

CHIRON

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clinical eNvironments - Grant Agreement no. : 100228

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Authors (Partner) (per company, if more than one company provide it together)		Luigi Albani (FIMI), Jan-Marc Verlinden (ZG), Mauro Giacomini (UNIGE), Jaap van der Voet (Philips), Miguel A. GONZALEZ (Alma), Cesar Mediavilla (ATOS), Cedric Marchessoux (Barco), Jure Lampe (MOBILI), John Gialelis (ISI)	
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LIST OF ABBREVIATIONS

CCR	Continuity of Care Record
CDA	Clinical Document Architecture
DB	Database
HMO	Health Maintenance Organization
HTTP	Hyper Text Transfer Protocol
ICD	International Statistical Classification of Diseases and Related Health Problems
IETF	Internet Engineering Task Force
IP	Internet Protocol
LOINC	Logical Observation Identifiers Names and Codes
MeSH	Medical Subject Headings
MLLP	Minimal Lower Layer Protocol
PHR	Personal Health Record
RIM	Reference Information Model
SIG	Special Interest Group
SNOMED CT	Systematized Nomenclature of Medicine Clinical Terms
UMLS	Unified Medical Language System



Executive Summary

Standardization is an important way to foster interoperability among multivendor devices/solutions/services and it is a key condition for the growth of the market.

The areas of main interest for the CHIRON project are the following ones:

- a. Technical and semantic interoperability among the health-related devices and systems,
- b. Wireless interoperability,
- c. Security and privacy,
- d. Patient-centric electronic health record.

The assessment of the existing standards will be the first step for the identification of gaps which need to be filled to allow an effective implementation of the concepts, solutions developed in CHIRON. This second part of the standardization activity in CHIRON will be covered by the deliverable D8.3.2 (Plan for the proposal of new standards) due on month M24.

This deliverable reports a review of the existing standards having an impact on the CHIRON research work and a list of applicable standards relevant for CHIRON is reported in the Appendix 1.

1. Introduction

The current trend – in line with the approach of ETSI¹ - is to consider interoperability in all its four components (technical interoperability, syntactical interoperability, semantic interoperability and organizational interoperability) and at different levels (content interoperability, service interoperability, device interoperability and device-to-device interoperability).

The majority of the existing standards – related to the intercommunication among the various components of the healthcare system – involve the devices and systems used in a clinical setting; they need to be extended to personalized, “non-hospital related” applications.

On the patient-end side the problem of device interoperability has to be solved on three principle levels:

- On lower-layers a standardized transport technology enabling basic connectivity has to be developed;
- On upper-layers application profiles have to be developed, which define the capabilities of the transport technology which need to be used to best support the application requirements;
- Finally on application level standardized data models and formats have to be developed.

While a significant amount of problems on the lower layers has been solved already and mature standards are available, more work at levels closer to the application is needed.

There are several alternative wireless technologies for short-range communication (the IEEE 802.11 (WLAN) and the IEEE 802.15 (WPAN) family of standards (both in the IEEE 802.15.1 (Bluetooth) version and in the IEEE 802.15.4 possibly in combination with ZigBee built on top of it). Although providing lower data rates than IEEE 802.11, it is mainly the IEEE 802.15 family that fits best the requirements of small-scale personal health devices in terms of low energy consumption and low complexity.

The design of energy efficient WSNs is still an open issue. Many works have focused on energy-efficient protocol stacks for IEEE 802.15.4-compliant networks. The main goal is to support multi-hop communication, pursuing at the same time energy efficiency issues. Results from the experience gathered from real test-bed deployments have clearly shown the advantage of cross-layer optimizations and the need for designing schemes which are robust to nodes malfunctioning and failures and to interference from different wireless technologies. For this reason, several research proposals have focused on geographic or hop-count based routing protocols, able to dynamically find a route toward the sink, according to current network topology and nodes duty cycles. In order to prolong the network lifetime, nodes follow a duty cycle, meaning that they are in a active (or awake) state for a percentage of time (e.g., duty cycle of 10%), while in the remaining part of time (e.g. 90%) they are in asleep mode, with the radio turned off.

To solve the interoperability problem on application level it is necessary that devices speak a common language by means of a common nomenclature, data types, message syntax and encoding rules. Many national and international organizations are working on standardization initiatives that enable upper-layer medical information exchange (ISO 11073 / IEEE 1073 family of standards which are intended to enable medical devices to interconnect and interoperate with other medical devices).

¹ See ETSI white paper “Achieving technical interoperability – The ETSI approach”, October 2006



In the second phase of the standardization activity in CHIRON (deliverable D8.3.2 – Plan for the proposal of new standards) we will foster the applicability of the x73 standards to a “non-clinical” context i.e. to personal healthcare systems, where sensors and battery powered devices demand for very low computational complexity and low power consumption.

In fact the x73 standards for point-of-care medical device communication are mainly designed for acute monitoring and treatment applications in the hospital domain. Important modifications are needed: for example, for the wireless devices used in personal healthcare in the home domain, the need of low power consumption translates into a minimization of the transmit power and the reduction of the transmission time through the reduction of protocol overhead.

Only recently a new ISO/IEEE 11073 working group devoted to Personal Health Data (PHD) has been established.

With regard to the standardization of Electronic Health Record (EHR) architecture, the CEN/ ISO EN 13606 standard has been identified; it describes all aspects of EHR in general, in a very theoretical way.

It is structured into five levels whose evolution is described below.

ISO 13606-1:2008 specifies the communication of part or all of the electronic health record (EHR) of a single identified subject of care among 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. It has been recognized that the main applications of these principles can be achieved by using HL7-V3 messages (implemented in XML).

ISO 13606-2:2008 specifies the information architecture required for interoperable communications among systems and services that need or provide EHR data. ISO 13606-2:2008 is not intended to specify the internal architecture or database design of such systems. ISO 13606-2:2008 defines an archetype model to be used to represent archetypes when exchanged between repositories or archetype services. The archetypes can be defined using two different methods: either openEHR or Clinical Document Architecture (HL7-CDA R2).

ISO 13606-3:2009 defines term lists, each specifying the set of values that particular attributes of the Reference Model defined in ISO 13606-1 may take. It also defines informative Reference Archetypes that correspond to ENTRY-level compound data structures within the Reference Models of openEHR and HL7 Version 3, to enable those instances to be represented within a consistent structure when communicated using ISO 13606-3:2009.

ISO/TS 13606-4:2009 describes a methodology for specifying the privileges necessary to access EHR data.

ISO 13606-5:2010 specifies the information architecture required for interoperable communications among systems and services that need or provide EHR data. The record extract and the scope of the communication is predominantly with respect to that person's care. ISO 13606-5:2010 defines a set of interfaces to request and provide:

- an EHR_EXTRACT for a given subject of care as defined in ISO 13606-1;
- one or more ARCHETYPE(s) as defined in ISO 13606-2;
- an EHR_AUDIT_LOG_EXTRACT for a given subject of care as defined in ISO/TS 13606-4.

For a complete description of the evolution of the standard see section 4.2.1.



Attention has to be paid also to Radio Frequency Identification (RFID) systems and to the standardization work in this area (e.g. the Electronic Product Code (EPC) Gen 2 standard developed by the EPCglobal industry group).

Finally another critical area is related to privacy and security. The U.S. Health Insurance Portability and Accountability Act (HIPAA) and the European Directive 95/46 are the references.

We notice other rising activities in the personal tele-health-care domain and in the area of near-range wireless connectivity:

- The IEEE P1073.0.1.1 Working Group is promoting the use of off-the-shelf technologies (IEEE 801.11 “WiFi”, IEEE 802.15.1 / “Bluetooth” and IEEE 802.15.4/ “Zigbee”) in a shared IT infrastructure where multiple devices and systems from diverse vendors can be integrated to provide safe and effective communication of medical data.
- The Zig-Bee Alliance aims to develop a new application profile in the area of health monitoring to enable plug-and-play interoperability of wireless ZigBee-enabled medical sensors and devices.
- The IEEE P1451.5 Project is working on defining wireless communication protocols and data formats for wireless transducers (sensors and actuators) based on the IEEE P1451 family of smart transducer interface standards. The expected standard will adopt the IEEE 802 family of the wireless communication protocols.

Attention will be given to the activity of the CEN/TC251/PT5-021 Project Team for the standardisation of the representation of digitised biomedical signals, measurements, events and alarms.

Standard interfaces for clinical data are already present in some high level clinical data treatment bodies (like veteran hospital network in the USA) or in some applied research project on continuity of care (e.g. Biomedical Research Integrated Domain Group, Muenster hospital). Unfortunately, they are not so spread in the EU territories to be the backbone of an effective clinical data interchange network to support a real continuity of care (see Appendix 4 for an overview of the current Electronic Health Record implementations).

2. Personal Area Networks and communication protocols

The Body/Personal Area Networks (BANs/PANs) constitute a network class which typically refers to communication of devices located in proximity to an individual. Hence, the typical range of such networks is a few meters. Of particular interest are the wireless variants of this class, called Wireless BAN/WPAN, which (typically) use radio transceivers for the transmission of data. These networks have seen rapid development in the previous years, and are still a hot topic in research.

The most widely recognizable form of WPAN is Bluetooth, which served as the basis of the IEEE 802.15 standard. IEEE has broken down the WPAN working group into 7 task groups, each focused on a different aspect of WPANs. They have issued the following standards:

- Task Group 1 - WPAN / Bluetooth: A WPAN standard initially based on the Bluetooth v1.1 specifications, later updated to include changes from Bluetooth v1.2, and published as IEEE 802.15.1-2005.
- Task Group 2 – Coexistence: A standard that addresses the issue of coexistence of WPANs with other wireless networks and devices operating in unlicensed frequency bands.
- Task Group 3 – High Rate WPAN: A standard for high data rate WPANs. This includes 3 different physical layer definitions.
- Task Group 4 – Low Rate WPAN: A standard that focuses on low data rate and long battery life.



- Task Group 5 – Mesh Networking: A standard that defines a recommended practice for mesh topologies of WPANs.
- Task Group 6 – BAN: This group focuses on technologies for Body Area Networks (BANs). Its goal is the definition of an ultra-low power and short range wireless communication standard.
- Task Group 7 – VLC: This group's goal is the definition of a standard for Visible Light Communications (VLC)

Bluetooth has also been developed and revised beyond the version standardized by IEEE in 802.15.1, and a new, ultra-low power technology has been integrated in the standard, named Bluetooth low energy.

The most recent and promising proposal comes from the 6lowpan group of the IETF initiative. 6lowpan is an acronym of Ipv6 over Low power Wireless Personal Area Networks and the scope of the 6lowpan group's efforts focus on the efficient transmission of IPv6 PDUs (Protocol Data Units) over 802.15.4 links and the reduction of the IP overhead.

Bluetooth / IEEE 802.15.1

Bluetooth is an open WPAN standard, created by telecoms vendor Ericsson and later formalized by the Bluetooth Special Interest Group (SIG). It was initially developed as a wireless alternative to RS232 data cable and has grown to be the most widely used form of WPAN, especially for connection of master devices with their peripherals. Bluetooth's radio technology is based on frequency-hopping spread spectrum on the unlicensed ISM 2.4GHz short-range band. The original specification uses Gaussian frequency-shift keying (GFSK) modulation, to achieve a gross data rate of 1 Mbit/s. Later versions, using different modulations, have boosted this to 2 and 3 Mbit/s. In order to standardize the way Bluetooth devices communicate with each other, interface specifications are used, called Bluetooth profiles. A Bluetooth device must be compatible with one or more Bluetooth profiles, in order to use services or expose its own to other devices. Profiles exist for a wide variety of services, like audio transfer, printing, faxing, dial up networking; file transfer, LAN access, serial port emulation and Personal Area Networking. Among its major versions, Bluetooth v4.0 better satisfies the needs of CHIRON, since this version adds Bluetooth low energy (previously known as Wibree), focused on ultra low power applications, to the Bluetooth technologies.

Bluetooth is generally characterized as a low power, short-range communications standard, and devices are classified into 3 power classes, according to their output power:

Power Class	Maximum output power (Pmax)	Nominal output power	Minimum output power (Pmin)	Power control	Range (approximate)
1	100mW (20 dBm)	N/A	1mW (0 dBm)	Pmin<+4 dBm to Pmax Optional: Pmin to Pmax	~100 meters
2	2.5mW (4 dBm)	1mW (0 dBm)	0.25mW (-6 dBm)	Optional: Pmin to Pmax	~10 meters
3	1mW (0 dBm)	N/A	N/A	Optional: Pmin to Pmax	~1 meter

Bluetooth low energy

Bluetooth low energy is a technology aimed at low power applications for wireless devices. Nokia began development on it, seeking to create a lower power standard with minimum deviation from Bluetooth. The new standard was further developed within EU FP6 project MIMOSA, and was released in October 2006 with brand name Wibree. Subsequently the Bluetooth SIG agreed to include it in the Bluetooth v4.0, under the name Bluetooth low energy technology. A major goal of the specification was the ability to use the technology in devices powered by a single coin cell battery, which translates to a peak current consumption of 15mA. The protocols have also been modified to increase battery life. It supports small packet sizes, ranging from 8 to 27 octets, transmitted at 1Mbit/s. Also, the time needed for connection setup and a small data transfer is less than 3ms, down from 100ms, needed when using the classic Bluetooth stack. This makes it practical to use one-time connections in situations where a connection has to remain established. Star topology is used and the 7 slave limit of classic Bluetooth is lifted (the limit is now implementation-dependant)

IEEE 802.15.3 – High-Rate WPAN

This IEEE Standard focuses on providing a specification for WPANs that can accommodate large transfers, such as video and digital still imaging, without sacrificing requirements for low complexity, low cost and low power consumption.

