

Project cc-eSanté

*Recommendations
on Standards
for eSanté*

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1 Introduction

The aims of this document are an overview of relevant standards and a proposal to handle these standards in the closer context of healthcare; closer in the sense of potential relevant for the next steps in eSanté.

The number of relevant standards is high. Different Standard Development Organizations SDOs and different Standard Setting Organizations SSOs are involved. Standards are not guaranteed to be interoperable at all -- or at least to be not mutual excluding. Do not using “important” standards may lead to an isolated situation. However, trying to use all possible standards can lead to a never ending definition and analyze phase – and even if finished it is still without any guarantee for total interoperability with other systems.

The selection of eHealth relevant standards and terminologies is of common interests, in particular for who is dealing with healths informatics. Another advantage of standards is the possibility of reuse existing results (code, vocabularies, ...) instead starting from scratch. The number of existing standards (sometimes redundant, sometimes contradictory) forces national authorities to select some of them in order to be recommended for national solutions. In this sense, this work presents in **chapter 2** some recommendations for the Luxembourgian market. The following chapters describe the way and the argumentation line to reach the given recommendations.

Chapter 3 is an overview on the world of SDOs and SSOs concerning their international, regional, and national relevant range.

Chapter 4 refers to a work initiated by the European Commission. The result was published in February 2009. It gives us a “reference list” of relevant standards and terminologies in eHealth. The list has been published as an annex because of its length. Having this list, the formal aim of the WP is done. But just finding the relevant list was not the only thought in mind when defining the Work Package.

Therefore **chapter 5** concerns about classification schemata for standards. **Chapter 6** describes the relevant Organizations, Technical Committees and Working Groups from ISO, over CEN to HL7. With **chapter 7** – also on that basis level – we describe the

commonly used and noted Terminologies, Ontologies, Classifications like LOINC, ICD, ATC, etc.

Chapter 8 presents the work of other groups with the same aims. In **chapter 9** we come to the “structure giving” initiatives like IHE, CEN TC251, EuroRec, Infoway, up to the EU mandate addressed to the European SDOs.

Chapter 10 describes some American, European and national initiatives with the same questions: how to select the eHealth relevant standards and terminologies.

Chapter 11 defines selection criteria for standards and nomenclatures and apply those criteria to get our recommendations with which we started in chapter 2. They are based on the lessons learned from other countries, as well as the personal impressions that has been earned and build up while preparing this research.

The **List of References** is noted as useful “chapter”: This document provides a number of information, only available in the Internet. It offers a comprehensive set of links for further study and verification. We want to beware the readers from following dead links to non existing documents. Therefore we offer permanent cached documents in many references by using the cache mechanism of WebCite <http://www.webcitation.org>.

The reader may follow the webcitation link, reflecting the (cached) status during document creation time. For more actual information, she or he may use the “normal” link, which - meanwhile - may be dead or may be replaced with other contents.

2 Recommendations

Depending on the date when a certain decision has to be taken we differentiate our recommendations into 6 groups:

- **“Choose”**: Decisions that are ready to take **now**, because the subject is in a final status and already established.
- **“Consider”**: The so tagged recommendations are weaker than the “Choose”. In **short term** period a decision for the eSanté projects is outstanding hereon. This

“consider” recommendation will be changed to a “choose” recommendation depending on actual information, just in time when the decision is necessary.

- **“Participate”**: This refers to result promising initiatives on European or international level for results in **short to medium term**. Supported by stakeholders like the European Commission these initiatives are future proof. As far as these initiatives offer the possibility of contribution, we recommend to do so instead of trying a quick solution in isolated manner.
- **“Monitor”**: Mostly these thematics are not yet of instant interests for Luxembourg or the elaboration is not yet far enough. Most probably they will change to “Contribute” in **medium term** future.
- **“Think about”**: If a decision has to be taken and we have no stronger recommendation on that topic these **medium to long term** recommendations should be evaluated anew based on most actual informations.
- **“Watch for”** recommendations are general recommendation for medium to long term planing.

2.1 Choose HL7-v2 and -v3 Messaging for Communication

HL7 version 2 is in use for message communication concerning the admission, transfer, and discharge of patients in hospitals as well as other informations like diagnostic or treatment messages between heterogeneous systems. This standards are used inside hospitals and other health related institutions like laboratories. Additional systems may be integrated by re-using already existing message streams. New, independent applications should use the message communication in XML syntax which is HL7 version 3 messaging.

2.2 Choose HL7 CDA for Persistent Documents Definition

HL7 Clinical Document Architecture (CDA) is an XML-based markup standard for persistent documents. It is used in many projects and it is and stays an important standard.

2.3 Choose HL7 RIM for System Architectures and Modeling

The HL7 Reference Information Model with its concepts of entity, role, participation, act, and act-relationship is a general modeling approach that has to be used for modeling of new applications in healthcare.

2.4 Choose LOINC for Laboratory Data

For Laboratory data communication and data storage the LOINC classification is commonly accepted. A prestigious institution as one of the free LOINC guarantees the future proof. The current laboratory projects in Luxembourg are committed to use LOINC.

2.5 Choose ATC for Medications and Drugs

The Anatomical Therapeutic Chemical (ATC) classification system is well founded for drugs within a useful ontology of the organs or systems on which they act and their chemical, pharmacological and therapeutic properties.

2.6 Choose DICOM for Digital Images

The open DICOM standard defines the storage format as well as the communication protocol for data exchange. It is widely used for any kind of medical image processing, for example for digital X-ray, MRT, CT, Sono. DICOM is the standard for picture archiving and communication systems (PACS).

2.7 Consider IHE Profiles

As IHE is a binding element between defined standards and real world use-cases, their work is very important. Profiles in context with treatment and diagnosis histories will have direct influence for decisions in eSanté.

2.8 Consider the Recommendations of M/403

The EU mandate M/403 that has been addressed to the three European standards organizations CEN, CENELEC and ETSI is an important milestone in synchronizing the standardization work. We have already referred the answer as THE list of relevant

standards in eHealth. We also include their recommendations as cited below: (see: [M403-pres-2008])

- It is important to concentrate the work on CEN/TC 251 and avoid a split of resources to ETSI and CENELEC except where necessary and the nature of the items relate to the other business of these bodies.
- The preferred route for new eHealth standards should be via the TC process and formal European Standards rather than CEN workshops.
- However, there is also a need for advisory guidelines on standards to apply for specific European applications where other forms may be considered.
- International co-operation via primarily ISO but also as relevant other standards bodies such as, IEEE, ITU, DICOM, GS1, HL7, OASIS, IHTSDO and WHO should be a strategy to achieve certain European goals.
- Consider financial support to ISO work in some cases

For the time until 2015 cross-border applications of EHR are addressed with the recommendations:

- To outline and agree on the principles
- To enable interoperability between health information shared among different healthcare systems
- To resolve the various challenges of achieving cross-border interoperability of electronic health record systems in the Community
- To assess not only benefits, but also the barriers, hurdles, and potential threats to achieving eHealth interoperability, and to identify the necessary preconditions and relevant incentives to overcoming these.

2.9 Consider EHRcom (CEN TC251, EN 13606)

We adapt a recommendation of the European Commission for EN13606. In February 2009 they published a report about the quality criteria for the production and publication of archetypes in repositories [Stroetmann-2009]. One of the recommendations for

semantic interoperability is to: “Agree to use archetypes as the standardized approach to representing and sharing clinical data structures across the EU. Use the **EN13606** EHR-standard to structure the EHR / patient summary.(..)”

As soon as one can say: "Choose HL7 EHR" and also “HL7 agrees on EN13606”, the recommendation for EN13606 will upgrade from "consider" to "choose".

2.10 Consider Regenstrief

The Regenstrief Center for Healthcare Improvement and Research (RCHIR) was founded in July 2007 by the Regenstrief Foundation to serve the current and looming demand for clinical data management, retrieval, and analyses. The center enhances the content and use of clinical data repositories for quality improvement and epidemiologic and prospective research. RCHIR is a center within the Regenstrief Institute that brings together the complementary expertise of users and producers of information critical to care improvement and research. The center provides services that include: timely data extraction, risk profiles, market projections, surveillance reports, clinical activity analyses, pre-research information, research data support, and other deliverables required for facile adaption and success in the rapidly evolving health care quality and translational research marketplaces. [Regenstrief-2009]

2.11 Consider Continuity of Care CCR and CCD

The Continuity of Care Record (CCR) from ASTM and the corresponding HL7-CDA implementation, called Continuity of Care Document (CCD) should be monitored for setting up histories of results in health records.

2.12 Consider Healthcare Services Specification Project (HSSP)

HSSP has setup a web page which should be monitored for new information.
<http://hssp.wikispaces.com/standards> (access 28.05.2009)

2.13 Consider UMLS Unified Medical Language System

UMLS unifies the most important terminologies into a meta thesaurus. This work should be considered as “including everything” in contrast to the UMLS-subparts CCAM and SNOMED-CT.

2.14 Participate in EpSOS for Trans-Border Applications

epSOS has a high remark on European interoperability. This aspect is very important for Luxembourg not only due to its central geographical position in Europe.

2.15 Participate (continue) in CALLIOPE

CALLIOPE projects are working in close collaboration with the eHEALTH INTEROP project launched by CEN, CENELEC and ETSI with the support of the European Commission. Because of their focus on cross-border eHealth interoperability they are of special interest for eSanté in Luxembourg. The epSOS-CALLIOPE collaboration meetings CALlepSO can combine both participations in one.

2.16 Monitor openEHR

OpenEHR as major open source initiative covers much of this work and cares about standards. EHR architecture requirements (ISO 18308) are mentioned as well as EHR interoperability given by ISO/EN 13606. An object model for the representation of archetypes (in UML) has been published by the *openEHR* foundation and also included as a normative specification in ISO/EN 13606 Part 2.

Ongoing research and development activities within the *openEHR* community are currently focused on: repository services to store and distribute archetypes, knowledge management services to support searching for and comparisons of different archetypes for specific purposes, template tools to profile and combine archetypes for specific clinical workflows, and the definition of business rules and design guidance for the binding of archetype nodes to SNOMED CT. University College London and Ocean Informatics are each also exploring the inclusion of application presentation and workflow instructions within archetypes that have been operationalised for internal EHR system use, towards the realization of fully knowledge-driven systems.[KalraD-2008]

2.17 Monitor HL7's TC on Electronic Health Records

The goal of the Electronic Health Record (EHR) Technical Committee is to support the HL7 mission of designing standards to support the sharing of electronic health records. It will accomplish this goal through contributing to the creation and promotion of appropriate and necessary standards including the definition of a high-level architecture to support the interoperability requirements among EHR Systems.

