="20110402" />
        <value xsi:type="PQ" value="15000" unit="mUI/mL" />
      </observation>
    </entry>
  </section>
</component>
```

Figure 5.19 CDA laboratory section

The HL7 CDA uses LOINC (Logical Observation Identifiers Names and Codes) codes to identify the transmitted concept. In this example, 11502-2 is used which is the code for Laboratory analysis, and 19180 – 9 which is the code for beta-HCG analysis from blood.

Human chorionic gonadotropin (HCG) is a hormone that is produced by the placenta of a pregnant woman. It can be detected in the blood and in the urine. It is important to know the beta - hCG level and it is important this value into consideration. A level or below the normal range may indicate an ectopic pregnancy. Beta-hcG levels can also be used to identify a multiple pregnancy like twins, triplets or multiples [87].

5.2.2.4. Results obtained using LabKey Server

After on the Server the LabKey tool creates an Excel file containing the necessary data (section II). The .xls file is imported in Labkey Server and after that the data will be displayed in a grid view. A screenshot is shown in Figure 5.20 [86].

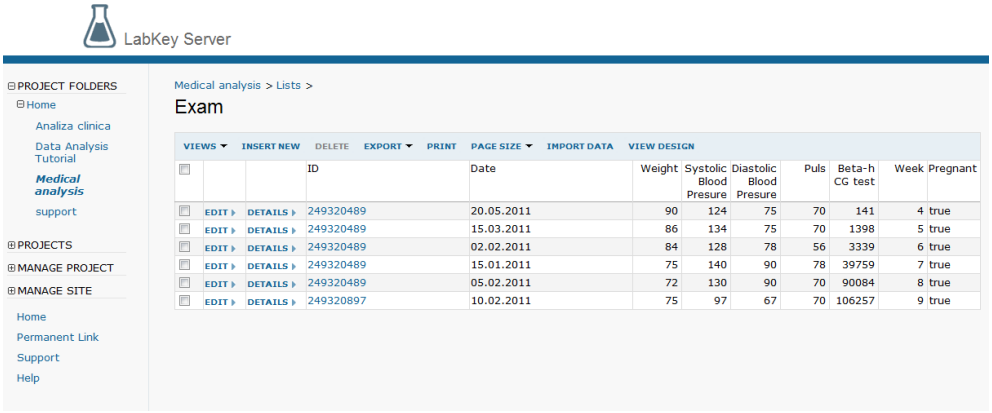


Figure 5.20 Excel file import in LabKey Server

After that it is possible to create a scatter plot chart based on the data imported. These are shown in Figure 5.21 and Figure 5.22 [86].

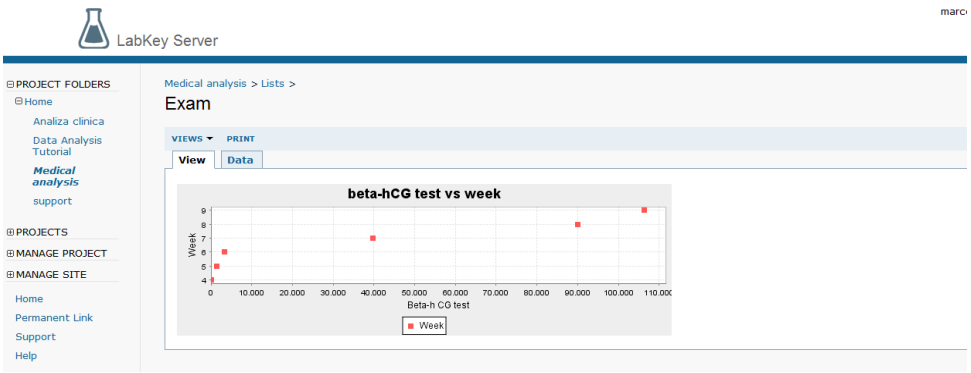


Figure 5.21 Chart shown the beta-hCG on weeks

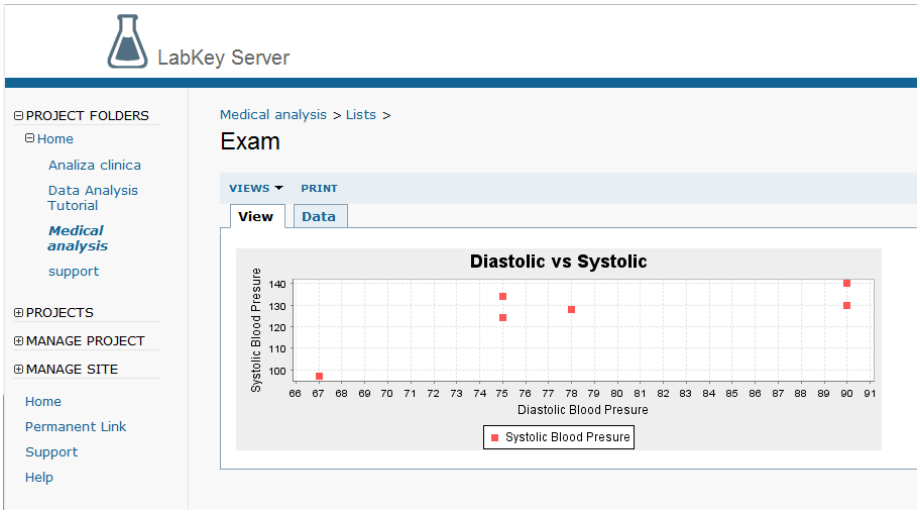


Figure 5.22 Chart shown the Diastolic blood pressure versus Systolic blood pressure

LabKey Server automatically updates the chart when new data is added. Another possibility is that the clinician, statistician or the scientist can sort and filter a data grid and so winnowing out irrelevant information while organizing the data records that matter to them. Figure 5.23 shows a filter which, if it is activated, can show the information that has as data a value less than the one inserted by the user [86].

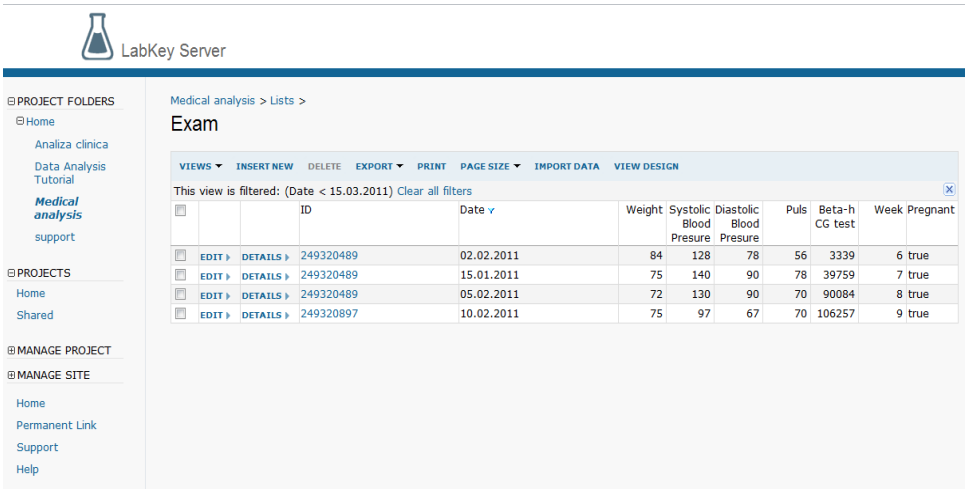


Figure 5.23 Filtering the data

With LabKey Server it is possible to do a lot of statistics, and it is possible to combine different Excel, MS-Word or PDF files. It is a tool which helps clinicians, statisticians and researchers [86].

After the physicians create the chart they can evaluate better the patient's health status better. These charts can be performed for one patient or for more, and can also be created for other important data in pregnancy. In the current example, the blood pressure of a pregnant woman is monitored. Two values higher than normal can draw attention to possible mother health problems that need further investigations or means slow fetal growth and low birth weight or increased risk of preterm delivery or placental abruption. The health problem has to be further investigated, monitoring has to continue, and personalized care must be performed according specific conditions. If the physician discovers in time the mother or fetus health issues by analyzing the charts, he can prevent a lot of pregnancy complications. Also monitoring the beta-HCG together with other clinical data can prevent the fetal chromosomal abnormalities at birth [86].

5.2.3. Transmission of patient data using cloud computing

This subchapter presents the experience gained, the results of transmitting data between different clouds. It is used the HL7 CDA Component to ensure a standardized communication.

Cloud computing, defined by NIST (National Institute of Standards and Technology) [88] is a technology that supports ubiquity, it is convenient, supplies on demand access to the network for sharing computing resources (e.g., networks, servers, storage, applications and services) and can be launched and developed quickly with minimal management and without service provider interaction.

In the medical field, cloud computing offers great potential for quick access to medical information. Health IT infrastructure is very complex. Therefore, organizations have deployed additional measures to protect the patient's private data under HIPAA. Maintaining confidentiality and integrity of information stored in all forms, and providing data backup and recovery processes in extreme cases are enormously important in this field. Quick access to medical history of each person at any location can accelerate diagnosis and treatment quality, avoiding complications, increasing quality and saving lives. In addition, cloud computing can help patients to gain access to their medical history from anywhere in the world via the Internet contributing to personalization in healthcare. The healthcare domain needs increased security and privacy levels, meaning that cloud computing technology has to be more carefully managed in order to achieve this requirements. The matter is less technical and more ethical and legal. Before cloud computing technology can be fully adopted as a structure for health IT, providers must gain the trust of society and demonstrate that they meet the HIPAA (Health Insurance Portability and Accountability Act) standard [89].

More than ever, healthcare services need cooperation between healthcare units due to high mobility of individuals for work or holidays. It is very important to ensure the availability of medical data to all the locations a patient is present. Several scenarios and developments are already available in literature and presented in the following.

In [90], a model of an integrated EMR system is presented, which can share medical data. The application is developed on a cloud platform that keeps the EMR system on the form of Software as a Service and can be used by government, hospitals, doctors, patients, pharmacies and health insurance organizations, through the Internet. This system allows access to national data sharing; the data center is common to all units. Communication between the data center and the healthcare

organizations is done via HL7 messages. All patient data are stored and accessed in the same location over the Internet from any healthcare organizations.

Using cloud computing in medicine brings more benefits to medical units and patients. Some of the benefits are:

- that can be used to store medical data (cloud computing is scalable and allows increase or decrease resources used as needed)
- offers remote access (the data can be accessed via the Internet from anywhere)
- allows data sharing between authorized units and the updates (consultations, prescriptions, hospitalization) are made in real time to the medical history of the patient, for future treatment validation.

In eHealth it is mandatory to use a standardized communication. In presenting the proposed system, one standard is used: HL7 CDA.

Regarding interoperability, cloud computing represents a big advantage. Cloud computing ensures high availability of resources, and systems are "always ON", and therefore, available to communicate with other computing systems in the cloud. Protocols used for interoperability are changing and improving continuously. Via cloud computing, updates are made automatically, and, in this way, people which use these protocols have access always to the latest versions.

The architecture for systems in the cloud is presented in Figure 5.24. All medical data is stored in a private cloud, and all departments of the hospital can access medical patient data when as needed. In this case, the medical act are performed quickly, and the typing errors reduced, all of this driving to higher quality [91].

For increased security, the suggested solution consists of a private cloud-based architecture where applications and data storage can be found within each private data center of the hospital (one in the Pediatrics hospital and one in the Ob-Gyn hospital). When individual patient data is needed from one department to another – both having different health information systems - it will be transmitted in real time to the proper location using an HL7 CDA message solution [91].

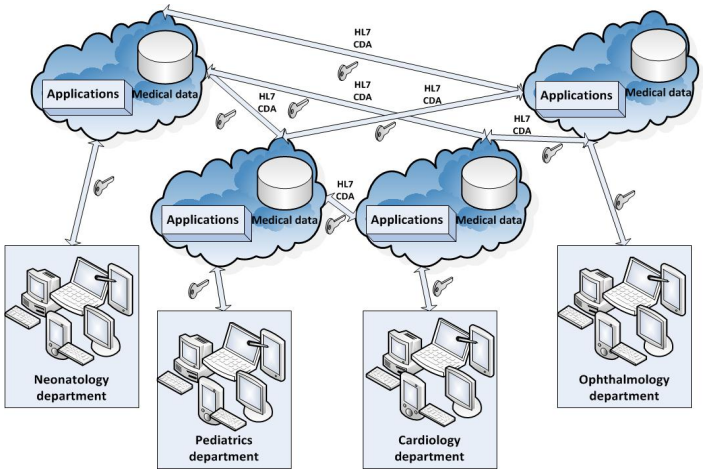


Figure 5.24 Architecture for hospital system using cloud computing

The information flow between the components of the model is presented in the followings. The Pediatrics application sends an XML document with the mother ID, baby's ID and the baby's birth date, the OGD IS reads the XML request document, identifies the needed data, and converts into an XML representation using the CDA format and sending it to the Pediatrics department where the data is read and filled in the baby's chart by as presented in Figure 5.25 [91].

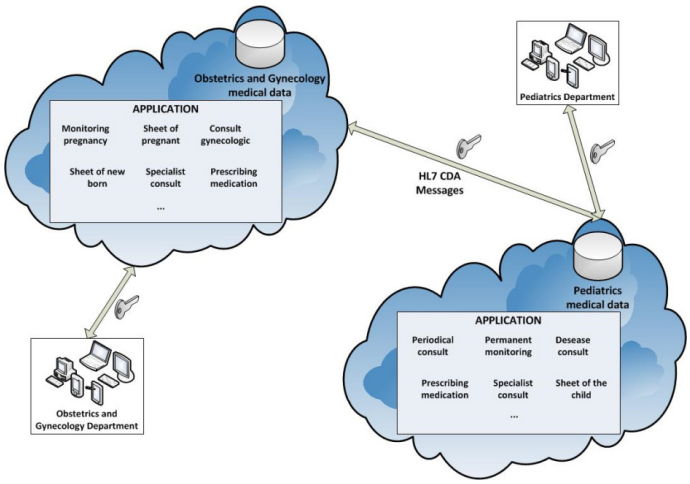


Figure 5.25 The communication between two departments (ObGyn and Pediatric departments) using cloud computing

To achieve interoperability we use XML files based on the HL7 CDA standard. Figure 5.26 presents the flow of data between the two medical units which exchange information [91].

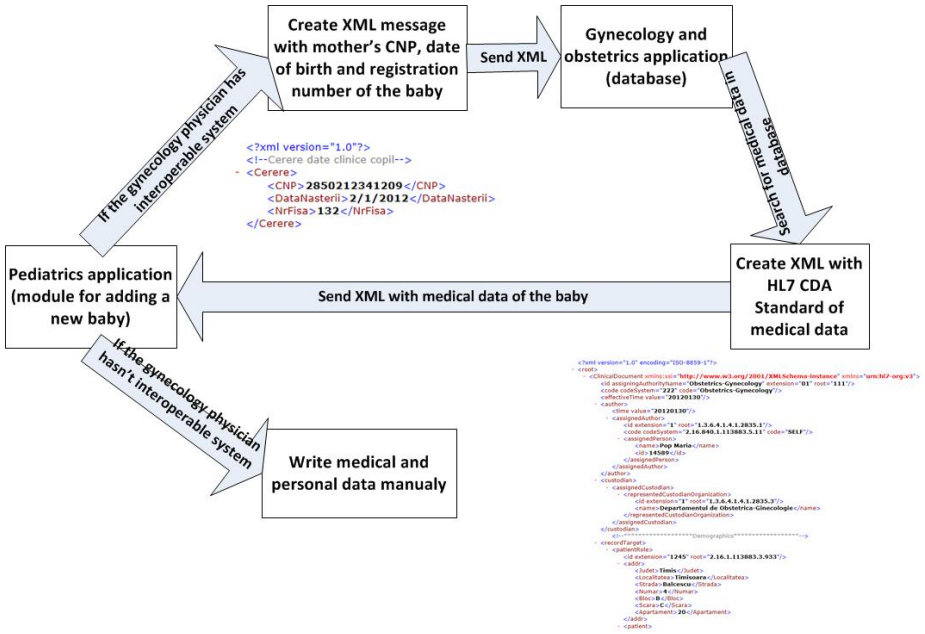


Figure 5.26 Exchange of medical data between units

When the data of a new born child is included in the database of the pediatrician, the physician will be asked if he/she wants to add the data manually or retrieve it from the database of the hospital, which technically located in the private cloud of the Obstetrics and Gynecology unit, where the baby was born. When the data acquisition from the Obstetrics and Gynecology unit option is chosen, the Pediatrics application will create an XML file with the PIN (Personal Identification Number) of the mother, date of birth and registration number of the child (every child is registered at birth with a unique identification number in the hospital). The XML file with these data will be sent to the data server in the private cloud of the unit of Obstetrics and Gynecology. When this data is available in the server, via a specific application it will check the validity of the received message, it will check via a specific application the request, and if the data exists in the server, the application will form another XML file which contains the medical data record of the baby from birth until to the day of discharge. This XML file is created in HL7 CDA standard format, and it will be sent to the unit who requested the data [91].

Once received the required medical data in XML format, the Pediatrics application will read the XML file and will display the medical records to the location point where the physician has added the patient. The received medical data will be saved on the database server in the private cloud of the Pediatrics unit. The pediatrician will have access to the medical history of the baby from birth and during pregnancy, information which is important for monitoring and treating the child [91].

5.3. Ontologies, terminologies and coding systems for EHR

In CDA and CCD standards deploy different codes: ICD (International Classification of Diseases), LOINC (Logical Observation Identifiers Names and Codes) and SNOMED (Systematized Nomenclature of Medicine – Clinical Terms). These codes are used depending on the country. For example, in Romania the appropriate codes used in CDA and CCD are in this moment: ICD-10-AM and LOINC codes.

5.3.1. International Classification of Diseases (ICD) – ICD 10

ICD-10-AM is a classification code for disease that can be defined as a category which morbid entities are assigned to according to established criteria. ICD-10-AM's goal is to enable recording, analyzing, interpretation and systematic comparison of morbidity data collected in different hospitals, states and countries. The ICD-10-AM provides the possibility of translating the diagnosis and procedures and other health problems from narrative text into an alphanumeric code that enables storing, finding and analysis [92].

It is important that while ICD was originally intended to classification of diseases and injuries with a formal diagnosis, not every problem or reason are contacted health services can be categorized in this way. Consequently, ICD offers a wide variety of signs, symptoms, abnormal findings, complaints and social circumstances that can replace diagnostic [92].

The classification core of ICD-10-AM is by a code with three characters, which is the codification of international mandatory reporting to WHO for general international comparisons [92].

This basic set of codes was extended to four and five characters enabling the identification of important specific diseases, also maintaining the ability to present data in large groups so that information obtained will be usable and understandable.

ICD-10-AM is a classification with six variables. Its structure is designed primarily to facilitate epidemiological analyses. Diseases are organized into the following groups [92]:

- Epidemic diseases
- Organic disease or general
- Localized disease ordered by location
- Increased disease
- Injury

The next lines present the chapters and the letters from Volume 1 – Tabular disease:

Chapter I – Infectious and parasitic diseases – letters A,B
Chapter II - *Tumors* – letters C,D
Chapter III – *Blood diseases, hematopoietic organs and others* - letter D
Chapter IV – *Endocrine nutritional and metabolic diseases* - letter E
Chapter V - *Mental and behavioral disorders* - letter F
Chapter VI - *Diseases of the nervous system* - letter G
Chapter VII - *Diseases of the eye and its annexes* – letter H
Chapter VIII - *Diseases of ear and mastoid epiphysis* – letter H
Chapter IX - *Diseases of the circulatory system* – letter I

Chapter X - *Respiratory diseases* - letter J
Chapter XI - *Digestive Diseases* - letter K
Chapter XII - *Skin and subcutaneous tissue diseases* – letter L
Chapter XIII - *Diseases of the osteoarticular system, muscles* - letter M
Chapter XIV - *Diseases of the genitourinary system* – letter N
Chapter XV - *Pregnancy, childbirth, puerperium* - letter O
Chapter XVI - *Some diseases whose origin lies between ..*– letter P
Chapter XVII - *Congenital malformations, deformations and anomalies.*-letter Q
Chapter XVIII - *Symptoms, signs and abnormal ...*– letter R
Chapter XIX - *Injury, poisoning and other ...*– letters S,T
Chapter XX *External causes of morbidity and mortality* - letters V,W,X,Y
Chapter XXI *Factors influencing health...* – letter Z

5.3.2. Logical Observation Identifiers Names and Codes (LOINC)

Logical Observation Identifiers Names and Codes (LOINC) is a universal code system for reporting laboratory results and other clinical observations [93]. Its purpose is to identify observations in electronic messages such as observations expressed in HL7 messages so that hospitals, health organizations, pharmaceutical industry, researchers, and public health departments can receive such messages from several sources. They can immediately archive records of the results in the right place in medical research and / or public health systems. For each observation, the database containing the LOINC codes will include a code (of which 25.000 are laboratory observations), a formal long name, a short name composed of 30 characters, and synonyms. The database is included in a program called Regenstrief LOINC Mapping Assistant (RELMA^{TM}) which assists in mapping local test results to LOINC codes, and LOINC facilitates the search results. The LOINC medical database contains records of over 30.000 different observations [93].

LOINC codes are used in several laboratories and federal agencies and are part of the Health Insurance Portability and Accountability Act (HIPAA). Internationally, they are accepted by Switzerland, Hong Kong, Australia and Canada and by the national German Standard Body Deutches Instituts for Normung. Laboratories should include LOINC codes in HL7 messages because clinics and customers in research can easily integrate their clinical outcomes and research results [93].

Nowadays, most systems and diagnostic laboratories in the U.S.A. provide their results to hospitals, clinics, health organizations, public health departments and other clients using HL7 messages. HL7 messages contain an entry for each test observation.

A formal, distinct and unique name is given for each term for test or for observation identity. The database contains over 50.000 terms or observations that can be accessed and understood by everyone. Each database consists of six fields for unique specifications for each single identified test, observation or measurement [93]:

- Component – to be measured, evaluated or observed
- Property type – characteristics being measured, such as length, weight, volume and so on
- Time aspect – the time when the observation or measure was taken
- System – type of context or specimen the observation was made (e.g., blood, urine)

- Size – measurement unit; size can be quantitative or narrative nominal

A unique code (format nnn-n) is assigned for each input for each record. Other fields in the database include information to change their status and manage the database, synonyms, relevant terms, mass information (e.g., molar mass) response for nominal size, translation [93].

Advantages of adopting LOINC codes are: providing significant improvement of health care, improve electronic medical records, automatically transferring reports to Public Health Authority, improving payment services and a significant improvement in health care by reducing errors in the system.

International interest in LOINC codes is growing. There are efforts to translate LOINC codes in various languages such as Chinese, German, and Spanish. Figure 5.27 shows some examples of terms and names of LOINC codes in English [93].

Code	Component	Property	Time	System	Scale	Method
8302-2	BODY HEIGHT:	LEN	PT	^PATIENT	QN	
3140-1	BODY SURFACE:	AREA	PT	^PATIENT	QN	DERIVED
8331-1	BODY TEMPERATURE:	TEMP	PT	MOUTH	QN	
8632-2	QRS AXIS:	ANGLE	PT	HEART	QN	EKG
8642-1	PUPIL DIAMETER:	LEN	PT	EYE.RIGHT	QN	AUTO
21611-9	AGE:	TIME	PT	^PATIENT	QN	ESTIMATED
19867-1	CAPACITY.VITAL:	VOL	PT	RESPIRATORY SYSTEM	QN	
9279-1	BREATHS:	NRAT	PT	RESPIRATORY SYSTEM	QN	
11882-8	GENDER:	FIND	PT	^FETUS	NOM	US

Figure 5.27 Example of LOINC terms and names in English (after [93])

Table 5.1 presents an example where the LOINC codes are translated into German [94]

Table 5.1 Example of LOINC terms and names in German (after [94])

Kategorie	Code	Bezeichnung	LOINC Bezeichnung
Medikation			
	10160-0	Medikamenten-Anamnese	HISTORY OF MEDICATION USE
	42346-7	Medikation bei Aufnahme	MEDICATIONS ON ADMISSION
	10183-2	Medikamente bei Entlassung aus dem Krankenhaus	HOSPITAL DISCHARGE MEDICATIONS
	19009-0	Jetzige Medikation	MEDICATION.CURRENT
	11369-6	Impfungen	HISTORY OF IMMUNIZATIONS

5.3.3. Systematized Nomenclature of Medicine – Clinical Terms (SNOMED-CT)

SNOMED CT (Systematized Nomenclature of Medicine -- Clinical Terms), is a systematically organized computer collection of medical terms providing codes,

terms, synonyms and definitions covering diseases, findings, procedures, microorganisms, substances, and so on. It provides a consistent way to index, store, retrieve, and aggregate clinical data across specialties and sites of care. It also helps in organizing the content of medical records, reducing the variability in the way data is captured, encoded and used for clinical care of patients and research [95].

Patients benefit from the use of SNOMED CT to more clearly describe and accurately record their care, in building and facilitating better communication and interoperability in electronic health record exchange, and in creating systems that support health care decision making [96].

There are more categories of benefits when using SNOMED-CT codes. The benefits are split in four categories [96]:

- General benefits
- Clinical use
- Other uses
- Communication

The general benefits are [96]:

- SNONED-CT is an International standard, has multilingual support and enables the provision of a platform independent, cross-cultural, health care record.
- It provides a consistent terminology across all health care domains.
- allows precise recording of clinical information
- It has an inherent structure. This provides for an unambiguous description of an individual concept in a logical way.
- It can be extended in a controlled fashion to further enhance its usability and coverage.
- The recording of clinical data through SNOMED CT enables the consistent retrieval, transmission and analysis of data from patient records across healthcare systems.
- It is well maintained and updated in collaboration with subject matter experts to represent current clinical knowledge.

The clinical use benefits are [96]:

- SNOMED-CT enables the capture of clinical information at a level of detail appropriate for the provision of healthcare.
- It enables patient data to be recorded by different people in different locations.
- The consistent use of SNOMED CT reduces the risk of differing and incorrect interpretation of data in healthcare records by reducing the implicit contextual meaning associated with entered data.