IEEE 802.15.4

The IEEE Standard 802.15.4 specifies the PHY and MAC layers for low rate WPANs. The emphasis of this standard is networks of low-cost, low-speed, low-power, high node count networks, with little or no infrastructure. The basic node conception assumes 10 meter range, though a lot of flexibility is offered, in order to allow adaptation to a wider range of applications. Depending on the application requirements, an IEEE 802.15.4 LR-WPAN may operate in either of two topologies: the star topology or the peer-to-peer topology.

The radio defined in the standard operates in ISM bands and uses Direct Sequence Spread Spectrum (DSSS) techniques, providing a data rate of 250kbit/s. Additional PHYs were defined in 802.15.4a; one operating in UWB, offering high precision ranging capabilities, and one using Chirp Spread Spectrum (CSS) over 2.45GHz, offering enhanced immunity to multipath fading and extended range for robust performance with very low transmit power. Medium Access Control is based on CSMA/CA techniques, but if it is needed by the application, the PAN Coordinator can employ a guaranteed time slot (GTS) mechanism, providing guaranteed and uncontested bandwidth for a node.

ZigBee:

ZigBee is a proprietary specification for higher level protocols intended to be used on top of 802.15.4 devices. Its focus is, as is in IEEE 802.15.4, low-cost, low-power, ubiquitous wireless communication. The network layer is in charge of organizing and providing routing over a multi-hop network. With respect to IEEE 802.15.4, ZigBee network layer supports more complex network topologies like tree and mesh. The routing algorithm used for route discovery in ZigBee is the well-known reactive Ad hoc On Demand Distance Vector (AODV). When a node needs a route to a certain destination, it broadcasts a route request (RREQ) message through the network to the destination. When the packet reaches the destination, it replies to the originator with a route replay (RREP) message along the path followed by the route request.

ZigBee also provides a security mechanism, based on 128bit keys and the AES cipher, and key distribution in a secure network is handled by a designated node, termed trust center.



LOW RATE UWB OF IEEE 802.15.4a

IEEE 802.15.4a is a standard for UWB. When UWB band (3.1-10.6GHz) is used, IEEE 802.15.4a has the smallest emission power density and power consumption among the other technologies such as Bluetooth and Zigbee. The UWB is a narrow pulse transmission system whose spectrum is spread across a wide range of frequencies. The UWB is a different solution compared to the carrier based communication. The lack of carrier also implies that the frequency band is not divided into a number of channels. Instead a number of pseudo-random sequences in the time domain replace what is normally referred to us as a channel. UWB is suitable for vital signs monitoring systems. The monitoring of human vitals and movements requires a relatively low data rate which means in the case of UWB very small transmitting power requirements and longer battery life. . In addition it is able to transmit at higher data rate which is suitable for real time continuous monitoring of many physiological signals.

IEEE 802.15.6 – BAN

IEEE 802.15.6 is a newly formed task group which focuses on the development of a standard for Body Area Networks. Nodes of this type of network can be either located on, around, or inside a person's body. Currently, there is a number of bands that could potentially be used for the standard, such as the MedRadio/MICS, ISM, WMTS, and UWB bands. Network topology will probably be star or mesh based, with mechanism for self organizing and healing, in order to increase robustness in case of link loss.

There is a number of challenges and issues that need to be tackled in this upcoming standard, such as the ultra low power requirements, small form factor and minimization of health hazard, while maintaining network robustness and quality of service.

2.1 FREQUENCY BANDS IN THE AREA OF WPANs / WBANs

WPANs support limited range wireless connectivity. Short range WPAN technologies can be exploited in medical scenarios for the connection of patient's wearable or implantable sensors with a bedside monitor or a PDA. Therefore, frequency bands for the CHIRON system become an important issue. Communication bands that have been used so far in WBAN's applications and are candidates for CHIRON use are :

- Medical Device Radiocommunications Service
- Wireless Medical Telemetry Services (WMTS)
- Ultra WideBand (UWB)
- ISM

ISM, WMTS, UWB or MedRadio can be exploited to support on-body communications. However, low-power BAN devices would suffer from severe performance degradation in the presence of high-power technologies in crowded ISM bands, thus making them less appealing for high fidelity medical applications. WMTS bands are also heavily used, and their use is restricted to healthcare facilities in the United States. A common problem for WMTS and MICS is that bandwidth of a single channel is usually narrow. That limits high data rate applications. Exploiting UWB for wearable applications brings forward the issue of coexistence with high-data-rate

multimedia applications. A summary of the major advantages and disadvantages of the aforementioned technologies is presented in Table 1.

Frequency (MHz)	Acronym	Advantage	Drawback
401~406	MedRadio (MICS)	Worldwide availability, good propagation characteristics, quiet channel, medical only	Secondary usage, body worn applications not allowed in 402-405MHz (MICS) core band, large antenna size, limited bandwidth, stringent rules
433.05~434.79	General Telemetry	Good Propagation Characteristics	EU/AU/NZ/SA only, crowded spectrum, large antenna, limited bandwidth
608~614, 1395~1400, 1427~1432	WMTS	Good propagation characteristics, medical only	Licensed secondary use limited to healthcare providers inside healthcare facilities in US, limited spectrum, heavily used
902~928	ISM	Good propagation characteristics	US/Canada only, crowded spectrum
2400~2483,5 (2400-2500)	ISM	Worldwide availability, small antenna, large bandwidth	Crowded spectrum, many standards and technologies
5725~5850	ISM	Worldwide availability, small antenna, large bandwidth	Existing standards and technologies, severe attenuation
4200~4800 7250~8500	UWB	Worldwide availability, short range, low power, huge bandwidth	Coexistence with high data rate multimedia applications, severe attenuation

Table 1. Properties of potential frequency bands.

2.2 INTERNET INVASION DOWN TO DEVICES (6lowpan)

6lowpan could contribute in the interconnection of the wearable or implantable sensors with monitoring or logging systems within ehealth applications. This solution could provide all the appropriate interoperability and flexibility, since the IP-enabled device of the user will be able to communicate with other network devices and transfer the sensitive medical data with the appropriate security and privacy. The development of IPv6 protocol, which is the successor of Ipv4 paved the way towards this direction. Ipv4 uses 32-bit addresses whilst Ipv6 uses 128-bit addresses extending the address space from 232 to 2128.

A challenging issue, that could emerge in CHIRON, could be the interconnection of wearable wireless sensor devices with the Internet. For example, 802.15.4's capabilities are more limited than other WPANs and WLANs (Bluetooth and Wi-Fi, respectively) as they have small frame sizes, low bandwidth, and low transmit power. Additionally, the microcontrollers typically coupled with low-power WPAN radios have limited memory and computing power. Due to these resource constraints and LoWPANs' multihop nature, supporting IPv6 over LoWPAN networks presents several challenges. IPv6 datagrams aren't a natural fit for LoWPANs, while low throughput, limited buffering, and frames (that are one-tenth the size of the IPv6 minimum transfer unit (MTU)) requirement, make datagram fragmentation and compression a necessity for

efficient operation. 6LoWPAN introduces an adaptation layer between the IP stack's link and network layers to enable efficient transmission of IPv6 datagrams over 802.15.4 links, as shown in the following figure

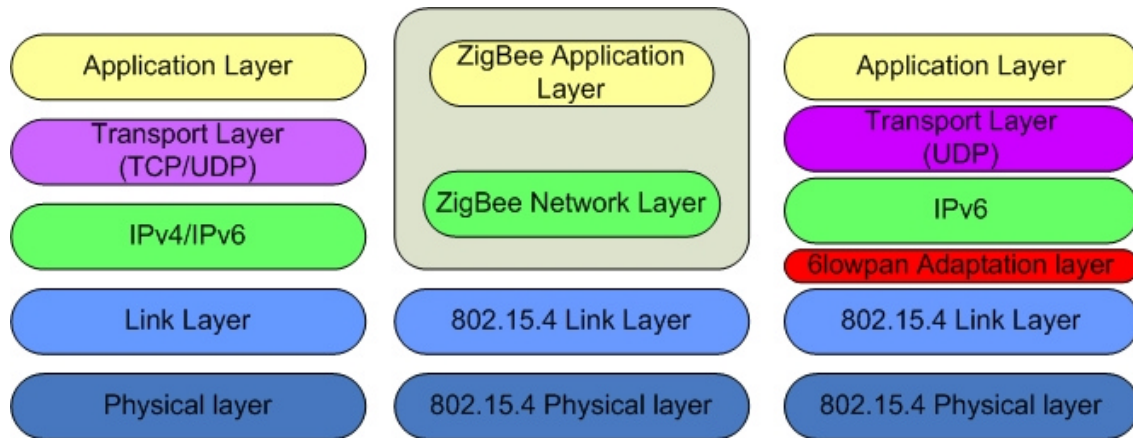


Figure 1. TCP/IP, ZigBee and 6lowpan stack.

2.3 COMMUNICATION MEDIA AND APPLICATION INTERFACES

Medical Data transmission is governed both by common communication and networking standards as well as commercially adopted medical data protocols. On the other hand industrial design approaches stimulated by system interoperability needs are being used.

Regarding communication media any TCP/IP compatible communication networks are employed with networking transports ranging from PSTN (phone networking), wireless (Bluetooth and Wi-Fi) to fixed Ethernet connection whereby relevant standards are applicable.

Regarding application interfaces the commonly adopted approach is to deploy device independent software based on Java API and HTTP application interfacing both on the user terminal and the back-office servers. Furthermore REST and WSDL WEB services are commonly used to provide access to back-office services in a flexible way for client software developers.

Within the medical domain of imaging systems the interoperability between machines of different vendors is dominated by two major protocols: DICOM (<http://medical.nema.org/>), while exchange of medical information between systems and devices is made using HL7 (<http://www.hl7.org/>).

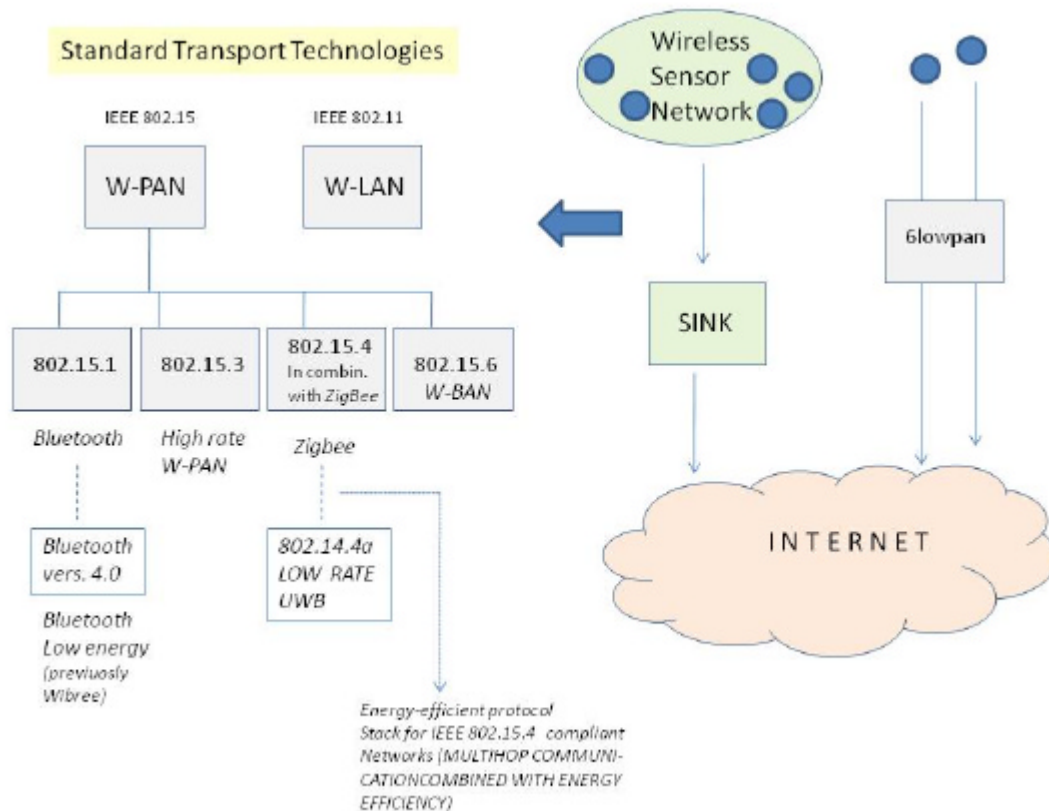


Fig.2 – W-PAN and Standards

3. Standards and Technologies in integration architecture

In this chapter we introduce standards, technologies and protocols involved in integration architectures.

They reach different levels of relevance and cover all different areas of an integration solution.