<http://www.hl7.org/Special/Committees/ehr/index.cfm#charter> (access 28.05.2009)

2.18 Monitor ISO TC 215 Work Group 9

The ISO TC215 has established its ninth work group concerning on the harmonization of the Standard Development Organization. Results of this WG must be monitored in the future.

2.19 Monitor Q-REC

For our aims Q-REC is relevant in the subset of data and processes concerning EHR. Everything they propose should be regarded when thinking about a later certification.

2.20 Monitor Extension of Clinical Pathways

As clinical pathways inside hospitals get more and more conventional, an extension towards a patient centralized disease pathway can be expected. The classical patient centralized health record documents represent the history while the disease pathway foresees the future of treatments independent of the institution (hospital, rehabilitation, ambulant care).

2.21 Think about CCAM adaptations

Concerning the documentation of medical procedures by using a classification it should be noted that groups in Australia are thinking about moving from the Australian Classification of Health Interventions (ACHI) towards an adaptation of the French Classification commune des actes médicaux (CCAM). See page 2 in: [NCCH-strat]

The German DIMDI also prospects CCAM or the American ICD-PCS (Procedure Coding System) as potential successor for the German OPS (Operationen- und Prozedurenschlüssel).

2.22 Think about SNOMED-CT

As well as CCAM also SNOMED-CT may be an alternative. SNOMED is now for free in most cases. [SNOMED-fee-2009]. Here it's important whether SNOMED is or will be used by other countries.

2.23 Watch for the Trend Setters

Due to its central position in Europa, the Luxembourgian eHealth solution has to be interoperable with the solutions of the neighbor countries. Nearly each EU country currently evolves its eHealth solutions – standalone or inside the European framework. It's mandatory to determine the trend setters. A further WP in the eSanté project focus on that topic. The CALLIOPE network should be used to find the trend setters in other countries, especially in the direct neighborhood of Luxembourg.

2.24 Watch for new Trends

Last to mention: The whole thematic is a moving target. It is evident to have a look for new trends – all times!

3 Overview of Standard Development Organizations and Standards Setting Organizations

This introducing overview on standards organizations uses a top down explanation from “world”, over “international” to “national”. “Regional” organs are mentioned afterwards.

- **World “wide” level:** The World Standards Cooperation WSC is a cooperation of ISO, IEC, and ITU.
- **International level:** The named ISO, IEC, and ITU above are the main international standards organizations: the International Organization for Standardization **ISO** founded in 1947, the International Electrotechnical

Commission **IEC** founded in 1906, and the International Telecommunication Union **ITU** founded in 1865.

- **National level:** ISO itself is composed of the so called National Standard Bodies NSB of each country. Besides the NSBs other standards developing organizations and standards setting organizations act on national level. Those may be coordinated or represented at ISO via the NSB of their country or economy, respectively.
- **Regional Europe:** here we have the Comité Européen de Normalisation **CEN**, the Comité Européen de Normalisation Electrotechnique **CENELEC**, the European Telecommunications Standards Institute **ETSI**, and the Institute for Reference Materials and Measurements **IRMM**.
- **Regional Asia and Pacific:** the Pacific Area Standards Congress **PASC**, the **ASEAN** Consultative Committee for Standards and Quality **ACCSQ**
- **Regional America:** the Pan American Standards Commission **COPANT**, the **MERCOSUR** Standardization Association **AMN**, the **CARICOM** Regional Organization for Standards and Quality **CROSQ**
- **Regional Africa:** the African Regional Organization for Standardization **ARSO**, the Southern African Development Community **SADC**, the Cooperation in Standardization SADCSTAN.
- **Regional Middle East:** the Arab Industrial Development and Mining Organization **AIDMO**, the International Arabic Union **IAU**.

Besides Standard Development Organizations so called **Industry Consortia** or Standard Setting Organizations **SSO** are very active.

Their members find together on individual technical or industrial experience in the contexts of concerns. W3C and IEEE are examples of Standard Setting Organizations.

The World Standards Services Network <http://www.wssn.net> is an entry point to SDO and SSO websites. Currently (Jun 2009) they list 52 international standardizing bodies,

11 regional, over 140 national members of ISO and IEC, and 5 other international or regional organizations. The SDO we outlined above are included.

4 The List of relevant Standards and Terminologies

In March 2007 the European Commission asked the European Standards Organizations CEN, CENELEC, and ETSI, which ones of their Standards are relevant in the context for eHealth applications [M403-call]. The answer was given nearly two years later with the “eHealth-INTEROP Report Inventory of Standards” and shows up a huge list of standards and terminologies. The well known authors of this Report, Evangelidis, Heidenreich, Parisot, and Reynolds decided to put the list itself in an annex. We will refer to this annex instead of copying the list: [M403Resp-2008] . Nevertheless the first page of 116 is shown below.

JOINT INITIATIVE ON SDO GLOBAL HEALTH INFORMATICS STANDARDIZATION
JOINT SDO WORK PROGRAM INVENTORY
Version 2.1, 20 August 2008

Name	Number	Stage	Description	Status	Comments
Health Informatics - Electronic health record communication - Part 1: Reference model	IS 13606-01	Published (CEN) Ballot FDIS (ISO)	Part 1 of this multipart standard on Electronic Health Record Communication specifies the communication of part or all of the electronic health record (EHR) of a single identified subject of care between EHR systems, or between EHR systems and a centralized EHR data repository. It may also be used for EHR communication between an EHR system or repository and clinical applications or middleware components (such as decision support components) that need to access or provide EHR data, or as the representation of EHR data within a distributed (federated) record system.	Joint	Joint Initiative Joint Work Program
Health Informatics - Electronic health record communication - Part 2: Archetype interchange specification	IS 13606-02	Published (CEN) Ballot DIS (ISO)	Part 2 of this multipart standard on Electronic Health Record Communication specifies the information architecture required for interoperable communications between systems and services that need or provide EHR data. This is not intended to specify the internal architecture or database design of such systems.	Joint	Joint Initiative Joint Work Program
Health Informatics - Electronic health record communication - Part 3: Reference archetypes and terms	prENIS 13606-03	Ballot Final (CEN) Ballot DIS (ISO)	Part 3 of this multipart standard on Electronic Health Record Communication is for the communication of part or all of the electronic health record (EHR) of a single identified subject of care between EHR systems, or between EHR systems and a centralized EHR data repository. It may also be used for EHR communication between an EHR system or repository and clinical applications or middleware components (such as decision support components) that need to access or provide EHR data, or as the representation of EHR data within a distributed (federated) record system.	Joint	Joint Initiative Joint Work Program
Health Informatics - Electronic health record communication - Part 4: Security	TS 13606-4	Published (CEN) Active (ISO)	Part 4 of this multipart standard on Electronic Health Record Communication describes a methodology for specifying the privileges necessary to access EHR data. This methodology forms part of the overall EHR communications architecture defined in Part 1 of this standard. This standard seeks to address those requirements uniquely pertaining to EHR communications and to represent and communicate EHR-specific information that will inform an access decision. It also refers to general security requirements that apply to EHR communications and points at technical solutions and standards that specify details on services meeting these security needs.	Joint	Joint Initiative Joint Work Program
Health Informatics - Electronic health record communication - Part 5: Interface specification	prENIS 13606-5	Active (CEN) Active (ISO)	Part 5 of this multipart standard on Electronic Health Record Communication specifies the information architecture required for interoperable communications between systems and services that need or provide EHR data. This standard is not intended to specify the internal architecture or database design of such systems. The subject of the record or record extract to be communicated is an individual person, and the scope of the communication is predominantly with respect to that person's care. Uses of healthcare records for other purposes such as administration, management, research and epidemiology, which require aggregations of individual people's records, are not the focus of this standard but such secondary uses could also find the standard useful. Part 5 of this standard defines a set of interfaces to request and provide: - an EHR_EXTRACT for a given subject of care as defined in Part 1 of this standard; - one or more ARCHETYPE(s) as defined in Part 2 of this standard; - an EHR_AUDIT_LOG_EXTRACT for a given subject of care as defined in Part 4 of this standard. Part 5 of this standard defines a set of interfaces to request and provide: - an EHR_EXTRACT for a given subject of care as defined in Part 1 of this standard; - one or more ARCHETYPE(s) as defined in Part 2 of this standard; - an EHR_AUDIT_LOG_EXTRACT for a given subject of care as defined in Part 4 of this standard. Part 5 establishes a common framework for the content and the structure of identification data held on healthcare data cards. Specifies the basic structure of the data, but does not specify particular data-sets for storage on devices.	Joint	Joint Initiative Joint Work Program VA CEN
Health Informatics - Patient healthcard data - Part 5: Identification data	prENISO 21549-5	Ballot Final (CEN) Ballot FDIS (ISO)	Part 5 specifies the basic structure of the data contained within the data object administrative data, but does not specify or mandate particular data sets for storage on devices.	Common	VA ISO
Health Informatics - Patient healthcard data - Part 6: Administrative data	prENISO 21549-6	Ballot Final (CEN) Ballot FDIS (ISO)	Part 6 specifies the basic structure of the data contained within the data object administrative data, but does not specify or mandate particular data sets for storage on devices.	Common	VA ISO
Health Informatics - Patient healthcard data - Part 7: Electronic prescription (medication data)	prENISO 21549-7	Ballot Final (CEN)	Part 7 specifies the basic structure of the data contained within the medication data object, but does not specify or mandate particular data-sets for storage on devices.	Common	VA ISO
Health Informatics - Patient healthcard data - Part 8: Linkage and reference data	prENISO 21549-8	Active (CEN) Active (EO)	Part 8 defines a method which facilitates access to distributed patient records using health cards. It defines the structure and elements of "links" typically stored in health cards and representing references to individual patients' records as well as to subcomponents of them. It is outside the scope of this work item to include access control data or mechanisms to ensure security and privacy.	Common	VA ISO Lead
Health Informatics - HL7 Electronic health record system functional model	prENISO 10781	Active (CEN) Active (EO)	The HL7 EHR System Functional Model provides a reference list of functions that may be present in an Electronic Health Record System (EHRIS). The function list is described from a user perspective with the intent to enable consistent expression of system functionality. The EHRIS Functional Model, through the creation of Functional Profiles for care settings and realms, enables a standardized description and common understanding of functions sought or available in a given setting (e.g. intensive care, cardiology, office practice in one country and primary care in another country).	Common	VA ISO
Health Informatics - Service architecture - Part 1: Enterprise viewpoint	IS 12967-1	Published (CEN) Active (EO)	This standard provides guidance for the description, planning and development of new systems as well as for the integration of existing information systems, both within one enterprise and across different healthcare organisations through an architecture integrating the common data and business logic into a specific architectural layer (i.e. the middleware), distinct from individual applications and accessible throughout the whole information system through services.	Common	
Health Informatics - Service architecture - Part 2: Information viewpoint	IS 12967-2	Published (CEN) Active (EO)	This document represents the second part of EN 12967, a multi-part standard that provides guidance for the description, planning and development of new systems as well as for the integration of existing information systems, both within one enterprise and across different healthcare organisations through an architecture integrating the common data and business logic into a specific architectural layer (i.e. the middleware), distinct from individual applications and accessible throughout the whole information system through services.	Common	
Health Informatics - Service architecture - Part 3: Computational viewpoint	IS 12967-3	Published (CEN) Active (EO)	This document represents the third part of EN 12967, a multi-part standard that provides guidance for the description, planning and development of new systems as well as for the integration of existing information systems, both within one enterprise and across different healthcare organisations through an architecture integrating the common data and business logic into a specific architectural layer (i.e. the middleware), distinct from individual applications and accessible throughout the whole information system through services.	Common	
Health Informatics - Data types for use in health care interchange	prENISO 21090	Active (CEN) Active (EO)	To provide a globally harmonized (ISO/CEN/HL7) set of representations for data used in the presentation and communication of health care information. This standardized set will be an internationally agreed upon, proper sub-set of data types currently adopted by national and trans-national health care standards development organizations. The communication of health information about individuals requires the accurate identification of specific entities and concepts, as well as the expression of complete, frequently complex semantic phrases. Experience has shown that representation of such data requires that a rich set of data types be built upon the primitive types normally specified for computer software. This set to be specified in this standard will provide the structures necessary to meet the basic requirements of health care information interchange. Should differences in cultures and business practices preclude the universal adoption of certain data types, these data types will be issued within informative annexes.	Joint	Joint Initiative Joint Work Program VA ISO Note ISO 8166 Harmonized Data Types for Information Interchange
Health Informatics - Pharmacovigilance - Test names and units for reporting laboratory results	prENISO 11596	Active (CEN) Active (EO)	The project will investigate existing relevant available standards and terminology resources and establish a single standardized subset of unit terms and codes that can be used to capture laboratory test units of measurement for pharmacovigilance reporting purposes. The project will need to take into account that there is a constant need for updates and maintenance of resources that list all relevant terms and will specify how the updated controlled vocabulary can be communicated to the reporting and receiving systems.	Joint	Joint Initiative Joint Work Program VA ISO