- The appropriate use of SNOMED CT can contribute to the reduction of error rates and can help ensure the comprehensive recording of relevant data.
- Through sharing data it can dramatically reduce the need to repeat health history at each new encounter with a healthcare professional.
- It enables efficient searching of patient records and retrieval of relevant clinical information.

- It facilitates point of care decision support, automatic identification of patient risk factors, and monitoring of response to treatment and adverse reactions to treatment.
- It can assist with identification of patients who match a given set of clinical criteria.
- It improves clinical efficiency by providing a standard clinically relevant terminology to the clinician for documentation of care.
- The history mechanism enables clinical information collected over time to be meaningfully correlated together.

The other uses benefits are [96]:

- SNOMED-CT can assist with public health monitoring. Encoding clinical information allows for the monitoring of diseases and disease trends at a population level.
- It enables the analysis of outcomes. There is an increasing focus on evidence based medicine in clinical practice today, but little usable information to base that evidence on.
- It can also facilitate performance analysis. As medicine moves towards evidence bases, fitness to practice and clinical revalidation are similarly moving towards performance related measures.
- It enables the easier, more effective analysis of data.
- It will enable the provision of large populations of consistent data for medical research.
- It can facilitate process improvement activities by more consistent and accurate documentation of clinical events and activities and linking these to process measurements and timeliness of delivery of care.

The benefits of using SNOMED CT in communication are [96]:

- It can be used for the sharing and consistent distribution of outcome analysis data.
- It can be used to setup and distribute decision support information in a consistent way.
- It can facilitate knowledge management through its standard terminology and the reference information embedded within.

The structure and technology behind SNOMED CT enables organizations to implement it and integrate it into their own clinical and business processes and applications [97]. The association of a set of Descriptions and a set of Relationships to each Concept is implemented using the ConceptId which is the primary or foreign key in the three tables as it is represented in Figure 5.23 [97].

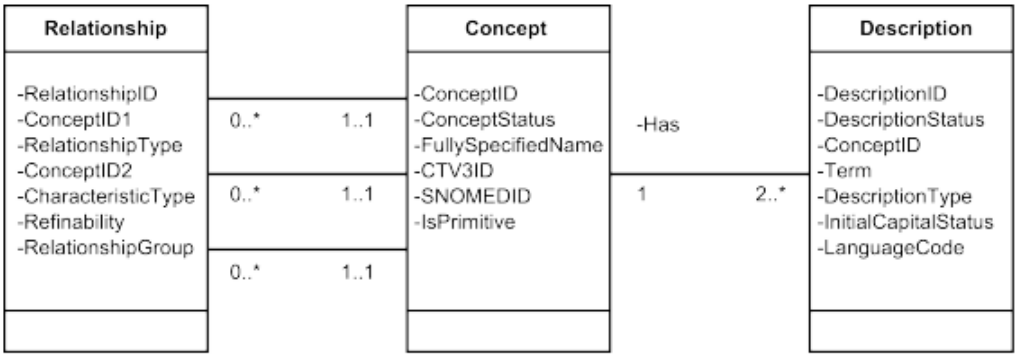


Figure 5.28 SNOMED CT table structure (after [97])

Figure 5.28 presents the attributes contained in Relationship, Concept and Description, and how they are interrelated.

5.4. Conclusions

The objectives of this chapter are: Analysis of interoperability between systems and especially between EHR systems taking into consideration definitions, interoperability levels, system architectures and their representation through ontologies, terminologies and coding systems related to EHR and Study of the Electronic Health Record and its properties in relation with the interoperability concept.

In the following lines, the contributions of this chapter are presented:

- A thorough synthesis of the HL7 CDA for clinical information exchange has been performed. Relevant RIM classes were shown, as support in developing the standard. Major parts of a CDA have been identified, the content of header and body was explained, and in the end, CDA parts were presented, which helped understanding how to develop by HL7 CDA Component.
- A thorough synthesis of HL7 CCD was performed, based on the statements: the scope of using this standard is for insuring the continuity of patient care; it is important for a medical unit to have all the patient information. The advantages of using this standard are emphasized and finally several examples adapted to the Romanian health system were presented. Further during the work, a CCD Component resulting in a real CCD will be created.
- In a first example I worked to show how the HL7 CDA sends information to the Egadss System. I developed the HL7 CDA Component using Visual Studio .NET, and C# language. I built the system architecture using the HL7 CDA Component. One of the issues I encountered was that the LOINC codes are not translated in Romanian. Coding was done using ICD10 and LOINC.

- The second example I worked on was to demonstrate how the HL7 CDA sends information to the LabKey Server. The LabKey Server is an open source platform. This software was installed and tested on received data and resulted in several diagrams that support the clinical activity of the physician

and researcher inside the healthcare organization (practical application was tested in Bega Clinic). I presented the system architecture which contains the HL7 CDA Component that has the ability to send the required information.

- The third example relates to a current challenge: Cloud computing applications in healthcare. The information systems which are uploaded on the cloud have the possibility to send information in a standardized way, using the HL7 CDA Component. Also, I created and presented the system architecture which uses a standardized communication and shows the communication between different hospital departments using cloud computing.
- A vast review has been performed describing some relevant code systems, like ICD10, LOINC, SNOMED. In Romania only the ICD10 codes are used. When the presented standards have been implemented in the future, LOINC and SNOMED-CT codes must be used, as they are more complex and adequate code systems for medical activities. For example, the ICD10 codes are used only for billing by the medical staff.

6. USING GCM FOR OBSTETRICS-GYNECOLOGY DEPARTMENT INFORMATION SYSTEM

This chapter is built around the OGD IS. It starts describing the activities and informational needs in OGD and the importance of having real and correct data mainly due to risks during pregnancy. The main original contribution of this thesis is the model of the OGD using GCM which is presented in this chapter. The OGD is modeled using BPMN and UML. A demonstrator of the modeled OGD is presented. The communication between OGD IS and departments (e.g. Pediatrics) is described and solved using HL7 CDA and CCD standards.

6.1. Describing the Obstetrics-Gynecology Department

An EHR system in obstetrics – gynecology department can be very helpful in keeping the data about the patients. Because its specific characteristics, it can include date calculator, ultrasound analysis and other relevant information about the patients. Because OB/GYNs often have two patients in one when dealing with pregnant women, having fast and easy access to information about things like drug interactions and effects on fetuses can be extremely important. OB/GYN-specific EHR is a great way to get that information consistently, comprehensively and quickly. A specific EHR system can help make a practice more efficient and effective [98].

The computer-based observation chart brings fundamental information about the patient for the clinical management. The information can be added very fast and easy to the observation chart after this is generated by different persons that are directly involved in the medical process. The observation chart information will be easier accessed and interpreted by all the persons who have legal access to that information (e.g. medical staff). It contains data about consultations, diagnostics, the admission reasons, patient evolutions, investigation results, and treatments, legal correspondence for that case, images resulted from different examinations or patient photo [99].

The observation chart in the obstetrics – gynecology department can be of two types: one for obstetrics and one for gynecology, and the data from obstetrics differ from the gynecology one.

In Romania and beyond, the obstetrics observation chart complies with the general observation chart, however there are some additional data: physical examination, genital exam – specialty. From the medical history, the patient's socio-cultural level aspects related to gynecology-specific issues are important. After a patient has delivered a baby, the observation chart for the new born is filled in sent to the neonatology department. The new born observation chart contains the name and surname, gender, birth date, weight, height, problems, present state of the newborn, investigations, epicrisis and recommendations [99].

6.2. The risks in Obstetrics-Gynecology Department activity monitoring pregnant women

For a high quality clinical act, it is needed a rich, coherent, integrated picture of a patient as well the identification of patients faced with the average risk to ensure earlier intervention is necessary. Recommended treatment plans can be compared with treatments received, and patients who need to complete additional treatments can be identified. In the end, the risk factors can be identified for diseases and conditions.

One of the risks which can appear during the pregnancy is preterm birth which is defined when a baby is being born before 37 weeks gestational age or before 259 days. Preterm birth results from three clinical conditions:

- medically indicated preterm birth,
- PPROM (Preterm Premature Rupture of Membranes) and
- spontaneous preterm birth.

There are medical indications related to maternal complications such as severe maternal hypertension, abruption placentae, or endangered fetal well-being, such as intrauterine growth retardation, or non-reassuring fetal state. Reported risk factors include personal obstetrical history, social factors and lifestyle. Currently recognized aetiological risk factors associated with clinical presentation of preterm birth are: medically induced preterm birth, which is maternal (pregnancy hypertension and vascular disorder, medical acute illness or chronic conditions, obstetrical complications, antepartum bleeding or maternal age greater than 35 years); PPROM (infection, uterine distension, cervical anomalies, Afro-American ethnicity, or disadvantaged population), and spontaneous preterm birth (previous preterm birth, preterm labor, low body mass, poor weight gain, strenuous physical workload, ergonomic factors, uterine anomalies, psychosocial stress, lifestyle, smoking, drug abuse, maternal age less than 18 years) [100].

Another risk factor is hypertension during pregnancy which can create severe risks for both mother and baby, including [101]:

- Health problems for the mother, such as heart attack and stroke
- Slow fetal growth and low birth weight
- Increased risk of preterm delivery
- Placental abruption (separation of the placenta from the uterine wall during delivery, which can cause bleeding and shock, placing both mother and baby in danger)

There are different types of high blood pressure in pregnancy:

- Pre-existing high blood pressure, when women already have high blood pressure before they become pregnant.
- Gestational high blood pressure, when women can develop new high blood pressure during their pregnancy.
- Pre-eclampsia and eclampsia. Pre-eclampsia is a condition that can affect some women who develop new high blood pressure after the 20th week of their pregnancy, and also it can be developed in women who have high blood pressure before they are pregnant (pre-existing high blood pressure), or in women who have pre-existing protein in their urine (e.g. due to pre-existing kidney problems). Eclampsia can be a complication of pre-eclampsia. It is when a woman with pre-eclampsia has one or more convulsions.

The blood pressure must be motorized, and it is important to keep the evidence of the past values. It is important to analyze the situation of a region because in the future it is possible to predict some complications in pregnancy.

6.3. Describing the framework using GCM for obstetrics-gynecology department

6.3.1. Describing the real workflow in OGD information system using Business Process Modeling and Notation and UML

Modeling the OGD system is performed according to the GCM Framework [102].

Regarding the third step of reducing the structural and behavioral complexity of the OGD IS by decomposing it, the considered OGD IS is composed by two major medical subsystems: gynecology and obstetrics.

Following, the fourth step, which reflects the system development process based on the RM-ODP views, are described [103]:

- The first step consists in defining the analyzed system, in our case the OGD IS.
- The second step deals with the separation of the domain of current interest (here the medical) from other domains which are not relevant for the moment (e.g., financial, administrative, security).
- The third step addresses the composition/decomposition of the analyzed system, considering four granularity levels (business concepts, relations network, aggregations and details).
- The fourth step consists in the model-driven development of the real OGD system based on the five RM-ODP views previously mentioned.

The first viewpoint is the Business view, in the RM-ODP called Enterprise view. In this view, the real workflow of the OGD is described, using Business Process Modeling and Notation for representing the process and UML for the IT perspective. Figure 6.1 presents the OGD workflow in BPMN [103].

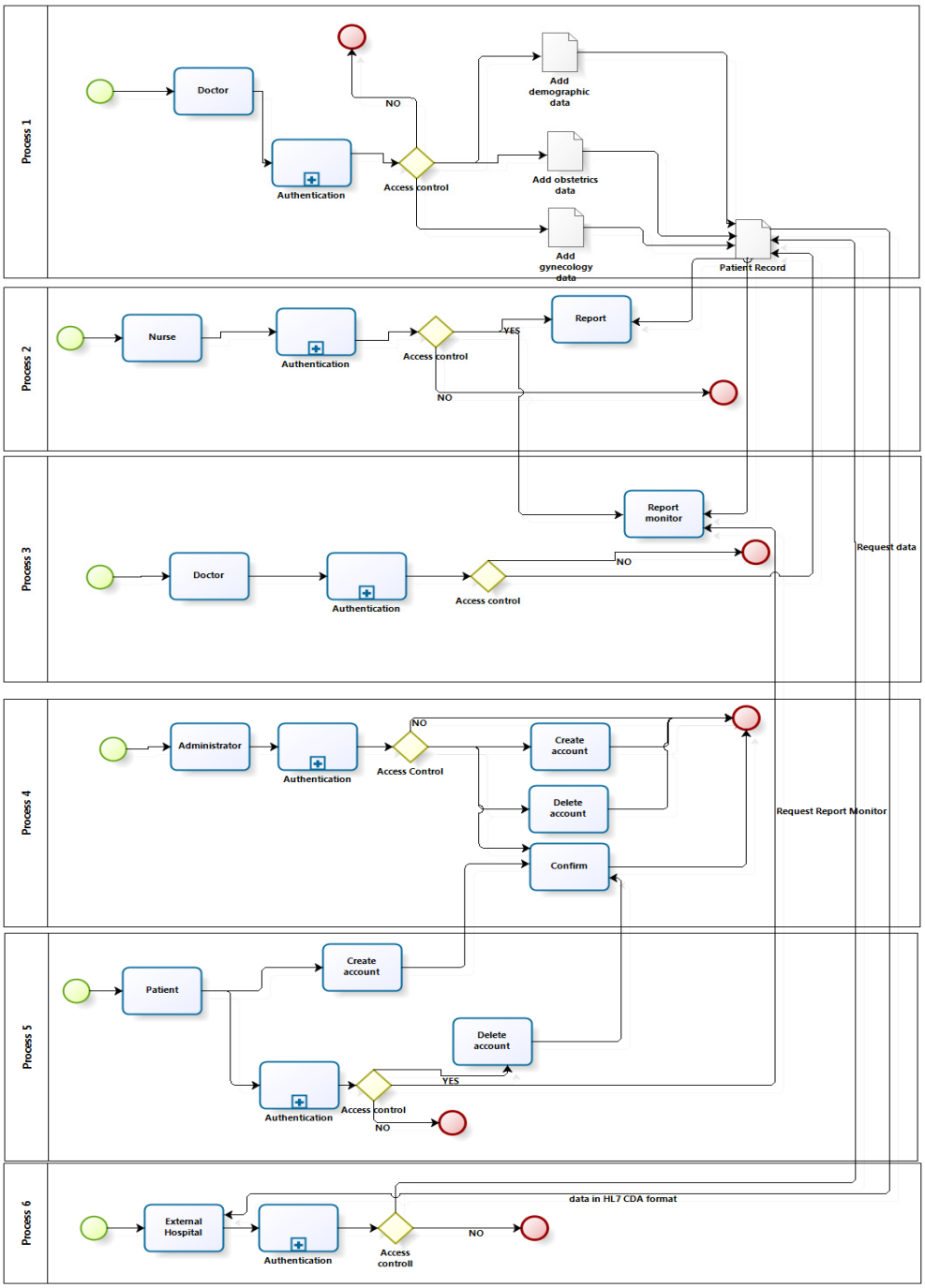


Figure 6.1 OGD IS modeled with BPM

In Process 1, the main actor is the doctor. If he/she wants to enter new data about a patient, the first step is to authenticate her to the system. The system verifies identity of the actor and his role regarding the privilege assignment for entering new data about the patient. If he/she is the right person in the appropriate role, he can enter patient data (demographics, gynecology and obstetrics) in the Patient Record previously created.

In Process 2, the main actor is the nurse which wants to access the report for getting patient data and using the report monitor. Firstly, she has to authenticate herself. After the system checked and verified that she has the appropriate privileges, she can receive the reports.

In Process 3, the main actor is the doctor. If he/she wants to add a new patient, the first step is to authenticate himself/herself, and when the system verified he/she is an appropriately privileged actor for access, the data will be added. Based on the right role, he can enter patient data (pregnancy monitoring data).

In Process 4, the main actor is the administrator. If he/she wants to make changes in the system, the first step is again the authentication. After the system verified the actor's access privileges, the changes into the system are operated. As actor with the privileged role, he/she has the possibility to create new accounts, delete accounts, to confirm the created or the deleted accounts. In most jurisdictions, medical data can never be deleted!

In Process 5, the main actor is the patient who can create a new account after her authentication and the verification by the system verifies as privileged actor. If allowed and if the actor has the right role, she can express the will to delete an account or request a report about monitored information about the pregnancy.

In Process 6, the main actor is an external hospital which requests data about a patient. Firstly, it had to authenticate itself, and the system checks the privileges. If they are correct, the data is send as an XML message in HL7 CDA format. The process is described in detail in Section 4.

A scenario of adding patient data is presented, using an UML use case diagram. Figure 6.2 demonstrates the use case for adding new information about a patient by a doctor.

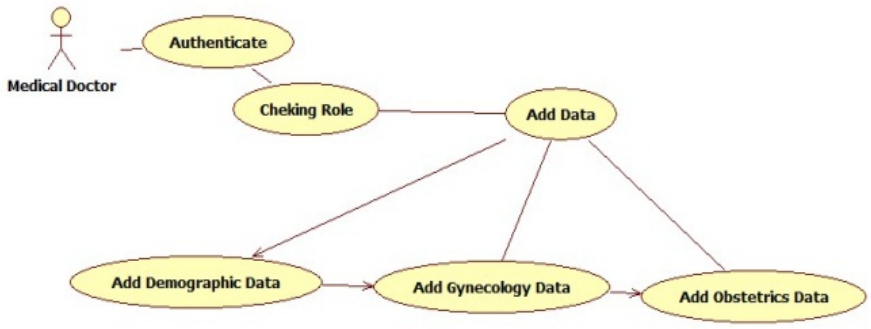


Figure 6.2 Use case – adding data

Doctor: The doctor uses the OGD IS for adding a new patient, or for amending information to an existing patient record. He/she can add demographic data, and thereafter he/she can enter gynecology and obstetrics data.

Interactions: The scenario starts when a doctor wants to add new information to a patient record. Once the doctor has logged into the system and the system checks that he/she has the privileges to add information, he/she can add or modify the medical record, registering the gynecology and obstetrics data, etc. It is important for them to create first an account by filling in firstly the patient's demographic data, before adding gynecology and obstetrics data. If the patient is already registered, she can add the gynecology and obstetrics data directly.

Figure 6.3 presents the sequence diagram for the use case described in Figure 6.2. It shows the interaction between objects in the sequential order when specific interactions occur.

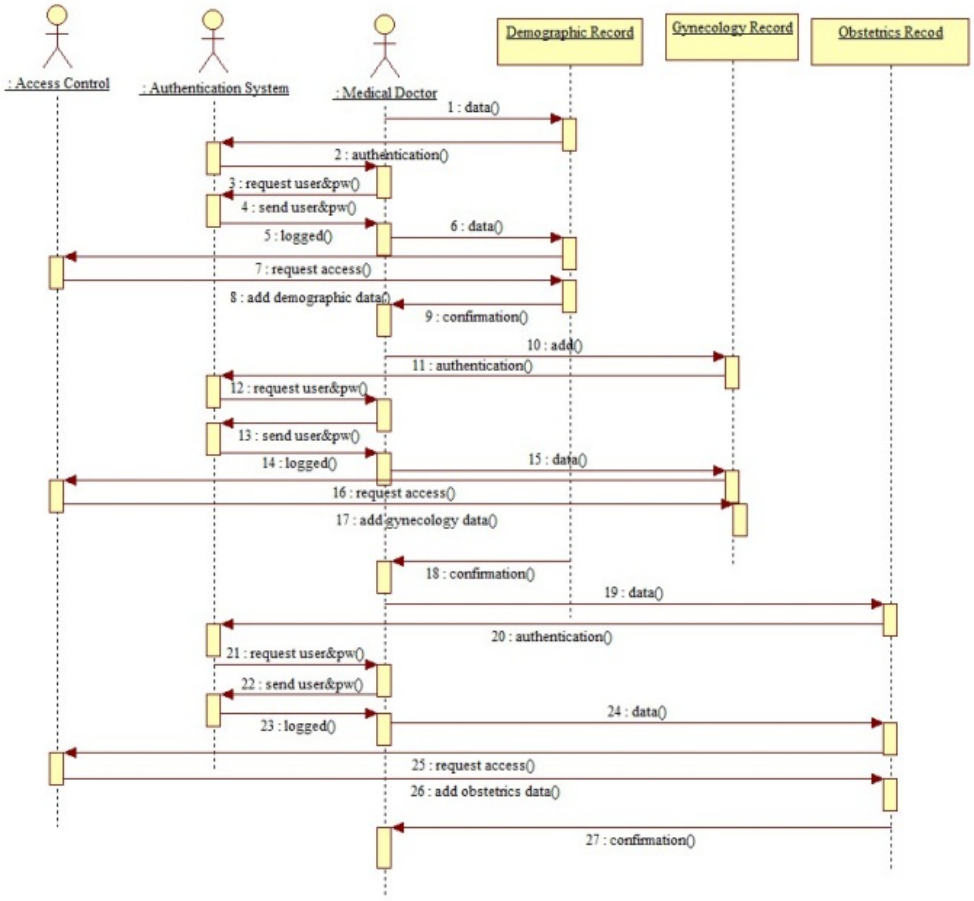


Figure 6.3 Sequence diagram for 'adding data' use case

Table 6.1 presents the interaction which occurs in sequence diagram for 'adding data' use case.

Table 6.1 Interactions in sequence diagram for 'adding data' use case

Interactions	Description
Interaction 1	The medical doctor wants to add a new patient.
Interaction 2	The doctor has to authenticate himself/herself in order to enter data.
Interaction 3	The OGD IS is requesting username and password.
Interaction 4	The medical doctor sends the username and password.
Interaction 5	The medical doctor is logged into the system.
Interaction 6.	The medical doctor wants to add demographic data.
Interaction 7	The OGD IS verifies if he/she has rights to enter data.
Interaction 8	If the medical doctor has appropriate privileges, the data can be added.
Interaction 9	The medical doctor receives a confirmation that the demographic data were entered successfully.
Interaction 10	The medical doctor wants to add patient's gynecology data.
Interaction 11	The doctor has to authenticate himself/herself in order to enter data.
Interaction 12	The OGD IS requests username and password.
Interaction 13	The OGD IS requests username and password.
Interaction 14	The medical doctor is logged into the system.
Interaction 15	The medical doctor wants to add gynecology data into the OGD IS.
Interaction 16	The OGD IS verifies if the medical doctor has rights to enter data.
Interaction 17	If the medical doctor has appropriate privileges, the data is entered.
Interaction 18	The medical doctor receives a confirmation that the gynecology data were entered successfully.
Interaction 19	The medical doctor wants to add patient obstetrics data.
Interaction 20	The doctor has to authenticate himself/herself in order to enter data.
Interaction 21	The OGD IS requests username and password.
Interaction 22	The medical doctor sends username and password.
Interaction 23	The medical doctor is logged into the system.
Interaction 24	The medical doctor wants to add obstetrics data.
Interaction 25	The OGD IS verifies if the medical doctor has appropriate privileges to enter data.
Interaction 26	If the medical doctor has rights the data is entered.
Interaction 27	The medical doctor receives a confirmation that the obstetrics data was entered successfully.

Figure 6.4 presents a use case demonstrating the possibility of OGD IS to send patient information to other medical units.

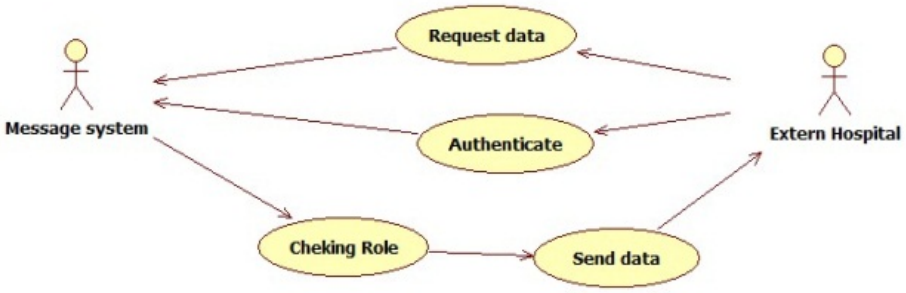


Figure 6.4 Use case 'OGD IS sending information to another medical unit'

Message system: The message system represents a component of the OGD IS that has the possibility to extract needed patient data and transform them into an XML message in HL7 CDA format.

External department/hospital: This actor can be the pediatrics department information system or the neonatology department information system and can request data about a certain patient from the OGD IS.

Interactions: The scenario starts when an external department/hospital requests information about a certain patient from the OGD IS. Firstly, the external hospital must authenticate itself, and secondly, the Message System checks whether the external hospital has the privileges to receive certain information. Thereafter, it extracts the data needed and converts it into an XML message in CDA format and sends it to the external hospital.

Figure 6.5 shows the sequence diagrams for the use case presented in Figure 6.7.