Those areas are generally divided in 4 categories:

- Transportation services
- Information description
- Service description
- Service list

Transportation services have the goal to move messages between applications. Common protocols are HTTP, SMTP, FTP, XMPP and BEEP. HyperText Transfer Protocol or HTTP is still the most used protocol; HTTP is a level 7 ISO/OSI protocol and is a standard of the World Wide Web Consortium. It was originally designed as a simple stateless Client/Server protocol with unencrypted information; messages sent through HTTP, if intercepted, can be read. HTTPS was designed to solve this security problem of HTTP, and could be used in any communication between applications where privacy is required.



A general integration between services has the essential need to move data; data interchange is generally reached using XML and JSON.

HL7 version 2.x (HL7 v2.x) application protocol for electronic data exchange is the industry standard for transporting clinical and administrative information between heterogeneous healthcare applications at present. The standard is based on the concept of application-to-application message exchange. HL7 version 3 (HL7 v3), like HL7 v2.x, is a standard for exchanging messages among information systems that implement healthcare applications. As a main difference to HL7 v2.x, HL7 v3 adopts an Object Oriented (OO) approach using Unified Modeling Language (UML) principles which is based on a data model called the Reference Information Model (RIM). HL7 v3 messages are XML documents that can be validated against XML schemas derived from the conceptual models. Unfortunately as it stands right now, there is an interoperability problem between HL7 v2.x and HL7 v3 messages because there is no well-defined mapping between these messages. All applications within CHIRON will exchange clinical data using HL7-V3 (XML) messages. Only in the case that some data will come from external sources already coded in HL7-v2.x messages specific interfaces will be implemented.

Extensible Markup Language or XML is the common **open standard for data**. It was designed by W3C as a collection of rules for a full description of an electronic document characterized by simple or complex data structures. Its extensible structure has made XML spread through a wide range of applications, and has generated a family of standards based on it. Examples of Markup language derived from XML are:

- Extensible Stylesheet Language for Transformation or XSLT, used to transform a specific XML document to a new output document that could be of the same XML family, like XHTML or WML, or converted to a completely different document format.
- Extensible Stylesheet Language for Formatting Objects or XSL-FO, used to apply a specific view style to an XML document.
- Extensible Markup Language Path or XPath, used to reach a given node of an XML document by using specific expressions able to locate elements and attributes of XML documents.
- Extensible Markup Language Schema Definition or XSD is a way to define structures, contents and semantics of XML documents. XSD specifies elements and attributes allowed inside XML and the hierarchical relationships between elements to be followed.

JSON represents today an alternative to XML to describe data. JSON is the acronym of Javascript Object Notation and is a lightweight data interchange format defined by RFC 4627. Data is represented through a simple key/value map format. JSON is typically used to send and receive data in javascript solutions.

The **Service Description** category describes all the information that applications must know about a specific service exposed to use it. Nowadays, the common standard of this categories is WSDL, a XML based language that supply a description model for specific services called Web Services. WSDL is able to describe the public interface of a web service, and how to interact with it. A WSDL documents contains:

- the operations offered by the specified service;
- the communication protocol to be used to talk to the service ;
- the data format given in input and returned by the service as output;
- the endpoint of a service, usually the URI to connect to the Web Service.

The **Service list** category represents a way to quickly list and detect services. The well known standard of this category is Universal Description Discovery and Integration or UDDI, that consists of an index, and of an ordered database based on XML. UDDI was originally designed to receive queries by SOAP messages and answer through WSDL documents with the features of the specified Service.

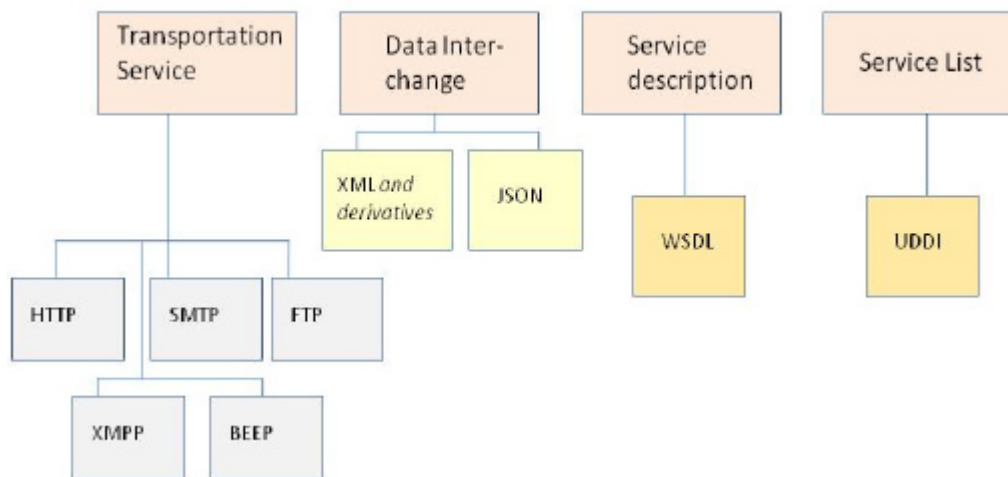


Figure 3 – Integration architectures and standards

4. Electronic Health Record

There is currently a major challenge for the healthcare industry in achieving interoperability among applications provided by different vendors. Each hospital department or medical clinic may use multiple applications to share clinical and administrative information among applications. These applications could be legacy applications or state-of-the-art applications. Unfortunately, each application may support multiple communications interfaces that must be continually modified and maintained. Achieving interoperability among heterogeneous healthcare information systems is very important because it will reduce costs associated with healthcare and will contribute to more effective and efficient patient treatment, management, and care

4.1 Personal Health Record, an overall view

The Patient Health Records (PHR) is defined by the ISO/TR 20514:2005 standard as a repository of information regarding the health of a subject of care, which exists in computer-understandable form, stored and transmitted securely, and accessible by multiple authorized users².

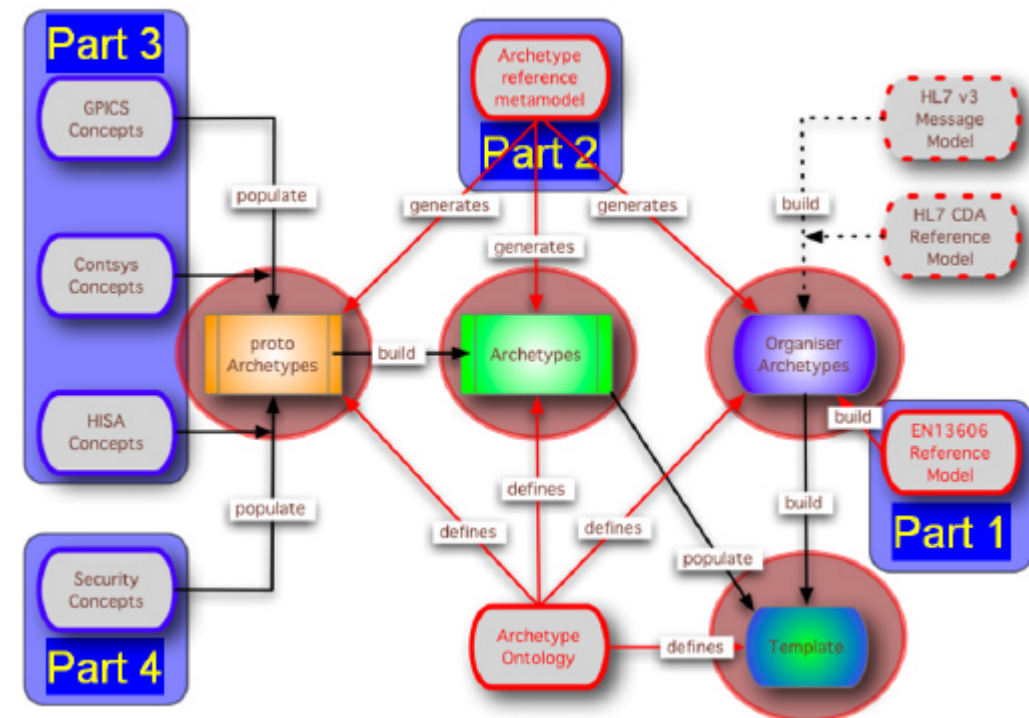
² ISO/TR 20514:2005 (Health informatics -- Electronic health record -- Definition, scope and context)

Structured electronic health documentation is a necessary requirement for modern information systems in health care and the use of PHR is becoming widely spread in healthcare today. PHR primary purpose is the support of efficient, high-quality integrated health care, independent of the place and time of health care delivery. Bringing up-to-date knowledge into PHRs for decision support is a critical step to foster evidence based care. PHRs are not only used to support daily care but also used to support important secondary uses, e.g. clinical research, quality assurance and education. They provide intelligent decision-support tools and information-processing techniques and produce improved reliability, accuracy and effectiveness of health care.

An interoperable PHR framework can facilitate the sharing of information and knowledge between not only human users but also participating software systems. To achieve these objectives, the semantic interoperability between information systems of different health care providers is a key issue.

Although considered advantageous compared to paper-based records, PHRs still have a long way to go in realizing their full potential as an integral part of a safe, effective and efficient health care system.

Making PHRs interoperable is a prerequisite to support increasingly distributed and diverse healthcare.



The infrastructure implementation for exchanging PHRs will need to address some challenges such as:

- **Setting the PHR standard:** In order to provide interoperability of the PHRs, a standard interface such as the HL7 Clinical Document Architecture (CDA)³ needs to be adopted. However, there are many different ways of organizing the same clinical information even when

³ Clinical Document Architecture, Release. Available from <http://www.hl7.org/v3ballot/html/infrastructure/cda/cda.htm>



the same PHR standard is used: the same content can be expressed through different components and the components can be aggregated differently⁴.

- **Developing mechanisms to verify the coded elements that appear in the PHRs:** Coded elements are used in EHRs to precisely express the medical terms and concepts independent of the words used to describe them.

Insufficient standardization in medical terminology represents one of the prevailing problems in processing any kind of medical-related data.

Various classification systems, nomenclatures, thesauri and ontologies have been developed to solve this problem, but the process is complicated by the existence of more than one hundred incompatible systems. The most extensive current project that supports conversions between major international classification systems and records relations among terms in heterogeneous sources is the Unified Medical Language System (UMLS).

UMLS is a compendium of many controlled vocabularies in the biomedical sciences. Some examples of the incorporated controlled vocabularies are ICD-10, LOINC, SNOMED CT, MeSH.

- ICD (International Statistical Classification of Diseases and Related Health Problems) provides codes to classify diseases and a wide variety of signs, symptoms, abnormal findings, complaints, social circumstances and external causes of injury or disease⁵.
- The scope of LOINC (Logical Observation Identifiers Names and Codes) effort includes laboratory and other clinical observations⁶.
- The Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) is a clinical healthcare Terminology with comprehensive, scientifically-validated content, used for electronic health records; it includes cross-maps to other international standards⁷.
- Medical Subject Headings (MeSH) consists of sets of terms naming descriptors in a hierarchical structure that permits searching at various levels of specificity⁸.

Moreover, UMLS provides a semantic network to supply a consistent categorization of all concepts represented in the UMLS meta-thesaurus and to offer a set of useful relationships between these concepts. All information about specific concepts is found in the meta-thesaurus; the network provides information about the set of basic semantic types, or categories, which may be assigned to these concepts, and it defines the set of relationships that may hold between the semantic types. The current release of the semantic network contains 135 semantic types and 54 relationships. The semantic network serves as an authority for the

⁴ PHRs are organized into document components such as sections, entries and data elements. Indeed, the prominent PHR standards like HL7 CDA and CEN 13606-1⁴ define the structure of the clinical documents from basic document components like “Sections” and “Entries” in HL7 CDA or “Compositions”, “Sections” and “Entries” in 13606-1 and aggregate these basic components as needed. In particular, CDA (Clinical Document Architecture) is an architecture that defines structure and semantics of medical documents for the purpose of exchange. CDA documents are encoded in Extensible Markup Language (XML). They derive their meaning from the HL7 Reference Information Model (RIM) and use the HL7 Version 3 Data Types, which are part of the HL7 RIM.

⁵ World Health Organization (<http://www.who.int/classifications/icd/en/>)

⁶ Regenstrief Institute, Inc. (<http://www.regenstrief.org/loinc/>)

⁷ International Health Terminology Standards Development Organisation (IHTSDO) (<http://www.ihtsdo.org/snomed-ct/>)

⁸ http://www.nlm.nih.gov/mesh/2010/mesh_browser/MBrowser.html

semantic types that are assigned to concepts in the meta-thesaurus. The network defines these types, both with textual descriptions and by means of the information inherent in its hierarchies.

The semantic types are the nodes in the Network and the relationships between them are the links. There are major groupings of semantic types for organisms, anatomical structures, biologic function, chemicals, events, physical objects, and concepts or ideas. The current scope of the UMLS semantic types is quite broad, allowing for the semantic categorization of a wide range of terminology in multiple domains⁹.