5 Classification schemata for standards

Published standards are in focus. But also standards under development are of interest. Besides that, withdrawn standards can be found on the websites of the SDO/SSO. For the latter ones the organizations themselves have already decided that those works may be duplicates of other works, or the proposals turned out to be incompatible with another (published) standards.

Standards can be grouped in (1) Architecture, (2) Modeling, (3) Communications, (4) Infrastructure, (5) Privacy, (6) Safety, (7) Terminology and ontology. [BlobelB-2007] ([Usage-Hint](#) for readers: [right mouse click](#) on the respective reference and open in new windows allows you to return easier.) Also (9) quality standards should be concerned – but are not in focus here.

A similar classification can be found within the working groups of ISO TC 215, the technical committee for “health informatics” of the International Standards Organization. ISO TC 215 itself is considered later. The first four working groups of ISO TC 215 are called Infrastructure work groups, WG5 to WG8 are Domain work groups and WG10 is declared as joint Initiative council for SDO harmonization:

(1) Data structure, (2) Data Interchange, (3) Semantic Content, (4) Security, Safety and Privacy, (5) Health Cards, (6) Pharmacy and Medicine, (7) Devices, (8) Business Requirements for Electronic Health Records, (9) Standards Development Organizations Harmonization. – WG1 to WG8 are candidates to use as classification schema. WG9 is the new working group of ISO to bringing better structure into the world of standards.

The German bit4Health [bit4Health-2004] study uses five groups under the headline “standards”: (1) nomenclatures and classifications, (2) Data models, message formats and document formats, (3) International and national standards activities, (4) selected projects and initiatives, (5) non-medical specific standards.

In the following chapters we describe the Organizations, Technical Committees, and Working Groups. We continue with terminologies and classifications and their “owners”. After that we come to a meta-level of the work of other groups and to structure-giving initiatives.

6 Organizations, Technical Committees, Working Groups

Having the overview of the previous section as a basis, the most cited organization, technical committees, and working groups in the context of eHealth “standards” are described next.

6.1 ISO – International Organization for Standardization

ISO is a network of the national standards institutes of 161 countries, one member per country, with a Central Secretariat in Geneva, Switzerland, that coordinates the system. ISO is a non-governmental organization that forms a bridge between the public and private sectors. <http://www.iso.org/iso/about.htm>. (access date 26.05.2009). For our needs it is one of the most important ones.

6.2 IEC – International Electrotechnical Commission

The International Electrotechnical Commission (IEC) headquartered in Geneva, Switzerland, is the organization that prepares and publishes international standards for all electrical, electronic and related technologies. (The corresponding standards organization for all other products and systems is the International Organization for Standardization – ISO). <http://www.iec.ch/> (access date 26.05.2009)

6.3 ITU – International Telecommunication Union

ITU is the leading United Nations agency for information and communication technology issues, and the global focal point for governments and the private sector in developing networks and services. (..)

From broadband Internet to latest-generation wireless technologies, from aeronautical and maritime navigation to radio astronomy and satellite-based meteorology, from convergence in fixed-mobile phone, Internet access, data, voice and TV broadcasting to next-generation networks, ITU is committed to connecting the world. ITU is based in Geneva, Switzerland, and its membership includes 191 Member States and more than 700 Sector Members and Associates. <http://www.itu.int/net/about/index.aspx> (access date 26.05.2009)

6.4 CEN – European Committee for Standardization

The European Committee for Standardization (CEN) is a business facilitator in Europe, removing trade barriers for European industry and consumers. Its mission is to foster the European economy in global trading, the welfare of European citizens and the environment. Through its services it provides a platform for the development of European Standards and other technical specifications.

CEN's 30 National Members work together to develop voluntary European Standards (Ens). These standards have a unique status, since they also are national standards in each of its 30 Member countries. <http://www.cen.eu/cenorm/aboutus> (access date 05.05.2009). CEN is also one of the most important SDO for our issues.

6.5 CENELEC – European Committee for Electrotechnical Standardization

CENELEC, the European Committee for Electrotechnical Standardization, was created in 1973 as a result of the merger of two previous European organizations: CENELCOM and GENEL. Nowadays, CENELEC is a non-profit technical organization set up under Belgian law and composed of the National Electrotechnical Committees of 30 European countries. In addition, 8 National Committees from neighbouring countries are participating in CENELEC work with an Affiliate status. <http://www.cenelec.eu/Cenelec/About+CENELEC> (access date 05.05.2009)

6.6 ETSI – European Telecommunications Standards Institute

The European Telecommunications Standards Institute (ETSI) produces globally-applicable standards for Information and Communications Technologies (ICT), including fixed, mobile, radio, converged, broadcast and internet technologies.

ETSI is officially recognized by the European Commission as a European Standards Organization. (..) ETSI is a not-for-profit organization with almost 700 ETSI member organizations drawn from 60 countries world-wide.

<http://www.etsi.org/WebSite/AboutETSI/AboutEtsi.aspx> (access date 05.05.2009)

6.7 EN by CEN, CENELEC and/or ETSI

European Standards (EN) are documents that have been ratified by one of the 3 European Standards Organizations, CEN, CENELEC or ETSI. They are designed and created by all interested parties through a transparent, consensual process.

<http://www.cenelec.eu> (access date 05.05.2009)

6.8 ASTM – American Society for Testing and Materials

ASTM International is one of the largest voluntary standards development organizations in the world (..) ASTM International, originally known as the American Society for Testing and Materials (ASTM), was formed over a century ago.

<http://www.astm.org/ABOUT> (access date 05.05.2009).

6.9 IEEE – Institute of Electrical and Electronics Engineers

The Institute of Electrical and Electronics Engineers has a legal seat at ANSI (American National Standards Institute). IEEE collaborates with CEN TC251 and ISO TC215, the ISO and CEN working groups for health informatics.

ISO and IEEE have signed an agreement to increase their cooperation in developing international standards. The agreement initially focuses on the subjects of information technology, intelligent transport systems and health informatics. <http://www.iso.org/iso/pressrelease.htm?refid=Ref1125> (last access date 26.05.2009)

6.10 W3C – World Wide Web Consortium

The World Wide Web Consortium (W3C) develops interoperable technologies (specifications, guidelines, software, and tools) to lead the Web to its full potential. W3C is a forum for information, commerce, communication, and collective understanding.

W3C primarily pursues its mission through the creation of Web standards and guidelines. Since 1994, W3C has published more than 110 such standards, called W3C

Recommendations. W3C Is an International Consortium. <http://www.w3.org/> (last access date 26.05.2009)

6.11 HL7 – Health Level Seven

Health Level Seven is one of several American National Standards Institute (ANSI) -accredited Standards Developing Organizations (SDOs) operating in the healthcare arena. Most SDOs produce standards (sometimes called specifications or protocols) for a particular healthcare domain such as pharmacy, medical devices, imaging or insurance (claims processing) transactions. Health Level Seven's domain is clinical and administrative data. <http://www.hl7.org/index.cfm> (last access date 26.05.2009).

That means that HL7 specifications are introduced into the official standardization process via ANSI.

HL7 has 26 International Affiliates: Argentina, Australia, Brazil, Canada, China, Croatia, Czech Republic, Denmark, Finland, France, Germany, Greece, India, Ireland, Italy, Japan, Korea, Lithuania, Mexico, New Zealand, Poland, Spain, South Africa, Switzerland, Taiwan, The Netherlands, and the United Kingdom. HL7/USA is said to be under consideration. [Blobel-QREC-2007]

The international affiliates coordinate their work together with HL7.org, they contribute towards ISO working groups and are involved in working groups of regional and national standards organizations. HL7 working results are used mainly for message exchange inside of hospitals. HL7 specifications are published as ISO standards.

6.11.1 HL7 v2 Messaging

Message specifications are historically evolved. The initial aim was a communication protocol between different application inside of hospitals. The definition belongs to the application level of the OSI layer 7, where the 7 in the name comes from.

Most popular is version with segments and field, where an analogous XML definition exists for – also in version 2.

6.11.2 HL7 v3 Messaging

In the context of HL7 version 3 the message formats were redefined regarding the RIM (see below). So they are conform to the new architectural model of HL7 version 3. They are only XML based.