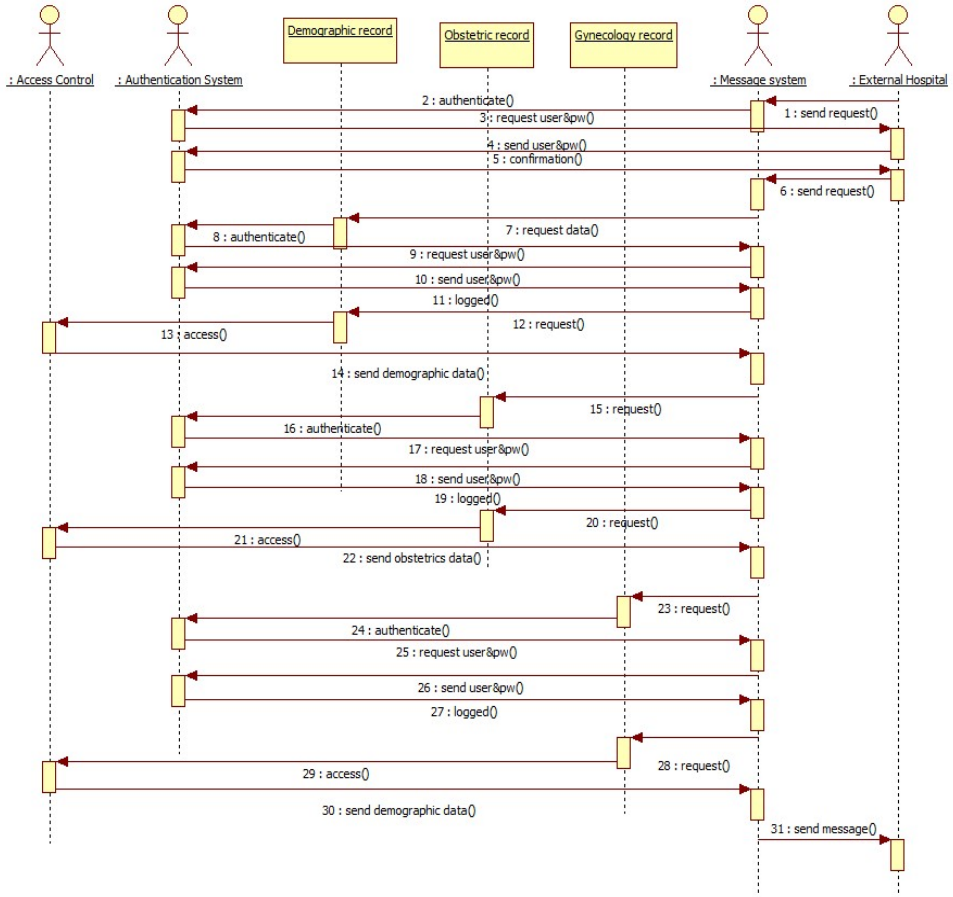


Figure 6.5 Sequence diagram for OGD IS 'sending information' use case

Table 6.2 presents the interactions which occur in the sequence diagram for OGD IS 'sending information' use case.

Table 6.2 Interactions in sequence diagram for OGD IS 'sending information' use case

Interactions	Description
Interaction 1	An external hospital sends a request to the OGD IS.
Interaction 2	To receive data, the external hospital has to authenticate itself.
Interaction 3	The OGD IS is requesting username and password.
Interaction 4	The external hospital sends the username and password.
Interaction 5	A confirmation is sent.
Interaction 6	The external hospital sends a request with the person id of the patient.
Interaction 7	The message system requests data to demographic record.
Interaction 8	For receiving data the message system must authenticate.
Interaction 9	The OGD IS is requesting username and password.

Interaction 10	The message system sends the username and password.
Interaction 11	A confirmation is sent.
Interaction 12	The message system requests data from a certain patient's demographic record.
Interaction 13	The user privileges are checked.
Interaction 14	The message system receives the request data.
Interaction 15	The message system requests data of the obstetrics record.
Interaction 16	For receiving data, the message system must authenticate itself.
Interaction 17	The OGD IS is requesting username and password.
Interaction 18	The message system sends the username and password.
Interaction 19	A confirmation is sent.
Interaction 20	The message system requests data from a certain patient's obstetrics record.
Interaction 21	The user privileges are checked.
Interaction 22	The message system receives the requested data.
Interaction 23	The message system requests data to gynecology record.
Interaction 24	For receiving data the message system must authenticate.
Interaction 25	The OGD IS is requesting username and password.
Interaction 26	The message system sends the username and password.
Interaction 27	A confirmation is sent.
Interaction 28	The message system requests data from a certain patient's gynecology record.
Interaction 29	The user privileges are checked.
Interaction 30	The message system receives the requested data.
Interaction 31	The external hospital receives the requested data in CDA format.

Figure 6.6 presents a use case of how can add data to the monitoring pregnancy chart and who can only see this in a report format.

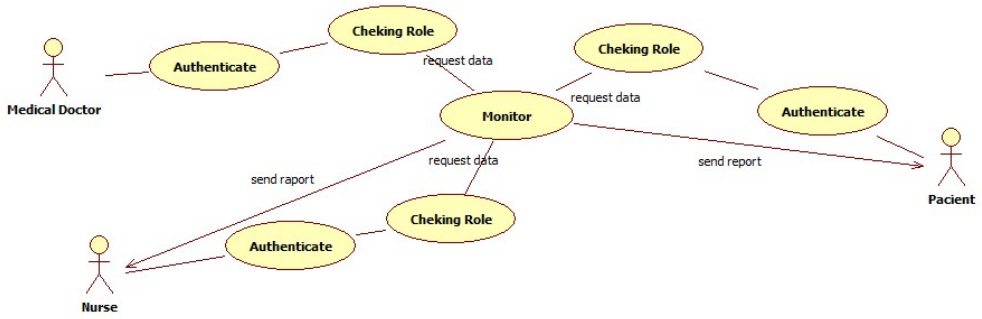


Figure 6.6 Use case of administration of pregnancy monitoring

Doctor: The doctor uses the OGD IS for adding the data for monitored pregnant patient.

Patient: The patient can check her health status.

Nurse: The nurse can check the patient health status.

Interactions: The scenario starts when a doctor wants to add new for monitored pregnant patient. Once the doctor has logged into the system and the system checks that he/she has the privileges to add information, he can add or modify the medical record, etc. It is important for them to create first an account by filling in firstly the patient's demographic data, before adding the monitored data. If the patient is already registered, he/she can add monitored data directly. Also, the patient if wants to access data must log into the system and the system checks that she has the privileges to access the data, and the nurse if wants to check the pregnant health status firstly, she must log into the system and the system checks that she has privileges to access the data.

Figure 6.7 shows the sequence diagram for Monitor the patient, and Table 6.3 presents the interaction which occurs in sequence diagram for OGD IS "administration of pregnancy monitoring" use case.

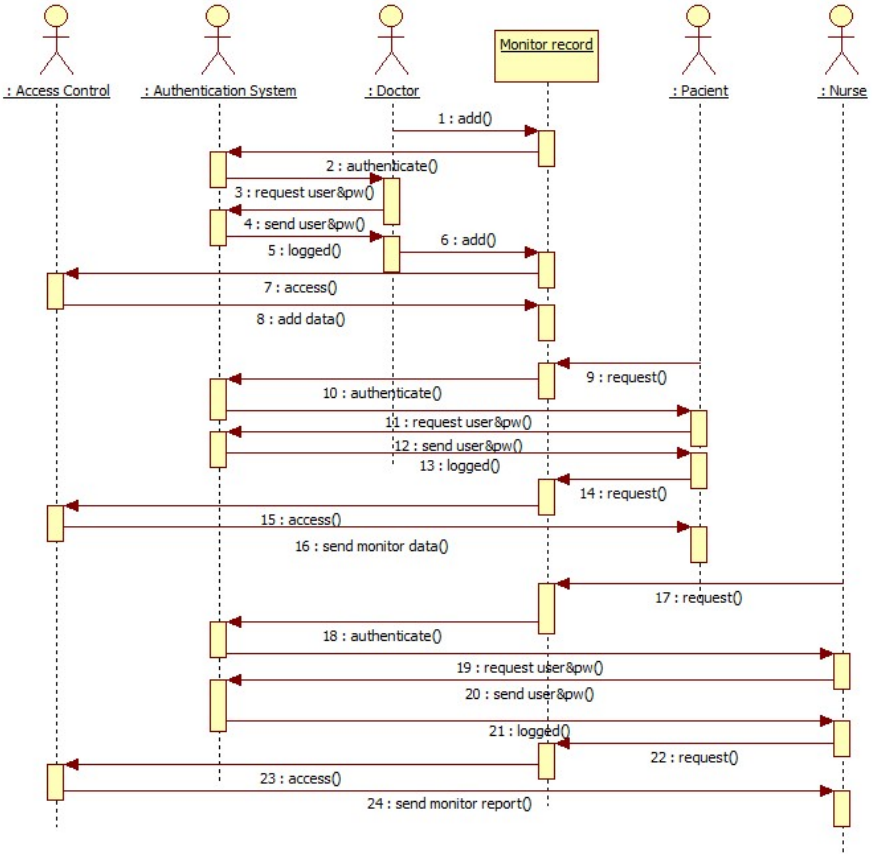


Figure 6.7 Sequence diagram of 'administration of pregnancy monitoring'

Table 6.3 Interactions in sequence diagram for OGD IS 'administration of pregnancy monitoring' use case

Interactions	Description
Interaction 1	The doctor wants to add data to monitor record.
Interaction 2	For adding data to monitor record the doctor must authenticate.
Interaction 3	It is requesting username and password.
Interaction 4	The doctor sends the username and password.
Interaction 5	A confirmation is sent.
Interaction 6	The doctor wants to add data to monitor record for a certain patient.
Interaction 7	Verify the user privilege.
Interaction 8	The doctor can add data to monitor record for the patient.
Interaction 9	The patient wants to receive data from monitor record.
Interaction 10	Request data from monitor record the patient must authenticate.
Interaction 11	It is requesting username and password.
Interaction 12	The patient sends the username and password.
Interaction 13	A confirmation is sent.
Interaction 14	The patient wants to receive her monitoring data.
Interaction 15	Verify the user privileges.
Interaction 16	The patient receives her monitoring data.
Interaction 17	The nurse wants to receive data from monitoring data.
Interaction 18	For receiving monitoring data the nurse must authenticate herself.
Interaction 19	Request username and password.
Interaction 20	The nurse sends the username and password.
Interaction 21	A confirmation is sent.
Interaction 22	The nurse wants to receive the monitoring data from a certain patient.
Interaction 23	Verify the user rights.
Interaction 24	The nurse receives the patient's monitoring data.

Figure 6.8 presents a use case creating a report using the patient data and this report can be created.

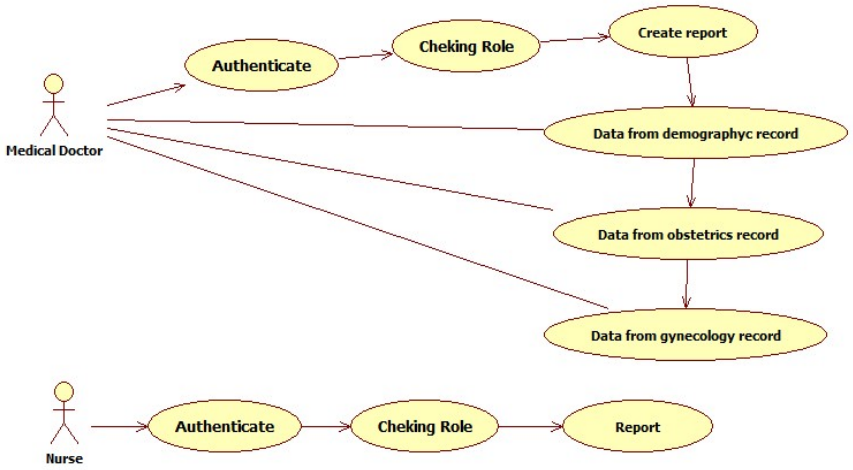


Figure 6.8 Use Case Model regarding creating and receiving reports

Doctor: The medical doctor uses the OGD information system for creating some reports based on introduced patient information.

Nurse: The nurse uses the OGD information system for receiving the report for a certain patient.

Interactions: The scenario starts when a doctor wants to create a report. Once a medical doctor logged into the OGD information system checks that he/she has rights to create reports. After the reports are created the nurse can access it after she logged into the OGD information system and if she has rights to access the reports.

Figure 6.9 presents the sequence diagram for creating and receiving reports and Table 6.4 shows the interaction which occurs in sequence diagram for OGD IS 'creating and receiving reports' use case.

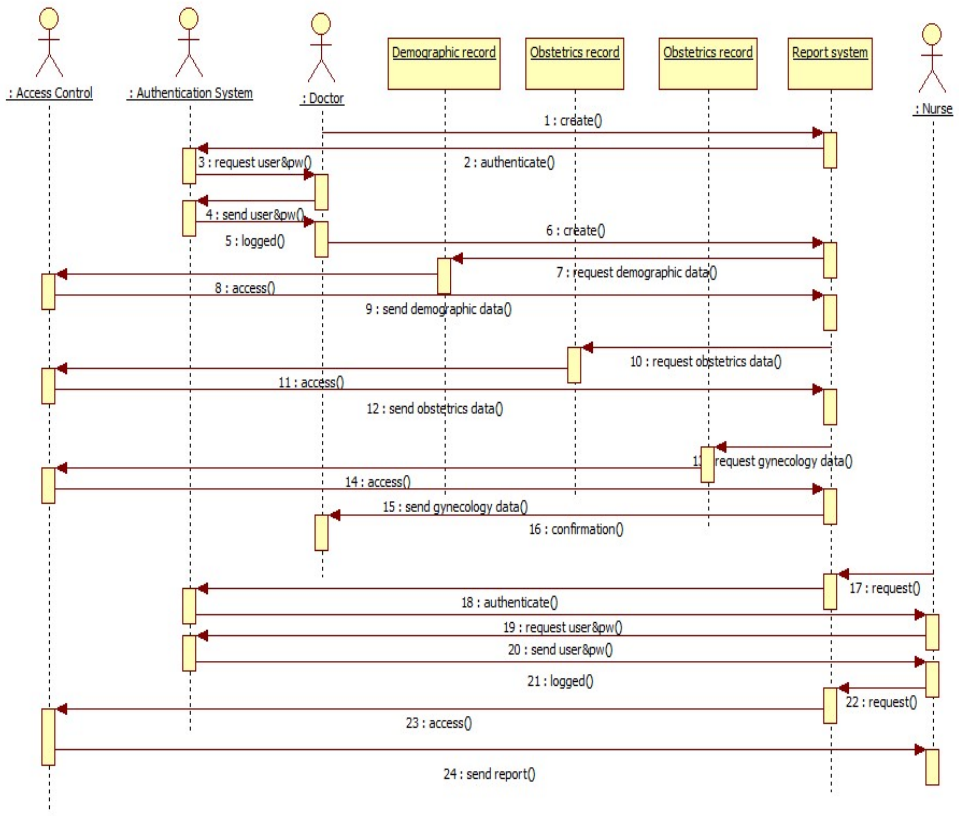


Figure 6.9 Sequence diagram for creating and receiving reports

Table 6.4 Interactions in sequence diagram for OGD IS 'creating and receiving reports' use case

Interactions	Description
Interaction 1	The doctor wants to create reports.
Interaction 2	For creating the reports the doctor must authenticate.
Interaction 3	Request username and password.
Interaction 4	A confirmation is sent.
Interaction 5	The doctor wants to create a report for a certain patient.
Interaction 6	The report system request demographic data from the demographic record.
Interaction 7	Verify the user rights.
Interaction 8	The report system receives the patient demographic data.
Interaction 9	The report system request obstetrics data from the obstetrics record.
Interaction 10	Verify the user rights.
Interaction 11	The report system receives the patient obstetrics data.
Interaction 12	The report system request gynecology data from the gynecology

	record.
Interaction 13	Verify the user rights.
Interaction 14	The report system receives the patient gynecology data.
Interaction 15	The report system sends a confirmation to the doctor that the report was created.
Interaction 16	The nurse requests a report.
Interaction 17	For receiving the report the nurse must authenticate.
Interaction 18	Request username and password.
Interaction 19	The nurse sends the username and password.
Interaction 20	A confirmation is sent.
Interaction 21	The nurse requests a report for a certain patient.
Interaction 22	Verify the user rights.
Interaction 23	The nurse receives the patient report which was created by the doctor.

Figure 6.10 presents a use case of for administrating the OGD IS.

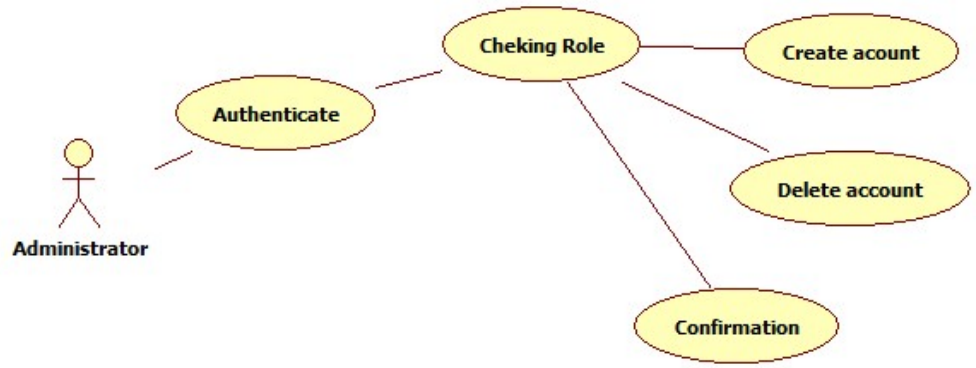


Figure 6.10 Use case for administrating the OGD IS

Administrator: The administrator can manage the OGD IS, he/she can create or delete an account but before the system check if he/she has the right to do the actions. Another role of the administrator is that he/she confirms if a patient wants to create an account or delete it.
Interactions: The scenario starts when an administrator wants to manage the OGD IS. Once the administrator logged into the OGD IS; the system checks that he/she has privilege to make modifications. If it is all right, the administrator can create or delete an account, or confirm if a patient wants to create an account or delete it.

Figure 6.11 presents the sequence diagram for OGD IS administration, and in Table 6.5 is presented the interaction occurring in sequence diagram for OGD IS 'OGD IS' use case.

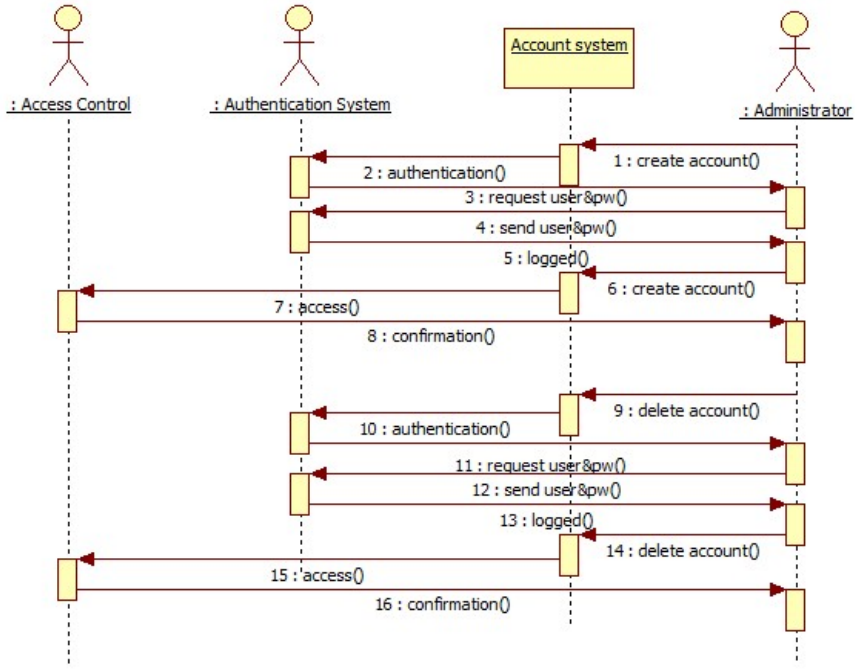


Figure 6.11 Sequence diagram for OGD IS administration

Table 6.5 Interactions in sequence diagram for OGD IS administration use case

Interactions	Description
Interaction 1	The Administrator wants to create an account.
Interaction 2	For creating the account the Administrator must authenticate.
Interaction 3	Request username and password.
Interaction 4	The Administrator sends the username and password.
Interaction 5	A confirmation is sent.
Interaction 6	The Administrator wants to create an account for a certain doctor/nurse.
Interaction 7	Verify the user rights.
Interaction 8	A confirmation is send that the account was created.
Interaction 9	The Administrator want to delete an account
Interaction 10	For deleting the account the Administrator must authenticate.
Interaction 11	Request username and password.
Interaction 12	The Administrator sends the username and password.
Interaction 13	A confirmation is sent.
Interaction 14	The Administrator wants to delete an account for a certain doctor/nurse/patient.
Interaction 15	Verify the user rights.
Interaction 16	A confirmation is send that the account was deleted.

Figure 6.12 presents a use case of how a patient can create or delete an account.

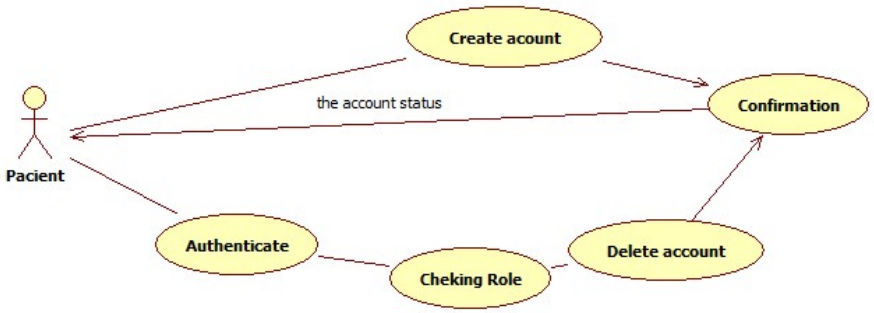


Figure 6.12 Use case of how a patient can create or delete an account

Patient: The patient can create a new account or delete his account but before can wait for administrator confirmation
Interactions: The scenario starts when a patient wants to create or delete his account. Once the patient logged into the OGD IS; the system checks that he has privilege to make modifications. If it is all right, the patient can create or delete an account, and after he must wait for patient confirmation.

Figure 6.13 presents the sequence diagram for creating and deleting a patient account and Table 6.6 presents the interaction which occurs in the sequence diagram for creating or deleting a patient account use case.

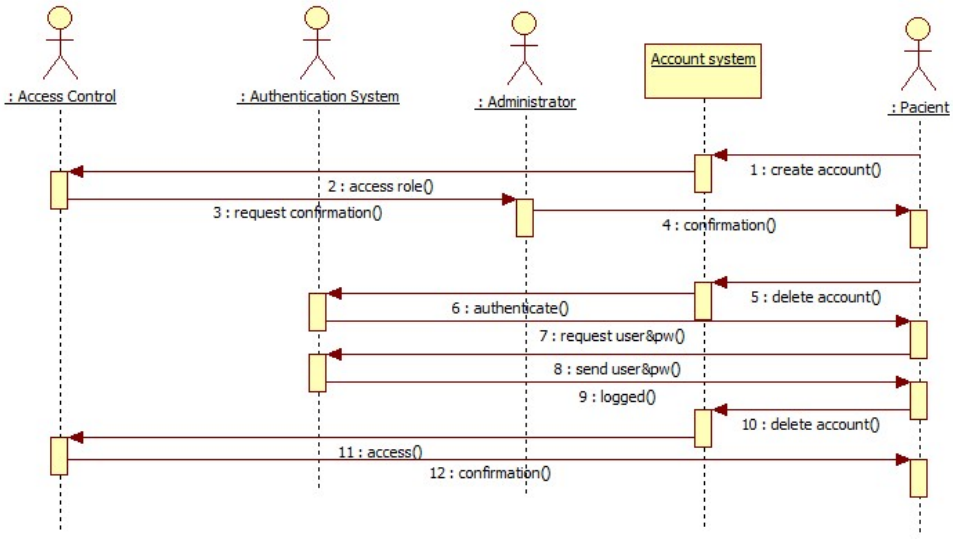


Figure 6.13 Sequence diagram for how a patient can create or delete an account

Table 6.6 Interactions in sequence diagram for how a patient can create or delete an account use case

Interactions	Description
Interaction 1	The patient wants to create an account.
Interaction 2	Verify the rights.
Interaction 3	It sends a request confirmation to the administrator.
Interaction 4	The administrator sends a confirmation that the account was made.
Interaction 5	The Patient wants to delete an account.
Interaction 6	For deleting the account the patient must authenticate.
Interaction 7	Request username and password.
Interaction 8	The patient sends the username and password.
Interaction 9	A confirmation is sent.
Interaction 10	The patient sends a request for deleting the account.
Interaction 11	Verify the rights.
Interaction 12	It sends a confirmation that the account was deleted.

6.3.2. OGD system information class diagrams

The class diagram contains the classes in Figure 6.14. These are the following:

- Patient
- Institution
- MedicalUnit
- Departments
- Consulation
- PatientLocation
- Personal
- Insurance
- Transfers
- Examination
- Account
- OtherInformation
- Admission
- Discharge
- AnatomoPathologicalEx
- DigestiveEx
- Diagnostics
- CardiologicalEx
- UroGenital
- SystemSeX
- EcographicEx
- RadiologyEx
- ObiectiveEx
- Epicrisis
- OncologyEx
- ChirurgicalIntervention

- LaboratoryResults
- SpecialityEx
- RespiratoryEx
- ObstetricsAntecedents
- ObstetricsResults
- Medication
- LaborEvolution
- DeathInformation

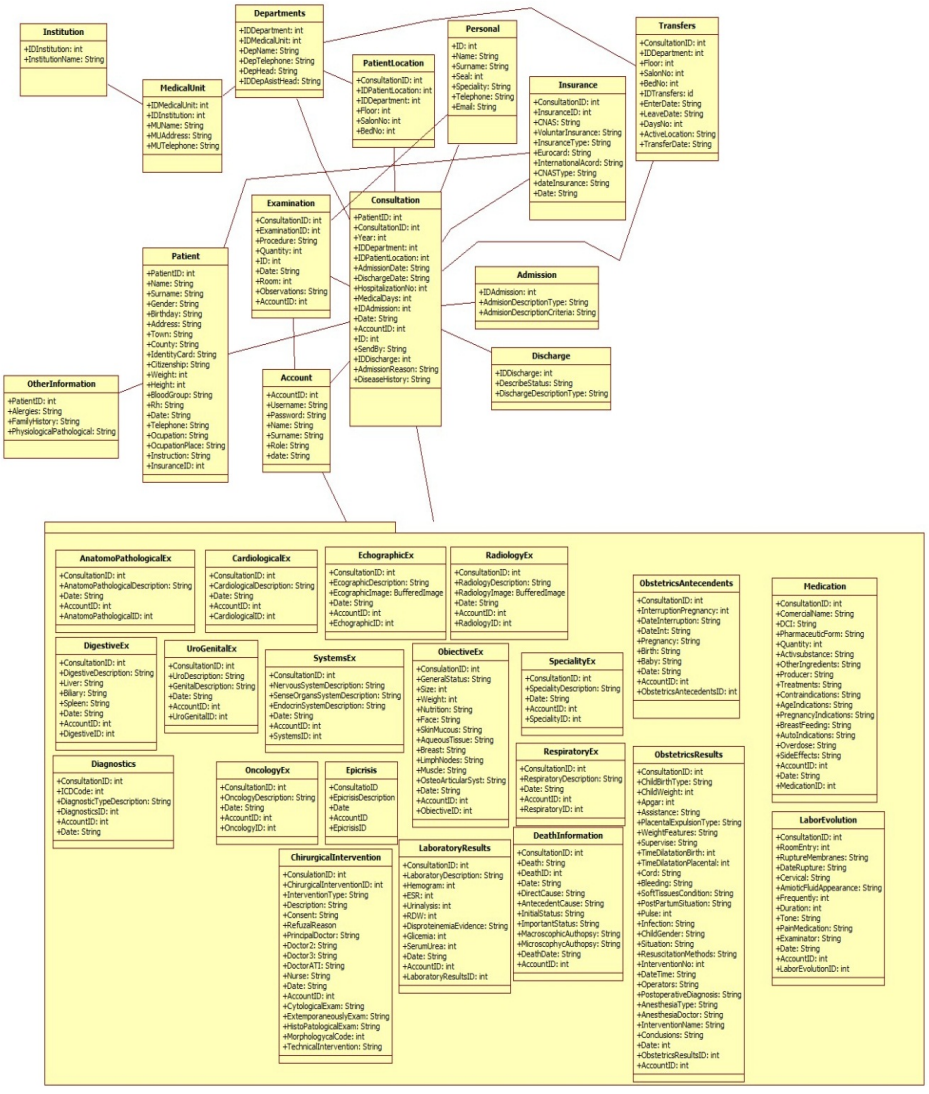


Figure 6.14 Class diagram for obstetrics-gynecology department

6.4. Developing the framework using GCM for obstetrics-gynecology department information system

The application is developed in Visual Studio 2010, using ASP .NET and C# language and as database SQL Server 2008. The fact that the application is online helps a lot the physicians because they can access the patient information from where they are.

