PREMIER REFERENCE SOURCE

E-Health Systems Quality and Reliability

Models and Standards

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CE LABEL: A Legal Requirement for Medical Devices in Europe

There are 17 European CE directives that specifically apply to manufacturers with the principal being for the medical devices:

- The Medical Devices Directive (MDD) applies to all general medical devices not covered by the Active Implantable Medical Devices Directive or the In Vitro Diagnostics Directive. 93/42/EEC & the new directive 2007/47/CE that extend the label requirements to software and telecommunications.
- The Active Implantable Medical Devices Directive (AIMDD) 90/385/EEC applies to all active devices and related accessories intended to be permanently implanted in humans.
- The In Vitro Diagnostics Directive (IVDD) 98/79/EC applies to all devices and kits used away from the patient to make a diagnosis of patient medical conditions.

The certification includes:

- Technical documentation/file or design dossier
- Device type examination
- Product quality assurance (based on ISO 13485)
- Production quality assurance (based on ISO 13485)
- Full quality assurance (ISO 13485)
- Batch verification/release

Further details of the CE market label in European Commission Enterprise and Industry European Standards.

The CCHIT® & CCHIT-Certified® labels are U.S. certification bodies that include all e-Health and Telemedicine products integrated inside the HIT (Health Information Technologies) including the Electronic Health Record (EHR). Certification criteria furnish a consensus baseline for these main aspects of an EHR. Certified products must demonstrate to trained, objective jurors all of the capabilities called for by the criteria.

That said, the criteria development and testing process builds on a number of checks and balances to position certification requirements so that they advance the progress of EHR capabilities while being careful not to require IT vendors to do the impossible.

The process for building a continually solid basis for EHRs, especially in the area of interoperability, takes a healthy appreciation for progressively scheduling higher levels of sophistication at the optimum pace and in the most logical sequence. The phased approach and tactical timeline can be found at the 'Introduction to Health IT Certification' (Certification Commission for Healthcare Information Technology, 2009).

Finally, the pharmaceutical industry had started a process of computer validation and management of the information technology in the healthcare and pharmaceutical industry with the following validation calendar, starting in 2009.

- January: Validation Planning (VMP, VP)
- February: Requirements Management and Process Mapping
- March: Specifications (including Migration and System Upgrades)
- April: Risk Management Process
- May: Supplier Evaluation / Audits / Subcontracting / Service Levels / Quality Plan
- June: Software Development (CMMI, ISO, Tools, Source Code Handling etc.)
- July: Software Testing (Development)
- August: Release Management and Hand-Over
- September: IQ: IT Infrastructure (Qualification)
- October: System and Acceptance Testing

Chapter 17
Standards in Telemedicine

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ABSTRACT

For many years, medical teams working on telemedicine have made a strong effort to define the telemedicine Body of Knowledge (BoK), and generate compatible standards that allow delivering telemedicine with adequate medical quality. The authors expect, after the European Commission statement on the Prague 2009 declaration, a new era for telemedicine. The essential barriers, which have already been encountered, include Literacy, Standard connectivity and Quality control. In the present chapter, the authors will address the item of Literacy regarding the type of standards in each of the topics of the Telemedicine Body of Knowledge.

INTRODUCTION

In 1998, we wrote, "the welfare expenses cannot be endlessly increased, whilst an efficient health provision system in the context of the information society, will mark a new trend to configure health care practice in the next century" (Ferrer-Roca & Sosa-Iudicissa, 1998).

In this century and in spite of ICT improvements, the provision of health at distance is not taken as a regular medicine delivery but a "special" service, many times included in the new technology units (UINT= Unit of informatics and new technology) of the hospitals.

If training and teaching schemes have to cope with society demands of *health quality (HQ)*, *health equity (HE)*, *efficient health delivery (HED)*, and *health security* (HS) medical training should devote a substantial part to e-health and telemedicine.

The main components of the Telemedicine-BoK as we defined in 1998 are listed in Table 1.

The health sector defines *telehealth* as an integrated term including any telematic application for health. It includes therefore any *medical informatics* and *health informatics*. The interna-

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Table 1. Body of knowledge of telemedicine

CHAPTER	CONTENTS
1	History of Telemedicine
2	Minimal Technical Requirements
3	Main Telemedicine Applications
4	Basic Technical Knowledge
5	Quality Control and Assessment
6	Use and Indication of Telematic Tools in Telemedicine: Internet
7	Training, including Distance Training, Teleworking and Teleteaching
8	Data Security and Privacy
9	Liability and Legal Aspects
10	Health Economics in Telemedicine
11	Technology Transfer and Social Aspects
12	Emerging Issues

tional consultation carried out by the WHO in 1997, came out with a definition of "health telematics": as a composite term for health related activities, services and systems carried out over a distance by means of information and communications technologies, for the purpose of global health promotion, disease control and health care, as well as education, management and research for health. This also embraces the telematics in health research and health services management, as well as specific applications for "telemedicine" and "tele-education in health". In the Table 2, we include a list of telehealth applications. Under each term, we can include provision or confirmation of diagnosis, surveillance, epidemiology, management, clinical and research information, literature search and retrieval, health and wellness, health and medical educational contents.

BACKGROUND

Redefinitions for 2009

Most terms previously used are outdated and substituted nowadays by the common word of *e-health*, that include an endless list of "*e-*" words such as: e-prescription, e-assistance, e-delivery, e-mail, e-patient etc. In fact, not everyone understands the same using the term of e-health and therefore it is important to define their limits.

For the purpose of the paper we define:

- E-health as *health in Internet*, meaning access to anything related with health with or without quality control.
- E-health system as *e-government in healthcare*, meaning any citizen-health bodies transactions not only administrative but also for collection of results (laboratory, final reports, hospital release, e-prescription....)
- E-healthcare as *telemedicine*, meaning health delivery with the required quality standards and lack of risks for patient and users including confidentiality and security. Items such as knowledge discovery, personalized-health, etc... belong to this and it is under the responsibility of the medical doctors, medical colleges and health authorities to achieve the required quality of healthcare.

The potential scope of telemedicine is therefore enormous and can be summarized in four main aspects presented in Table 3.

ROBOTICS & COMPUTER ASSISTED MEDICINE

i.e. CAS / AEP[8]/ Intelligent devices

If you take into consideration the above scheme, many of the items treated in the field of telemedicine should be taken out. For that reason, it is important to define the limit of competences regarding e-administration for the healthcare items including electronic transactions or citizens' information and advertisement from the

