The ISO/EN 13606 Standard for the Interoperable Exchange of Electronic Health Records

Pilar Muñoz, MSc[1,*]; Jesús D. Trigo, MSc[1]; Ignacio Martínez, PhD[1]; Adolfo Muñoz, PhD[2]; Javier Escayola, MSc[1]; José García, PhD[1]
[1]Aragon Institute for Engineering Research (I3A), University of Zaragoza (UZ), Spain.
[2]Telemedicine and Information Society Department, Health Institute "Carlos III" (ISCIII), Madrid, Spain

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ABSTRACT
The standardization of Electronic Health Records (EHR) is a crucial factor for ensuring interoperable sharing of health data. During recent decades, a plethora of initiatives – driven by international organizations – has emerged to define the required models describing the exchange of information between EHRs. These models cover different essential characteristics for building interoperable EHRs, such as architecture, methodology, communication, safety or terminology, among others. In this context, the European reference frame for the standardized exchange of EHR is the recently approved ISO/EN 13606 standard. This multi-part standard provides the syntactic and semantic capabilities (through a dual model approach) as well as terminology, security and interface considerations for the standardized exchange of EHR. This paper provides (a) an introduction to the different standardization efforts related to the interoperable exchange of EHR around the world, and (b) a description of how the ISO/EN 13606 standard provides interoperable sharing of clinical information.

1. ELECTRONIC HEALTH RECORDS AND STANDARDIZATION

There are many definitions of Electronic Health Records (EHR), but a broadly accepted one is that of the Health Information Management Systems Society (HIMSS): "*Health records are longitudinal records of patient health information generated by one or more encounters in any care delivery setting. Included in this information are patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data and radiology reports*" [1]. The traditional health

*Corresponding Author: Pilar Muñoz, Aragon Institute for Engineering Research (I3A), c/ María de Luna, 1. 50018 – Zaragoza (Spain). Phone: (+34) 976761000 ext. 5462. Fax: (+34) 976762111. E-mail: pmg@unizar.es. Other authors: jtrigo@unizar.es; imr@unizar.es; adolfo.munoz@isciii.es; javier.escayola@unizar.es; jogarmo@unizar.es.

records were maintained in paper format. As computer-based systems have become popular since the end of the last century, the application of Information and Communication Technologies (ICT) in all social or industrial sectors has resulted in remarkable advantages for the management and exploitation of resources. Within the particular environment of the healthcare sector, the relevant role of ICT has led to the transformation of those traditional paper-based health records into EHRs.

This change to a paperless health work environment has provided a plethora of benefits, such as more agile management of health records, lower maintenance costs or faster administrative response, among others. Besides the noteworthy benefits, a wide variety of challenges and opportunities have emerged. One of the most interesting is the capability of inter-connecting EHR Systems [1]. EHRs are usually generated and maintained *within an institution*, such as a hospital, integrated delivery network, clinic, or any other provider [3]. These EHRs integrate the longitudinal record of all care services provided over the patient's lifetime, but this record is usually separated in different systems and interconnecting this information is a requisite for effectively retrieving the whole longitudinal record of care. However, the lack of common criteria while developing these systems has hampered efforts to achieve a satisfactory exchange of clinical information. Furthermore, the possibility of building an EHR system by means of any programming language, any architecture design or internal workflow entails a lack of interoperability.

Based on the above considerations, a desirable goal would be to achieve an interoperable exchange of EHR. However, in order to accomplish such an objective, several requirements (technical, architectural, etc.) must be considered and defined. These requirements are formally translated into norms or standards provided by the appropriate organizations such as the Standard Development Organizations (SDO). Depending on their area of influence, SDOs can be international, national or regional. The most relevant organizations for world-wide standardization can be classified as shown in Table 1. These entities are independent (except for the Technical Committees), but their parallel development and results in similar fields of work has propitiated the need for establishing collaborative relationships between them, such as the Vienna Agreement between ISO and CEN [4] that guarantees that the documents developed within one body will be notified for simultaneous approval by the other. A complete relationship scheme of SDOs is detailed in Figure 1.

Communication and cooperation between different EHR systems and their components in a complex and highly dynamic environment requires the adoption of common terminologies and ontologies, advanced security, safety and privacy services and the separation between the logical and terminological points of view. The existence of such a wide variety of requirements implies the definition of specialized standards, classified according to the specific area to which they are related. Table 2 details the actual status of standardization of EHR grouped into the main specification areas: identification, architecture, infrastructure, communication models and security policies, among others [5, 6]. The incorporation of such standards and models into new EHR system designs would allow a further step to be taken in the utilization of future eHealth systems, preventing the proliferation of non-reusable prototypes.

Table 1. Normalization and standard development organizations for electronic health records

International	International Electrotechnical Commission	IEC	*http://www.iec.ch/*
	Institute of Electrical and Electronics Engineers	IEEE	*http://www.ieee.org/index.html*
	International Organization for Standardization	ISO	*http://www.iso.org/iso/home.html*
	ISO-Technical Committee 215	ISO TC215	*http://cen.iso.org/*
	Digital Imaging and Communications in Medicine	DICOM	*http://medical.nema.org/*
	HL7 International	HL7	*http://www.hl7.org/*
	Integrating the Healthcare Enterprise	IHE	*http://www.ihe.net/*
	Organization for the Advancement of Structured Information Standards	OASIS	*http://www.oasis-open.org/home/index.php*
	OASIS International Health Consortium	IHC	*http://www.oasis-open.org/committees/ihc/charter.php*
	Object Management Group	OMG	*http://www.omg.org/*
	United Nations Centre for Trade Facilitation and Electronic Business	UN/CEFACT	*http://www.unece.org/cefact/*
	World Wide Web Consortium	W3C	*http://www.w3.org/*
	International Telecommunication Union	ITU	*http://www.itu.int/en/pages/default.aspx*
	ITU's Telecommunication Standardization Sector	ITU-T	*http://www.itu.int/net/ITU-T/info/Default.aspx*
	International Health Terminology Standards Development Organisation	IHTSDO	*http://www.ihtsdo.org/*
European	European Committee for Standardisation	CEN	*http://www.cen.eu/cen/pages/default.aspx*
	Technical Committee of CEN for Health Informatics	CENTC 251	*http://cen.iso.org/*
	CEN Information Society Standardisation System	CEN/ISSS	*http://www.cen.eu/cen/sectors/sectors/isss/pages/default.aspx*
	CEN / ISSS e-Health Standardization Focus Group	CEN/ISSS e-Health	*http://www.cen.eu/cen/sectors/sectors/isss/pages/eHealth_FG.aspx*
	European Telecommunications Standards Institute	ETSI	*http://www.etsi.org/website/homepage.aspx*
	IHE Europe	IHE Europe	*http://www.ihe-europe.net/*
	European Committee for Electrotechnical Standardisation	CENELEC	*http://www.cenelec.eu/cenelec/homepage.htm*
Other	American National Standards Institute	ANSI	*http://www.ansi.org/*
	American Society for Testing Materials	ASTM	*http://www.astm.org/*
	Japan Industries Association of Radiological Systems	JIRA	*http://www.jira-net.or.jp/e/index.htm*
	National Electrical Manufacturers Association	NEMA	*http://www.nema.org/*