The application provides information about monitoring the pregnant patient because of the episodic character of obstetric care with frequent visits (monthly initially, increasing to weekly or even more frequently at term), the amount and the specificity of information to be captured and reviewed changing with the progression of the pregnancy.

The obstetrics – gynecology application is connected with other departments for transmitting the needed data using a standardized communication, in our case HL7 CDA which is shown in Figure 6.15.

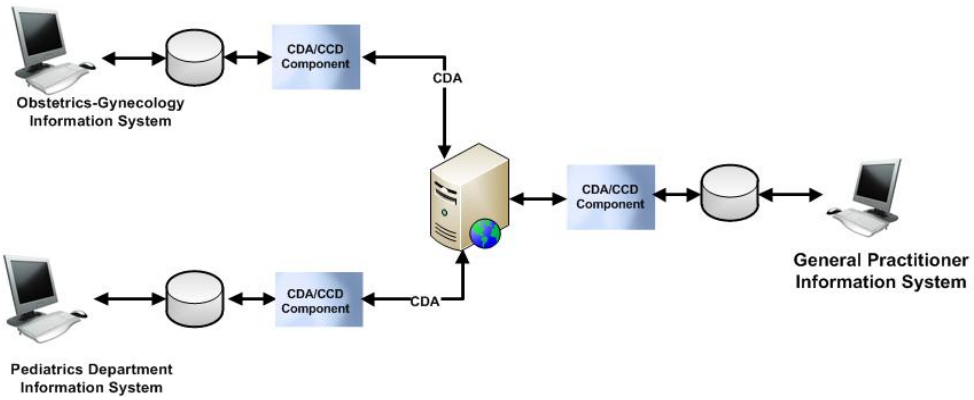


Figure 6.15 Communication between OGD IS and other departments

Three user interfaces are presented from the OGD IS in Figure 6.16-6.18.

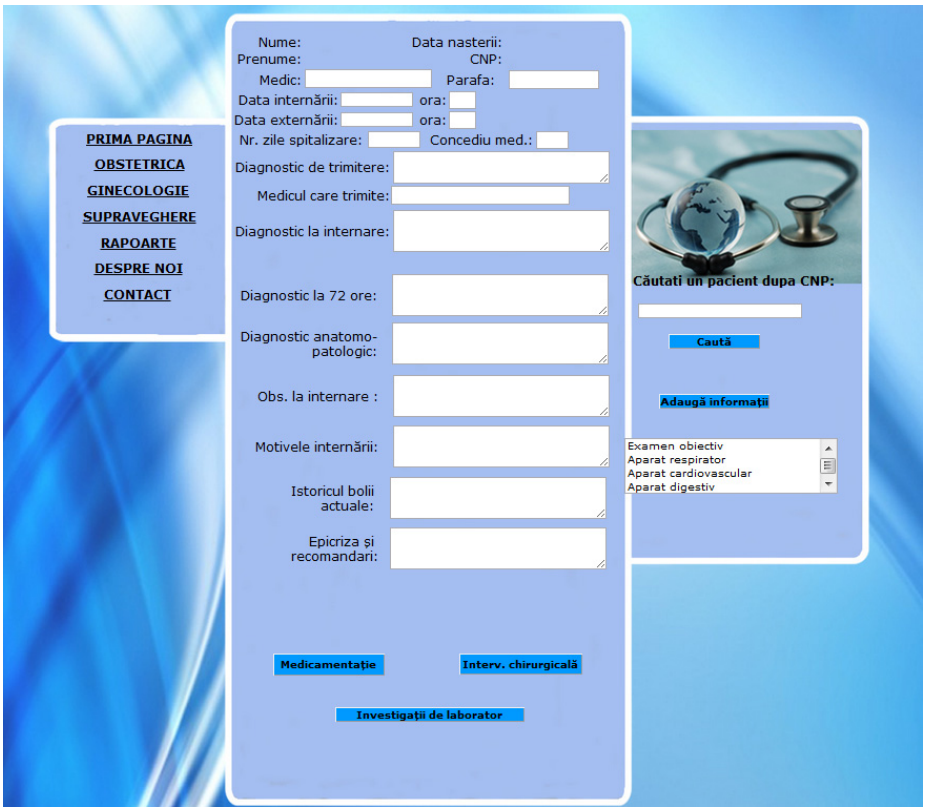


Figure 6.16 Entering gynecology data

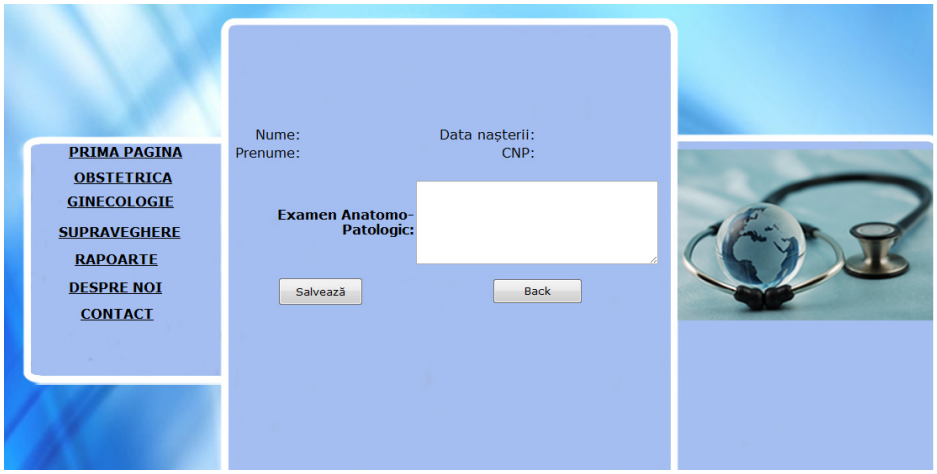


Figure 6.17 Entering anatomic pathology examination

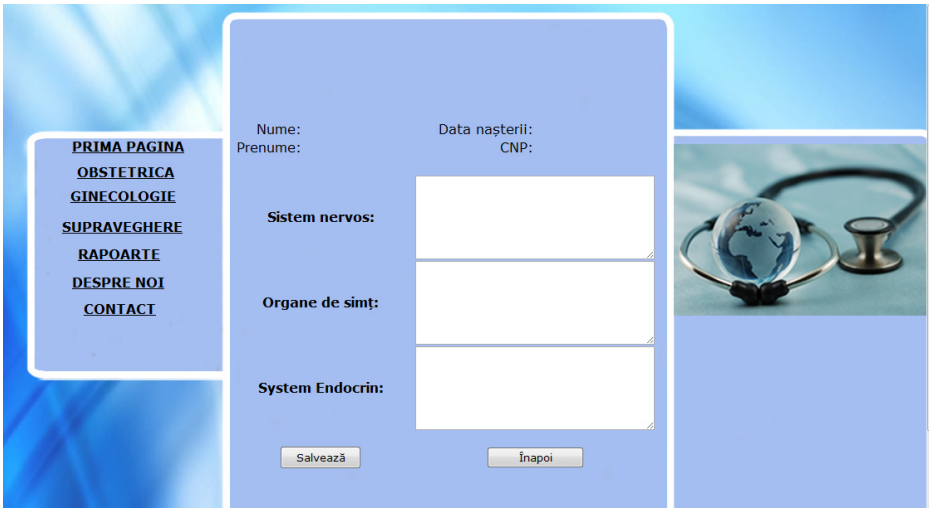


Figure 6.18 Entering system examination

Figure 6.22 presents the database diagram which contains the tables and the relationships between them.

The description of the databases tables is presented in Annex 1

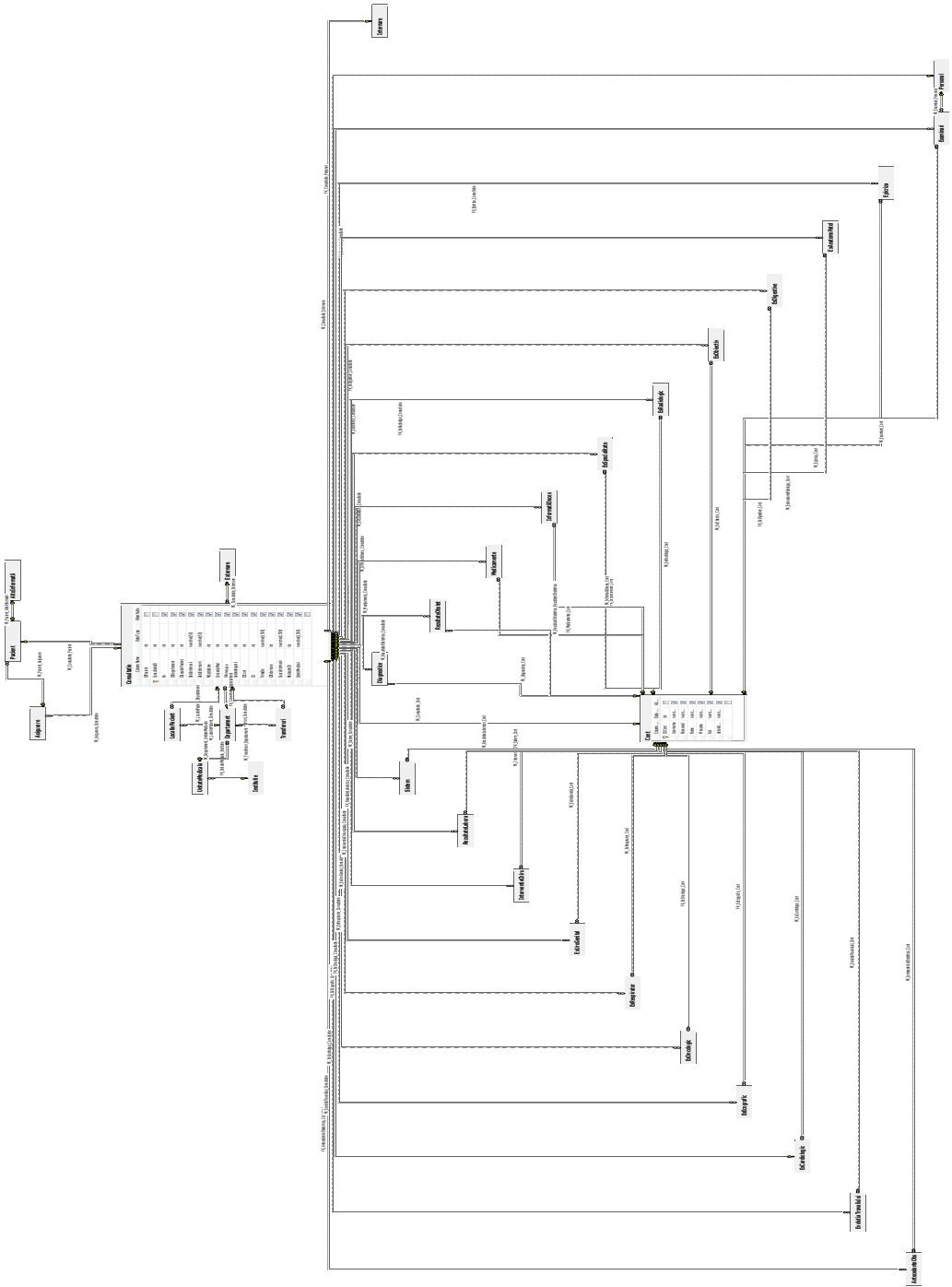


Figure 6.19 Database diagram

6.5. Access control regarding the OGD information system

Data security is very important in an EHR system and represents the protection of data from unauthorized (accidental or intentional) modification, destruction, disclosure and other issue is that if the data is available [104].

Other issue that it is important to take into consideration is the privacy which is the subjective condition a person experiences when two factors are in place firstly, he or she must have the power to control information about himself-herself and secondly, he or she must exercise the control consistent with his/her interests and values [104].

EHR systems must be secure and privacy compliant at all times and must be based on [104]:

- Trustworthy and reliable communication
- Application security services

EHR system must rely on [104]:

- Confidentiality
- Authenticity
- Data integrity
- Accountability

Confidentiality happens when the data are generated, transferred or stored (e.g. information on the person's health status can be gained by intruding on the communication channels) [101].

Authenticity of data including non-repudiations is threatened by hampering the data at the front-end [104].

Data integrity can happen during transmission or during storage [104].

Accountability means that the users can rely on the information provided. It implies that all the actions are traceable. This requires ethical standards and legal regulations [104].

Security services are composed of application security services and communication security services [105].

Application security services contain authorization and access control, covering accountability of principals, audit track and auditing of these principals, services ensuring integrity and confidentiality of data and functions [105].

Communication security services contain identification/authentications, verification of communication principals, integrity checks, authenticity, confidentiality, accountability, non-repudiation of origin, receipt and information exchanged and availability [105].

Figure 6.20 presents the Layered Security Model describing security consisting of aforementioned two concepts, realized as services implementing mechanisms, deploying algorithms applied to data [105].

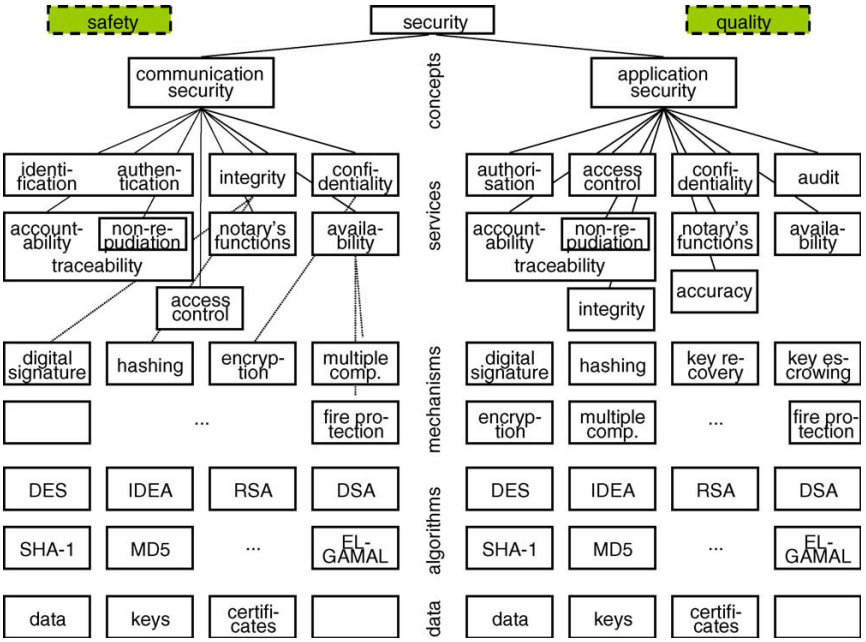


Figure 6.20 Layered Security Model (after [106])

Relationships between users and applications are done by [107]:

- authentication component using different possible authenticators and infrastructure services (e.g. Public Key Infrastructure - PKI)
- an authorization component (e.g., Privilege Management Infrastructure - PMI)
- a provision component (e.g., role engineering)

Privilege management and authorization can be dedicated to an individual actor or to groups of individual actors which have the same role. The actors which interact with the system components are called principals, which can be a human user, a system, an application, a component, a device or even an object. To obtain the structure and the functionality a number of models, mechanisms, processes and object are described [107].

Two basic class types are important regarding privilege management and access control management, these are: Entities and Acts. Entities can be specialized to principals, policies, documents, and roles. Specializations of an Act are: Policy Management, Privilege Management, Principal Management, Authentication, Authorization, Access Control Management and Audit [104].

The class Acts must enable the described security services. A series of static and dynamic models is introduced to describe the entities and to define how the activities will be performed [107]. Some of the models are:

- Domain Model
- Delegation Model
- Control Model
- Document Model
- Policy Model
- Role Model

- Information Distance Model
- Authorization Model
- Access Control Model

In the following are described the most relevant models for this PhD thesis: Role Model, Authorization Model and Access Control Model.

Role Model

It can be a role for any actor. Roles are associated to actors and to acts. For managing the relationships between the entities which influence an activity, two different roles have been defined [107]:

- Organizational roles which are on entity's side
- Functional roles which are on act's side

Structural roles are quite static, while functional roles are highly dynamic. Structural roles context the structural roles provide the prerequisites for entities to perform an interaction within their specific functional roles [107]. In Table 6.41 is presented some example of structural and functional role.

Table 6.7 Examples of structural and functional roles

Structural role	**Functional Role**
Medical doctor	The doctor who is caring the patient
Nurse	Medical assistant which can only visualize the patient information
Patient	The patient which has the possibility to see his information

Functional roles can be defined into levels of authorizations and access privileges in the following generic way reusing a little changed definition which was established in the Australian HealthConnect Project [108]. The list will be described in the following lines, and fixing the set of functional roles applied to manage the creation, access, processing, and communication of health information [107]. The list is:

- subject of care (patient)
- responsible healthcare professional (the healthcare professional with closest relationship to the patient)
- subject of care agent (parent or legal representative)
- privileged healthcare professional
- healthcare professional (involved in providing direct care to the patient)
- health-related professional (indirectly involved in patient care)
- administrator

The formal model of functional roles is presented in Figure 6.21 [107].

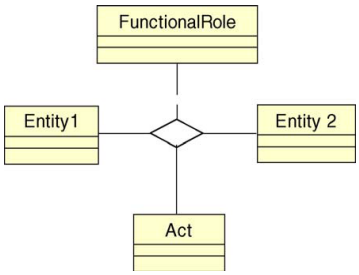


Figure 6.21 Functional role model (after [107])

Structural (organizational) roles permits the user to participate in the organization's workflow by title, job or position but do not specify detailed permissions on specific information objects [107].

The structural role is provided within an act between entities according to specific act-related functional roles. The Figure 6.22 shows an example for provision of a structural role certificated issued by a certification authority to a client to be certified [107].

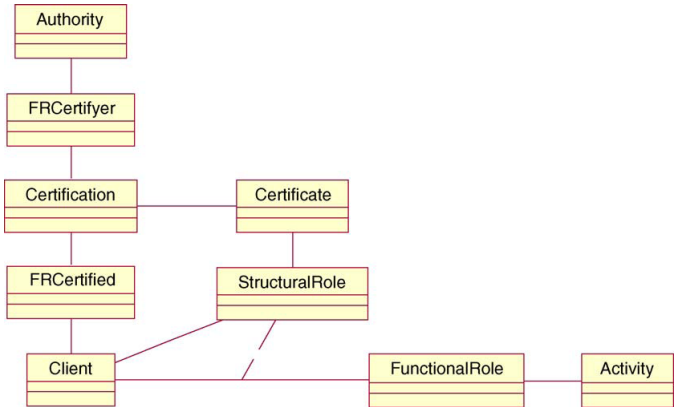


Figure 6.22 Establishment of a structural role within an Act according to specific functional roles ([107])

Authorization Model

Authorisation deals with granting privileges and assigning permissions. In the next lines are described some possible scenarios [107]:

- Any number of roles can be defined by any Attribute Authority (AA)
- The role itself and the members of a role can be defined and administered separately, by different AAs
- Role membership, just as any other privilege, may be delegated
- Roles and membership may be assigned any suitable lifetime.

Figure 6.22 is presents the Privilege Management and Access Control Model [107]. Also, in the figure it can be seen that the privilege management has three principle decisions: request authorized, request denied and request modifier.

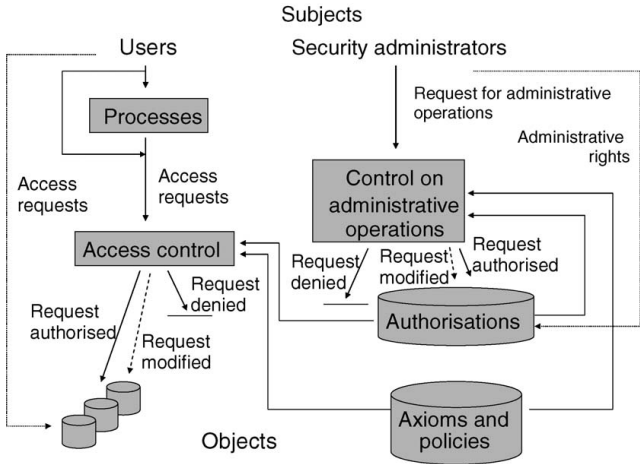


Figure 6.23 Privilege Management and Access Control Model (after [107])

The general privilege management model consists of three entities: the object, the privilege asserter, and the privilege verifier.

Access Control Model

Access control is a process which occurs in different ways in both security services. The security services are: communication security services and application security services [107].

When using an access control system, the outcome request can be: allowing, denying, or changing the access request. This scenario for using access control can be used for EHR system, where a health professional might be allowed to access the EHR system, but not the EHR (component) of a specific patient he is not caring for [107].

In the OGD IS, the access control is used for determine who have privileges to make changes, add information or to read the information about the patients. In Chapter 6.1 the real workflow in an OGD is presented using BPMN, and Figure 6.24 shows an example, how the access control in OGD is used. In the figure, only a part from the real workflow in an OGD is presented.

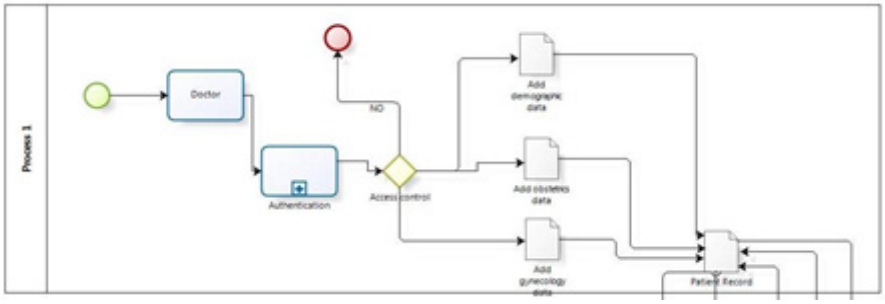


Figure 6.24 Using access control in OGD information syste

Figure 6.24 describes how a doctor wants to add patient information. The access control is used to check if the authenticate person has privilege to add patient information.

6.6. Transmission of patient data from OGD information system to Pediatrics department information system using HL7 CDA Component

The CDA Component is an application developed in Visual Studio .NET 2010 using C# language which has the possibility to extract data from different database and to create XMLs in CDA format. This component was used for communication between different departments and will be presented in the following lines.

Figure 6.25 presents the communication between different hospital departments which communicates using HL7 CDA standard [72].

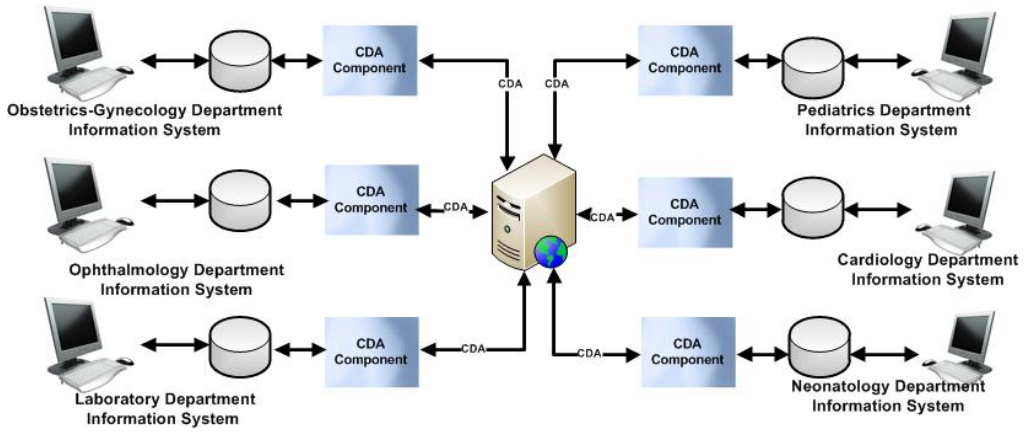


Figure 6.25 The communication between different departments using HL7 CDA standard

Figure 6.26 presents the communication between Obstetrics-Gynecology Department Information System (OGD IS) and Pediatrics Department Information System (Pediatrics Department IS) which use CDA Components [72].

