Report from the CEN/ISSS e-Health Standardization Focus Group

Current and future standardization issues in the e-Health domain: Achieving interoperability

Part 2: Annexes

Final version
2005-03-31

This report was prepared by the CEN/ISSS
e-Health Standardization Focus Group after public comment.

Contents

Part One: Main text

1 Preface 3
2 Executive summary 4
3 Introduction 10
4 Priorities for the application of ICT to health 15
5 The world of standardization and standardization policies 18
6 Achieving Interoperability 36
7 Analysis 44

Part two: Annexes

Annex A Terms of reference 3
Annex B Membership 8
Annex C Methodology 9
Annex D Electronic trading of goods 10
Annex E Analysis of national strategies and policies on priorities for application of ICT to health 11
Annex F Analysis of EU strategies and policies on priorities for application of ICT to health 20
Annex G Structure and work of key standardization bodies 29
Annex H Classified list of existing standards and work in progress 49
Annex I Case studies 66
Annex J Glossary 75
Annex K References 78

Annex A

Terms of Reference for the CEN/ISSS e-Health Standardization Focus Group

A.1 Task description

The CEN/ISSS e-Health Focus Group is formed to prepare an overview report on current and future standardization issues in the e-Health domain.

A.2 Objectives

- to consider, with all the relevant stakeholders, priorities and objectives for e-Health standardization and interoperability and how the CEN system and others can contribute;
- to overview the existing achievements and current programme of work of CEN/TC251, starting from the report presented to the Commission in June 2001, and to consider its current achievements and Business Plan;
- to overview other current and proposed e-Health related and relevant standardization activities, in formal standardization and industry consortia, and in particular interface with the recommendations of the e-Health Standardization Co-ordination Group recently formed by an ITU-T initiative, and which includes CEN/TC251, ISO/TC215, ITU, DICOM and HL7;
- to consider the standards implications of the Ministerial Declaration of 22 May 2003, following the Commission/Presidency e-Health 2003 Conference (Annex A);
- to take due account of requirements of eEurope Health Online key actions;
- to take due account of other policy and legal requirements in the European context, including initiatives at national and regional level;
- to prepare a draft report, containing proposals and priorities for future standardization work, and present this to a Commission-organised Open Meeting;
- to finalise the report in the light of public comments and the Open Meeting discussions.

A.3 Scope

The activities of the CEN/ISSS e-Health Focus Group should cover the concept of e-Health as defined in the context of eEurope – the application of information and communications technologies (ICT) across the whole range of functions and services which, one way or another, affect the health of citizens and patients, specifically:

- delivery of care to patients by healthcare professionals;
- health-related information;
- electronic trading of healthcare goods.

A.4 Membership

The Focus Group will be open to all interested parties through public web announcement.

Participants in existing relevant European standards shall be invited to join the Focus Group, as will the CENELEC Central Secretariat and ETSI Secretariat and other interested members of the ICT Standards Board.

Representatives of the health sector including Governments, industry, insurance companies, health professionals and patient associations shall be invited to attend, as will the European Health Telematics Association (EHTEL), EUROREC and the CEN Sector Forum for the medical sector (CHeF).

The European Commission DGs ENTR, EMPL, INFOSOC, SANCO and the EFTA Secretariat shall be invited as Observers.

A.5 Working methods

The CEN/ISSS e-Health Standardization Focus Group shall be formally responsible to the CEN/ISSS Forum, which shall endorse the Terms of Reference and the final Report.

The Chair will be nominated by the Group and endorsed by the Forum. The Secretariat shall be provided by a CEN Member.

A Steering Committee will be formed to ensure that the Focus Group is effectively managed and the results representative. It will comprise five people and be co-ordinated by the Focus Group Chair.

The Group will work on a voluntary basis. Physical meetings may be held as required, but full electronic working facilities shall also be provided.

The Group shall organise the drafting of the report, and may select and manage a document Editor, for which initial Terms of Reference will be prepared and endorsed at the Kick-Off meeting. The Group will work by consensus; otherwise it may choose its own operational methods. It shall provide progress reports to the CEN/ISSS Forum and ICT Standards Board.

The selection and appointment of one paid editor shall be made under CEN/ISSS rules.

The Group will be disbanded on completion of its final report.

A.6 Expected deliverable(s)

Report containing proposals and priorities for e-Health standardization activities in connection with the eEurope 2005 Action Plan.

