TÉCNICO LISBOA

CODEGOM: A governance model for clinical ontologies

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Resumo

Esta dissertação apresenta o CODEGOM, um modelo de governação para o desenvolvimento e manutenção de ontologias clínicas. O modelo inspira-se no trabalho realizado noutras áreas relacionadas, como Gestão de Projecto, Engenharia de Software e Engenharia das Ontologias. Assenta sobre i) a existência de uma organização que suporte ontologias clínicas e que providencie serviços às comunidades interessadas em conduzir iniciativas de desenvolvimento de ontologias clínicas, e sobre ii) a existência de um grupo de especialistas com todas as competências necessárias para conduzirem o desenvolvimento e suporte de uma ontologia clínica. Em ambiente clínico, a qualidade é fundamental, e a avaliação da qualidade de uma ontologia clínica requer a existência de processos que garantam a qualidade do processo de desenvolvimento da ontologia. A metodologia de desenvolvimento de ontologias clínicas proposta requer uma monitorização continua do processo para satisfazer um conjunto de requisitos e listas de verificação de qualidade definidos para cada etapa. Este trabalho também apresenta um levantamento dos modelos de governação das principais terminologias e classificações clínicas internacionais, incluindo como estas são geridas no Serviço Nacional de Saúde. Para auxiliar na definição e acompanhamento de projectos de desenvolvimento de ontologias clínicas usando o modelo de governação, este trabalho inclui um modelo de um projecto genérico de desenvolvimento de uma ontologia clínica, que consiste num projecto modelo customizável, listas de recursos e listas de verificação de qualidade.

Palavras-chave: Ontologias Clínicas, Modelo de Governação, Interoperabilidade Semântica, Cuidados de Saúde, Centro para as Ontologias Clínicas, Avaliação de Qualidade

Abstract

This thesis presents CODEGOM, a governance model for the development and maintenance of clinical ontologies. The model is inspired by work in related domains, such as Project Management, Software Engineering and Ontology Engineering. It assumes at the start i) an established organization for supporting clinical ontologies providing services to communities interested in carrying out clinical ontology development initiatives, and ii) the availability of a group of experts with all the skills required for carrying out the development and support of a clinical ontology. In clinical settings, quality is paramount, and the assessment of the quality of a clinical ontology requires quality assurance procedures for the ontology development process. The proposed clinical ontology development methodology requires continuous monitoring to satisfy a set of quality requirements and assessment checklists defined for each step. The study also surveys the governance models of major international clinical terminologies and classifications, including how they are managed within the Portuguese National Health System. To assist on the definition and tracking of clinical ontology development projects using the governance model, this work includes a clinical ontology development template consisting of customizable project templates, resource lists and quality assessment checklists.

Keywords: Clinical Ontologies, Governance Model, Semantic Interoperability, Healthcare, National Release Center, Quality Assessment

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Table of Acronyms

Acronyms	Definition
ACES	Agrupamento de Centros de Saúde (Primary Care Centers Grouping)
ACSS	Administração Central do Sistema de Saúde (Portuguese Health System's Central Administration)
AMT	Australian Medicines Terminology
APMGF	Associação Portuguesa de Medicina Geral e Familiar (Portuguese Association of General Practitioners and Family Physicians)
ARS	Administração Regional de Saúde (Portuguese Regional Health Administration)
ATC/DDD	Anatomical Therapeutic Chemical Classification System with Defined Daily Doses
CAIC	Comissão de Acompanhamento da Informatização Clínica (Portuguese Clinical Informatization Monitoring Committee)
CBMI	Center for Biomedical Informatics
CC	Collaborating Centers
CDM	Classificação de Dispositivos Médicos (Classification of Medical Devices)
CEO	Chief Executive Officer
CFT	Classificação Farmacoterapêutica dos Medicamentos (Pharmacotherapeutical Classification of Drugs)
CIC	Comissão para a Informatização Clínica (Portuguese Clinical Informatization Committee)
CIDESI	Centro de Investigação Desenvolvimento em Sistemas de Informação em Enfermagem (Portuguese ICN-Accredited Centre for Information Systems Research and Development)
CIPE	Classificação Internacional para a Prática de Enfermagem
ClaML	Classification Mark-up Language
CMM	Capability Maturity Model
CMS	Centers for Medicare and Medicaid Services
CNPD	Comissão Nacional de Protecção de Dados (Portuguese Data Protection Authority)
COC	Clinical Ontologies Center
CPAL	Catálogo Português de Análises de Laboratório (Portuguese Catalog of Clinical Laboratory Tests)
CPARA	Catálogo Português de Alergias e Reações Adversas (Portuguese Catalog of Allergies and Other Adverse Reactions)
CTC.PT	Centro de Terminologias Clínicas em Portugal (Clinical Terminologies Centre in Portugal)
CTV3	Clinical Terms Version 3

DGS	Direcção Geral da Saúde (Portuguese Directorate-General of Health)
DPS/ACSS	Departamento de Gestão e Financiamento de Prestações de Saúde da ACSS (ACSS's Healthcare Financing Department)
DRG	Diagnostic Related Group
EHR	Electronic Health Record
EPE	Entidade Pública Empresarial (Corporate Public Entity)
ESEP	Escola Superior de Enfermagem do Porto (Porto Nursing School)
FIC	Family of International Classifications
GA	General Assembly
GAFID/OE	Gabinete de Formação, Investigação e Desenvolvimento da Ordem dos Enfermeiros (OE's Training, Research and Development Office)
GCAC	Gabinete de Codificação e Auditoria Clínica (Coding and Clinical Audit Office)
HCDSNS	Historia Clínica Digital del Sistema Nacional de Salud (Spanish National Health System's Digital Health Records Project)
HHS	United States Department of Health and Human Services
HL7	Health Level Seven International
HSCIC	Health & Social Care Information Centre
ICD	International Classification of Diseases
ICD-10	International Classification of Diseases, Tenth Revision
ICD-10-AM	International Classification of Diseases, Tenth Revision, Australian Modification
ICD-10-CA	International Classification of Diseases, Tenth Revision, Canadian Enhancement
ICD-10-CM	International Classification of Diseases, Tenth Revision, Clinical Modification
ICD-10-PCS	International Classification of Diseases, Tenth Revision, Procedure Coding System
ICD-9-CM	International Classification of Diseases, Ninth Revision, Clinical Modification
ICD-O-3	International Classification of Diseases for Oncology, Third Edition
ICF	International Classification of Functioning, Disability and Health
ICHPPC	International Classification of Health Problems in Primary Care
ICIH	International Classification of Health Interventions
ICN	International Council of Nurses
ICNP	International Classification for Nursing Practice
ICPC	International Classification of Primary Care
ICPC-2	International Classification of Primary Care 2
IHTSDO	International Health Terminology Standards Development Organization
INE	Instituto Nacional de Estatística (Statistics Portugal Institute)
INFARMED	Autoridade Nacional do Medicamento e Produtos de Saúde (Portuguese Authority for Drugs and Health Products)
ISO	International Organization for Standardization

KPA	Key Process Areas
LOINC	Logical Observation Identifiers Names and Codes
MRG	Mortality Reference Group
NCBO	National Center for Biomedical Computing
NCHS	United States National Center for Health Statistics
NCTIS	National Clinical Terminology and Information Service
NEHTA	National E-Health Transition Authority
NHS	National Health Service
NLM	United States National Library of Medicine
NRC	National Release Center
OE	Ordem dos Enfermeiros (Portuguese Nurses Board)
OM	Ordem dos Médicos (Portuguese Physicians Board)
OWL	Web Ontology Language
PH3C	Primary Health Care Classification Consortium
PMBOK	Project Management Body of Knowledge
PNS	Plano Nacional de Saúde (Portuguese National Health Plan)
QC	Quality Characteristics
RDF	Resource Description Framework
RELMA	Regenstrief LOINC Mapping Assistant
RF2	Release Format 2
RNCCI	Rede Nacional de Cuidados Continuados Integrados (National Long-term Care Network)
RSG	Revision Steering Group
SNOMED CT	Systematized Nomenclature Of Medicine Clinical Terms
SNOMED RT	SNOMED Reference Terminology
SNOP	Systematized Nomenclature of Pathology
SPAIC	Sociedade Portuguesa de Alergologia e Imunologia Clínica (Portuguese Society of Allergology and Clinical Immunology)
SPICE	Software Process Improvement and Capability Determination
SPMS	Serviços Partilhados do Ministério da Saúde (Portuguese Ministry of Health Shared Services)
TAG	Topic Advisory Group
UKTC	United Kingdom Terminology Centre
UMLS	Unified Medical Language System
UN	United Nations
URC	Update and Revision Committee
USF	Unidade de Saúde Familiar (Family Healthcare Unit)

WBS	Work Breakdown Structure
WHO	World Health Organization
WICC	WONCA's International Classification Committee
WONCA	World Organization of Family Doctors (World Organization of National Colleges, Academies and Academic Associations of General Practitioners/Family Physicians)
XML	Extensible Markup Language

Chapter 1

Introduction

Over the last five decades the amount of data and knowledge produced by scientists and healthcare professionals has been continuously increasing worldwide. They have been using the processing power and storage of computers to efficiently store, manage and retrieve such amounts of information. However, the major challenge is to store this information in a way that computers are able to automatically reason about it, making the most out of the information available. Computers must be able to store information as knowledge and process it, thus creating more knowledge (Spear, 2006).

Particularly in healthcare, massive amounts of information and data are produced every moment by clinicians, nurses and other sources. Nowadays, these data are introduced and stored into computers, namely into electronic health records (EHRs) which are being implemented worldwide and have undergone significant improvements in the last two decades (Tripathi, 2012). According to Park and Hardiker (2009), some of this information is still introduced using natural language, also called free text. This information is meaningless to the computer unless it is captured in a structured and systematic form so that it can be machine readable.

The goal is that different systems may communicate unambiguously with one another, thus reducing clinical error resulting from misinterpretation or lack of shared information. Interoperability between different systems makes it possible to share and exchange information, supporting clinical research, healthcare management and enhancing healthcare provision nationwide and cross boarders. In order to attempt to standardize the capture and representation of this information, clinical terminologies and classifications have been developed and implemented in healthcare provision.

Clinical terminologies and classifications are Knowledge Representation structures. A clinical terminology consists of a logical semantic model where a set of clinical concepts (ideas) and relationships between them are defined. Several clinical terminologies have been developed for different purposes, domains, and degrees of granularity. They are commonly used to standardize information input into clinical databases. On the other hand, a clinical classification is a taxonomy of terms or concepts, where its elements are organized into a hierarchical structure. These structures are commonly used for statistical purposes, whether they are administrative, research, or public health purposes.

In Portugal, several studies report an increase of clinical error and risk when providing healthcare,

due to the lack of clear and timely information. The Ministério da Saúde (2013*b*) intends to promote the improvement of electronic health records and their sharing at national and international level as key factors for an effective, efficient and modern health system. In 2012, the Portuguese Ministry of Health created the Comissão para a Informatização Clínica (CIC, Clinical Informatization Committee), which identified several gaps in clinical documentation within the institutions of the Portuguese National Health Service (NHS). By 2013, the use of international coding systems to classify diseases was not yet a common practice, except for codification for funding purposes. However, the use of clinical coding systems can contribute to mitigate data interoperability issues and to facilitate future epidemiological studies. It is necessary to increase the quality and quantity of the information available on clinical electronic records in the Portuguese NHS in a structured and standardized way.

Portuguese healthcare professionals have been using clinical terminologies and classifications. Some examples are the International Classification of Diseases (ICD), the International Classification of Primary Care 2 (ICPC-2), the International Classification for Nursing Practice (ICNP) and the Logical Observation Identifiers Names and Codes (LOINC). These terminologies and classifications are governed and maintained by international entities responsible for maintaining and distributing their products. However, it is not clear who are the entities responsible for this tasks nationwide. The information available regarding this matter is scattered and occasionally is not completely transparent. In some cases, the use and maintenance of some of these coding systems are not being appropriately overseen by an approved entity.

In addition, in January 2014 Portugal acquired the license to officially manage and distribute the Systematized Nomenclature Of Medicine Clinical Terms (SNOMED CT) in the country and became a member of the International Health Terminology Standards Development Organization (IHTSDO). IHTSDO is a not-for-profit organization owned and governed by its country members that owns, administers and develops SNOMED CT clinical terminology. As a result, the Portuguese Ministry of Health has the responsibility to coordinate and facilitate all the tasks and responsibilities related to managing, licensing and distributing SNOMED CT in Portugal, operating as a National Release Center (NRC).

Given the coding systems already in use, the uncertainty of how they were being governed in Portugal, and the need to act as an NRC of SNOMED CT, the Portuguese Ministry of Health decided to create the Centro de Terminologias Clínicas em Portugal (CTC.PT, Clinical Terminologies Centre in Portugal). CTC.PT (2015) is an organization operating over an online platform that aims to act not only as a NRC of SNOMED CT, but also as competence center to normalize and orchestrate the use of clinical terminologies, classifications and other standards for clinical information registration in national territory. Also, it intends to support the introduction of good practices that encourage the sharing of such information, thereby improving the health care provided to citizenss.

At the start of the development of this dissertation, the CTC.PT was in an early stage of deployment. One missing critical component was a governance model to guide, provide quality assurance and support the development and maintenance of clinical terminologies and classifications.

1.1 Goals

The main goal of this work was to develop a proposal of a governance model for the development and maintenance of clinical terminologies and classifications. A governance model describes i) the structure behind a process and the responsibilities associated with that structure, ii) the development methodology for the process, and iii) the monitoring activities which provide quality assurance. The proposal was designed to be adopted by a Clinical Ontologies Center (COC) — a national organization whose main responsibility is to support the creation, management and deployment of clinical ontologies at national level — and by parties interested in developing and managing these coding systems. The governance model was developed to address the following requirements:

- Define a COC as a national body for clinical terminologies and classifications, thus normalizing and supporting their development and deployment at national level. It supports the development of new clinical ontology projects and can also operate as an NRC of international clinical ontologies;
- Provide a basis methodology to carry out clinical terminologies or classifications development projects. Such projects comprise the creation process of the clinical coding system itself and the identification of the required services to support its continuous deployment and improvement (life cycle management);

Nowadays, Knowledge Representation structures, such as clinical terminologies and classifications, are growing and evolving into more complex and consistent semantic structures, getting closer to the logical models that characterize strong ontologies (Obrst, 2009). According to Gruber (1995), in Information Science an ontology may be defined as an explicit and formal specification of conceptualization. It describes the concepts and relationships of a specific domain, thus constraining a semantic structure of the domain. Within the scope of this work, the expression *clinical ontologies* is used as a broad term which comprises these coding systems.

1.2 Contributions

The work developed lead to the following results:

- A governance model named CODEGOM (Clinical Ontology DEvelopment GOvernance Model). CODEGOM constitutes a starting point for any group or organization intending to carry out a clinical ontology development project. It comprises a methodology which presents a set of development phases and monitoring activities which constitute a clinical ontology development project. The model positions CTC.PT as the Portuguese COC and supports the development and dissemination of clinical ontologies in the country;
- Support material to assist the implementation of a clinical ontology development project following the proposed methodology. This work provides a set of templates to support project management tasks, which include project templates developed in a project management software and a set of quality assessment checklists to be verified at each phase of the development process. The set of

editable files that constitute the project templates are available for download and may be adapted to the scope of a specific clinical ontology development project;

An additional result is a survey of the use of clinical ontologies in Portugal. The survey concerns international clinical ontologies that are used in Portugal and it also addresses some simple national clinical classifications. These national classifications focus on specific clinical domains, identified as priorities by the Portuguese Ministry of Health.

1.3 Methodology

The development of the CODEGOM governance model entailed the following steps:

- Survey the major clinical ontologies used at international level. The survey addressed the major stakeholders of the ontologies and how their life cycle is managed and assured by those stakeholders. Namely, it focused on licensing distribuition, updating and review processes, translation processes, mapping processes and user feedback management;
- Survey foreign national organizations for clinical ontologies to understand how they operate and which services they provide to support the development and deployment of clinical ontologies in their countries;
- Collect data on how clinical ontologies were being used and managed in Portugal. I identified which national organizations were responsible for governing the use of international clinical ontologies locally and how this process was carried out. National clinical classifications were also address at this stage;
- Conduct a literature review on several related fields such as Knowledge Representation, Project Management, Software Engineering and Ontology Engineering. I identified the best practices in these fields as research for developing CODEGOM. Namely, this stage addressed some Project Management processes and Software Process Improvement models and standards.
- Identify key features and requirements of CODEGOM. Determine which services were required to assure the life cycle of a clinical ontology and which were the main phases and activities that a clinical ontology development project should comprise to assure its quality.
- Develop a proposal of the CODEGOM governance model.

1.4 Structure

This dissertation is organized as follows:

Chapter 2 introduces some concepts that are relevant to understanding the context of this dissertation, including a literature review on Knowledge Representation, Project Management, Software Engineering and Ontology Engineering. It introduces ontologies within the field of Information Science. In addition, this chapter introduces Project Management concepts;

Chapter 3 presents a comprehensive review on some of the most widely used international clinical ontologies regarding their governance and life cycle management. It includes a brief review of foreign national organizations for clinical ontologies describing their structure and the services they provide. This chapter also surveys the available mappings between these international clinical ontologies. In addition, it presents how these international clinical ontologies and some national clinical classifications are used within the Portuguese NHS and how the are governed;

Chapter 4 introduces CODEGOM, the Clinical Ontology DEvelopment GOvernance Model. It adresses each development phase and monitoring activity that the proposed model comprises;

Chapter 5 presents the main conclusions of this work, summarizing the contributions, limitations and future prospects for continued development.

Chapter 2

Software and Knowledge Engineering

This chapter introduces some relevant concepts to understand the work developed in this master's thesis. Section 2.1 addresses the Knowledge Representation field and it introduces ontologies within the field of Information Sciences. Section 2.2 reviews some aspects of the Software Engineering field, given the logical nature of ontologies as software artifacts. It defines projects, processes and process improvement. Section 2.3 addresses the growing Ontology Engineering field and introduces the basic components of an ontology.

2.1 Knowledge Representation

Any given language, whether it is a spoken language or a programming language, may be broken down into its semantics and syntax. Semantics addresses the study of meaning while syntax concerns the structure of the language (Obrst, 2009).

Knowledge Representation is defined as a field of artificial intelligence with focus on representing information in a way that computers can use in order to achieve complex tasks (HL7, 2014). To make this possible, information must be registered in a structured and systematic manner, allowing the computers to understand the exact meaning of each piece of information and how it can relate to others.

This is where ontologies come in as a solution. Historically, Ontology is a branch of philosophy which deals with the study of reality. It seeks to understand which entities exist and what are the relationships that each entity may have with the others. According to Gruber (1995), in Information Science an ontology may be defined as an explicit and formal specification of conceptualization. This means that an ontology is a description of the concepts and relationships that exist in a domain of discourse (specific subject area or area of knowledge), thus constraining a semantic structure of part of a domain through implicit knowledge (axioms). This description must be explicit and formal so that it may be unambiguous and computer processable (Obitko, 2007).

Obrst (2009) considers that this definition corresponds to a high-end ontology within an ontology spectrum. The author refers to this sort of ontologies as Logical Models (strong ontologies). The spectrum presents a range of semantic models in increasing order of semantic expressiveness. High-end

ontologies present a more complex structure. Some of these models concern terms semantics while others focus on concepts semantics. A concept may be defined as an idea or entity in the mental or knowledge representation model. On the other hand, terms are natural language words or phrases that name concepts and their underlying meaning.

Taxonomies are located on the low-end of the spectrum. These semantic models consist of a set of elements (terms or concepts) organized into a hierarchical structure. Strong taxonomies have its elements linked by parent-child relationships with consistent semantics (generalization/specialization relationships). This model is ideal to define classifications, as it enables the elements to be grouped into classes with the desired degree of granularity.

Thesauri consist of a controlled vocabulary (terms) and are located around the middle of the spectrum. A controlled vocabulary is an approved set of terms limited to those used in the specific environment to which it was developed for (HL7, 2014). This set of terms is structured in a way that establishes equivalence (synonymous terms), homographic (homonym terms), hierarchical, and associative (related terms) relationships among its terms. Also according to Obrst (2009), the hierarchical relationships may be seen as a backbone term taxonomy.

A thesaurus is sufficient when there is no need to define the concepts of the model, but only the terms that refer to those concepts. However, if there is the need to define properties, attributes and values, relationships and constraints on concepts, other models should be used. In such cases, a conceptual model (weak ontology) or a logical theory (strong ontology) based on axioms are the indicated models to apply. Only conceptual models and logical theories allow semantic interoperability (ability of different systems to share data unambiguously). Logical models designed for clinical purposes are often referred to as clinical terminologies.

2.2 Software Engineering

Software Engineering may be defined as a sub-field of engineering which focuses on the systematic design, development and maintenance of software and the management of the underlying processes. Software engineering aims to produce software that meets specific requirements and specifications (Mills, 1980). Given the logical nature of ontologies, it is possible to retrieve significant knowledge from Software Engineering to be transposed and applied into the field of ontology engineering. Subsection 2.2.1 describes what a project is and what its management requires. Subsection 2.2.2 focuses on processes and on the importance of establishing governance models to define them. Finally, subsection 2.2.3 addresses the basics of process improvement methodologies.

2.2.1 Projects

The terminology used in this dissertation for discussing projects uses the terminology of the Project Management Institute (2013). Theses concepts are detailed below:

- A project is “a temporary endeavor undertaken to create a unique product, service, or result”. Al-

though some of the underlying activities of a project may be found in different projects, this does not change the unique characteristics of that project. In turn, project management is “the application of knowledge, skills, tools, and techniques to project activities to meet the project requirements”. Projects are initiated by an entity external to the project usually known as sponsor. The sponsor is responsible for allocating funding and resources to the project. Projects are initiated due to internal business needs or external influences;

- Project management involves several processes, which are grouped into five Process Groups: Initiating; Planning; Executing; Monitoring and Controlling; Closing. Managing a project usually involves identifying requirements, addressing needs and concerns of the various stakeholders and supporting effective communications among stakeholders. Simultaneously, several project constraints are constantly being balanced, such as scope, quality, schedule, budget, resources, and risks;
- Stakeholders are individuals or groups of individuals that may affect or be affected by a decision, activity or outcome of a project. These include all project team members and other interested parties, whether they are internal or external to the organization. Every project has a project manager responsible for leading the team and achieving the project’s objectives. The manager is the link between the strategy and the team. The project team is constituted by the project manager, the project manager staff and all the members who carry out project work but do not necessarily perform management activities;
- Since its start until its closure, a project undergoes a series of phases. This set of phases is called the project’s life cycle. A project may be broken down into any number of phases, whether by partial objectives, intermediate deliverables or results, milestones or financial availability. The five Process Groups described earlier are not project life cycle phases. It fact, is possible that a given project may be completed within a single phase.

2.2.2 Processes

Zahran (1998) defined process as “a sequence of steps performed for a given purpose, for example the software development process”, according to the IEEE-STD-610 (IEEE Standard Glossary of Software Engineering Terminology). The same process may be used as a basis to conduct multiple projects with similar goals. According to the Project Management Institute (2013), a process is defined by its inputs, the tools and techniques that can be applied, and the resulting outputs. Project processes may be separated into two major categories:

Project management processes: processes that ensure the effective flow of the project during its life cycle. There are 47 project management processes grouped into 10 Knowledge Areas. A Knowledge Area represents a set of activities that constitute a project management field/area of specialization. The Knowledge Areas are: Project Integration Management, Project Scope Management, Project Time Management, Project Cost Management, Project Quality Management, Project Human Resource Management, Project Communications Management, Project Risk Management,

Project Procurement Management and Project Stakeholder Management.

Product-oriented processes: processes that specify and create the actual project's product or result. These are typically defined by the project's life cycle.

The creation and documentation of a governance model is a critical step for the definition of processes within an organization. According to Gardler and Hanganu (2015) both structural information and technical management processes should be documented. A governance model describes the following:

- The structure of the organization behind the process and the responsibilities associated with each component of that structure;
- The development methodology, including the decision making process;
- The monitoring and quality assurance processes;
- The rules for the general community to participate in the process and how they may contribute to the process.

A governance model should state the process's goals, stages and tasks. It should also define the roles and responsibilities underlying the process. The efficiency and transparency of the decision making process, contribution process and quality assurance process are fundamental to the overall process's sustainability and acceptance.

However, a process is more than documented procedures. An effective process environment includes the following (Zahran, 1998):

Process definition which describes the procedures and activities;

Process training that ensures that the people who perform process procedures and activities have the appropriate knowledge;

Process monitoring and enforcement to guarantee that process activities and procedures are performed according to the documented process and to assure that the goal are accomplished.

Processes should be internalized by the people who perform process activities and institutionalized within the organization by being enforced. Improved and more mature processes lead to higher discipline, capability and predictability of results. Process focus and process improvement seek to assure and enhance the quality of the process itself and the quality of its outputs. In fact, quality management concepts are the roots of process improvement and maturity models.