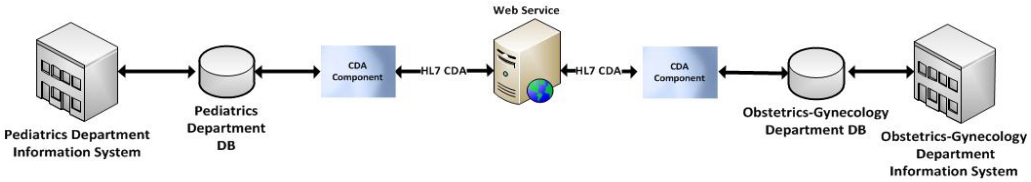


Figure 6.26 The communication between OGD IS and Pediatrics Department IS

Figure 6.27 shows a scenario in which the HL7 CDA standard is used. The scenario is described in the next lines: "Retrieve data child from Obstetrics" will load a page where we enter the mother's social security number (CNP) the child's, date

of birth of the child and number of files. Thereafter, the data is sent as XML file to the Obstetrics department. After receiving the response from Obstetrics, the data will be load in the page, adding the patient, and enabling the pediatrician to add data not available yet [72].

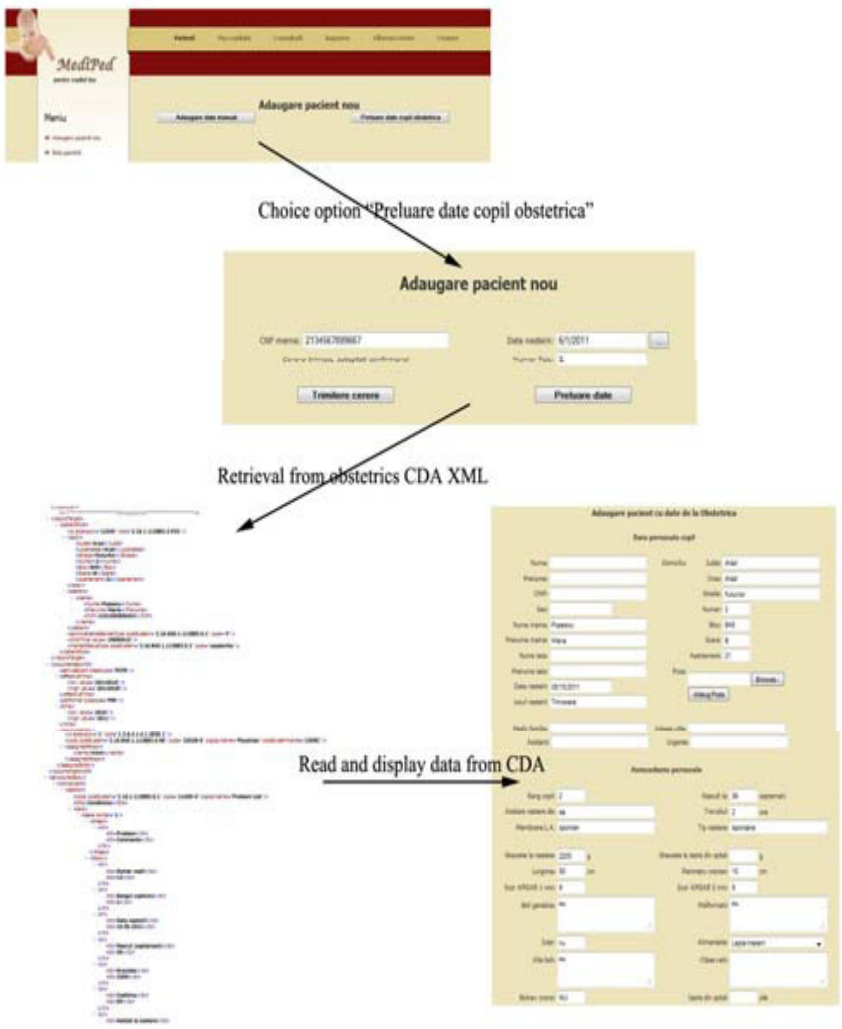


Figure 6.27 Retrieve data from Obstetrics

Figure 6.28 presents a CDA example which the OGD IS can send to Pediatrics Department Information System.

```
<section>
  <code code="101155-0" codeSystem="2.16.840.1.113883.6.1"
   codeSystemName="LOINC" />
  <title>Alergii si Reactii Adverse</title>
  <text>
    <list>
      <item>Penicilina - Urticarie</item>
    </list>
  </text>
  <entry>
    <observation classCode="OBS" moodCode="EVN">
      <code code="L50.0" codeSystem="2.16.840.1.113883.6.3"
       displayName="Urticarie" />
      <entryRelationship typecode="MFST">
        <observation classCode="OBS" moodCode="EVN">
          <code code="Z88.0" codeSystem="2.16.840.1.113883.6.3"
           codeSystemName="ICD10" displayName="Alergie la penicilina" />
        </observation>
      </entryRelationship>
    </observation>
  </entry>
</section>
```

Figure 6.28 CDA example

6.7. Transmission of patient data from OGD information system to General Practitioner Office information system

The CCD Component is an application developed in Visual Studio .NET 2010, using C# language which has the possibility to extract data from different databases and to create XMLs documents in CCD format. This component was used for communication between different departments and a General Practitioner Information System and will be presented in the following sections [109].

Figure 6.29 presents the communication between different hospital departments and the General Practitioner Information System which communicates using CCD standard. The hospital departments send CCD only if the General Practitioner does not have information about a patient. They send CCD with the entire patient medical history or just a CDA when only updates are needed [109].

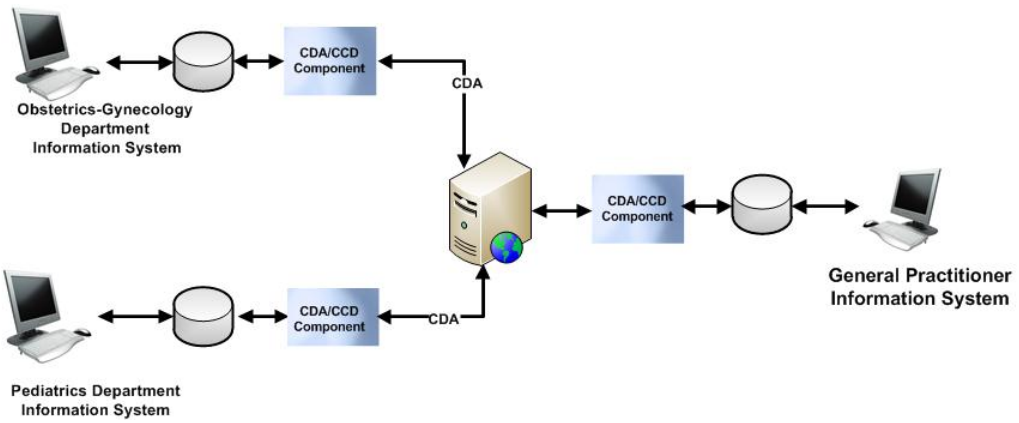


Figure 6.29 System architecture which uses the CCD standard

Figure 6.30 presents an XML document in CCD format with laboratory results, which is send from the hospital department to general practitioner.

```
- <component>
  - <observation classCode="OBS" moodCode="EVN">
      <templateID root="11"/>
      <code displayName="Eritrocite" codeSystem="2.16.840.1.113883.6.1" code="11273-0"/>
      <statusCode code="completed"/>
      <effectiveTime>20110515</effectiveTime>
      <value value="5.36" unit="x10^6/uL" xsi:type="PQ"/>
    - <methodeCode codeSystem="2.16.840.1.113883.5.84" code="460179">
        - <referenceRange>
            - <observationRange>
                <text>4.00-5.80 x10^6/uL</text>
              </observationRange>
          </referenceRange>
      </methodeCode>
    </observation>
</component>
```

Figure 6.30 CCD example

The XML in CCD format contains a laboratory result: erythrocytes, which are codified with LOINC code 11273-0, adapted for Romanian health system and the value of this test result.

6.8. Using Web Services for transmitting the data

Web Services enable flexible communication between different applications that exchange information using different hardware, different operating systems and different programming languages. Using Web Services results in automate connection, and human support is reduced to minimum [110].

Web Services can send public functions or messages of a Web-application to the rest of the world. The basic Web Services platform is XML and HTTP [111].

For increasing life expectancy and rising the quality of clinical processes in Romania, there is a need for a better care for the patient that can be reached by supporting the medical staff real time access to information about the patient health status, and by providing them with smart tools that improve efficiency. In an emergency case, it is important for the medical staff to have access in real time to the information about the patient. This will reduce medical errors and raise the quality of the patient's care [112], [113].

A solution for better communication between medical information systems and CDS systems consists in using Web Services and using standards (ensuring interoperability). Two known standards in medical informatics are introduced earlier already: HL7 Clinical Document (HL7 CDA) and Continuity of Care Document. These two standards are used to create XML files which can be sent over the Internet, using Web Services.

The benefits of sending XML files using Web Services are [114]:

- platform independence

- communication between applications is flexible, collaborative, and compatible
- avoids overlapping investment of the ICT utilization and development
- enables sharing different applications

In [115], several languages and standards are described that support the Web service-based workflow definition and executions and medical information systems which use Web Services for communication.

Mykkanen et al. [116] proposed a model which is used to define services and solutions for healthcare applications from the requirements in the healthcare processes. A comparison between three services scenarios is presented using 11 phases for design.

In [117], the EU Artemis project is described where the messages or documents are exchanged using Web Services. Furthermore, some advantages are presented of introducing Web Services into the healthcare domain.

Marcheschi et al. [118] from CNR Institute of Clinical Physiology developed a medical information system, which sends the HL7 CDA standard conformant information using Web Services.

An integrated system is presented in [119], which consists of a prototype laptop-based portable monitoring system, fuzzy-rules-based software, and uses two standards: Continuity of Care Record (CCR) and HL7 CDA. The communication is realized using Web Services and using the two standards that enable the system to exchange homecare information.

For ensuring interoperability between different medical information systems and CDS systems, a solution is the HL7 version 3 messaging standard. Figure 6.31 presents the abstraction layers for message transmission [120].

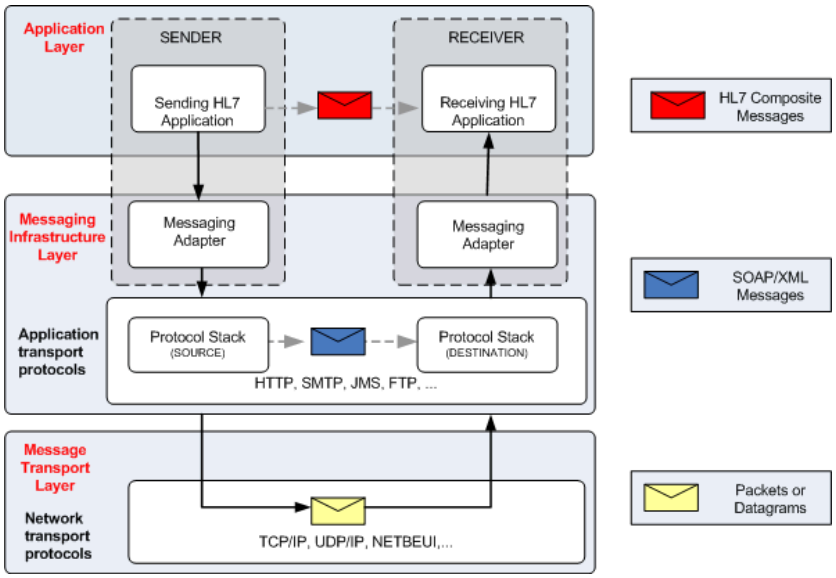


Figure 6.31 Abstraction Layers for message transmission (after [114])

The HL7 CDA XML payload encapsulated in the body of a SOAP message. The SOAP message is directed to the application which receives the message using the network protocol.

Communication systems are subdivided into layers. The seventh level is the application layer. HL7 is the application layer in which work is done and interaction takes place in the delivery of patient's care. For the current application, the HL7 version 3 messages are presented as HL7 CDA messages created by the CDA Component. The Sending HL7 Application is the CDA Component which extracts the data needed and converts it into a XML document expressed in CDA and sends it to the Receiving HL7 Application. The Messaging Infrastructure Layer is responsible for the HL7 messages transfer following the rules specified by the HL7 applications. For the presented process, the Message Transport Layer is built on TCP/IP, the communication protocol for the Internet, and defines the rules for computer communication on Internet [76], [120].

A scenario that shows how the XML document in standard format (HL7 CDA or CCD) is sent from one application to another application using Web Services is presented in the following.

The Component HL7 CDA or CCD sends the XML document which is passed to a Web Services Messaging Adapter. For the Messaging Infrastructure Layer is important to configure the message by adding appropriate metadata. The configuration information will contain some of the following elements: Messaging Protocol's Source, Destination, definition of the delivery assurances required for the particular interaction, security characteristics. By the Web Services Messaging Adapter, a SOAP envelope is added to create XML payload which is sent to the Source that uses the Messaging Protocol. This will ease control and message transfer. In the end, the Web Services Messaging Adapter will remove the SOAP envelope, headers and metadata, and then deliver the adapted HL7 messages adapted after [120].

The Web Services used for communicating between different medical information systems is Windows Communication Foundation (WCF). WCF is a Microsoft technology and designed using service oriented architecture (SOA) principles, which can support distributed computing where services have remote consumers. Messages sent using WCF are asynchronous messages transferred from one service endpoint to another (WCF, 2012). With this technology, different Microsoft applications can communicate, but it is also possible to communicate with other applications which are not Microsoft applications (e.g. Java applications). The application are developed using Visual Studio .NET 2010, ASP.Net pages and using C# language.

WCF firstly implemented a set of classes on the top of the .NET Framework's Common Language Runtime (CLR). This offers some facilities to the developers to create service – oriented application in an easier way [121].

WCF has three important aspects [121]:

- Unification of the original .NET Framework communication technologies
- Interoperability between applications based on other technologies
- Explicit support for service-oriented development.

A set of WCF features described in [121] are:

- Service orientation
- Interoperability
- Multiple message patterns
- Service metadata

- Data contacts
- Security
- Multiple transports and encodings
- Reliable and queued messages
- Transactions
- Ajax and REST support
- Extensibility

Figure 6.32 presents the Obstetrics-Gynecology Department Information System, the Pediatrics Department Information System, the General Practitioner Information System and the Clinical Decision Support system which communicate using Windows Communication Foundation as Web Services.

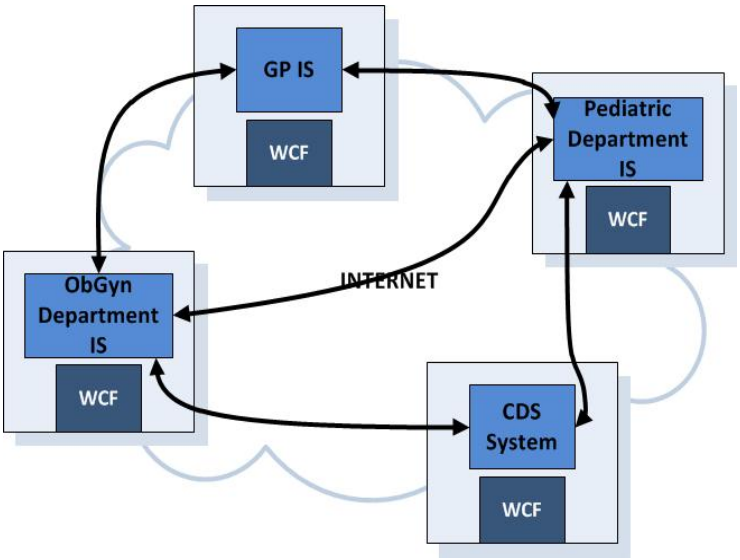


Figure 6.32 System architecture using Web Services

Using Web Services will improve the interoperability between different medical information systems because the messages will be transmitted in an automated way and in real time. If the Pediatrics Department Information System needs information from the Obstetrics-Gynecology Department Information System, the Pediatrics Department Information System will send an XML file which contains the patient's information. The Obstetrics-Gynecology Department Information System will read the XML document and will send the data requested as an XML document in HL7 CDA format.

Following, a relevant scenario is provided as example:

A mother with her baby comes to the Pediatrics Department. The first time when she comes with the baby, the medical doctor will enter the data of the baby in the Pediatrics Department Information System. The Pediatrics Department Information System will request data from the Obstetrics-Gynecology Department Information System. The Obstetrics-Gynecology Department will search the baby's information after the mother's ID, the number of the baby and date of birth. After obtaining the information, the system will send the data to the Pediatrics

Department Information System. The communication is realized using Web Services and using a standardized communication, in this case using HL7 CDA.

The solution connects 4 medical information systems - Obstetrics-Gynecology Department Information System, Pediatrics Department Information System, General Practitioner Information System and Clinical Decision Support System. Making them interoperable provides clear benefits by increasing the quality of patient's care through less medical errors and by proving clinicians proper information available from anywhere and at any time. Using the suggested technology with Web Services and Windows Communication Foundation (WCF), the communication can be done without human help, and the data can be transmitted in real time. All the applications are web based which means that that they can be accessed from anywhere; the only restriction is that the user needs an Internet connection.

6.9. Conclusions

In this chapter, the objective 1 was to model the information and activity workflow in an Obstetrics-Gynecology department to be ready for high interoperability degree using GCM, and to design and to implement the related application.

Following, the contribution from this chapter are presented:

- An analysis was performed based on the real activities in the Obstetrics-Gynecology Department, and thereby identifying the information and communication needs in support of medical staff and patients related to the important subject of the risk in OGD clinical practice.
- A complex and sound model was created for the real informational workflow in OGD using Business Process Modeling and Notation and UML. Regarding the IT perspective, the business view as well as RM-ODP views of the Development Process have been described using the Generic Component Model. The models have been developed using Bizagy software which supports BPMN. For UML modeling, Star UML support was used. Related to BPMN, a detailed description of the process was made, and for UML, use cases, actors, actions, sequence diagrams were described.
- The very complex OGD IS class diagram was built based on the previous models representing the Information view and the Computational view;
- A demonstrator for OGD IS was created, representing the platform dependent part of the GCM, the Technologic, and Engineering views; consequently, the very complex database was created; this was developed under SQL Server 2008.
- Design and implementation of a complex OGD IS has been demonstrated based on the developed models, using Visual Studio 2010.NET, ASP.NET and C#.
- Design and implementation of the Access Control service used in OGD IS.
- Design and development of the HL7 CDA and CCD Component for the communication with different medical components (CDA for Pediatrics Department Information System and CCD and CDA for the General Practitioner communication). The HL7 CDA and CCD Components were developed in Visual Studio.Net 2010, using C# language.

7. IMPLEMENTATION OF A SERVICE SUPPORTING INTEROPERABILITY BETWEEN MEDICAL INFORMATION SYSTEM

For quick development of interoperable medical applications there is a need for new software tools. This chapter presents a control for ASP.NET toolbox that can load the proper tables and field names. Its purpose is to support configuring the components which are in charge to create XMLs in a standardized format. It can access different databases such as SQL Server, Access and Oracle.

7.1.General control toolbox information

Re-usability is a technique important for software developers. Instead of wasting time with reinventing the wheel, functionality already built and tested should be deployed. This increases the productivity by reducing the total amount of written code and enhance reliability, since by using tested code, the probability is higher that the code works reliably [123].

ASP.NET gives the possibility of reusing different source codes. The first is the wide variety of built-in server controls that ship with ASP.NET. These server controls alone can eliminate even thousands of code lines need to be written to achieve the same effect in classic ASP. In addition, the .NET Framework Class Library provides hundreds of classes to perform actions that in classic ASP would have required purchasing a third-party component or making calls into the WIN 32 API [122].

The concept of extensibility goes hand in hand with reuse. It is the ability to take the existing functionality provided by the .NET Framework and ASP.NET and extend it to perform actions that are more tailored to your particular applications and problem domain. ASP.NET offers a significant number of avenues for extensibility [122]:

- Custom server controls – allows you to create the entirely new controls for use with ASP.NET or to derive from existing controls and extend or modify their functionality
- Components – as in classic ASP, component are the primary means for extending an ASP.NET application by encapsulating the application's business logic into an easily reusable form. With the .NET Framework, it's easier than ever to build components, and components are more interoperable across languages than in the COM world. .NET components can also communicate with COM components through an interoperability layer.
- HttpHandlers and HttpModules - are components that are used to perform the processing of specific types of requests made to IIS. HttpModules are components that participate in the pipeline processing of all requests for a given ASP.NET application.

For the reuse practice ASP.NET user controls and custom server controls are recommended and for extensibility, custom server controls. Custom server controls can easily be shared across multiple applications, making reuse simpler [122].

Regarding user controls, the simplest form of reuse in classic ASP is including files, adding the following directive [122]:

```
<!-- #include file = "filename.inc" -->
```

ASP developers can place the content of the specified file in line with the page in which the directive appeared. But this reuse technique is not so good and makes sometimes application debugging harder [122].

A better way for providing the same kind of reuse is through a new feature called used controls. Meanwhile, ASP.NET supports include files. User controls consist of HTML, a server-side script and controls, in a file with the .ascx file extension. When added to a Web Form page, ASP.NET considers the user controls as objects; these user controls have the possibility to expose properties and methods like any other object. The render output of user controls can also be cached to improve application performance [122].

However, user controls are not always the best way for reuse. They are good for quickly reusing existing user interface elements and code, but are not especially useful for developing reusable building blocks for multiple web applications. A better solution is the custom server control [116].

A custom server control is a class that derives from either the Control of WebControl class of the System.Web.UI namespace, or from one of the classes that derive from these controls. Custom server controls can be used in your ASP.NET Web Forms pages in very much same way you use the built-in server controls that come with ASP.NET. There are two primary categories of custom server controls [122]:

- Rendered controls – consist of custom rendering of the text, tags, and any other output you desire, which may be combined with the rendered output of any base class your control is derived from. Rendered controls override the Render method of the control they derive from. This method is called automatically by the page containing the control when it's time for the control output to be displayed.
- Compositional controls analogue to the former bullet point are composed of existing control whose rendered output forms the UI of the custom control. They create their constituent controls by overriding the CreateChildControls method of the control they derive from. This method, like the Render method, is automatically called by ASP.NET at the appropriate time.

When a new custom server control is designed, it is important to take into consideration which type of control to create [122]:

- Does one existing control provide most, but not all, of the functionality you desire? Then a rendered control that derives from that control may be the right choice.
- Could the desired functionality be provided by a group of existing controls? Then a compositional control may be a great way to reuse those controls as a group.

- Do you want to do something that is completely beyond existing controls? Then you may want to derive your control from the control class and override the Render method to create your custom output.

Custom server controls expose all public members of the class from which they are derived. The exposure is taken into consideration when designing a control for use by other developers to limit the customization. For instance, developers might not want to change the font size of a control. In such a case, is recommended to avoid deriving from a control that exposes that property [122].

The chapter presents original work that proposes a web custom server control developed for Visual Studio .net 2010 toolbox which can be used in ASP.NET pages. This control has the possibility to show the databases tables and fields and it can be applied in this stage to SQL Server, Access and Oracle databases, but in the future its functionality will be extended for other databases (e.g., MySQL). The control works with CDA and CCD standard to transfer the medical information in other application.

Web Custom controls are compiled codes that can facilitate different user actions, but are more difficult to create them. It is possible to add them it to the toolbox and display them in a visual designer with full Properties window support and all the other design-time features of ASP.Net server controls. Another important feature is that it is suitable for creating dynamic layouts [123].

7.2. Service for medical information system interoperability

Figure 7.1 presents the use case where a user accesses the control in OGD IS.

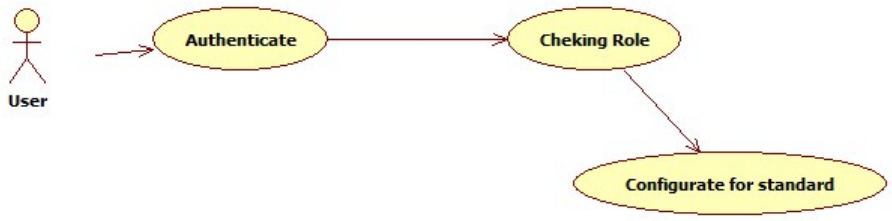


Figure 7.1 Use case regarding the control use

User: The user wants to configure the location and database type. He can access different databases (SQL Server, Access, Oracle).

Interactions: The first step is configuration of data extraction details. Once the user has logged into the system and the system checks that he has the privileges to add information, he can configure the component which is in charge to create the XML files in standard format.

Figure 7.2 presents the performed actions in a sequence diagram. For that purpose, a squence diagram was created, and in Table 7.1, the interaction is presented which occurs in the sequence diagram for configurating the coponent which is in charge to create the XML file in standardized format.

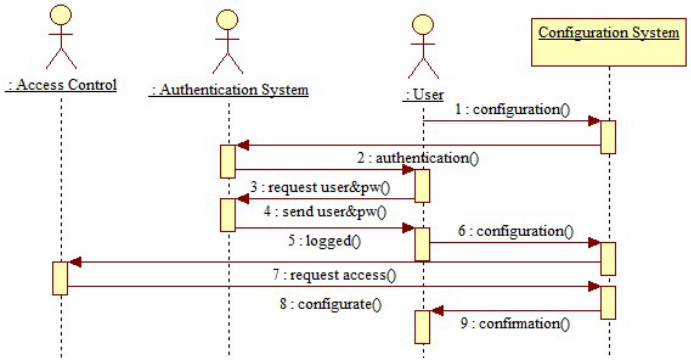


Figure 7.2 Sequence diagram for a use case where a user can configure the database component

Table 7.1 The detailed interaction from the sequence diagram

Interactions	Description
Interaction 1	The user wants to configure the component which creates the XML document in standardized format
Interaction 2	The system sends a request to the authentication system
Interaction 3	The authentication system requests the user name and password
Interaction 4	The user sends the user name and password
Interaction 5	The authentication system sends the confirmation that the user is logged
Interaction 6	The user sends a request to the configuration system
Interaction 7	The configuration system checks if the user has privileges for that action
Interaction 8	The access control sends a confirmation that it can be configured
Interaction 9	The user can configure the component.