A.7 Appendix 1 to Terms of Reference

Ministerial Declaration
Brussels, 22 May 2003

Ministers of EU Member States, Acceding and Associated countries, as well as EFTA countries met on 22nd May 2003 in the framework of the *e-Health* 2003 conference organised jointly by the European Commission and the Greek Presidency of the Council.

e-Health refers to the use of modern information and communication technologies to meet needs of citizens, patients, healthcare professionals, healthcare providers, as well as policy makers.

On this occasion, Ministers expressed their commitment to the development of national and regional *e-Health* implementation plans as an integral part of *e*Europe 2005. Ministers declared their willingness to work together towards best practices in the use of Information and Communication Technologies (ICT) as tools for enhancing health promotion and health protection, as well as quality, accessibility and efficiency in all aspects of healthcare delivery.

Ministers welcomed the e-Health Conference initiative of the Greek Presidency working in close collaboration with both the public health and information society directorates of the European Commission.

Promoting quality of and enhancing efficiency in health care through e-Health applications

The ministers recognised that efficient national planning and evaluation of health policy, as well as cost effective delivery of health care, require speedy, accurate and comprehensive exchange of data.

Ministers noted that the accessibility to appropriate health information can be enhanced through the use of secure shared e-Health applications, such as those described in the objectives of the eEurope 2005 Action Plan [3], and agreed in the Council's Resolution of 18 February 2003 on the implementation of the eEurope 2005 Action Plan.

Ministers reiterated their commitment to the developing of an information system for the early warning, detection and surveillance of health threats, both on communicable diseases and on non-communicable diseases.

The ministers acknowledged that *e-Health* applications can enhance efficiency and bring added value to health care by avoiding duplicate or unnecessary diagnostic or therapeutic interventions, by supporting the continuity of care, by improving communication between healthcare establishments and by widening access to health knowledge and evidence-based medicine.

Ministers welcomed the initiative on the European Health Insurance Card announced at the Barcelona Council and endorsed by the Seville Council as part of the eEurope 2005 Action Plan. Ministers encouraged the Commission to explore further initiatives in developing European Electronic Health Cards also taking into account the recent Communication from the Commission (COM (2003)73) on the European Health Insurance Card.

A.7.1 Facilitating citizen involvement through access to high quality information.

The Ministers shared the view that citizens' needs must be at the centre of attention in the development of high quality health related information services. Ministers noted the

potential for citizen empowerment through widespread availability of high quality appropriate health information on the internet. Ministers welcomed the Commission Communication on Quality Criteria for Health related Websites [22] and encouraged the Commission to explore the possibilities of EU level Quality Seals.

The ministers expressed concern about the possible exclusion of sectors in society that do not enjoy easy access to the internet. Ministers acknowledged the need to widen the provision of public access points to the internet to facilitate wide citizen accessibility to appropriate health related information. Ministers noted that such access points and publicly supported health related websites should comply with guidelines on Web Accessibility [30].

A.7.2 Implementing and sharing best practices of *e-Health*

Ministers agreed to share experiences on the utilisation, efficiency and impact of *e-Health* applications, and to assist the Commission in further dissemination of information on best *e-Health* practices.

Ministers supported concerted actions to address particularly the development of standards enabling interoperability of diverse systems and services and to especially explore the possibilities of open source applications for achieving this objective.

Ministers took note of the best practices in the utilisation of *e-Health* technologies identified and presented at the conference and agreed to explore further how best to use them within their countries, across Europe and internationally. Ministers invited the Commission to further refine and develop assessment methodologies for *e-Health* ICT applications.

A.7.3 Looking to the future

The ministers recognised that full exploitation of e-Health goes beyond local information systems and Internet based provision of information to integrated or linked e-Health systems, that serve the needs of citizens, patients, healthcare professionals, health service providers as well as policy makers.

Ministers welcomed the Commission's initiative to explore the possibilities to promote co-ordination at a European level, in order to meet the targets and objectives laid down in the eEurope 2005 Action Plan and the Programme of Community Action in the Field of Public Health (2003-2008), and liaising with other Community initiatives as appropriate.

Ministers encouraged Member States, Acceding and Associated countries as well as EFTA countries, to take, as appropriate, effective legislative, executive, administrative and other measures, to promote the adoption and use of e-Health applications.