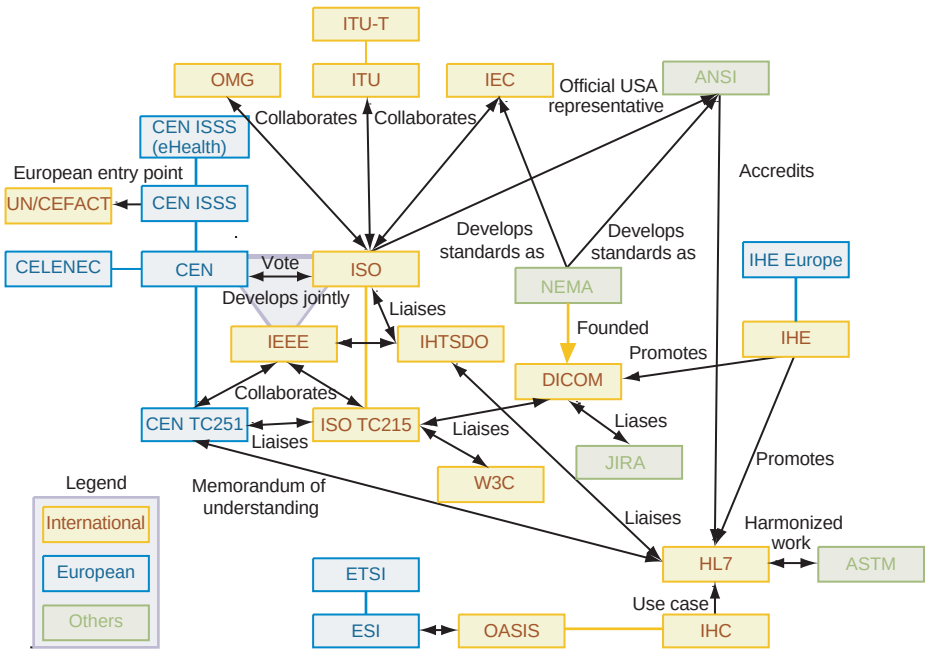

Figure 1. Relationship scheme of normalization and standard development organizations for electronic health records.

Within this context of interoperable exchange of EHRs, a wide range of initiatives have been proposed. Health Level 7 (HL7) [7], founded by American vendors of medical devices and recognized by ANSI, is an international standard for medical message exchange. It specifies a uniform syntax in the seventh level of the protocol stack, for information representation in a simple structure of segments, data type flags, and mapped fields. HL7 is a workable solution for the interoperable exchange of EHR and it is being widely used in the US and Canada. However, the semantic/syntactic model of HL7 can be enhanced by means of a dual model approach that represents clinical information and clinical knowledge separately. This was envisioned by different organizations that proposed a new dual-based model. Such initiatives include the openEHR Foundation, which proposed the openEHR specification [8] and the Technical Committee CEN/TC251, which developed the ISO/EN 13606 standard [9]. While HL7 is widely applied in the US and Canada, openEHR and ISO/EN 13606 are two closely related efforts (ISO/EN 13606 leveraged appropriate parts of openEHR) that are likely to be used in a collaborative fashion in Europe. Additionally, the European Commission encourages interoperability in the healthcare field through publications such as article 16 of 2008/0142 (COD) [10] or 2008/594/EC [11]. The European Commission plans to support large-scale pilots–through European funded projects such as the epSOS project [12] or ARGOS e-Health [13]–and aims to agree on

Table 2. Relevant standards for electronic health record systems (HI = Health Informatics, IT = Information Technologies, SAGE = Security Algorithms Group of Experts, ESI = Electronic Signatures and Infrastructures)

Requirement and Analysis	ASTM E2212-02a	Standard Practice for Healthcare Certificate Policy
	ISO 18812:2003	HI - Clinical analyser interfaces to laboratory information systems–Use profiles
	ISO 22857:2004	HI - Guidelines on data protection to facilitate trans - border flows of personal health information
	ISO TR 20514:2005	HI - Electronic health record - Definition, scope and context
	ISO TS 18308:2004	HI - Requirements for an electronic health record architecture
Architecture	CEN EN 12967:2006 (HISA)	HI - Service architecture Part 1: Enterprise viewpoint - Part 2: Information viewpoint - Part 3: Computational viewpoint
	CEN EN 13606-1:2010	**HI - EHR communication Part 1: Reference Model**
	CEN EN 13606-4:2010	**HI - EHR communication Part 4: Security requirements and distribution rules**
Modelling and Methodology	ASTM E1715-01	An object - oriented model for registration, admitting, discharge, and transfer functions in HCIS
	ASTM E2085-00a	Standard guide on security framework for healthcare information
	CEN CR 12587	CEN Report: Medical Informatics - Methodology for the development of healthcare messages
	CEN EN 13940-1:2006	HI - System of concepts to support Continuity of care - Part 1: Basic concepts
	CEN EN 14463:2006	HI - A syntax to represent the content of medical classification systems (ClaML)
	CEN ENV 13940:2002	HI - System of concepts to support continuity of care
	CEN TR 15300	HI - Framework for formal modelling of healthcare security policies (CEN Report)
	IETF RFC 3281	An Internet Attribute Certificate Profile for Authorization
	ISO HL7 21731:2006	HI - HL7 version 3 - Reference Information Model Release 1
	ISO DIS 27799	HI - Security management in health using ISO/IEC 17799

Table 2. (*Continued*)

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	ISO IEC 10118	IT - Security techniques - Hash-functions
	ISO IEC 10181	IT - Open Systems Interconnection - Security frameworks for open systems
	ISO IEC 10736	IT - Telecommunication/information exchange between systems, transport layer security protocol
	ISO IEC 10745	IT - Open Systems Interconnection, Upper layers security model
	ISO IEC 13335-1:2004	IT - Security techniques - Management of information and communications technology security
	ISO IEC 15408:2005	IT - Security techniques - Evaluation criteria for IT security
	ISO IEC 27001:2005	IT - Security techniques - Information security management systems - Requirements
	ISO IEC 27002	IT - Security techniques - Code of practice for info security management (ISO/IEC17799:2005IT)
	ISO IEC 27003	Information security management systems - Implementation guidance
	ISO IEC 27004	Information security management systems - Measurements
	ISO IEC 27005	Information security management systems - Risk assessment
	ISO IEC NP 27000	IT - Information security management - fundamentals and vocabulary
	ISO IEC TR 13335:1998	IT - Guidelines for the management of IT Security - Parts 3, 4 and 5
	ISO PAS 28000:2005	Security management systems for the supply chain
	ISO PAS 28003:2006	Requirements for bodies providing audit/certification of supply chain security management system
Communication	CEN EN 1064:2006	HI - Standard communication protocol - Computer-assisted electrocardiography
	CEN EN 12052:2005	HI - Digital imaging - Communication, workflow and data management
	CEN EN 13606-5:2010	**HI - EHR communication Part 5: Interface Specification**
	CEN EN 13608:2006	HI - Security for healthcare communication - Parts 1, 2 and 3.