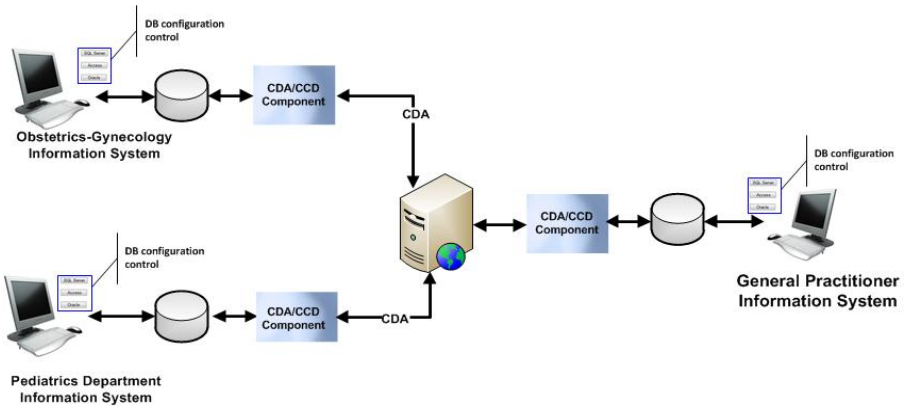


Figure 7.3 System architecture using the control

Each application has a database configuration control (DB configuration control) which has the possibility to show the database tables and fields. This control allows the extraction of the needed data in a standardized manner and sends the information to other applications.

Figure 7.4 shows the steps that a user has to follow in accessing the database tables and fields, and this will finally result in selecting the needed fields for HL7 CDA and CCD standards format [124], [125].

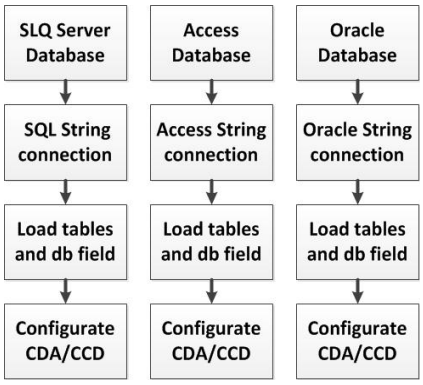


Figure 7.4 Control functionality

This control can access different databases, for example SQL Server, Access and Oracle database. Figure 7.5 shows the interface where the user can select the needed database [124].

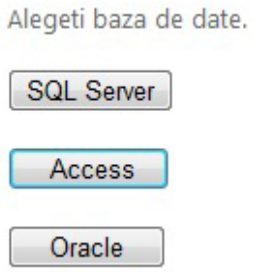


Figure 7.5 Database selection

Figure 7.6 demonstrates how the user can access the Microsoft Access database.

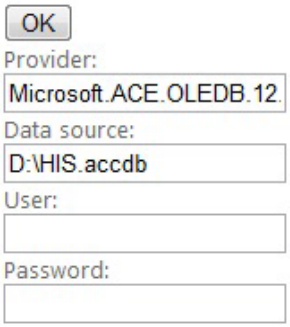


Figure 7.6 Create connection to Access database

Figure 7.7 represents the tables from the selected database after the connection is performed [124].

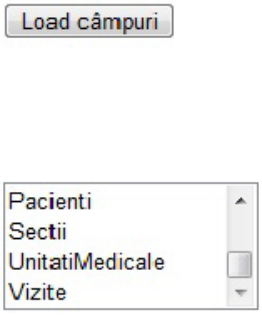


Figure 7.7 Tables from database

Figure 7.8 shows two screen shots with the fields from a database.

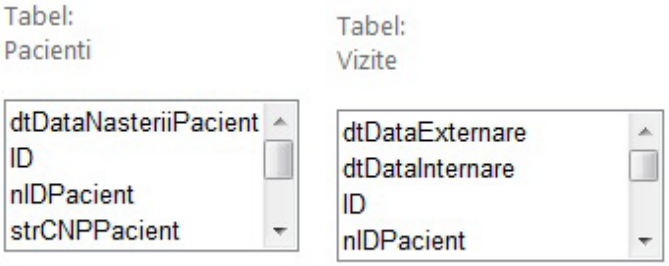


Figure 7.8 Fields from database

Figure 7.9 demonstrates how the user can access the SQL Server database [124].

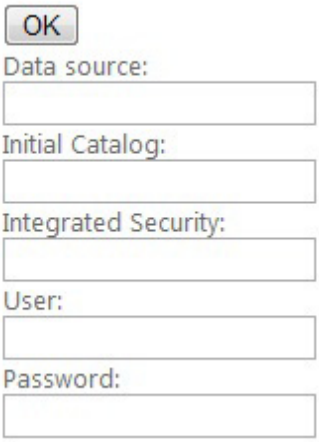
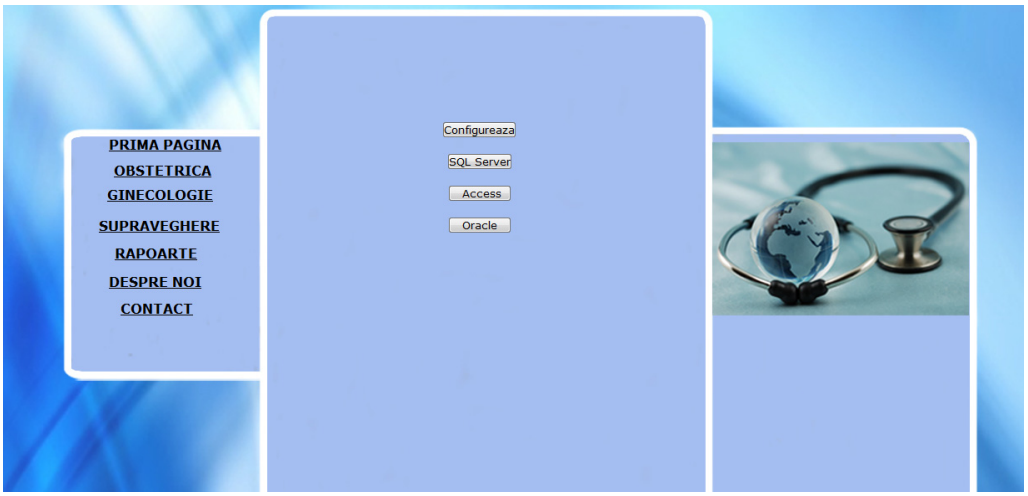
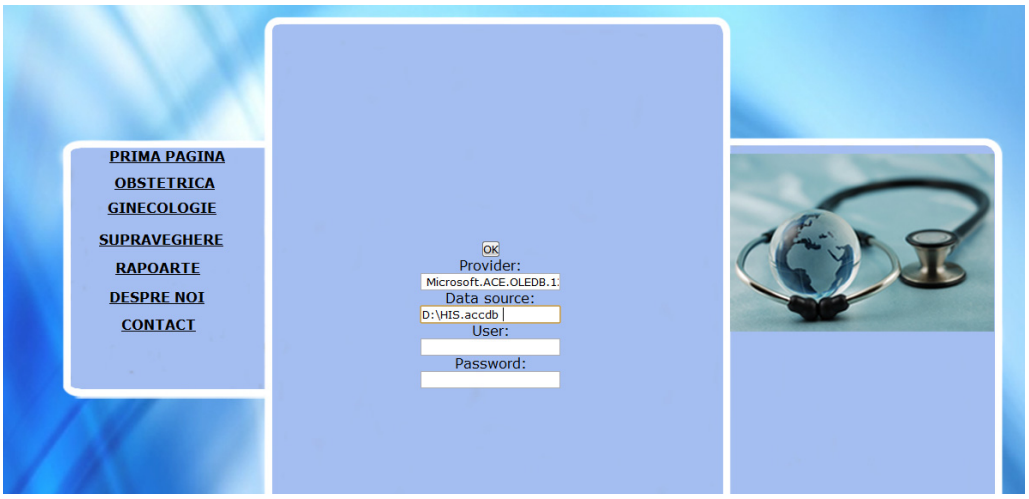


Figure 7.9 Configuration of the SQL Server database

Figure 7.10 presents several screenshots from OGD IS to show how the control at work.




PRIMA PAGINA
OBSTETRICA
GINECOLOGIE
SUPRAVEGHERE
RAPOARTE
DESPRE NOI
CONTACT
OK
Provider:
Microsoft.ACE.OLEDB.1
Data source:
D:\HIS.accdb
User:
Password:


PRIMA PAGINA
OBSTETRICA
GINECOLOGIE
SUPRAVEGHERE
RAPOARTE
DESPRE NOI
CONTACT
Load câmpuri
AlteInformatiiPacienti
DiagnosticePacienti
ExAnatomoPatologic
ExApCardioVascular

Figure 7.10 Screen shots from OGD IS using the control

7.3. Conclusions

In this chapter, the objective was to design and to implement a web service for medical information systems. In the following lines, the contributions of this chapter are presented:

- Modeling toolbox control functionalities using UML
- Designing the control for ASP.NET toolbox. This can load the tables and fields names of a database to configure the component which is in charge to create XML files in standardized format so, preparing easily any system for interoperability. It can access different databases (SQL Server, Access, and Oracle).
- Developing a web custom control for Visual Studio.NET toolbox for ensuring the interoperability between medical information systems; this control can be used only for ASP.NET pages. It is demonstrated how the control can be used for the OGD IS. It is possible to add it to the toolbox and display it in a visual designer with full Properties window support and all the other design-time features of ASP.Net server controls. An important feature is that it is suitable for creating a dynamic layout.

8. EVALUATION OF THE OBSTETRICS-GYNECOLOGY DEPARTMENT INFORMATION SYSTEM

In this chapter, two types of evaluation of the described OGD IS are presented. The first is a quality evaluation of the OGD IS from the interoperability point of view, and the second is an evaluation of the potential interoperability using the LISI (Level of Information System Interoperability) model.

8.1. Quality evaluation of Obstetrics-Gynecology Department Information System

After [119], the quality of a system is defined as "the degree to which the system satisfies the stated and implied needs of its various stakeholders and provides value".

In order to evaluate the product quality, ISO [126] has defined eight characteristics: functional suitability, performance efficiency, compatibility, usability, reliability, security, maintainability and portability, as presented in Figure 8.1.

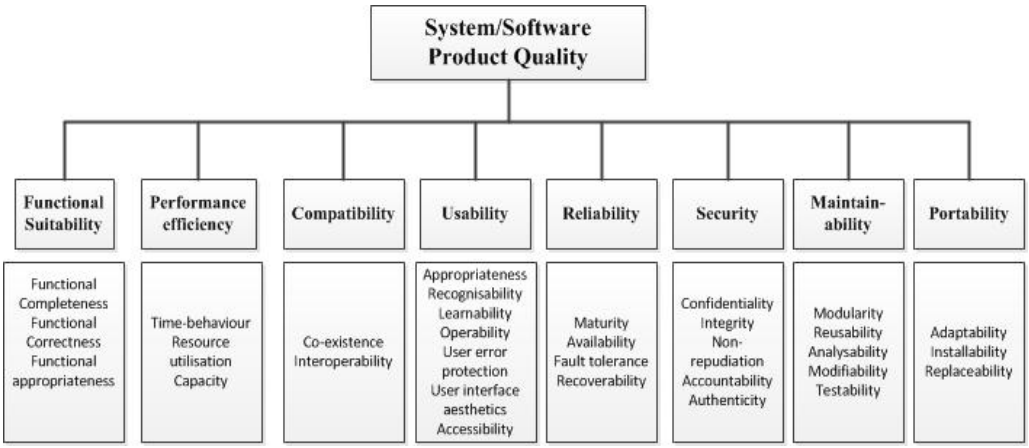


Figure 8.1 Product quality model (after [120])

In the next lines, all the characteristics and sub-characteristics listed in Figure 8.1 are described.

Functional suitability is a characteristic of system/software product quality and contains 3 sub-characteristics: functional completeness, functional correctness and Functional Appropriateness.

Functional suitability is defined by [127] as: "degree to which a product or system provides functions that meet stated and implied needs when used under specified conditions".

Functional completeness is a sub characteristic of functional suitability and [127] defines this as: "degree to which the set or functions covers all the specified tasks and user objectives".

Functional correctness is a sub-characteristic of functional suitability, and [127] defines this as "degree to which a product or system provides the correct results with the needed degree of precision".

Functional appropriateness is a sub-characteristic of functional suitability, and [127] defines this as "degree to which the functions facilitate the accomplishment of specified tasks and objectives".

Performance efficiency is a characteristic of system/software product quality and contains 3 sub-characteristics time-behavior, resource utilization, capacity.

Performance efficiency is defined by [127] as: "performance relative to the amount of resources used under stated conditions".

Time behavior is a sub-characteristic of performance efficiency, and [127] defines this as "degree to which the response and processing times and throughput rates of a product or system, when performing its functions, meet requirements".

Resource utilization is a sub-characteristic of performance efficiency, and [127] defines this as "degree to which the amounts and types of resources used by a product or system when performing its functions meet requirements".

Capacity is a sub-characteristic of performance efficiency, and [127] defines this as "degree to which the maximum limits of a product or system parameter meet requirements".

Compatibility is a characteristic of system/software product quality and contains 2 sub-characteristics co-existence and interoperability.

Compatibility is defined by [127] as "degree to which a product, system or component can exchange information with other products, systems or components, and/or perform its required functions, while sharing the same hardware or software environment".

Co-existence is a sub-characteristic of compatibility, and [127] defines this as "degree to which a product can perform its required functions efficiently while sharing a common environment and resources with other products, without detrimental impact on any other product".

Interoperability is a sub-characteristic of compatibility, and [127] defines this as "degree to which two or more systems, products or components can exchange information and use the information that has been exchanged".

Usability is a characteristic of system/software product quality and contains 6 sub-characteristics: appropriateness recognizability, learnability, operability, user error protection, user interface aesthetics and accessibility.

Usability is defined by [127] as "degree to which a product or system can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use".

Appropriateness recognizability is a sub-characteristics of usability, and [127] define this as "degree to which users can recognize whether a product or system is appropriate for their needs".

Learnability is a sub-characteristic of usability, and [127] defines this as "degree to which a product or a system can be used by specified users to achieve specified goals of learning to use the product or system with effectiveness, efficiency, freedom from risk and satisfaction in a specified context of use".

Operability is a sub-characteristic of usability, and [127] defines this as "degree to which a product or system has attributes that make it easy to operate and control".

User error protection is a sub-characteristic of usability, and [127] defines this as "degree to which a system protects users against making errors".

User interface aesthetics is a sub-characteristic of usability, and [127] defines this as "degree to which a user interface enables pleasing and satisfying interaction for the user".

Accessibility is a sub-characteristic of usability, and [127] defines this as "degree to which a product or system can be used by people with the widest range of characteristics and capabilities to achieve a specified goal in a specified context of use".

Reliability is a characteristic of system/software product quality and contains 4 sub-characteristics: maturity, availability, fault tolerance and recoverability.

Reliability is defined by [127] as "degree to which a system, product or component performs specified functions under specified conditions for a specified period of time".

Maturity is a sub characteristic of reliability, and [127] defines this as "degree to which a system meets needs for reliability under normal operation".

Availability is a sub-characteristic of reliability, and [127] defines this as "degree to which a system, product or component is operational and accessible when required for use".

Fault tolerance is a sub-characteristic of reliability, and [127] defines this as "degree to which a system, product or component operates as intended despite the presence of hardware or software faults".

Recoverability is a sub-characteristic of reliability, and [127] defines this as "degree to which, in the event of an interruption or a failure, a product or system can recover the data directly affected and re-establish the desired state of the system".

Security is a characteristic of system/software product quality and contains 5 sub-characteristics confidentiality, integrity, non-repudiation, accountability and authenticity.

Security is defined by [127] as "degree to which a product or system protects information and data so that persons or other products or system have the degree of data access appropriate to their types and levels of authorization".

Confidentiality is a sub-characteristic of security, and [127] defines this as "degree to which a product or system ensures that data are accessible only those authorized to have access".

Integrity is a sub-characteristic of security, and [127] defines this as "degree to which a system, product or component prevents unauthorized access to, or modification of, computer programs or data".

Non-repudiation is a sub-characteristic of security, and [127] defines this as "degree to which actions or events can be proven to have taken place, so that the events or actions cannot be repudiated later".

Accountability is a sub-characteristic of security, and [127] defines this as "degree to which the actions of an entity can be traced uniquely to the entity".

Authenticity is a sub-characteristic of security, and [127] defines this as "degree to which the identity of a subject or resource can be proved to be the one claimed".

Maintainability is a characteristic of system/software product quality and contains 5 sub-characteristics: modularity, reusability, analyzability, modifiability and testability.

Maintainability is defined by [127] as "degree of effectiveness and efficiency with which a product or a system can be modified by the intended maintainers".

Modularity is a sub-characteristic of maintainability, and [127] defines this as "degree to which a system or computer program is composed of discrete components such that a change to one component has minimal impact on other components".

Reusability is a sub-characteristic of maintainability, and [127] defines this as "degree to which an asset can be used in more than one system, or in building other assets".

Analyzability is a sub-characteristic of maintainability, and [127] defines this as "degree of effectiveness and efficiency with which it is possible to assess the impact on a product or system of an intended change to one or more of its parts, or to diagnose a product for deficiencies or causes of failures, or to identify parts to be modified".

Modifiability is a sub-characteristic of maintainability, and [127] defines this as "degree to which a product or system can be effectively and efficiently modified without introducing defects or degrading existing product quality".

Testability is a sub-characteristic of maintainability, and [127] defines this as "degree of effectiveness and efficiency with which test criteria can be established for a system, product or component and tests can be performed to determine whether those criteria have been meet".

Portability is a characteristic of system/software product quality and contains 3 sub-characteristics: adaptability, installability, replaceability.

Portability is defined by [127] as "degree of effectiveness and efficiency with which a system, product or component can be transferred from one hardware, software or other operational or usage environment to another".

Adaptability is a sub-characteristic of portability, and [127] defines this as "degree to which a product or system can effectively and efficiently be adapted for different or evolving hardware, software or other operational or usage environments".

Installability is a sub-characteristic of portability, and [127] defines this as "degree of effectiveness and efficiency with which a product or system can be successfully installed and/or uninstalled in a specified environment".

Replaceability is a sub-characteristic of portability, and [127] defines this as "degree to which a product can be replaced by another specified software product for the same purpose in the same environment".

Each characteristics or sub-characteristics of the software can be measured. The software process quality can be evaluated by measuring [127]:

- internal properties (measure the static of the intermediate products)
- external properties (measure the behavior of the executed code)
- quality in use properties (in this case is measured the product when is real or simulated use).

The software process quality measurement is represented in Figure 8.2 [127].

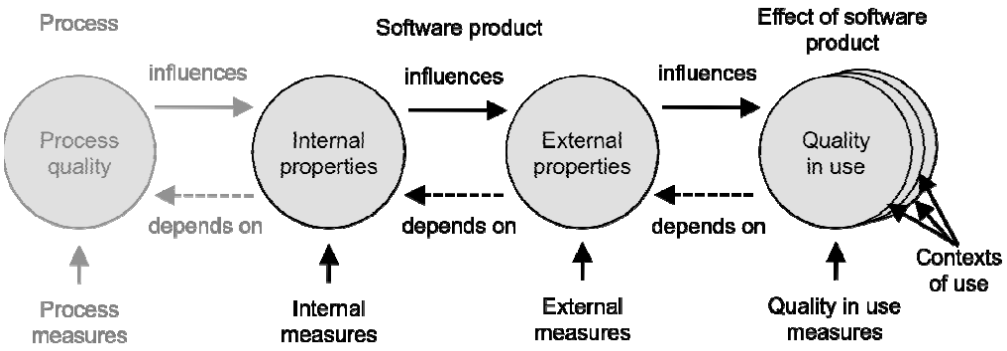


Figure 8.2 Quality in the lifecycle (after [127])

The internal metric can be applied to software which is not running, during designing and coding cycles.

The external metric is used to measure the behavior of the system when testing, operating and observing the executable software or system. For this purpouse, it will measure the interoperability between different EHR systems, using the interoperability metric. This metric can measure an attribute as the number of functions or appearance of the transferred data. Furthermore, it can be transferred easily between software product and other systems, other software products, or connected equipment [128].

In the following 3 interoperability metric are presented, their purpose and the interpretation of a measured value.

The first metric is data exchangeability (data format based). The purpose of this metric is: How complete are the downstream interface functions for a specified data transfer? [128]. The formula associated to the metric is [128]:

$X = A/B$

where,

X – data exchangeable format

A – number of data formats which are approved to be exchanged with other software or system during testing on data exchanges

B – total number of data formats to be exchanged

The interpretation of this measured value: 0<=X<=1, closer to 1.0 is better [ISO, 1999].

The second metric is data exchangeability (User's success attempt based), with its purpose: How often the data transfers between targeted software and other software is successful? and Can the user usually succeed to exchange data? [ISO, 1999]. The formula for this metric is [ISO, 1999]:

$Y = 1 - (A/B)$

where,

Y – user successful data exchange ratio

A – number of cases when the user fails to exchange data with other software applications or systems

B – number of cases in which the user attempts to exchange data

The interpretation of the measured values is: 0<=Y<=1, the closer to 1.0 is better [128].

The third metric is intersystem interface standard consistency, with its purpose: Is the standard for interface design identified in the specifications followed consistently? [128]. The formula for this metric is [128]:

X = A/B

where,

X – interface standard consistency ratio

A – number of checked items of intersystem interface which are approved at testing that they are consistent with standard/rule of intersystem

B – total number of checked items of intersystem interface

The interpretation of the measured values is: 0<=X<=1, the closer to 1.0 is the better [128].

The OGD IS sends patient data to the Pediatrics Department Information System. Figure 8.3 and Figure 8.4 show the exchanged data, where the XML's in CDA format contain the data about the birth status during 2009 – 2010.

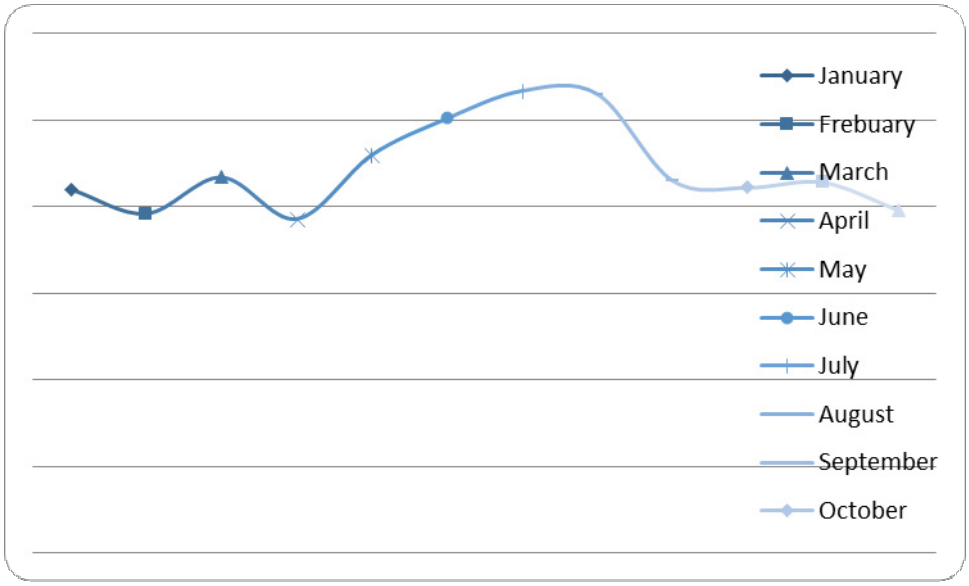


Figure 8.3 Obstetrics data transmitted from OGD IS in 2009

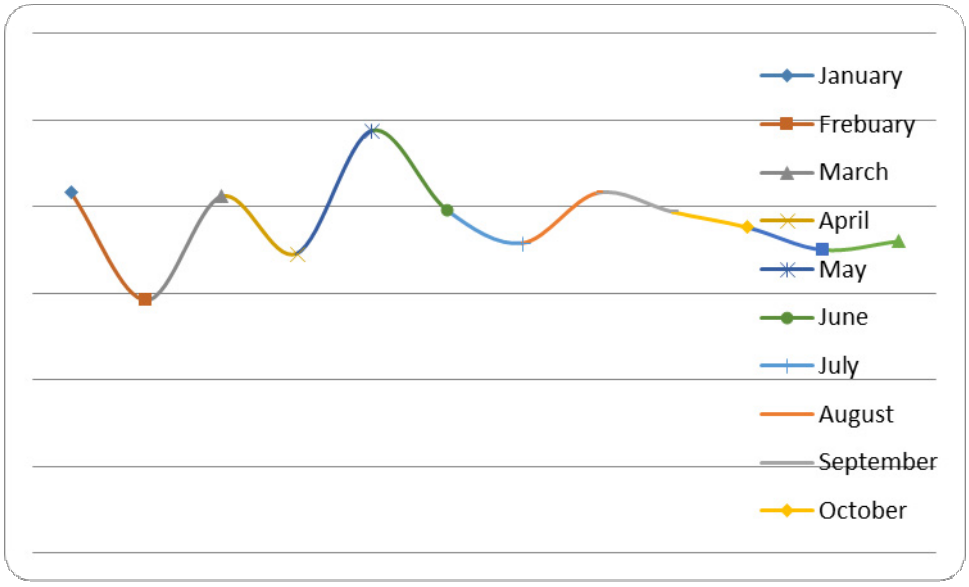


Figure 8.4 Obstetrics data transmitted from OGD IS in 2010

In order to evaluate the interoperability from a quality point of view for OGD IS two other applications are taken into consideration, one for the neonatology department [129], and another an application calculating the risk in an obstetrics-gynecology department [130]. Details about the applications will follow. Figure 8.5 presents the flow of information for the neonatology application.