2.2.3 Process Improvement

According to Zahran (1998), in order to provide an effective software process improvement environment, an overall framework should be established. Such framework should comprise the following components:

Process infrastructure: organizational roles and responsibilities, managerial roles and responsibilities and technical facilities and tools in order to support process activities;

Process improvement roadmap: set of defined steps and stages for the improvement of the process infrastructure. The roadmap states what is required to achieve its upper levels;

Process assessment method: method to access and determine the current state of the process infrastructure. The infrastructure is compared against the roadmap in order to determine which areas need to be improved to move up the scale of the improvement roadmap;

Process improvement plan: defined set of activities to improve the infrastructure, according to the assessment results.

The process support infrastructure should be flexible to accommodate projects of different sizes, to accommodate different project/product requirements and to adapt to varying costumer needs and standards requirements. The infrastructure also includes the tools and human resources required to assure all the roles and responsibilities of a process.

There are several software process improvement models and standards. The most popular are the Capability Maturity Model (CMM) and the international standard ISO/IEC 15504, also known as Software Process Improvement and Capability dEtermination (SPICE). These models have many potential users, such as software purchasers (acquirers), software developers (suppliers) and software process auditors and accessors. They may be used as the basis of software process assessments, software process audits, capability evaluations, certification of software subcontractors and self-improvement programs. Organizations without capability of developing software may use these models and standards as a basis to evaluate and qualify their software subcontractors. On the other hand, organizations which do have capability of developing software may use these roadmaps to design their own software processes or to develop a self-assessment method to support a program for software process improvement.

The assessment is the starting point of the process improvement. It is the basis of any process improvement plan. It is fundamental to know the current state of the process in order to know which direction to take to improve it. The assessment cycle may be divided into the following generic phases: Pre-assessment/Pre-planning, Assessment Cycle and Post-assessment/Process Improvement Plan. Figure 2.1 illustrates the generic assessment cycle. The pre-assessment takes place before the decision to carry out an assessment. It aims to understand the business context and goals and to assess if conducting an assessment is feasible. The pre-planning stage takes place after the decision to conduct an assessment and comprises activities such as defining the scope of the assessment, who will be performing it and who will be funding and sponsoring the assessment. The actual assessment cycle may be subdivided into four generic steps:

Planning: Similar to any project plan, the plan should define the activities, resources, timeframes, logistics, milestones and deliverables of the assessment;

Fact gathering: Consists of accessing the current state of the process and practices within the organization. It also involves gathering input from individuals on possible improvement areas;

Fact analysis: Aims to identify strengths and weaknesses by analyzing the facts gathered which depict accurately the current state of the process;

Reporting: Finally, findings and recommendations are summarized and presented back to the sponsor.

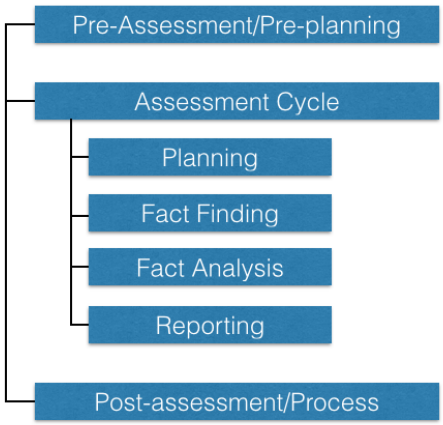

Figure 2.1: Generic phases of the assessment cycle (Zahran, 1998).

The post-assessment phase usually consists of implementing the recommendations through the elaboration of a process improvement plan.

The final stage is the development of a process improvement action plan, which comprises the following steps:

- Prioritize and convert assessment findings into recommendations. The findings which result from the assessment are too general and sometimes their scope goes beyond process improvement;
- Convert recommendations into actions by identifying focus areas and the actions they require;
- Group actions into action plans or work packages by classifying required actions into groups and assigning them to the available resources;
- Allocating these groups of actions (action plans and work packages) to improvement projects and teams. The definition of roles and responsibilities is a key factor when developing these plans. In addition, these roles and responsibilities must be supported by policies and procedures institutionalized by the organization, thus enforcing the actual process improvement activities (Zahran, 1998).

Appendix A contains a summarized description of the CMM and ISO/IEC 15504 standards.

2.3 Ontology Engineering

Ontology Engineering focuses on the design, development and maintenance of ontologies. Software Engineering is considered a mature field, given the existence of widely accepted methodologies within it, such as the IEEE Standard for Developing Software Life Cycle Processes, 1074-1995. However, in the Ontology Engineering field, there is a significant variety of ontologies and methodologies to build and maintain ontologies. Consequently, there is no standard process to be followed and each working group follows the methodology they think is best. It is still a relatively immature field. Ontologies are often developed to be integrated into software and a lot may be learnt with the Software Engineering field. Some studies have presented overviews of several existing methodologies for the creation and

development of ontologies, establishing their strengths and weaknesses (Lopez, 1999; Jones et al., 1998; Noy and McGuinness, 2001).

Lopez (1999) proposes criteria to analyze and compare methodologies among themselves. It establishes some evaluation criteria to support their analysis. The criteria include the following aspects: detail of the methodology; recommendations for knowledge formalization; strategy for building ontologies; strategy for identifying concepts; recommended life cycle; recommended techniques. The paper concludes that none of the analyzed methodologies are fully matured when compared to the IEEE Standard for Developing Software Life Cycle Processes.

As seen in Section 2.1, ontologies must be built based on explicit and formal languages. Ontology languages are formal languages as they enable the coding of a domain's knowledge and rules. Ontology languages are commonly based on either first-order logic or on description logic (Guizzardi, 2007). Some examples of existing ontology languages are the CycL, the Web Ontology Language (OWL) and the Resource Description Framework (RDF).

Usually, some of the basic components of an ontology include:

Instance: also known as individual, it is a ground level concept of the ontology. It does not constitute a class;

Class: a concept that has one or more "child" concepts, due to parent-child (generalization-specialization) relationships;

Attribute: Property or characteristic of a concept;

Relationship: Connection between a pair of concepts.

As in every project, when developing an ontology it is crucial to define the steps and tasks to be performed, the sequence in which they must be carried out and also all the stakeholders involved in the process.

Chapter 3

Clinical Ontologies

The goal of this chapter is to survey on how clinical terminologies and classifications are structured and how they are governed and maintained by their major stakeholders. It also describes how the clinical ontologies are used in Portugal, addressing both international and national clinical ontologies. Appendix B describes the basic structure of the Portuguese public health sector. In the context of this work, clinical ontologies are ontologies which were developed for and are used in healthcare provision by a variety of professionals.

Section 3.1 surveys the governance models of some of the most widely used and known international clinical ontologies in clinical pratice worldwide. Section 3.2 addresses the existing mappings between the clinical ontologies described in Section 3.1. Section 3.3 covers some foreign national organizations for clinical ontologies and how they manage the life cycle of clinical ontologies in their countries. Section 3.4 addresses the use of international clinical ontologies in Portugal while Section 3.5 describes Portuguese clinical classifications and how they are used and governed in the country. Section 3.6 provides some final considerations regarding the governance models described throughout the chapter.

3.1 Clinical Terminologies and Classifications

This section describes five clinical terminologies and classifications and their governance — the Systematized Nomenclature Of Medicine Clinical Terms (SNOMED CT), the International Classification of Diseases (ICD), the International Classification of Primary Care 2 (ICPC-2), the International Classification for Nursing Practice (ICNP) and the Logical Observation Identifiers Names and Codes (LOINC). It follows a framework that consists of the following characteristics:

Overview describes the purpose/goal of the terminologies and classifications, target users, general structure and historical context;

Organization identifies the stakeholders involved in governing the terminologies and classifications and describes the structure of those organizations and how they carry out their work;

Licensing and distribution outlines how these products are distributed to users and describes how the public may request a license to use them. It also provides information on which are the current

versions of the clinical ontologies and expected release dates for future versions;

Release life cycle describes the process that these products undergo between releases in order to improve and enhance their coverage and assure their quality;

Translations describes the guidelines to create national editions of these products in local languages and how to carry out the translation process. It also presents their coverage at international level.

3.1.1 SNOMED CT

Overview

SNOMED CT is a clinical terminology with a broad spectrum of clinical specialties and requirements. SNOMED CT is used to represent clinical information consistently and comprehensively as electronic health information. It supports the development of comprehensive clinical content in electronic health records. The terminology allows to represent clinical phrases captured by the clinician in a way that it is both machine and human readable. SNOMED CT is owned and distributed around the world by the International Health Terminology Standards Development Organisation (IHTSDO, 2015*a*,*b*).

The early days of this terminology date back to 1965 when the College of American Pathologists published the Systematized Nomenclature of Pathology (SNOP). SNOP was a nomenclature to describe morphology and anatomy. It was revised and expanded several times into posterior versions until it was developed into a logic-based clinical terminology called SNOMED Reference Terminology (SNOMED RT), which was released in 2000. SNOMED CT resulted from a three-year project to merge SNOMED RT with the Clinical Terms Version 3 (CTV3). Formerly known as the Read Codes, CTV3 are a coded thesaurus developed by the United Kingdom that have been used by their NHS since 1985. The first version of SNOMED CT was release by January 2002. In 2007, the IHTSDO acquired the intellectual property rights to the SNOMED CT terminology (IHTSDO, 2015*b*; HSCIC, 2015*b*).

According to IHTSDO (2014*e*), SNOMED CT is structured according to a logical model which rules how its major three components interact with each other:

Concepts are clinical ideas and each one has an unique numeric identifier. Concepts are organized into a hierarchy where the top of the hierarchy is called the root concept. The direct child-concepts of the root concept are referred to as the Top Level Concepts and name the main branches of the hierarchy;

Descriptions are the terms that name concepts. A concept may have more than one description where each description is a synonym that describes that same concept. One of this descriptions is selected as the Fully Specified Name and represents the distinct meaning of that concept. Furthermore, in a given language, dialect or context of use one synonym is marked as the ”preferred term” for use by the clinicians, while the remaining synonyms are identified as ”acceptable terms”;

Relationships link a source concept to a destination concept by representing associations between them and they also have an associated unique numeric identifier. Within SNOMED CT there are sub-type relationships and attribute relationships. The first kind consists of parent-child relationships that organize concepts into hierarchies from the most specific concepts (bottom of the

hierarchy) to the more general ones (top of the hierarchy). Each concept may have multiple parent concepts, resulting in a poly-hierarchy. On the other hand, attribute relationships contribute to the definition of the source concept by associating it to another concept. Attribute relationships represent characteristics of the source concept and are defined by the type of relationship and its corresponding value (destination concept). Each type of attribute relationship is limited to a certain domain of source concepts and to a range of destination concepts.

The presented content and logical model enables SNOMED CT to represent not only clinical concepts, but also clinical phrases. Postcoordinated expressions contain more than one SNOMED CT numerical identifier and increase greatly the depth of detail that the terminology allows to represent without having to consider every possible combination of concepts (IHTSDO, 2014*e*).

Reference sets complement the core components of the terminology and they have a unique numeric identifier as well. They support customization and enhancement of SNOMED CT in order to match certain requirements of use. Reference sets are used to represent:

- Language, dialect and context of use preferences concerning preferred and acceptable descriptions (terms);
- Subsets of components for use in a particular context;
- Structuring and ordering of lists and hierarchies to assist the entry of data using the terminology;
- Mappings to or from other coding systems.

The International Edition of SNOMED CT may be adjusted or enhanced by adding Extensions that support national, local or organizational requirements. Some clinical concepts, descriptions or relationships may be relevant in a specific environment of use and not be previously included in the International Edition of SNOMED CT. However, there is the possibility to add content by managing an Extension. In order to create an Extension, an organization must have a Namespace Identifier that distinguishes the components of the International Edition from the ones added by the organization. An Extension may include additional concepts, a translation to a national language or dialect or Reference Sets. A National Extension together with the International Edition is called a National Edition (IHTSDO, 2014*d*).

Organization

SNOMED CT is owned and administrated by the IHTSDO, a not-for-profit organization owned and governed by its country members and owns the rights to SNOMED CT and related terminology standards.

The IHTSDO (2014*e*) has six advisory bodies which provide advice to the Management Board. Four of this bodies are standing committees. Committees members are nominated based on their experience and skills by IHTSDO members and elected by the GA. They meet in person twice a year and often conduct conference calls. The committees are the following:

Content Committee: provides advice regarding the maintenance of SNOMED CT clinical content, structure and related standards;

Implementation and Education Committee: provides advice in order to enable effective and useful implementation of SNOMED CT;

Quality Assurance Committee: provides advice to ensure SNOMED CT quality and that internal and external standards being followed;

Technical Committee: focuses on technical issues such as frameworks and tools regarding the application of SNOMED CT.

The remaining two advisory boards are Forums (IHTSDO, 2015*a*):

Member Forum: promotes consultation at an operational level within the organization and collaboration between the IHTSDO members. Member Forum representatives should be aware of all operational and business components of SNOMED CT's life cycle management and easily communicate with their GA representative. This forum may present its own issues of concern to the Management Board, as well as to be asked by the Board to deliver feedback on specific matters (IHTSDO, 2014*e*,*d*);

Vendor Liaison Forum: enables vendors to provide feedback and input into the development, release and implementation of SNOMED CT.

In addition to these advisory bodies, there are other working groups called Special Interest Groups which are open forums that focus on specific topics regarding core functional areas (Functional groups) or healthcare specialty areas (Professional specialty groups). Functional groups report to one of the standing committees, while Professional groups report to the Healthcare Professional Coordination Group. This group is the seventh advisory body to the Management Board, and it is constituted by the chairs of each Professional specialty group (IHTSDO, 2014*e*,*d*).

The IHTSDO (2015*a*, 2014*e*) currently has 27 member countries. According to its website, "Members of IHTSDO can be either an agency of a national government or other bodies (such as corporations or regional government agencies) endorsed by an appropriate national government authority within the country it represents". To become an IHTSDO member, the payment of a fee based on national wealth is required. In addition, each member must nominate an organization to act as National Release Center (NRC). Within a member's jurisdiction, a NRC operates as an official interface between IHTSDO, national users, and other country members. Its main goal is to promote and support the use of SNOMED CT nationwide.

Licensing and distribution

If a person or organization within a member country wishes to use the International Edition of SNOMED CT, IHTSDO does not charge for its use. However, they must agree to the terms of the SNOMED CT affiliate license agreement (IHTSDO, 2014*f*) and to eventual additional terms issued by the member country, thus becoming Affiliate Licensees. Member countries and their NRCs may act as intermediaries between IHTSDO and affiliates by issuing affiliate licenses themselves and simultaneously providing IHTSDO with information about these licenses.

According to IHTSDO (2014*d*,*e*), members may issue national licenses to IHTSDO affiliates regarding the use of their national extension of SNOMED CT (including translations, additional content or reference sets). However, these licenses do not replace the SNOMED CT affiliate license agreement.

SNOMED CT is distributed to IHTSDO members and affiliates as a set of downloadable files containing the data required to implement the terminology. New versions of SNOMED CT are released in a specific format called Release Format 2 (RF2). This format supports a history tracking mechanism which optimizes installation and updating. Every release of the International Edition contains three types of release:

Full release: contains a full record of past versions of every component of the terminology;

Delta release: contains only what was changed since the last release (created, inactivated and changed components). It is significant smaller when compared to the previous type and it is ideal to update the previous full release to the new full release;

Snapshot release: contains only the most recent version of each component. This type of release is allows a simple installation. However, it lacks the full record of past versions.

Release life cycle

A new version of the International Edition of SNOMED CT is publicly released twice a year on the 31st of January and on the 31st of July.

However, two months before the public release, a beta release is provided to IHTSDO members. Despite the fact that IHTSDO (2014*d*) conducts a quality assurance process on every new version prior to its release, members are given the opportunity to conduct their own quality assurance processes and provide additional feedback to the organization.

One month prior to the public release, the final release files are provided to members. The slightest change to the International Edition of SNOMED CT may have impact on a member's National Extension. Therefore, a reconciliation period is required so that NRCs may update their own National Extensions according to the new version of the International Edition. This allows that NRCs may be ready to distribute their National Editions simultaneously to the public release of the International Edition.

Feedback from users is a key component in the continuous process of developing and enhancing SNOMED CT. NRCs have the responsibility to gather feedback from users regarding errors, limitations and suggestions for changes to the terminology content. Requests concerning the National Edition should be managed locally by the NRC, while the ones concerning the International Edition should be forwarded to the IHTSDO by submitting them through the online system designed for that purpose (SNOMED CT International Request Submission System).

Translations

Extensions may be managed by IHTSDO members (National Extension) and affiliates (Affiliate Extension). In order to develop an Extension, NRCs and affiliates must be issued with a Namespace Identifier by the IHTSDO to identify the origin of each Extension component (IHTSDO, 2014*e*,*d*).

According to IHTSDO (2014*b*), many of the IHTSDO's member countries do not use English as the primary language. Other than the English language, only a Spanish translation is managed within the IHTSDO, as a consequence of the terms of transfer of intelectual property of SNOMED CT to the IHTSDO. However, there are various other translations managed within member countries. Despite being created and managed by a member, the intelectual property of any translation work belongs to the IHTSDO and must be shared with other members.

The IHTSDO provides guidance and documentation to assiste members in the process of translating SNOMED CT. This guidance takes into consideration the IHTSDO quality assurance framework. The organization also provides financial support by reimbursing all the expenses due to the translation of a core or starter set of concepts, which should not be greater than 5000 concepts. In order to receive this monetary support members should prove to the IHTSDO that the work was developed according to the IHTSDO guidance and quality assurance framework. Once the first version of the translation is developed and released, the member must keep working on the translation so that it is updated according to the versions released avery six months. Translations of the International Edition of SNOMED CT do not need to be full translations. A member may choose to translate only a core set of components to be used in a specific context.

Some of the members who created and maintain National Extensions and translations are the following (IHTSDO, 2015*b*):

Australia: National Extension including Australian English;
Canada: National Extension including English and French components;
Denmark: National Extension including a full Danish translation;
Netherlands: National Extension including a Dutch translation;
Spain: National Extension including European Spanish;
Sweden: National Extension including a full Swedish translation;
United Kingdom: National Extension including UK English;
United States: National Extension.

Translation Project Owners should ensure that the guidelines provided by the IHTSDO (2012*b*) are followed and the quality of the translation process and of the translation itself. The assessment of the translation's quality is based on a number of quality characteristics (QCs) and metrics, outlined and defined by the IHTSDO. There are three types of QCs:

Structure QCs concern the management and organization of the translation project;
Process QCs concern the activities that take place during the actual translation process;
Outcome QCs concern the target language result of the translation.

There is a short-list of 9 QCs. Each QC has its quality metrics and sample questionnaires that assist the process of evaluation. In the end, an overall rating is assigned.

The translation process should follow an onomasiological approach (concept-based) as opposed to a semasiological approach (term/word based). A concept-based approach must be used to assure semantic equivalence of concept representation and avoid literal translations. The translation

process must involve an interdisciplinary collaboration between specialists in Health and Informatics, and linguists and terminologists. Approved sources of information should be available to translators and other specialists working on the translation process, including a valid list of internet references citepsnomed:translationguide.

Before starting a translation project, members should consider the following steps (IHTSDO, 2012*a*):

Establish a team of specialists with a diversified background including health and social care professionals, medical translators, terminologists and health informatics specialties amongst other.

Establishing the Editorial Board to coordinate the translation project. It should be composed of an interdisciplinary team composed of professionals with educational and empirical backgrounds (medicine and nursing, linguistics and terminology, information science) which have great knowledge and understanding of the English language.

Subset selection of the core concepts to be translated. The goal is to allow the selection of team members with appropriate background. The prioritization of SNOMEC CT's subsets to be translated can be a vital component of the process of introducing the terminology at a national level.

According to IHTSDO (2012*b*), the translation process may be summarized into four stages: Translation, Review, Editing and Progress monitoring and follow-up.

The Translation stage should involve at least a translator and a proof-reader to verify the initial translation. Translator must have good linguistic skills and also good insight in healthcare. This stage should be followed by a review carried out by health and social care professional, assessing the quality of the translated content and to assure that the translated terms reflect the underlying concept. The editorial board must define and maintain translation process guidelines, approve the validity of the sources of information available to translators and reviewers and act as an advisory board during the whole process. It must deal with particularly complicated translations and questions by the translation team. An appointed project manager should be continuously monitoring and assessing the translation project's status.

After the translation process, clinical validation of the translated terms is required to resolve possible post-translations issues. It should be carried out by health and social care providers. The goal is to assure that the translational is useful in clinical and social care settings. There is always the possibility that the reviewers may have misunderstood the source language term or that a correctly translated term is not psychologically acceptable to the clinicians who may be used to refer to that concept through a different term.

Member countries should provide IHTSDO with feedback on the translations, namely regarding national terms or concepts that could be candidates to be translated to English and integrate the International Edition of SNOMED CT.

3.1.2 ICD

Overview

ICD is a clinical classification that belongs to the Family of International Classifications (FIC). This family of classification belongs to the World Health Organization (WHO). FIC is meant to be internationally adopted by WHO's members. According to WHO (2015*b*), the goal is to facilitate storage, retrieval, aggregation, analysis and comparison of data nationally and internationally in a systematic and consistent way.

The three main classifications that constitute this family of classifications are the ICD, the International Classification of Functioning, Disability and Health (ICF) and the International Classification of Health Interventions (ICHI). They are called reference classifications as they cover the essential parameters of health. The family of classifications also includes derived classifications which are based on reference classifications. They intend to provide additional detail that is not provided by reference terminologies or may result from aggregation or rearrangement of items from one or more reference classifications. The International Classification of Diseases for Oncology, 3rd Edition (ICD-O-3) is one of these derived classifications. It is mainly used for classification of the site (topography), morphology, behavior, and grading of neoplasms.

ICD is a coding system for classifying diseases, including a variety of signs, symptoms, abnormal findings, complaints, social circumstances, and external causes of injury or disease. It is used to classify diseases and other health problems and to monitor the incidence and prevalence of those diseases and problems. It supports the compilation of national mortality and morbidity data by WHO member states. ICD is also used for reimbursement and resource allocation management by member countries. Most countries (117) use ICD to report mortality data, a primary indicator of health status. International health statistics using this coding system are available at the Global Health Observatory page on the WHO's website (WHO, 2015*f*).

In 1893, a French physician named Jacques Bertillon introduced the Bertillon Classification of Causes of Death at a congress of the International Statistical Institute in Chicago. In 1898, after some revisions and expansions the American Public Health Association recommended its adoption in Canada, Mexico and in the United States. It also recommended that the system should be revised every ten-years in order to keep the system updated. The first international conference to revise the International Classification of Causes of Death took place in 1900. The first revisions contained minor changes. However, the sixth revision added morbidity and mortality conditions to the classification. Its title was modified to International Statistical Classification of Diseases, Injuries and Causes of Death. Prior to the sixth revision, ICD revisions were a responsibility of the Mixed Commission, composed of representatives from the International Statistical Institute and the Health Organization of the League of Nations. In 1948, WHO assumed responsibility for preparing and publishing the revisions to the ICD every ten-years (WHO, 2015*h*).

The tenth revision of ICD (ICD-10) is the current revision of the classification. It was endorsed by the World Health Assembly in May 1990 and is being used by WHO member states since 1994. The ICD is

currently under revision and is expected to be released by 2018.

ICD-10 comprises three volumes: Volume 1 contains the main classifications; Volume 2 provides guidance and instruction to users of the ICD; and Volume 3 is the Alphabetical Index to the classification. The classification is divided into 21 chapters (WHO, 2010):

Chapters I to XVII cover diseases and other morbid conditions;

Chapter XVIII covers symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified;

Chapter XIX covers injuries, poisoning and certain other consequences of external causes;

Chapter XX covers external causes of morbidity and mortality;

Chapter XXI focuses on factors influencing health status and contact with health services. It is intended for the classification of data explaining the reason for contact with health-care services of a person not currently sick, or the circumstances in which the patient is receiving care at that particular time.

The first character of an ICD code is a letter. Each chapter is subdivided into homogeneous 'blocks' of three-character categories (a letter followed by 2 numeric characters). Most of these categories are subdivided into up to 10 subcategories. To identify these subcategories, the classification uses a fourth numeric character after a decimal point.

Within the three- and four-character categories, there are usually listed some other terms. These are known as inclusion and exclusion terms. Inclusion terms act as examples of the diagnostic statements to be classified to that category. On the other hand, exclusion terms are examples of events that are to be classified elsewhere, despite the fact that their title might suggest that they were to be classified in that same category. In the context of ICD, a rubric denotes either a three-character category or a four-character subcategory (WHO, 2010).

Organization

ICD and the FIC to which it belongs are owned and administrated by WHO. WHO (2015*a*,*c*,*e*, 2014) is the higher health authority within the United Nations (UN). Every member country of the UN may become a member of WHO by accepting its constitution. Currently WHO is composed by 194 member countries.