Table 2. (*Continued*)

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CEN EN 13609-1:2005	HI - Messages for maintenance of supporting information in healthcare systems - Part 1
CEN EN 14720-1:2006	HI - Service request and report messages - Part 1
CEN EN 14822-1:2006	HI - General purpose information components - Parts 1, 2 and 3.
CEN ENV 13607:2000	HI - Messages for the exchange of information on medicine prescriptions
CEN ENV 13609-2:2000	HI - Messages for maintenance of supporting information in healthcare systems - Part 2
CEN ENV 13730-1:2002	HI - Blood transfusion related messages - Part 1
CEN TS 14822-4:2006	HI - General purpose information components - Part 4
ETSI ETR 277 (March 1996)	SAGE - Requirements specification for an encryption algorithm for use in audio visual systems
ETSI ETR 278 (March 1996)	SAGE - Report on the specification and evaluation of the GSM cipher algorithm A5/2
ETSI SR 002 176 V1.1.1 (2003-03)	Algorithms/Parameters for Secure e-Signatures
ETSI SR 002 298 V1.1.1 (2003-12)	ESI - Network and Information Security: Proposal for a European Policy Approach
ETSI TR 101 375 V1.1.1 (1998-09)	SAGE - Report on the specification, evaluation and usage of GSM GPRS Encryption Algorithm
ETSI TR 101 690 V1.1.1 (1999-08)	SAGE - Rules for the management of GSM CTS Authentication and Key Generation Algorithms
ETSI TR 101 740 V1.1.1 (1999-08)	SAGE - Rules of the management of the standard GSM GPRS Encryption Algorithm 2 (GEA2)
ETSI TR 102 038 V1.1.1 (2002-04)	ESI - TC Security - Electronic Signatures and Infrastructures. XML format for signature policies
ETSI TR 102 047 V1.2.1 (2005-03)	International Harmonization of Electronic Signature Formats
ETSI TR 102 272 V1.1.1 (2003-12)	Electronic Signatures and Infrastructures (ESI); ASN.1 format for signature policies
ETSI TS 101 733	Electronic Signature Formats
ETSI TS 101 862 V1.3.3 (2006-01)	Qualified Certificate profile
ETSI TS 101 903 V1.2.2 (2004-04)	XML Advanced Electronic Signatures (XAdES)

Table 2. (*Continued*)

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	ETSI TS 102 023 V1.2.1 (2003-01)	ESI - Policy requirements for time-stamping authorities
	ETSI TS 102 176 V1.2.1 (2005-07)	ESI - Algorithms and Parameters for Secure Electronic Signatures; Parts 1 and 2
	ISO 12052:2006	HI - Digital imaging and communication in medicine DICOM (workflow and data management)
	ISO 17432:2004	HI - Messages and communication - Web access to DICOM persistent objects
	ISO 18232:2006	HI - Messages and communication - Format of length limited globally unique string identifiers
	ISO IEC 13888	IT - Security techniques - Non-repudiation
	ISO IEC 14888	IT - Security techniques, Digital signature with appendix, multiple Parts (1–3).
	ISO IEC 9796	IT - Security techniques, Digital signature scheme giving message recovery, multiple Parts (1–2).
	ISO IEC 9797	IT - Security techniques, Message authentication codes.
	ISO IEC 9798	IT - Security techniques - Entity authentication
	ISO TR 21089:2004	HI - Trusted end-to-end information flows
	NEMA DICOM 3.0	Digital Imaging and Communications in Medicine
Infrastructure	CORBA	Common Object Request Broker Architecture
	ETSI TS 101 861 V1.3.1 (2006-01)	Time stamping profile
	ISO IEC 27001:2005	IT - Security techniques - Information security management systems (ISMS) - Requirements
	ISO/IEC 15816:2002 (ITU-T X.841)	IT - Security techniques - Security information objects for access control
	ISO/IEC TR14516:2002 (ITU-TX.842)	IT - Security techniques - Guidelines for the use and management of Trusted Third Party services
	ISO/IEC 15945:2002 (ITU-T X.843)	IT - Security techniques - Specification of TTP services to support digital signatures
	ISO IS 17090-1:2002	HI - Public key infrastructure - Parts 1, 2 and 3
	ISO TS 21091:2005	HI - Directory services for security, communications and identification of professionals/patients
	ISO TS 21298	Functional and structural roles
	ITU-T X.1051	Information security management system - Requirements for telecommunications (ISMS-T)

Table 2. (*Continued*)

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	NIST Special Publication 800-61	Computer Security Incident Handling Guide
Privacy	ASTM E1714-00	Standard guide for properties of a Universal Healthcare Identifier
	ASTM E1987-98	Standard guide for individual rights regarding health information
	CEN EN 14484:2004	HI - International transfer of personal health data covered by the EU data protection directive
	CEN EN 14485:2004	HI - Guidance for handling personal health data in international applications (EU directive)
	CEN ENV 12924	Medical Informatics - Security Categorisation and Protection for Healthcare Information Systems
	ISO IEC DTS 25237	HI - Pseudonymisation practices for the protection of personal health information/related services
	ISO 22857:2004	HI - Guidelines on data protection to facilitate trans-border flows of personal health information
	ISO TS 21091	HI - Directory services for security, communications, and identification of professionals/patients
	ISO TS 22600:2006	HI - Privilege management and access control - Parts 1 and 2
	OASIS 200201	Directory Services Mark-up Language (DSML) v2.0
	OASIS SAML	Security Assertion Mark-up Language (SAML) v2.0
	OASIS SPML	Service Provisioning Markup Language (SPML) v2.0
	OASIS XACML	eXtensible Access Control Mark-up Language TC v2.0 (XACML)
Safety	CEN CR 13694	HI - Safety and security related software quality standards for healthcare (SSQS) CEN Report
	CEN TR 15299	HI - Safety procedures for identification of patients and related objects
	CEN TS 15260	HI - Categorisation of risks from health informatics products
	ISO DTS 25238	HI - Classification of safety risks from health informatics products
	ISO TR 21730:2005	HI - Use of mobile wireless communication and computing technology in healthcare facilities