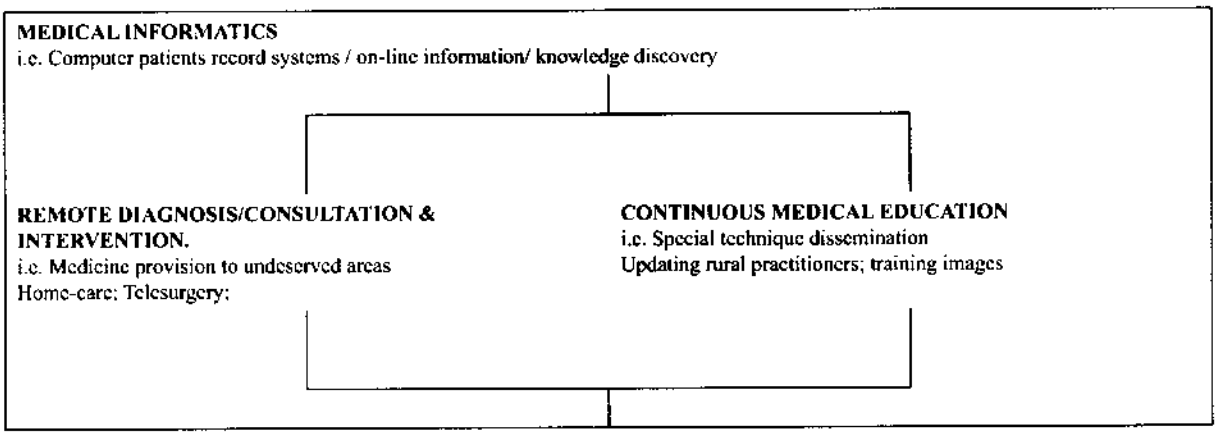
Table 2. Telehealth applications

	CATEGORY	USERS
1	All forms of medicine at distance:	Physicians
	Teleconsultations, telepathology, teleradiology, telepsychiatry,	Health care professionals
	Teledermatology, telecardiology etc. Distant exploratory systems: EC[1], holter etc. Robotic surgery and telesurgery and CAS[2] etc. All forms of telementoring	Health care institutions Medical outsourcing
2	Inter-institutional, patient and clinical records and information systems	Health care institutions
	Electronic health and clinical records and data bases accessible by network	Health care professionals
	Laboratory results access	Health care workers
	Pathology results access	Physician's office
	Patient images access Text-mining and automatic disease classification /metadata annotation. PoC[3] controlling: vital signs and other parameters	Researchers Intensive care units
3	Public Health and Community Health Information networks (CHINS) Multiple-use health information networks	Government Epidemiologists
	Assisted Electronic prescription (AEP)	Public health professionals
	Health GRID for genetics, oncology, etc…	Physicians offices
	Knowledge discovery in patho-pharmacology p-Health	Pharmacies Clinics and CHINS
		Personal health policies
4	Tele-education and multimedia applications for health professionals	University and colleges
	and patients and networked research data bases. Internet services.	Associations
	Knowledge discovery. Data mining.	Researchers
	Patient EHR access and laboratory results access.	Physicians
		Health Care professionals
		Patients
5	Telemonitoring, telecare networks, Alarm systems, GPS[4] location PAN[5] telemetric devices: Diabetes, GI endoscopy, Telephone – SMS triages	Customers Elderly Chronically ill
	Home-care. Emergency networks	Disaster victims Accident victims
	Hospital PoR[6] of medical ambulances	Telenursing
	Telementoring in emergency actions	Call centre users
	Disaster relief and emergencies (POC[7]s teleassistance)	Call centre operators

telemedicine aspects in the hands of the health-care workers doctors or assistant people. Some electronic transactions nevertheless are purely in hands of the doctors such as clinical-records or prescriptions as well as knowledge discovery or personalized treatments based on proteomics or genomics.

In an efficiently networked healthcare system, doctors and nurses should get competencies and qualifications in distant attendance, control and treatment in order not to put in danger their own

Table 3. Scope of the telemedicine



security and the health and security of the patients. Competencies in a topic have always been classified as follows:

1. General competencies to be able to use the tools and know the risks.
2. Specific competencies to be able to indicate applications, test them and change/adapt the tools.
3. Professional competencies to be able to design and implement strategies, software and hardware devoted to telemedicine assistance.

According to this design, all nurses and doctors should have to have general competencies and get during their carrier specific competencies in each of the basic medical knowledge and thereafter the specific competencies linked to their own specialties.

Obviously, professionals in the field of telemedicine should provide this knowledge. Those professionals have to have a role in each of the specialties or departments. As an example close to me, it will not be possible to run a fully automatic pathology department capable of handling and tracking biological specimens for personalized diagnosis and treatment unless a patho-informatics service is in place. This service handle specimen tag and informatics recognition, machine handling for automatic cutting, inclusion, staining and slide preparation; digitize and archive digital slides, together with electronic diagnosis with automatic metadata incorporation for data mining in and out of the Hospital information system (HIS), specimen anonimization and tracking, tissue microarray incorporation and protein and gene detection and archive working a GRID environment with other research groups in personalized treatment.

In fact, to focus on the Body of Knowledge of telemedicine we should take as a reference the publications of the ISI Journal citation Reports Science Edition, which are included in the group of HEALTH CARE SERVICES & SCIENCES where all Telemedicine Journals are included. By contrast, MEDICAL INFORMATICS is lacking of all basic knowledge link to telemedicine with only 20 journals and a limited impact factor. Finally, most technical aspects are better referred in the Journals of ENGINEERING, ELECTRICAL & ELECTRONIC that includes around 229 journals. This again poses the question of when the carrier of Medicine is going to be updated including Information Technologies items directly related with telemedicine.

PRAGUE 2009 DECLARATION

Motivation

The motivation of the promotion of the telemedicine by the EC that ended in the Prague declaration was based on:

- **The Recommendation (COM (2008)3282 final)** of July 2, 2008 on **interoperability**: applied to the clinical record but it is comparable to all aspects of the Telemedicine). It specified that its lack is one of the major obstacles to obtain economic and social advantages of the telemedicine.
- **The Communitarian Politics:** The initiative i2010 of growth and deployment of ICTs. According to the 'Leading markets in Europe', the e-health & telemedicine is one of the most important sectors in the creation and marketing of innovative products and services.

Recommended Policies: The Decalogue

The aspects to be addressed by EU countries according to the EC are a Decalogue:

1. **Infrastructure:** A change and adaptation is required that warrants the levels of quality and security in the provision of health care,
   - With framework conditions, organizational structures and complex application procedures.
   - With national and regional strategies in the field of e-health/telemedicine for cohesion and territorial development.
   - With assignation of resources in e-health/telemedicine, including direct incentives and financial mechanisms of indirect incentives to allow adoption, acquisition or modernization of the systems.
2. **Planning** with five years in advance of the activities directed to guarantee the interoperability. This is the limit market by the CE to guarantee the political coherence that often is a previous requisite to improve investment and innovation.
3. **Re-engineering:** Incorporating users and interested parties (local and regional authorities, healthcare professionals, patients and industry) in interoperability; establishing mechanisms for direction and control, management, public-private association of call for tenders, planning, application, evaluation, training, information and education.

   Due to the fact that interoperability is based, among others, on accomplishing **standard norms**, health care professionals and involved parties should know them.
4. **Technical Compatibility** of the systems, pre-requisite for the interoperability. Therefore the member-states should:
   - Have a memory of the existing infrastructure and technical standards.
   - Include a study of models and standards of structured information.
   - Establish the open standards and forced the standardization bodies in similar direction.
   - Considering the mandate M 403 (Standardization mandate to CEN, CENELEC and ETSI in the ICTs involved in electronic health).
5. **Semantic interoperability** is essential for the quality and security of patients, public health, clinical investigation and health care management. As a consequence, they should:
   - Use international clinic-medical terminologies, nomenclatures and classification of diseases including those related with pharmaco-surveillance and clinical trials.

- Standardized the semantic interoperability using data structures (arquetypes and sheets), and subconjunct of terminology systems and ontologies adapted to user demands;
- Developed a system of sustainable reference concepts (ontology) that take into account the variation of professional languages, juridical terminologies and classical coding systems;
- Have methodologies and tools to easily incorporate the semantic content to daily applications and train the professionals;
- Establish solid systems of evaluations and control.