WHO is organized into six regional offices (Africa, Europe, South-East Asia, Eastern Mediterranean, Western Pacific and the Americas) in order to attend specific needs of each area of the globe (WHO, 2015*g*). WHO conducts several programs, partnerships and other projects on world's health. To support the programs, WHO designates certain institutions such as research centers and universities as Collaborating Centers (CCs) to carry out program specific activities. Currently there are over 700 CCs in over 80 member countries.

The FIC is one of those projects. The WHO-FIC Network was established to support WHO on the management and administration of this family of classifications. The network is responsible for supporting the development, maintenance and use of the classifications. It is composed by the WHO

Collaborating Centres for the FIC, Non-Governmental Organizations in official relations with WHO and Academic Research Centres designated by WHO as Collaborating Centers.

The CCs represent a geographic region or a country and may be specialized in a specific language. The formation of new CCs is encouraged by WHO and if a member country is not associated with a CC it may participate in the Network by appointing representatives. The Network meets once a year and conducts its daily work through Committees and Reference Groups.

The Committees have the responsibility of making progress on a specific area of the strategic work plan outlined by the Network. Within the Committees there may be time-limited and topic specific working groups, established in the annual meeting of the Network. The Network has established four committees:

Education and Implementation Committee: provides advice to the Network in implementing the classifications, improving the quality of their use and in supporting education and training to create a network for sharing expertise on these matters;

Family Development Committee: is responsible for assuring the classifications's logical structure, identify and prioritize gaps and needs in the FIC and recommend strategies for developing or revising the classifications;

Informatics and Terminology Committee: focuses on developing policies on electronic standards used for the FIC, promoting their international implementation and managing applications and tools for the FIC;

Update and Revision Committee supports the WHO-FIC Network in keeping the classifications updated.

The Reference Groups operate as forums to provide more technical discussion and support the participation of a wider range of experts and other interested parties. These groups focus on specific areas of classification such as mortality, morbidity or functioning and disability. The Network has establish three Reference Groups: the Mortality Reference Group, the Morbidity Reference Group and the Functioning and Disability Reference Group. These groups focus on mortality data, morbidity data and functioning and disability data, respectively. All of them aim to improve international comparability of data and support the development of software to be used internationally for coding and classification. They report to the Update and Revision Committee with annual recommendations.

Committees and Reference Groups should include permanent members from WHO (as well as from the regional offices) and from each CC, responsible for developing and carrying out strategies to achieve the goals outlined in the strategic work plan.

WHO members, CCs, Committees and Reference Groups are represented in the WHO-FIC Advisory Council. The Council is responsible for governing the WHO-FIC Network and developing the strategic work plan for the Network, with the help of the Small Executive Group. This group supports the Council in managing the Network but is not a decision-making body.

Licensing and distribution

WHO issues three types of licensees: licenses for comercial use, licenses for internal use within an organization or institution and licenses for non-comercial use.

WHO (2015*i*) may issue commercial licenses to companies wishing to incorporate and distribute WHO classifications in their software products that will be sale to customers in certain countries. This type of license is non-exclusive, non-transferable and time limited. It authorizes the use of the codes and descriptions in a product that will be sold and distributed in specific countries. However, licensees are not allowed to modify, translate or amend the codes or descriptions of the classification and there should be no suggestion of endorsement of the product or the company by WHO. To obtain a commercial license, companies must complete an application form detailing the proposed use of the classifications and the type of product to be developed. The request is to be evaluated by WHO.

Organizations and institutions should apply to an internal license if they intend to incorporate WHO classifications into their internal information systems, for use by employees for administrative purposes. They should provide WHO with a short summary of the intended use of WHO classifications within their information systems.

In case an organization would like to use WHO's classifications for non-commercial or research purposes, it may register online and request a license for non-commercial research use. If accepted, the organization requesting the license will be granted access to the Classification Download Area where it will be able to download the classifications and other related materials.

To request a license for use of clinical modifications (see Sub-subsection 3.1.2), local authorities responsible for these projects should be contacted directly.

ICD-10 is currently being distributed in the Classification Mark-up Language (ClaML) format. ClaML is a Extensible Markup Language (XML) based format designed specifically for classifications.

Release life cycle

The Update and Revision Committee (URC) (WHO, 2015*j*) assesses the need for updating the ICD and recommends changes to the classification each year. The Committee may identify where major revision is required and how such a revision could be undertaken. Specific reference groups report to the URC with annual recommendations.

Regarding the ICD-10 update process, the URC establishes policies and criteria on the updating process. It also has the responsibility to evaluate the update mechanism. The URC receives input from the Mortality Reference Group (MRG) and from member states through the WHO CCs. By the end of the process the committee submits recommendations on ICD-10 updating to the Heads of CCs.

Prior to ICD-10, updates were not made between revisions. Mechanisms for updating ICD-10 became operational in 1999 and the URC was established in March 2000.

The tabular list is updated very three years for major changes and annually for minor ones. On the other hand, the index is updated annually for changes that do not impact on the structure of the tabular list. A major change includes action such as addition of new code, deletion of a code, movement of

a code to another chapter or category or introduction of a new term into the index. Minor changes include enhancing a code description, the addition of an inclusion/exclusion term or a correction of a typographical error. Every new version of ICD-10 is labeled with the year of implementation.

The updating process follows the following steps:

- URC members (MRG and WHO CCs) submit proposed updates to the URC secretariat;
- URC secretariat collates and distributes the proposals to URC members;
- Members submit comments on the proposals to the secretariat;
- Secretariat collates comments from members and makes recommendation for ICD-10 updates. These recommendations are recirculated between members for further comments.
- Members submit comments on the recommendations to the secretariat;
- Secretariat submits final recommendations to WHO for distribution to the Heads of CCs;
- URC recommendations for ICD-10 updates are ratified at WHO Heads of Centres annual meeting in October;
- WHO disseminates the official updates through CCs, national organizations and the WHO website by the end of January.

To submit an update suggestion to ICD-10 it is necessary to fill a specific form. This form is to be addressed to the Head of the local CC, who will send recommendations to the URC.

Since its sixth revision, ICD has been maintained by WHO. The classification is periodically revised approximately every ten years.

According to WHO (2013), ICD is currently undergoing its 11th revision process. When the revision was due in 2000, a moratorium was suggested to come up with a modern revision strategy. This was suggested due to the level of ICD-10 adoption amongst member states. Only 96 member states out of 191 were using ICD-10. The objectives of the revision process are to:

- revise the classification in line with scientific advances;
- continue to serve as an international standard in multiple languages and settings to allow for comparable data;
- be compatible with computerized health information systems and electronic health applications.

An International Revision Process Plan was developed to revise the classification's content according to scientific and medical advances and to add functionalities taking into consideration modern health informatics standards. The goal of the process is to gather input from all stakeholders in an open and documented way. The revision process is structured into the following main components:

A Public Internet Platform where all interested parties may participate in the revision process by making comments, suggestions or participating in field trials. The platform also includes discussion forums and links to social media discussion groups.

Topic Advisory Groups (TAGs) composed by experts which guide and review the work done on the classification. There are vertical TAGs and horizontal TAGs. Vertical TAGs focus on specific content areas of ICD, such as Internal Medicine, Pediatrics, Neoplasms, Injuries, Mental Health or

Neurology. Horizontal TAGs concern the whole classification. Some examples are the horizontal TAGs for mortality, Morbity and Quality and Safety indicators.

A Revision Steering Group (RSG) to oversee and assist WHO on the coordination of the revision process. The RSG includes the Heads of the TAGs.

The revision process is continuously shared with the WHO FIC Network. WHO's CCs also participate in the revision process by incorporating their national modifications, reviewing the ICD drafts, making suggestions and coordinating or taking part in field trials conducted in their respective countries. It also includes extensive consultations with external organizations. These include medical organizations and specialty groups, health information management organizations, the informatics sector and other standards development organizations such as IHTSDO, the Health Level Seven International (HL7) and the International Organization for Standardization (ISO).

The eleventh revision of ICD is currently in the Beta phase. This revision process comprises three distinct phases:

Alpha phase: An alpha draft was developed by a group of experts, WHO collaborating centers and external advisors. In this phase architectural and modeling alternatives were discussed and agreed.

Beta Phase: The first draft evolved into a beta draft. This second draft is more stable and includes all national modifications, TAGs proposals and suggestions from other organizations. This draft was presented to the public for review, comment and testing.

Finalization and Maintenance Phase: When the beta draft is stable enough, it will be submitted to WHO governing bodies.

As an ongoing process, there are still some task to be completed:

Review process: consists of an international scientific peer review process conducted by experts which will review certain sections and aspects of ICD. TAGs will act as editorial boards to evaluate the results of the review.

Public Proposals: Additional proposals submitted through the internet platform by interested parties will be subjected to the peer review process. These proposals include comments and suggestions for naming, inclusions and other references.

Field Trials: field trials aim to get feedback on the applicability, reliability and utility of the ICD from the actual users.

Translations: Priority must be given to WHO official languages (Arabic, Chinese, English, French, Russian, and Spanish) and to German and Brazilian Portuguese as WHO Regional Office languages

Finalization of ICD-11 as a package: The final package, containing all three volumes, will be available for public consultation and will include additional material for transition guidance and tables for correspondence between ICD-10 and ICD-11.

This revision process's infrastructure is expected to be adopted for the continuous maintenance and update of the ICD for the following years after the completion of the revision process. The mechanisms

for new proposals and review may continue to serve as the basics of ICD update process. It will possibly replace the current ICD-10 update mechanism.

Translations

ICD-10 is available in the six official languages of WHO (Arabic, Chinese, English, French, Russian and Spanish) and 36 other languages including Brazilian Portuguese. Points of contact for the remaining 36 unofficial translations are national organizations such as the local Ministry of Health (WHO, 2015*d*).

The governments of certain countries have developed clinical modifications. National clinical modifications of ICD usually include more detail and sometimes have separate sections for procedures. However, WHO is not responsible for these modifications. Some examples of clinical modifications are the US Clinical Modification (ICD-9-CM/ICD-10-CM), the US Procedure Coding System (ICD-10-PCS), the Australian Modification (ICD-10-AM) and the Canadian Enhancement (ICD-10-CA).

3.1.3 ICPC-2

Overview

ICPC is a clinical classification developed by the World Organization of Family Doctors's International Classification Committee (WICC). According to WHO (2015*b*) and to the World Organization of Family Doctors (WONCA, 2011), it is used to code clinical information in the domains of general and family practice and primary care. It allows healthcare profissional to classify and code three major elements of a medical encounter: patient's reason for encounter, health problems or diagnosis and procedures. It is available in both printed and electronic form. The copyright of the classification is owned by WONCA (KITH, 2012).

After the second World War, there was a significant development of primary care services. The information in need to be coded changed and was not completely covered by the available classifications such as the ICD. The coding needs in primary care led to the publication of the International Classification of Health Problems in Primary Care (ICHPPC) by WICC in 1976. This classification maintained a similar structure to the ICD.

Two other classifications were also developed in this context: The Reason for Encounter which classified the reasons that led the patient to seek medical attention; and the International Classification of Health Process in Primary Care (IC-Process-Pc) that intended to classify procedures. These two classifications and the ICHPPC were merged to create the International Classification of Primary Care (ICPC). The ICPC was developed by WICC and was first published in 1987 by Oxford University Press. In 1998, the second major version of the ICPC was developed. It contains inclusion and exclusion terms, as it was explained in Subsection 3.1.2. ICPC-2 was accepted within the WHO's FIC in 2003.

ICPC is currently in its second major version (ICPC-2). Its structure is similar to ICD's. The classification is also organized into chapters. However, its chapters are classified based only on the anatomical systems. ICPC-2 has a biaxial structure and consists of 17 chapters. Each chapter is represented by a

letter and is divided into seven components which remain the same for every chapter. The content of a component within a given chapter is numbered with a two digit code.

Organization

WONCA (2015*a*,*b*) is an acronym comprising the first five initials of the World Organization of National Colleges, Academies and Academic Associations of General Practitioners/Family Physicians. It is a not-for-profit organization founded in 1972 by member organizations in 18 countries. It has 118 member organizations in 131 countries and territories. WONCA interacts with international bodies such as WHO, with whom it has official connections as a non-governmental organization and is engaged in several collaborative projects.

The organization comprises several Working Parties, Special Interest Groups and Young Doctors' movements that aim to make progress on specific areas of interest to WONCA and its members. These groups are constituted by hundreds of family doctors. WONCA's geographic scope is divided into seven regions (Africa, Asia Pacific, East Mediterranean, Europe, Iberoamericana, North America, and South Asia). Each region has its own regional Council and oversee their own regional activities and conferences.

One of WONCA's Working Parties is the WICC. It is WONCA's longest serving committee. Its mission is to develop and maintain classifications that accommodate the complete domain of family medicine and general practice. The WICC has a wide collection of publications, including the ICPC.

The Primary Health Care Classification Consortium (PH3C, 2015) supports the activities of WICC and its website. The website provides access to the work published by the committee since its creation. It focuses mainly on ICPC but also about other tools concerning information retrieval in primary care.

Licensing and distribution

Non-comercial users may acquire and use ICPC-2 free of charge. On the other hand, to use ICPC-2 for commercial purposes or in national or local coding systems, the user is required to pay a fee to WONCA. The fee is set by negotiation with WONCA (KITH, 2012).

WONCA (2011) must appoint specific organizations responsible local promotion and distribution of the electronic version of ICPC-2. They also have the responsibility to manage licensing and payment of the respective fees.

The Norwegian Directorate of Health – Department of Standardization maintains a web page on behalf of WICC. It always contains the latest version of ICPC-2e (English version). Currently the latest version is ICPC-2e-v.4.4 (January 2015) and it is published in Excel, Access and ClaM.

Release life cycle

According to the WICC (2005), ICPC version numbering consist of three fields. They denote the major version, the minor version, and the update version, respectively. The major version field is attached to the name ICPC. The letter "e" emphasizes that it is the electronic version of the classification. As an

example, ”ICPC-2e-v.1.1” indicates major electronic version 2 of ICPC, minor version 1 of ICPC-2e, and the update version 1 of minor version ICPC-2e-v.1.

A major version includes modifications of the structure or large changes in the main rubrics of ICPC. This includes rubrics added, deleted or rearranged. A rearrangement comprises merging or splitting rubrics or moving rubrics from one component or chapter to another. A major version is usually published together with a new edition of the ICPC book and supersedes any prior documentation for major, minor, and updates versions.

A minor version includes significant changes to the content of the rubrics of ICPC, but not their structure or title. It may consist of alterations in the criteria, inclusions and exclusions of the rubrics. Publication of a new minor version has to be approved by the whole WICC group. A minor version is published online. The documentation for a minor version amends the documentation of the prior major version and any prior minor version of that major version.

An update version consists of relatively small changes of ICPC. It includes errata and linguistic improvements. The documentation for an update version amends the documentation of the prior minor version. Publication of an update version may be approved by the WICC Update Group alone, but only if there is full agreement within the group.

In order to provide feedback regarding the classification, users should contact the local representative of the WICC or the WICC directly (WONCA, 2011).

ICPC-2 is revised by the WICC. The full revision cycle is currently 11 years. Mappings to other classifications may need revision in shorter intervals to account for changes in other classifications (KITH, 2012).

Translations

WONCA (2011) states that ICPC-2 is available in electronic form and has been translated into 19 languages: Catalan, Chinese, Croatian, Danish, Dutch, English, Finnish, French, German, Greek, Italian, Japanese, Norwegian, Portuguese, Romanian, Russian, Serbian, Slovenian and Spanish.

Editions including additional information, translations or any sort of changes must be submitted to the WICC prior to publication, in order to be recognized as official editions.

The WICC encourages the public in general to contact them to arrange cooperative work in order to promote or undertake translations of ICPC-2. Translations of ICPC-2 must include the whole book and not just the rubrics. The translation process must be carried out by approved translators working in cooperation with the WICC. WONCA retains the copyright of any translated material. However, they usually grant translating organizations the right to retain royalties on their versions. In these situations a formal agreement between WONCA and the organization or publisher is required (KITH, 2012).

According to the WICC Update Group, a translation of ICPC should carry the same version numbering as the original that it was translated from. In addition, it should be followed by a two digit code (ISO 3166 country codes) that indicates what country the translation originates from. A second and third field may be added to state the language and to describe local adaptations respectively (e.g., ICPC-2e-v.1.0 GB, Welch, extended version) (WICC, 2005).

3.1.4 ICNP

Overview

ICNP is a clinical classification that nurses can use to describe and report their practice in a systematic way. It is used to represent diagnosis, interventions and outcomes (Coenen and Bartz, 2009). It is a product of the International Council of Nurses (ICN, 2014*a*,*b*). The resulting coded information is used to support effective care and decision-making, and enhance nursing education, research and health policies. The classification is owned and copyrighted by ICN.

A new release of ICNP is published every two years at the ICN Congress/Conference. Its current version is the 2013 release. It comprises 783 pre-coordinated diagnosis and outcome statements and 809 pre-coordinated intervention statements.

ICNP is constituted by entities. Each entity is represented by a unique 8-digit numerical code identifier, a preferred term and its synonyms.

The 7-axis model is an alternative representation of ICNP in which each post-coordinating ICNP entity is organized into one of seven axes: Focus (F), Judgment (J), Action (A), Means (M), Location (L), Client (C) and Timing (T). Although there have been some successes with the 7-axis model, the trend has been to use pre-coordinated entities regarding diagnosis/outcomes and interventions. In this cases, each pre-coordinated expression is assigned to one of two axes: diagnosis/outcomes entities (DC) and interventions entities (IC).

ICNP catalogues are subsets of nursing diagnoses, interventions and outcomes for a specific area of nursing practice. They allow to deliver the classification to its users in information systems in clinically relevant packages. Each catalogue addresses at least one health priority and one client. A health priority may be a specialty area or setting (e.g., palliative care, peri-operative nursing), a nursing focus (e.g., adherence to treatment, pain management) or a medical or health condition such as diabetes and depression. On the other hand, a client may be either an individual, a family or a community. The following are examples of ICNP catalogues: Nursing Care of Children with HIV and AIDS, Pediatric Pain Management, Palliative Care, Community Nursing (Coenen and Bartz, 2009).

Organization

ICN (2014*c*) is a federation comprising more than 130 national nurses associations across the world. It was founded in 1899. The council is operated by nurses and leading nurses internationally and it aims to ensure quality nursing care, sound health policies, the enhancement of nursing knowledge, and a satisfied nursing workforce worldwide. ICN is governed by the Council of National Nursing Association Representatives. Its responsibilities include setting policies, admitting new members and electing the Board of Directors. A National Representative is a nurse appointed by a member association to be its representative.

ICN (2015) has identified three major program areas as fundamental to nursing and health: Professional Practice, Regulation, and Socio-Economic Welfare. They are called ICN's Pillars and the organization focuses its activities on these areas. In particular, the Professional Practice field concerns

the following areas:

- Ethics and Human Rights;
- eHealth;
- Leadership Development;
- Communicable Disease;
- Noncommunicable Diseases.

The ICN eHealth program includes ICNP, the ICN Telenursing Network and the Connecting Nurses initiative which provides an online forum for nurses worldwide to share ideas, advice and innovations.

Part of ICN's work is developed in collaboration with other associations and organizations including national associations, nursing leaders and specialty groups around the world. An ICN centre may be an institution, faculty, department, national association or other group designated and approved by ICN as a Centre for Research and Development. ICN centers are organized into consortiums. In particular, there are specific ICN centers for ICNP, organized into an ICNP consortium to support the development and application of ICNP. ICNP Centres may be organized by language, area of specialization or research expertise. They must report on their work at least once per year in the ICN eHealth Bulletin and should attend the consortium meeting organized by ICN. To be considered as an ICN Accredited Centre for ICNP Research & Development , interested parties must submit an application to be reviewed by ICN. ICN conducts a review of each ICNP Centre every three years. Based on the review process, ICN decides whether to re-accredit an ICNP Centre (ICN, 2013).

Licensing and distribution

Any party interested in using ICNP is required to sign an agreement authorizing such use, whether for commercial use or not. Comercial users wishing to incorporate ICNP into their products must pay a licensing fee. ICN (2014*a*) has a Licensing & Distribution Agreement which is required in these cases. Non-commercial and non-profit users that intend to use the classification for academic or research purposes are not required to pay any fee. In such cases the Agreement for Non-commercial Use of ICNP is required. Situations where organizations and institutions intend to use the classification within their internal information systems (e.g., National Health Service) should be negotiated case-by-case with ICN.

ICNP is distributed as CSV files and PDF files. Other file formats such as ClaML and OWL are available only on request. Several translations in PDF format are available on the ICN website for non-commercial use only.

Release life cycle

The ICNP program encourages and supports individuals and groups to contribute to the development and maintenance of the classification. The program established a process for submission and review of new concepts or changes to existing ones. Concept changes include modification or inactivation but

never deletion. To submit a proposal for an addition or change to the classification, users must fill out appropriate form and send them to the ICN (2014*a*).

The review process is usually accomplished via email or a web-based application. A team of ICN reviewers is responsible for commenting on the submission. The reviewers must have expertise in the area of the concept to be reviewed. ICN encourages nurse experts to join ICNP concept reviewers.

The submission and review process follows the following steps:

- ICN staff reviews the submitted suggestions;
- ICN staff sends the suggestions for further review to nursing practice and/or technical and informatics experts;
- Expert reviewers make recommendations to the ICN staff, advising whether to accept, deny, or further review the suggestion;
- ICN staff reviews the recommendations and changes may be applied to ICNP;
- The author of the sumbission is then notified of the review process result.

During a translation process, concepts may also be identified and submitted to ICN for addition, modification or inactivation.

The continuing management, maintenance, development and translation of ICNP,involves several parties worldwide and from different backgrounds, such as nurses, researchers, informatics and linguistic experts, software developers, and policy makers (ICN, 2008).

Translations

The translations of ICNP available in PDF format on the ICN website are the following (ICN, 2014*a*):

- Brazilian Portuguese: 2013 Release;
- Chinese (Simple): 2013 Release;
- Chinese (Traditional): 2013 Release;
- English: 2013 Release;
- Farsi (Persian): Version 2;
- French: 2013 Release;
- German: 2011 Release;
- Icelandic: 2011 Release in development;
- Indonesian: Version 1.1;
- Italian: 2013 Release;
- Japanese: Version 1.0;
- Korean: 2013 Release;
- Norwegian: 2013 Release;
- Polish: 2013 Release;
- Portuguese: 2011 Release;
- Romanian: Version 2;

- Spanish: 2013 Release;
- Swedish: 2013 Release.

ICNP translations are usually accomplished by nurses cooperating with the local National Nursing Association, on a voluntary basis. Before starting a translation process, the ICNP Program should be contacted to request permission to translate the classification. If ICN grants permission to initiate the translation process, a translation agreement must be signed.

A translation process is a complex process. It requires transferring data from the source language to the target language while maintaining cross-cultural semantic equivalence of concepts, beyond literal translation of terms. As a result, ICN (2008) as issued guidelines regarding the translation process of ICNP:

- After ICN grants permission to initiate a translation process and the translation agreement is signed, the translating entity should outline a systematic and documented process to assure validity and quality of the translation result;
- The translation team should always include nurses as active participants. Translators should have a clear understanding of the material to be translated and the people who will use the resulting translation. In addition, they should have in-depth knowledge of the source language and the target language and culture. Team members should also include linguistic experts;
- The source of the translation should be the most recent version of the English edition of the classification. Other translations of that same version may be used as auxiliar material to assist in the translation process, if suitable;
- In case there is no adequate term in the target language, the source term may be translated into a set of words using its definition. On the other hand, a set of words in the source language may be translated into a semantically equivalent single word. In both cases, ambiguous terms must be avoided;
- Translating parties should conduct field validity testes. This step is crucial to refine the resulting translation, assure its quality and increase its application in actual nursing practice.

3.1.5 LOINC

Overview

LOINC is a clinical terminology owned and maintained by the Regenstrief Institute (2015*a*) and the LOINC committee. It provides a set of universal names and ID codes for identifying laboratory and clinical observations.

LOINC was initiated in 1994 by the Regenstrief Institute and developed in cooperation with the LOINC committee as a response to the demand for transferring clinical data from laboratories and other institutions such as hospitals. It was released online in April of 1996.

LOINC's current version is LOINC 2.52. It was released on the 29^{th} of June 2015 and it is divided into two portions: the laboratory portion and the clinical portion.

According to McDonald et al. (2014), the scope of the laboratory portion of LOINC includes all observations reported by clinical laboratories including the specialty areas: chemistry (including therapeutic drug monitoring and toxicology), hematology, serology, blood bank, microbiology, cytology, surgical pathology and fertility. It also contains a set of terms used in veterinary medicine. In addition, it includes non-test measurements that are usually required to interpret test results and included as part of the lab report (e.g., for a blood bank, the number of units dispensed; for arterial blood gases, inspired oxygen; for drug concentrations used in pharmacokinetics, the dose).