Ministers noted that the full exploitation of the benefits of e-Health technologies requires continued commitment to the development and use of a robust, secure and interoperable infrastructure, as well as to wide availability and use of broadband communications to maximise the efficiency of e-Health systems and applications. Ministers acknowledged the importance of continued commitment to the implementation of e-Health applications, as agreed to by the Heads of State through the eEurope 2002 Action Plan and noted that benchmarking of such implementation will be carried out under the eEurope 2005 Action Plan.

Ministers encouraged the continued investment in research and technological development [40], ensuring steady advancement of European e-Health technology applications that meet European demands for confidentiality [41], data security and interoperability.

Ministers noted the successful collaboration on issues related to e-Health with the World Health Organisation, the Council of Europe and the OECD and encouraged its further continuation.

Ministers welcomed the initiative of the Irish Government to take stock of further e-Health developments at the second e-Health Conference in 2004.

Annex B

Membership

Membership of the Focus Group was open to all who wished to join. The members were:

Pantelis	ANGELIDIS	VIDAVO
Olivier	BAILLE	XR-Partner
Jos	BAPTIST	NICTIZ (National ICT Institute for Healthcare in The Netherlands)
Cristina	BESCOS	Telemedicine Alliance (ESA, WHO, ITU)
Johan	BEUN	NICTIZ
Bernd	BLOBEL	University Hospital Magdeburg
Timothy	BOLT	GITI, Waseda University
Karima	BOURQUARD	GMSIH
Frank	BRUGGEMANN	EMEA
Allan	BUCHANAN	Danish Standards
Hans-Peter	BURSIG	COCIR
Paul	CHESHIRE	Atos Origin
Catherine	CHRONAKI	Foundation for Research and Technology Hellas
Geert	CLAEYS	Agfa Healthcare
Pascal	COLLOTTE	European Commission - DG INFSO Unit D6
Emmanuel	CORDONNIER	ETIAM
Trevor	CROTCH-HARVEY	Innovision Research & Technology Plc
Simao	DE CAMPOS NETO	ITU
Filip	DE MEYER	RAMIT
Georges	DE MOOR	RAMIT - EUROREC
Freddy	DE VOS	EUROFER
Gemma	DELER	Applus + CTC
Hans Werner	EISERMANN	German Federal Ministry for Health and Social Security
Björn	EMANUELSSON	Swedish National Board of Health and Wellfare
Rolf	ENGELBRECHT	GSF National Research Centre
Alessandra	EPIDENDIO	UNI – TC on Health Informatics
Ramon	Farré	ERS
Roger	FRANCE	UCL Centre for Medical Informatics
George	FRASER	AXrEM
Gerard	FRERIKS	G. Freriks
Juergen	GAMBAL	ON - Austrian Standards Institute
Lorenzo	GASTON	AXALTO
Barbara	GATTI	CEN/ISSS
Dimitar	GEORGIEV	IHHII - International healthcare and Health Insurance Institute
Edgar	GLÜCK	KITH
Christoph	GOETZ	KV of Bavaria
Shirin	GOLYARDI	NEN-Healthcare
Electre	GUILLER	AFNOR
Richard	HOFBAUER	Data Systems Austria AG
Peter	JENSCH	OFFIS e.V.
Tim	JONES	National Health Service Programme for Information Technology (NHS NPfIT)