Table 2. (*Continued*)

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Token	CEN ENV 13729	HI - Secure user identification – Strong authentication using microprocessor cards
	CEN ENV 1387	Machine readable cards - Health care applications - Cards: General characteristics
	CEN ENV 1867	Machine readable cards - Health care applications - Numbering system and registration procedure
	CEN ENV 13735	HI - Interoperability of patient connected medical devices
	ISO 20301	HI - Health cards - general characteristics
	ISO 20302	HI - Health cards - numbering system and registration procedure for issuer identifiers
	ISO 21549	HI - Patient health card data
Quality	ASTM E2117-00	Guide for identification/establishment of a quality assurance program for medical transcription
	CEN CR 13694	HI - Safety and security related software quality standards for healthcare (SSQS). CEN Report
	ISO 13485:2003	Medical devices - Quality management systems - Requirements for regulatory purposes
	ISO 14969:2004	Medical devices - Quality management systems - Guidance on the application of ISO 13485
	ISO 15378:2006	Primary packaging materials for medicinal products. Application of ISO 9001:2000 (GMP)
	ISO 9000:2005	Quality management systems - Fundamentals and vocabulary
	ISO 9001:2000	Quality management systems - Requirements
	ISO TS 16949:2002	Quality management systems - Particular requirements for the application of ISO 9001:2000
Policy	ASTM E2212-02a	Standard Practice for Healthcare Certificate Policy
Terminology and Ontology	ASTM E1633-02a	Standard Specification for Coded Values Used in the Electronic Health Record
	ASTM E2457-06	Standard Terminology for Healthcare Informatics
	CCOW v1.5	Clinical Context Object Workgroup Version 1.5
	CEN EN 1068:2006	HI - Registration of coding systems
	CEN EN 12264:2005	HI - Categorial structures of systems of concepts - Model for representation of semantics
	CEN EN 12435:2006	HI - Expression of the results of measurements in health sciences

Table 2. (*Continued*)

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	CEN EN 13606-2:2010	**HI - EHR communication Part 2: Archetype Model**
	CEN EN 15521:2006	HI - Categorical structure for terminologies of human anatomy
	CEN EN 1614:2005	HI - Structure for nomenclature, classification, and coding of properties in clinical laboratory
	CEN EN 1828	Categorial structure for classifications and coding systems of surgical procedures
	CEN EN 1828:2002	HI - Categorial structure for classification and coding systems of surgical procedures
	CEN ENV 12017	Medical Informatics Vocabulary (MIVoc)
	CEN ENV 12611	Categorial structure of systems of concepts - medical devices
	CEN TS 14463:2006	HI - A syntax to represent the content of medical classification systems (ClaML)
	HL7v2.XML	HL7 Version 2.5
	ISO 15225:2000	Specification for a nomenclature system for medical devices for regulatory data exchange
	ISO 18104:2003	HI - Integration of a reference terminology model for nursing
	ISO 19218	Medical devices - Coding structure for adverse event type and cause
	ISO 20225	Global medical device nomenclature for the purpose of regulatory data exchange
	ISO 21731	HL7 version 3 - Reference Information Model
	ISO TS 17117:2002	HI - Controlled health terminology - Structure and high-level indicators
	ISO TS 21667:2004	HI - Health indicators conceptual framework
	LOINC	Logical Observation Identifiers Names and Codes – Laboratory and clinical observations.
	SNOMED-CT	Systematized Nomenclature of Medicine – Clinical Terms - Clinical Information
ID Management & Security	ASTM E1714-00	Standard guide for properties of a Universal Healthcare Identifier
	CORBA PIDS	Person Identification Service
	HL7/CORBA EIS	Entity Identification Service
	HL7 MPI	Master Patient Index
	ISO	Digital Object Identifier
	LOINC	Logical Observation Identifiers Names and Codes

processes for the implementation of interoperable solutions throughout Europe. As ISO/EN 13606 is the European standard for the interoperable exchange of EHR and given the European commitment to deploying interoperable eHealth solutions, this standard is likely to become the European reference frame for the interoperable exchange of EHR and hence there is a need to promote it.

The latest version of the standard defines the syntax and semantics–along with other terminology, security and interface considerations–for the interoperable exchange of EHRs. In spite of the recent approval of the standard (February 2010), it is already being used in some pioneer countries in Europe such as Sweden [14], United Kingdom [15] and Slovak [16]. Furthermore, it is also used in research projects, such as the *co-operative Clinical E-Science Framework* (CLEF) [17], and in commercial applications, e.g., the *Electronic Record Services* (ERS) [18]. This review article provides a comprehensive but summarized overview of this standard, since it is the European reference in this context. Additionally, an overview of the EHR standardization arena, enumerating related SDOs and relevant documents, is presented to provide the background context.

2. THE ISO/EN 13606 STANDARD

The ISO/EN 13606 standard [9] has been developed by CEN/TC251, the technical committee responsible for developing standards in the field of Health Information and Communications Technology in Europe. ISO/EN 13606 provides a model for representing the information that can be included in an EHR and, at the same time, it defines the information exchange between EHR systems. The main objective of this standard is to define the way that EHRs are exchanged, but it specifies neither the internal architecture of an EHR system nor the way data are stored.

ISO/EN 13606 is based on a dual model: a Reference Model which supports the *information*, and an Archetype Object Model (AOM). AOM allows defining *knowledge*, i.e., the concepts of the clinical domain by means of Archetypes. Archetypes are patterns that represent the specific characteristics of the clinical data. A main concept of this dual approach is that if *knowledge* changes (e.g., additional health characteristics are required to be included), only the archetype under the data will change. For example, the following declaration can be assimilated to *knowledge*: "A routine blood chemistry measures the following chemical substances in the blood: glucose, urea, creatinine, sodium and potassium". On the other hand, *information* is the instantiation of that archetype for one patient at one specific point of time: "January 2nd, 2010 at 08:43 a.m. John Smith had glucose = 80 mg/dL, urea = 11 mg/dL, creatinine = 0.77 mg/dL, sodium = 141 mmol/dL, and potassium = 4.1 mmol/dL". Eventually, due to new discoveries in medicine, it may become important to include additional measurements (for example, chlorine levels) in the routine blood chemistry tests. In such a case, only the archetype (*knowledge*) would change while the Reference Model remains unaltered. The ISO/EN 13606 standard is divided into five different parts that are detailed below:

- **Part 1: Reference Model**. This part defines basic generic components that support *information* and the relationships between those components. Figure 2 (extracted from ISO/EN13606-1) shows a simplified scheme of these components.