- **Determining the patient identification mechanisms:** Patient identifiers are currently used to locate the EHRs of a patient. Yet each healthcare organization may (and typically will) have a different patient identifier domain. To be able to share the PHRs, the different patient identifiers need to be mapped to one another. In these cases a higher identification authority will be involved for merging processes. Since demographic and identification information in Europe are officially managed by civil authorities, specific agreement with these authorities is foreseen for system implementation.
- **Developing the healthcare professional identification mechanisms:** The healthcare professional identity is also an indispensable part of the EHRs because of the medico-legal requirement that a healthcare professional has to assume responsibility for a clinical document. This mechanism should be stronger than plain user name password credentials. Like in the previous point a specific agreement is foreseen with local authorities of the testing sites. They are responsible for healthcare professional registry maintenance and in some cases they could share a strong identification mechanism already tested for other purposes.
- **Developing mechanisms to provide the security and privacy of the PHR:** PHRs contain highly sensitive data and therefore the security and privacy of the patients must be preserved.
- **Deciding on the transport protocols:** A PHR is a document and constitutes a message payload. In other words document instances need to be carried over the network using transport protocols and HL7 Version 3 provides three transport specifications¹⁰ - ebXML, Web Services and Minimal Lower Layer Protocol (MLLP) - for the exchange of HL7 based content, messages and documents. In CHIRON implementation, HL7 Web Services Profile¹¹ will be used as the communication infrastructure.

In the following figure a schematic representation of these standards is summarized.

⁹ The SemanticHEALTH project, is a Specific Support Action funded by the European Union 6th R&D Framework Programme (FP6). In essence the SemanticHEALTH goal is to work towards and support collaboration among human actors and stakeholders, rather than only interoperability among computers. The project developed a longer-term research and deployment roadmap for semantic interoperability. Its vision is to identify key steps towards realizing semantic interoperability across the whole health value system, thereby focusing on the needs of patient care, biomedical and clinical research as well as of public health through the re-use of primary health data.

This research distinguishes several levels of interoperability:

Level 1: Technical and syntactical interoperability (no semantic interoperability)

Level 2: Partial semantic interoperability: unidirectional semantic interoperability or bidirectional semantic interoperability of meaningful fragments

Level 3: Full semantic interoperability, sharable context, seamless co-operability

(see the SemanticHEALTH project report

http://ec.europa.eu/information_society/activities/health/docs/publications/2009/2009semantichealth-report.pdf)

¹⁰ HL7 version 3 standard: Transport specification - web services profile, release 2. Available from:
<http://www.hl7.org/v3ballot/html/infrastructure/transport/transport-wsprofiles.htm>

¹¹ Web Services Security User name Token Profile 1.1, OASIS Standard Specification, 1 February 2006. Available from: <http://www.oasisopen.org/committees/download.php/16782/wss-v1.1-spec-os-UsernameTokenProfile.pdf>

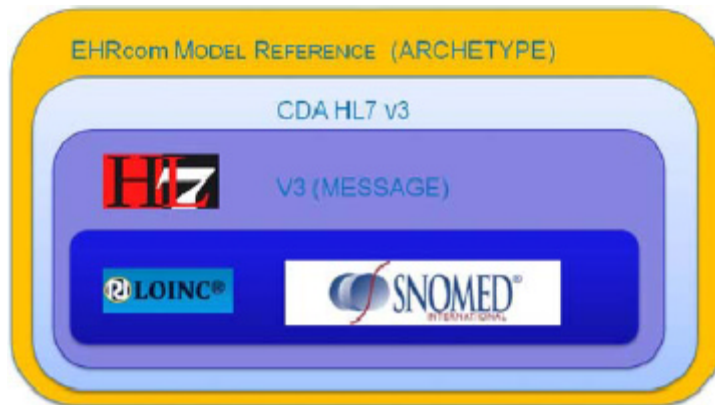
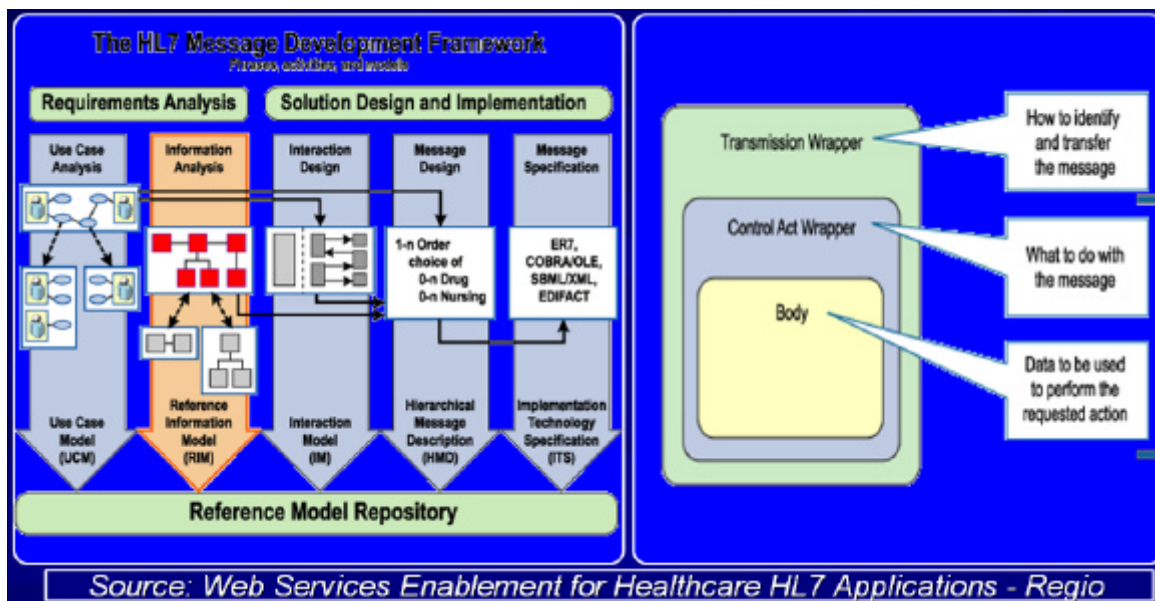


Figure 4 – Schematic representation of PHR standards

The scheme above clarifies that the general model of ISO13606 (also called EHRcom) will be used as an external level, as an overall framework (archetype). Within this archetype each section can be modeled with the HL7-CDA prototypes that will contains some specific HL7-V3 messages. These messages, in order to be understandable will use standard vocabularies to correctly maintain and transfer specific values.

HL7’s RIM is a “static model of healthcare information representing the aspects of the healthcare domain undertaken so far by HL7 standards development activities”. The HL7 v3 standard development process defines rules used to implement and derive domain-specific information models from the RIM, finally generating XML schema definitions (XSD) associated with a particular message type. The HL7 RIM standard “provides a substantial level of message functionality between applications by structuring envelopes which support message exchange between applications. HL7 message envelopes are called wrappers, initially modeled by defining classes and relationships in the RIM. These specifications are then used to create the XML schema for the message wrappers, following a process outlined in the HL7 Message Development Framework.

HL7 RIM:



Source: Web Services Enablement for Healthcare HL7 Applications - Regio



Beyond the state-of-the art

Currently, medical records are kept by health agencies (Health Maintenance Organizations (HMO) Database), with patients having limited access to their records. Also, if patients want to keep a record of their own medical data, such as their blood pressure over time, they would have to build their own system. CHIRON intends to propose a fully integrated system for personal PHRs and an European PHR platform, for automatic the recording of health status, analysis and comparison of data patients with the same disease, treatment, adverse effects, at an European level or as well as being accessible via an online secured PHRs platform for the benefit of the patient and enhanced medical knowledge.

In this model, patient management will comprise the following benefits:

- Extend health care into the patient home
- Monitoring and early warning using multi bio-sensor data collection
- Schedule reminders for medicine taking
- Integrate and analyse risk groups
- Remote consultation: e-mail, chat, video conferencing
- Assistance with daily health and monitoring tasks
- Emergency response

An integrated health system has to include automatic and manual tools to upload medical, social, and lifestyle information and to download info from the HMO databases and from other sources external to the system.

We need to implement communication interface with PHR systems maintained by the each patient's HMO, which will further implement secured protocols for medical information exchange. The system will support standards such as HIPPA, EDI, CONTSYS (EN 13940), HISA (EN 12967), in order to support multiple access methods used by different HMOs. An integrated use of several standards has to be used to support these data interchange above all with external systems.

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- [5] Peter Schloeffel, Thomas Beale, George Hayworth, Sam Heard, Heather Leslie (Ocean Informatics Pty Ltd, Sydney, Australia), “The relationship between CEN 13606, HL7, and openEHR”



4.2 Electronic Health Record - Standards

The EHR of a patient is represented as a digitally stored healthcare information record about an individual's lifetime with the purpose of supporting continuity of care, education and research, and ensuring confidentiality at all times. A number of standardization efforts are in place to provide the interoperability of EHRs such as CEN/TC EHRcom, openEHR, and HL7 Clinical Document Architecture (CDA). Standards such as CEN/TC 251 EHRcom, openEHR, and CDA aim to structure and markup the clinical content for the purpose of patient data exchange. There is also an industry initiative called Integrating the Healthcare Enterprise (IHE) which specifies the Cross-Enterprise Document Sharing (XDS) integration profile for this purpose. As previously discussed with HL7 messaging, considerable clinical information about a patient is passed around through the messages exchanged among healthcare applications. So what are the differences between the patient data contained in an HL7 message compared with the patient data contained in an EHR? The differentiation is evident because an EHR is the collection of relevant data about an individual's lifetime usually in a document structure.

4.2.1 From CEN ENV 13696 to ISO 13606 through EN13606

1997 – Pre-standard ENV 12265

The CEN ENV 12265 1997 defines the basic architectural components of an EHR and their logical inter-relationships. The architecture is defined to enable clinicians to make their own decisions about what to record and in what format to record it. It supports a common understanding of the necessary variety of the content and format of records. The pre-standard was built on extensive experience developed in a number of projects funded under the Advanced Informatics in Medicine Programme of the EU, in particular the Good European Health Record (GEHR) project. GEHR developed a comprehensive multi-media data architecture for using and sharing electronic healthcare records, with a strong focus on meeting the clinical, technical, educational and ethico-legal requirements [W. Grimson 1998].

2000 – Pre-standard ENV 13606

In 2000, CEN TC/251 developed the CEN Prestandard ENV 13606:2000 Electronic Healthcare Record Communication [CEN ENV 13606 2000] which is a message-based standard for the exchange of electronic healthcare records. The standard defines an Electronic Health Record (EHR) information model as an extension of the earlier prestandard ENV 12265 [CEN ENV 12265 1997] [M.Eichelberg 2005].

CEN ENV 13606 defines a list of machine-readable domain terms that can be used to structure EHR content, a method for specifying distribution rules, that is, rules under which certain EHR content may be shared with other systems. Finally, “request and response messages” that allow systems to exchange subsets of an EHR. ENV 13606 do not attempt to specify a complete EHR system; it focuses instead on the interfaces relevant for a communication among EHR systems. ENV 13606 was intended to be the first fully-implementable EHR standard, and was partially implemented in a number of EHR projects in the UK, Denmark, the Netherlands, Sweden, and Norway. However, none of these projects used the complete ENV 13606 specification, and implementation experience showed a number of weaknesses in the standard that limited its usefulness and market uptake. The single-level modeling approach made the information model extremely complex with many optional clauses and a level of abstraction that made the model quite difficult to comprehend and implement.

2001-2004 - Standard EN 13606

In 2001, CEN/TC 251 decided to revise ENV 13606 into a full European Standard, EN 13606, taking into account the existing implementation experience and to adopt the openEHR archetype methodology (already defined by HL7.org). [M. Eichelberg 2005]. The overall goal of EN 13606 is to define a rigorous and durable information architecture to represent the EHR, in order to support the interoperability of systems and components that need to interact with EHR services.

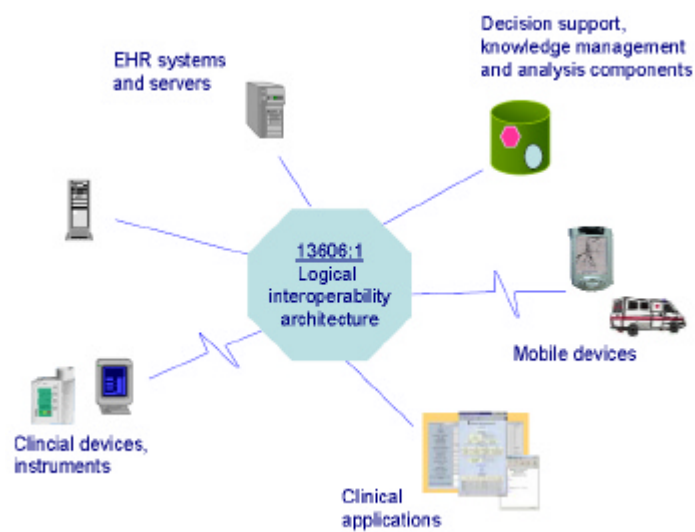
The CEN/ISO EN13606 is a European norm from the European Committee for Standardization (CEN) also approved as an international ISO standard. It is designed to achieve semantic interoperability in the electronic health record communication.

EN13606 defines the logical models and interfaces required to support the generic communication of EHR data and archetypes between heterogeneous EHR systems. It adopts many of its constructs in a simplified form that are perhaps better suited to the more simple architectures within most contemporary EHR systems.

The goals of the EN13606 norm are (see the EN13606 introduction):

"The overall goal of this 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:

- *preserving the original clinical meaning intended by the author,*
- *reflecting the confidentiality of that data as intended by the author and patient."*



The main architectural features for EHR components are:

- to act as discrete systems or as middleware components;
- to access, transfer, add or modify health record entries;
- to operate via electronic messages or distributed objects;
- to preserve the original clinical meaning intended by the author;
- to reflect the confidentiality of that data as intended by the author and patient.