The scope of LOINC's clinical portion covers tests, measures, and other observations about a patient that can be made without removing a specimen from them. Such observations comprise vital signs, hemodynamics, intake/output, EKG, obstetric ultrasound, cardiac echo, urologic imaging, gastroendoscopic procedures, pulmonary ventilator management, radiology studies, clinical documents, selected survey instruments (e.g., Glasgow Coma Score, PHQ-9 depression scale, CMS-required patient assessment instruments), and other clinical observations.

LOINC names name the observations. They fully specify observations on six main axes (Vreeman et al., 2012):

Component specifies the analyte or attribute being measured or observed (e.g., sodium, body weight);

(Kind of) Property differentiates kinds of quantities relating to the same substance (e.g, mass concentration, catalytic activity);

Time (Aspect) identifies whether the measurement is made at a point in time or a time interval (e.g. 24h for a urine sodium concentration);

System specifies the specimen, body system, patient, or other object of the observation (e.g. cerebral spinal fluid, urine, radial artery);

(Type of) Scale identifies the scale or precision that differentiates among observations that are quantitative, ordinal (ranked choices), nominal (unranked choices), or narrative text;

(Type of) Method is an optional axis. It identifies the way the observation was produced. It is used only to distinguish observations that have clinically significant differences in interpretation when made by different methods.

Some of these major axis are organized into minor axes. The individual elements (atomic parts) that constitute a fully specified LOINC name are called LOINC Parts and each Part has an identifier that begins with the prefix "LP".

Organization

The Regenstrief Institute (2015*a*,*b*) is a non-profit medical research organization associated with Indiana University (USA). It is an internationally respected healthcare and informatics research organization, known for its role in improving quality of care and increasing efficiency of healthcare delivery. One of its centers for research is the Center for Biomedical Informatics (CBMI). Dr. Daniel Vreeman, an investigator at CBMI, directs the development of LOINC, as Associate Director for Terminology Services at the Regenstrief Institute.

The LOINC Committee plays a central role in LOINC's development. The Committee defines the overall naming conventions, policies and priorities for the development process. It works in collaboration with the Institute and other stakeholders. Individual members may participate in the development as well, namely acting as content experts. The Committee has two primary divisions: the Laboratory LOINC committee and the Clinical LOINC committee. The Clinical committee comprises a subcommittee that aims to provide codes for observations at specific stages of the nursing process.

Licensing and distribution

LOINC and the Regenstrief LOINC Mapping Assistant (RELMA) (see Section 3.2) are both copyrighted by Regenstrief Institute. The LOINC committee also owns the copyright of LOINC classification and materials. The public is allowed to use, copy and distribute LOINC and RELMA materials for any commercial or non-commercial purposes, subject to certain terms and conditions stated by the Institute. There is no need to pay any license fees or royalties (McDonald et al., 2014).

New versions of both LOINC and RELMA are released twice a year, in June and December. The latest release may be downloaded from the LOINC website. A zip file is available with the RELMA program installer and all the core LOINC files. The primary files in the LOINC release are the following: the LOINC table, LOINC Users' Guide, RELMA and RELMA Users' Manual. The LOINC table contains LOINC codes for each of the six parts of the formal name of a LOINC name, synonyms, comments, and other information. It is distributed as a Microsoft Access database and as a CSV text file (Regenstrief Institute, 2015*a*).

Release life cycle

The Institute welcomes requests for new LOINC content (terms, codes, text descriptions and synonyms) and suggestions of revisions to existing content. LOINC has been developed as an open standard with the help of several volunteers. Users should read the submission policy (available online) before submitting any request (McDonald et al., 2014; Regenstrief Institute, 2015*a*).

Requests should be submitted using RELMA's built-in functionality. As an alternative, there are appropriate templates available on the LOINC web site. Complex requests require discussion and decision by the LOINC Committee before the Institute completes them.

Translations

There are LOINC users in 163 different countries (Regenstrief Institute, 2015*a*). Several countries have adopted LOINC as a national standard, including Australia, Brazil, Canada, Cyprus, Estonia, France, Germany, Mexico, Mongolia, the Netherlands, Rwanda, Thailand, Turkey, and the United States. Other countries where there are large-scale health information exchanges using LOINC include Hong Kong, Italy, the Philippines, Spain, Singapore, and Korea (McDonald et al., 2014). Some users have translated LOINC material to meet their local language needs. Currently, the available linguistic variants, which accommodates storage of different dialects of the same language, are the following:

- Chinese (China);
- Dutch (Netherlands);
- Estonian (Estonia);
- English (United States) - Official Distribution;
- French (Belgium);
- French (Canada);
- French (France);
- French (Switzerland);
- German (Germany);
- German (Switzerland);
- Greek (Greece);
- Italian (Italy);
- Italian (Switzerland);
- Korean (Republic of Korea);
- Portuguese (Brazil);
- Russian (Russian Federation);
- Spanish (Argentina);
- Spanish (Mexico);
- Spanish (Spain);
- Turkish (Turkey).

The LOINC license encourages translation of any of the distributed LOINC materials (Vreeman et al., 2012). It states that the intellectual property rights of these derivative works belong to the Regenstrief Institute. This policy ensures the availability of translated materials to the entire international LOINC community, in the same way as the source material.

The Institute does not establish a specific method for performing the translation. All interested parties are welcome to contribute to LOINC's translation work, whether they are dedicated individuals or a national research organization. However, based on previous experiences the Institute encourages interested parties to perform a part-based translation process. Given that a certain term may integrate several different LOINC names, this approach can significantly reduce the overall translation work. The atomic part only needs to be translated once and then it may be reused in all LOINC names.

Nevertheless, if a user wishes to translate any of the licensed materials, he should contact the Institute via email to coordinate the process (McDonald et al., 2014).

Along with every LOINC release, the Institute generates a special translation file to serve as the source for translations. This file contains a list of the unique atomic parts that the classification comprises. The translation source file is distributed as a Microsoft Access database. To get access to this file, the Institute needs to grant translator privileges the account of the user wishing to coordinate a translation process (Regenstrief Institute, 2009).

3.2 Mappings

According to the IHTSDO (2014*e*), mappings are links between codes, concepts or terms of two different code systems that have the same or similar meanings. Mappings are developed for a specific purpose through a systematic and documented process. This means that there may be different mappings between the same pair of code systems to meet different purposes. The completeness of mapping between two code systems depends on the scope, level of detail of each code system and the precision of mapping required to meet the intended purpose. The purpose of a mapping may include the following (Imel and Campbell, 2003):

- Use data collected for one purpose for another purpose;
- Retain the value of data when migrating to different database formats and schemas;
- Avoid entering data multiple times leading to potential costs and errors.

Given the complexity of a mapping process, a mapping is not necessarily bidirectional. After converting a given code from coding system A to coding system B, its conversion back to coding system A may not lead to the same original code. This is due to the fact that when converting a code between to coding systems, there may be several destination codes to choose from (WONCA, 2011).

IHTSDO (2015*b*, 2014*c*) and the Regenstrief Institute Inc. signed a long-term agreement in July 2013 to cooperate in linking their clinical terminologies, SNOMED CT and LOINC. The goal is develop a mapping between the terminologies to the extent necessary to enable convergence towards a common semantic foundation and to allow duplication between them to be minimized. The alpha prototype, released in May 2014 consisted of 117 LOINC terms linked to SNOMED concepts.

Since ICD is widely used in health care for administrative purposes (reimbursement and statistical), IHTSDO (2013) also provides mappings from SNOMED CT to this classification. In the WHO Executive Board in 2005 and 2006, WHO established a collaborative arrangement with IHTSDO to align ICD and SNOMED CT by an official agreement that was reached in 2009 (WHO, 2013). SNOMED CT to ICD-10 and SNOMED CT to ICD-9-CM mappings are published with every release as derivatives of SNOMED CT (IHTSDO, 2015*b*; Imel and Campbell, 2003). According to the 2013 IHTSDO/SNOMED CT Annual Activity Report, IHTSDO published an ICD-10 baseline mapping for the first time in that year (IHTSDO, 2014*a*). The SNOMED CT to ICD-10 mapping published with the July 2013 release contained 40,905 active SNOMED CT concepts mapped to 7,067 distinct ICD-10 target codes.

There is also a mapping to ICD-10-CM, developed by the U.S. National Library of Medicine (NLM) in Washington, USA. It uses the March 2014 release of the US Edition of SNOMED CT and the 2014 version of ICD-10-CM. As of September 2014, the mapping file is available through the US Edition of SNOMED CT (IHTSDO, 2012*c*; NLM, 2014).

IHTSDO (2014*g*) has published an evaluation version of SNOMED CT General and Family Practice subsets and mapping to ICPC-2. Subsets facilitate SNOMED CT integration in software systems by grouping terms for specific clinical uses, thus reducing the cost of implementing SNOMED CT in such systems. The subsets and mapping resulted from a collaborative project between WICC and IHTSDO special interest groups. The goal was to enable clinical data to be reused for different purposes such

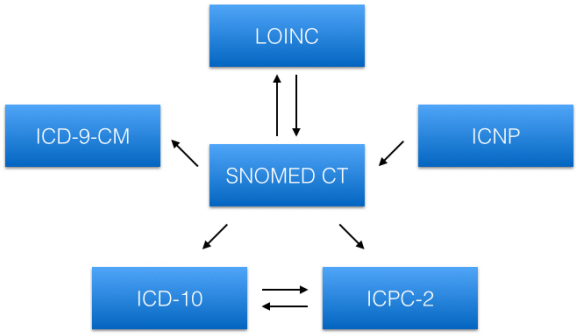

Figure 3.1: Illustration of the mappings described in section 3.2.

as public health reporting or transferring patient records between healthcare facilities. Both the subsets and mapping were released to member countries by the end of 2014 as a Candidate Baseline release for evaluation purposes only and not for use in live systems.

As seen in Chapter 10 of the ICPC-2 book, each rubric includes every correspondent ICD-10 rubric. If the ICPC-2 rubric corresponds to the entire ICD-10 three digit code, it is indicated in the rubric. In case it correspondes only partially to the ICD-10 three digit code, every ICD-10 four digit code to which it corresponds is indicated in the ICPC-2 rubric.

Chapter 11 of the ICPC-2 book (WONCA, 2011) presents a conversion table from every ICD-10 three digit code to ICPC-2. However, if only a set of the content of an ICD-10 three digit rubric corresponds to the same ICPC-2 code, the table presents the conversion of all the ICD-10 four digit codes that it contains. An ICD-10 code may appear multiple times in the conversion table, as it may correspond to more than one ICPC-2 code. ICD-10 rubrics contained in chapter XX which covers external causes of morbidity and mortality are not included in the table, given that ICPC-2 is based only on the anatomical systems and not on etiology.

In September 2014, ICN (2014*a*) and IHTSDO announced an updated collaboration between the two organizations. One of the goals of this project is the joint publication of full equivalence tables from ICNP to SNOMED CT: equivalence table between SNOMED CT and ICNP for Nursing Diagnoses/Outcomes and equivalence table between SNOMED CT and ICNP for nursing interventions. ICNP to SNOMED CT Equivalency Table for Diagnosis and Outcome is already available for request at the ICN website (Matney et al., 2014).

Along with every release of LOINC, the Regenstrief Institute (2015*a*) also releases a new version of the Regenstrief LOINC Mapping Assistant (RELMA). It is a Windows-based mapping utility to facilitate searches through the LOINC database and to assist in the process of mapping from a local coding system to LOINC coding system. Some of its best features include: the ability to import a set of local terms from a sample of HL7 messages; an automated tool for finding a ranked list of candidate LOINC terms for each local code in a given set; displaying details about a particular LOINC; submission to Regenstrief Institue of new LOINC codes; multilingual searching.

Figure 3.1 illustrates the mappings described above. An arrow simbolizes a mapping from coding system A to coding system B.

As seen in Figure 3.1, SNOMED CT may be used as a common reference terminology, instead of developing "everything to everything" mappings between several different coding systems (IHTSDO, 2014*e*).

3.3 National Organizations for Clinical Ontologies

This section presents an overview of foreign national organizations for clinical ontologies and how they support the deployment and promote the use of international clinical ontologies in their countries. It addresses the following organizations: the National Clinical Terminology and Information Service (Australia), the UK Terminology Centre (UK), the Ministerio de Sanidad, Servicios Sociales e Igualdad (ES), the Ministerio de Salud (CL) and the National Library of Medicine and the National Center for Biomedical Ontology (US).

3.3.1 The National Clinical Terminology and Information Service (AU)

The National E-Health Transition Authority (NEHTA, 2015) is the lead organization for eHealth in Australia. It aims to support and accelerate the adoption of eHealth solutions in Australia's health system, thus enhancing healthcare provision at national level.

Within NEHTA's website, there is the National Clinical Terminology and Information Service (NCTIS). It supports the management, development and distribution of terminologies to support eHealth requirements of the Australian healthcare community. NEHTA is Australia's representative to IHTSDO (2015*b*), having the responsibility to act as the Australian NRC of SNOMED CT.

NEHTA's clinical terminology solutions include SNOMED CT-AU and Australian Medicines Terminology (AMT). AMT provides codes to identify originator and generic brands of medicines commonly used in Australia. It also allows to describe medications. The NCTIS and its dedicated support team assist license holders in their understanding and implementation of SNOMED CT-AU and AMT. Its website contains the SNOMED CT-AU and AMT release files, support and education resources and information regarding licensing. Access to terminology release files is limited to license holders. Online services regarding SNOMED-CT also include submission of reference sets, requesting Namespace Identifiers and requesting licenses.

3.3.2 The UK Terminology Centre (UK)

Health & Social Care Information Centre (HSCIC, 2015*a*) is the national provider of information, data and IT systems for commissioners, analysts and clinicians in health and social care. It is an executive non-departmental public body, sponsored by the United Kingdom (UK) Department of Health. It was set up in April 2013.

One of its goals is to support the delivery of IT infrastructure, information systems and standards. It is within this scope of action that the United Kingdom Terminology Centre (UKTC) was created. The

UKTC is responsible for the UK management of SNOMED CT, Read codes and other healthcare terminology products. It is the local NRC for SNOMED CT for the UK responsible for distributing and managing SNOMED CT within the country (IHTSDO, 2015*b*). The UKTC distributes the UK edition of SNOMED CT and related documentation, subsets and mappings via the Technology Reference data Update Distribution service. Users need to be registered to get access to this area.

Similar to NEHTA, the website contains information and documentation regarding terminologies and other information standards, allows to submit change requests, license request and to download the latest versions of the terminologies.

3.3.3 The Ministerio de Sanidad, Servicios Sociales e Igualdad (ES)

The Ministerio de Sanidad, Servicios Sociales e Igualdad (Spanish Ministry of Health, Social Services and Equality, 2015) is the responsible entity for proposing and implementing government policy regarding healthcare. Under its supervision, the Historia Clínica Digital del Sistema Nacional de Salud (HCDSNS, Spanish National Health System's Digital Health Records Project) aims to support interoperability and assure that healthcare professionals have access to the most relevant clinical documentation of each patient.

Within the scope of this project Spain became a member of IHTSDO (2015*a*) in 2008. The Ministry of Health, Social Affairs and Equality is its representative within the organization and has the responsibility to operate as the Spanish NRC of SNOMED CT.

2013 activities included developing the Spanish Drug Extension and more than 30 specific Subsets for different clinical variables within the scope of HCDSNS. More than 1,500 terms were translated into the Spanish of Spain (es-ES) Extension. In 2013, 105 new Affiliate Licenses were awarded, representing a 38% increase compared to 2012. The current number of Affiliate Licensees is 273, comprising public administrations, vendors, researchers and other individuals.

SNOMED CT documentation is available online on the Ministry website. There is also a specific area to submit license requests and to download SNOMED CT contents.

3.3.4 The Ministerio de Salud (CL)

The Chilean national health informatics strategy aims to ensure appropriate use of EHRs at national level and to improve the quality and availability of digital clinical information. As a result, The goal of the Chilean government is to implement terminology services in the entire public health system, which accounts for 80% of its health system. The Ministerio de Salud (Chilean Ministry of Health, 2015) is working on a National Pharmaceutical Terminology and it is the responsible organization for the distribution of SNOMED CT in national territory. Chile became a Member of IHTSDO (2015*a*) on November 1^{st} 2013 and SNOMED CT was legally defined as Chile's reference terminology. The Ministry used an IHTSDO tool to set up an online distribuition center which allows user to submit license requests.

3.3.5 The NLM and the NCBO (US)

The National Institutes of Health (NIH, 2015) is part of the United States Department of Health and Human Services (HHS). It is the national medical research agency and comprises 27 Institutes and Centers, each with a specific research agenda. The National Library of Medicine (NLM, 2015) is one of this institutes. Within HHS, NLM is the central coordinating body for clinical terminology standards. It supports the development and distribution of clinical coding systems such as SNOMED CT and LOINC. NLM aims to support nationwide implementation of an interoperable health information technology infrastructure. It maintains and makes available a vast print collection on a wide range of topics and includes electronic information services such as MEDLINE on PubMed.gov. NLM supports and conducts research, development, and training in biomedical informatics and health information technology.

NLM is the United States representative within IHTSDO (2015*a*) acting as the local NRC. It distributes SNOMED CT as part of the Unified Medical Language System (UMLS) Metathesaurus. The UMLS is a set of files and software that brings together a variety of biomedical vocabularies and standards to enable interoperability between computer systems. UMLS content and related documentation is available online on the NLM website (NLM, 2015). The UMLS has three tools, which are known as Knowledge Sources:

Metathesaurus: Terms and codes from various vocabularies such as ICD-10-CM, LOINC and SNOMED CT;
Semantic Network: Broad categories (semantic types) and their relationships (semantic relations);
SPECIALIST Lexicon and Lexical Tools: Natural language processing tools.

In 2013 NLM published the US Edition of SNOMED CT as the official source of SNOMED CT for use in the US healthcare system. In addition, mappings from ICD-9-CM to SNOMED CT were extended (both procedure and diagnosis codes) to support the transition from the use of ICD-9-CM to SNOMED CT.

The National Center for Biomedical Ontology (NCBO, 2015) aims to support biomedical researchers who develop and use biomedical ontologies in their work, to maintain a repository of biomedical ontologies and to educate trainees and the scientific community about biomedical ontologies. NCBO sponsors workshops, tutorials and conferences and other support materials such as videos addressing what ontologies are, how they are used, what are the best pratices and how to use the portal and its services. The Center is funded by NIH and combines the expertise of leading investigators from across the country. The main resource of NCBO is the web-based BioPortal. It allows the distribution of more than 270 of the biomedical ontologies, including SNOMED CT, ICPC, ICNP, LOINC, ICD-10 and the Read Codes (CTV3). It also supports several services which enable investigators to use the ontologies in their studies (Musen et al., 2012). NCBO it is not restricted to clinical ontologies and presents a broader view of ontologies and their possible applications.

3.4 The Portuguese Practice: International Clinical Ontologies

This section focuses on four of the international clinical ontologies described in section 3.1 — the International Classification of Diseases (ICD), the International Classification of Primary Care 2 (ICPC-2), the International Classification for Nursing Practice (ICNP) and the Logical Observation Identifiers Names and Codes (LOINC) — and their current use and governance at national level. SNOMED CT was not considered in this section as Portugal had recently acquired the license to distribute it and it was not yet officially in use within the Portuguese health system.

3.4.1 ICD

The International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) was created by the United States National Center for Health Statistics (NCHS). It started being used in the United States in 1979 (ACSS, 2015*a*). ICD-9-CM is based on ICD-9 and it provides additional morbidity detail. It is updated every year on October 1st. The classification comprises three volumes: volume one is the tabular listing; volume two is an index; volume three contains procedure codes. The NCHS and the Centers for Medicare and Medicaid Services (CMS) are the US governmental agencies responsible for overseeing all changes and modifications regarding ICD-9-CM. Two other American associations are also a part of the four Cooperating Parties for ICD-9-CM. They are the American Hospital Association and the American Health Information Management Association (CDC and NCHS, 2013; CMS and NCHS, 2011).

According to the Administração Central do Sistema de Saúde (ACSS, 2010*a*, 2014*a*, 2015*a*), in Portugal clinical information regarding diagnostics and procedures performed on hospital inpatients and outpatients is coded using ICD-9-CM. Its use is mandatory. The resulting coded information aims to characterize morbidity within hospitals. It constitutes a source of information from which it is possible to gather epidemiological data regarding incidence and morbidity. In turn, these data provide information about specific health needs of the population, supporting the creation of optimized resource allocation strategies both at regional and national level. It constitutes the basis of hospitals's financing and billing systems. Hospital discharges are registered as a mandatory clinical document, including deceased and transferred patients. ICD-9-CM is used for coding hospital discharges since 1989, thus allowing inpatients and outpatients to be grouped into Diagnostic Related Groups (DRGs) (Ministério da Saúde, 1989).

DRGs constitute a classification system of acute hospital inpatients. It groups similar patients according to resources consumption into clinical coherent groups. The system identifies hospital products (goods and services) that each patient receives according to his needs and pathology. Each group is assigned a weighing coefficient that reflects the expected treatment cost of a typical patient of that group. This coefficient is expressed in relative terms to the average cost of typical a patient at national level. The goal is to obtain hospitals's Case Mix Index. This index is the ratio between the number of equivalent patients weighted by their respective DRG coefficients and the total number of equivalent patients. It reflects which hospitals have a higher share of patients with complex pathologies, thus consuming more

resources.

The Instituto Nacional de Estatística (INE, Statistics Portugal Institute) uses ICD-10 to code mortality data since January 1st, 1998.

The Departamento de Gestão e Financiamento de Prestações de Saúde da ACSS (DPS/ACSS, ACSS's Healthcare Financing Department) is responsible for studying, implementing and assuring the quality of patient's classification systems, including performing clinical codification audits.

Clinical coding is performed by coding physicians who took a specific course provided by ACSS regarding clinical coding and DRGs. These physicians code the information using ICD-9-CM's version in force at the time of the episode's codification, according to the guidelines and general agreements approved by ACSS (2013*b*).

Every hospital has its own Gabinete de Codificação e Auditoria Clínica (GCAC, Coding and Clinical Audit Office). Its mission is to code clinical information, group it into the appropriate DRGs and to perform internal audits assuring the quality of the coding process. There are specific sheets where to code clinical information. These sheets contain a minimal set of basic data of clinical, administrative and demographic nature essential to classify patients into DRG's. They include the following fields (ACSS, 2013*a*):

- Age;
- Gender;
- Admission date;
- Discharge date;
- Destination after discharge;
- Principal diagnosis;
- Other diagnosis;
- Procedures.

After collecting and coding the data, these are introduced into a computer application specifically designed to receive these inputs called WebGDH. Afterwards, they are grouped into DRGs. ACSS establishes WebGDH's functionalities and rules, while SPMS is responsible for the application's development and maintenance. It was implemented in hospitals of the Portuguese NHS by October 1st 2009. Hospitals that use other applications which are not provided by the Portuguese Ministry of Health are responsible for the parameterization of their own systems This concerns both DRGs and ICD versions and updates (ACSS, 2014*b*, 2013*c*).

ICD-9-CM's Portuguese edition was translated from the original American edition in 1988 and distributed by ACSS to every hospital in the Portuguese NHS. ICD-9-CM's translation process into Portuguese is not institutionalized nor professionalized. It has been carried out by ACSS in collaboration with coding physicians responsible for the translation of new codes every year. The Portuguese translation is implemented in computer applications such as WebGDH. Coding physicians code using the English book edition of the classification.

As mentioned above, ICD-9-CM exists in the USA since 1979. According to ACSS (2015*b*), currently

this classification is no longer suitable to code all existing pathologies and procedures. WHO authorized the government of the USA to adapt ICD-10 to be able to classify diagnosis and procedures as well. As a result, the USA developed ICD-10-CM to replace ICD-9-CM (volumes 1 and 2) regarding the classification of diagnosis and ICD-10-PCS to replace ICD-9-CM (volume 3) regarding the classification of procedures.

In Portugal, there was no possibility to start using ICD-10, due to the fact that DRG's used are based on ICD-9-CM codification. However, a project lead by DPS/ACSS is ongoing to adopt and implement ICD-10-CM/PCS in the Portuguese NHS to classify diagnosis and procedures, replacing its predecessor ICD-9-CM. It is expected that ICD-10-CM/PCS will be in use as of January 1st, 2016 (Ministério da Saúde, 2013*a*).

ICD-10-CM contains a significant increase in the number of available diagnosis codes. It contains about 68.000 codes, while ICD-9-CM has around 13.000. ICD-10-CM codes are alphanumeric up to seven digits, thus allowing a greater number of subcategories and to classify laterality and bilaterally. At the same time, ICD-10-PCS contains 71.957 codes as opposed to the 3.838 procedure codes existing in ICD-9-CM. Its codes present a very different structure, making it very difficult to convert from one coding system to the other. ICD-10-CM/PCS presents a significant improvement in clinical codification. In particular, it allows to increase significantly the clinical detail of coded information.