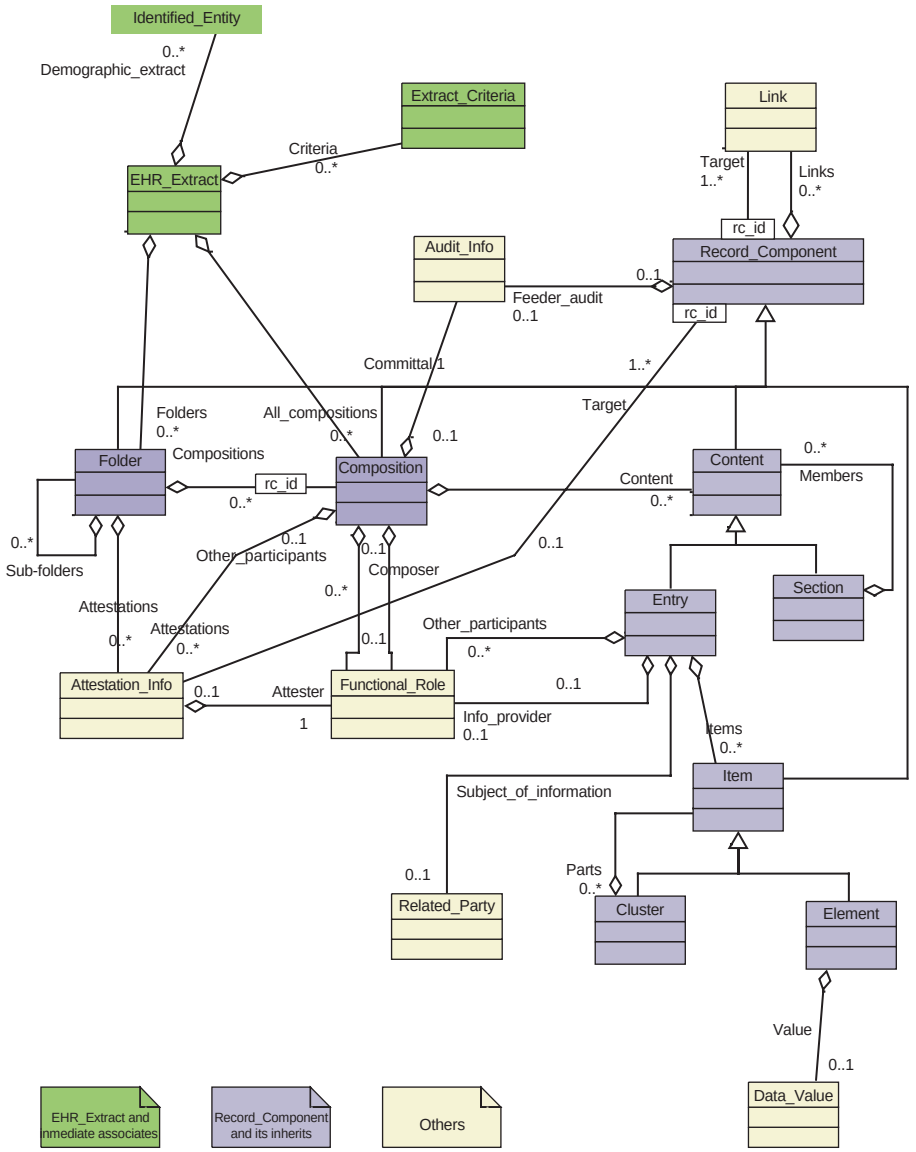

Figure 2. ISO/EN13606 Reference Model (simplified scheme from ISO/EN13606-1).

The EHR is comprised of the following logic blocks (Figure 3):

- *EHR_Extract*: The top-level container of part or all of the EHR of a patient.
- *Folder*: Some high level organization within an EHR (episode of care, compartments of care, etc.)

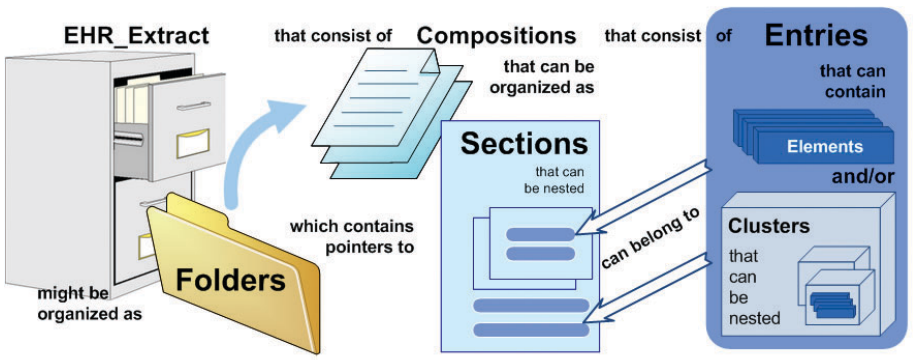

Figure 3. Component relationships of the ISO/EN13606 Reference Model.

- *Composition*: A single clinical encounter or record documentation session (reports, test results, etc.)
- *Section*: Clinical headings reflecting flow information (subjective symptoms, findings, treatment, etc.).
- *Entry*: Clinical statements (a measurement, a symptom, etc.).
- *Clusters*: The means to organize nested multi-part data structures (tables, time series, etc.)
- *Element*: A container of a single data value. This is the leaf node of the hierarchy.

Thus, the Reference Model sets hierarchical relationships between its components, achieving in this way syntactic interoperability, i.e., identifying different elements in the system and establishing rules for combining them, thus allowing any system to be able to understand the structure of the information. A deeper analysis shows other relevant characteristics related to the use of the standard, such as the following:

- The ability of signing every single element by means of defining the ATTESTATION_INFO class. As can be seen, the existing association relationship between this class and RECORD_COMPONENT is inherited by the rest of the elements, given that all of them derive from this abstract class. Thus, every RECORD_COMPONENT can be signed independently.
- The separation of the demographic information allows transmitting clinical information anonymously, an essential factor in health environments for security reasons. All components of the system (organizations, devices, healthcare professionals, subjects of care or other classes of people) are identified by unique identifiers.
- Auditory capabilities are present through the AUDIT_INFO class, which can be used to track what data has been introduced, when and by whom, and also the reason for that information to be modified.
- To achieve this, the Reference Model establishes a mechanism of versioning records; thus deletion is not allowed (if a record needs to be removed, it is marked as non-valid).
- It also allows recording every single request to the EHR system, whether accepted or not, as well as the reason for the rejection.

- **Part 2: Archetype Model.** The Archetype Model represents the semantics of the dual model approach. An archetype is used for modelling domain concepts (blood pressure, body weight, etc.), constraining the Reference Model at run-time by defining the structure of the instance and/or limiting the value range of an attribute (see Figure 4). Since this part of the norm leverages appropriate parts of the openEHR model for defining archetypes, openEHR and ISO/EN13606 share the basis of the archetype model [19].