In enfacing this challenge, the goal has been to specify the information architecture required for communications interoperability between systems and services that might request or provide EHR data. This standard is neither intended to specify the internal architecture or database design of such systems, no to prescribe the kinds of clinical applications that might request or contribute EHR data in particular settings, domains or specialist fields. For this reason, the information model might be used to define a message, an XML document or schema, or an object interface as described in CEN/TC 251/N04-012 published on Health Informatics in 2004.

The EHRcom reference model consists of four packages, Extract, Demographics, Access Control, and Message, which together describe any aspect of an EHR that are relevant for communication of EHR extracts among information systems.

1. The Extract package defines the root class of the reference model (EHR EXTRACT) and the data structures for EHR content.
2. The Demographics package provides a minimal data set to define the various subjects, software agents, devices and organizations that are referenced within the EHR extract. These data structures are based on the General Purpose Information Components (GPICs) defined in CEN prEN 14822-1 [2003].
3. The Access Control package defines a representation for EHR access policies (such as consents for disclosure).
4. The Message package defines the attributes required to communicate the EHR extract to a requesting process via a message or other serialized form.

This part of the EHRcom standard also include an Health Level 7 (HL7) Domain Message Information Model (D-MIM) corresponding to the EHRcom reference model, that is, to allow HL7 version 3 messages to be used for communication of EHR extracts. The structure of these messages will be described in the rest of this paragraph.

The EHRcom was finished in 2004 and became a full de jure standard in the 25 countries of the European Union at that time [HL7org].

The EHRcom was the base for the standard ISO 13606, which is divided into five parts.

2004 – ISO Technical Specification TS 18308:2004

In 2004 the ISO Technical Committee on Health Informatics, ISO/TC 215, developed the ISO Technical Specification TS 18308:2004 Health Informatics, Requirements for an Electronic Health Record Architecture [ISO/TS 18308], which is not a complete EHR architecture but only provided individual building blocks. This specification only lists requirements for an electronic health record architecture but does not specify the architecture itself. Therefore, the primary target group are developers of EHR architecture standards like CEN EN 13606 and other reference architectures such as openEHR. In fact, the first known compliance test against the ISO TS 18308 requirements has been done for the openEHR reference model. [M.Eichelberg 2005].

ISO/TS 18308 specifies the requirements for data and record structures, clinical documentation and communication processes, medico-legal, ethical and EHR systems evolution. ISO/TS 18308 is the result of a merger between Australian open standards developers and a team from University College, London, together with some convergence involving European EHR standards and HL7.

The Australian government first endorsed HL7 as its nominated health-care messaging standard in 1997.



2008-2010 The evolution of ISO 13606

- **Part 1: Reference Model**

comprehensive, generic model for communicating part or all of an EHR between heterogeneous systems

ISO 13606-1:2008 specifies the communication of part or all of the electronic health record (EHR) of a single identified subject of care among 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. ISO 13606-1:2008 is predominantly used to support the direct care given to identifiable individuals, or to support population monitoring systems such as disease registries and public health surveillance. Use of health records for other purposes such as teaching, clinical audit, administration and reporting, service management, research and epidemiology, which often require to be made anonym or to be aggregated, are not the focus of ISO 13606-1:2008 but such secondary uses might also find this document useful.

- **Part 2: Archetype Specification**

constraint-based approach for defining clinical “business objects” that are built from the Reference Model - adopted from *openEHR*

ISO 13606-2:2008 specifies the information architecture required for interoperable communications among systems and services that need or provide EHR data. ISO 13606-2:2008 is not intended to specify the internal architecture or database design of such systems. The subject of the record (i.e. record extract) to be communicated is an individual person, and the scope of the communication is predominantly with respect to that person's care. ISO 13606-2:2008 defines an archetype model to be used to represent archetypes when communicated between repositories, and between archetype services. It defines an optional serialized representation, which may be used as an exchange format for communicating individual archetypes. Such communication might, for example, be between archetype libraries or between an archetype service and an EHR persistence or validation service.

- **Part 3: Reference Archetypes and Term Lists**

an initial set of inter-reference model conversion archetypes, mapping to *openEHR* and to the HL version 3 RIM Act classes. Vocabularies for the Part 1 model

ISO 13606-3:2009 defines term lists that each specify the set of values that particular attributes of the Reference Model defined in ISO 13606-1 may take. It also defines informative Reference Archetypes that correspond to ENTRY-level compound data structures within the Reference Models of *openEHR* and HL7 Version 3, to enable those instances to be represented within a consistent structure when communicated using ISO 13606-3:2009.



- **Part 4: Security**
measures and models to share the access control, consent and auditability of EHR communications

ISO/TS 13606-4:2009 describes a methodology for specifying the privileges necessary to access EHR data. This methodology forms part of the overall EHR communications architecture defined in ISO 13606 1. ISO/TS 13606-4:2009 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.

- **Part 5: Interface specification**
message and service interfaces to enable EHR and archetype communications.

ISO 13606-5:2010 defines a set of interfaces to request and provide:

- an EHR_EXTRACT for a given subject of care as defined in ISO 13606-1;
- one or more ARCHETYPE(s) as defined in ISO 13606-2;
- an EHR_AUDIT_LOG_EXTRACT for a given subject of care as defined in ISO/TS 13606-4.

ISO 13606-5:2010 defines the set of interactions for requesting each of these artefacts, and for providing the data to the requesting party or declining the request. An interface to query an EHR or populations of EHRs, for example for clinical audit or research, is beyond its scope, although provision is made for certain selection criteria to be specified when requesting an EHR_EXTRACT which might also serve for population queries. ISO 13606-5:2010 defines the Computational Viewpoint for each interface, without specifying or restricting particular engineering approaches to implementing these as messages or as service interfaces. ISO 13606-5:2010 effectively defines the payload to be communicated at each interface. It does not specify the particular information that different transport protocols will additionally require, nor the security or authentication procedures that might be agreed between the communicating parties or required by different jurisdictions.

4.2.2 Two level modelling with archetypes and openEHR (NEN13606)

OpenEHR (www.openEHR) describes a two-level modelling methodology **Errore. L'origine riferimento non è stata trovata.** and two sets of specifications - an information part and a knowledge part. The first one defines a stable reference model that describes the EHR as a container that holds compositions (documents) which in turn may have entries (observations, evaluations, instructions, etc.). Although the selection of entries is based on a certain model of decision making in healthcare, the model itself does not attempt to represent clinical knowledge. It comes from a variety of sources - terminologies, ontologies, classifications, measurement systems, etc. - and the application of computable knowledge representation to the information model is how data acquires its context-specific meaning. The full computable data models of clinical concepts are called archetypes: blood pressure is an archetype, so is a synoptic report, pathology lab result, etc.

The archetype is meant to represent all the clinical knowledge regarding a certain concept. However, in order to make a practical use of archetype libraries we combine them in semantic templates, which, for example, may specify that we need the systolic and diastolic blood pressure,

and the arterial, or the pulse, neither are we interested in discussing whether the patient was sitting, standing, etc.

In different circumstances, e.g. in sports medicine we may want to have a baseline reading and then repeat it every 5,10mins. Archetypes allow for different constraints in different templates, so long as we use the same basic clinical models. Once we've selected the template we can further enhance the semantics by querying available terminologies (SNOMED, ICD) and producing bindings to the terminology subsets that should be used with particular archetypes/templates. If our understanding of medicine is enriched, we can produce a new version of the archetypes, or in order to dig deeper, we can specialise them and so on.

The beauty of the openEHR approach which formed the basis of an international standard (CEN/ISO 13606) is that it produces fully computable EHRs that serve as the platform for application development. Semantic interoperability, which simply means that data captured by one application should be reusable by any other application without transformation, is based on archetype libraries freely available in the public domain. Archetypes are produced by clinicians who are the data modelers using a freely available Archetype Editor. ADL, the archetype definition language, is part of the international standard and every single bit of the openEHR specifications is available from the openEHR foundation.

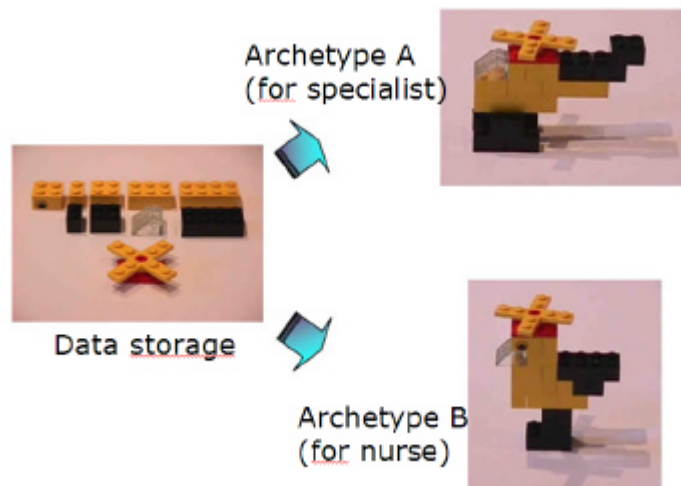
The set of openEHR archetypes need to be quality managed to conform to a number of axioms such as being mutually exclusive. The archetypes can be managed independently from software implementations and infrastructure, in the hands of clinician groups to ensure they meet the real needs on the ground. Archetypes are designed to allow the specification of clinical knowledge to evolve and develop over time. Challenges in implementation of information designs expressed in openEHR centre on the extent to which actual system constraints are in harmony with the information design.

In the field of Electronic health records there are a number of existing information models **Errore. L'origine riferimento non è stata trovata.** with overlaps in their scope which are difficult to manage, such as between HL7 V3 and SNOMED CT. The openEHR approach faces harmonisation challenges unless used in isolation.

While individual health records may be vastly different in content, the core information in openEHR data instances always complies to archetypes. The way this works is by creating archetypes which express clinical information in a way that is highly reusable, even universal in some cases.

To get to the point where information is suitably presented for clinical care it always involves a number of archetypes. These combinations of archetypes are called 'templates'; aggregations of archetypes which may also be refined for use in a particular situation. Templates may be used to specify forms, documents or even messages.

Archetypes are like the designs for Lego structures, which come printed on paper in a Lego box. Each Lego



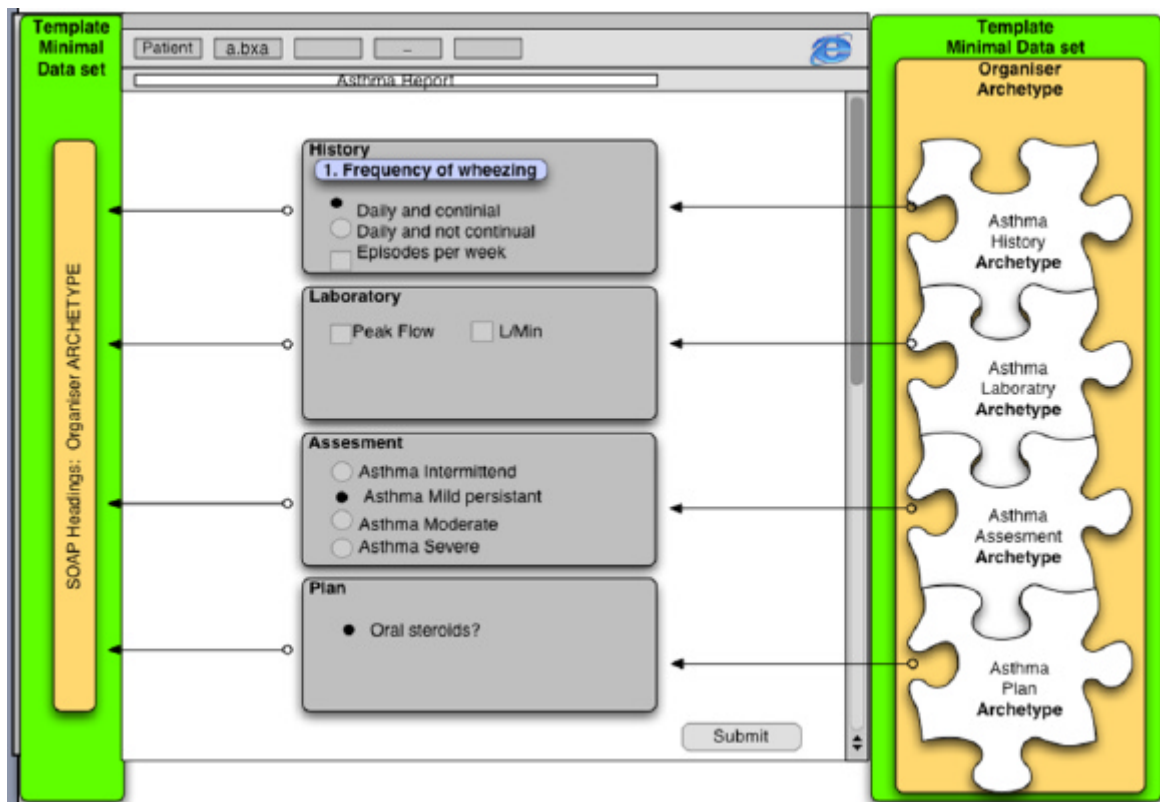
design expresses a meaningful structure, such as a house, a tractor or a dog. The designs constrain the use of the Lego pieces to a meaningful structure space, which although vast, is not nearly as vast as the total possible structure space, i.e. all possible (but mostly meaningless) combinations of Lego bricks.