6. **System certification**: Include the conformance procedures issued by authorities recognized trans-border (of autonomous communities or nations). Those should:
   - Apply existing standards and gain user confidence;
   - Establish nationwide evaluation and certification mechanisms;
   - Demand the industry/enterprise to build self-conformance statements for their products;
   - MD (medical devices) certification requires a CE mark, where software and telecommunications are included. Resolution of call for tenders should take into consideration the certification of quality of the enterprises. Enterprises fulfilling quality requirements should be registered and listed and should have periodical audits.
7. **Personal data protection:** following 95/46/CE and 2002/58/CE directives, should consider the legal safeguard to design and deployment of health care systems.
   - Furthermore, a specific juridical framework to manage healthcare data should be considered.
8. **The Telemedicine legal Framework** should consider:
   - The risk analysis for data management and in-house solutions;
   - The autodetermination as a patient right;
   - The degree of data availability.
   - The level of protection in accessing and manipulating data and trusted ID systems for patients and professionals;
   - Storage of data and samples following legal demands;
   - Audit requirements.
9. **Supervision and evaluation** of the interoperability, security and risk. Demand
   - An observatory to supervise, evaluate, determine the technical and semantical interoperability;
   - Alternatively, an interoperability certificate, issued by the competent authority.
   - To assess applications with a qualitative and quantitative criteria.
   - **Health Technology Assessment (HTA)** should not be limited to cost-benefit, efficiency and clinical value of the Evidence-based Medicine (EBM). Those bodies should also be competent in risk quantification, transaction quality and standardization or norms requirements.
   - Specific services could be built to solve those problems assuring the technical-delivery quality, auditing, and tracking the biological specimens in and out of the biobanks.
10. **Education and sensitization.** The member-states should:
    - Sensitize ICT producers and providers, health care providers, public health institutions, insurance companies and all involved parts;

- Fix the education requirements and knowledge and training of decision bodies in the field of healthcare policies and healthcare professionals;
- Educate and train in the areas of: registry of electronic operations; storage and treatment of clinical information; demand of informed consent of patients and limit of the use of biosamples and data.
- Propose comparable information and training activities to patients.

The ten points could be summarized in three: (1) Use standards to assure quality, interoperability and efficiency. (2) Assure the legal framework in security, data protection and health delivery and (3) Control risk management putting in place the control and certification mechanisms.

The three actions standards are the CORE premise.

STANDARDS IN TELEMEDICINE

The degree of maturity of a technology is linked to the *quantity and quality of researchers together with the number of available standards and protocols and the professional acceptance.* Telemedicine is not yet mature since quality of researchers is still limited as well as the professional acceptance. In spite of the fact that telemedicine has already arrived to an important degree of development because, technically speaking, it is feasible, precise, the sensitivity and specificity is similar to regular medicine provision, the clinical results of its benefits are deploying and cost-benefits are still being collected.

As mentioned, the number of standards is linked to degree of maturity. As we will see in the chapter, most of the standards belong to other technological fields (telecommunications, informatics etc...) and only very few are telemedicine specific such as the Plug and Play IEEE 11073 or ISO/PRF TS 22600 for privilege and access control, etc...

The section of the chapter regarding the body of knowledge, with the exception of the history, provides specific standards that will help on two fundamental items when applied to telemedicine:

- Favoring connectivity and integration of applications
- Assuring quality

In the present section, we will list in the joint table the type of standards recognized in each topic of the body of knowledge, but also can be studied in specific web sites (Medical device standards Portal – USA, 2009; American National Standards Institute – HITSP, 2009).

SEMANTICS

Healthcare applications have stable, granular code sets across several conceptual domains. However, most terminologies used in telemedicine assistance technology are not included, because we develop a specific ontology for telemedicine (Ferrer-Roca et al., 2005) based on the body of knowledge.

Some of the domains and their code sets in Medicine are:

Laboratory Tests and Observation Code Sets:

- Logical Observation Identifiers Names and Codes (LOINC)
- Systematized Nomenclature of Medicine—Clinical Terms (SNOMED-CT)

General Medical Code Sets:

- International Classification of Diseases (ICD-9 and ICD-10)
- MEDCIN point of care terminology
- Medical Subject Headings (MESH)
- Systematized Nomenclature of Medicine—Clinical Terms (SNOMED-CT)

Medication Code Sets (including Medication allergies):

Public

- National Drug Codes (NDC)
- NHS Read Codes
- Health Canada Drug Product Database (DPD)
- US Veterans Administration Drug File (NDF-RT)

Commercial (in alphabetic order)

- First Data Bank National Drug Data File (NDDF)
- Gold Standard (Alchemy)
- Lexi-Comp
- Medi-Span Master Drug Database (MDDB)
- Micromedex DRUGDEX
- Multum Lexicon
- Systematized Nomenclature of Medicine--Clinical Terms (SNOMED-CT)

Units of measure:

Table 4. Standards related with each topic of the BoK of Telemedicine by O.Ferrer-Roca

N	TOPIC	STANDARDS
1	**History of Telemedicine**	Not applied
2	**Minimal Technical Requirements**	
	Ergonomy	ISO9241 **ISO** 9241-410:2008 **ISO** 9241-20. **Ergonomics** of human-system interaction **ISO** 9241 y 13406. Series y1992 **Ergonomic** requirements Monitors **ISO** 10651-2, ISO10651-2. Lung ventilators **ISO** 11064-1, ISO11064-1. **Ergonomic** design of control centers OSHA **ergonomics** requirements - **ISO** 9241, AZSI B11 **ISO** 14155-1 COWs or Computer on wheels Tablet-PC
	ID	PUI[9]; TCI[10]; LOINC[11]
	Audio	MP3; UL 1492; Audio USMLE Step 2; ATSC HDTV standards and supports 8-channel digital audio; G.711; G.723; G.722; G.728; AAC-LD
	Video	MPEG-2 (ISO / IEC 13818-7); MPEG-4 part 3 (ISO / IEC 14496-3) DICOM. ITU H.324 (POTS): video H.263 ; audio G.723; ITU H.320 (ISDN): Audio G.711- G.723; video H.261- H.263; ITU H.323 (LAN): VoIP, Video H261 & H263 H.360 end to end QoS. ITU H610 (ADSL) ITU H241: HD: video AVC / H.264 (MPEG-4 part.10, ISO / IEC 14496-10). ISO IEC 14496 CODING H.120, 768-2000 kbps, small picture H.261, baseline video compression MPEG-1-Video part (ISO/IEC 11172-2) H.262=MPEG2-Video, high rate video MPEG-2- Video part (ISO/IEC 13818-2) H.263, improved lower rates; Same core as original video part of MPEG-4 MPEG-4 Video part (ISO/IEC 14496-2) H.264/AVC Advanced video coding MPEG-4 Part 10 AVC (ISO/IEC 14496-10)
	Compression	JPEG2000

continued on following page

Table 4. continued

N	TOPIC	STANDARDS
	Wireless	Bluetooth; EN 50 371; EN 300 328; EN 301 489-1&17 ZigBee, WIFI: IEEE 802.11 a, b, d, g, h, d; IEEE 802.11 n-MIMO. The ISO 14443 and 15693 standards and EPCglobal's Gen 2 standard, protocols for testing ultra-wideband (UWB) and Wi-Fi RFID devices RFID: ISO/IEC 15693 and ISO/IEC 18000-3 IEEE 1471:2000: Standard Architecture view and view points IEEE 802.11b WIFI and WLAN IEEE 802.15.4 Zig Bee IEEE 802.15.3a UWB Ultrawide band IEEE 802.16 a/c WIMAX
	ICM-Electromagnetic	UN-11 telework & telemeasure (PIRE = 500 mW). UN-30 short-access. UN-85 of RLANs inside (PIRE=200 mW) or outside (PIRE=1W). UN-129 for RFID (PIRE =500mW)
	Telecomm	G.991.1 (G.hdsl) - High bit rate Digital Subscriber Line (HDSL) transmission system on metallic local lines. G.992.1 (G.dmt) - Asymmetrical Digital Subscriber Line (ADSL) Transceivers. G.992.2 (G.lite) - Splitterless Asymmetrical Digital Subscriber Line (ADSL) Transceivers. G.992.3 Asymmetric digital subscriber line transceivers - 2 (ADSL2.dmt) G.992.4 Splitterless asymmetric digital subscriber line transceivers - 2 (ADSL2.lite) G.992.5 - Asymmetric Digital Subscriber Line (ADSL) Transceivers - Extended Bandwidth ADSL2 (ADSL2plus) (Jan '03) G.995.1 - Overview of Digital Subscriber Line (DSL Recommendations). G.991.2 (G.shdsl) - Single pair High bit rate speed Digital Subscriber Line G.993.1 (G.vdsl) - Very high bit-rate Digital Subscriber Line G.994.1, G.996.1 and G.997.1 for tests, management and handshake G.983-x series Optical systems for access networks Broadband PON. Passive Optical Network up to 622 Mbit/s symmetrical / asymmetrical G.984.1 – General Characteristics of Gigabit-capable PONs G.984.2 –Gigabit-capable PONs: Physical media dependent layer specification
	Medical & Health care Robotics	Robot assisted surgery: da Vinci surgical system FDA approved 2000. Robotic Sterostaxis (electrophysiology, biopsy) Catheter Robotics RCMS ISO/TC 184/SC 2/WG 7 ISO 80601-2-XX series DICOM WG 24- Dicom in surgery COWs, computer on Wheel Socially assistive robotics (SAR) Human-Robot Interaction (HRI) *human-machine collaborative systems*
	Health Cards	ISO 7816 & EMV2 2000
	Cryptography	DES[12]: 3DES EDE CBC; Secure Hash Algorithm (SHA); AES SHA-224, SHA-256, SHA-384, SHA-512, SHA-1, RIPEMD-160 QES (Qualified Electronic Signature) DID[13]
	Security	ISO/DIS 17090; ISO/PRF TS 22600; RSA electronic signature system; ISO/TS 17090; UNE/ISO/IEC 15408; UNE/ISO/IEC 17799:2005; ISO/IEC 18014 X.509 ; SSL / HTTPS encryptions; Card-Verifiable-Certificates (CVC)
	Medical Devices	UNE209001: IN2002; CE-label (European Commission Enterprise and Industry European Standards, 2009) ISO 1497n1 ISO 13485