Karin	KAJBJER	SIS
Dieter	KAMPE	Das Deutsche Referenz Zentrum für die elektronische Krankengeschichte e.V.
Petko	KANTCHEV	ITU
John	KETCHELL	CEN/ISSS
Gunnar	KLEIN	Cambio Healthcare Systems
Nikolaus	KOVACS	DIN
Rose	KREMSER	FEPPD
Christophe	LAURENT	AZ Monica vzw.
Anne	LEHOUCK	EC DG ENTR D4
Cor	LOEF	Philpis Medical Systems Nederland B.V
Gwen	LYLE	US Mission to the European Union
Reinhold	MAINZ	Kassenaerztliche Bundesvereinigung (KBV)
François	MENNERAT	The EuroRec Institute
Peter	MILDENBERGER	Johannes Gutenberg - Universität Mainz
José Luis	MONTEAGUDO	PROREC SPAIN
Rob	MULDER	Philips Medical Systems Nederland B.V.
Marc	NYSSEN	Vrije Universiteit Brussel (VUB)
Torbjorn	NYSTADNES	KITH
Gerd	OCHEL	ETSI Secretariat
Heinrich	OEHLMANN	Eurodata Council
Matti	OJALA	National Research and Development Centre for Welfare and Health (STAKES)
Willem	OVERLAET	TOSHIBA
Dittmar	PADEKEN	Ministerium für Gesundheit und Sociale Sicherung
Cristiano	PAGGETTI	Medea - MEDical and Engineering Applications
Yves	PAINDAVEINE	European Commission
Charles	PARISOT	General Electric Medical Systems
Enrico	PORRI	Electro-medical Device Manufacturers Association
Freek	POSTHUMUS	NORMAPME
Joy	REARDON	Dragon Health International Ltd
Juan	REIG	PROREC SPAIN
Melvin	REYNOLDS	AMS Consulting
Jean-Marie	RODRIGUES	Université de St. Etienne
Ray	ROGERS	Dragon Health International Ltd.
Angelo	ROSSI MORI	Instituto Tecologie Biomediche, CNR (HL7 & PROPEC Italy)
Stefan	RUEEGSEGGER	SIEMENS
Pekka	RUOTSALAINEN	National Research and Development Centre for Welfare and Health (STAKES)
Anne	SALONVAARA	Finnish Standards Association
Laura	SATO	National Health Service Programme for Information Technology (NHS NPfIT)
Stefan	SAUERMANN	AKH Vienna
Karl-Heinz	SCHOPPE	IQ-Data GmbH
Stephan	SCHUG	ZTG Zentrum für Telematik im Gesundheitswesen (Centre for Health Telematics Ltd)
Juergen	SEMBRITZKI	ZTG Zentrum für Telematik im Gesundheitswesen (Centre for Health Telematics Ltd)

Mary	SHARP	The Provost Fellows and Scholard of the College of the Holy and Undivided Trinity of Queen near Dublin (T.C.D. Trinity College Dublin)
Horst	SIEBOLD	Siemens Medical Solutions
Kees	SMEDEMA	Philips Medical Systems Nederland B.V.
Benedict	STANBERRY	AVIENDA Limited
Adrian	STOKES	Independent Consultant
Horst Dieter	STRÜTER	Das Deutsche Referenz Zentrum für die elektronische Krankengeschichte e.V.
Michèle	THONNET	French Ministry of Health (eHealth department)
Manolis	TSIKNAKIS	Foundation for Research and Technology Hellas
Frans	Van Bommel	VEKTIS
Christopher	VARIAN	Kodak Health Imaging Group - EAMER
Joël	VAN Hoolandt	Atomikos
Meike	VEDDER	ZVEI - Central Association of the Electronic and Electrical Industry (Germany)
Paul	VEITHEN	AGFA Europe NV
Mario	VELOSO	CENTIS
Patricia	VILLAGE	NHS Information Authority
Peter	ZANSTRA	University Medical Centre Nijmegen

Annex C

Methodology

C.1 Overall approach

The overall approach adopted by the Focus Group was to:

- identify strategic priorities for the application of ICT to health in Europe in the period 2005 to 2010 from national, stakeholder and EU viewpoints;
- identify the priority applications which are required to achieve those strategic aims;
- identify the standards currently available (both infrastructure and application specific) which are currently available or under development;
- consider the requirements for achieving interoperability;
- undertake an analysis of strategic aims and the ICT applications and infrastructure required to fulfil them and identify issues which need to be addressed;
- establish what needs to be done and make recommendations.

C.2 Work packages

To undertake the work, five work packages (WPs) were pursued:

- WP1 identified priority applications of ICT to health as expressed in national strategies, policies or plans (or their equivalent) as well as expressed in EU policy documents;
- WP2 reviewed any known existing national and EU policies on standardization in e-Health;
- WP3 defined the priority requirements from the perspective of stakeholders;
- WP4 reviewed and classified existing standards and work programmes;
- WP5 addressed the analysis and recommendations.