  Archetypes can make use of standardized health terminology to simplify the decoding of the received data and they are defined using different formal languages such as the Ontology Web Language (OWL) and the Archetype Definition Language (ADL) [20]. In Figure 5, the top-level structure of an ADL archetype is represented. The current version of ADL language (v1.4) uses three syntaxes to describe constraints on data:
  - cADL: constraint form of ADL, used to express the archetype *definition* section.
  - dADL: data definition form of ADL, used to express data that appears in the *language, description, ontology*, and *revision_history* sections.
  - First-Order Predicate Logic (FOPL), to express data which appears in the *declarations* and *invariant* sections.

Figure 6 shows a simplified scheme of the Archetype Model, extracted from ISO/EN13606-2. Describing a well defined archetype is not a simple task. As seen in Figure 6, the ISO/EN 13606 standard offers different mechanisms to enable this modelling, such as the *archetype_description*, the *ontology* and the *constraint_model*.

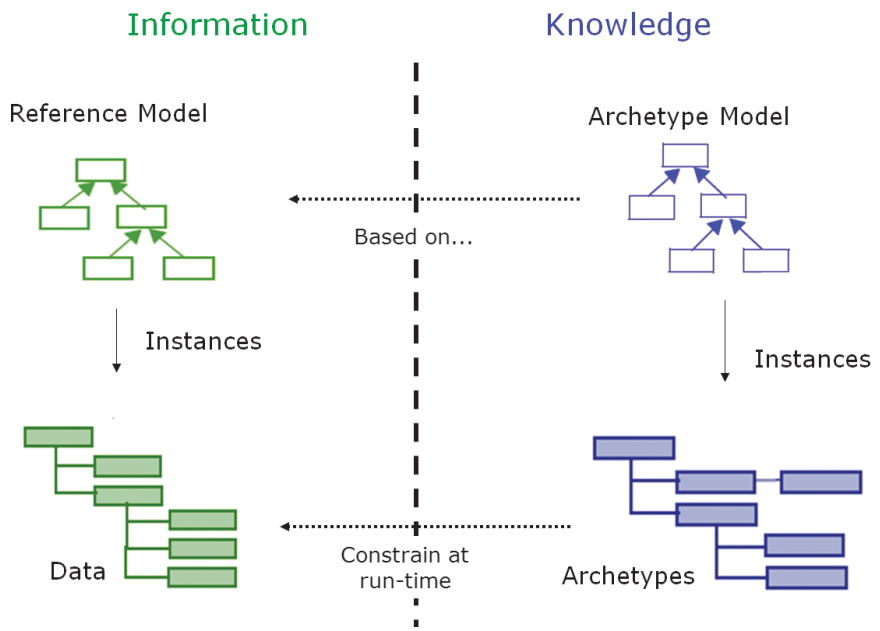

Figure 4. Relationship between information (instances of Reference Model) and knowledge (instances of Archetype Model) [19].

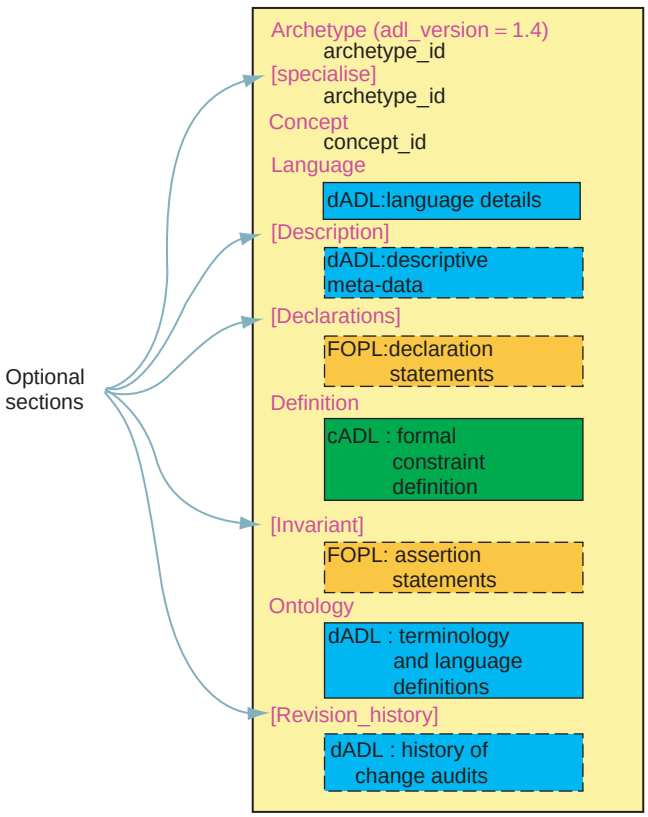

Figure 5. Top-level structure for an Archetype Definition Language (extracted from ISO/EN13606-2).

The *archetype_description* allows associating additional data (metadata) to the archetype, for instance, a translation into a different language. The *ontology* is used to bind archetype nodes to specific health terms. Finally, the *constraint_model* specifies a hierarchical schema that defines how an instance must be built.

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

- **Part 3: Reference Archetypes and Term lists**. This part establishes a normative set of coded terms, each one defining a controlled vocabulary for a Reference Model attribute contained in ISO/EN 13606-1. This part includes different groups of terms such as terms related to the subject of an *Entry* (*SUBJECT_CATEGORY*), the category of information of any *ELEMENT* or