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Table 4. continued

N	TOPIC	STANDARDS
	Transport	standard E.800 definitions, QoS[14], NP[15] and QoE[16] SG 12: End to end quality, as perceived by the users. It is fully addressed to Quality, and WP3/12 is dedicated to QoS for IP. SG 13: WP4/13 is dedicated to Network Performance NP SG 2: Mainly on operational aspects of QoS and SLA. New QoS handbook and activities on the impacts of routing on QoS. QSDG: 1 forum meeting each year and QSDG Magazine SG 4: Management of QoS and SLA. SG 9: QoS for cable networks and video assessment. SG 11: QoS signaling. SG15: System-specific requirements for network and transport equipment. SG 16: QoS Mechanisms for H.323-based multimedia systems. Quality of speech and video coders. SG 17: Frame Relay QoS. G.1000 'Communications Quality of Service: A framework and definitions ' G.1010 'End-User multimedia QoS categories ' E.860 'Framework for service level agreement' Y.1541 'IP Performance objective and allocations' Y.1540 ' IP Packet transfer and availability performance parameter" M.3341 ' Requirements for QoS/SLA management over TMN X-interface for IP-based services M.2301 *IP Network Provisioning & Maintenance*
	Medical Informatics	ISO 9126;EN/ISO/IEEE 1073; ISO/IEC 2382-01; ISO/TS; UNE-EN ISO 13606 18303:2002 CHA[17] IHE or Integrated Health Enterprise Sensor Event Platform (Websphere) Open Health
	Text mining	Predictive Model Markup Language (PMML) XML for Analysis and OLE DB for Data Mining SQL/MM Part 6: Data Mining Java Data Mining (JDM) - Java Specification Request 73 (JSR-73) CRoss Industry Standard Process for Data Mining (CRISP-DM) OMG Common Warehouse Metadata (CWM) for Data Mining Web services (SOAP/XML, WSRF, etc) Grid services (OGSA, OGSA/DAI, etc.) Semantic Web Standards (RDF, OWL, etc.) Standards for KDD workflow Standards for process workflow Standards for data transformations Standards for real time data mining Standards for data webs Open Source Efforts: R ; Weka ; GNU Octave
	Data management	XML; HL7; ICD10; MESH;
	Risk management	UNE 71502:2004; ISO/IEC 27004; ISO/IEC 15408; ISO/IEC 27001:2005; ISO/CD TS 25238
	Domotic	X.10; EN 50090-ISO/IEC 14543-3; ZeegBig; Z-wave; EN 13321-1; PLC[18]; Home-plug 1.0; Home-plug 1.0 Turbo; Home-plug AV at 200 Mbps; IMS- Internet Protocol Multimedia Subsystem, Open IPTV Forum; Digital Living Network Alliance (DLNA).
	Web 2.0	GoogleHealth
3	**Telemedicine Applications**	ISO 9126

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Table 4. continued

N	TOPIC	STANDARDS
	EHR	ISO13606;EN-TS14796; OpenEHR; EN/ISO/IEEE 1073; prEN 12967 HISA; ENV 12612 Messages for the Exchange of Healthcare Administrative Information EN 13606 EHRcom[19] prEN 13940 CONTsys[20] prEN 14463 ClaML[21] EN 14720 Service request and report messages EN 14822 GPIC[22] EN 1828 Categorial structure for classifications and coding systems of surgical procedures. ISO- TR 18307 Health informatics - Key characteristics for interoperability and compatibility in messaging and communications standards ASTM-CCR[23]; ISO 8601(date/time); NCPDP-script[24] CCHIT [25] **HL-7:** HL7-CDA2-CCD[26] ; HL7-21731-RIM[27]; HL7-AQL[28]; HL7-CTS[29] ; HL7-OMG-HSSP[30]; HL7-CCOW[31]; HL7 CMET[32]; HL7 CMS[33]. E1239 Standard Practice for Description of R-ADT[34] for EHR E1284 Standard Guide for Construction of a Clinical Nomenclature for Support of EHR E1384 Practice for Content and Structure of EHR E1633 Specification for Coded Values Used in EHR E1714 Standard Guide for Properties of a UHID[35] E1715 Standard Practice for An Object-Oriented Model for RADT Functions in EHR E1744 Practice for View of Emergency Medical Care in the EHR E1762 Standard Guide for Electronic Authentication of Health Care Information E1869 Standard Guide for Confidentiality, Privacy, Access, and Data Security Principles for Health Information including EHR E2171 Standard Practice for Rating-Scale Measures Relevant to the Electronic Health Record E2183 Standard Guide for XML-DTD Design, Architecture and Implementation E2184 Standard Specification for Healthcare Document Formats E2211 Standard Specification for Relationship Between a Person (Consumer) and a Supplier of an EHR E2369 CCR Specification for CCR[36] E2473 Practice for the Occupational/ Environmental Health View of EHR EUA[37]
	Laboratory reports	**ELINCS** EHR-Lab Interoperability and Connectivity Standards
	Vital Signs	EN/ISO/IEEE 1073 ENV 13734:2000 Health Informatics – Vital signs information representation EN 1064:2005 Communication protocol for computed assisted ECG
	Virtual Slides	JPEG200; SSVS[38]
	PACS-Picture archiving & communication system	DICOM DICOM SR DICOM Structured Reporting
	HIS-Hospital Information Sys.	EN/ISO/IEEE 1073; ENV13939
	PIS- Pathology Information Sys.	EN/ISO/IEEE 1073; ENV13939 **ISO** TR 18112:2006, **Clinical Laboratory** Testing and in Vitro ISO/IEC 17000 ISO/IEC 17011 ISO/IEC 17025 as an essential standard for accreditation ISO/TC 212, Clinical Laboratory Testing and In Vitro Diagnostic Test Systems