Changing from ICD-9-CM to ICD-10-CM/PCS will imply the following:

- ICD-9-CM will no longer be updated;
- Clinical software needs to be altered in order to support the new and different structure of ICD-10-CM/PCS;
- Replacing the DRG's for new ones based on ICD-10-CM/PCS;
- Disseminating information within healthcare professionals and institutions regarding the implications of adopting the new classification;
- Providing training for coding physicians and IT personnel.

The USA created solutions to facilite the transition process between the classifications. These include a mapping between ICD-9-CM and ICD-10-CM/PCS. Nevertheless, the mapping is not immediate. The diversity of the new classification leads to situations where the coding physician is presented with multiple possible ICD 10 CM/PCS codes.

The translation process of ICD-10-CM/PCS into Portuguese will comprise essentially two main stages. In the beginning, the classification needs to be translated in full. Then, the translation will have to be maintained, according to ICD-10-CM/PCS updates. According to CMS, ICD-10-CM/PCS is in the public domain and may be used freely (ACSS, 2014*c*).

3.4.2 ICPC-2

According to Pinto (2011), ICPC-2 is the official classification for primary care in Portugal. It is used by the Ministry of Health to monitor productivity in primary healthcare and measure quality and performance indicators (Pinto, 2011, 2012). Private practices and insurance companies outside the NHS do not use

ICPC-2. However, they represent a very small fraction of primary healthcare in Portugal (Pinto, 2012). Every EHR software in use in Portuguese NHS primary healthcare centers must use ICPC-2, whether they are provided by the Ministry of Health or by private companies. It is a requirement of the Portuguese Ministry of Health for NHS primary care services. However, none of the softwares used require ICPC-2 coding to be made in each visit. Hospital referrals are also coded with ICPC-2.

ICPC-2 is under the supervision of ACSS and the Associação Portuguesa de Medicina Geral e Familiar (APMGF, Portuguese Association of General Practitioners and Family Physicians). APMGF is the owner of the rights to use ICPC-2 in Portugal and has a specific interest group that focuses on the classification. The department is constituted by family and general practitioners (WONCA, 2011). ICPC-2 licensing for use in EHR software must be agreed by each software manufacturer with APMGF.

According to ACSS (2010*b*), during its first decade in Portugal, there was no substantial incentives so that the classification would be used systematically by primary health care physicians, nor any regular auditing process of the coded information. As a result, the Portuguese Ministry of Health considered a priority to constitute a working group that would focus on these issues and outline a national plan for registering and coding clinical information in primary health care. The working group comprised members from ACSS, the five Administrações Regionais de Saúde (ARSs, Portuguese Regional Health Administrations) and APMGF. They initiated their work in March 2010. The project aimed to enable the implementation of a financing model based on the healthcare needs of the population. The goal was to be able to plan national healthcare delivery according to the differences between regions and to highlight and prioritize areas of intervention. To make this possible, availability of high quality coded clinical information is essential. To accomplish its goal, the work group adopted a methodology which included the following steps:

- Develop a training plan for the Clinical Boards of ACESs, regarding registering and coding clinical information;
- Develop a training plan for primary healthcare physicians, regarding registering and coding clinical information;
- Develop a national and regional plan for codification auditing;
- Propose recommendations to define incentives and penalties to assure the quality of clinical records.

Each ARS is responsible for implementing the guidelines established by the working group in their primary healthcare centers. In the early stages of the project, the working group selected 18 disease groups to focus on. The groups were prioritized according to the prevalence of the diseases they comprise and their associated costs. Within the selected groups, there were defined criteria and guidelines to each ICPC-2 code to assist the process of registering and coding the information in primary healthcare. These guidelines may be found in the Manual de Codificação Clínica (Portuguese Manual for Coding Clinical Information in Primary Healthcare) (ACSS and APMGF, 2010), which resulted from the work of this group. The project played an important role in disseminating the classification in Portugal and increasing its use in primary healthcare (WONCA, 2011).

Following the work carried out by the working group, ACSS and APMGF decided to review the ICPC-2. A second edition of the ICPC-2 book was published in 2011. The book edition was widely distributed upon its release and a copy was provided to each new member of APMGF. By September 2011 almost every family doctor in mainland Portugal and the Madeira archipelago was using EHR software.

As mentioned in Subsection 3.1.3, ICPC-2 was developed in 1998. According to Pinto (2011, 2014), in the following year the Portuguese translation was published. It was the first translation of the second major version of the classification to be published. Its electronic version was released in 2000. The translation process was coordinated by APMGF, formerly known as the Portuguese Associations of General Practitioners (WONCA, 2011). The Portuguese translation was updated in 2011 based on ICPC-2-v3.0. The translation process was carried out by the ICPC-2/APMGF interest group in collaboration with ACSS. By 2011, training of family doctors was scarce as there are only about six individuals considered national experts on ICPC-2 and there was no funding so support training opportunities.

By 2014, training standardization and reaching all family and general practitioners had still not been adequately achieved. There was discussion about creating an online training course. In the same year, APMGF and the Ministry of Health engaged in an effort to update the Portuguese translation to ICPC-2e-v4.3, correcting inconsistencies and poorly translated sections.

3.4.3 ICNP

The Portuguese Edition of ICNP is known in Portugal as Classificação Internacional para a Prática de Enfermagem (CIPE). The classification is used within the Portuguese Ministry of Health's information system SClínico (private email by Ana Simões, in 2015) and other IT clinical softwares developed by private companies. It is estimated that CIPE is currently being used by approximately 90% of the clinical software used at national level.

In April 2006, the Ordem dos Enfermeiros (OE, Portuguese Nurses Board) released CIPE 1.0. In the mean time, OE worked on a second release of CIPE (CIPE 2). Its browser was presented on October 6, 2010. The classification is available online on a restricted area of OE's website for consultation and download (Ordem dos Enfermeiros, 2010). Any party interested in using CIPE must submit a request to the OE.

One of ICN-Accredited Centres for ICNP Research and Development is located on Porto, Portugal. It is known as the ICN-Accredited Centre for Information Systems Research and Development (CIDESI) of the Porto Nursing School (ESEP). It aims to improve the quality of nursing education and care through research and development of nursing information systems and to support the development of the classification. The center works in collaboration with ICN, ESEP's research unit (UNIESEP) and the Portuguese Nurses Board (OE) (ICN, 2014*a*; ESEP, 2015).

3.4.4 LOINC

Currently the LOINC terminology is not yet being used in the Portuguese NHS as an official coding system. However, the Portuguese Catalog of Clinical Laboratory Tests (CPAL) will be released soon by

SPMS (see Section 3.5.4). The catalog is to be used in the entire Portuguese Health System and will be mapped to the LOINC terminology.

3.5 The Portuguese Practice: National Clinical Classifications

This section focuses on four Portuguese clinical classifications — the Classificação Farmacoterapêutica dos Medicamentos (CFT, Pharmacotherapeutical Classification of Drugs), the Classificação de Dispositivos Médicos (CDM, Classification of Medical Devices), the Catálogo Português de Alergias e Reações Adversas (CPARA, Portuguese Catalog of Allergies and Other Adverse Reactions) and the Catálogo Português de Análises de Laboratório (CPAL, Portuguese Catalog of Clinical Laboratory Tests) — and their current use and governance at national level. These classifications were developed to suit specific needs of the Portuguese NHS. As a result, few information is published and available to the public. This section provides an overview regarding the purpose of the classification, its structure and the stakeholders responsible for its governance and quality assurance.

3.5.1 CFT

According to the Ministério da Saúde (2014*a*), CFT groups drugs according to their identity and to their approved therapeutic indications. It allows healthcare professionals to easily identify products to a specific therapeutic drug. The Portuguese Ministry of Health approved it in 2014. There is also a mapping between CFT and the Anatomical Therapeutic Chemical Classification System with Defined Daily Doses (ATC/DDD).

ATC/DDD is a drug classification. It aims to facilitate for drug utilization research and to improve quality of drug use. The classification divides drugs into five different levels of granularity, according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties. It is an international classification maintained by the WHO Collaborating Centre for Drug Statistics Methodology (WHO, 2015*b*).

CFT was adopted in official national instruments that support drug prescription, such as the Prontuário Terapêutico and the Formulário Hospitalar Nacional de Medicamentos. It is also used in the process of authorizing the introduction of new drugs in the national market and in official documents regarding State's co-payments of drugs. The classification is organized into the following groups:

Group 1 Anti-infective drugs;
Group 2 Central nervous system;
Group 3 Cardiovascular system;
Group 4 Blood;
Group 5 Respiratory system;
Group 6 Digestive system;
Group 7 Genitourinary system;
Group 8 Hormones and drugs used in the treatment of endocrine diseases;

Group 9 Musculoskeletal system;

Group 10 Anti-allergic drugs;

Group 11 Nutrition and metabolism;

Group 12 Correction of blood volume and electrolyte disturbances changes;

Group 13 Skin condition drugs;

Group 14 Otolaryngology condition drugs;

Group 15 Eye condition drugs;

Group 16 Antineoplasic drugs and immunomodulators;

Group 17 Intoxication treatment drugs;

Group 18 Vaccines and immunoglobulins;

Group 19 Diagnostic methods;

Group 20 Bandaging materials, local hemostatics, medicinal gases and other products.

CFT is maintained by INFARMED (2015) as it is the entity responsible for authorizing the introduction of drugs for human use in the national market. All the stakeholders in the drug business such as manufactures, suppliers and pharmacies are subject to a set of obligations and procedures which are verified by INFARMED.

3.5.2 CDM

According to INFARMED (2015), medical devices are used to prevent, diagnose or treat human disease. They differ from therapeutical drugs because their mechanisms are not based on pharmacological, metabolic nor immunological actions.

CDM aims to act as a control system, according to the potencial risks of each medical device. According to the Portuguese Law no. 145/2009 of June 17, medical devices are divided into four risk classes: Class I (low risk); Class IIa and IIb (medium risk); Class III (hight risk). The classification is being revised to became aligned with international standards (GS1 Portugal, 2012). The classification of a given medical device is based on four main characteristics:

- Duration of contact with the human body (temporary, short term or long term);
- Level of invasiveness of the procedure performed with the device;
- The anatomy affected by its use;
- Potencial risk due to its design and manufacture.

CDM is maintained by INFARMED. All the stakeholders in the medical devices business such as manufactures, suppliers and users are subject to a set of obligations and procedures which are verified by INFARMED. The classification is assigned by the device's manufacturer, according to the guidelines issued in the Portuguese Law no. 145/2009:

- It is the device's purpose that determines their classification;
- In sets of devices, the rules are applied to each of the devices individual;

- Accessories are classified separately;
- When a device is meant to be used in multiple body parts, it should be classified according its most critical use;
- When several rules apply, follow the most rigorous ones that lead to a higher risk class.

3.5.3 CPARA

CPARA was the first structured system to support electronic record of allergies and other adverse reactions (SPMS, 2015*b*). Registering an allergy comprises the statement of several fields. Each field may be described with a number of possible values, presented in a specific table. There are seven mandatory fields (SPMS, 2015*a*):

- Origin (Patient, Physician or other healthcare professional);
- Category of the reaction (whether it is food related, drug related or other)
- Allergen;
- Type of reaction;
- Severity;
- State of register (whether it is active, inactive, confirmed or unconfirmed)
- Adverse reaction's observation date.

The first version (version 1.0) of the CPARA was developed in July 2012 by the Comissão para a Informatização Clínica (CIC, Portuguese Clinical Informatization Committee) in collaboration with the Sociedade Portuguesa de Alergologia e Imunologia Clínica (SPAIC, Portuguese Society for Clinical Allergology and Immunology). The Portuguese Ministry of Health issued a document recommending that all doctors and nurses of the Portuguese NHS should always register allergies and adverse reactions using CPARA. It also stated that auditing of such records is the responsibility of clinical and nursing directors. Each institution should assure the availability of appropriate software to track the author, date and time of each registration (DGS, 2012).

In 2015, SPMS worked on the development of the third version of this catalog (version 3.0). The project was available for public consultation until April 22nd, 2015 on the Centro de Terminologias Clínicas em Portugal (CTC.PT, Clinical Terminologies Centre in Portugal) website. The goals of the project included the following:

- Revise the existing content of the catalog in order to add or remove concepts if necessary;
- Standardize the language used in the catalog by adopting SNOMED CT.

The third version of CPARA includes a mapping between ICPC-2 and CPARA V3.0 and a mapping between ICD-9-CM and CPARA V3.0.

3.5.4 CPAL

The Portuguese Ministry of Health maintains tables of prices that should be applied on the NHS. Each entry of this table is identified by an individual code which belongs to a national coding system designed

for this purpose. One of these tables concerns clinical laboratory tests. This table was the starting ground to initiate the CPAL project.

The Comissão de Acompanhamento da Informatização Clínica (Portuguese Clinical Informatization Monitoring Committee) identified clinical laboratory tests as a critical area in healthcare provision. As a result, CPAL was initiated in 2012 by ACSS and SPMS (2015*b*) in collaboration with the Colégio de Patologia Clinica da Ordem dos Médicos (Clinical Pathology College - Portuguese Psysicians Board) (Ministério da Saúde, 2014*b*). The project aims to standardize the language and documentation used in the context of clinical laboratory testing by developing a common structure to follow when registering such information. The goal is to implement this catalog in entire Portuguese Health System, including both public (NHS) and private sector.

Currently in Portugal, most laboratories use their own local codes which have no correspondence to any other coding system. In order to facilitate exchange of information both at national and international level, SPMS decided to adopt the LOINC terminology and SNOMED CT international standards to create this catalog. CPAL (version 1.0) is now in its final stage of development and it will be available for public consultation on the CTC.PT website.

3.6 Summary

The five international ontologies addressed in this chapter present different degrees of complexity and governance models with different levels of maturity. However, they all aim to assure a specific set of services required to maintain the life cycle of the ontologies. These services include licensing and distribution, update and review processes, translation processes and user's feedback management. These clinical ontologies are mapped to other ontologies, thus facilitating information sharing and semantic interoperability. Given the available mappings, SNOMED CT may be used as reference terminology for mapping processes, as opposed to developing mappings from "everything to everything".

Each international ontology is owned and governed by international organizations responsible for assuring the core of the life cycle of the ontologies. These organizations cooperate with national organizations, which operate as local liaisons and assist them in managing some processes locally, such as licensing, distribution and translation processes. Some of this organizations go even further. An example is NCBO, which covers a variety of biomedical ontologies (not only clinical ones) and supports and promotes research and development actives regarding these ontologies.

In Portugal some clinical ontologies are used in clinical practice. These include international clinical ontologies — ICD, ICPC-2 and ICNP — and also some Portuguese national clinical ontologies — CFT, CDM and CPARA. These are simple clinical classifications which concern very specific clinical domains and purposes. The Portuguese Ministry of Health has identified specific clinical domains — such as allergies and other adverse reactions and clinical laboratory tests — as critical and priority areas in healthcare provision. In an effort to introduce SNOMED CT and LOINC in the Portuguese health system, these critical areas were targeted and the CPARA catalog was mapped to SNOMED CT and the CPAL catalog is being mapped to LOINC and SNOMED CT. On the other hand, an increase in SNOMED CT's

deployment in Portuguese territory is expected, following the recent acquisition of the SNOMED CT's distribution license by the Portuguese Ministry of Health.

These national clinical coding systems are governed at national level by different Portuguese organizations which are often not specialized in clinical ontologies. Each one has its own clinical ontology life cycle management infrastructure to support the services required to manage these products and may lack a formal governance model. In comparison to the international organizations which own international clinical ontologies, these Portuguese organization present few public documentation regarding the national processes for managing these clinical terminologies and classifications.

Chapter 4

The CODEGOM Governance Model

This chapter presents the CODEGOM (Clinical Ontology DEvelopment GOvernance Model) governance model for the development and maintenance of clinical ontologies. CODEGOM was developed to be used by a Clinical Ontologies Center (COC) — a national organization whose main responsibility is to support the creation, management and deployment of clinical ontologies at national level — and by parties interested in developing and managing clinical ontologies.

CODEGOM comprises a basis methodology to carry out clinical ontology development projects. In the context of this work, an ontology development project includes the creation process of the ontology itself and the identification of the required services to support the ontology's continuous deployment, improvement and update (ontology life cycle management). CODEGOM was developed based on the idea that the infrastructure of a COC such as the CTC.PT may provide assistance and a set of services to any group or organization intending to develop and maintain a clinical ontology. The model is targeted for smaller scale projects that complement each other, such as the Catálogo Português de Alergias e Reações Adversas (CPARA, Portuguese Catalog of Allergies and Other Adverse Reactions) and the Catálogo Português de Análises de Laboratório (CPAL, Portuguese Catalog of Clinical Laboratory Tests) projects. As a result, there is no need for each group or organization in charge of developing or maintaining a clinical ontology to establish its own independent infrastructure.

The governance model was inspired by models developed for other domains such as Project Management, Software Engineering, Ontology Engineering and by some national organizations for clinical ontologies. Some of the processes described in the Project Management Body of Knowledge (PMBOK), developed by the Project Management Institute (2013), were adapted specifically for the context of a clinical ontology development project.

The ontology development methodology of CODEGOM applies some of these processes. It is structured into one bootstrap stage, six development phases and three monitoring activities:

- Bootstrap Stage:
  - Clinical Ontologies Center;
- Development Phases:
  - Ontology Charter Development;

  - Stakeholder Identification;
  - Scope Definition;
  - Ontology Development Definition;
  - Project Team Planning;
  - Ontology Development;
- Monitoring Activities:
  - Stakeholder Control;
  - Scope Control and Validation;
  - Quality Management and Control.

Monitoring and controlling activities aim to track and review the project's progress, to identify possible areas where the plan should be adjusted and to take action to make those adjustments. They enable project performance to be assessed at regular intervals or between tasks, thus increasing the probability of success of a project. In each development phase of a clinical ontology development project, monitoring activities should take place. The goal is to assure that the project does not deviate from what was carefully planned and that it fulfills its goals as efficiently as possible.

The development phases are depicted in a sequential way. However, if needed some of these phases may be repeated before proceeding to the following phase. Figure 4.1 illustrates the CODEGOM development project's bootstrap stage, development phases and monitoring activities.

Appendix C contains some support material to assist the implementation of a clinical ontology development project following the proposed methodology.

In order to illustrate each phase of the model, the Catálogo Português de Alergias e Reações Adversas (CPARA, Portuguese Catalog of Allergies and Other Adverse Reactions) (see Subsection 3.5.3) is used as a specific example of application.

Section 4.1 introduces the concept of a Clinical Ontologies Center within the context of the CODEGOM governance model. Sections 4.2 through 4.10 describe each clinical ontology development project's development phase and monitoring activity, while addressing specific processes of Project Management Knowledge Areas such as Stakeholder Management, Scope Management, Human Resource Management and Quality Management. Section 4.11 provides a final overview of the model described in the chapter.

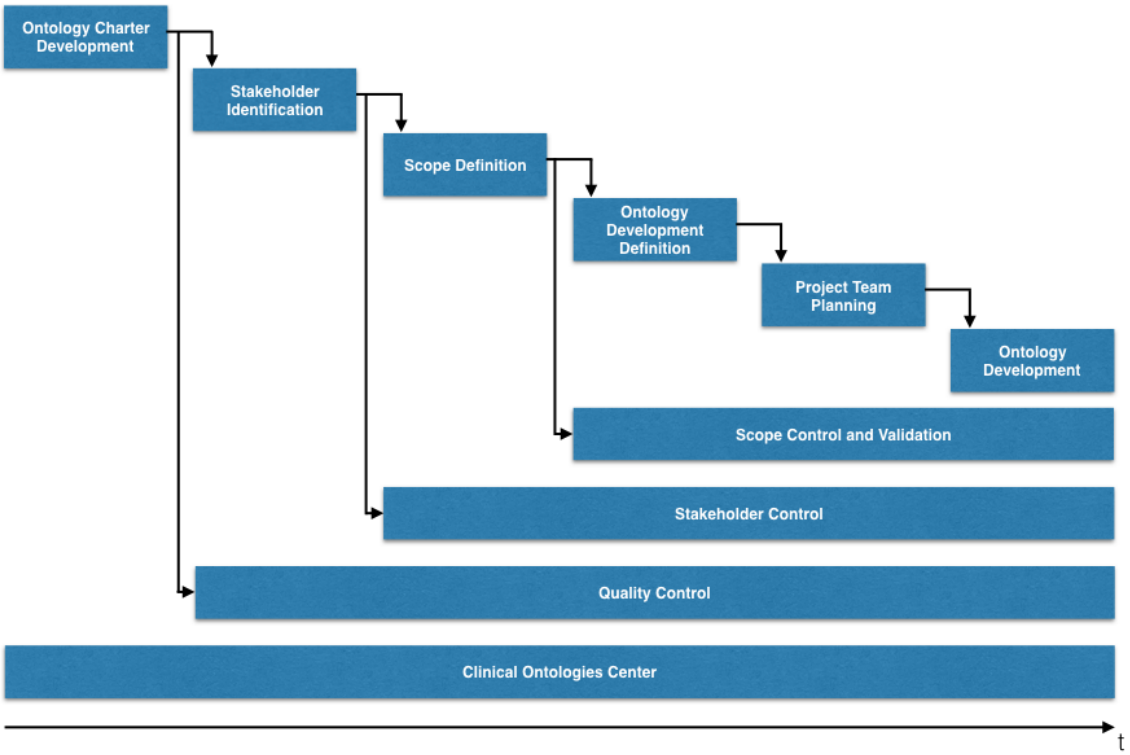

Figure 4.1: Illustration of the clinical ontology development project's lifecycle.

4.1 Clinical Ontologies Center

The bootstrap stage consists of establishing a Clinical Ontologies Center (COC). A COC is a national organization whose main responsibility is to support the creation, management and deployment of clinical ontologies at national level. In the context of this work, a COC is understood as a national body that can support several different clinical ontologies simultaneously. Such an organization may share its expertise and support national clinical ontology development projects.

On one hand, a COC may be limited to the distribution of a few international clinical ontologies, opereating as a small team National Release Center (NRC). On the other hand, a COC may wish to become a bigger and more complex infrastructure, assuring several other services regarding the clinical ontologies's life cycle management. The following responsibilities may be undertaken by a COC:

- Support the development and maintenance of new national clinical ontology development projects;
- Operate as a contact point for the international and national organizations that own and manage clinical ontologies;
- Operate as a contact point for national users, providing guidance regarding the use of clinical ontologies and encouraging experts to contribute to the development of these ontologies;
- Support licensing and distribution of clinical ontologies;
- Gather feedback from the users by managing change requests and other reported issues.
- Develop and manage language translations from the international edition of the ontology to the local language;

- Support versioning of the of the clinical ontologies's national editions;
- Develop and manage mappings between clinical ontologies;
- Provide consultancy, education and training regarding the use of clinical ontologies at national level.
- Maintain a website and/or online platform, which supports and facilitates several of the services and tasks described above.

The developed governance model positions CTC.PT as the Portuguese COC and assumes that it could share its expertise and infrastructure to support new emerging clinical ontology development projects.

4.2 Ontology Charter Development

This development phase aims to produce a document that formally authorizes the existence of a clinical ontology development project under sponsorship of the COC and empowers a project manager to coordinate the project. The project manager should be assigned as soon as possible so that he may participate in the development of the project charter and fully understand project requirements.

By means of a formal contract, the project charter establishes which organizations are in charge of the project. One of these organizations is identified as the sponsoring organization and is responsible for allocating funding and resources to the project. The charter also contains high-level information regarding stakeholders identification and requirements, project goals and milestone identification. As a result, this document acts as a baseline that can be used in meetings to assist in monitoring and validation activities.

CODEGOM projects could be initiated by an organization within the Ministry of Health or outside of it, due to internal needs or external influences. In the case of the CPARA project (version 2.0), the responsible organizations were the Direcção-Geral da Saúde (DGS, Portuguese Directorate-General of Health) and the Sociedade Portuguesa de Alergologia e Imunologia Clínica (SPAIC, Portuguese Society of Allergology and Clinical Immunology), in collaboration with the Serviços Partilhados do Ministério da Saúde (SPMS, Portuguese Ministry of Health Shared Services). In turn, the development of CPARA's third version (version 3.0) was conducted by the SPMS, in collaboration with the DGS. The CPARA project was outlined after the Comissão para a Informatização Clínica (CIC, Clinical Informatization Committee) detected serious shortcomings in the way allergies and adverse reactions were being registered in the institutions of the Portuguese National Health Service (NHS). The registries were often non-existent or unstructured, which could result in serious implications for the safety of NHS's patients. There was no national recommendation regarding a standard format of these records or its electronic format. Allergic reactions such as the ones due to insect bites or ingestion of certain foods may be responsible for life threatening clinical conditions. Furthermore, studies have demonstrated that a large number of medical errors were associated with poor or no registration of allergies and adverse reactions. As a result, the identification and registration of allergies and adverse reactions was considered a priority by DGS. The

CIC proposed the development of the CPARA classification so that all the Portuguese Health System's computer applications would be able to share among them this type of information in an unambiguous way (DGS, 2012).