6.11.3 HL7 v3 RIM – Reference Information Model

The RIM's aim is defining a general data model for any actual and future HL7 based message and document formats. Or in the words of the free downloadable description: The Health Level Seven (HL7) Reference Information Model (RIM) is a static model of health and health care information as viewed within the scope of HL7 standards development activities. It is the combined consensus view of information from the perspective of the HL7 working group and the HL7 international affiliates. The RIM is the ultimate source from which all HL7 version 3.0 protocol specification standards draw their information-related content. [HL7-RIM-2003]

6.11.4 HL7 v3 CDA – Clinical Document Architecture

The HL7 Clinical Document Architecture (CDA) is an XML-based markup standard intended to specify the encoding, structure and semantics of clinical documents for exchange.

CDA is part of the HL7 version 3 standard. It was developed using the HL7 development Framework (HDF) and it is based on the HL7 Reference Information Model (RIM). CDA documents are persistent in nature.

The CDA specifies that the content of the document consists of a mandatory textual part (which ensures human interpretation of the document contents) and optional structured parts (for software processing). The structured part relies on coding systems (such as from SNOMED and LOINC) to represent concepts [HL7-book-CDA]. CDA has approved as ANSI standard in November 2000. <http://www.hl7.org/about/> (last access 26.05.2009).

6.11.5 HL7 v3 CCOW – Clinical Context Management Specification

Specifies the Health Level Seven Context Management Architecture (CMA). This architecture enables multiple applications to be automatically coordinated and synchronized in clinically meaningful ways at the point-of-use. CCOW has approved as ANSI standard in September 2000. [HL7-what-is] . The Name CCOW originally means Clinical Context Object Workgroup.

6.12 OASIS – Organization for the Advancement of Structured Information Standards

OASIS (Organization for the Advancement of Structured Information Standards) is a not-for-profit consortium that drives the development, convergence and adoption of open standards for the global information society. The consortium produces more Web services standards than any other organization along with standards for security, e-business, and standardization efforts in the public sector and for application-specific markets. Founded in 1993, OASIS has more than 5,000 participants representing over 600 organizations and individual members in 100 countries. (..)

OASIS was founded in 1993 under the name SGML Open as a consortium of vendors and users devoted to developing guidelines for interoperability among products that support the Standard Generalized Markup Language (SGML). OASIS changed its name in 1998 to reflect an expanded scope of technical work, including the Extensible Markup Language (XML) and other related standards [OASIS-who].

6.13 OMG – Object Management Group

OMG™ is an international, open membership, not-for-profit computer industry consortium. OMG Task Forces develop enterprise integration standards for a wide range of technologies, and an even wider range of industries. OMG's modeling standards enable powerful visual design, execution and maintenance of software and other processes. OMG's middleware standards and profiles are based on the Common Object Request Broker Architecture (CORBA®) and support a wide variety of industries. [OMG-about]

OMG's flagship specification is the multi-platform Model Driven Architecture (MDA), recently underway but already well known. It is based on the modelling specifications the MOF (Meta Object Facility), the UML (Unified Modeling Language), XMI (Metadata Interchange), and CWM (Common Warehouse Metamodel). OMG's own middleware platform is CORBA (Common Object Request Broker Architecture), which includes the Interface Definition Language (IDL), and protocol IIOP (Internet Inter-ORB Protocol) [BlobeI-QREC-2007]

6.14 DICOM and NEMA

DICOM is managed by the Medical Imaging & Technology Alliance - a division of NEMA – the National Electrical Manufacturers Association, a U.S. industry group representing those who design and manufacture electrical equipment.[DICOMbyNEMA]

NEMA participates extensively in the IEC at both technical and management levels. NEMA provides the Secretariat support for six IEC Technical Committees (TCs). An IEC TC Secretary manages the day-to-day Committee activities [IECandNEMA].

DICOM consists of 17 parts, 1—8 and 10—18 that can be downloaded after registration at [DICOMdownload].

Part 1: Introduction and Overview; Part 2: Conformance Part 3: Information Object Definitions Part 4: Service Class Specifications Part 5: Data Structures and Encoding Part 6: Data Dictionary Part 7: Message Exchange Part 8: Network Communication Support for Message Exchange Part 10: Media Storage and File Format for Media Interchange Part 11: Media Storage Application Profiles Part 12: Media Formats and Physical Media for Media Interchange Part 14: Grayscale Standard Display Function Part 15: Security and System Management Profiles Part 16: Content Mapping Resource Part 17: Explanatory Information Part 18: Web Access to DICOM Persistent Objects (WADO)

The missing Part 9: Point to Point Communication Support for Message Exchange has been rescinded some years ago.

6.15 UN/CEFACT – United Nations Centre for Trade Facilitation and Electronic Business

United Nations Centre for Trade Facilitation and Electronic Business – UN/CEFACT, a United Nations body, has a global remit. It encourages close collaboration between governments and private business to secure the interoperability for the exchange of information between the public and private sector [UNECE-about].

They published work in the field of EDI (Electronic Data Interchange) and ebXML (Electronic Business using XML).

6.16 xDT and Kassenärztliche Bundesvereinigung

In Germany xDT is an widely used exchange format for data transfers between general practitioners and medical services. The Kassenärztliche Bundesvereinigung KBV is the German wide organization of general practitioners and specialists organizing their billing with the compulsory health insurance companies.

In the term xDT the x is a placeholder and DT originally means data transport media (Daten-Träger) but can be interpreted as Data Transfer.

6.16.1 ADT

Abrechnungs-Datentransfer – the billing data in form of coded diagnoses and billing codes on diskettes since 1987, and since some years on secure connections between medical office software and Kassenärztliche Bundesvereinigung.

6.16.2 BDT

Behandlungs-Datentransfer – for export and import of whole patient records between medical office software systems. Mainly designed for system exchange, the KBV forces medical office software systems that ensure a clean BDT export. This gives some security in case of insolvent software manufactures. Now the BDT format is also used for data exchange between general practitioners and specialists.

6.16.3 GDT

Geräte-Datentransfer – data transfer from medical devices to medical office software system. Even a HL7-GDT-Bridge exists, enabling medical devices to deliver their data to hospital information systems, if the HIS understands HL7 and the medical device speaks GDT.

6.16.4 LDT

Labor-Datentransfer – the order entry from general practitioner or specialist to laboratory and the result reporting back to the doctors office. (Remark: in Germany the GP sends the blood and other bio material to a laboratory, and he informs the patient on the results.)

The xDT descriptions are published by the Kassenärztliche Bundesvereinigung and a German union of medical office software vendors called QMS. As far we know, xDT is not a formal standard, but very often implemented.

xDT Standards are forced by Kassenärztliche Bundesvereinigung. [KBV-xDT].

6.17 CDISC – Clinical Data Interchange Standards Consortium

Clinical Data Interchange Standards Consortium CDISC is a global, open, multidisciplinary, non-profit organization that has established standards to support the acquisition, exchange, submission and archive of clinical research data and metadata. The CDISC mission is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare. CDISC standards are vendor-neutral, platform-independent and freely available via the CDISC website [CDISC-MS].

6.18 GS1 (Global Standards 1)

GS1 Healthcare is a voluntary, global Healthcare user group bringing together all related Healthcare stakeholders: pharmaceutical and medical devices manufacturers,

wholesalers and distributors, group purchasing organisations, hospitals, pharmacies, logistics providers, governmental and regulatory bodies, and associations.

The goal of the Global Healthcare User Group is to be the recognised, open and neutral source for regulatory agencies, trade organisations and other similar stakeholders who are seeking input and direction for global standards in healthcare for patient safety, supply chain security & efficiency, traceability and accurate data synchronisation [GS1-HC-about].

7 Terminologies and Ontologies

The report of the European Commission [Stroetmann-2009] defines the usage of the terms: controlled vocabulary, code, lexicon, ontology, classification, thesaurus, terminology, coding system, ontology. We reduce the chapters headline to “Terminologies Ontologies”, because those terms summarize most of the other definitions.

Terminologies and ontologies for eSanté are inevitable for semantical data exchange. We start with diagnostic related ones, medical procedures, which are also used for billing issues, medication classification and general schemata. The separation is not that clear in any case.

7.1 SNOMED-CT and IHTSDO – Systematized Nomenclature of Medicine-Clinical Terms; International Health Terminology Standards Development Organization

The International Health Terminology Standards Development Organization (IHTSDO) is a not-for-profit association that develops and promotes use of SNOMED CT to

support safe and effective health information exchange. <http://www.ihtsdo.org/> (last access 27.05.2009)

SNOMED CT (Systematized Nomenclature of Medicine-Clinical Terms) is considered to be the most comprehensive, multilingual clinical healthcare terminology in the world. SNOMED CT intellectual property rights were transferred to the SNOMED SDO® in the formal creation of the IHTSDO.

SNOMED CT was originally created by the College of American Pathologists by combining SNOMED RT and a computer based nomenclature and classification known as Clinical Terms Version 3, formerly known as Read Codes Version 3.

The fact that SNOMED-CT has not been truly open was a major barrier to large scale international development. However, things have improved since the creation of the IHTSDO: SNOMED CT research and evaluation licences are free of charge; the technical specifications are open, as is the collaborative website, and everybody can participate in working groups. [Stroetmann-2009](Page 21, Chapter 4.3.2). The IHTSDO webpage on actual “fees” is [SNOMED-fee-2009].

7.2 LOINC and Regenstrief Institute Inc. – Logical Observation Identifiers Names and Codes

Regenstrief Institute, an internationally recognized informatics and healthcare research organization, is dedicated to the improvement of health through research that enhances the quality and cost-effectiveness of healthcare. Established in 1969 by philanthropist Sam Regenstrief on the campus of the Indiana University School of Medicine in Indianapolis. [Regenstrief-2009]

LOINC (Logical Observation Identifiers Names and Codes) was developed to provide a definitive standard for identifying clinical information in electronic reports. The LOINC database provides a set of universal names and ID codes for identifying laboratory and clinical test results in the context of existing HL7, ASTM E1238, and CEN TC251 observation report messages. One of the main goals of LOINC is to facilitate the exchange and pooling of results for clinical care, outcomes management, and research. LOINC codes are intended to identify the test result or clinical observation. Other fields

in the message can transmit the identity of the source laboratory and special details about the sample. [LOINC-RELMA]

Regenstrief Institute also provides a mapping utility called the Regenstrief LOINC Mapping Assistant (RELMA) to facilitate searches through the LOINC database.

7.3 C-NPU, SC-NPU and IUPAC – Nomenclature, Properties, and Units in Laboratory Medicine, International Union of Pure and Applied Chemistry

C-NPU - Nomenclature, Properties, and Units in Laboratory Medicine. This database contains the current C-NPU coded properties; it is searchable by C-NPU code (e.g. NPU01234) or by the elements of which the properties consist (e.g. blood).