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Table 4. continued

N	TOPIC	STANDARDS
	LIS- Laboratory Information Sys	EN/ISO/IEEE 1073; ENV13939; ENV1613; ISO 18812; LIS09-A Standard Guide for Coordination of Clinical Laboratory Services in EHR & networking LoC= Lab on Chip ISO 15189:2003 ISO/IEC 17025 ASTM E1381-02 Standard Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems ISO/IEC 11179 standard
	MIS, minimal invasive surgery	EN/ISO/IEEE 1073; ENV13939; VITAL
	CAS, computer aided surgery	EN/ISO/IEEE 1073; ENV13939; VITAL
	PoC (point of care)	EN/ISO/IEEE 1073; ENV13939; VITAL HL7- CCOW IEEE 11073-10201 PoC medical device communications - DIM[39] CLSI[40] PoC laboratory control ISO 15197 Quality Assessment SMBG[41] NCCLS National Committee for Clinical Laboratory Standards NIST-CAB[42]= National Institute of Standards and Technology -Consortium on Advanced Biosensors
	PoR (point of reception)	EN/ISO/IEEE 1073; ENV13939; VITAL
	RS, Robotic surgery	EN/ISO/IEEE 1073; ENV13939; VITAL
	pHealth	IEEE2407 o PHI (*Personalized health informatics*) ISO/IEEE11073 (X73-PHD –*personal health devices*)
4	**Basic Technical Knowledge**	
	Plug & Play	EN/ISO/IEEE 1073
	Messaging	HL7; EN/ISO/IEEE 1073;
	Health Cards	ISO 14443-Proximity Health Cards ISO/IEC 7816 Smart Card standard ISO/IEC 7811 Identification Cards ISO/IEC 24727 Card Services framework (eEHIC[43]) BSI TR-03105 EMVCo Contactless Level 1 EMVCo Contact Level 1 and Level 2 ISO 17025, ISO 10373 ISO 15693 CEN/TS 15480 EU Citizen cards ENV 12018 Health card logic structure ISO/IEC 7816-2 Secure Module Card (SMC)

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- Unified Code for Units of Measure (UCUM)

Procedures:

- Current Procedure Terminology (CPT)

Specialty Code Set Examples:

- Current Dental Terminology (CDT)
- Diagnostic and Statistical Manual of Mental Disorders (DMS-IV)

All can be studied in the Unified Medical Language System (UMLS) list of sources. There are over 100 terminology sources, without counting the homegrown terminologies that are still in use in many institutions for various domains.

Table 4. continued

N	TOPIC	STANDARDS
	Tracking systems	RFID ISO18000 RFID standards ISO/IEC 18004:2006; ISO/IEC15961 ISO/IEC 24710 ISO/IEC 24791- Software system infrastructure ISO/IEC 29160- RFID emblem ISO/IEC 24730- Real time location IoT[44] & GS1 standards ISO /IEC 29100 MIIM[45] ISO/IEC 15693 Identification cards -- Contactless integrated circuit cards – Vicinity cards ISO/IEC 14443 Identification cards -- Contactless integrated circuit cards – Proximity cards ISO/IEC 21481 *Information technology -- Telecommunications and information exchange between systems -- Near Field Communication Interface and Protocol -2 (NFCIP-2)* ISO/IEC 18000-3 Mode 3 (EPCglobal HF Gen 2) RFID ETSI ERM TG34 AIM Global CENELEC TC106x * Electromagnetic fields in the human environment CEN TC225 * AIDC technologies EDItEUR EPCglobal™ ; ITU-R ; IATA ; IEEE ; GS1 ISO/IEC JTC1/SC31/WG2 * AIDC – Data Structure ISO/IEC JTC1/SC17/WG8 * Identification cards and related devices - integrated circuit cards without contacts ISO/IEC JTC 1/SC27 ISO TC23/SC19/WG3 * Animal Identification ISO TC104 * Freight containers ISO TC122 * Packaging and JWG * Supply Chain Applications ISO/TC184/SC4 ISO TC204 * Intelligent Transport Systems Universal Postal Union EDItEUR ETSI EN 300 220 - ETSI EN 300 330 - ETSI EN 300 440 - ETSI EN 302 208 - ETSI TR 102 436 - ETSI TS 102 562 - ETSI TR 102 649
	Bar-coding	ISO/IEC 15417 Bar code symbology specification - Code 128 ISO/IEC 15420 Bar code symbology specification - EAN/UPC ISO/IEC 15424 Data carrier identifiers (including symbology identifiers) ISO/IEC 15424 Bar code symbology specification - PDF417 ISO/IEC 16022 Bar code symbology specification - Data Matrix ISO/IEC 16023 Bar code symbology specification - Maxicode ISO/IEC 16388 Bar code symbology specifications - Code 39 ISO/IEC 16390 Bar code symbology specification- Interleaved 2-of-5 ISO/IEC 18004 Bar code symbology QR Code ISO/IEC 24723 EAN.UCC Composite bar code symbolic Specification ISO/IEC 24724 Reduced Space Symbology (RSS) bar code symbology specification ISO/IEC 24728 MicroPDF417 bar code symbology specification ISO/IEC 24778 Aztec Code bar code symbology specification
	Medical Imaging	DICOM JPEG200
	Domotics	ISO/IEEE11073 (X73-PHD–*personal health devices*); X.10; EN 50090-ISO/IEC 14543;

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Table 4. continued

N	TOPIC	STANDARDS
	Optical Biopsy	UH-OCT[46]; US[47]; PAM[48]; DOT[49], CE[50]
	Ambient Intelligence	SOUPA (Standard Ontology for Ubiquitous and Pervasive Applications) ISO 9241 H.323; MPEG-7 Near Field Communications (NFC): Bluetooth SIG; IEEE, 802.3 OSGi VME or Virtual mobile environments Standard Self Organizing Map (SOM) EMMA[51]. Agent- related technologies and standards (WSDL, OWL-S, WSMO, UDDI, JXTA, FIPA, LARKS, etc.) Registry types (UDDI, LDAP, ebXML) FIPA[52] set of standards Perceptive particle swarm optimization – PPSO, standard PSO (SPSO)
	Semantics-Terminology	ISO 13606-2-ADL [53]; HL7 CDA[54],SNOMED-CT,LOINC[55], ICDx ISO CD 15225:2000 – Nomenclature – Specification for a nomenclature system for medical devices for the purpose of regulatory data Exchange ISO/DTS 22789:2007, Health informatics – Conceptual framework for patient findings and problems in terminologies ISO 1804 for nursing terminologies, CEN EN 1068 Registration of coding systems CEN EN 12 264 for the definition of a Categorial structure, CEN EN 1828 Categorical structure for surgical procedures, CEN EN 12 611 for clinical laboratory, CEN EN 13 940 for continuity of care CEN EN 15 521 for human anatomy ISO/CD 25720 Genomic sequence variation markup language ISO/NP TS 27527 Health Informatics -- Provider Identification
5	**Quality Control and Assessment**	
		ISO 13485 Compliant Quality Management System ; ISO/TS 16949, Good Manufacturing Practice (GMP) ISO 15189:2003
	HIT or Health Care Information Technology	HITSP-Healthcare Information Technology Standards Panel. CCHIT- Certification Commission for Healthcare Information Technology.
	ISO 9001-medical requirements	21 CFR Part 11 (see risk management).
	ISO 9001-Laboratory requirements	ISO 9001:2000 Quality management systems-Requirements ISO 9000:2005 Quality management systems-Fundamentals and vocabulary ISO 13485:2003. Risk management EN 45001General criteria for the operation of testing laboratories /ISO 25 ISO 15189:2007 Medical laboratories – Particular requirements for quality and competence ISO 15190 standard on clinical laboratory safety ISO 15197 Blood glucosae monitoring systems for self testing ISO/IEC 17025: 2005 General requirements for the competence of testing and calibration laboratories ISO 20776:2007 Laboratory testing & In vitro diagnosis infectious diagnosis ISO/TR 22869:2008 Clinical laboratories ISO 22870:2006 Point-of-care testing (POCT) – Requirements for Quality and competence 21 CFR 58 Good Laboratory Practice for Non-Clinical Lab Studies iPassport Laboratory EQMS[56] 21 CFR Part 606 Good manufacturing for Blood & blood components Committee for Clinical Laboratory Standards (NCCLS) EQALM (European committee for External Quality Assessment Programmes in Laboratory Medicine)