In the picture the same data is shown differently to the different professional.

In the data warehouse a lot of data (lego bricks) are stored totally unstructured. The use of Archetypes will make this data semantic interoperable. So the Archetype will add medical data to the image, and will present this data in a different format to each health care professional.

In the same way, EHR Archetypes constrain the use of GOM objects to valid, agreed upon structures, such as for “blood pressure” or “audiology results”. And in the same way that Lego bricks were standardised and manufactured prior to the development of many (or any) designs, the GOM can be standardised independently of its archetypes. Conversely, the development of both Lego designs and EHR Archetypes may continue forever, while still using the same basic building blocks. Old blocks can be used for new archetypes; new blocks can be used with old archetypes.

A general overview of Archetypes:



4.2.3 Communication between EHRs

In order to have two different EHR's to communicate there are several standards developed. Notice that these standards has no influence on semantic interoperability and the (re-) use of data, it is purely to transport data from A to B.



- **ASTM CCR** - Continuity of Care Record - a patient health summary standard based upon XML, the CCR can be created, read and interpreted by various EHR or Electronic Medical Record (EMR) systems, allowing easy interoperability between otherwise disparate entities.
- **ANSI X12 (EDI)** - Used for transmitting virtually any aspect of patient data. Has become popular in the United States for transmitting billing information.
- **HL7** – XML messages are used for interchange between hospital and physician record systems and between EMR systems and practice management systems; HL7 Clinical Document Architecture (CDA) documents are used to communicate documents such as physician notes and other material.

4.2.4 The work within HL7

Founded in 1987, HL7 (Health Level Seven) [HL7] is a non-profit, ANSI accredited Standards Developing Organization that provides standards for the exchange, management, and integration of data that supports clinical patient care and the management, delivery, and evaluation of healthcare services [M.Eichelberg 2005]. It develops specifications mainly for application-level messaging among health information systems, but also in other areas such as clinical documents and decision support [openEHR foundation]. The HL7 standard is developed with the assumption that an event in the healthcare world, called the trigger event, causes the exchange of messages between a pair of applications. When an event occurs in an HL7-compliant system, an HL7 message is prepared by collecting the necessary data from the underlying application systems and it is passed to the requestor, usually as an EDI (Electronic Data Interchange) message. For example, a trigger event, occurs when a patient is admitted to a facility, and this may cause the data about the patient to be collected and sent to a number of other application systems.

Currently, there are two message protocols supported by HL7, Version 2 and Version 3, the first parts of which were approved in 2004 by the American National Standards Institute [ANSI 2004] while the second one became normative edition in 2009.

HL7 Version 2 Messaging Standard is currently the most widely implemented standard for healthcare information in the world; but the feature of being HL7 Version 2-compliant does not imply direct interoperability among healthcare systems. This stems from the fact that Version 2 messages have no precisely defined underlying information model; the definitions for many data fields are rather vague, and there are a multitude of optional data fields. This vagueness and optional features provides great flexibility but make compulsory detailed bilateral agreements among the healthcare systems to achieve interoperability.

To avoid this problem, HL7.org developed Version 3 [HL7-V3] which is based on an object-oriented data model called Reference Information Model (RIM) [HL7 RIM] [M.Eichelberg 2005]. Message content schemas are derived by a restriction process which starts from the Reference Information Model (RIM), and ends with schemas in XML [openEHR foundation]. Up to the Version 2.5 [HL7 2.5 2000], the scope of the HL7 standard was limited to the exchange of messages among medical information systems. Starting with Version 3.0, a document markup standard, called the Clinical Document Architecture (CDA), has been proposed [M.Eichelberg 2005]. The Clinical Document Architecture is a relatively generic model for the communication of clinical documents, very close to the ideas expressed into the "Composition" class of CEN 13606 and into openEHR methodology. It was originally intended as a standardized way of communicating clinical notes, but the CDA user community tend to use it more as a persistence specification. It is regarded by some as the HL7 equivalent of a record architecture, although it does not address significant requirements in this area, such as distributed version control, flexible EHR Extract structures, archetypes, or querying. CDA release 2.0 defines the structural organization of fine-grained information inside a document [openEHR foundation]. The HL7 Clinical Document Architecture (CDA) is not an EHR standard since it only defines parts of an EHR architecture. However, the CDA forms an important component of an EHR and is



harmonized with the equivalent structures in EN 13606 and openEHR. CDA is a subset of the EN 13606 Reference Model, and EN 13606 is compliant with CDA Release Two [M.Eichelberg 2005].

HL7 Clinical Document Architecture (CDA) Release 2 (R2) is a document markup standard, encoded in markup languages as XML or RDF, that specifies the structure and semantics of a clinical document for the purpose of exchange. CDA documents can be exchanged in HL7 messages or exchanged using other transport solutions and can exist independently outside the transferring message. HL7 CDA R2 provides an object model in order to represent a technical diagram of the CDA specification and structure. The basic structure of CDA Release 2 is formed by two parts fully RIM derived: a *header* and a *body*.

The *header* purpose is to set the context for the document as a whole, to enable clinical document exchange across and within institutions, to facilitate clinical document management and to facilitate compilation of an individual patient's clinical documents into a lifetime electronic patient record. The *header* identifies and classifies the document and provides information on authentication, the encounter, the patient, the involved providers. It also allows to manage less common scenarios as when several CDA header participants are played by the same person (e.g., where a physician sees a patient as a consultant, dictates a note, and later signs it, the physician is participating as author and legal authenticator) and related documents (e.g., document that has been replaced or appended by the current CDA document or is the source document that was transformed into the current CDA document).

The other part, the *body*, contains the clinical report and it can be either an unstructured blob or can be comprised of structured markup. In the second case, the *body* is divided up into recursively nestable document *sections*. Each *section* contains a single "*narrative block*", any number of CDA *entries* (derived from classes in the RIM) and external references (such as some other image, some other procedure, or some other clinical document). The "*narrative block*" represents content to be rendered, expressed in human language. CDA *entries* and external references encode content are presented in the "*narrative block*" and so represent structured content provided for other computers. Every *section* can contain a clinical statement which is one of the following: an *observation*, a *substance administration*, a *supply*, a *procedure*. Each clinical statement in turn can relate to another one with a semantic relationship (e.g., cause, component, reason). In detail: the *substance administration* is used for representing medication-related events such as medication history and medication administration orders. In conclusion and the *supply* is used to represent the provision of a material by one entity to another (e.g., to indicate a pharmacy request to dispense a certain quantity of pills or a certain number of refills), and coupled with a *substance administration* can be used to represent a medical prescription.

The CDA structure allows a representation of the concept of "context": contextual components (participants, confidentiality status, language) can be set in the header, then these propagate to the *body*, to the *sections*, and to nested *entries*, unless overridden. If a particular section specifies a different value for authorship, confidentiality, or language, it overrides the value propagated from the header, and the new value propagates to nested components.

Data types used in CDA define the structural format of the data carried within an RIM class's attribute, and influence the set of allowable values an attribute may assume. Several CDA components are designed to carry concepts drawn from HL7-defined or HL7-recognized coding systems such as LOINC or SNOMED CT. Value sets for these components specify allowable codes, and each value set is assigned a coding strength. When the only allowable values for the CDA component are those in the stated value set, "*Coded, No Extensions*" (CNE) is applied. As alternative, when values outside the stated value set can be used if necessary, "*Coded, With Extensions*" (CWE) is applied.

For more information, you have to register with your national HL7 organization in order to be allowed to consult HL7 cd-rom.



5. Medical imaging

Digital Imaging and Communications in Medicine (DICOM) is a standard for handling, storing, printing, and transmitting information in medical imaging. It includes a file format definition and a network communications protocol. The communication protocol is an application protocol that uses TCP/IP to communicate between systems.

DICOM enables the integration of scanners, servers, workstations, printers, and network hardware from multiple manufacturers into a picture archiving and communication system (PACS).

DICOM is known as NEMA standard PS3, and as ISO standard 12052.

Appendix 1: Overview of applicable standards relevant for CHIRON

Type	Standard	Description
Connectivity	IEEE 802 series standards	IEEE 802-11 (WLAN), IEEE 802.15 (WPAN) (including the IEEE 802.15.1 (Bluetooth) version and the 802.15.4 possibly in combination with ZigBee built on top of it)
	IEEE 11073 (or IEEE 1073)	Related to medical and personal health device communications. The IEEE 11073 has been the vehicle by which the global work on point-of-care medical device communication has been harmonised by merging CEN and IEEE work.
Exchange of medical data	Health Level 7 HL7 v.3 and HL7 v.2.x (http://www.hl7.org)	HL7 is a non-profit, ANSI accredited Standards developing organization, founded in 1987 that provides standards for the exchange, management and integration of data to support patient clinical care and the management, delivery and evaluation of healthcare services. Although HL7 started as a message exchange standard, it is no longer only a point-to-point messaging standard. In particular the Clinical Document Architecture (CDA) is designed to support standards for storing and retrieving persistent information such as Medical Records. Other documents issued by HL7 are: HL7 Security Service Framework, Functional Profiles for Personal and Medical Health Records. Although an application layer standard (thus the 7 in its name from the number of the application layer in the ISO OSI reference model), HL7 also produces infrastructure (transport) specifications for its messages, by building upon a selection of IT standards such as ebXML. (see also section 4.2.4)
	ASTM CCR (Continuity of Care Record)	A patient health summary standard based upon XML, the CCR can be created, read and interpreted by various EHR or Electronic Medical Record (EMR) systems, allowing easy interoperability between otherwise disparate entities.
	ANSI X12 (EDI)	Used for transmitting virtually any aspect of patient data. Has become popular in the United States for transmitting billing information.
	DICOM (www.medical.nema.org)	Standard for transfer ring diagnostic medical images and information between medical devices (see also Appendix 2)

Type	Standard	Description
EHR Architecture	ISO 18308	Defining requirements for an Electronic Health Record (EHR) Reference Architecture
	ENV 12265	Electronic Healthcare Record Architecture
	CEN/ISO EN13606	It is designed to achieve semantic interoperability in the electronic health record communication. (see also section 4.2)
	ISO/DTR 20514	Provides the Definition, Scope and Context of the Electronic Health Record (EHR)
Health Informatics	EN 14822:2005	General purpose information components: <ul style="list-style-type: none"> • Part 2: Non clinical • Part 3: Clinical
	ISO/IEC 15414:2002	Information technology: <ul style="list-style-type: none"> • Open distributed processing • Reference model • Enterprise language
	EN 12264:2005	Categorial structures for systems of concepts
	EN 12381:2005	Time standards for health care specific problems
Terminology Standards	ISO/IEC 1087-1:2000	Terminology and Vocabulary: <ul style="list-style-type: none"> • Part 1: Theory and application
	ISO 10241:1992	International Preparation and layout Terminology Standard
	ISO 704:2000	Terminology work: principles and methods
	ICD-10	International Classification of Diseases http://www.who.int/classifications/icd/en/
Procedures, Regulations and Policies	ICPC-2	The International Classification of Primary Care http://www.ulb.ac.be/esp/wicc/table-en.html , http://www.fmrc.org.au/icpc2/
	SNOMED CT	A standard to represent clinical concepts or language http://www.snomed.org/
	WK4363 ASTM	Continuity of Care Record (CCR) Standard http://continuityofcarerecord.org/x6169.xml
	ebXML	Electronic Business using eXtensible Markup Language http://www.ebxml.org/



Type	Standard	Description
	XDS	Cross-Enterprise Document Sharing http://www.itl.nist.gov/div897/docs/XDS.html , http://www.nist.gov/ehealth/
	EN 13940-1 CEN TC 251	System of Concepts to support continuity of care: http://www.sanitaelettronica.cnr.it/c4bioit/documenti_c4bioit/N06-065_prEN13940-1_2006E_Final.pdf The activity of the CEN/TC251/PT5-021 Project Team is addressing the standardisation of the representation of digitised biomedical signals, measurements, events and alarms;

Appendix 2 - Standardization Bodies and their initiatives

Standardization Body / Organization	Description
	<p>Existing standards ensure compliance on the physical layer between two devices but it does not ensure interoperability as there are many different ways to transmit the same information over a physical layer interface. On the patient-end side, the problem of device interoperability has to be solved also on upper-layers by developing application profiles which define what capabilities of the transport technology have to be used to best support the application requirements. Moreover, application level standardized data models and formats have to be developed. While a significant amount of problems on the lower layers has been solved already and mature standards are available, more work at levels closer to the application is needed. Finally – concerning the backend part of the system – the data need to be translated into the HL7 (Health Level 7) standard, which is usually employed by medical records repositories. Here the CHIRON project will promote the extension of existing standards (the x73 standards family) for personalised / non-clinical applications. In fact the x73 standards for point-of-care medical device communication are mainly designed for acute monitoring and treatment applications in the hospital domain. Important modifications are needed: for example, for the wireless devices used in personal healthcare in the home domain, the need of low power consumption translates into a minimization of the transmit power and the reduction of the transmission time through the reduction of protocol overhead.</p>
Bluetooth SIG	Medical Devices Working Group established in May 2006
CEN Technical Committee TC 251 for Health Informatics	Health information standards in the support of care in its widest sense (educational, preventative, diagnostic, therapeutic and palliative)
Clinical Data Interchange Standards Consortium (CDISC) www.cdisc.org	<p>Development of global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare.</p> <p>Acquisition, exchange, submission and archive of clinical research data and metadata</p>
<p>Continua Health Alliance (www.continuaalliance.org)</p> <p>Continua Version 1 Guidelines (2009)</p>	<p>An organization of more than 150 members (product manufacturers, healthcare providers, research organizations).</p> <p>Continua adopts a Use case driven process and its goal is not to create new standards but to identify the best in class existing standards that satisfy the Use Case requirements.</p> <p>The version 1 of its Guidelines includes:</p> <ul style="list-style-type: none"> - The Bluetooth Health Device Profile (HDP), - Specifications for the Bluetooth SIG for wireless connectivity, - The USB Personal Health Device Specification for wired device connectivity, - Personal Health Device Specifications from ISO / IEEE for