<http://dior.imt.liu.se/cnpu/> ([search-mask](#)) Allow pop-ups of this page to get results.

SC-NPU database has been freely available in English, Danish and Swedish for several years and currently used in Denmark and in Sweden. It is now being developed in German, French, Portuguese and Spanish versions. Notes, explanations, and links to various precisions will also be added to the database.

The International Union of Pure and Applied Chemistry (IUPAC) serves to advance the worldwide aspects of the chemical sciences (...) IUPAC is a scientific, international, non-governmental and objective body. <http://www.iupac.org/> (last access 27.05.2009)

7.4 Collaboration of the owners of LOINC, SNOMED-CT, and NPU

On April 1, 2009, the owners of three standards that contain laboratory test terminology – the Logical Observation Identifiers, Names, Codes (LOINC), Nomenclature, Properties and Units (NPU), and the Systematized Nomenclature of Medicine - Clinical Terms (SNOMED CT) – began an operational Trial of prospective divisions of labor in the generation of laboratory test terminology content. This Trial will provide practical experience and important information on opportunities to decrease duplication of effort in the development of laboratory test terminology and to ensure that SNOMED CT

works effectively in combination with either LOINC or NPU [LOINC-SNOMED-coop-2009].

7.5 VITAL – Vital Signs Information Representation

The Technical Committee for Medical Informatics, TC251 of the European Committee for Standardisation (CEN) has established a project team (CEN/TC251/PT5-021) to standardize the representation of digitized biomedical signals, measurements, events and alarms which are called vital signs in this context. The intended application areas of this standard proposal are found in the equipment used in intensive care, anaesthesia, neurophysiological measurement laboratories, sleep laboratories etc. The long-term goal in this work is to enable interoperability between the real time computer systems of different manufacturers also in time critical applications in hospitals, i.e. plug and play. [VITAL-Czywietz]. VITAL is related to: ISO 11073, CEN TC251 PT5-021, CEN ENV 13734:2000, CEN/TS 14271:2003

7.6 UCUM from Regenstrief Institute – Unified Code for Units of Measure

The Unified Code for Units of Measure is a code system intended to include all units of measures being contemporarily used in international science, engineering, and business. The purpose is to facilitate unambiguous electronic communication of quantities together with their units. The focus is on electronic communication, as opposed to communication between humans. A typical application of The Unified Code for Units of Measure are electronic data interchange (EDI) protocols [UCOM-Schadow]

7.7 ICD and WHO (International Classification of Diseases, World Health Organization)

WHO (World Health Organization) is the directing and coordinating authority for health within the United Nations system. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards,

articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends. <http://www.who.int/about/en> (last access 27.05.2009)

ICD-10 was endorsed by the Forty-third World Health Assembly in May 1990 and came into use in WHO Member States as from 1994. The classification is the latest in a series which has its origins in the 1850s. (..) WHO took over the responsibility for the ICD at its creation in 1948 (...) The ICD is the international standard diagnostic classification for all general epidemiological, many health management purposes and clinical use [ICD10-WHO]. Contact points for 42 language versions of ICD-10 are given at the WHO homepage.

Several adaptations and extensions are in use:

- International Classification of Diseases for Oncology, 3rd Edition (ICD-O-3)
- International Classification of External Causes of Injury (ICECI)
- International Classification of Primary Care, Second edition (ICPC-2)
- The ICD-10 for Mental and Behavioural Disorders Diagnostic Criteria for Research
- The ICD-10 for Mental and Behavioural Disorders Clinical Descriptions and Diagnostic Guidelines
- The International Classification of Health Interventions (ICHI) is designed to replace the "International Classification of Procedures in Medicine" (ICPM)
- The International Classification of Functioning, Disability and Health, known more commonly as ICF, is a classification of health and health-related domains.

7.8 DRGs – Diagnosis-Related Groups

For DRGs the coding system is an abstraction of an abstraction: It is applied to lists of ICD codes that are themselves derived from medical records. The purpose of DRG coding is to provide a relatively small number of codes for classifying patient

hospitalizations, while also providing some separation of cases based on severity of illness. The principal bases for the groupings are factors that affect cost and length of stay.[HammondW-1999] (page 236).

7.9 3BT (Belgian Thesaurus)

The starting point of the Belgian Thesaurus was a Thesaurus created in Amsterdam by the department of Prof. H. Lamberts (UvA), in collaboration with Ghent University, Department of General Practice and Primary Health Care. But this Thesaurus has been refused as such by developers and users especially because of the lack of clinical labels useful as text in the EPR. Search terms and ICD/ICPC labels (the content of the Amsterdam Thesaurus) are not always the preferred text in a medical record. The Belgian GP needs also a perfect bilingual system by which all information (codes and labels) became completely interexchangeable from one language to another (French/Dutch) and from one software system to another. For this reason each collection of search terms (doctor's vocabulary) has been linked to a specific 'clinical label' (terminology of clinical concepts) useful as terminology in the EPR and to the appropriate pair of classification codes (clusters of concepts): ICPC-2-ICD10. Each clinical label is perfectly bilingual French/Dutch. [VerbekeM-et-al-2006]

7.10 Alpha-Id and DIMDI (an extension of ICD10)

Alpha-Id extends the ICD10 and allows a more precise classification. It is maintained by DIMDI (Deutsches Institut für Medizinische Dokumentation und Information) [Alpha-Id].

7.11 UMLS and NLM – Unified Medical Language System, National Library of Medicine

The purpose of National Library of Medicine's Unified Medical Language System® (UMLS) is to facilitate the development of computer systems that behave as if they "understand" the meaning of the language of biomedicine and health. To that end, NLM

produces and distributes the UMLS Knowledge Sources (databases) and associated software tools (programs) for use by system developers (..) [UMLS-whatism].

The Unified Medical Language System contains medical terms and their semantical relationships. The terms are taken out of nearly 100 different categorization systems and nomenclatures in currently 15 languages. The result is a meta thesaurus, where the concepts are related together in a semantic network.

7.12 MeSH and NLM – Medical Subject Headings

Medical Subject Headings (MeSH) is the National Library of Medicine's controlled vocabulary thesaurus. It consists of sets of terms naming descriptors in a hierarchical structure that permits searching at various levels of specificity. MeSH descriptors are arranged in both an alphabetic and a hierarchical structure. At the most general level of the hierarchical structure are very broad headings such as "Anatomy" or "Mental Disorders" [MeSH-whatism].

7.13 FMA – Foundational Model of Anatomy Ontology

The FMA is a reference ontology for the domain of anatomy. It is a symbolic representation of the phenotypic structure of the human body. Over 75,000 anatomical classes ranging from macroscopic to molecular level are organized in an Aristotelian-type class subsumption hierarchy, using the Protege frame-based knowledge acquisition tool. The ontology is made available by various servers that are part of the Digital Anatomist Information System. The symbolic modeling of the structure of the human body is in a form that is understandable to humans and is also navigable and interpretable by machine-based systems. (...) The FMA contains 8,500 Latin, 4,700 French, 500 Spanish, 350 German terms [Washington-FMA].

The Foundational Model of Anatomy ontology (FMA) is open source and available for general use. A pre-published PDF of a Springer publication can be found at [RoseC-2007].

7.14 ICPM and other classification of procedures – International Classification of Procedures

ICPM International Classification of Procedures published by the WHO in 1978. The classification should give transparency on invoicing medical treatments. It was extended and adopted by several countries. Support was frozen by WHO since 1989 because of lack of resources and the awaiting of results out of “Galen” (see below).

7.14.1 ICPM-DE – Dutch

The Netherlands version ICPM-DE, DE means dutch extension

7.14.2 OPS-301 – Germany, Operationen- und Prozedurenschlüssel

Operationen- und Prozedurenschlüssel, the German adaptation of ICPM

7.14.3 CCAM – France, Classification commune des actes médicaux

Classification commune des actes médicaux, the French Classification of Procedures is independent of ICPM.

7.14.4 ACHI – Australian Classification of Health Interventions

The Australian Classification of Health Interventions (ACHI) is also independent of ICPM.

7.14.5 ICD-10-PCS – United States, Procedure Coding System

The Procedure Coding System is the US Classification of Procedures independent of ICPM, provided by HCFA (Health Care Financing Administration)

7.14.6 CPT – Current Procedural Terminology – United States

CPT is a list of descriptive terms and identifying numeric codes for medical services and procedures that are provided by physicians and health care professionals. CPT codes are compiled in Level 1 of the Healthcare Common Procedure Coding System (HCPCS). Current Procedural Terminology (CPT) is a product of the American Medical Association (AMA).

7.14.7 UCM / CNS Codes – Luxembourg

Concerning a coding schema for billing of medical procedures, the CNS Codes can be seen in this line for Luxembourg.

7.15 ICNP and ICN – International classification for nursing practice, International Council of Nurses

The ICNP® is a unified nursing language system. It is a compositional terminology for nursing practice that facilitates the development of and the cross-mapping among local terms and existing terminologies. [ICN-ICNP]

This classification covers Nursing phenomena (nursing diagnoses), Nursing actions, Nursing outcomes. The International Council of Nurses (ICN) is a federation of national nurses' associations (NNAs), representing nurses in more than 128 countries.

7.16 NIC – Nursing Intervention Classification

The *Nursing Interventions Classification* (NIC) is a comprehensive, standardized language describing treatments that nurses perform in all settings and in all specialties. NIC interventions include both the physiological (e.g. Acid-Base Management) and the psychosocial (e.g. Anxiety Reduction). There are interventions for illness treatment (e.g. Hyperglycemia Management), illness prevention (e.g. Fall Prevention), and health promotion (e.g. Exercise Promotion). Interventions are for individuals or for families (e.g. Family Integrity Promotion). Indirect care interventions (e.g. Emergency Cart Checking) and some interventions for communities (e.g. Environmental Management: Community) are also included. [DonahueW]

7.17 HHCC – Home Health Care Classification

The Home Health Care Classification (HHCC) System was developed by Saba and colleagues from research conducted at the Georgetown University School of Nursing...to develop a method to assess and classify home health Medicare patients in order to predict their need for nursing and other home care services (resource requirements) as well as to evaluate (measure) their outcomes of care. [SabaV-2002]

7.18 ATC/DDD and WHOCC – Anatomical Therapeutic Chemical, WHO Collaborating Centre)

In the Anatomical Therapeutic Chemical (ATC) classification system, the drugs are divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties. (..)