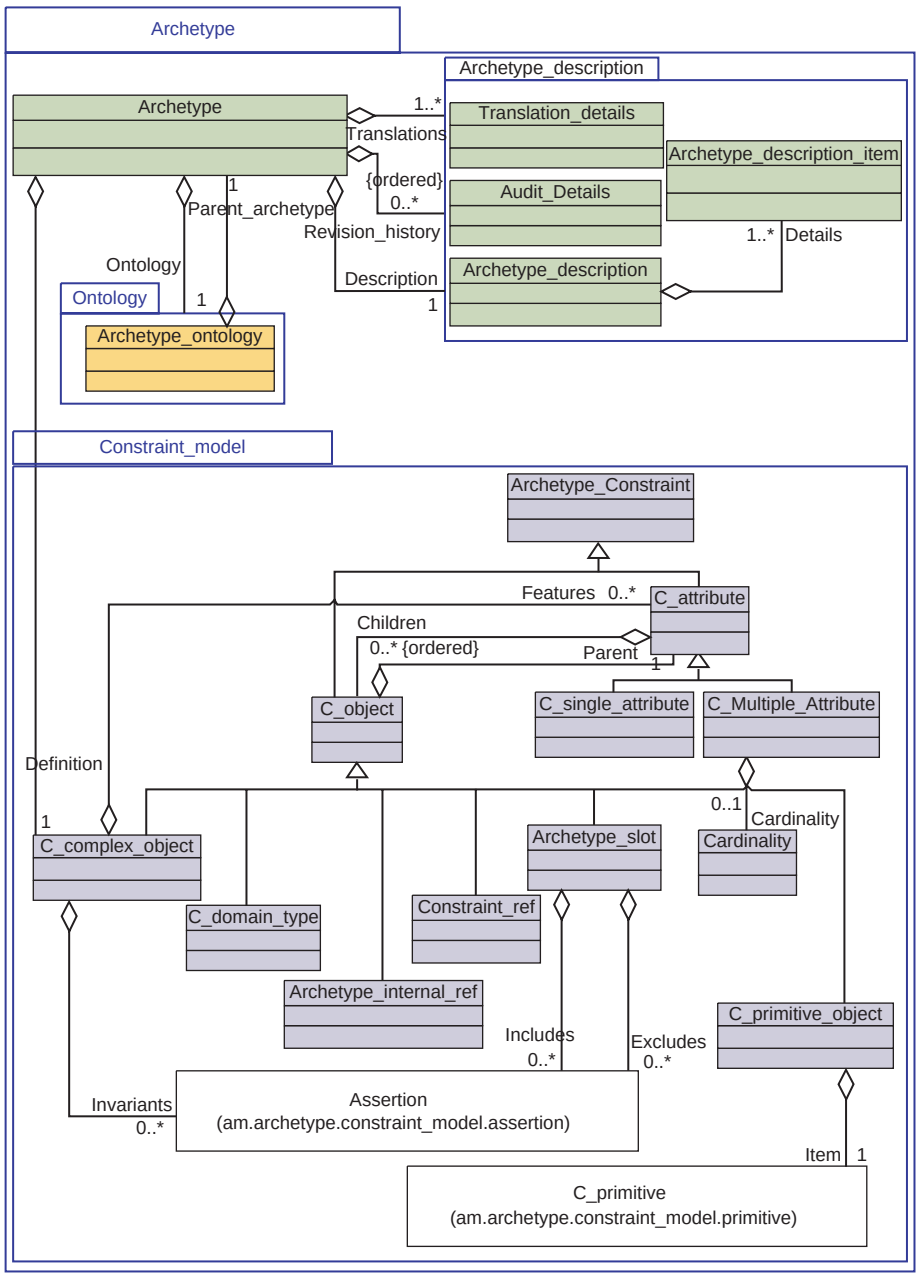

Figure 6. Archetype model (simplified scheme from ISO/EN13606-2).

CLUSTER (*ITEM_CATEGORY*), the status of a particular version of a *record_component* (*VERSION_STATUS*), the physical or electronic means by which an *Entity* participates (*MODE*), the act status values for a particular *Entry as* included in EN 12967-3 [21] – the computational viewpoint of Health Informatics Service Architecture (HISA) – (*ACT_STATUS*), the semantics of the relationship between the source and target *record_component* (*LINK_NATURE*) and a subcategory of the corresponding link terms (*LINK_ROLE*), and finally, the structural organization of a *Cluster* (*STRUCTURE_TYPE*).

- **Part 4: Security**. This part describes a methodology for specifying the privileges necessary to access EHR data and some other general security requirements that should apply to EHR communications. For example, it provides a double input table, the functional role of the requester and the sensitivity of the record. The *information* is only accessible if the functional role of the requester (coded with a number) is at least equal to the sensitivity of the record. This security part also defines both general and specific access policies able to deny or grant access to identified parties or specific functional roles.
- **Part 5: Interface Specification.** This part describes a set of interfaces to request access to the information and resolve the request. Three specific interfaces are defined:
  - REQUEST_EHR_EXTRACT, to request a specific EHR_EXTRACT (as defined in ISO/EN 13606-1). The only mandatory parameter is *subject_of_care_identity*, but optional parameters are also available. These optional parameters can be used to specify the time range of the retrieved information (for example, it is possible to request either all previously requested records or any record within a given time range).
  - REQUEST_ARCHETYPES, to request one or more ARCHETYPES (as defined in ISO/EN 13606-2). There is no mandatory parameter in this case. Archetypes can be requested based on a particular concept (for example, it is possible to request a specified set of identified archetypes or all the archetypes).
  - REQUEST_EHR_AUDIT_LOG_EXTRACT, to request a specific EHR_AUDIT_LOG_EXTRACT (as defined in ISO/EN 13606-4). In a manner analogous to REQUEST_EHR_EXTRACT, it defines optional parameters to filter the retrieval of information and to determine access policies, since special privileges are required to access specific control information.

The ISO/EN13606 standard has been recently completed after Part 5 was ratified by ISO and CEN in February 2010. As a multipart standard, the different parts were approved by separate polling, while further comments in the voting process led to changes in some parts. The ratification dates for the 5 parts of the standard by CEN and ISO are shown in Table 3.

The mandatory attributes required to be transmitted as well as the *data types* and their meaning within the standard are shown in Table 4. Additionally, other relevant information can be expressed by including optional parameters. For instance, information such as the date and the time interval the item was observed, a screenshot of the test or even information related to whether the extract has been automatically generated by a machine or triggered by any other provider. Moreover, by the use of the optional attributes *archetype_id* and *meaning* semantic interoperability can be provided by specifying the archetype that has been used or if that record conforms to any concept domain that uses health terminology like SNOMED-CT [22]. The observed item should

Table 3. Ratification dates for the 5 parts of ISO/EN13606 by CEN and ISO

	Status in CEN	Status in ISO
ISO/EN13606-Part 1: Reference Model	Published in February 2007	Published in February 2008
ISO/EN13606-Part 2: Archetype Model	Published in July 2007	Published in November 2008
ISO/EN13606-Part 3: Reference Archetypes and Term Lists	Published in February 2008	Published in January 2009
ISO/EN13606-Part 4: Security	Published in March 2007	Published in September 2009
ISO/EN13606-Part 5: Interface Specification	*Published jointly by CEN and ISO in February 2010 (according to the Vienna Agreement)*	

be expressed in the optional attribute *value* in ELEMENT, failing which it must be indicated by the *null_flavour* attribute inherited from RECORD_COMPONENT.

To date, the ISO/EN 13606 standard has been based on a subset of CEN/TS14796 for describing *data types* but this is expected to change in the future. Due to the Memorandum of Understanding [23] between HL7, CEN/TC251 and the Joint Initiative on SDO [24], a new document is being discussed in order to harmonize CEN *data types* (CEN/TS14796) and HL *data types*. This document (ISO/FDIS 21090), still in draft status, is being designed to replace CEN/TS14796 and align with HL7 *data types*. The number of classes defined in ISO/FDIS 21090 is higher than in CEN/TS14796, particularly in the case of structured text, since it is intended to cover all those records that were previously stored as free text. Another point to take into account is the intention of including specific classes to represent information related to the demographic package, such as addresses or entity names.