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Table 4. continued

N	TOPIC	STANDARDS
	Risk Management	ISO 13485; ISO/IEC 15443 ; UNE71502:2004; ISO/IEC 27004; ISO /CD TS 25238; **21 CFR Part 11.** Based on the FDA's risk-based assessment for regulatory compliance 21 CFR 820 Quality System Regulation 21 CFR 806 Medical Devices; Reports Of Corrections And Removals 21 CFR 803 Medical Device Reporting 21 CFR 808 Exemptions From Federal Preemption Of State And Local Medical Device Requirements 21 CFR 814 Premarket Approval of Medical Devices
	CE Label	ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories ISO/IEC 17021:2006 Conformity assessment -- Requirements for bodies providing audit and certification of management systems
	Benchmarking	JCAHO; PSI; PPE
	AAL, Ambient Assistance living	X.10; Digital Living Network Alliance (DLNA) certification IEC 62481-1 and IEC 62481-2 WPAN, IEEE 802.15.4 is under development
	EBTm[57],	
	Device management	ISO 13485;
	Electro-Magnetic fields & SARS	EN 50371 and EN 62311 ANSI C63.19 ISO/PRF TR 21730- Health informatics -- Use of mobile wireless communication and computing technology in healthcare facilities -- Recommendations for electromagnetic compatibility (management of unintentional electromagnetic interference) with medical devices
6	**Telematic Tools in Telemedicine: Internet**	
	Data mining Semantic Web	Open Archives Initiative Protocol for Metadata Harvesting (OAI-PMH) and has been ratified as IETF RFC 5013, ANSI/NISO Standard Z39.85-2007, and ISO Standard 15836:2009. ISO 3166 ISO 639
	Metadata registry	ISO/IEC 11179 emphasizes, among other features, the use of non intelligent identifiers (RE: ISO/IEC 11179-5 and 111179-6) for data elements specified for sharing
	Knowledge discovery	
	Web services, GRID technology & Cloud	XML, WSDL, SOAP, SADL, MSDL, ASIDL, OCS[58] OGSI[59] standards
	Distant 3D reconstruction	
	Cloud computing	REST, RSS, ATOM, ATOM-PP
	IoT (internet of things)	The GS1 System of standards includes: GS1 Identification Keys: numbering schemas for products, locations, patients, caregivers, and assets GS1 Bar Codes: several types of bar code, linear and 2-dimensional, for use by GS1 members depending on the application GS1 EPCglobal: supporting the use of radio frequency identification RFID GS1 GDSN: ensuring global data synchronization and accurate product data across supply chain partners GS1 eCom: supporting electronic document interchange technologies
7	**Training, including Distance Training, Teleworking and Teleteaching**	
	Multimedia data sharing	ISO-15938-12:2008 (MPQF), we implicitly refer also to ISO-24800-3 (Part 3 of JPSearch)

continued on following page

Table 4. continued

N	TOPIC	STANDARDS
	Multimedia Querying	ISO-15938-12:2008 (MPQF[60]),
8	**Data Security and Privacy**	
	Public key infrastructure	ISO /DIS 17090 **Security on health informatics** **ISO/CD TS 21298**- Health informatics -- Functional and structural roles ISO/IEC 9594-8 (X.509)- Authentication by means of cryptographically derived credentials (PKI)
	Registry Authorities	ISO 646; ISO/IEC 7812; ISO/IEC 10036 ; **ISO**/IEC 6523- RAI[61] ISO/IEC 11179- Metadata registry for global electronic information interchange; **ISO**/TS 19127 IRDI is an internationally unique Identifier
	Certify authorities	Revocation Lists
	Privilege management	ISO/ PRF TS 22600 Health informatics -- Privilege management and access control
	Digital signature	**Title 21 CFR Part 11 of the FDA**
	Time stamping	ISO/IEC 18014; ISO 8601
	IS- Information Security	ISO/IEC 38500:2008, for the corporate governance of information and communication technology; ISO27000- Vocabulary ISO27001:2005, ISMS[62] - BS7799 in UK. ISO/IEC 27002:2005 (prior ISO/IEC 17799) - IS controls, ISO/IEC 27003-Implementation ISO/IEC 27004- Security indicators ISO/IEC 27005:2008, IS risk assessment, and BS3110-British Risk Management Standard. ISO/IEC 20000:2006 IT service management based on ITILv3, independently certificated. BS25999:2007, British Business Continuity Management Standard; ISO/IEC 24762, IT disaster recovery standard, and BS25777, the British IT Service Management Continuity Standard. CMMI[63] A quality management tool to describe typical organizational behavior at each of five levels of process 'maturity'. ASIS international guidelines ISO/IEC 15443 Information Technology- Security techniques. ISO/IEC-TR 15446:2004 Information Technology- Security techniques- Guide for the production of Protection Profiles and Security Targets ISO/IEC 15408:2005 Information technology- Security techniques- Evaluation criteria for IT security ISO/IEC 18014 Time stamping ISO/IEC 27001:2005 Information Security management systems- Requirements ISO/IEC 27004 Information Security Management measurements
9	**Liability and Legal Aspects**	
	Biological specimen tracking	EPC[64], GS1Healthcare; ISO 18000-2, 18000-3 Mode 2, 18000-4, 18000-6 and 18000-7; ISO 24730-2 and 24730-5 real-time locating system (RTLS) standards; The ISO 14443 and 15693 standards and EPCglobal's Gen 2 standard will also be included, as will protocols for testing ultra-wideband (UWB) and Wi-Fi RFID devices
	LOPD	
	LOAP	
		UI[65], used within the context of the DICOM Standard, are registered values as defined by ISO 9834-3 to ensure global uniqueness
10	**Health Economics in Telemedicine**	

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Table 4. continued

N	TOPIC	STANDARDS
	Utility	CUA[66]; CVA[67]
		Quality live: QALY[68]; DALY[69], HALY[70]
		ISO 13485:2003 Quality Management. (ISO 9001:2000 for healthcare)
	Cost-Benefits	CEA[71]; CBA[72]
11	**Technology Transfer and Social Aspects**	
	Technology cycle	PLM Product lifecycle management. PCV Product centric view Business Process Reengineering (BPR)
	ERP[73]	G21: IS auditing guideline. ISAKA auditing standards. COBIT's information criteria Business Process Reengineering (BPR)
	Enterprise 2.0	B2B (business to business). Integration service providers
12	**Emerging Issues**	
	Nanodevices	ISO FDX –B ISO 15693 1 ISO 7816 tarjeta proximidad Microchips iso and 21.1 MP chip ISO/IEC 7811 Identification Cards ISO/IEC 17025:2005 ISO 13485 ISO/TS 16949 and ISO/IEC 17025 ISO 14001:2004 ISO IEC 14496 CODING OF AUDIO VISUAL OBJECTS
	Lab on Chip (LoC)	ISO standards: 14443A 14443B, and 15693
	Implantable devices	
	IoT (Internet of Things)	EPC ™ /RFID[74]. Bar coding: **ISO** 15426; **ISO** 15394:2009; **ISO**/IEC 15416 IRDI is an internationally unique Identifier ISO/IEC 11179-6 Metadata of data elements Data Semantics: ISO/IEC 11179 (Metadata Registries) Terminology: ISO 704 (Principles of Terminology) ISO 1087-1 (Vocabulary for terminology work) ISO/TC 37/SC 4 (Language Resources Management) Interoperability: ISO/IEC 19763 (Framework for Metamodel Interoperability) ISO/IEC 20944 (Interoperability and bindings)
	Pervasive computing	PHD, IEEE 11073 family, AAL. ISO/IEEE240-PHI Event Driven Architecture (EDA)
	Cloud computing with VMware	IaaS[75], DaaS[76], PaaS[77],... SLA[78]

Semantic Interoperability

The semantic interoperability is a problem not only in Medical informatics applications but also in the Medical terms itself.