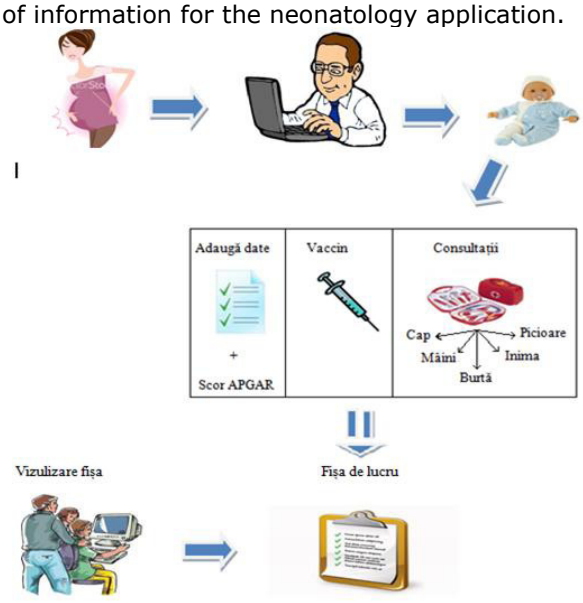


Figure 8.5 Neonatology application functions

The application which calculates the pregnancy risk makes a management of the obstetrics department activity, calculating the pregnant woman's risk. Knowledge of the risk during pregnancy is extremely important for proper follow-up of mother and fetus with the possibility to intervene promptly and for increasing the rate of born children without problems. The system can be accessed under related rights by both obstetricians and by the parents. The management module can be used according to the privileges assigned of users such as an administrator's accounts, health professional and his/her patient. A doctor will have access only to his patients' data. When the medical user's prvileges allow processing of patient both from laboratory and general data, he/she can calculate the pregnancy risk, displaying it in text or graphical form. The patient module is intended to be used by for patients who can view or enter minimal data.

According to the metric described above, the results are:

- data exchangeability - Data format base

For the neonatology department information system, X is 0,49 on a scale from 0 to 1. This means that the neonatology department IS needs 49% from OGD IS data capacity.

For the application for calculating the risk for pregnant woman, X is 0,25 on a scale from 0 to 1. This means that application for calculation the risk for pregnant woman needs 25% from OGD IS data capacity. This small percentage can be an indication that the actual data in the IS are more demographics and for reimbursements than for clinical use.

- data exchangeability - user's success attempt based

The communication between OGD IS and the Pediatrics Department Information System was tested. The result of Y is 0.92 on a scale from 0 to 1. This shows that the systems are interoperable in a high degree.

- intersystem interface standard consistency

This metric was calculated for the OGD IS and the Pediatrics Department Information System. The resulting was X is 1, which means that all the interfaces implied in the communication are working as specified.

In conclusion, the OGD IS is prepared to interconnect with the neonatology application and the application for calculation the pregnancy risk. Furthermore, it communicates in a standardized manner with the Pediatrics Department Information System. All the results show that the OGD IS is interoperable with other medical information systems in quite a good proportion.

8.2. LISI model for assessing the interoperability degree of medical information systems

8.2.1. Describing the LISI model

LISI (Levels of Information System Interoperability) is a complete, descriptive model of classification with levels of interoperability based on individual, unique project specifications [131].

LISI is one of the models which provide a basis for measuring the interoperability between systems. Other maturity – based methods are: LCIM, LCI, NMI, OAIM and OIM [132].

Methods with 5 levels are: LISI (Levels of Information System Interoperability) with 4 attributes, LCIM (Levels of Conceptual Interoperability Model), NMI (Nato C3 Technical Architecture Reference Model for Interoperability), OAIM (Organizational Interoperability Agility Model) with 3 attributes, OIM (Organizational Interoperability Maturity) with 4 attributes; and with 9 levels: LCI (Layers of Conceptual Interoperability Model). [132], [133], [134], [135].

In this study, LISI was chosen because it has a classification with levels of interoperability and it is more appropriate to measure the potential interoperability for medical informatics systems.

LISI is a reference model for assessing information systems interoperability. It is used for defining, measuring, assessing, and certifying the degree of interoperability required or achieved between organizations or systems [131].

LISI Interoperability Maturity Model has 5 levels [131] which are adapted for healthcare informatics systems [130].

The LISI levers are [131], [137]:

- Level 0 named Isolated (Environment: Manual), which is nonconnected, and represents manual gateway (diskette, tape and hard copy manual gateway). An example, the case of information exchange between two hospitals based on paper documents as is represented in Figure 8.6.

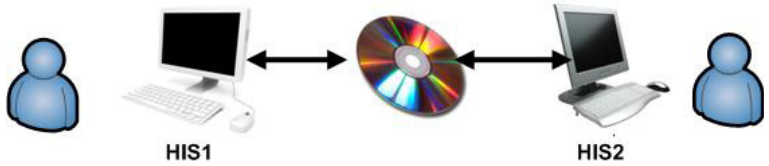


Figure 8.6 Level 0 computing environment

- Level 1 named Connected (Environment: Peer-to-Peer), which implies electronic connection, with separate data and applications, and represents heterogeneous product exchange (voice, text files, and messages). An example is the information exchange between two hospitals when using emailing as represented in Figure 8.7.

Figure 8.7 Level 1 computing environment

- Level 2 named Functional (Environment: Distributed), which has minimal common functions, separate data and applications, represents heterogeneous product exchange for basic collaboration, group collaboration (exchange of annotated images, maps with overlays). For example, the information transmitted between two hospitals is radiography from the radiology laboratory and it is represented in Figure 8.8.

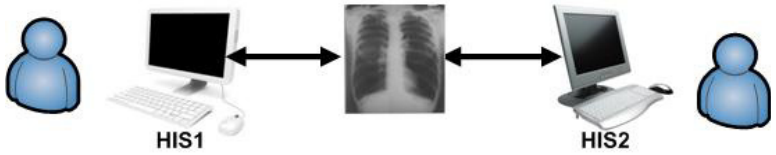


Figure 8.8. Level 2 computing environment

- Level 3 named Domain (Environment: Integrated), which has shared data and separate applications, represents shared databases, and sophisticated collaboration (common operating Picture). An example is the case of three hospitals where the information exchange is done by using a shared database as presented in Figure 8.9.

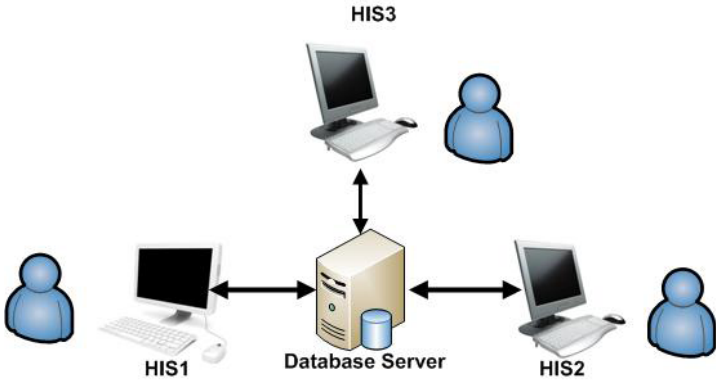


Figure 8.9 Level 3 computing environment

- Level 4 named Enterprise (Environment: Universal), which has interactive manipulation, shared data and applications, or as the current case, different medical informatics systems (HIS, RID, pharmacy, GP's information systems), represents distributed global information and applications, simultaneous interactions with complex data, advanced collaboration, event-triggered global database update. For example,

communication, based on HL7 v3 standard between hospital, HIS, pharmacy and CAS (National Insurance House), as presented in Figure 8.10.

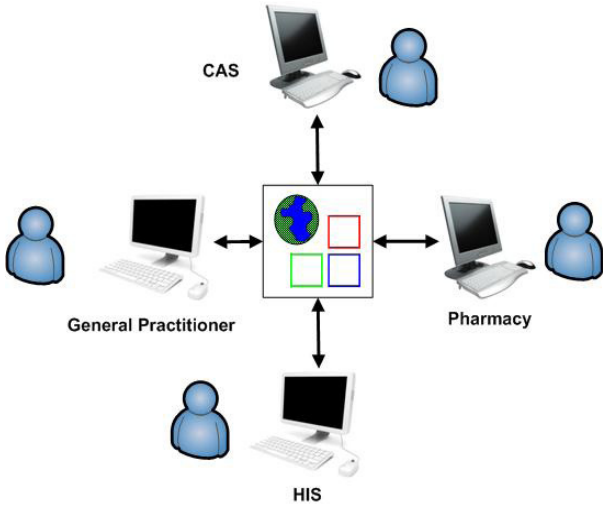


Figure 8.10 Level 4 computing environment

To fit into a LISI level, we studied two types of interoperability: operational and technical. Two scores obtained from analyzing the two interoperability types will obtained representing the interoperability degree of the studied medical information system. A scale corresponding for each LISI level will be considered (e.g., if the scale is 0 the level is Level 0 - Isolated).

LISI attributes

Each level's prescription of capabilities must cover all four enabling attributes of interoperability, named PAID (Procedures – Applications – Infrastructure – Data) [131].

Procedures attributes are the policies and procedures helping in system's development through established standards and the procedures and processes which influence system integration and functional operational requirements.

Applications attributes are the functions a system is intended to perform.

Infrastructure attributes represent the infrastructure required to support the system operations.

Data attributes are the data structures used to support both the functional applications and system infrastructure.

LISI Scope of Analysis

Figure 8.11 presents the LISI scope of analysis for two HIS systems (Hospital Information Systems) [131].

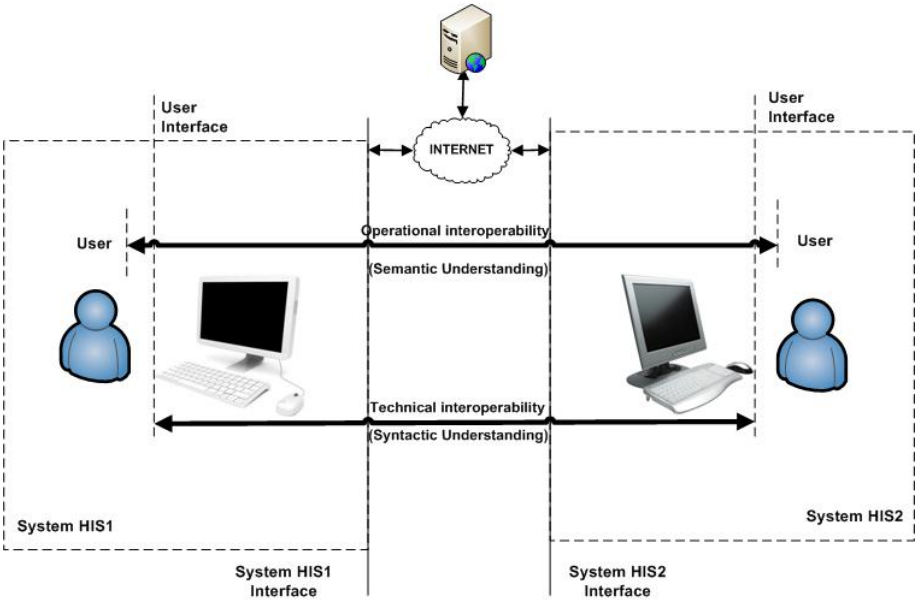


Figure 8.11 Scope of Analysis (after [131])

Operational interoperability is the ability of medical informatics systems to provide services to or to access services from other medical informatics systems and use the services to operate effectively together.

Technical interoperability is the condition achieved among electronic systems or items of communications when information or services can be exchanged directly and satisfactorily between them and their users. The degree of interoperability should be defined when referring to specific cases.

However, we distringuish five levels of interoperability as described in more detail in in Chapter 2.5, the LISI Scope of Analysis is modified to cover these levels of interoperability: technical interoperability, structural interoperability, syntactic interoperability, semantic interoperability, organizations/service interoperability.

8.2.2. Applying an algorithm for assessing the interoperability degree of medical information systems from a syntactic point of view

Figure 8.12 presents the studied healthcare system architecture comprising the obstetrics-gynecology department, 2 radiology (1 internal and 1 external) departments, 4 analysis laboratories (1 internal and 3 external), and 1 general practitioner office. The syntactic interoperability degree for the obstetrics-gynecology medical information system is studied below. This medical information system communicates using standards: with the radiology and analysis laboratory using HL7 CDA, and with the general practitioner using CCD [131].

A scale is proposed to evaluate systems' interoperability potential from a syntactic interoperability point of view:

- 0 – 35 points: the systems are not interoperable that means that the system is on LISI level 0 or level 1,
- 36 – 65 points: the systems are interoperable in some degree that means that the system is on LISI level 2 or 3,
- 66 – 100 points: the systems are interoperable that means that the system is on LISI level 4.

To study the interoperability degree, an adapted algorithm after [131] is applied for the medical information systems.

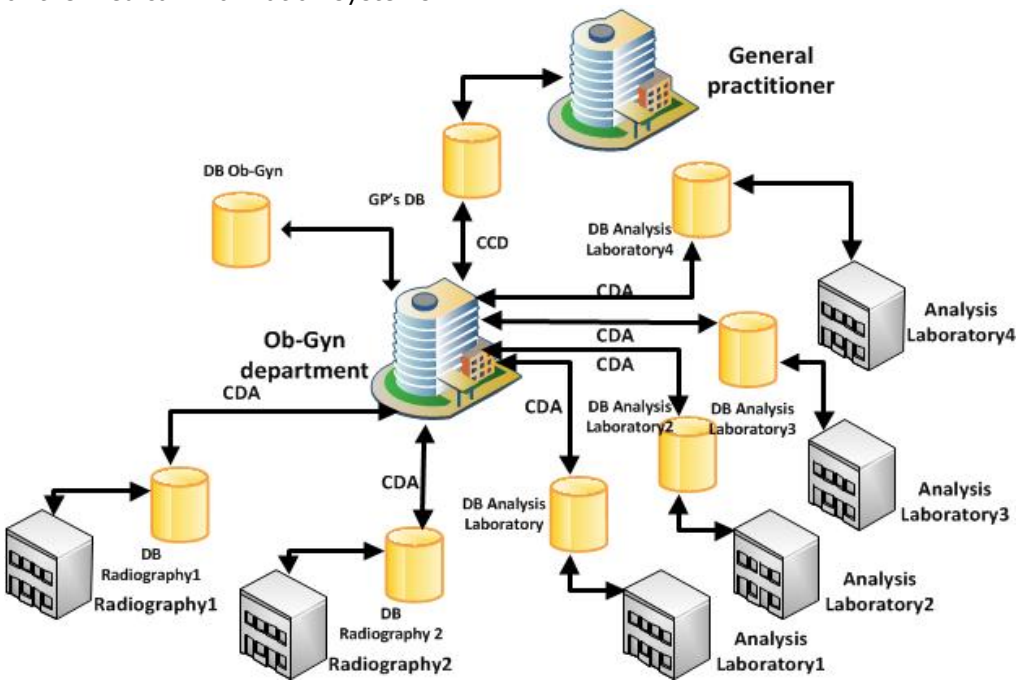


Figure 8.12 System architecture

For each step of the testing process, points have been associated in order to reflect the interoperability score for the systems. For each step, a score is allocated; it represents how well the system meets the requirements (e.g., if the system has the possibility to communicate using standards, and how many system are interconnected). In the next lines, the testing steps are presented [137], [138]:

Step 1. Analyzing the functionalities are the same

In order to establish that the system functionalities are the same, the data workflow and management between obstetrics-gynecology, radiology, laboratory and general practitioner was monitored during a week at County Emergency Hospital Timisoara, Romania – Bega Clinic, obstetrics-gynecology department. The referrals studied, the data sets were identified and based on these, the conclusion was that the system functionalities are the same. The scored obtained at this step is 7/10.

Step 2. Study the degree in which the communication is based on the same standards.

We assumed that the messages are transmitted with the help of HL7 CDA standard in laboratory analysis, radiology cases, and with CCD for the general practitioner assuming that the GP doesn't have information about the patient. For each case, two Components were developed, one which extracts data for creating the CDA and the second to extract data for CCD. The score obtained in this step is 9/10.

Step 3. Analyze if the message data elements are common.

The data elements are common because the ob-gyn department sends referrals to the analysis laboratory, radiology, and the general practitioner office and receives back the same type of documents. All the communication between medical information systems presented here is based on CDA and CCD standards. The scores obtained at this step is 7/10.

Step 4. Calculate the connectivity index with the formula:

$$c_i = \frac{k}{n*(n-1)}$$

where: c_i = connectivity index for HIS;

k = number of connection (path between nodes),

n = number of nodes (participating units).

k = 7; n = 8; c_i = 0.125

The scored obtained at this step is 2/10.

Step 5. Monitoring the protocols and data flow in departments and analyzing the information exchange.

The ob-gyn department sends an XML file in CDA format to the analysis laboratory, to radiology, and in CCD format to the general practitioner office, and so the data flow between the medical units is standardized. The scored obtained at this step is 3/10.

Step 6. Calculate the capacity of the ob-gyn department which is the rate at which data may be passed over time.

$$Q_{eff} = (Q_{\max} - Q_{oh}) * (t_f - t_p)$$

where,

Q_{ef} = effective system capacity (data rate);

Q_{max} = maximum data rate;

Q_{oh} = system overhead data rate;

t_f = time slot duration (unit transmission);

t_p = unit propagation time.

Another measure is the calculus of the department's overload which occurs when more data must be exchanged than the system is able to transmit. The overload is placed in a queue and it is transmitted when capacity is available.

$$M_{OL} = n_t * \sum_{y=1}^{n_r} (M_q)_y$$

where,

M_{OL} = system message overload;

n_t = number of transmitting nodes;

M_q = messages in queue to be transmitted by node.

The system underuse was calculated, occurring when the system data rate/message load is less than full capacity but messages are waiting in queues to be transmitted.

$$Q_{uu} = M_{OL} \text{ , for } M_{OL} \leq (Q_{eff} - Q)$$

$$Q_{uu} = Q_{eff} - Q \text{ , for } M_{OL} > (Q_{eff} - Q)$$

where,

Q_{uu} = system underutilization (data rate);

Q = measured/observed data rate

Another parameter calculated was the under capacity of the system, which occurs when messages remain in queues and the system data rate is at the maximum.

$$Q_{uc} = (Q + M_{OL}) - Q_{eff}$$

where,

Q_{uc} = system under capacity (data rate)

For the laboratory a maximum number of 300 messages a week was estimated, supported by the system: for the radiology internal department 100 messages a week, for the external department of radiology 80 messages a week, 50 messages for general practitioner.

In order to compute the interoperability score, 2 days were considered for the time of message transmission (T_f) and 4 days for the response time (T_p), because in Romanian health system the patient must wait in minimum 4 days to receive the laboratory results.

- Ob-gyn->Laboratory = 40 messages / day =>200 messages / week
- Ob-gyn->Radiology intern department = 15 msg / day => 75 msg / week
- Ob-gyn->Radiology extern = 10 msg / day => 50 msg / week
- Ob-gyn-> General practitioner = 10 msg/day => 50 msg/week
- T_f = 2 days
- T_p = 4 days
-

The results after applying the formulas are:

Q_{eff} = 1804; M_{OL} = 96; Q_{uu} = 96; Q_{uc} = - 1594

The scored obtained at this step is 17/40.

Step 7. Interpreting the result and analyzing the data elements in HIS.

Analyzing all the steps, we concluded that this type of system architecture benefits of a standardized communication; it is possible to add other medical information systems; the systems can be improved a lot; the medical information system can support more messages, because after computing the underuse capacity we concluded that more messages can be added without affecting the communication. The scored obtained at this step is 9/10 [Vida et al, 2012].

Table 8.1 represents a summary of the steps analysis [Vida et al, 2012].

Table 8.1 Interoperability score

Steps	1	2	3	4	5	6	7
Ob-gyn points	7/10	9/10	7/10	2/10	3/10	17/40	9/10
Total	54/100 points						

After applying these steps and computing the scores, the result was that the obstetrics-gynecology department has a score of 54 points, which represents a percentage of 54/100, regarding the interoperability potential with the analysis laboratory, radiology and general practitioner from the syntactic interoperability point of view. This score shows that the medical information system for ob-gyn department is ready to communicate to other medical information systems, but improvements have to be made [131].

8.3. Conclusions

In this chapter the objective was the evaluation of the developed solutions from a quality point of view and evaluation of the interoperability potential using LISI model.

In the following lines, the contributions of this chapter are presented:

- Defining three metrics to evaluate the interoperability of OGD-IS from a quality point of view, demonstrating the readiness of the OGD-IS to interconnect with a neonatology application and an application assessing the pregnancy risk which I contributed on, together with a team. Standardized communication with the Pediatrics Department Information System was investigated. The results show that the OGD-IS is fully interoperable with other medical information systems.
- Concluding a vast search with selecting and adapting a model of evolution, the LISI model for the OGD IS to find the degree of interoperability readiness of the OGD IS.
- A methodology proposed for Evaluation of the OGD IS regarding the interoperability potential.
- Application of the proposed methodology and interpretation of results for the OGD IS
  The obtained score shows that the healthcare information system for OGD is well ready to communicate to other healthcare information systems

9. CONCLUSION AND FUTURE DIRECTIONS

Conclusions

In the following, each objective of the thesis is associated with chapters tackling it, and related contributions.

Contributions related to stated objectives

Objective 1 – in Chapters 2 and 5:

- A thorough synthesis related to interoperability between systems, definition, basic requirements, and systems' architecture definitions and principles that prepared the support for the entire work.
- A list of interoperability characteristics selected from literature tailored for the actual OGD system.
- A review of the levels of interoperability for the actors involved in communication and cooperation between medical systems, depending on related objectives and requirements.
- A thorough synthesis for the standards after a vast literature review: ISO/TC215, CEN-TC 251, Health Level 7, DICOM, IHE Retrieve Information for Display (RID), IHE Cross – Enterprise Document Sharing (XDS), Medical Markup Language (MML), HL7 CDA and CCD that resulted in the selection of standards HL7 CDA and CCD useful in creating a complex EHR with a high degree of interoperability.

Objective 2 – in Chapter 3:

- A complex review related to system modeling applied in healthcare that resulted in selecting the Generic Component Model (GCM) due to its generic power for modeling the OGD IS.
- A vast synthesis of UP, RUP, MDD and MDA for creating a model-driven architecture for the development of the OGD Information System. Also, one related to the modeling tools, BPMN and UML that were further used for the actual modeling.

Objective 3 - in Chapters 4 and 5:

- A solid review study representing the need of using EHR, presenting its advantages, EHR models, comparisons between solutions, as a basis to create an easy to develop and ready to interoperability OGD IS model
- A thorough synthesis of the HL7 CDA standard for clinical exchange; relevant RIM classes were shown, as support in developing the standard, and the CDA parts for correct and clear development of the HL7 CDA Component.
- A comprehensive synthesis of CCD as a support for continuity of patient emphasizing its advantages and original solutions as XML files built as an adaptation for the Romanian healthcare system; it is the basis for the CCD Component related to the OGD system communication.

- 3 complex case studies for which I built architectures as instances of GCM as a modeling solution for healthcare
    1. An original architecture and implementation for showing how the HL7 CDA Component is used for sending information to Egadss System (as clinical decision support system that has as inputs HL7 CDA standard messages as XML files). The HL7 CDA Component was developed under Visual Studio .NET, and C# language. The issue that LOINC codes are not translated in Romanian was surpassed using ICD10 and suggesting a hybrid solution for LOINC codes.

    2. An original architecture and implementation of a medical system that includes 2 obstetrics departments and one laboratory that communicate information using HL7 CDA. The communication is based on Web Services and information is stored from different sources in a database and after that sent to the LabKey server in different formats (Excel, Word, pdf) to support physicians, scientists or statisticians in their research and clinical activity.
       This software was installed and tested on received data from Bega Clinic, Timișoara.
    3. An original Cloud computing architecture and application in healthcare was proposed, and developed. The information systems uploaded on the cloud and tested were for an OGD and Pediatrics department and exchange information in a standardized way using the developed HL7 CDA Component.
- A vast review describing relevant coding systems: ICD10, LOINC, SNOMED discussing the necessity for LOINC and SNOMED codes to be translated in Romanian, as more complex and adequate coding systems for medical activity than the current used ICD10 codes.

Objective 4 - in Chapter 6:

- An analysis based on the real the activities in the Obstetrics-Gynecology Department, and identification of the information and communication needs in support of medical staff and patients related to the important subject of the risk in OGD clinical practice.
- A complex and sound model was created for the real informational workflow in OGD using Business Process Modeling and Notation and UML, from the IT perspective, describing the Enterprise view, the RM-ODP views, according with Generic Component Model. The model is developed using Bizagy software which supports BPMN. For UML modeling was used Star UML support. Related to BPMN, a detailed description of the process was made and for UML, use cases, actors, actions, sequence diagrams were described.
- The very complex OGD IS class diagram was built based on the previous model representing the Information view and the Computational view;
- A demonstrator for OGD IS was created, this representing the platform dependent part of the GCM, the Technologic, and Engineering views; consequently the very complex database was created; this was developed under SQL Server 2008.
- Design and implementation of a complex OGD IS based on the developed model, using Visual Studio 2010.NET, ASP.NET and C#.
- Design and implementation of the Access Control used in OGD IS.

- Design and development of the HL7 CDA and CCD Component for the communication with different medical components (CDA for Pediatrics Department Information System and CCD and CDA for the General Practitioner communication). The HL7 CDA and CCD Components were developed in Visual Studio.Net 2010, using C# language.

Objective 5 - in Chapter 7:

- Modeling a toolbox control functionalities using UML
- Designing the control for ASP.NET toolbox. This can load the tables and fields name of a database to configure the component which is in charge to create XMLs in standardized format, preparing easily any system for interoperability. It can access different databases (SQL Server, Access and Oracle).
- Developing a web custom control for Visual Studio.NET toolbox for ensuring the interoperability between medical information systems; this control can be used only for ASP.NET pages. It is demonstrated in detail how the control can be used for the OGD IS. It is possible to add it to the toolbox and display it in a visual designer with full Properties window support and all the other design-time features of ASP.Net server controls. An important feature is that it is suitable for creating dynamic layout.

Objective 6 - in Chapter 8:

- Defining three metrics to evaluate the interoperability of OGD-IS from a quality point of view, demonstrating the readiness of the OGD-IS to interconnect with a neonatology application and an application assessing the pregnancy risk which I contributed on, together with a team. Standardized communication with the Pediatrics Department Information System was investigated. The results show that the OGD-IS is fully interoperable with other medical information systems.
- Concluding a vast search with selecting and adapting a model of evolution, the LISI model for the OGD IS to find the degree of interoperability readiness of the OGD IS.