Another remarkable feature of ISO/EN 13606 is the alignment it presents to other relevant standards shown in Table 1:

- **Part 1** can be seen as a subset of the openEHR Reference Model and presents a partial alignment with HL7 Clinical Document Architecture (CDA) Release 2.0. It can also be mapped to relevant portions of EN12796, EN13940, and specific metadata of the IHE Cross Enterprise Document Sharing (XDS).
- **Part 2** leveraged the openEHR model and its requirements have been adopted with minor revision by HL7.
- **Part 3** contains mapping to HL7 Act Relationship codes, ACT_STATUS TERMS mapped with HISA, etc.
- **Part 4** aligns with ISO 22600 and has been contributed to IHE in defining its privacy management services.
- **Part 5** can be considered as a specialization of HISA services relating to clinical data and to clinical knowledge, and most parts of it can be mapped to IHE XDS query parameters.

Table 4. Mandatory attributes of the ISO/EN13606 Reference Model

EHR_EXTRACT	Container of part, or all, of the EHR of a single patient. It contains Compositions, optionally organized by folder hierarchy.		
	ehr_id	Instance Identifier	The identity of the EHR from which this EHR Extract has been created
	ehr_system	Instance Identifier	The identity of the EHR provider system from which the EHR_EXTRACT was created
	rm_id	String	The identity and version of the Reference Model standard under which the EHR_EXTRACT was created
	subject_of_care	Instance Identifier	Unique identifier of the subject of care
	time_created	Time Point	Date/time at which data from this subject of care's EHR was queried/ exported to create the EHR_EXTRACT
RECORD_ COMPONENT	Abstract class. Classes derived from RECORD_COMPONENT inherit its attributes		
	name	Text	Name of the record
	rc_id	Instance Identifier	Unique identifier of the record
	synthesised	Boolean	TRUE if this RECORD_COMPONENT has no corresponding node in the EHR from which it was extracted
COMPOSITION	Inherited attributes of RECORD_COMPONENT and a mandatory association committal (to AUDIT_INFO), which contains those attributes:		
	committer	Instance Identifier	The party responsible for committing the RECORD_COMPONENT
	ehr_system	Instance Identifier	EHR system in which the RECORD_COMPONENT was committed
	time_committed	Time Point	Date/time at which the RECORD_COMPONENT was committed within the identified EHR system
ENTRY	Inherited attributes of RECORD_COMPONENT, and:		
	uncertainty_expressed	Boolean	If it contains data that indicates some degree of uncertainty
CLUSTER	Inherited attributes of RECORD_COMPONENT and Item, and:		
	structure_type	Code Simple Value	Time/spatial organization of data within this CLUSTER
ELEMENT	Inherited attributes of RECORD_COMPONENT and item		

3. FORTHCOMING CHALLENGES FOR THE EHR

ISO/EN 13606 is a very recent standard (it was fully completed on February 2010). Hence, there is still a wide range of further research to be carried out, as was concluded in the "CEN/ISO EN13606 Invitational Workshop" [25]. Around 40 people from twelve countries were selected as representatives of the different projects that have adopted the ISO/EN 13606 standard. Those attending the workshop shared best implementation practices and identified the main problems and future challenges related to the ISO/EN 13606 standard. Since the standard is in its early stages and it does not state the implementation technologies to be used, one of the drawbacks discussed was the lack of resources or implementation guides. Regarding this issue, attendants agreed to collaborate in many ways, for example, by creating educational resources and good practices for the adoption of the standard or by developing technical artefacts, such as eXtensible Markup Language (XML) schemas and implementation guidelines, that will enable the standard to be adopted more easily and used consistently. Another drawback discussed was the absence of archetype governance. The potential of developing proprietary archetypes may prevent the sharing of *knowledge*. Regarding this issue, two main axes of action were suggested: the creation of regional or national archetypes repositories and the development and sharing of tools for creating archetypes for use with SNOMED-CT and other terminologies. Both axes would contribute to enhancing quality in modelling clinical concepts. In this context, the importance of developing Detailed Clinical Models (DCM) - i.e., new ways to structure health information by combining expert knowledge, data specification and terminologies–and certifying specifications to generate them was also covered. Another issue addressed was the global problem of the identification of patients or healthcare professionals in order to release functional ISO/EN 13606 EHR systems. After the main drawbacks were identified, attendants agreed to develop an ISO/EN 13606 community of users and study other future mechanisms of collaboration with the objective of publicizing best practices based on real implementations and providing feedback for work in CEN, ISO and in conjunction with existing organizations such as openEHR, the International Health Terminology Standards Development Organization (IHTSDO), and EuroRec [26].

Additionally, the exchange of clinical information with the emerging Personal Health Records (PHR) systems is a closely related challenge. A PHR system is essentially an EHR system but the main distinction, as pointed out by ISO, is that in PHRs the individual who is the subject of the record is the key stake-holder determining its content and with rights over that content. Several commercial PHR systems, such as Microsoft Health Vault [27], Google Health [28] or Dossia [29] are already available and all of them allow tracking the health status and the evolution of any measurement record of the patient. All these systems contain information eligible to be included in EHR Systems in order to improve the continuity of care of the patient. A new ISO item of work (ISO/NWIP #14292 Health Informatics) has been launched to define PHR, its scope, context and global variations of use.

There are other parallel challenges, such as systems quality, in improving EHRs. EHRs are not always as functional as may be desired, and at times they do not meet

minimum interoperability requirements. A parallel European project is being conducted to establish systematic and comparable certification procedures for assuring the quality of eHealth products. One of the most important functions of EHR is to provide continuity of care, but EHRs are also legal documents, potentially used for research, teaching, etc.

4. CONCLUSION

The exchange of clinical information is a crucial factor to enable provision of high quality health services. The application of ICT in this process vastly improves the management and exploitation of traditional health records. However, the development of non-standardized, heterogeneous communication architectures has caused syntactic and semantic divergences. The internationally adopted strategy to overcome the interoperability gap is the application of standards that provide descriptions of all the elements involved, such as syntactic, structural and semantic interoperability. The ISO/EN 13606 standard covers the entire EHR needs within its five parts and, since its final approval in February 2010, it has gained steadily growing acceptance by being implemented, supported or adopted by several European projects, academic institutions, hospitals and health organizations. The main technical improvement of ISO/EN 13606 is its dual model approach, which provides a clear separation between *information* (Reference Model) and *knowledge* (Archetype Model). The interaction of these two models vastly improves the capability for developing and sustaining up-to-date, medically-accurate information systems. Besides the reference and information models, the standard provides three additional normative parts. These parts address essential issues in the conception of modern EHR systems such as normative, controlled nomenclature (part 3), security methodology and specifications (part 4), and interface definitions to request specific extracts, archetypes or audit log extracts (part 5). Thus, the recently published ISO/EN 13606 standard bridges the existing interoperability gap by providing a normative framework for building interconnected, standardized EHR systems.

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