The Administração Central do Sistema de Saúde (ACSS, Portuguese Health System's Central Administration) is another national health authority that may take part in a clinical ontology development project. The Ordem dos Enfermeiros (OE, Portuguese Nurses Board), the Ordem dos Médicos (OM, Portuguese Physicians Board) and other organizations representing healthcare professionals such as psychologists, nutritionists and physiotherapists may also be interested in participating actively in such a project.

4.3 Stakeholders Identification

This phase comprises the steps required to identify the parties that may impact or be impacted by the project and to analyze stakeholder impact on the project.

Stakeholders are the people, groups or organizations that may affect or be affected by a decision, activity, or outcome of a project. The goal of this CODEGOM development phase is to analyze and document information regarding their interests and expectations, involvement, interdependencies, influence and potential impact on project success. Having determined these factors, the project manager may focus on managing them in order to ensure the success of the project.

The project charter should be used as an input at this stage as it should already contain a primary stakeholder list, including the responsible organizations (DGS, SPMS and SPAIC) and the assigned project manager. In addition, individuals who have already participated in other clinical ontology projects may be of significant assistant. For example, members of the DGS, ACSS or the Associação Portuguesa de Medicina Geral e Familiar (APMGF, Portuguese Association of General Practitioners and Family Physicians) who were involved in the Portuguese NHS's adoption process of the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and the International Classification of Primary Care 2 (ICPC-2). Beyond the responsible organizations and the project manager, the stakeholder list of a clinical ontology development project should comprise the following groups:

Vendors: companies that develop specific software products to be used within the Health System to register clinical information (clinical software). These companies should follow the development process as they may be potentially interested in including such a clinical ontology within their products. Glintt Healthcare Solutions, Maxdata, MedicineOne and HIS e-Health Innovation Systems are some examples of developers to consider when developing such a project in Portugal;

Clients: institutions or organizations that will eventually adopt the use of the ontology within their services (whether it is through a clinical software product or not). Depending on the scope and purpose of the clinical ontology, these may include hospitals, primary care centers and laboratories which perform clinical laboratory tests. Potential clients are not limited to the Portuguese NHS's instituitions. Private healthcare providers such as José de Mello Saúde should also be considered. In the CPARA project, hospitals and primary care centers were the main clients.

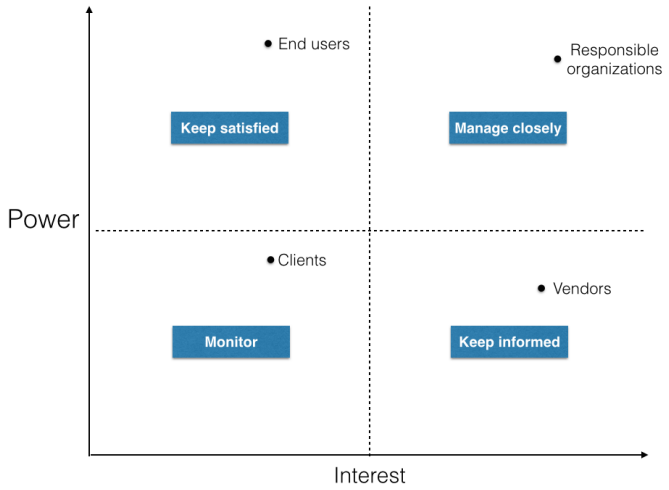

Figure 4.2: Illustration of the placement of four groups of stakeholders in a power/interest grid.

End users: professionals who will be ultimately responsible for using the ontology/clinical software and performing data entry. Depending on the scope of the ontology they may comprise physicians, nurses, administrative personnel, healthcare technicians and laboratory technicians. These are particularly important as stakeholders. Healthcare professionals must understand the benefits of adopting such an ontology and be willing to adapt to the necessary changes to be made in their work environment and methods. End users are potential resistant and supportive stakeholders and they constitute a key factor for the project's overall success. In the CPARA project, physicians and nurses were the primary concern;

Other institutions and organizations: there are a number of other institutions and organizations that may be considered as stakeholders in such a project. These include institutions that may be interested in the data output created by these clinical ontologies and also institutions that audit information quality and privacy standards. Some examples are the Instituto Nacional de Estatística (INE, Statistics Portugal Institute), the World Health Organization (WHO), the OE, the OM and the Comissão Nacional de Protecção de Dados (CNPD, Portuguese Data Protection Authority). Given that CPARA uses the Systematized Nomenclature Of Medicine Clinical Terms (SNOMED CT) standard, the International Health Terminology Standards Development Organization (IHTSDO) was also taken into consideration.

The PMBOK defines a power/interest grid, where "power" refers to the stakeholder's level of authority and resulting ability to impose their will (Project Management Institute, 2013). These groups of stakeholders described above may further be classified according to such a power/interest grid, in order to determine which stakeholders to keep satisfied, manage closely, keep informed or simply monitor. Figure 4.2 illustrates the placement of four groups of stakeholders in a power/interest grid, according to their influence and interest in a given clinical ontology development project.

Stakeholders may also be classified according to their level of engagement. They may be unaware of project and potential impacts (Unaware), aware of project and resistant to change (Resistant), aware of project yet neither supportive nor resistant (Neutral), aware of project and supportive to change (Sup-

portive), aware of project and actively engaged in contributing to project's success (Leading). This classification will be important to manage stakeholder engagement throughout the project (see Section 4.7).

4.4 Scope Definition

The scope definition of a CODEGOM development project ensures that the project includes all the work required and only the work required. This development phase defines what is included in the project and what is not.

The first step is to determine, document, and manage stakeholder needs, requirements and expectation, thus providing the basis for scope definition. Requirements comprise conditions or capabilities to be met by the project or by the clinical ontology itself. Requirements may include business requirements (high-level requirements of the responsible organizations) and solution requirements (technical requirements, describing features or characteristics associated with the clinical ontology).

Both the ontology charter and the stakeholder list constitute inputs for this phase and should be used as a starting point. The ontology charter provides high-level description of the clinical ontology, while the stakeholder list identifies who can provide information on the requirements. Stakeholder's requirements may be collected using the following techniques:

- Direct interviews;
- Questionnaires and surveys;
- Forums, where certain stakeholders may address specific topics;
- Direct observations of healthcare professionals within their job environment;
- Benchmarking, in order to identify best practices in the field of clinical ontologies and generate ideas for improvement.

Group decision-making techniques may be required in the process of establishing project and product requirements. Some example of commonly used techniques are the Delphi technique (Hsu and Sandford, 2007) which is used to reach unanimity and decision by majority (over 50%).

Having collected all the requirements, the scope can be defined. Scope is defined by developing a detailed description of the project and the clinical ontology. It establishes which of the collected requirements will be included in and excluded from the scope. This process is carried out by high management, such as the project manager and the responsible organizations.

The scope of a CODEGOM development project is to create a clinical ontology and to determine which services must be assured to support the ontology's life cycle. Furthermore, the scope of the clinical ontology itself must be defined by stating which features and functions will characterize the ontology. In order to do so, some questions need to be addressed:

- What domain will the ontology cover (e.g., one or more clinical specialties, laboratory tests, drugs, nursing practice, primary care, intensive care)?

- What is the required level of granularity?
- For what is it going to be used? Which clinical activities will require its use and what information is to be retrieved from the coded clinical information?
- What kind of organizations will adopt the ontology and who will be performing data entry?

In the case of the CPARA project, the goal was to develop a clinical classification which would cover the domain of allergies and other adverse reactions. The classification was designed to be used to support the electronic registry of these entities. Each allergy entry should comprise the statement of seven fields and each field could be described with a specific set of values. The classification was created to be used in the entire Portuguese NHS by all physicians and nurses registering allergies and other adverse reaction. However, it is possible that in the initial scope of a project is not exactly the same. It is expected that the answers to these questions undergo some refinement along the ontology development process.

Another technique to help determine the scope of an ontology is to determine a set of questions that the knowledge base based on the ontology should be able to answer. These are known as competency questions. The following questions are examples of possible CPARA competency questions:

- Was the adverse reaction due to drugs or food?
- Which drug caused the adverse reaction?
- How many lobster induced adverse reactions were documented by physicians?
- Where there any acute reactions induced by cosmetics documented by patients?

At this point, reusing existing ontologies should be considered. There is the possibility that a similar ontology already exists. In such a case, that ontology may eventually be refined, extended or adapted in order to meet the requirements of the clinical ontology in development. Plus, using existing ontologies may be a requirement in order to meet information and communication standards already in use. The third version of the clinical classification CPARA includes a mapping to the SNOMED CT coding standard.

In order to conclude the clinical ontology project's scope definition, it is necessary to identify the required services to support the life cycle of the clinical ontology to be developed. Such an infrastructure must comprise the following activities:

- Language translation process of the ontology and all its support material (if applicable);
- Mapping process between the ontology and other standards already in use (if applicable);
- Distribution of the ontology and associated materials;
- License management (if applicable);
- Feedback management;
- Reporting to owner International Organization (if applicable);
- Performing National Update/Review Process (if applicable).

To assure such services, there is no need to build a new and specific infrastructure to the clinical ontology being developed. A COC such as the CTC.PT may provide assistance and its infrastructure to

the organizations in charge of such clinical ontology development projects to facilitate the maintenance of their ontology's life cycles, thus acting as a central body for clinical ontologies in Portugal.

4.5 Ontology Development Definition

This development phase of the CODEGOM governance model consists of subdividing the ontology development project deliverables and scope into smaller steps. It provides a structured and hierarchical view of the work to be performed, also known as Work Breakdown Structure (WBS).

The collected requirements and the scope definition established in the scope definition phase constitute inputs for this process and should be used as a starting point. The common method is to use a top-down approach, where the major deliverables of the project — the clinical ontology itself and the list of services required to support its life cycle — constitute the second level of decomposition and they may be further decomposed into smaller steps which will constitute the third level. The level of decomposition depends on the desired degree of control to manage the project effectively. In fact, excessive decomposition may actually become counterproductive and decrease project efficiency. The decomposition result may be verified by confirming that that the lower-level steps are the ones necessary and sufficient in order to complete their parent activity.

The following list details the steps that need to be performed in order to create a clinical ontology. Moreover, it identifies the services required to support the clinical ontology's continuous deployment and improvement:

- Ontology Creation:
  - Initial List of Concepts;
  - Define Backbone Taxonomy;
  - Define Attributes;
  - Refine Thesaurus;
  - Publish documentation;
  - Field Trials;
- Ontology Life Cycle Management:
  - Language Translation Process;
  - Mapping Process
  - Distribution and Licenses;
  - Feedback Management
  - Report to International Organization
  - National Update/Review Process

Figure 4.3 illustrates the hierarchical structure of the work to be performed.

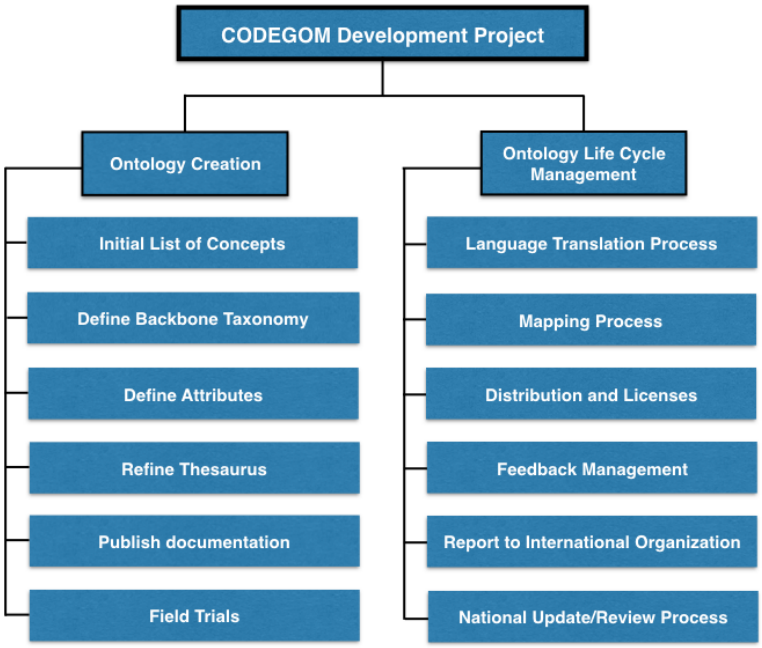

Figure 4.3: Illustration of the clinical ontology project's WBS.

4.5.1 Initial List of Concepts

This first step consists in establishing an initial list of concepts that the clinical ontology should contain. The goal is to define an initial list of terms, without the concern of distinguishing between concepts, relationships, attributes, classes or instances. In a clinical ontology, such a list would contain terms like as diabetes, pneumonia, procedure, bacteria, causative agent, oxygen level, body structure, liver, left arm and color. CPARA's list would contain terms such as food allergen, severity, type of reaction, rice, peanut, shrimp, anaphylaxis, asthma, severe and mild.

This list is to be used as a starting point for the following two steps. Defining the backbone taxonomy and concept's attributes are complex and closely connected tasks and represent a crucial moment of the clinical ontology's creation process.

4.5.2 Define Backbone Taxonomy

Defining the backbone taxonomy consists of establishing parent-child relationships — also known as sub-type or generalization-specialization — between concepts.

There are several approaches to establish this hierarchy. A top-down approach starts by defining the most general concepts in the clinical domain and then their respective sub-type concepts. On the other hand, a bottom-up approach starts by defining the most specific classes, the lower levels of the hierarchy and then groups these classes into more general concepts.

Within the context of this methodology regarding the development of a clinical ontology, a hybrid approach is recommended, combining both the top-down and bottom-up approaches. Such an approach consists in starting with the concepts present in the previously developed list of concepts and then generalize and/or specialize them as needed. As an example the concept "food allergen" may be generalized

into the concept “allergen” and specialized into concepts such as “carrot”, “lobster” or “peanut”. Different approaches may be carried out during this step, depending on the clinical experts’s view of the domain.

Depending on the required level of detail for the clinical ontology, the taxonomy may be structured with a higher or lower degree of granularity. In addition, the taxonomy may allow multiple inheritance. This occurs when a certain class is a subclass of more than one class.

4.5.3 Define Attributes

After defining concepts (classes) and their hierarchical structure, it is necessary to define their internal structure. Having sorted the classes from the initial list of concepts, the remaining ones probably refer to attributes — also known as properties or slots — of those classes (e.g., causative agent, color).

The first step is to assign each attribute to the class it describes. The attribute should be assigned to the most general class that has that attribute, as all the respective subclasses will inherit it. The second step is to define the values that each attribute may have. The definition is based on specifying the attribute’s value type, the number an attribute may have (cardinality) and which values are allowed to be assigned to that attribute. Common value types include strings, numbers (integer or float), Booleans, enumerated slots (list of possible values) and other concepts. Attributes whose value type are concepts constitute an attribute relationship, as they represent a relationship between two concepts. Attributes require the additional definition of a list of concepts (classes or instances) which may be used as values for that attribute. As an example, CPARA’s attribute “state of register” may only be assigned with one value at a time. This value has to be chosen from the following pre-determined set: “active”, “inactive”, “confirmed active” and “confirmed inactive”.

This pre-determined set of allowed value is called the attribute’s range. It might be necessary to define different ranges according to which concept the attribute is describing. On the other hand, the set of concepts that the attribute describes is called the attribute’s domain. As the first step was to assign each attribute to the class it describes, the domain is already defined. It is the set of concepts which are described by that attribute.

In order to easily distinguish between classes and attributes, a common methodology is to use prefixes and suffixes in attributes’s names (e.g., has causative agent, causative agent of).

4.5.4 Refine Thesaurus

Having established the clinical ontology’s core, the team may focus on refining the thesaurus, namely regarding the definition of synonyms. Within the clinical field, the vocabulary used by healthcare professionals may vary from individual to individual. As a result, it is necessary to address each one of the concepts defined so far and determine which terms are normally used to describe them. This step could also comprise an initial assessment of the core ontology and check for the need of adding, removing or editing concepts.

4.5.5 Publish documentation

This step aims to elaborate and publish all the support and educational documentation regarding the created clinical ontology. Such documentation may include information on how the ontology is structured, a detailed description of its content and guidelines on how to use the ontology to code clinical information.

4.5.6 Field Trials

Finally, a last step should be performed before declaring the clinical ontology ready for use and distribution. Field trials should be conducted within a controlled group of healthcare professionals who work with the clinical domain that the ontology covers. The goal is to get feedback on the applicability and reliability of the clinical ontology. The resulting feedback may require action to be taken and some of the previous steps may have to be addressed again.

4.5.7 Language Translation Process

If the clinical ontology project started with the creation of a new ontology to be used at national level, this service will not be required, as the ontology would have been developed in the local language. However, if the project consist in adopting an international ontology which is not translated into the local language, this is the first step to be performed.

When performing this step, the content of the clinical ontology should also be reviewed. It is possible that part of the content was developed specifically regarding the characteristics of a country or local area and that that same content may not apply to the country where the ontology is being adopted. For example, if the ontology was developed in Australia and it contains certain allergens or flora and fauna that cannot be found on the Portuguese territory, maybe it is not necessary to proceed to the translation of those subsets of the ontology. On the other hand, some content specific to the Portuguese context may be necessary to be added, namely to facilitate billing processes within the Portuguese NHS.

The translation process should be concept-based and not term/word based. The goal is to assure semantic equivalence of the concept in both languages and avoid literal translations. Moreover, it may happen that one concept in the source language need to be translated into more than one concept in the destination language and vice-versa. The translation process should also address all the clinical ontology's documentation.

The COC may provide interested parties or groups with guidelines and support material to carry out translation processes.

4.5.8 Mapping Process

Whether the project refers to a new clinical ontology or an international one that is about to be adopted, it may be necessary to map the ontology to other clinical information standards which may already be in use within the national health system. The usage of the new ontology in the clinical field may require

the ability to interact with clinical information already coded with these standards, thus requiring the production of mappings between these standards.

This step consists in identifying which mappings need to be developed and then carrying out the mapping process. In a similar way as described in previous step, it may happen that one concept in the source clinical ontology corresponds to more than one concept in the destination clinical ontology and vice-versa.

In Portugal, primary healthcare professionals had been using ICPC-2 to code three elements of medical encounters: patient's reason for encounter, health problems or diagnosis and procedures. As a result, within the scope of CPARA the project team developed a mapping between the two classifications, so that correlations could be made between existing allergy and other adverse reaction registries using ICPC-2 and new registries coded with CPARA. The COC may provide interested parties or groups with guidelines and support material to carry out mapping processes.

4.5.9 Distribution and License Management

Having the clinical ontology ready for use, it is necessary to assure and support the distribution of the ontology and its documentation to interested parties. This can be accomplished by setting up a website/platform where any interested party may register and apply for a license to use the ontology. After the license is granted, the user could download the latest version of the product and documentation by logging in with his official credentials also granted alongside with the license.

Currently in Portugal, the CTC.PT uses a similar model to manage licenses and distribution of the SNOMED CT coding system. A COC could provide its infrastructure and support to groups or organizations carrying out clinical ontology development projects. As a result, there would be no need to build their own infrastructure to distribute their clinical ontologies. At the same time, the COC operates as a centralized body for the distribution and management of clinical ontologies at national level.

However, in some particular cases such as the ICD, requests must be submitted directly to the international governing organization which in this particular case is WHO. In this cases, the COC would provide instructions regarding the use of the clinical ontology and redirect to the appropriate location.

4.5.10 Feedback Management

Feedback management is a major service which needs to be assured in order to support the clinical ontology's life cycle. The feedback resulting from the field trials provides important information in the early development stages of the ontology. However, there is always room for an ontology to be improved. This is specially true when talking about a clinical ontology. The clinical domain is constantly evolving and clinical ontologies need to be updated accordingly. On the other hand, a certain version of the ontology may be published with errors that will certainly be detected by end users. It is imperative to provide a service that allows the users to submit errors and change requests to the managing organization. The goal is to keep the ontology updated and functional at the highest level possible.

This service would also be provided through the COC infrastructure, where the user could log in and

submit change requests which require actions such as adding, removing or editing a concept, synonym, relationship, concept description, parent concept or child concept. Depending on the clinical ontology concerned (national or international), one of the two following steps should be addressed.

4.5.11 Report to International Organization

If the feedback management refers to an international clinical ontology which is governed/owned by an international organization, the COC would be responsible for collecting the feedback and submit it to the international organization for review. In the case of SNOMED CT in Portugal, CTC.PT and SPMS are responsible for assuring this service.

4.5.12 National Update/Review Process

If the feedback received by the COC refers to a national clinical ontology or to a translation issue of an international clinical ontology, the COC has to communicate with the organization that owns that ontology so that it can process the feedback and eventually conduct a review/update process of the clinical ontology or of the translation of the ontology. The owner organization should define the periodicity of these processes and designate specific commits or groups to access the submitted feedback and then elaborate recommendations to be implemented into the following release of the clinical ontology. As an example, a new medicine or chemical product may require the introduction of a new term in the CPARA catalog. The new term would have to be discussed by clinical and linguistics experts before being adding it to the catalog and releasing a new and improved version of CPARA.

4.6 Project Team Planning

The project team comprises the human resources that are assigned with roles and responsibilities within the project. Project team members (also known as project's staff) may present a broad scope of skill sets and may be added or removed as the clinical ontology project progresses.

Despite the fact that each team member is assigned with specific responsibilities, the involvement of all team members/departments in project planning and decision making is likely to increase project's success. Team member's involvement adds expertise to these steps and increase their commitment to the project.

The first step is to identify and document project roles, responsibilities and skills required. A subset of the clinical ontology project team — the project management team — is responsible for the project's management and leadership activities. This team should be identified and assembled when developing the ontology charter and assigning the project manager. The goal of this development phase is to identify the team that will perform the steps defined in Section 4.5.

Roles and responsibilities can be documented in a matrix-based chart called a responsibility assignment matrix. In such a matrix, rows represent the steps to be performed while columns represent individuals or groups of individuals with a specific skill set. The matrix can be used to assign human

resources to their respective activities. At the same time, roles and responsibilities should also be documented in text format detailing the role description, responsibilities and competencies (skills required).

The second step is to confirm the availability of the required human resources, acquire the team and brief the team on the scheduled activities. The final step consists of providing any necessary training to improve the team's competencies, teamwork and enhance their motivation and performance throughout the project. A clinical ontology project's team should comprise the following groups:

Clinical Domain Experts: Depending on the scope of the clinical ontology, these may include healthcare professional such as physicians, nurses and healthcare technicians. The participation of clinical experts in the production process of the ontology assures the accuracy of the ontology's clinical content. Since one of the goals of the ontology is to facilitate communication between these individuals in their work field, their view of the domain should be reflected in the ontology. For instance in the CPARA project the team included members of the Portuguese Society of Allergology and Clinical Immunology (SPAIC, 2015);

Linguistics Experts: Linguistics is the science that studies language, focusing on syntax, semantics and context. Given that semantic interoperability is one of the major goals of using clinical ontologies to code clinical information, it is fundamental that the team comprises experts that can contribute to the construction of the lexicon and assure the ontology's linguistic quality. To assure eventual translation processes, linguistics experts on the source language are required as well. Ideally, they would have expertise in both local and source language.

Ontology Engineering Experts: These experts are responsible for the actual implementation of the ontology as a software product. They work in close collaboration with both domain and linguistics experts. There several editor tools which provide graphic user interfaces to assist in the development of ontologies, such as the Stanford University's Protégé;

Health IT Support Specialists: This group is necessary to support the development and maintenance of the website, servers and online platform that will support most of the services that the COC provides. In addition, they also contribute to the feedback management process, namely gathering and organizing the received feedback. In Portugal, these specialists could be provided by the CTC.PT infrastructure.

Anyone with previous experience in similar projects may constitute a significant contribute to the overall performance of the team and project.

These groups do not necessarily work in separate. In fact, domain, linguistics and software engineering experts work in close collaboration throughout the majority of the clinical ontology project's development phases. In addition, in certain situations such as the national update/review process and the quality monitoring activities, these groups may be organized into several multidisciplinary committees and forums. The following committees should be formed:

Content Committee: focuses on the content of the clinical ontology. It may be further divided into smaller groups to address individually specific subsets of the ontology's domain (e.g., clinical specialties).

Responsibility Assignment Matrix	Clinical Domain Experts	Linguistics Experts	Ontology Engineering Experts	Health IT Support Specialists
Initial List of Concepts	X	X	X	
Define Backbone Taxonomy	X	X	X	
Define Attributes	X	X	X	
Refine Thesaurus	X	X	X	
Publish Documentation	X		X	
Field Trials	X			
National Translation Process	X	X	X	
Mapping Process	X	X	X	
Distribution and Licenses			X	X
Feedback Management				X
Report to International Organization	X			X
National Update/Review Process	X	X	X	X

Figure 4.4: Illustration of a responsibility assignment matrix regarding a clinical ontology development project.