- A methodology proposed for Evaluation of the OGD IS regarding the interoperability potential.
- Application of the proposed methodology and interpretation of results for the OGD IS
  The obtained score shows that the healthcare information system for OGD is well ready to communicate to other healthcare information systems

Future directions

Many aspects of the complex subject of interoperability in healthcare information systems were dealt with in this paper. The subject is complex and a lot of work can be further done.

A future direction is the continuity of improving the HL7 CDA and CCD Component related to the issue of LOINC and SNOMED codes that are not translated in Romanian Language.

Other future developments can be made in improving the OGD IS with more functionalities, and improve the communication security.

In the future, connecting the OGD IS with more medical information systems better validations and future improvements can be made.

ANNEX 1

The OGD IS database is described in the following:

The Table Institution (Institutii) is presented in Table A 1.

Table A 1. Table Institution

Column Name	Data Type	Allow Nulls	Description
IDInstitutie	int	no	the field which contains the institution ID
NumeInstitutie	nvarchar	yes	the field which contains the name of the institution

The Table MedicalUnit (UnitateMedicala) is presented in Table A2.

Table A 2. Table MedicalUnit

Column Name	Data Type	Allow Nulls	Description
IDUnitateMedicala	int	no	the field which contains the medical unit ID
IDInstitutie	int	yes	the field which contains the institution ID
UMNume	nvarchar	yes	the field which contains the name of the medical unit
UMAndress	nvarchar	yes	the field which contains the adress of the medical unit
UMTelefon	nvarchar	yes	the field which contains the telephone of the medical unit

The table Departments (Departament) is presented in Table A3.

Table A 3. Table Department

Column Name	Data Type	Allow Nulls	Description
IDDepartament	int	no	the field which contains the departament ID
IDUnitateMedicala	int	yes	the field which contains the medical unit ID
NumeDepartament	nvarchar	yes	the field which contains the name of the departament
TelefonDepartament	nvarchar	yes	the field which contains the name of the departament
SefDepartment	nvarchar	yes	the field which contains the name of the head of the department
SefAsistDepartament	nvarchar	yes	the field which contains the name of the head of the head assistent in the department

The Table PatientLocation (LocatiePacient) is presented in Table A4.

Table A 4. Table PatientLocation

Column Name	Data Type	Allow Nulls	Description
ConsultatieID	int	Yes	the field which contains the consultation ID
LocatiePacientID	int	No	the field which contains the patient location ID
DepartamentID	int	yes	the field which contains the departament ID
Etaj	int	yes	the field which contains the floor of where the patient is
NrSalon	int	yes	the field which contains the number of the salon
NrPat	int	yes	the field which contains the number of the bed

The Table Personal (Personal) is presented in Table A5.

Table A 5. Table Personal

Column Name	Data Type	Allow Nulls	Description
ID	int	No	the field which contains the personal ID
NumePersonal	nvarchar	Yes	the field which contains the name of the person
PrenumePersonal	nvarchar	yes	the field which contains the surname of the person
Parafa	int	yes	the field which contains the seal number
Specialitate	nvarchar	yes	the field which contains the specialization
Telefon	nvarchar	yes	the field which contains the telephone number
Email	nvarchar	yes	the field which contains the email

The Table Insurance (Asigurare) is presented in Table A6.

Table A 6. Table Insurance

Column Name	Data Type	Allow Nulls	Description
ConsultatieID	int	yes	the field which contains the consultation ID
AsigurareID	int	no	the field which contains the insurance ID
CNAS	nvarchar	yes	the field which contains that the patient is insured or not
AsigurareVoluntara	nvarchar	yes	the field which contains that the patient is voluntary insured
TipAsigurare	nvarchar	yes	the field which contains the insurance

			type
Eurocard	nvarchar	yes	the field which contains Eurocard
AcordInternational	nvarchar	yes	the field which contains the international accord
TipCNAS	nvarchar	yes	the field which contains the insurance type
dataAsigurarii	nvarchar	yes	the field which contains the Insurance Type
dataAdaugarii	nvarchar	yes	the field which contains when was added

The Table Transfers (Transferuri) is presented in Table A7.

Table A 7. Table Transfers

Column Name	Data Type	Allow Nulls	Description
ConsultatieID	int	yes	the field which contains the consultation ID
DepartamentID	int	yes	the field which contains the department ID
Etaj	int	yes	the field which contains the floor number
NrSalon	int	yes	the field which contains the number of the salon
NrPat	int	yes	the field which contains the number of the bed
TransferID	int	no	the field which contains the transfer ID
DataIntrarii	nvarchar	yes	the field which contains the enter date
DataPlecarii	nvarchar	yes	the field which contains the leaving date
NrZile	int	yes	the field which contains the number of the days
LocatieActiva	nvarchar	yes	the field which contains the active location
DataTransferului	nchar	yes	the field which contains the transfer date

The table Examination (Examinari) is presented in Table A8.

Table A 8. Table Examination

Column Name	Data Type	Allow Nulls	Description
ConsultatieID	int	yes	the field which contains the consultation ID
ExaminareID	int	no	the field which contains the examination ID
Procedura	nvarchar	yes	the field which contains the procedure
Cantitate	int	yes	the field which contains the quantity
ID	int	yes	the field which contains the personal ID
Data	nvarchar	yes	the field which contains the date

Camera	int	yes	the field which contains the room
Observatii	nvarchar	yes	the field which contains the observations
ContID	int	yes	the field which contains the cont ID

The table Patient (Pacient) is presented in Table A9.

Table A 9. Table Patient

Column Name	Data Type	Allow Nulls	Description
PatientID	int	no	the field which contains the patient ID
CNP	nchar	yes	the field which contains the unique patient ID
Nume	nvarchar	yes	the field which contains the name of the patient
Surname	nvarchar	yes	the field which contains the surname of the patient
Gender	nvarchar	yes	the field which contains the gender of the patient
DataNasterii	nvarchar	yes	the field which contains the birthdate of the patient
Adresa	nvarchar	yes	the field which contains the address of the patient
Orasul	nvarchar	yes	the field which contains the city of the patient
Tara	nvarchar	yes	the field which contains the country of the patient
Buletin	nvarchar	yes	the field which contains the identity card of the patient
Cetatenie	nvarchar	yes	the field which contains the citizenship of the patient
Greutate	real	yes	the field which contains the weight of the patient
Inaltime	real	yes	the field which contains the height of the patient
GrupaSanguina	nvarchar	yes	the field which contains the blood goup of the patient
Rh	nvarchar	yes	the field which contains the patient Rh
DataAdaugarii	nvarchar	yes	the fied which contains the date when the information was added
Telefon	nvarchar	yes	the field which contains the patient telefon number
Ocupatie	nvarchar	yes	the field which contains the occupation of the patient
LoculMunca	nvarchar	yes	the field which contains the patient occupation place
Observatii	nvarchar	yes	the field which contains additional information about the patient
Asigurare	nvarchar	yes	the field which contains the insurance ID

The Table Consultation (Consultatie) is presented in Table A10.

Table A 10. Table Consultation

Column Name	Data Type	Allow Nulls	Description
IDPacient	int	no	the field which contains the Patient ID
ConsultatieID	int	yes	the field which contains the Consultation ID
An	int	yes	the field which contains the year of the consultation
IDDepartament	int	yes	the field which contains the department ID
IDLocatiePacient	int	yes	the field which contains the location of the patient in the hospital ID
DataInternarii	nvarchar	yes	the field which contains the admission date
DataExternarii	nvarchar	yes	the field which contains the discharge date
NrSpitalizare	int	yes	the field which contains the number of the days the patient was in hospital
ConcediuMed	int	yes	the field which contains the number of medical holiday
IDInternare	int	yes	the field which contains the admission ID
DataAdaugarii	int	yes	the field which contains the date when the consultation was added
IDCont	int	yes	the field which contains the cont ID
Sendby	nvarchar	yes	the field which contains the name of who send the patient
IDExternare	int	yes	the field which contains the discharge ID
CauzaInternarii	nvarchar	yes	the field which contains the reason why the patient is in the hospital
MedicatieID	int	yes	the field which contains the medication ID
IstoricMedical	nvarchar	yes	the field which contains the patient medical history

The Table Account (Cont) is presented in Table A11.

Table A 11. Table Account

Column Name	Data Type	Allow Nulls	Description
IDCont	int	no	the field which contains the Cont ID
Username	nvarchar	yes	the field which contains the username of the person
Password	nvarchar	yes	the field which contains the password
Nume	nvarchar	yes	the field which contains the name of the person
Prenume	nvarchar	yes	the field which contains the surname of the person
Rol	nvarchar	yes	the field which contains the role in the OGD IS
dataAdaugarii	nvarchar	yes	the field which contains the date when the consultation was added

The Admission (Internare) table is presented in Table A12.

Table A 12. Table Admission

Column Name	Data Type	Allow Nulls	Description
InternareID	int	no	the field which contains the admission ID
TipulInternarii	nvarchar	yes	the field which contains the type of the admission
CriteriulInternarii	nvarchar	yes	the field which contains the criteria of the admission

The Discharge (Externare) table is presented in Table A13.

Table A 13. Table Discharge

Column Name	Data Type	Allow Nulls	Description
ExternareID	int	no	the field which contains the discharge ID
DescriereaStarii	nvarchar	yes	the field which contains the described status
DescriereaTipuluiExternarii	nvarchar	yes	the field which contains the discharge description type

The OtherInformation (AlteInformatii) table is presented in Table A14.

Table A 14. Table OtherInformation

Column Name	Data Type	Allow Nulls	Description
PacientID	int	no	the field which contains the patient ID
Alergii	nvarchar	yes	the field which contains what allergies has the patient
IstoricMedical	nvarchar	yes	the field which contains the medical history of the patient
FizologicPatologic	nvarchar	yes	the field which contains PhysiologicalPathological information

The AnatomoPathologicalEx (ExAnatomoPatologic) table is presented in Table A15.

Table A 15. Table OtherInformation

Column Name	Data Type	Allow Nulls	Description
ConsultatieID	int	yes	the field which contains the Consultation ID
AnatomoPatologicalDescriere	nvarchar	yes	the field which contains the information about AnatomoPathological
dataAdaugarii	nvarchar	yes	the field which contains the date when the information was added
ContID	int	yes	the field which contains the account ID
AnatomoPatologicalID	int	no	the field which contains the AnatomoPathological ID

The CardiologicalEx (ExCardiologic) table is presented in Table A16.

Table A 16. Table CardiologicalEx

Column Name	Data Type	Allow Nulls	Description
ConsultatieID	int	yes	the field which contains the Consultation ID
DescriereCardiologica	nvarchar	yes	the field which contains the information about cardiological condition
dataAdaugarii	nvarchar	yes	the field which contains the date when the information was added
ContID	int	yes	the field which contains the account ID
CardiologicID	int	no	the field which contains the cardiological ID

The EchographicEx (ExEcografic) table is presented in A17.

Table A 17. Table EchographicEx

Column Name	Data Type	Allow Nulls	Description
ConsultatieID	int	yes	the field which contains the Consultation ID
DescriereEcografica	nvarchar	yes	the field which contains the information about ecography
ImagineEcografica	image	yes	the field which contains the ecographic images
dataAdaugarii	nvarchar	yes	the field which contains the date when the information was added
ContID	int	yes	the field which contains the account ID
EcografieID	int	no	the field which contains the ecographyc ID

The RadiologyEx (ExRadiografie) table is presented in Table A18.

Table A 18. Table RadiologyEx

Column Name	Data Type	Allow Nulls	Description
ConsultatieID	int	yes	the field which contains the Consultation ID
DescriereRadiografie	nvarchar	yes	the field which contains the information about radiology
Imagineradiografie	image	yes	the field which contains the radiology images
dataAdaugarii	nvarchar	yes	the field which contains the date when the information was added
ContID	int	yes	the field which contains the account ID
RadiografieID	int	no	the field which contains the radiology ID

The DigestiveEx (ExDigestive) table is presented in Table A19.
Table A 19. Table DigestiveEx

Column Name	Data Type	Allow Nulls	Description
ConsultatieID	int	yes	the field which contains the Consultation ID
DescriereDigestive	nvarchar	yes	the field which contains the information about digestive

Liver	nvarchar	yes	the field which contains information about the liver
CaiBiliare	nvarchar	yes	the field which contains billary information
Splina	nvarchar	yes	the filed which contain information about the spleen
dataAdaugarii	nvarchar	yes	the field which contains the date when the information was added
ContID	int	yes	the field which contains the account ID
DigestiveID	int	no	the field which contains the digestive ID

The UroGenitalEx (ExUroGenital) table is presented in Table A20.

Table A 20. Table UroGenitalEx

Column Name	Data Type	Allow Nulls	Description
ConsultatieID	int	yes	the field which contains the Consultation ID
UroDescriere	nvarchar	yes	the field which contains the information about urological
GenitalDescriere	nvarchar	yes	the field which contains information about genital
dataAdaugarii	nvarchar	yes	the field which contains the date when the information was added
ContID	int	yes	the field which contains the account ID
UroGenitalID	int	no	the field which contains the UroGenital ID

The SystemEx (System) table is presented in Table A21.

Table A 21. Table SystemEx

Column Name	Data Type	Allow Nulls	Description
ConsultatieID	int	yes	the field which contains the Consultation ID
SistNervosDescriere	nvarchar	yes	the field which contains the information about nervous system
OrganeSimtDescriere	nvarchar	yes	the field which contains information about sens organs system
dataAdaugarii	nvarchar	yes	the field which contains the date when the information was added
ContID	int	yes	the field which contains the account ID
SystemID	int	no	the field which contains the system ID

The Diagnostics (Diagnostice) table is presented in Table A22.

Table A 22. Table Diagnostics

Column Name	Data Type	Allow Nulls	Description
ConsultatieID	int	yes	the field which contains the Consultation ID
ICDCode	nt	yes	the field which contains the information about ICD Codes
TipDiagnosticeDescriere	nvarchar	yes	the field which contains information about

			diagnostics types
DiagnosticeID	nt	no	the field which contains the diagnostics ID
dataAdaugarii	int	yes	the field which contains the date when the information was added
ContID	nvarchar	yes	the field which contains the account ID

The OncologyEx (ExOncologic) table is presented in Table A23.

Table A 23. Table OncologyEx

Column Name	Data Type	Allow Nulls	Description
ConsultatieID	int	yes	the field which contains the Consultation ID
OncologicDescription	nvarchar	yes	the field which contains the information about oncologic situation
dataAdaugarii	nvarchar	yes	the field which contains the date when the information was added
ContID	nt	yes	the field which contains the account ID
OncologicID	int	no	the field contains the oncologyc ID

The Epicrisis (Epicriza) table is presented in Table A24.

Table A 24. Table Epicrisis

Column Name	Data Type	Allow Nulls	Description
ConsultatieID	int	yes	the field which contains the Consultation ID
DescriereEpicriza	nvarchar	yes	the field which contains the information about epicriza
dataAdaugarii	nvarchar	yes	the field which contains the date when the information was added
ContID	nt	yes	the field which contains the account ID
EpicrizaID	int	no	the field contains the epicrisis ID

The ObiectivEx (ExObiectiv) table is presented in Table A25.

Table A 25. Table ObiectivEx

Column Name	Data Type	Allow Nulls	Description
ConsultatieID	int	yes	the field which contains the Consultation ID
Stare generala	nvarchar	yes	the field which contains the information about general status
Talie	nvarchar	yes	the field which contains the information about size
Greutate	int	yes	the field which contains the patient weight
StareNutritie	nvarchar	yes	the field which contains the information about nutrition
Facies	nvarchar	yes	the field which contains the information about face
TegumentMucoase	nvarchar	yes	the field which contains the information about skin mucous
TesutConjunctiv	nvarchar	yes	the field which contains the information about aqueous tissue

Sanul	nvarchar	yes	the field which contains the information about the breast status
GanglioniLimfatici	nvarchar	yes	field which contains the information about Limph nodes
Muschi	nvarchar	yes	the field which contains the information about muscle
SistOsteoarticular	nvarchar	yes	field which contains the information about OsteoArticular system
dataAdaugarii	nvarchar	yes	the field which contains the date when the information was added
ContID	int	yes	the field which contains the account ID
ObiectivID	int	no	the field contains the obiectiv ID

The ChirurgicalIntervention (InterventieChirurgicala) table is presented in Table A26.

Table A 26. Table ChirurgicalIntervention

Column Name	Data Type	Allow Nulls	Description
ConsultatieID	int	no	the field which contains the Consultation ID
IDInterventie	int	no	the field which contains the information about interventoion ID
TipInterventie	nvarchar	yes	the field which contains the information about intervention type
Descriere	nvarchar	yes	the field which contains the description of the intervention
Consimtamant	nvarchar	yes	the field which contains the patient consent
MotivRefuz	nvarchar	yes	the field which contains the refusal reason
DoctorPrincipal	nvarchar	yes	the field which contains the name of principal doctor
Doctor2	nvarchar	yes	the field which contains the second doctor name
Doctor3	nvarchar	yes	the field which contains the third name of the doctor
DoctorATI	nvarchar	yes	field which contains the ATI doctor name
Nurse	nvarchar	yes	the field which contains the nurse name
dataAdaugarii	nvarchar	yes	the field which contains the date when the information was added
ContID	int	yes	the field which contains the account ID
ExamCitologic	nvarchar	yes	the field which contains the information about cytological exam
ExamExtemporaneu	nvarchar	yes	the field which contains the information about extemporaneously exam
ExanHistoPatologic	nvarchar	yes	the field which contains the information about histopatological exam
MorfologicCode	nvarchar	yes	the field which contains the information about morphological code
TehnicaInterventiei	nvarchar	yes	the field which contains the information about technical intervention

The LaboratoryResult (RezultateLaborator) table is presented in A27.

Table A 27. Table LaboratoryResult

Column Name	Data Type	Allow Nulls	Description
ConsultatieID	int	yes	the field which contains the Consultation ID
DescriereLaborator	nvarchar	yes	the field which contains the information about laboratory result
Hemograma	int	yes	the field which contains the hemogram values
ESR	int	yes	the field which contains the ESR values
AnalizaUrina	int	yes	the field which contains the Urinalysis
RDW	int	yes	the field which contains the RDW values
ProbeDisproteinemie	nvarchar	yes	the field which contains the dispoteinemia evidence
Glicemia	int	yes	the field which contains the glicemia values
UreeSer	int	yes	the field which contains the uree ser values
dataAdaugarii	nvarchar	yes	the field which contains the date when the information was added
ContID	int	yes	the field which contains the account ID
LaboratorID	int	no	the field contains the laboratory result ID

The SpecialityEx (ExSpecialitate) table is presented in A28.

Table A 28. Table SpecialityEx

Column Name	Data Type	Allow Nulls	Description
ConsultatieID	int	yes	the field which contains the Consultation ID
DescriereSpecialitate	nvarchar	yes	the field which contains the information about speciality
dataAdaugarii	nvarchar	yes	the field which contains the date when the information was added
ContID	int	yes	the field which contains the account ID
SpecialitateID	int	no	the field contains the speciality ID

The RespiratoryEx (ExRespirator) table is presented in Table A29.

Table A 29. Table ExRespiratory

Column Name	Data Type	Allow Nulls	Description
ConsultatieID	int	yes	the field which contains the Consultation ID
RespiratieDescriere	nvarchar	yes	the field which contains the information about respiratory system
dataAdaugarii	nvarchar	yes	the field which contains the date when the information was added
ContID	int	yes	the field which contains the account ID
RespiratieID	int	no	the field contains the respiratory exam ID

The DeathInformation (InformatiiDeces) table is presented in Table A30.

Table A 30. Table DeathInformation

Column Name	Data Type	Allow Nulls	Description
ConsultatieID	int	yes	the field which contains the Consultation ID
Decedat	bit	yes	the field which contains the information that the patient is death
DecesID	int	no	the field which contains the deathID
DataDeces	nvarchar	yes	the field which contains the date of death
CauzaDirecta	nvarchar	yes	the field which contains the information direct cause
CauzaAntecedenta	nvarchar	yes	the field which contains the information abour antecedent cause
StariMorbideInitiale	nvarchar	yes	the field which contains the information initial status
StariMorbideImportante	nvarchar	yes	the field which contains the information important status
MacroscopieAutopsie	nvarchar	yes	the field which contains the information about macroscophic authopsy
MicroscopieAutopsie	nvarchar	yes	the field which contains the information about microsophyc authopsy
DeathDate	nvarchar	yes	the field which contains the information about date of patient death
ContID	int	yes	the field which contains the account ID

The ObstetricsAntecedents (AntecedenteObstetrica) table is presented in Table A31.

Table A 31. Table ObstetricsAntecedents

Column Name	Data Type	Allow Nulls	Description
ConsultatieID	int	yes	the field which contains the Consultation ID
IntrerupereSarcina	nvarchar	yes	the field which contains the information about pregnancy intrerruption
DataIntreruperii	nvarchar	yes	the field which contains the information about intrerruption date
DataInitiala	nvarchar	yes	the field which contains the initial date
Sarcina	nvarchar	yes	the field which contains information about pregnancy
Nasterea	nvarchar	yes	the field which contains information about birth
Copil	nvarchar	yes	the field which contains information about baby
DataAdaugarii	nvarchar	yes	the field which contains the date when the information was added
ContID	int	yes	the field which contains the account ID
AntecedenteObstetricaID	int	no	the field contains the obstetrics antecedent ID

The ObstetricsResults (RezultateObstetrica) table is presented in Table A32.

Table A 32.Table ObstetricsResults

Column Name	Data Type	Allow Nulls	Description
ConsultatieID	int	yes	the field which contains the Consultation ID
TipulNasterii	nvarchar	yes	the field which contains information for birth type
GreutateCopil	int	yes	the field which contains the value of the baby weight
Apgar	int	yes	the field which contains the value of the Apgar
Asistenta	nvarchar	yes	the field which contains information about the assistance
TipulExpulzieiPlacentei	nvarchar	yes	the field which contains information about placental expulzion type
CaracteristicileGreutatii	nvarchar	yes	the field which contains information about weight features
Supervizat	nvarchar	yes	the field which contains information about the person who is supervized
TimpDilatareNastere	int	yes	the field which contains the time of the birth dilatation
TimpDilatarePlacenta	int	yes	the field which contains the time of the placenta dilatation
Cord	nvarchar	yes	the field which contains information about cord
Sangerare	nvarchar	yes	the field which contains information about the blooding
ConditiaTesutuluiMoale	nvarchar	yes	the field which contains information about the condition of the soft tissue
SituatiaPostPartum	nvarchar	yes	the field which contains information about post partum condition
Pulse	int	yes	the field which contains the value of the pulse
Infectie	nvarchar	yes	the fied which contain information if an existed infection
GenCopil	nvarchar	yes	the field which contains the baby gender
Situatie	nvarchar	yes	the field which contains information about the general situation
MetodeResuscitare	nvarchar	yes	the field which contains information about the resuscitation methods
NrInterventiei	int	yes	the field which contains the number of the intervention
Data	nvarchar	yes	the field which contains the date
Operatori	nvarchar	yes	the field which contains the name who performed the intervention
DiagnosticPostoperator	nvarchar	yes	the field which contains information about the post partum diagnostic
TipAnestezie	nvarchar	yes	the field which contains the anesthesia type
DoctorAnestezist	nvarchar	yes	the field which contains the name of the anesthesia doctor
Concluzii	nvarchar	yes	the field which contains the conclusions
ContID	int	yes	the field which contains the account ID
RezultateObstetricaID	int	no	the field contains the obstetrics results ID
ContID	int	yes	the field which contains the account ID

The LaborEvolution (EvolutiaTravaliului) table is presented in Table A33.

Table A 33. Table LaborEvolution

Column Name	Data Type	Allow Nulls	Description
ConsultatieID	int	yes	the field which contains the Consultation ID
CameraIntrare	int	yes	the field which contains the information about the entry room
RupturaMembranelor	nvarchar	yes	the field which contains the information about membrane rupture
DataRupturii	nvarchar	yes	the field which contains the date of the rupture
Cervical	nvarchar	yes	the field which contains information about cervical
AparitiafluiduluiAmiotic	nvarchar	yes	the field which contains information about amiotic liquid appearance
Frecventa	int	yes	the field which contains the frecvence
Durata	int	yes	the field which contains the duration
Tonus	nvarchar	yes	the field which contains information about tonus
MedicatieDurere	nvarchar	yes	the field which contains information about the pain medicamentation
Examinator	nvarchar	yes	the field which contains the name of the examinator
DataAdaugarii	nvarchar	yes	the field which contains the date when the information was added
ContID	int	yes	the field which contains the account ID
EvolutiaTravaliuluiID	int	no	the field contains the obstetrics results ID

The Medication (Medicamente) table is presented in Table A34.

Table A 34. Table Medication

Column Name	Data Type	Allow Nulls	Description
ConsultatieID	int	yes	the field which contains the Consultation ID
NumeComercial	nvarchar	yes	the field which contains the comercial name
DCI	nvarchar	yes	the field which contains the medication prescribed as common international name
FormaFarmaceutica	nvarchar	yes	the field which contains the pharmaceutic form
Cantitate	int	yes	the field which contains the quantity
SubstantaActiva	nvarchar	yes	the field which contains the active substance
AlteIngrediente	nvarchar	yes	the field which contains information about other ingredients
Producator	nvarchar	yes	the field which contains the name of the producer
Tratamente	nvarchar	yes	the field which contains information about treatements
Contraindicatii	nvarchar	yes	the field which contains information about contraindications

IndicatiiVarsta	nvarchar	yes	the field which contains information about age indications
IndicatiiSarcina	nvarchar	yes	the field which contains information about pregnancy indications
Alaptare	nvarchar	yes	the field which contains information about breast feeding indications
IndicatiiAutovehicule	nvarchar	no	the field which contains information about auto indications
Supradosaj	nvarchar	yes	the field which contains information about overdose
EfecteSecundare	nvarchar	yes	the field which contains information about adverse reactions
ContID	int	yes	the field which contains the account ID
DataAdaugarii	nvarchar	yes	the field which contains the date when the information was added
MedicamenteID	int	no	the field contains the medication ID

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