In order to measure drug use, it is important to have both a classification system and a unit of measurement. To deal with the objections against traditional units of measurement, a technical unit of measurement called the Defined Daily Dose (DDD) to be used in drug utilisation studies was developed. [ATC-DDD-about]

The WHO Collaborating Centre for Drug Statistics Methodology was established in 1982. The Centre is situated in Oslo at the Norwegian Institute of Public Health. The Centre is funded by the Norwegian government. Since 2009, the ATC catalog is available in English and Spanish only.

7.19 PZN – Germany, Pharmazentralnummer

The PZN Pharmazentralnummer is a German wide unique identifier for each medication. The number is used for structuring issues only. It must be renewed each 2 years - for a fee.

Die PZN ist eindeutig, d.h. sie identifiziert einen Artikel (Handelsform) bestimmter Bezeichnung, Packungsgröße und Artikeltyp eines bestimmten Anbieters. Wenn zur Unterscheidung oder Abgrenzung von anderen Artikeln erforderlich, müssen weitere

Kriterien wie Darreichungsform, Farbe, Form, Größe etc. als artikelidentifizierende Merkmale herangezogen werden [PZN-2003].

7.20 NDC (National Drug Code) – NCPDP, FDA, U.S.A.

The National Council for Prescription Drug Programs, Inc. (NCPDP) is a not-for-profit ANSI-Accredited Standards Development Organization consisting of over 1,500 members representing virtually every sector of the Pharmacy services industry. <http://www.ncdp.org/> (accessed 27.05.2009).

The Drug Listing Act of 1972 requires registered drug establishments to provide the Food and Drug Administration (FDA) with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by it for commercial distribution. (...) Drug products are identified and reported using a unique, three-segment number, called the National Drug Code (NDC), which is a universal product identifier for human drugs [NDC-2009].

7.21 RxNorm from NLM, U.S.A.

RxNorm, a standardized nomenclature for clinical drugs for humans, is produced by the U.S. National Library of Medicine (NLM). RxNorm is one of a suite of designated standards for use in U.S. Federal Government systems for the electronic exchange of clinical health information. [RxNorm-2009]

RxNorm can mediate messages between systems not using the same software and vocabulary. <http://www.nlm.nih.gov/research/umls/rxnorm/index.html> (access 27.05.2009).

7.22 MedDRA and IFPMA – Medical Dictionary for Regulatory Activities, International Federation of Pharmaceutical Manufacturers and Associations

MedDRA terminology applies to all phases of drug development, excluding animal toxicology. It also applies to the health effects and malfunction of devices.

MedDRA - the Medical Dictionary for Regulatory Activities - is a pragmatic, medically valid terminology with an emphasis on ease of use for data entry, retrieval, analysis, and display, as well as a suitable balance between sensitivity and specificity within the regulatory environment. It was developed by the International Conference on Harmonisation (ICH) and is owned by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) acting as trustee for the ICH steering committee. <http://www.meddrasso.com/MSSOWeb/index.htm> (access 27.05.2009)

7.23 Further Lists of Terminologies and Classifications

The list of terminologies, ontologies and classifications stays incomplete out of its nature. We have listed the – out of our viewpoint – more important ones. For further interest, the International Healthcare Consultants maintain a list of coding systems [INHCC-cs] and [HL7-cs] is a the list of codes used in HL7. It's worth to have at least a look at the HL7 list.

8 Lists of eSanté related Standards

As expected, research work on eSanté related standards and classification is an actual topic for many working groups, technical committees and also initiated by an EU mandate.

- The European Union in March 2007 addressed a mandate M/403 to the European standardization organizations and, in short, asked them which of their standards have relevance for eHealth issues [M403-call]. The response to this M/403 end of 2008 is a reused central part of our WP. [M403Resp-2008] .

- A work in the same context was published under Q-REC label in January 2007 under the title “Inventory of Relevant Standards for EHR Systems”. [Blobel-QREC-2007]
- A presentation at the “Workshop ID-Management” in Berlin of December 2008 gives a short introduction: [Blobel-itstand-2007]
- This presentation of Rector et. al. covers some aspects of Decision Support Systems beside the main terminology part. [RectorA-2008]
- A Canadian non-for-profit institution published in May 2008 their results on standards for eHealth [Infoway-Ca-2008].
- In July 2007 a presentation concerning standards provides some good explaining graphic on page 11: Main topics here are HL7, DICOM, CEN TC251, and IHE [Bourquard -2007].
- The eHealth Competence Center at the University of Regensburg published a presentation in July 2007 with the German title “Erfordernisse, Stand und Perspektiven der modernen eHealth - Standardisierung” [BlobelB-2007].
- The ARTEMIS project, co-funded by the European Commission between 2002 and 2006, published results on standards [Artemis-2004].
- A German presentation in December 2004 (but still valid) focusing on HL7's RIM, openEHR (GEHR), CEN ENV 13606, and DICOM Structured Reporting [BottO-2004]
- A report prepared by the Health Informatics Research Environment (SHIRE) at the University of Salford in August 2004 presents a study of key technical standards and specifications relating to record, document, message and data architectures [Salford-2004].
- The preparation of the German national eHealth project summarizes the relevant standards in eHealth out of a their viewpoint [bit4Health-2004].
- A cooperation of the Middle East Technical University (Ankara, Turkey) and the OFFIS Institute for Information Technology (Oldenburg, Germany) publishes in

2006 their research results “ ELECTRONIC HEALTH RECORD STANDARDS – A BRIEF OVERVIEW” [Offis-METU-2006]

- A list of SDO and Standards in Medicine, maintained by the International Healthcare Consultants can be found at [INHCC-sdo].

The joint project eHealth-INTEROP, addresses the requirements of the European Commission mandate M/403 to the European Standards Organizations (ESOs) on standardization in the field of e-health. The final report to M403 Phase 1 has been approved by the three European Standardisation Organizations and has been submitted to the European Commission for formal approval in February 2009.

Even this report stated that it may be incomplete in listing all the relevant standards. A broad and deep international coverage was – as the authors mentioned – not possible within the given time frame and budget. Nevertheless we find it very exhaustive and we refer to their “Inventory of Standards” in its version of 22nd December 2008 published in February 2009 (see [M403Resp-2008]).

Instead of providing a hard copy here, we refer to the “Inventory of Standards” as our basis.

9 Structuring Initiatives

Some international acting organizations and technical committees define so called profiles or use cases that match real world needs. Their profiles refer to standards and terminologies, ontologies, thesauri, etc.

Profiles are on higher abstraction level because they are defined by using an amount of standards and terminologies. When we decide for a certain profile, we automatically decide for all used standards and terminologies. In this way the profiles and their defining initiatives are very helpful for our own decision criteria.

We have got a large list of relevant standards and terminologies by the European Mandate M/403. To get an overview that is more manageable “structure giving initiatives” like IHE, EuroRec, etc. will help.

The definition of selection criteria on meta-level guarantees that we stay compatible with the referred initiatives and the surrounding world in eHealth. For example the statement: “This Labo-application is IHE compatible” is provable – for example by a IHE connectaton.

In contrast the statement “This Labo-application follows the following 25 standards and is compatible with the nomenclatures N1 to N9” is not that easy to handle. May be the 26th standard does not fit, but this is one of the most essential.

In this sense the initiatives on meta level (IHE, Q-REC, etc.) helps defining manageable criteria for software developments. The burden of keeping standards is broken down to definable requirements that can be proofed by 3rd parties.

9.1 IHE

IHE is an initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information. IHE promotes the coordinated use of established standards such as DICOM and HL7 to address specific clinical need in support of optimal patient care. Systems developed in accordance with IHE communicate with one another better, are easier to implement, and enable care providers to use information more effectively. <http://www.ihe.net> (access 28.05.2009)

Over 200 products have been released with support for one or more IHE Profiles. (...) IHE profiles are defined for Cardiology, Eye Care, IT Infrastructure, Laboratory, Patient Care Devices, Quality, Research and Public Health, Radiation Oncology and Radiology [IHE-profiles]. IHE work also covers patient care coordination, pathology and pharmacy.

9.2 ISO TC 215 Health Informatics

ISOs technical committee TC 215 for health informatics is organized in nine work groups:

(1) Data structure, (2) Data Interchange, (3) Semantic Content, (4) Security, Safety and Privacy, (5) Health Cards, (6) Pharmacy and Medicine, (7) Devices, (8) Business Requirements EHR, (9) SDO Harmonization.

ISOs TC 215 reports approximately 50 published standards, technical reports ISO/TR and technical specs ISO/TS related to healthcare informatics [ISO-TC215-pub-2009]. The same amount of nearly 50 are under development.

9.3 CEN TC 251 Health Informatics

The Comité Européen de Normalisation CEN TC 251 for health informatics establishes four working groups. Remark: They overlap with the first four of ISO TC 215.

(1) Information Models, (2) Terminology and knowledge representation, (3) Security, safety and quality, (4) Interoperability.

CENs TC 251 shows nearly 80 technical reports CEN/TR, technical specs CEN/TS, European norms CEN EN, pre-norms called CEN/prEN or CEN/ENV, and CEN reports CR [CEN-TC251-pub-2009]. Additionally they have approximately 30 more under development.

9.4 CEN HISA (ENV 12967) – Health Informatics Service Architecture

The CEN Standard Architecture for Healthcare Information Systems (ENV 12967), Health Informatics Service Architecture or HISA is a standard aimed at enabling the development of modular open systems to support healthcare. HISA is a services standard for inter-system communication in a clinical information environment.

9.5 EHRcom (EN 13606)

The overall goal of this Health informatics - Electronic Health Record Communication (EN 13606) European Standard is to define a rigorous and stable information architecture for communicating part or all of the Electronic Health Record (EHR) of a

single subject of care (patient). This is to support the interoperability of systems and components that need to communicate (access, transfer, add or modify) EHR data via electronic messages or as distributed objects. [Wiki_EN13606]. EHRcom tries to harmonize with other standards: [KalraD-2006]

- ISO TS 18308 (EHR requirements) adopted as the official requirements basis by 13606
- 13606 has been related to concepts defined in ISO DTR 20514 (EHR Definition and scope)
- Access control approach maps to ISO TS 22260 (Privilege Management and Access Control)
- Cross mapping to HISA and CONTSYS draft standards
- Cross working group activities on information models
- concerning HL7, meets the infrastructure requirements of the EHR functional model
- An 13606-1 conformant R-MIM has been designed
- Detailed cross-mapping to Clinical Document Architecture
- Working together on a joint CEN/HL7 archetype specification
- Contributed to the Clinical Statement model design
- An HL7 13606 Implementation Guide is being developed
- An IHE XDS specification: mapping to registry metadata

9.6 CONTSYS (EN 13940) – Continuity of care, System of concepts

CONTSYS (EN 13940) is a system of concepts to support Continuity of care. Belongs to CEN TC 251 WG II. “Closed shop” <http://www.contsys.eu>, no information accessible.