METATHESAURUS is the conceptual backbone in which medical terminology terms are correlated with the same or similar conceptual meanings from different sources.

In the *Metathesaurus maps* the source codes provided by the creators of the different code sets to unique strings (SUIs), normalized lexical terms (LUIs) and distinct concepts (CUIs). This information is located in the first file, the MRCONSO.

(Metathesaurus Relational Concepts and Sources). The second is the MRREL file that contains the relationships between concepts that supports the traversal of a source's ontology.

Pervasive and Mobile Computing

Information technology is moving towards pervasive and mobile computing, not only at home, but at the hospital and at the work place. On this progressive development the *issue of interferences* of wireless signals introduced before is an essential one (see below).

In medicine, personal monitoring scenarios require standardized features and functionalities. Its integration and implementation have been carried out using the Point of Contact standard ISO/IEEE11073 (X73). The result is the Personalized Health Informatics ISO/IEEE240-PHI and the Personal Health Data (PHD) standard the latter based on the 11073 family of standards also called Plug & Play for medical devices. It is applied to small devices with limited resources of processor, memory and power of the short-range wireless technology (see below WSN). Adapt the Domain Information Model and nomenclature of the 11073 to create the new standard that facilitates the remote patient monitoring with a mature technology-service.

However, there is still a lack of development in areas such as standardization of the sensor's communication interface, integration into electronic healthcare record systems or incorporation into ambient-intelligent scenarios.

In ambient intelligence, the Ambient Assisted Living (AAL) is an essential application where, among others, pervasive computing vision plays a role. The most reliable system is a wireless sensor network (WSN) on platforms (i.e. SunSPOT) building a specific services architecture. This architectural model allows the decoupling of applications in components such as ECG's monitor, position system or location awareness etc...

In Domotics the Intelligent Home control (IHC) standard have developed being commercialized in Europe and other countries under Schneider-Electric, or their dependent enterprises (LK in Holland, Alombard in France, Lexel in Holland & UK,...) The so-called "Thinclient", a very small device (minimum software and an operative system) with few electronics is able to open a session capable of administering the devices from the HTPC (Home Theater Personal Computer) server. The Internet Protocol Multimedia Subsystem-IMS based on System Initiation Protocol-SIP-standard, defines how IP networks manage voice calls and data transfer maintaining separated the underlying network services. This could integrate mobile and Wi-Fi.

In virtualization (either VMware or Cloud computing) where the software can simultaneously simulate various operative systems in one hardware simultaneously or use limited-computing portable systems to let the Cloud to take care of it either to distribute the task or to carry out in complex devices or store in huge systems.

Most people cannot distinguish what is a CLOUD-computing and what is a GRID-computing. In a simplistic manner, one thinks of a CLOUD as a virtualization and of a GRID when complex heavy-computing work is required.

GRID computing is ideal when a huge computation power is required in an application. By contrary virtualization is ideal when a numerous simultaneous applications are used most of them consuming a limited computation potential.

In the CLOUD, it is irrelevant whether a Grid or VMware structure is used. You just start the application in the Cloud and allow the Cloud to search the required tools.

The Cloud uses any virtualization architecture: Grid, SaaS (software as a service), PaaS, IaaS (Infrastructure as a Service), DaaS (Database as a Service) etc...all can run in the Cloud simultaneously. The cloud is build with any block consider to be of interest for a task.

GRID: Grid and grid-like technologies—including virtualization, automation, service oriented architecture (SOA) and distributed computing—are all part of the IT infrastructure to enable knowledge-based, global economy. Open Grid Service Infrastructure (OGSI) standards (Dobrev et al., 2002) are based on XML-based Web service protocols for interconnecting resources and defining the way in which elements of a network of computers can interact. In domotics, OGSI is used as a home-gateway but not in the *internal* infrastructure. It has limitations since publish/subscribe protocol does not suit for domotics. In fact, it is possible to provide subscription, but there is no notion of topics, which is a problem since home environment, has very rich ontologies.

Events generated by sensors should be fused, for security reasons, to generate higher-level events (i.e.: if someone is laying down the fall event is trigger if there is also an acceleration event). To fuse sensor data, a rule engine is connected to the WS-Notification interface. The hierarchy of events (event tree) is managed in a separated component. Notice that the event tree is a dynamic structure that can be modified at run time by the event server, but also by clients via appropriate WSDL calls. Client registration to events is stored in an appropriate database in the event server. Registrations to atomic or complex events can be made anytime. Registration may expire or be cancelled. The WS-Notification protocol includes the possibility of having *preconditions* and *selectors* connected with the registration of an event and controlling its generation and delivery. For instance, a client could register to the event of the home user fall, only under the condition that it is night.

Published Standards, Guidelines and Benchmarking

Up to now the latest publications on Telemedicine standards include the so called ATA "Core standards for telemedicine applications", those are the list of standards that we collected in 1998 in the Handbook of Telemedicine and that updated in the new releases in 3 different languages (Spanish, Russian and Greek) as well as in the latest proceedings of the Winter Course of the CATAI of 2007 based on Standards in Telemedicine, 2008 based on Quality control in Medicine. Biobanking and the 2009 proceedings dealing with the role of telemedicine in Superresolution and Optical Biopsy.

It is of paramount importance to realize that from the medical point of view there is no benchmarking in telemedicine, and no accreditation in telemedicine established by the Joint Commission on accreditation of Health Care organizations (JCAHO). That means that we cannot compare the results of medicine with or without telemedicine for the patients because there are no indicators established such us *mortality-index*, *remission-index* or *complication-index* associated to the *risk* or any other parameters that could be used to compare.

Furthermore, there are not PSIs or Patient Security Indicators or even worse, there are no PPEs or Patient Prevention Errors that are closer to the use of *e-health-systems* (i.e.: over dosage or prevention of adverse reactions with AEP or Assisted Electronic prescription...)

Very limited publications deal with well-designed trials that analyze patient benefits of face-to-face consultation versus telemedicine (Ferrer-Roca et al., 2009). This means that the EBM (evidence-based medicine) in telemedicine-EBTM is very limited, maybe with one exception: The clear benefits of the Tele-ictus or Stroke Units based on telemedicine, show for increasing number of patients for whom anticoagulant treatment was indicated, the speed up of diagnosis and treatment.

Healthcare Provider IT Strategies service offers in-depth coverage of the technologies that provide the most clinical value in terms of quality, cost, time, and agility and are transforming precare, point of care (POC), and postcare today.

CE LABEL: A Legal Requirement for Medical Devices in Europe

There are 17 European CE directives that specifically apply to manufacturers with the principal being for the medical devices:

- The Medical Devices Directive (MDD) applies to all general medical devices not covered by the Active Implantable Medical Devices Directive or the In Vitro Diagnostics Directive. 93/42/EEC & the new directive 2007/47/CE that extend the label requirements to software and telecommunications.
- The Active Implantable Medical Devices Directive (AIMDD) 90/385/EEC applies to all active devices and related accessories intended to be permanently implanted in humans.
- The In Vitro Diagnostics Directive (IVDD) 98/79/EC applies to all devices and kits used away from the patient to make a diagnosis of patient medical conditions.

The certification includes:

- Technical documentation/file or design dossier
- Device type examination
- Product quality assurance (based on ISO 13485)
- Production quality assurance (based on ISO 13485)
- Full quality assurance (ISO 13485)
- Batch verification/release

Further details of the CE market label in European Commission Enterprise and Industry European Standards.

The CCHIT® & CCHIT-Certified® labels are U.S. certification bodies that include all e-Health and Telemedicine products integrated inside the HIT (Health Information Technologies) including the Electronic Health Record (EHR). Certification criteria furnish a consensus baseline for these main aspects of an EHR. Certified products must demonstrate to trained, objective jurors all of the capabilities called for by the criteria.