Quality Control Committee: focuses on verifying the quality of each development phase's output. Its members are responsible for reviewing and approving those outputs as fit for use. The committee may contain project team members that participated in the development phase under assessment, but it should also comprise individuals external to the actual phase. This should be a highly multi-disciplinary committee in order to be able to cover all aspects of the ontology. It should comprise clinical experts, linguistics experts, ontology engineering experts and representatives of the project management team;

Stakeholders Forums: enable interested parties such as clinical software companies and healthcare professionals to participate and provide feedback during the ontology development phases.

Figure 4.4 illustrates the responsibility assignment matrix of a clinical ontology development project. It assigns the groups described in this section to each one of the steps described in the ontology development definition section (see Section 4.5).

Appendix C contains some screenshots of the human resource allocation phase within a project management software environment.

4.7 Stakeholder Control

In CODEGOM, managing and controlling stakeholder's engagement comprises the following activities:

- Communicating and working with stakeholders to keep them satisfied by meeting their needs and expectations;
- Anticipating possible future problems;
- Addressing and resolving issues as they occur;

CPARA Stakeholder Engagement Matrix	Unaware	Resistant	Neutral	Supportive	Leading
Clinical Software Company 1		T		D	
Clinical Software Company 2			T	D	
Hospital Management 1	T			D	
Hospital Management 2			T	D	
Allergy/Immunology specialists					T D
General Practitioners			T	D	
DGS					T D

Figure 4.5: Illustration of a stakeholder engagement matrix's example regarding the CPARA project.

- Promoting stakeholder's engagement and continued commitment throughout the project's development phases;
- Monitoring relationships amongst stakeholders;
- Adjusting individual stakeholder approaches;

The goal is to increase stakeholder support, minimize stakeholders resistance and to maintain or increase the efficiency and effectiveness of stakeholder engagement throughout the clinical ontology project's development phases.

An issue log should result from this monitoring activity, containing a list of all issues, change requests and actions taken. This information should be processed and distributed periodically to every stakeholder involved in the project. Common and affective formats used to keep stakeholders updated include spreadsheets, graphical illustrations and slideshow presentations. Stakeholders should also be presented with information regarding current project performance.

During the clinical ontology development project, stakeholder's engagement can be managed and documented using a stakeholder engagement matrix. The matrix indicates the assessed level of engagement of each stakeholder at a given time (T) and also the desired level of engagement (D). Figure 4.5 illustrates an example of such a matrix, displaying possible desired and current level of engagement of some stakeholders involved in the CPARA project.

The project management team is responsible for filling this matrix throughout the project. As a result, the team can prioritize the approach to specific stakeholders and correct eventual discrepancies between the desired and actual level of stakeholder's engagement. During these activities the project manager's interpersonal skills are put to the test, as he is required to overcome stakeholder's resistance to change and eventual conflicts.

4.8 Scope Control and Validation

Scope control consists of monitoring the scope of the clinical ontology development project and the scope of the clinical ontology itself. The goal of this CODEGOM's monitoring activity is to maintain the scope baseline throughout the project's development phases. These activities are particularly important when stakeholders introduce a new requirement or change request while the project is in motion. A

Requirements Traceability Matrix			
Requirements	Project Development Deliverables	Checklist	Major Deliverables
Clinical ontology to support electronic record of allergies and other adverse reactions, to be used by doctors and nurses of the Portuguese NHS	Initial List of Concepts	✔	Clinical classification CPARA
	Backbone Taxonomy	✔	
	Attributes and respective domains and ranges	…	
	Refined Thesaurus	…	
	Support documentation	…	
	Field trials results	…	
Infrastructure to support the ontology's continuous deployment and improvement	Infrastructure and processes to support translation tasks	✔	Portuguese Clinical Ontologies Center (COC)
	Infrastructure and processes to support mapping tasks	✔	
	Infrastructure and processes to support distribution tasks	✔	
	Infrastructure and processes to support license managing	…	
	Infrastructure and processes to support feedback management	…	
	Infrastructure and processes to support reporting to ontology's owner organization	…	
	Infrastructure and processes to support national update/review process	…	

Figure 4.6: Example of a traceability matrix at a given time of a clinical ontology development project.

document should be produced periodically stating how the project scope is performing when compared to the initially defined scope.

In turn, scope validation consists of formally accepting each project deliverable, thus increasing the chance of satisfaction regarding the developed clinical ontology. Deliverables must be inspected by the Content Committee, to assure that they meet the clinical ontology's requirements. The inspection process is often referred to as a review or audit. After the Committee's assessment, stakeholders's representatives and the project management team must also validate that the deliverables meet the requirements and specifications agreed at the beginning of the project. The documentation containing all the gathered requirements and scope definition are inputs to these activities and constitute the basis for validating the deliverables.

In order to keep track of the scope of a clinical ontology development project, a requirements traceability matrix can be created. The matrix links the clinical ontology requirements to the deliverables that satisfy them. It can also be used as a checklist to verify that the project is evolving within the planned scope. Figure 4.6 illustrates an example of a traceability matrix at a given time of a clinical ontology development project.

4.9 Quality Management and Control

According to the ISO 9000 standard, quality is "the degree to which a set of inherent characteristics fulfill requirements" (Project Management Institute, 2013). Quality management addresses the following concepts:

Customer satisfaction: ensures that customer expectations are met, that the project produces the required clinical ontology and that it is fit for use;

Prevention over inspection: Quality should be planned and continuous, and not only inspected at the end of the whole project. The cost of preventing mistakes or defects is generally inferior to the cost of correcting those issues by the end of the project or even during usage of the clinical ontology;

Continuous improvement: Performing quality assurance and control is the basis to identify potential issues and take action to improve the quality of a clinical ontology development project's processes and the quality of the clinical ontology itself. The goal is to improve the overall process capability and maturity.

To conduct this CODEGOM's monitoring activity, the first step consists on identifying quality requirements and standards for the clinical ontology development project and its deliverables. The scope and requirements documentation are used as inputs for this activity. One simple way of planning quality management is to determine the sequence of development phases which are required to be performed. It is important to define which phases or activities need to be completed before starting the following one (see Figure 4.1). This may be further complemented with a detailed list of inputs and outputs for each process. Each process's inputs and outputs are described in their respective section of this chapter.

Benchmarking is another useful technique to maximize a clinical ontology development project's quality. Benchmarking consists of identifying the best practices in similar projects, and comparing them to the current project. The goal is to create ideas for improvement and provide a basis for performance measuring. There are several international clinical ontologies with different levels of maturity, such as SNOMED CT, ICD, ICPC-2, ICNP and LOINC. Important lessons may be learnt by analyzing how these ontologies are structured and governed (see Chapter 3).

Nevertheless, the major output of this activity is the definition of quality assessment checklists. Quality checklists are used by the Quality Control Committee to verify that a specific set of required steps has been performed. They allow to determine that the development phase was completed successfully and the following one may be carried out. The checklists developed within the scope of this work also address the Stakeholder Control and Scope Control and Validation monitoring activities, as these must be performed before moving on to the following development phase.

On the other hand, the quality checklist verification may conclude that the development phase was not completed successfully. In that case, the checklist helps to identify the cause of the unsatisfactory result and to understand were the process failed. As a result, this monitoring activity supports continuous process improvement, allowing activities to be refined into more efficient and effective ones, by identifying the causes of underachieving outcomes, highlighting all the lessons learned and recommending/taking action to eliminate those issues. The development phase should be improved and repeated until its output meets the quality checklist's requirements.

Figures 4.7 through 4.12 illustrate the quality checklists to be applied in each development phase of a clinical ontology development project such as the development of the CPARA classification.

Quality Checklist		
Project: Clinical Ontology Development (CPARA) **Process**: Ontology Charter Development **Date**: August 2015		
Quality Item	**Assessment**	**Comments/Recommendations**
Product charter documentation was produced	✔	
Project charter documentation was elaborated by representatives of the sponsoring and requesting organization	✔	
Project charter documentation contains high-level information regarding stakeholders identification and requirements, project goals and milestone identification	...	

Figure 4.7: Illustration of the Ontology Charter Development quality checklist.

Quality Checklist		
Project: Clinical Ontology Development (CPARA) **Process**: Stakeholders Identification **Date**: August 2015		
Quality Item	**Assessment**	**Comments/Recommendations**
Stakeholder register was produced	✔	
The documentation contains quantitative and qualitative information regarding stakeholder's interests, expectations, potential impact and desired level of engagement	...	
Documentation was produced by the project management team and representatives of the sponsoring institution	...	

Figure 4.8: Illustration of the Stakeholder Identification quality checklist.

4.10 Ontology Development

The final CODEGOM's development phase consists in performing all the steps and activities planned and described throughout the model, including the monitoring activities associated with each phase. The entities responsible for the project would check with the COC which ontology life cycle services could be supported by the center, thus avoiding the need to also create a completely new infrastructure specifically to support the clinical ontology being developed. The output of this development phase is the actual clinical ontology, fully operational and ready for deployment.

4.11 Summary

CODEGOM describes how to conduct a clinical ontology development project and the importance of a COC to support the development and deployment of those projects. The expertise of a COC such as CTC.PT is of high importance. A COC can support simultaneously multiple parties carrying out clinical ontology development projects, sharing expertise by providing guidelines and experienced human resources and also by providing their insfrastruture and services to assure a part or the entire life cycle of the clinical ontology.

The model comprises one bootstrap stage, six development phases and three monitoring activities that must be carried out in a parallel way to the actual development of the clinical ontology. The first

Quality Checklist		
Project: Clinical Ontology Development (CPARA) **Process**: Scope Definition **Date**: August 2015		
Quality Item	**Assessment**	**Comments/Recommendations**
Stakeholder's requirements were gathered through appropriate methods and documented	✔	
Scope documentation contains detailed description of project scope	✔	
Scope documentation contains detailed description of product scope	...	
The documentation was produced by the project management team, sponsor representatives and stakeholders representatives	...	
Stakeholders were informed and approved the final documentation	...	

Figure 4.9: Illustration of the Scope Definition quality checklist.

Quality Checklist		
Project: Clinical Ontology Development (CPARA) **Process**: Ontology Development Definition **Date**: August 2015		
Quality Item	**Assessment**	**Comments/Recommendations**
Project deliverables (ontology and NRC infrastructure) were divided into smaller tasks/ processes	✔	
A hierarchical work structure was created, with an appropriate level of decomposition. Lower-level components are the ones necessary and sufficient to complete the project	✔	
The hierarchical structure was documented, defining each one of its components	...	
The documentation was produced by the project management team and stakeholders representatives	...	
Stakeholders were informed and approved the final documentation	...	

Figure 4.10: Illustration of the Ontology Development Definition quality checklist.

development phase consists of producing a document to formalize the existence of a clinical ontology development project. The document should include information regarding the motivation for the project, the entities responsible for the project, the project manager and high-level information concerning major stakeholders, project requirements, project scope and clinical ontology requirements. The following two phases aim to fully identify and document project stakeholders, stakeholder's requirements, project scope and the clinical ontology scope. After defining the steps required to create the clinical ontology and their hierarchical structure, the project team must be identified and acquired. Roles, responsibilities and required skills must be documented and assigned to the appropriate team members. The project team required to developed a clinical ontology development project must be multidisciplinary, comprising clinical domain experts, linguistics experts, ontology engineering experts and health IT support specialists.

All the monitoring activities must be performed while carrying out the clinical ontology development phases and steps. It is necessary to manage stakeholders satisfaction and engagement and avoid both

Quality Checklist		
Project: Clinical Ontology Development (CPARA) **Process**: Project Team Planning **Date**: August 2015		
Quality Item	**Assessment**	**Comments/Recommendations**
Project roles and responsibilities were identified and documented, defining role's description, level of authority, responsibilities and skills required	✔	
Availability of project team members was verified	✔	
Project team was acquired	...	
Project team was assigned to their roles (responsibility assignment matrix) and briefed about the project and their responsabilities	...	
Appropriate committees/forums were formed to facilitate project work, including a Content Committee, Quality Control Committee and Stakeholders Forums	...	
The project team planning and documentation was performed by the project management team	...	
Stakeholders were informed and approved the final documentation	...	

Figure 4.11: Illustration of the Project Team Planning quality checklist.

Quality Checklist		
Project: Clinical Ontology Development (CPARA) **Process**: Ontology Development Execution **Date**: August 2015 **Note**: This is a standard checklist is to be used after each one of the processes defined in the Ontology Development Definition process		
Quality Item	**Assessment**	**Comments/Recommendations**
The process was carried out by the appropriate team members (check the responsibility assignment matrix)	✔	
The output/deliverable was review by the Quality Control Committee and it satisfies the requirements that it was developed for (check the traceability matrix)	...	
Stakeholders were informed and approved the output/deliverable	...	

Figure 4.12: Illustration of the Ontology Development Execution quality checklist.

project scope and clinical ontology scope deviations. After each development phase or step, quality control must be applied to assure that the all the required activities were performed and to identify possible flaws in the development process.

Developing a clinical ontology is a highly iterative process. Within a certain development phase, project activities may be intentionally repeated. This may happen due to an increase of the project team's understanding of the project and of the clinical ontology itself or to an unsatisfactory quality control result. Despite the fact that there is an initial high-level definition of the clinical ontology development project's scope, the detailed scope is determined and refined in each iteration. Carrying out project phases in an iterative way contributes to risk reduction, allowing the team to incorporate feedback and lessons learned in each iteration. Lessons learned by the project team during the iterative process may result in actual process improvement and/or project team refinement.

Chapter 5

Conclusions

Clinical ontologies are widely used at the international level. This work covered five of the most widely known and used in clinical practice worldwide: the Systematized Nomenclature Of Medicine Clinical Terms (SNOMED CT), the International Classification of Diseases (ICD), the International Classification of Primary Care 2 (ICPC-2), the International Classification for Nursing Practice (ICNP) and the Logical Observation Identifiers Names and Codes (LOINC). These clinical ontologies present different levels of maturity. Some were born several decades ago and under different names. Some of them started as simple nomenclatures and then evolved through consecutive expansions and mergers with other coding systems. However, these evolution processes often occurred in an ad-hoc and unstructured manner. Nowadays, clinical ontologies still present inconsistencies and limitations and are far from being able to represent comprehensively and consistently the human discourse and its semantic relationships.

Nevertheless, the governance models of the most mature clinical ontologies are similar and allow some degree of semantic interoperability between them, through the development of mappings. They require a common set of services and quality issues to be address in order to appropriately manage their life cycle: content management and update, quality assurance, licensing, distribution, translations and mappings to other clinical ontologies. These clinical ontologies are governed and maintained by international organizations which are responsible for assuring their quality, fitness for use and continuous improvement. In turn, these organizations often collaborate with national organizations for clinical ontologies which act as a local liaisons. They may manage licenses and distribution locally, create and maintain a local translation of the ontology, develop mappings to other national ontologies and gather feedback at national level and submit it to the governing organization of the ontology. In addition, these organizations may support the creation and management of new national clinical ontologies.

This master's thesis developed the CODEGOM governance model for the creation and management of clinical ontologies under the guidance and infrastructure of a Clinical Ontologies Center (COC) such as the CTC.PT. The COC provides a common infrastructure to manage their life cycle and to operate as a national education and training center regarding clinical ontologies, playing the part of a centralized office for supporting the deployment and distribution of clinical ontologies at national level.

CODEGOM was specifically developed for the creation and management of national clinical ontolo-

gies. It provides support material to assist the implementation of a clinical ontology development project following its proposed methodology. Namely, it provides a set of templates to support the development life cycle of a clinical ontology. These templates include a project template designed in a Project Management software tool named ProjectLibre (2014). This editable template contains the overall structure of the clinical ontology development project (development phases and monitoring activities) and allows to manage several project management dimensions, such as time management, cost management and resources management. In addition, the CODEGOM templates also include three matrixes (engagement matrix, responsibility assignment matrix and stakeholder engagement matrix) and several quality assessment checklists to be used in clinical ontology development projects.

The overall quality of a clinical ontology development project and of the resulting clinical ontology is assured by the quality of the development process itself. The CODEGOM development process relies on a clearly defined scope to be carried out by individuals or groups of individuals with high expertise and adequate skill sets. The entire process must be continuously monitored so that it satisfies all the quality requirements and assessment checklists.

The work developed in this master's thesis presents some limitations and it may still be improved:

- The proposed governance model could be further detailed. It is a starting point for carrying out a clinical ontology development project, as opposed to a comprehensive guide regarding all the dimensions of a clinical ontology development project;
- Some Project Management Knowledge Areas were not addressed within the scope of this master's thesis, namely Time Management and Cost Management. To make it more comprehensive, the duration of each project development phase and their respective steps could be determined based on empirical data from previous developments. The project team planning phase could also be improved by covering the amount of time that each team member or group is allocated to a certain task. The template developed in the project management software allows to introduce and manage these variables. In addition, it also allows to manage project budget by introducing the costs of materials and human resources;
- This work focused primarily on the CODEGOM's clinical ontology development methodology. CODEGOM's decision process, roles and responsabilities could be further detailed. In addition, the investment and effort required to set up the COC's infrastructure were not researched;
- CODEGOM does not include a process improvement approach for clinical ontology production. The quality assessment checklists constitute a starting point to assess and evaluate the ontology development process. However, the governance model could include a methodology to assure continuous process improvement so that it may evolve and reach higher maturity levels. This process improvement methodology could take as a starting point the maturity models and standards mentioned in Chapter 2;
- The CODEGOM governance model has not been yet used to carry out a realistic clinical ontology development project. It only simulated how it would work for some development projects that did not formally apply CODEGOM. The model should undergo a simulation or test addressing all the previous components before being actually used in a clinical ontology development project.

One possible way to perform this would be to simulate the creation of a small example clinical ontology with the assistance of a small project team and an ontology editing tool such as Stanford University's Protégé;

- The CODEGOM governance model could be released for public discussion on the CTC.PT website.

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Appendix A

Software process improvement standards

A.1 The Capability Maturity Model standard

The Capability Maturity Model (CMM) is a roadmap defining the areas to be addressed by an organization in order to improve a chaotic process into a continuously improving process. The model is based on the assumption that the higher the process maturity, the higher the process capability of an organization. CMM comprises five maturity levels:

Level 1 Initial: ad hoc or chaotic process. Process designed for a specific problem/task, which is not intended to be generalizable or adaptable to other purposes;
Level 2 Repeatable: disciplined process;
Level 3 Defined: standard and consistent project;
Level 4 Managed: predictable project;
Level 5 Optimizing: continuously improving project (Zahran, 1998).

Maturity levels comprise key process areas (KPA). KPAs identify the areas to be addressed in order to achieve that maturity level. Each KPA is organized into 5 subsections called common features. These represent the key practices to be address in order to reach the goal of a KPA. Figure A.1 illustrates the internal structure of the CMM model (Zahran, 1998).

There are assessments that use the CMM model as a roadmap against which to compare the assessments. In these cases, one of the main instruments used is the process maturity questionnaire. The questionnaire contains questions that relate to the goals of the model's KPAs and it may be customized. Both the model and the questionnaire were developed by the Software Engineering Institute (Zahran, 1998).

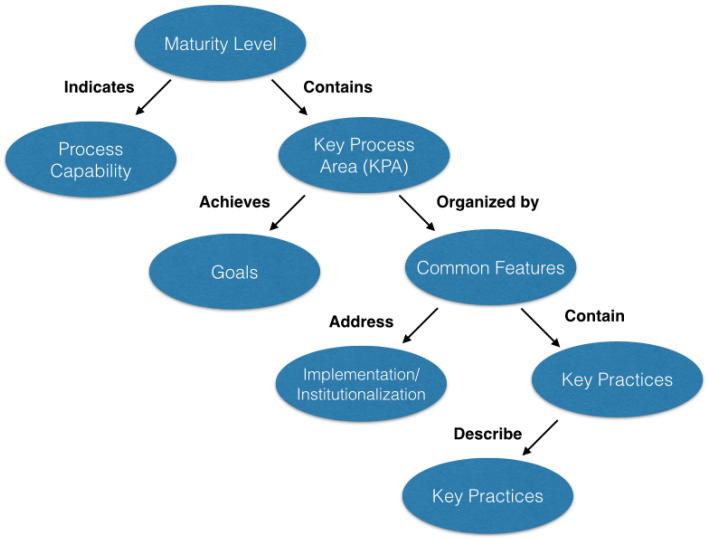


Figure A.1: Internal structure of the CMM (Zahran, 1998).

A.2 The ISO/IEC 15504 standard

The ISO/IEC 15504 process standard — also known as Software Process Improvement and Capability dEtermination (SPICE) — can be used in two modes: the process improvement mode, and the capability determination mode. As a result, the reference model for processes and process capability comprises two dimensions. The Process dimension, which is characterized by process purposes and their respective expected outcomes. On the other hand, the Process Capability dimension which is characterized by a set of process attributes (Zahran, 1998).

The processes within the Process dimension are grouped into 5 process categories, according the type of activities they deal with: the Customer-Supplier process category; the Engineering process category; the Support process category; the Management process category; the Organization process category. The Engineering category deals with processes that specify, implement or maintain a system/software product and its user documentation. It is constituted by 7 processes (Zahran, 1998).

The capability dimension includes 6 process capability levels:

Level 0 - Incomplete
Level 1 - Performed Process
Level 2 - Managed process
Level 3 - Established process
Level 4 - Predictable process
Level 5 - Optimizing process (Zahran, 1998)

Each level comprises a set of attributes which represent a significant increase of capability in the performance of a process. In total, levels 1 through 5 incorporate nine process attributes. Attributes are measurable characteristics. They are rated according to the level of achievement in each attribute: Not achieved (0 - 15%); Partially achieved (16 - 50%); Largely achieved (51 - 85%); Fully achieved (86 -

100%). The capability level is then derived from the attributes rating, based on a specific table design for that purpose (Zahran, 1998).

Appendix B

Portuguese Health Sector

Several European countries, including Germany, France, Austria and the Netherlands, based their health systems on the Bismark model. According to Oliveira (2010), these systems are based on a compulsory social insurance, paid either by workers or by employers. Insurance payments are mainly based on the payer's earnings. On the other hand, countries such as the United Kingdom, Sweden, Denmark, Spain and Portugal are based on the Beveridge model. Patients usually have access to healthcare through primary healthcare centers. Beveridge systems rely predominantly of taxes and healthcare is free of charge or tends toward being free of charge, according to the economic and social conditions of the citizens.

According to the Ministério da Saúde (2013*d*, 2015*a*,*b*,*c*), the provision of healthcare in Portugal is characterized by the coexistence of a National Health Service (NHS), public and private subsystems specific for certain professional categories and private voluntary insurances. The NHS is the main provider of healthcare comprising all integrated healthcare, including health promotion and surveillance, disease prevention, diagnosis and treatment of patients and medical and social rehabilitation.

The Portuguese NHS was created in 1979 — 31 years after the creation of the United Kingdom's NHS in 1948 — as an instrument of the state to ensure the right to health protection under the Constitution. According to the economic and social conditions of citizens, these may be required to pay user fees for the NHS services provided to them.

The Portuguese NHS comprises a hierarchical set of institutions and official healthcare providing services, working under the supervision and authority of the Portuguese Ministry of Health. It has administrative and financial independence and it is structured into a decentralized organization comprising central, regional and local offices. It provides primary healthcare services and differentiated healthcare services.

The hospital network in mainland Portugal comprises 212 hospitals, of which 91 are private. 363 primary care centers were organized into 74 Agrupamentos de Centros de Saúde (ACESs, primary care centers groupings). In 2012, 342 Unidades de Saúde Famimliar (USFs, family healthcare units) and 186 community care units were active. In the Rede Nacional de Cuidados Continuados Integrados (RNCCI, National Long-term Care Network), there were 5595 contracted beds in operation until the

end of December 2011. These beds presented the following distribution: 906 convalescent beds, 1747 medium term and rehabilitation beds, 2752 long-term and maintenance beds and 190 palliative care beds.

The Portuguese Ministry of Health is the government's department that is responsible for defining and conducting the national health policy, ensuring a sustainable implementation and use of resources. Its responsibilities include exercising regulatory, planning, funding, guidance, monitoring, evaluation, auditing and inspection functions, regarding the Portuguese NHS. The Ministry of Health carries out its responsibilities through integrated services under the direct administration of the state, integrated organisms under the indirect administration of the state, advisory bodies and other structures and entities integrated into state-owned companies.

Under the direct administration of the State, there are four central services. These services comprise the Direcção Geral da Saúde (DGS, Portuguese Directorate-General of Health). DGS's responsibilities include regulating, guiding and coordinating activities to promote health and disease prevention, defining the necessary technical conditions for the proper provision of healthcare, defining the national quality policy for the health system, developing and implementing the Plano Nacional de Saúde (PNS, Portuguese National Health Plan) and coordinating the Ministry's international relations.