9.7 CEN ISSS

In addition to formal CEN Technical Committees, CEN/ISSS provides a less formal environment through CEN/ISSS Workshops. These offer the opportunity for direct participation in the standardization process. They are ongoing working groups that are open to all interested parties, including vendors, service providers, regulators, users and consumer groups.

CEN/ISSS Workshops aim to arrive at a European consensus on an issue that can be published as a CEN Workshop Agreement (CWA). These deliverables may take the form of best practice agreements, codes of conduct or pre-standards, with the formal backing of CEN. [CEN-ISSS-whatIs]

9.8 HSSP and OMG Healthcare DTF (formerly CORBAMed)

The OMG Healthcare Domain Task Force is actively engaged as part of a joint collaboration with the Health Level 7 (HL7) Standards Group in producing industry healthcare SOA standards. The Healthcare Services Specification Project (HSSP) is the moniker under which these joint activities are occurring. All current work, minutes, agendas, and activities are available on a shared wiki site, available at: <http://hssp.wikispaces.com> [OMG-HDTF-2009].

9.9 EuroRec Institute

The EUROREC Institute (EuroRec) is an independent not-for-profit organisation, promoting in Europe the use of high quality Electronic Health Record systems (EHRs). One of its main missions is to support, as the European authorised certification body, EHRs certification development, testing and assessment by defining functional and other criteria.

EuroRec is organised as a permanent network of National ProRec centres and provides services to industry (developers and vendors), healthcare providers (buyers), policy

makers and patients. <http://www.eurorec.org/whoarewe/introduction.cfm> (access 28.05.2009)

9.9.1 Q-REC (EuroRec labeled)

The main objective of Q-REC is to create an efficient, credible and sustainable mechanism for the certification of Electronic Health Record (EHR) systems in Europe by addressing mainly: 1. EHR Systems Quality Labelling and Certification Development, (...), 2. Resources for EHR Interoperability, (...), 3. Benchmarking Services (...) <http://www.ehealthnews.eu/content/view/892/66/> (access 28.05.2009)

9.9.2 EHR-QTN (EuroRec labeled)

EHR-QTN is supported by the European Commission under the Competitiveness and Innovation Programme. EHR-QTN intends to prepare the Health Community across Europe for more systematic, comparable and large scale quality assurance and certification of e-Health products (with a special emphasis on Electronic Health Care Record systems). CRP Henri Tudor - SANTEC on of the “beneficiaries”. <http://www.eurorec.org/RD/index.cfm> (access 28.05.2009)

9.9.3 epSOS – Smart Open Services for European Patients

European Patients Smart Open Services - epSOS, (previously known as S.O.S. - "Smart Open Services open eHealth initiative for a large scale European pilot of patient summary and electronic prescription) is a Europe-wide project organized by 27 beneficiaries representing twelve EU-member states, including ministries of health, national competence centres and numerous companies. This makes it the first European project clustering such a large number of countries in practical cooperation.

The overarching goal of epSOS is to develop a practical eHealth framework and an Information & Communication Technology (ICT) infrastructure that will enable secure

access to patient health information, particularly with respect to basic patient summaries and ePrescriptions between different European healthcare systems.

The project is co-financed by the European Commission within the Competitiveness and Innovation Programme (CIP). epSOS was launched on July 1, 2008 and will be in progress for 36 months.

To achieve this goal, the national entities cooperating within epSOS test both services in pilot applications, which interconnect national solutions. The approach, which is based on advanced and distinct use cases and associated infrastructural components, aims to deliver both a methodological process and durable implementations: building blocks. These building blocks will form the basis for a longer term, pan-European approach to develop interoperable service solutions.

The project is structured into work packages (WPs) which analyze the current situation in the participating countries, explore the legal questions, develop technical specifications covering all basic components of secure use of personalised health data, and finally set-up the test environment where the findings can be validated in a close to real life situation.

Dissemination and communication activities will accompany the project throughout the entire period, supported by the CALLIOPE Thematic Network. [epSOS-about-2009]

The epSOS page also provides useful links to further EU related initiatives.

<http://www.epsos.eu/links-collaborations.html> (access 28.05.2009)

9.9.4 CALLIOPE – Call for Interoperability

CALLIOPE stands for "CALL for InterOPERability" with the focus on eHealth.

The main goal of the CALLIOPE Network is to produce value for decision makers for national eHealth implementations. CALLIOPE comprises a dedicated forum where decision makers, implementers, professionals, patients and other stakeholders can share visions, experiences and good practices on how to establish interoperable eHealth services.

CALLIOPE is set up by the EU-funded Thematic Network “CALLIOPE - Creating a European coordination network for eHealth interoperability implementation”. The project was launched on 1 June 2008 with a duration of 30 months. [CAL-2009]

9.9.5 i2010

The i2010 strategy brings together all European Union policies, initiatives and actions that aim to boost the development and the use of digital technologies in every day working and private life. These technologies - also known as information and communication technologies (ICT) – make a positive contribution to economic growth, job creation and the enhancement of the quality of life. i2010 is part of the Lisbon strategy to make Europe a more competitive and dynamic knowledge-driven economy. [i2010-flyer]

9.10 openGALEN – Generalized Architecture for Languages, Encyclopaedias and Nomenclatures in medicine

GALEN represents a paradigm shift in the approach to medical terminologies. This shift is:

- away from enumerative classification of concepts and terms towards compositional models of medical concepts with formal properties
- away from single structures of concepts and terms towards language independent concept systems which are interpreted through separate grammars and lexicons of terms

The aim is to capture within a formal model the general principles and knowledge that underlay the use of medical terminology. This knowledge can then be used to generate all and only the sensible medical concepts and associated terms. For example an earlier section considered extending a traditional scheme to cover diseases of different degrees of severity. In the compositional, generative approach it is sufficient to state that diseases can have a severity. There after it is possible to generate all diseases of all severities, if required, and classify each one of them as if it had been enumerated. [OpenGALEN-2009]

9.11 SCIPHOX – Standardized Communication of Information Systems in Physician Offices and Hospitals using XML

SCIPHOX – the Standardized Communication of Information Systems in Physician Offices and Hospitals using XML – was founded by HL7 Germany and the union QMS.

They extend the xDT family by XML based interface definitions to communicate data in context with disease management programs (DMP) between practitioners and hospitals. One aim was a German extension for the Clinical Document Architecture CDA <http://sciphox.hl7.de/> (access 28.05.2009)

9.12 GEHR – Good European Health Record

The Good European Health Record, was a three year project within the European Health Telematics research programme (Advanced Informatics in Medicine) 1991-1995. It has developed a comprehensive multi-media data architecture for using and sharing electronic healthcare records, meeting clinical, technical, educational and ethico-legal requirements.

The GEHR project consortium involved 21 participating organisations in seven European countries, and included clinicians from different professions and disciplines, computer scientists in commercial and academic institutions, and major multi-national companies. The architecture object model, exchange format, term sets and the specifications of access and integration tools have been placed in the public domain. [GEHR-1997]

Participants from Luxembourg were the Association des Medecins et Medecins Dentistes Microdata SARL and the Centre de Recherche Rublic Henri Tudor.

9.13 openEHR (the successor of GEHR)

openEHR is an international not-for-profit Foundation, working towards making the interoperable, life-long electronic health record a reality, and improving health care in the information society. It does this by developing open specifications, open-source software and knowledge resources, engaging in clinical implementation projects, participating in international standards development, supporting health informatics education. <http://www.openehr.org/about> (access 28.05.2009)

The members of *openEHR* work through CEN, HL7 and ISO to contribute to standards development internationally. <http://www.openehr.org/148-OE.html> (access 28.05.2009)

9.14 CCR – Continuity of Care Record (from ASTM)

The Continuity of Care Record (CCR) is a core data set of the most relevant administrative, demographic, and clinical information facts about a patient's healthcare, covering one or more healthcare encounters. It provides a means for one healthcare practitioner, system, or setting to aggregate all of the pertinent data about a patient and forward it to another practitioner, system, or setting to support the continuity of care. The primary use case for the CCR is to provide a snapshot in time containing the pertinent clinical, demographic, and administrative data for a specific patient. To ensure interchangeability of electronic CCRs, this specification specifies XML coding that is required when the CCR is created in a structured electronic format. Conditions of security and privacy for a CCR instance must be established in a way that allows only properly authenticated and authorized access to the CCR document instance or its elements. The CCR consists of three core components: the CCR Header, the CCR Body, and the CCR Footer. [ASTM-CCR]

9.15 CCD – Continuity of Care Document (from HL7)

CCD is a HL7-CDA implementation of the Continuity of Care Record (CCR).

HL7 balloted a standard for the Continuity of Care Document (CCD), which is an HL7 Clinical Document Architecture, Release 2 (CDA) specification in accordance with

requirements set forward in ASTM E2369-05 Standard Specification for Continuity of Care Record (CCR). This specification shares many common elements with public health information systems. In particular the CCD specification document includes race and ethnicity, functional status, procedure codes, language spoken, and encounter data amongst other things. [DavisB-2007] (last page).

9.16 Health IT – U.S.A.

Health information technology (Health IT) allows comprehensive management of medical information and its secure exchange between health care consumers and providers. <http://healthit.hhs.gov> (access 28.05.2009)

The National Health Information Network (NHIN) is an ambitious modernization plan proposed by the U.S. government. The idea is to move as an entire nation from paper medical files to electronic medical files that are shared. Specifically, the government goal is to digitize patients' health records and medical files and create a national network to place the information in. The network, called the NHIN, would be a sophisticated network that hospitals, insurers, doctors, and others could potentially access. Such a network brings patient privacy, security, and confidentiality issues into sharp relief. As of spring 2009, the development of the network is well underway. (..) http://www.worldprivacyforum.org/medicalprivacy_NHIN.html (access 28.05.2009)

9.16.1 NHIN – Nationwide Health Information Network

The Nationwide Health Information Network (NHIN) is being developed to provide a secure, nationwide, interoperable health information infrastructure that will connect providers, consumers, and others involved in supporting health and healthcare.

9.16.2 FHA – Federal Health Architecture

The Federal Health Architecture is an E-Government Line of Business initiative. It is a response to the need for increased efficiency and effectiveness in all government operations.