That said, the criteria development and testing process builds on a number of checks and balances to position certification requirements so that they advance the progress of EHR capabilities while being careful not to require IT vendors to do the impossible.

The process for building a continually solid basis for EHRs, especially in the area of interoperability, takes a healthy appreciation for progressively scheduling higher levels of sophistication at the optimum pace and in the most logical sequence. The phased approach and tactical timeline can be found at the 'Introduction to Health IT Certification' (Certification Commission for Healthcare Information Technology, 2009).

Finally, the pharmaceutical industry had started a process of computer validation and management of the information technology in the healthcare and pharmaceutical industry with the following validation calendar, starting in 2009.

- January: Validation Planning (VMP, VP)
- February: Requirements Management and Process Mapping
- March: Specifications (including Migration and System Upgrades)
- April: Risk Management Process
- May: Supplier Evaluation / Audits / Subcontracting / Service Levels / Quality Plan
- June: Software Development (CMMI, ISO, Tools, Source Code Handling etc.)
- July: Software Testing (Development)
- August: Release Management and Hand-Over
- September: IQ: IT Infrastructure (Qualification)
- October: System and Acceptance Testing

- November: Go Live and Validation Reporting (Training)
- December: Support, Repair and IT Management Services
- January 2010: Results and generation of Validation White Paper (Draft for Review)
- March 2010: Validation White Paper (Final)

In Spain, for example, there is a trend for SIS (Sistemas de informacion Sanitaria) certification based on semantic interoperability, which builds on translation parses. This is part of the quality label and certification of the electronic health record systems in Europe (EuroRec, 2009). The standard for the message format was the CEN TC251, ENV 13606 standard, which is now being incorporated into the HL7 standard for clinical record transfer.

The UK experience in achieving a Standard Query Language for Primary Care systems is wider. The vendor must submit its software to an Accreditation process (NHS Connecting for Health, 2009). Part of this accreditation involves the inclusion of a 'HQL' (HEalth Query Language) interpreter. This allows a health community to extract anonymized data in a standard format for clinical audit, commissioning, governance etc. There is a crown copyright implementation of HQL called MIQUEST (Morbidity and Inquiry Export Syntax).

Furthermore, the GS1 UK Healthcare User Group (GS1, 2009) is leading the utilization and development of global standards for the UK healthcare industry, with the primary focus on automatic product identification to improve patient safety, as we will mention in the next paragraph regarding RFID. They are developing, promoting and implementing a global industry response for solutions in preventing medical errors, combating counterfeits and improving supply chain efficiencies throughout the healthcare industry.

RFID & EMI (Electromagnetic Interference)

Interferences are caused by the radio waves of one device, which distort the waves of another. Cells phones, wireless computers and even robots in factories can produce radio waves that interfere with RFID tags. Therefore, it is essential to incorporate new standards that enable interoperability.

RFID has an important role to play in healthcare. Auto-ID systems can help improve infection control and reduce dispensing errors. They can help monitor maintenance activities and locate critical equipment. CoreRFID's healthcare solutions include real time asset location, staff tracking; maintenance management and supplies logistics control systems.

Details of the human interaction can be studied in the CENELEC TC106x Electromagnetic fields in the human environment and the ISO RFID standards can be studied in (ISO RFID Standards, 2009; EPCglobal Inc, 2005; RFID Standards, 2009).

In the UK, as mentioned before, the Global Supply Channel- GS1 group (GS1, 2009) search for automatic identification, traceability, and data synchronization in health care include:

- GS1 Identification Keys: numbering schemas for products, locations, patients, caregivers, and assets
- GS1 Bar Codes: several types of bar code, linear and 2-dimensional, for use by GS1 members depending on the application
- GS1 EPC[79]global: supporting the use of radio frequency identification-RFID
- GS1 GDSN: ensuring global data synchronization and accurate product data across supply chain partners
- GS1 eCom: supporting electronic document interchange technologies

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ENDNOTES

1. EC= Endoscopic capsule
2. CAS= Computer assistant surgery
3. PoC= Point of Care
4. GPS= Global positioning systems
5. PAN= Personal area networks
6. PoR= Point of Reception
7. POCs= Points of contact (Disaster mitigation and relief operations)
8. AEP= Assisted Electronic Prescription
9. PUI= Patient Unique Identifier;
10. TCI= Telemedicine Center Identifier
11. LOINC= Logical Observation Identifiers names and codes
12. DES= Data Encryption Standards
13. DID= Doctor ID
14. QoS= Quality of Service
15. NP= Network performance
16. QoE= Quality of Experience
17. CHA= Continua Health Alliance

[18] PLC= Power Line Communications.
[19] Electronic healthcare record communication
[20] Systems of Concepts to Support Continuity of Care
[21] A syntax to represent the content of medical classification systems
[22] General purpose information components
[23] CCR = Continuity Care Record (ASTM E 2369)
[24] NCPSP= National Council for Prescription Drug Programs (e-prescription)
[25] CCHIT= Certification Commission for Healthcare Information Technology
[26] CDA-CCD=Clinical document architecture-Continuity of Care document
[27] RIM= Reference information model
[28] AQL=Archetype query language.
[29] CTS= Common terminology Services
[30] OMG-HSSP= Object management group-Healthcare Services Specification Project.
[31] CCOW= Clinical Context Management Specification
[32] Common Message Element Types
[33] Context Management Standard
[34] RADT= Reservation/Registration - Admission, Discharge, Transfer
[35] UHID= Universal Healthcare Identifier
[36] CCR= Continuity of Care Record
[37] EUA= Enterprise User Authentication
[38] SSVS= Small size virtual slides
[39] DIM= Domain information model
[40] CLSI=Clinical Laboratory standard Institute
[41] SMBG= Self Monitoring blood glucosae
[42] NIST-CAB is integrated by Becton Dickinson Advanced Diagnostics, Ciba-Corning Diagnostics,
Dow Chemical Co., E.I. duPont de Nemours and Co., Miles Inc. And Ohmicron Corp.
[43] eEHIC= electronic European Health Insurance Card
[44] IoT= Internet of Things
[45] MIIM=Mobile item identification and management
[46] UH-OCT= Ultra high resolution Optical coherence tomography;
[47] US = Ultrasound
[48] PAM= Photoacustic microscopy
[49] DOT= Diffuse optical tomography
[50] CE= Confocal Endoscopy
[51] EMMA= Extensive multimodal annotation mark up language
[52] FIPA= Foundations for Intelligent physical agents
[53] ADL=Archetype definition language
[54] CDA= Clinical Document Architecture
[55] LOINC= Logical Observation Identifiers Names and Codes
[56] EQMS= Electronic quality management system
[57] EBTm= Evidence Based Telemedicine
[58] OCS= Open Cloud Standard
[59] OGSI= Open Grid Service Infrastructure
[60] MPQF= Mpeg query function
[61] RAI=Registration Authority Identifier
[62] ISMS= Information Security Management systems
[63] CMMI= Capability Maturity Model Integrated
[64] EPC= Electronic Product Code standards
[65] UI= Unique Identifiers
[66] CUA= Cost Utility Analysis
[67] CVA= Cost Validity Analysis
[68] QALY= Quality adjusted life years
[69] DALY= Disability adjusted life years
[70] HALY= Health Adjusted life years
[71] CEA= Cost Effectivity Analysis
[72] CBA= Cost Benefit Analysis
[73] ERP= Enterprise Resource Planning
[74] Electronic Product Code™/Radio Frequency Identification
[75] IaaS= Infraestructure as a service
[76] DaaS= Data Base as a services
[77] PaaS= Platform as a service
[78] SLA= Service Level Agreedments
[79] EPC = Electronic Product Code