Annex D

Electronic trading of healthcare goods

The notion of “healthcare goods” may encompass purchasing, distribution, and delivery of a variety of proper goods, as well as of services. Examples of these are:

- handling of prescriptions using telematics means, the so-called 'e-prescription', with its associated statistical by-products, such as a better day-to-day knowledge of reimbursement flows;
- drugs marketing on the internet as distinct from e-prescriptions: even if the actual extent of this is difficult to appraise, the marketing of pharmaceutical products, including medicines, on the Internet has become a reality notwithstanding national regulations, and the circumvention even of judicious interdictions or warnings;
- remote booking for diagnostic or therapeutic services;
- access to medical services, such as counselling, advice, and even remote consultations, often at the fringe of lawfulness or beyond, thereby creating a damaging confusion with true telemedicine;
- access to information and documentation for patients and citizens, rightly contributing to patients' empowerment.

Extensive use of telematics applications may strengthen initiatives for the containment of health expenditure without threatening, or even perhaps improving, the quality of health care.

The use of telematics in healthcare applications, which nowadays is overwhelmingly via the Internet or similar techniques (intra- or extranets, now web services, etc.), does not differ radically from applications in other domains, with however three major concerns:

- conformance to the local law and relevant regulation, including:
    - data protection, confidentiality, and privacy;
    - safety and security.

Thus, on strictly technical ground little specificity, if any, can be found in the use of telematics in health, as compared to other areas. Generic specifications and standards exist that may be used also for health care. Conversely, it is mainly in the legal area that much remains to be done: for instance, in most cases, the legal framework for the management of responsibilities still awaits clarification. Admittedly, this may in turn impact on the design details of information systems including, but not limited to, message formats to comply with specific requirements.

This seems to be currently the only area where standardization in e-trading may be necessary, with a degree of urgency which depends heavily on the moves taken or not by public authorities to better focus regulations to the evolution of the citizens' usual behaviour, and of the resulting market.

E-pharmacy currently appears as the domain where standards regarding e-trading are the most urgently needed. Otherwise the Focus Group took the view that the requirements for standards for e-Business within health care differed little, if any, from those of e-business generally. The group therefore decided not to examine this area or to make recommendations concerning it.

Annex E

Analysis of national strategies and policies on priorities for application of ICT to health

E.1 Sources of information

Ideally the Focus Group would have wished to have drawn on information on national priorities for the application of ICT to health from at least all the Member States of the EU and EFTA. However this has not been possible because:

- not all countries have a national strategy or national polices in the area of e-Health;
- it has not proved possible to gather any information from some countries;
- it has not proved possible to gather the latest information from some countries even where it is known that they have a national strategy or national policies.

Nevertheless a significant amount of information was available or gathered from:

- a questionnaire;
- EHTEL studies.

E.2.2 EHTEL studies

E.2.2.a Priorities for the application of ICT

EHTEL undertook a 2-phase study [1] [2] of the priorities for the application of ICT to health and the priorities for e-Health standards across a number of European countries.

Phase 1 comprised a baseline study to determine:

- the priority business areas for the application of ICT and for standardization;
- what international standards existed to serve those priorities.

The study was conducted by questionnaire and the main target was members of the EHTEL A1 Working Group who represent national authorities and thereby policy makers. The A1 Working group represented 12 countries and responses were received from 8. In addition a number of key individuals known to have policy making responsibilities in other countries were contacted. The overall result was authoritative responses from:

- Belgium;
- Denmark;
- England;
- Finland;
- France;
- Germany;
- Norway;
- Russia;
- Slovenia;
- Sweden.

The EHTEL A4 Working Group representing patients was also contacted and they provided a consolidated response.

Although the questionnaire was sent to over 100 suppliers only 9 responded.

Part A of the questionnaire sought views on the business areas which were priority for the application of ICT. For policy makers four areas clearly emerged above all others:

- health/patient records including the medication record;
- communications (with emphasis on e-prescriptions);
- protecting personal information (with emphasis on Public Key Infrastructure and professional data cards);
- prescribing (with emphasis on e-prescriptions).

The views of the EHTEL A4 Patients Working Group were closely aligned to that of policy makers but showed a greater emphasis on e-consulting and patient transportable records in the form of smart/data cards.

Business areas in the middle rank of priorities were:

- support for clinical processes through telemedicine;
- support for public/patients;
- support for clinical decisions;
- epidemiology/statistics;
- support for professional (web);
- hospital PACS/RIS;
- ensuring semantic meaning.

Details of the findings are in Table 1 below.