Under the indirect administration of the State and supervised by of the Health Minister, there are five institutions, five Administrações Regionais de Saúde (ARSs, Portuguese Regional Health Administrations) and all the public services and facilities of the Portuguese NHS, namely the ACESs, hospitals and local health units. Two of the five institutions are the Administração Central do Sistema de Saúde (ACSS, Portuguese Health System's Central Administration) and the Autoridade Nacional do Medicamento e Produtos de Saúde (INFARMED, Portuguese National Authority for Drugs and Health Products).

ACSS is responsible for managing the financial and human resources of the Portuguese Ministry of Health and of the Portuguese NHS. It manages NHS's facilities and equipment and develops policies and regulations in the health sector. In coordination with the ARSs, ACSS coordinates the contracting of healthcare provision. It is also responsible for implementing and ensuring the quality of patient classification systems and their respective coding audits.

INFARMED (2015) supervises the sectors of medicines, medical devices and cosmetics and body hygiene products. It follows hight standards of public health protection and aims to assure the quality, safety and effectiveness of these products.

ARSs are responsible for ensuring that the population within their geographical area of intervention has access to healthcare provision. At the same time, they must adjust the available resources to current needs and comply with health policies and programs in their area of intervention. There are five ARSs, each one responsible for one geographical area (North, Center, Lisbon and Tagus Valley, Alentejo and Algarve).

Finally, there is the state-owned company sector, which comprises several Entidades Públicas Empresariais (EPEs, corporate public entities). These include the Serviços Partilhados do Ministério da Saúde (SPMS, Portuguese Ministry of Health Shared Services) and corporate public hospitals, hospital centers and local health units.

SPMS (2015*d*) is a public corporation created in 2010, working under the supervision of the Ministries of Health and Finance. Its mission is the provision of shared services — in the areas of purchasing and logistics, financial services, human resources and information and communication technologies — to entities with specific activity in Health, in order to ”centralize, streamline and rationalize” the acquisition of goods and services in the Portuguese NHS (SPMS, 2015*c*). SPMS is now responsible for licensing SNOMED CT in national territory so that Portuguese health organizations and the general public may benefit from its use. It has the responsibility to coordinate and facilitate all the tasks and responsibilities related to managing, licensing and distributing SNOMED CT in Portugal. SPMS will develop dissemination actions, intended to encourage the use and implementation of SNOMED CT nationwide (IHTSDO, 2015*a*). Figure B.1 illustrates the Portuguese Ministry of Health's organogram.

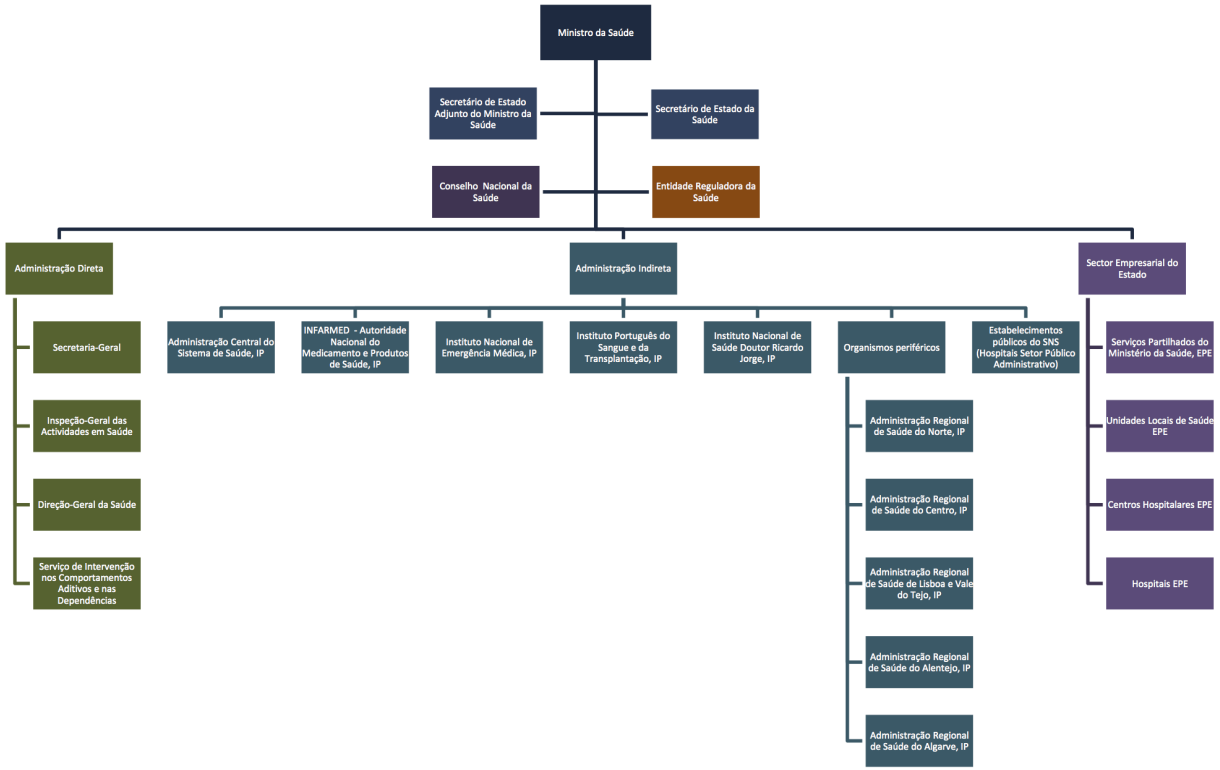


Figure B.1: Portuguese Ministry of Health's Organogram. Source: `http://www.portaldasaude.pt/portal/conteudos/a+saude+em+portugal/ministerio/organograma/organograma.htm`

In 2012, the Ministério da Saúde (2013*b*) created the Comissão para a Informatização Clínica (CIC, Clinical Informatization Committee). CIC was responsible for outlining the strategic direction in the area of clinical computerization of the Portuguese NHS.

In 2013, the CIC was extinct and the Comissão de Acompanhamento da Informatização Clínica (CAIC, Portuguese Clinical Informatization Monitoring Committee) was created. CAIC was created within the framework of SPMS and it is responsible for collaborating in presenting proposals to define the clinical IT strategy of the Portuguese NHS and monitor its implementation. The Committee also intends to deploy national and international collaboration models to promote clinical data sharing. It comprises the chairman of the SMPS's board of directors (coordinator), one DGS representative, one ACSS representative and one SPMS representative. Several working groups were defined within the committee, including the working group for semantic interoperability (Ministério da Saúde, 2013*c*).

Appendix C

CODEGOM Development Project Templates

This appendix describes the content of the CODEGOM development project's templates and how they can be used to assist the development of such a project following the methodology contained in the CODEGOM governance model. The template files were designed to support some project management tasks and are available for download at `http://tinyurl.com/pm84hsy`.

The templates includes two XML files containing a clinical ontology development project template designed in an open source project management software (ProjectLibre - `http://www.projectlibre.org`). The original POD files are also available for download. The XML files were exported from the original POD files, as the XML format is compatible compatible with ProjectLibre and Microsoft Project. Both tools enable the management of several project management dimensions, such as time management, cost management and resources management. The two template files contain the same overall structure of the clinical ontology development project, including the development phases and the monitoring activities. The "Clinical Ontology Development Project Template HR" XML file has the same content as the "Clinical Ontology Development Project Template" XML file. However, it also includes an example of a clinical ontology development project team and demonstrates how its members may be assigned to project tasks and activities.

Figure C.1 presents the Gantt chart depicted by the project management software. The chart displays the development phases and monitoring activities to be carried out during the project, their duration and the phases or activities which need to be completed before starting another one. The time factor was not addressed when developing this project management template. All the phases are presented with the default duration of one day, except for the monitoring activities which are continuously carried out since their start until the end of the project's development phases. The duration of the tasks may be edited accordingly within the template file ("Clinical Ontology Development Project Template" XML file).

	Nome
1	Ontology Charter Development
2	Stakeholder Identification
3	Scope Definition
4	Ontology Development Definition
5	Project Team Planning
6	**Ontology Development**
7	**Ontology Creation**
8	Initial List of Concepts
9	Define Backbone Taxonomy
10	Define Attributes
11	Refine Thesaurus
12	Publish Documentation
13	Field Trials
14	**Ontology Life Cycle Management**
15	Language Translation Process
16	Mapping Process
17	Distribution and License Management
18	**Feedback Management**
19	Report to International Organization
20	National Update/Review Process
21	Scope Control and Validation
22	Stakeholder Control
23	Quality Management and Control

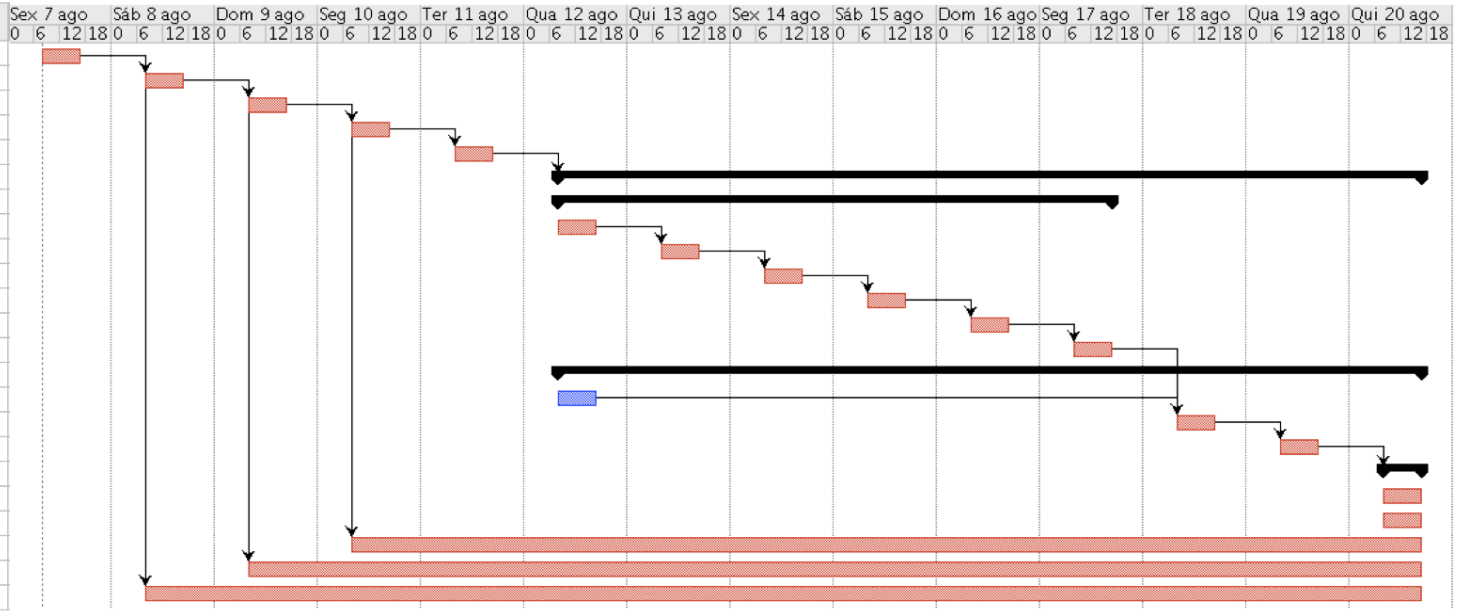


Figure C.1: The Gantt chart of the clinical ontology development project template.

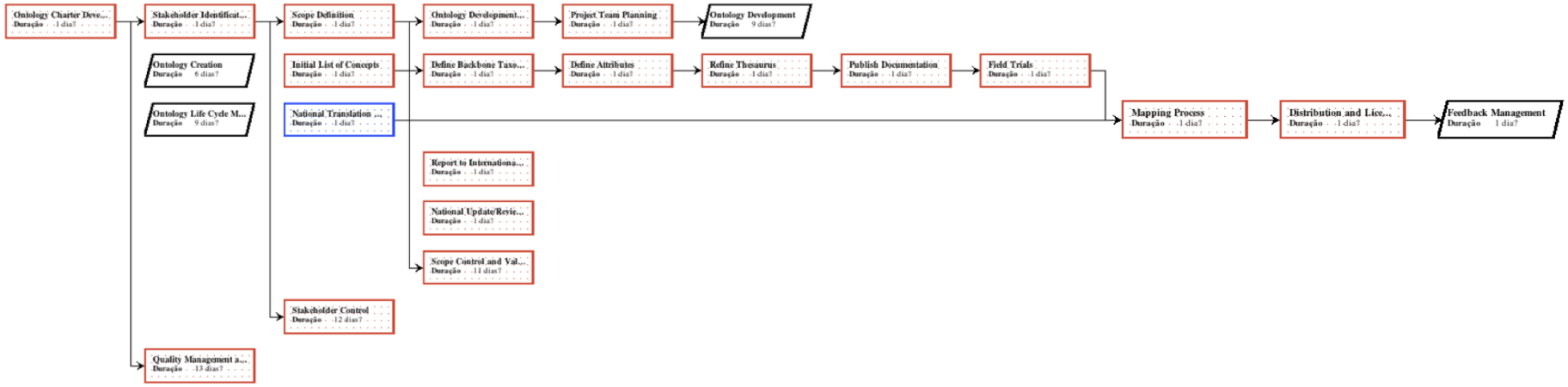


Figure C.2: Flow diagram of the clinical ontology development project template.

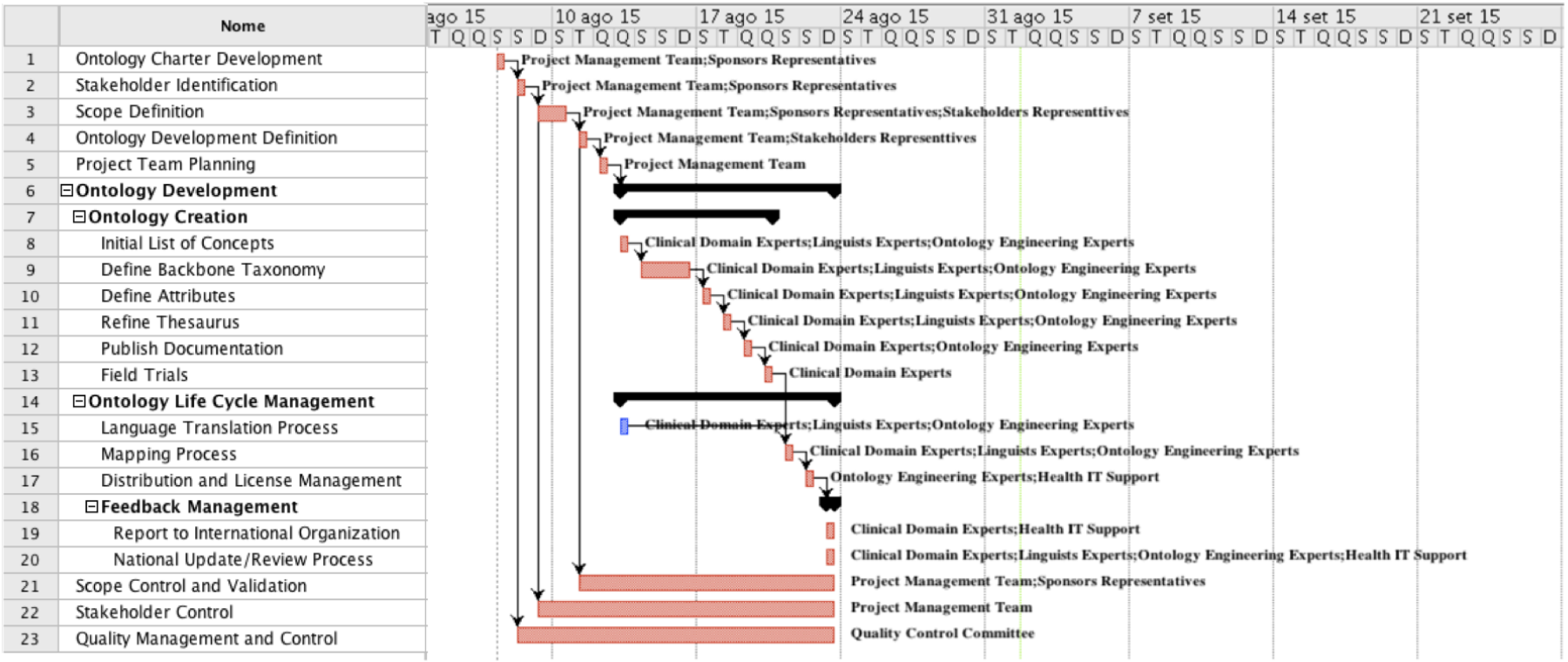
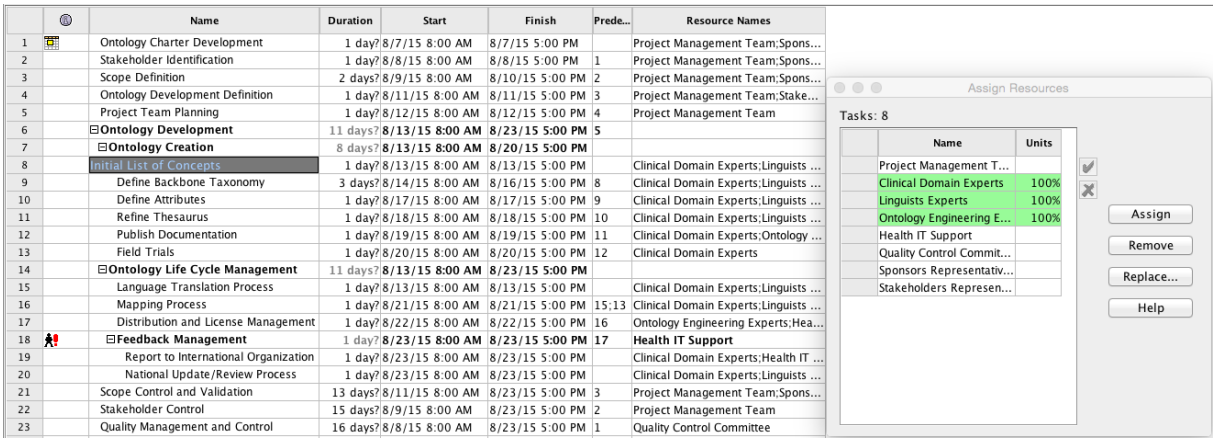


Figure C.3: The Gantt chart of the clinical ontology development project template, considering the assigned project team.

	Name	RBS	Type	E-mail Address	Material Label	Initials	Group	Max. Units	Standard Rate	Overtime Rate	Cost Per Use
1	Project Management Team		Work			PM		100%	$0.00/hour	$0.00/hour	$0.00
2	Clinical Domain Experts		Work			C		100%	$0.00/hour	$0.00/hour	$0.00
3	Linguists Experts		Work			LE		100%	$0.00/hour	$0.00/hour	$0.00
4	Ontology Engineering Experts		Work			OE		100%	$0.00/hour	$0.00/hour	$0.00
5	Health IT Support		Work			IT		100%	$0.00/hour	$0.00/hour	$0.00
6	Quality Control Committee		Work			QC		100%	$0.00/hour	$0.00/hour	$0.00
7	Sponsors Representatives		Work			Sp		100%	$0.00/hour	$0.00/hour	$0.00
8	Stakeholders Representtives		Work			Stk		100%	$0.00/hour	$0.00/hour	$0.00

(a) The clinical ontology development project team within the project management software.



	Name	Duration	Start	Finish	Prede...	Resource Names
1	Ontology Charter Development	1 day?	8/7/15 8:00 AM	8/7/15 5:00 PM		Project Management Team;Spons...
2	Stakeholder Identification	1 day?	8/8/15 8:00 AM	8/8/15 5:00 PM	1	Project Management Team;Spons...
3	Scope Definition	2 days?	8/9/15 8:00 AM	8/10/15 5:00 PM	2	Project Management Team;Spons...
4	Ontology Development Definition	1 day?	8/11/15 8:00 AM	8/11/15 5:00 PM	3	Project Management Team;Stake...
5	Project Team Planning	1 day?	8/12/15 8:00 AM	8/12/15 5:00 PM	4	Project Management Team
6	**Ontology Development**	11 days?	**8/13/15 8:00 AM**	**8/23/15 5:00 PM**	5	
7	**Ontology Creation**	8 days?	**8/13/15 8:00 AM**	**8/20/15 5:00 PM**		
8	Initial List of Concepts	1 day?	8/13/15 8:00 AM	8/13/15 5:00 PM		Clinical Domain Experts;Linguists ...
9	Define Backbone Taxonomy	3 days?	8/14/15 8:00 AM	8/16/15 5:00 PM	8	Clinical Domain Experts;Linguists ...
10	Define Attributes	1 day?	8/17/15 8:00 AM	8/17/15 5:00 PM	9	Clinical Domain Experts;Linguists ...
11	Refine Thesaurus	1 day?	8/18/15 8:00 AM	8/18/15 5:00 PM	10	Clinical Domain Experts;Linguists ...
12	Publish Documentation	1 day?	8/19/15 8:00 AM	8/19/15 5:00 PM	11	Clinical Domain Experts;Ontology ...
13	Field Trials	1 day?	8/20/15 8:00 AM	8/20/15 5:00 PM	12	Clinical Domain Experts
14	**Ontology Life Cycle Management**	11 days?	**8/13/15 8:00 AM**	**8/23/15 5:00 PM**		
15	Language Translation Process	1 day?	8/13/15 8:00 AM	8/13/15 5:00 PM		Clinical Domain Experts;Linguists ...
16	Mapping Process	1 day?	8/21/15 8:00 AM	8/21/15 5:00 PM	15;13	Clinical Domain Experts;Linguists ...
17	Distribution and License Management	1 day?	8/22/15 8:00 AM	8/22/15 5:00 PM	16	Ontology Engineering Experts;Hea...
18	**Feedback Management**	1 day?	**8/23/15 8:00 AM**	**8/23/15 5:00 PM**	17	**Health IT Support**
19	Report to International Organization	1 day?	8/23/15 8:00 AM	8/23/15 5:00 PM		Clinical Domain Experts;Health IT ...
20	National Update/Review Process	1 day?	8/23/15 8:00 AM	8/23/15 5:00 PM		Clinical Domain Experts;Linguists ...
21	Scope Control and Validation	13 days?	8/11/15 8:00 AM	8/23/15 5:00 PM	3	Project Management Team;Spons...
22	Stakeholder Control	15 days?	8/9/15 8:00 AM	8/23/15 5:00 PM	2	Project Management Team
23	Quality Management and Control	16 days?	8/8/15 8:00 AM	8/23/15 5:00 PM	1	Quality Control Committee

(b) The human resources allocation process within the project management software.

Figure C.4: The human resource allocation functionality of the project management template

Figure C.2 presents the clinical ontology development project's flow diagram. It contains the same information as the Gantt chart while organized into a flow diagram form.

Figure C.3 presents the Gantt chart depicted in the template which considers the human resource allocation process ("Clinical Ontology Development Project Template HR" XML file). The Gantt chart presents next to each development phase and activity the team elements or groups that were assigned to that task. The duration of some of the tasks were adjusted automatically by the software, due to the fact that the same resource was assigned to two or more tasks that take place simultaneous. However, the duration of the tasks and processes was not a concern within the scope of this work.

Figure C.4 presents some screenshots illustrating the human resource allocation functionality of the project management template. They also illustrate the possibility of introducing salaries as one of the required variables to manage project budget.

In addition, the project template includes four XLSX files containing three matrixes's templates — the engagement matrix, the responsibility assignment matrix and the stakeholder engagement matrix — and a set of quality checklists's templates used to conduct a clinical ontology development project according to the proposed methodology. These templates may be edited according to the project's scope.

The "Engagement Matrix" XLSX file contains the template of a engagement matrix. The matrix is used to document, manage and control stakeholder's engagement. It the assessed level of engagement of a stakeholder at a given time (T) and the desired level of engagement (D).

The "Project Team Matrix" XLSX file contains the template of a responsibility assignment matrix. The matrix is used to assign human resources to their respective activities. Rows represent the steps to be performed while columns represent individuals or groups of individuals with a specific skill set. This

matrix is useful to document and assign responsibilities during the project team planning phase.

The “Traceability Matrix” XLSX file contains the template of a requirements traceability matrix. The matrix links the clinical ontology requirements to the deliverables that satisfy them. It can also be used as a checklist to verify that the project is evolving within the planned scope. This matrix is useful to keep track of the scope of a clinical ontology development project during Scope Control and Validation activities.

The “Quality Checklists” XMLS file contains six templates of quality assessment checklists. Each checklist refers to one of the six clinical ontology development phases. The checklists contain a set of steps which need to be verified before determining that the development phase was completed successfully and moving on to the following one.

All the files were designed as templates to a clinical ontology development project following the CODEGOM governance model. Development phases and monitoring activities may be added or removed according to the scope of the project. The same applies to the content of each quality assessment checklist.