Standardization Body / Organization	Description
	<p>protocol and data definitions,</p> <ul style="list-style-type: none"> - Guidelines for integration with standards-based electronic health records (EHRs) which combine the CDA-based Personal Health Monitoring (PHM) Specification from HL7 and the XDR Specification from IHE. <p>The version 2 will be published in 2011.</p>
<p>DICOM WG24 and DICOM Part 14</p>	<p>The goals of DICOM are to achieve compatibility and to improve workflow efficiency between imaging systems and other information systems in healthcare IT worldwide; more specifically to create and maintain international standards for communication of bio-medical diagnostic and therapeutic information in disciplines that use digital images and associated data.</p> <p>DICOM WG 24 is defining standards for surgical planning and virtual patient models.</p> <p>The DICOM Part 14 is related to “Grayscale Standard Display Function” and the Chiron Consortium will propose an extension of this standard to take into account the characteristics of high dynamic range displays developed in the WP5 of the CHIRON Project.</p>
<p>Project “eHealth-INTEROP”</p>	<p>It is addressing the requirements of the European Commission mandate (M/403) to the European Standards Organizations (ESOs) (i.e. CEN, CENELEC, ETSI) on standardization in the field of e-health.</p> <p>The mandate aims to provide “a consistent set of standards to address the needs of this rapidly-evolving field for the benefit of future healthcare provision”.</p> <p>The final report M403 Phase 1 has been submitted to the EC for formal approval in February 2009. The Project Team is now working in preparation of the Phase 2; starting with real use cases from real national and regional projects the initiative aims at avoiding new standards development (unless there is nothing appropriate available) and at making existing standards work in today’s practice. Among the recommended use cases one is specifically relevant for CHIRON and is related to “ubiquitous care outside conventional care facilities, involving the interoperability necessary for mobile and/or home-based monitoring devices”.</p> <p>Four actions were defined for the Phase 2 of the project:</p> <ul style="list-style-type: none"> • Fill the gaps in provision (i.e. enable development of integrated safety / security and privacy strategy, enable development of integrated infrastructure for care outside conventional care facilities); • Facilitate semantic interoperability; • Resolve inconsistencies (or at least facilitate co-existence between Base Standards based on fundamentally different principles (e.g. Electronic Records exchange formats using either CEN 13606 or



Standardization Body / Organization	Description
	<p>HL7 RIM based documents);</p> <ul style="list-style-type: none"> • Increase European impact in international standardization (e.g. coordination with IEEE for acute and home care devices communications, with standards organizations for classification (semantic level) and terminology (WHO and IHTSDO).
epSOS – European Patient Smart Open Sources	<p>Project supported by the European Commission. 12 Member States (Austria, Czech Republic, Denmark, France, Germany, Greece, Italy, The Netherlands, Slovakia, Spain, Sweden, UK) are participating to the project having as objective to foster interoperability of the national e-Health systems (i.e. to allow the access to the medical data of the patients quickly and accurately from all the medical European institutions wherever the patient is when he needs to be assisted by the health service).</p> <p>The main goal of the EC funded project epSOS is to develop a practical eHEALTH framework and an Information & Communication Technology (ICT) infrastructure to enable secure access to patient health information, particularly with respect to basic patient summaries and ePrescriptions between different European healthcare systems.</p>
EPC Global Industry Group	Development of the Electronic Product Code Gen. 2 standard for RFID systems
ETSI	<p>Technical Report TR 102 764 on “eHealth architecture - User service models and application classification into service models”</p> <p>The models address interoperable solutions for healthcare data collection, transmission, storage and interchange with the required security, privacy and reliability.</p>
ICTSB (www.icts.org)	<p>ICTSB is an initiative of the ESOs to coordinate specification activities in the field of ICT.</p> <p>Among the topics addressed , ICTSB is dealing with Design for All and Assistive Technologies, Smart House standards and Network & Information Security.</p> <p>Recently they established the web site on “eHealth and standardization” (www.icts.org/eHealth_standardization.htm)</p>
IEEE	New Personal Health Data (PHD) working group established
<p>IHE (Integrating the Healthcare Enterprise) (www.IHE.net)</p> <p>IHE Technical Frameworks</p>	<p>IHE is not developing standards but integrates existing Base Standards to enable fulfillment of identified tasks. Its process starts with the precise definition of healthcare tasks, the specification of standards-based communication between systems required to support these tasks and the testing of systems to determine that they conform to the specifications.</p> <p>IHE is an initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information.</p>



Standardization Body / Organization	Description
	IHE promotes the coordinated use of established Base Standards such as ISO, DICOM, HL7, IETF, OASIS, W3C, etc.
IHTSDO (International Health Terminology Standards Development Organization)	Based in Denmark, it develops, maintains, promotes and enables the uptake and correct use of its terminology products in health systems, services and products around the world. The focus is on enabling the implementation of semantically accurate health records that are interoperable.
W3C (World Wide Web Consortium) www.w3.org	Semantic Web Health Care and Life Sciences Interest Group (HCLS) www.w3.org/2001/sw/hcls/ W3C is an International Consortium devoted to develop web standards. The HCLS group intends to exploit the benefit of the adoption of Semantic Web technologies in healthcare as a way to get interoperability of information from many domains and processes for efficient decision support.
WHO (World Health Organization)	Creation of a Global Health Information Standards Repository: WHO plans to build an international health information objects repository and to coordinate health information standards implementation aspects on a web-based platform,
ZigBee Application Framework	The Zig-Bee Alliance aims to develop a new application profile in the area of health monitoring to enable plug-and-play interoperability of wireless ZigBee-enabled medical sensors and devices. A Personal / Home Health Care study group was established.

Appendix 3 Temporal evolution of the Medical Information standards.

As a summary a synoptic table is added in order to compare the temporal evolution of different standards in different countries.

Date	Event	Note
1987	HL7 is founded	It is a nonprofit organization recognised by ANSI (Accredited Standards Developing Organization) that provides standards for the exchange, management and integration of data that supports clinical patient care and the management, delivery and evaluation of healthcare services.
1995	CEN ENV 12265 Electronic Healthcare Record Architecture	It is a foundation standard defining the basic principles upon which electronic healthcare record should be based.
2000	CEN ENV 13606 Electronic Health Record Communication	It is a message-based standard for the exchange of electronic healthcare record. It is focused on the interfaces relevant for a communication among EHR system.
2001	EN 13606 becomes EHRcom	CEN/TC 251 decides to revise ENV 13606 into a full European standard, adopting the openEHR archetype methodology.
2003	CEN prEN 14822-1	It defines the General Purpose Information Components (GPICs). It provides a data structure for the "Demographics" package of EHRcom.
2004	EHRcom is finished	The complete 5 part EHRcom is finished and becomes a full de jure standard in the 25 countries of the European Union at that time.
	ANSI approved HL7 v2	HL7 v2 is a messaging standard but does not apply direct interoperability among healthcare system.
	ISO/TS 18308 Requirements for an Electronic Health	It specifies the requirements for data and record structures, clinical documentation and communication processes, medico-legal, ethical and EHR system evolution.



Date	Event	Note
	Record Architecture	
2005	ANSI approved HL7 v2.5 HL7 v3 is proposed	
2008	ISO 13606-1:2008	It specifies the communication of part or all of the electronic health record (EHR) of a single identified subject of care among EHR systems, or between EHR systems and a centralized EHR data repository.
	ISO 13606-2:2008	It specifies the information architecture required for communication interoperability among systems and services that need or provide EHR data.
2009	ISO 13606-3:2009	It 2009 defines term lists that each specify the set of values that particular attributes of the Reference Model defined in ISO 13606-1 may take.
	ISO 13606-4:2009	It describes a methodology for specifying the privileges necessary to access EHR data.
	HL7 becomes Normative Edition	
2010	ISO 13606-5:2010	It specifies the information architecture required for communication interoperability among systems and services that need or provide EHR data.



Appendix 4 - Current Electronic Health Record implementations

A. United States

In the United States, the Department of Veterans Affairs (VA) has the largest enterprise-wide health information system that includes an electronic medical record, known as the Veterans Health Information Systems and Technology Architecture (VistA). A key component in VistA is their VistA imaging System which provides a comprehensive multimedia data from many specialties, including cardiology, radiology and orthopedics. A graphical user interface known as the Computerized Patient Record System (CPRS) allows health care providers to review and update a patient's electronic medical record at any of the VA's over 1,000 healthcare facilities. CPRS includes the ability to place orders, including medications, special procedures, X-rays, patient care nursing orders, diets, and laboratory tests.

The 2003 National Defense Authorization Act (NDAA) ensured that the VA and Department of Defense (DoD) would work together to establish a bidirectional exchange of reference quality medical images. Initially, demonstrations were only worked in El Paso, Texas, but capabilities have been expanded to six different locations of VA and DoD facilities. These facilities include VA polytrauma centers in Tampa and Richmond, Denver, North Chicago, Biloxi, and the National Capitol Area medical facilities. Radiological images such as CT scans, MRIs, and x-rays are being shared using the BHIE. Goals of the VA and DoD in the near future are to use several image sharing solutions (VistA Imaging and DoD Picture Archiving & Communications System (PACS) solutions).^[2]

Clinical Data Repository/Health Data Repository (CDHR) is a program that allows for sharing of patient records, especially allergy and pharmaceutical information, between the Department of Veteran Affairs (VA) and the Department of Defense (DoD) in the United States. The program shares data by translating the various vocabularies of the information being transmitted, allowing all of the VA facilities to access and interpret the patient records.^[3] The Laboratory Data Sharing and Interoperability (LDSI) application is a new program being implemented to allow sharing at certain sites between the VA and DoD of "chemistry and hematology laboratory tests." Unlike the CHDR, the LDSI is currently limited in its scope.^[4]

One attribute for the start of implementing EHRs in the States is the development of the Nationwide Health Information Network which is a work in progress and still being developed. This started with the North Carolina Healthcare Information and Communication Alliance founded in 1994 and who received funding from Department of Health and Human Services.^[5]

The Department of Veterans Affairs works with Kaiser Permanente to further develop software which allows sharing information with private health care providers.^[6] This software called 'CONNECT' uses Nationwide Health Information Network standards and governance to make sure that health information exchanges are compatible with other exchanges being set up throughout the country. CONNECT is an open source software solution that supports electronic health information exchange.^[7] The CONNECT initiative is a Federal Health Architecture project that was conceived in 2007 and initially built by 20 various federal agencies and now comprises more than 500 organizations including federal agencies, states, healthcare providers, insurers, and health IT vendors.^[7]



A. United Kingdom

As of 2005, the National Health Service (NHS) in the United Kingdom also began an EHR system. The goal of the NHS is to have 60,000,000 patients with a centralized electronic health record by 2010. The plan provides general practitioners in England access to the National Program for IT (NPFIT).^[8] However, the plan has been greatly delayed and frequently criticized.^{[9][10][11]}

England is the first European country that broadly adapted the NEN13606. England's NHS has developed the Connecting for Health concept which is fully based on the use of this model. See <http://www.connectingforhealth.nhs.uk/> **Errore. L'origine riferimento non è stata trovata.**, the NHS Archetypes are open for re-use. In the Netherlands these Archetypes are translated at <http://www.detailedclinicalmodels.nl/> **Errore. L'origine riferimento non è stata trovata.**

B. Australia

Australia is dedicated to the development of a lifetime electronic health record for all its citizens. HealthConnect is the major national EHR initiative in Australia, and is made up of territory, state, and federal governments. MediConnect is a related program that provides an electronic medication record to keep track of patient prescriptions and provide stakeholders with drug alerts to avoid errors in prescribing.^[12]

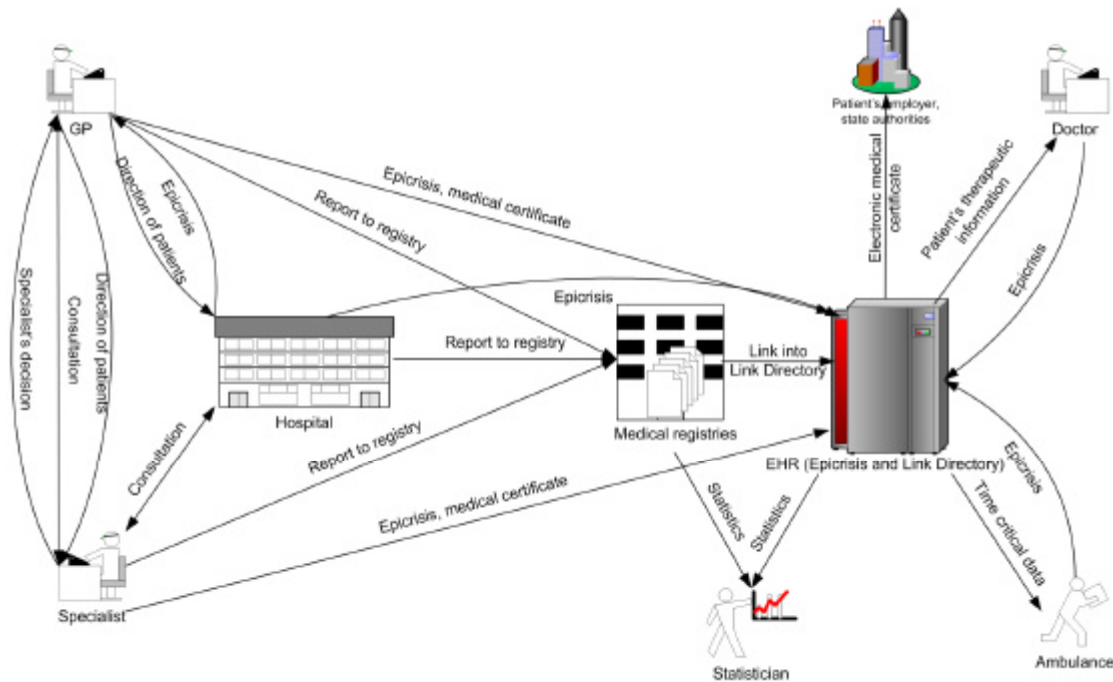
C. Canada

The Canadian province of Alberta started a large-scale operational EHR system project in 2005 called Alberta Netcare.