TABLE ONE

Priorities for the application of ICT to business areas from EHTEL report

Business area	**Number of times referred to as a priority**		
	Policy Makers	**EHTEL A4 WG**	**Suppliers**
Hospital processes	**XX**		**X**
- *integrating hospital systems*			
- *patient records (see later)*			
- *order communications and results reporting*			
- *patient administration*			
- *nursing*			
- *pharmacy*			
- *radiology PACS/RIS*	XX		X
- *pathology*			
- *medical device communications*			
- *human resources*			

- *finance*			
- *particular specialties*			
General Practitioner processes	**X**		
- *electronic patient record (see later)*			
- *generation of prescriptions*	X		
- *practice administration*			
- *hospital booking*			
Community processes			
- *community nursing*			
- *health visiting*			
- *midwifery*			
Dentistry			
Ophthalmic Opticians			
Pharmacy/prescribing	**XXXXXXX**		**X**
- *administration*			
- *e-prescribing*	XXXXXXX		X
- *drug distribution*	X		
- *medication management*	XX		
- *web pharmacies*			

Business area	**Number of times referred to as a priority**		
	Policy Makers	**EHTEL A4 WG**	**Suppliers**
Ambulance services			
- *administration*			
- *communications e.g. to base, to hospitals*			
Screening			
- *breast*			
- *cervical*			
Registers			
- *transplant/donors, cancer, cardiology*			
Remote clinical processes (through telemedicine)	**XXXX**	**X**	
- *radiological/images*	XX		
- *psychiatry*			
- *pathology*			
- *dermatology*			
- *tele-consulting*	XXXX	X	
- *professional tele-conferencing*			
- *telemonitoring / telecare*	XX		
- *home monitoring / homecare*	XX		
- *health & social services in primary units*	XX		
- *support patients and relatives*	X		
Health/patient records including medication record	**XXXXXXXXXXXX**	**X**	**XXXXXX**
- *EPR hospital*	XXXXXX		
- *EPR GPs*	XX		
- *multi-user EPRs*	XXXXX		XX

- *EHR / EHR birth to death*	XX	X	X
- *services for disabled and elderly*	X		
- *emergency data*			X
- *community*	X		
- *architecture / domain models*	XXX		X
- *long term preservation*	X		
Continuity of care	**X**		**XXX**
Home services and social care	**X**		
Supporting clinical decisions	**XXX**		**XX**
- *decision support systems*	XXX		
- *disease management / clinical pathways*	X		XX
- *clinical audit / QA feedback*	X		
Support for professionals through web	**XXX**		**X**
- *clinical guidelines & equivalent*			
- *clinical evidence*			
- *educational / e-learning*	XXX		X
- *knowledge management and library functions*	X		

Business area	**Number of times referred to as a priority**		
	Policy Makers	**EHTEL A4 WG**	**Suppliers**
Support for public/patients	**XXXX**		**X**
- *web content /quality*			
- *patient leaflets etc*	X		
- *access to own data*	X		
Epidemiology/statistics	**XXX**		**X**
- *hospital activity statistics / minimum data sets*	XX		X
- *population health statistics*	XX		
- *aggregated health information / health indicators*	X		
Reducing administrative costs	**X**		
Health insurance	**X**		
- *claims*	X		
Communications	**XXXXXXXXX XXX**	**X**	**XXXXX**
- *GP / hospital for on-line bed booking*	X	X	
- *GP / hospital for referrals & discharges*	XX	X	X
- *GP / specialists communications*	X		
- *GP / hospital for laboratory tests*	XX		X
- *GP / hospital images*			X
- *GP to GP communications*			X
- *physicians health letters*	XX		X
- *clinician / patient*			X
- *professional to professional communications*	X		X
- *e-prescriptions*	XXXX	X	X
- *fees / reimbursement*			XX
- *hospitals and external providers*	X		
- *hospitals / community*	X		
- *with social care*	X		

- *health network*	XXX		
Protecting personal data	**XXXXXXXXXX**	**X**	**XXXXX**
- *admin / technical measures*			
- *encryption*			
- *public key infrastructure*	XXXX	X	X
- *health professional card*	XXXXX		X
- *unique patient identification*	XX		XX
- *access rules / audit trails*	XXX		X
- *professional directories*			X
- *electronic signatures*	XXX		X
- *biometric identification*			
- *network security*	X		
- *internet / web based security for sensitive info.*	XXX		
- *legal aspects*			X