9.16.3 HIPAA – Health Insurance Portability & Accountability Act

The Office for Civil Rights (OCR) has published new Health Insurance Portability & Accountability Act of 1996 (HIPAA) Privacy Rule guidance documents as part of a Privacy and Security Toolkit to implement The Nationwide Privacy and Security Framework for Electronic Exchange of Individually Identifiable Health Information (Privacy and Security Framework).

9.16.4 AHIC successor NeHC – National eHealth Collaborative

In 2008, HHS initiated a new private sector entity, the AHIC Successor Inc., with broad-based participation from the public and private sectors to further advance the use of common standards and policies. The AHIC Successor has been incorporated and renamed the National eHealth Collaborative (NeHC).

9.16.5 HITSP – Healthcare Information Technology Standards Panel

The mission of the Healthcare Information Technology Standards Panel (HITSP) is to serve as a cooperative partnership between the public and private sectors for the purpose of achieving a widely accepted and useful set of standards specifically to enable and support widespread interoperability among healthcare software applications, as they will interact in a local, regional and national health information network for the United States. <http://www.ahrq.gov/>

9.16.6 ONC or ONCHIT – Office of the National Coordinator for Health Information Technology

ONC is organizationally located within the Office of the Secretary for the U.S. Department of Health and Human Services (HHS). ONC is the principal Federal entity charged with coordination of nationwide efforts related to the implementation and use of electronic health information exchange. <http://healthit.hhs.gov> → Federal Health IT Programs → ONC

9.17 AHRQ – Agency for Healthcare Research and Quality's

The Agency for Healthcare Research and Quality's (AHRQ) mission is to improve the quality, safety, efficiency, and effectiveness of health care for all Americans. Information

from AHRQ's research helps people make more informed decisions and improve the quality of health care services. AHRQ was formerly known as the Agency for Health Care Policy and Research. <http://www.ahrq.gov>

9.18 CCHIT – Certification Commission for Healthcare Information Technologie

CCHIT is a private, non-profit organization formed to **certify EHRs** against a minimum set of requirements for functionality, interoperability and security. It was founded in 2004 by three industry associations(HIMSS, AHIMA and the Alliance). (..) Despite the HHS contract, CCHIT is not an extension of the federal government. <http://www.cchit.org> (access 28.05.2009)

10 American, European and other national Initiatives

We use the list of potentially relevant standards concerning eSanté as it is provided by an European Union mandate [M403Resp-2008] as starting point. The question is: which ones of those standards are essential with respect to a national eHealth strategy. At least inside Europe the eHealth applications should be interoperable on a minimum of emergency data and for ePrescription of drugs (and medical treatments).

First we have a look at other countries:

10.1 Infoway - inforoute – Canada

Created in 2001 as an independent, not-for-profit organization, Canada Health Infoway is funded by the federal government to accelerate the development and adoption of electronic health record projects in Canada that will be compatible with a national electronic health information system. [Infoway-Ca-2008].

They refer to HL7v2 and v3, SNOMED and ISO/TC215 - Health Informatics. LOINC is used as the basis for the pan Canadian Laboratory Observation Code Database (pCLOCD).

10.2 RIDE (Roadmap for Interoperability of eHealth Systems)

RIDE is a roadmap project for interoperability of eHealth systems leading to recommendations for actions and to preparatory actions at the European level. This roadmap will prepare the ground for future actions as envisioned in the action plan of the eHealth Communication COM 356 by coordinating various efforts on eHealth interoperability in member states and the associated states. [DogacA-RIDE]

Especially the “European Best practices in providing semantic interoperability in eHealth domain“ are a good starting point for further research. [METU-good-pr]

10.3 KVSafeNet

The Kassenärztliche Vereinigung (KV) has established KV-SafeNet. KV-SafeNet is an IT infrastructure based on VPN. German GPs and medical specialists are interconnected with the Kassenärztliche Vereinigung and other healthcare players.

Current applications are:

- Electronic invoicing with KV (mandatory for all in 2010),
- Interconnection to other medical networks (hospitals) and with other GPs
- Disease Management Program Documentation (DMPs)
- Data exchange with the German Berufsgenossenschaften DALE-UV

The German information is provided at [KVnet-2008].

10.4 Doctor To Doctor (D2D) / Padok

D2D establishes secure and trusted transfer of medical data between medical professionals and the German Kassenärztlichen Vereinigung. D2D can be used via ISDN or via the VPN solution of KV-SafeNet. Current applications are

- Discharge Letter / Doctor's Letter
- ePrescription (medication, consultation, co-treatment, CPOE)
- Electronic Health Record, patient or case related

In real usage are the applications noted at KV-SafeNET. Since 2008 the transfer of laboratory results – order entry and result reporting is possible and in use.

<http://www.d2d.de/> (access 28.05.2009)

10.5 VHitG Arztbrief

The VHitG Arztbrief is a widely used CDA extension for discharge letters. Several providers of medical information systems formed the German VHitG <http://www.vhitg.de/> (access 28.05.2009). Experts of industry as well as external consultants define implementation advises concerning HL7's CDA for special tasks: letter of discharge, rehabilitation and laboratory extensions with LOINC, patient identification, order and coordination of appointments.

10.6 VCS Communication Standard

Provided by a consortium of German software solution providers (VDAP, Verband Deutscher Arztpraxis-Softwarehersteller) the VDAP Communication Standard (VCS) was created and is in use since 2000. [VDAP-VCS]

10.7 ARTEMIS – Web Service-based P2P Infrastructure

A Semantic Web Service-based P2P Infrastructure for the Interoperability of Medical Information systems. The project was co-funded by the European Commission within the Sixth Framework Programme (2002-2006). [Artemis-2004].

10.8 Kmehr-Bis – Kind messages *for* electronic healthcare record – Belgian implementation

Kmehr is a proposed Belgian medical data standard, in order to enable the exchange of structured clinical information. It is funded by the Belgian federal Ministry of public health and assessed in collaboration with Belgian industry. [Kmehr-wiki]

For further information, see: <http://www.chu-charleroi.be/kmehr/htm/services.htm>

10.9 Other Initiatives

There is still a large number of initiatives we haven't analyzed yet:

- CEN ISSS Standardization Focus Group [CEN-ISSS-whatis]
- European Medicines Agency (EMA)
- EHTEL – European Health Telematics Association
- SEE and ILNAS
- EUCLIDES
- Continua (Consortium of >180 member companies)
- Normenausschuss NA 063-07 FB "Medizinische Informatik"
- COCIR – Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
- EHTO – European Health Telematics Observatory

- Open Healthcare
- Open Source Health Care Alliance
- Canadian Institute for Health Informatics
- Center for Devices & Radiological Health
- Korean PACS Standard Committee
- National Cancer Institute
- PHASTT
- EDISANTEHPRIM
- EDISANTE
- AFNOR —CNIS
- Patienten Dossier
- Intranet Health Clinic
- PharmDIS, PharmDIS-e+ and C³
- eMed
- C-Care
- Semantic Mining
- Share
- eProLearn
- ePrescript
- LiverDoc,
- EHCR Support Action

- Synapses project
- ICTSB and JIC
- JIRA (Japanese Industry Radiology Apparatus)
- ACR, ACC, AAO, ADA, CAP, ESC, SFR, DRG, SIRM, MISAT,

.... , but surely, the list is much longer.

11 Selection Criteria for eSanté Luxembourg

Selection criteria can be defined for the use of single standards or terminologies. But after the study it seems to be more adequate to decide towards whole profiles or even to follow or contribute the most important initiatives.

Back to our focus for what we want to select the standards and terminologies or, as explained, the profiles and initiatives. The first topics in eSanté for Luxembourg are:

- **ePrescription** including medication interaction check
- exchange and **share of structural medical data**, starting with **laboratory**
- exchange and **share of picture** and film data (x-ray, ultrasound, film sequences, etc.), starting with **radiology** x-rays
- exchange and **share of administrative data**
- **health cards** and health professional cards including a **unique identification**
- **anonymization** and pseudonymization for statistical evaluation

Exchange means direct exchange from A to B, storing and retrieving those data items on a central server, i.e. sharing the information over institutions.

The selection criteria are discussed next.

11.1 ISIS Report

The ISIS report gives a good overview which standards are already in use in health context in Luxembourg.

11.2 Already in Use Anywhere Else

Standards, de-facto or de-jure, that are already in use in some projects have been proven on their practical relevance.

11.3 Existing IHE Profiles

IHE profiles are of practical relevance and therefore good selection criteria for the importance of standards.

11.4 Projects in other Countries

Projects in other countries will be discovered in WP6 of eSanté. First impressions which selection criteria they may have choose flows into our selection. Germany and Canada provides some insight.

11.5 Avoid Local, European, International incompatibilities

In case of incompatibilities between EU work and International work, we should decide by each case. Again it is important to stay compatible with the decisions in other countries – having a future cross-border interoperability in mind.

11.6 European or International Initiatives on the Same Track

Our goals match with the current work of some European and international initiatives. We should participate there with the advantage of saving time and more important – being compatible later on.

11.7 Applying the Selection Criteria

The columns in our table below shows the first eSanté applications, the rows list our selection criteria, and the cells themselves contains the (subjective) implications for standards, classifications and initiatives.

	ePrescription	Structural Medical data	Picture and films	Administr. Data	Health cards	Anonym and pseudo
ISIS, already in use in L.		HL7v2, LOINC	DICOM	HL7v2		DICOM
In use anywhere else	HL7v3 CDA	HL7v2, HL7v3 CDA, RIM, CCAM, SNOMED	DICOM	HL7v2, HL7v3, CCOW, CCAM		?
IHE profile (see [IHE-profiles])		IHE-LSWF, XD*-LAB, LTCS (LOINC)	IHE-XDS, IHE-XDSi, ARI, ATNA, CPI, MAMMO, NM	IHE-SWF, PIR, PWF	IHE-MS, XPHR, EDR, QED	QED?
Other countries (future)	HL7v3 CDA, CCOW, ATC/ DDD	HL7v2, HL7v3 CDA, LOINC, EN13606, CCAM, SNOMED	HL7v2, HL7v3, DICOM	HL7v2, HL7v3, CCOW, CCAM	CCOW, DICOM, RIM, EN13606	DICOM
Avoid incompati	ATC/DDD	CDA, CDA, RIM, LOINC, EN13606	DICOM	HL7v3 CDA, RIM, CCAM	CDA, RIM, EN13606	DICOM, LOINC

bilities		CCAM, UMLS				
Same Track	HL7v3 CDA, ATC/DDD	HL7v2, HL7v3, LOINC, CCR/ CCD, CCAM, UMLS	HL7v3, DICOM	HL7v2, HL7v3 CDA, RIM, CCR/CCD, CCAM	HL7v3, CDA, RIM, CCR/CCD	DICOM, LOINC

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