D. Estonia

Estonia is the first country in the world that has implemented a nationwide EHR system, giving full access of it to its citizens. Main purpose of the EHR System is to create a nation-wide integral network of interoperable eHealth services which make it possible to exchange all types of health data between doctors^[13]. Main features of Estonian's EHR are:

- The central database of HER includes two types of data:
 - 1) Patient's primary information (for example the contact information, allergies, important drug information etc).
 - 2) Link directory that points to other sources which include some medical data about the patient (for example IT systems of hospitals and GPs)
- EHR connects current IT systems of hospitals, GP's and other Health Service providers through interfaces, so there is no need to replace these IT systems.
- EHR gives to the doctors possibility to see patient's entire health information when they need it.
- EHR provides time critical information to ambulance (for example if patient has any allergies or if there are any drugs that are dangerous to the patient).
- GP can send patient's medical information through EHR system to the specialist who treats the patient. The patient doesn't have to carry any papers himself. GP can also choose the most appropriate specialist for the patient through EHR.
- EHR gives doctors possibility to receive consultation from colleagues as they can exchange patient's medical information through EHR system.
- Patient can receive medical certificates through EHR without having to deal with any papers. These certificates can also be sent to employers or state authorities through EHR system in electronic form.



Flow Chart of the Estonian EHR System

E. UAE

Abu Dhabi is leading the way in using national EHR data as a live longitudinal cohort in the assessment of risk of cardiovascular disease. [14]

F. Germany

In 2004 Germany started testing electronic health insurance cards which will eventually contain the patients' complete health history in digital format. The high-tech card is Germany's largest IT project.

But the introduction of electronic health cards in Germany has been stalled because doctors are refusing to buy the necessary equipment to read them.

Health insurance companies say that they are ready to roll-out the cards to their 80 million members but will not do so unless doctors and pharmacies install the equipment.

The aim of Germany's electronic health cards is to improve communications among all sectors of German healthcare providing better data exchange throughout the industry. The cards will initially be used to identify patients and improve the processing of health insurance claims.

Doctors, hospitals, pharmacies and service providers in the health system have a matching professional card allowing them to view the patients' data when given the patients' card.

However, the installation of equipment in practices to read the cards is not compulsory and has to be paid at least partly by doctors and institutions. Some are refusing to implement to systems.

The German health ministry has responded to the delay by saying that it is still confident that all patients will be using the electronic health cards by the end of the year as planned.



The new card will replace Germany's existing health insurance card, which only shows the name, date of birth and the insurance company of the holder. The new health card has a photograph of the user, as well as holding basic health information, such as prescription data. Once introduced the plan is to use the card for more clinical data in the future.

The data can be updated online and if the patient consents additional information, such as history of surgery, doctors' letters and information for emergencies can be added.

It also doubles up as a European Health Insurance Card, which replaced E111 form at the beginning of 2006 enabling holders to receive healthcare in other European countries^[15].

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APPENDIX 5 : Legislation on Data Protection

In order to remove the obstacles to the free movement of data without diminishing the protection of personal data, Directive 95/46/EC (the data protection Directive) was developed to harmonise national provisions in this field. As a result, the personal data of all citizens will have equivalent protection across the Union. The fifteen Member States of the EU were required to bring their national legislation in line with the provisions of the Directive by 24th October 1998.

The data protection Directive applies to 'any operation or set of operations which is performed upon personal data,' called 'processing' of data. Such operations include the collection of personal data, its storage, disclosure, etc. The Directive applies to data processed by automated means (e.g. a computer database of customers) and to data that are part of or intended to be part of non automated 'filing systems' in which they are accessible according to specific criteria. (For example, the traditional paper files, such as a card file with details of clients ordered according to the alphabetic order of the names).

The data protection Directive does not apply to data processed for purely personal reasons or household activities (e.g. an electronic personal diary or a file with details of family and friends). It also does not apply to areas such as public security, defence or criminal law enforcement, which are outside the competence of the EC and remain a national prerogative. National legislation generally provides protection for individuals in these areas.

In addition, there is a separate Directive, Directive 97/66/EC, that deals specifically with the protection of privacy in telecommunications. This Directive states that Member States must guarantee the confidentiality of communication through national regulations. This means that any unauthorised listening, tapping, storage or other kinds of interception of surveillance of communications is illegal. Where calling-line identification is offered, users must be given the possibility to not subscribe to this service or not having their identification revealed when making a telephone call. Conversely, subscribers to this service must have the possibility to reject incoming calls from individuals who have blocked their calling-line identification. Additionally, the Directive states that where printed or electronic telecommunication directories exist, individuals are entitled to omission from the list, in principle, at no cost.

State of the art - National Legislation on Data Protection

In the most European countries involved in the CHIRON Project the Legislation on Data Protection follows the European Directive 95/46/EC. Further more specifically the Working Group N.39 of EC is studying and defining the treatment of Electronic Health Record (EHR) as described in Working Document on the processing of personal data relating to health in electronic health records (EHR) adopted on 15 February 2007, where the Data Security is discussed.

Italy

The Italian Data Protection Authority (Garante per la protezione dei dati personali) is an independent authority set up to protect fundamental rights and freedoms in connection with the processing of personal data, and to ensure respect for individuals' dignity through the Data Protection Code 196/2003.



In particular the sensitive data is regulated by *Section 20 (Principles Applying to the Processing of Sensitive Data) of this Code*. Processing of sensitive data by public bodies shall only be allowed where it is expressly authorized by a law specifying the categories of data that may be processed and the categories of operation that may be performed as well as the substantial public interest pursued.

Referring to electronic processing data by *Section 34 (Processing by Electronic Means) of Protection Code*, the processing personal data by electronic means shall only be allowed if the minimum security measures referred to below are adopted:

- a. computerised authentication,
- b. implementation of authentication credentials management procedures,
- c. use of an authorisation system,
- d. regular update of the specifications concerning scope of the processing operations that may be performed by the individual entities in charge of managing and/or maintaining electronic means,
- e. protection of electronic means and data against unlawful data processing operations, unauthorised access and specific software,
- f. implementation of procedures for safekeeping backup copies and restoring data and system availability,
- g. keeping an up-to-date security policy document,
- h. implementation of encryption techniques or identification codes for specific processing operations performed by health care bodies in respect of data disclosing health and sex life.

Further the *Section 76 (Health Care Professionals and Public Health Care Bodies) of the Protection Code* is dedicated to the “PROCESSING OF PERSONAL DATA IN THE HEALTH CARE SECTOR”. Health professionals and public health care bodies may process personal data disclosing health, also within the framework of activities in the substantial public interest.

Recently, the Italian DPA dated 16 July 2009 promulgate the “Guidelines on Electronic Health Records and Health Files”, according to the rule established by the European Working Group N.39. The considerations made herein apply to the EHR and the HF insofar as they represent a set of medical data relating, as a rule, to a given individual and contained in several inter-linked electronic records that can be shared by various public and private health care bodies.

Greece

The Greek Authority for the Protection of Personal Data, known unofficially as Data Protection Authority (www.dpa.gr), is a constitutionally guaranteed independent administrative authority established by Greek Law 2472/1997 in order "to protect the individual from the processing of personal data", which incorporates into Greek law the European Directive 95/46/EC.

The Greek legislation on personal data privacy, particularly related to personal health data, reports:

Article 7 – Paragraphs 2d, 3e



The collection and processing of sensitive data is prohibited. Exceptionally, harvesting and processing of sensitive data, including the establishment and operation of relative files, is permitted after permission of the Authority, when:

- these data involve health content and data processing is executed by a person engaged in the profession by providing health services and is subject to a duty of confidentiality or related codes of conduct, provided that the processing is necessary for medical prevention, diagnosis, treatment or health management services, or
- the data processing is performed by a public authority and is necessary in order to protect public health.

Article 7A – Paragraph 1d

The processing controller is exempt from obtaining a special permission (denoted in previous paragraph) in case health data are processed and made by doctors or others that provide health services, where the controller is bound by confidentiality or otherwise confidential under law or code of ethics and data are transmitted or communicated to third parties. For the purposes of this provision, the courts and public authorities are not treated as third, where the transmission or communication requires law or judicial decision. Not covered by the exemption of this provision are legal persons or organizations providing health services such as clinics, hospitals, rehabilitation and detoxification, pension funds and insurance companies, and the controllers of personal data where processing is carried out under programs or telemedicine medical services through a network.

Belgium

In Belgium the processing of personal data is defined in the Belgian privacy law.

Scope of Belgian privacy law is the processing of personal data wholly or partly by automatic means, and to the processing otherwise than by automatic means of personal data which form part of a filing system or are intended to form part of a filing system;

Personal data are defined as any information relating to an identified or identifiable natural person. An identifiable person is one who can be identified directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity;

Processing is defined as any operation or set of operations which performed upon personal data, whether or not by automatic means, such as collection, recording, organization, storage, adaptation or alteration, erasure or destruction,...

Where the Privacy policy vs. security policy is defined as:

Privacy policy focuses on the content and the processing of personal data within the relationship between the health professional and his patient;

Security policy focuses on the technical and organisational measures within the relationship between the controller and the processor.



In particular the recommendations of the Privacy Commission established by the Belgian Federal House of Representatives with the Act of 8 December 1992 are resumed in:
<http://www.privacycommission.be/publicaties/referenciemaatregelen%20vs%2001.pdf>

In particular the Belgium legislation reports:

Art. 16 DPA, general structure:

- Security obligation
- Security obligation: in general
- Security obligation: specific
- Processor / Contract between the controller and the processor
- Confidentiality obligation

Recommendations of the Belgian privacy commission for each processing of personal data, 10 action domains:

1. The drafting of a security policy;
2. The appointing of a security consultant;
3. The description of the responsibilities and the management process of the security of personal data (and the integration of all this within the general organisation structure and activity);
4. Measures with regard to the physical protection of personal data;
5. The security of the networks;
6. The importance of access control;
7. Logging, detection and analysis of the access (records);
8. The supervision, inspection, control and maintenance (with regard to technical and organisational security measures);
9. The management of security incidents and continuity;
10. The keeping of a complete, centralized documentation.

Other recommendations:

- Recommendation (97) 5 of the Committee of Ministers to Member States on the protection of Medical Data, 13 February 1997 (Council of Europe);
- Specific recommendations of the Belgian Privacy Commission with regard to health data;
- Recommendations of the “Orde van Geneesheren”;

The Netherlands

The Dutch Legislation is based on the Wbp (Wet bescherming persoonsgegevens) enacted in September 2001. The law describes what the rights are of those whose personal identifiable information is used by agencies or companies, and the duties of these agencies and companies in the processing and use of these data.

The Wbp relates to every use - 'processing' - of personal data, from the collection of these data up to and including the destruction of personal data.

The Ministry of Justice published Guidelines for personal data processors. The main items treated are:



Notification obligation and exemption from the notification obligation

The supervisory authority, the Dutch DPA must be notified of all processing of personal data. The Dutch DPA keeps a public register of these notifications. However, a large number of socially well known and accepted processing operations have been exempted from the notification obligation. On this web site, the Dutch DPA offers a checklist for the use of the exemption decree.

Technology

The Wbp has a separate section (Section 13) on the use of technology in the protection of personal data.

Supervision of compliance with the Wbp and enforcement of the Wbp

The Wbp also governs the tasks and powers of the supervisor of the act, the Dutch DPA. As a national supervisory authority, the Dutch DPA is the successor of the former Registratiekamer. The Dutch DPA is authorised to impose sanctions.

Data protection officer

Organisations can also appoint their own internal supervisor, the data protection officer. In particular the WGBO (Evaluation of the Dutch Medical Treatment Act) which regulates the doctor patient contract. This act regulates (a) the right of patients to be informed and to give consent and (b) how to deal with confidential patient data.