Business area	**Number of times referred to as a priority**		
	Policy Makers	**EHTEL A4 WG**	**Suppliers**
Ensuring semantic meaning	**XX**		**XX**
- *diseases*			
- *operations & procedures*			
- *comprehensive clinical terms e.g. SNOMED CT*	X		X
- *medicinal products*			
- *ambulatory care*			
Technical aspects/technologies			
Messaging technical	**X**		**X**
- *HL7*			X
- *EDIFACT*			
- *XML and ebXML*	X		X
Domain/reference models/metadata	**XX**		
Multimedia workstations	**X**		
Health cards and equivalent		**X**	**X**
- *health professional card*	XXXXX		X
- *identification or entitlement*	XX		X
- *emergency data*	X		
- *medical records*	X	X	
- *prescriptions*	X		
Wireless/mobile applications	**XXXX**		
Enhancing ICT market	**X**		
Auxiliary service providers – outsourcing			**X**

E.2.2.b Priorities for standards and commitment to international standards

Part B and C of the questionnaire sought views on priorities for standards and for interoperability. Correlation would be expected with Part A concerning business area priorities for the application of ICT and that was so. The top priorities for policy makers were:

- communication/messaging mainly electronic prescribing and relationships between EDIFACT, HL7, XML, DICOM etc;
- security (dominantly Public Key Infrastructure);
- electronic health/patient records;
- semantics, classifications and coding (e.g. comprehensive clinical terms and medicinal products).

These priorities were also broadly those of the EHTEL A4 Patient Working Group.

Part D of the questionnaire sought opinions on the roles of national authorities, such as the Ministry of Health, in the area of standardization. A1 Working Group members recognised a range of roles with most emphasis on creating an EU legislature environment and sponsoring pilot implementation of standards. The CEN/TC251 national heads of delegation who were contacted placed more emphasis on sponsorship of standards development and user guides as did suppliers. The latter however placed highest priority on sponsoring interoperability pilots

Having established priority business areas for the application of ICT and for standards, the next step was to ascertain whether there are international standards to support those priorities. The EHTEL Phase 1 report contained a list of existing international standards (CEN, ISO, HL7, DICOM, IEEE, WHO).

However in the case of electronic records responses did not make clear the scope of terms like EPR, EHCR, EHR, and the most significant of the applicable standards, CEN ENV 13606, was undergoing substantial revision but nevertheless was regarded as having high potential. In the case of messaging there were many CEN and HL7 standards including for e-prescriptions and the problem was more of choice and interoperability. It was clear that many respondents were looking to HL7 Version 3 and XML for solutions. In the area of security, where the key concern was a Public Key Infrastructure and associated data cards or equivalent for professionals, the ISO standards on PKI and health cards were only then about to be published. In the context of terminological standards, there were framework and structure standards but ISO and CEN had decided not to be involved in content standards. As to a comprehensive terminology for clinical terms there is SNOMED CT, a definitive version of which was then awaited, but issues of licensing and translation were creating barriers to uptake. Several respondents identified a need for a classification for medicinal products suitable for electronic records and prescriptions: none that exist appeared fully suitable or were international.

E.2.2.c Conjoining policy makers and standards makers

In Phase 1 policy makers declared a commitment to international standards but reality demonstrated that the commitment was very weak. One reason was that the links between policy makers in ministries of health or equivalent, and international standards makers, was elusive and very indirect.

Phase 2 of the project sought to establish whether there were means for bringing together European policy makers as a group with standards makers so as to make a reality of expressions of commitments to, and legal obligations towards, international standards.

Phase 2 involved face-to-face meetings. All those seen supported a meeting between policy makers and standards makers but the value to attendees would depend on the agenda. It would need to be focused on a real, realisable objective which aligned with country priorities and undertaken to a timetable aligned with such priorities.

Possible steps, the report suggested, might cover all or some of the following:

1. Policy makers to identify the priority application area which will be pursued with standards makers. The top candidate appears to be e-prescribing including PKI and professional and patient data cards. It might be preferable to focus even further either on the e-prescription or PKI or professional and patient data cards for identification and access control/security (maybe encompassing the eEurope health insurance card/E111). Although electronic health records were a shared high priority, it was generally felt that attempting this application might be too ambitious.

2. Refine the definition of the chosen application perhaps by a high level process and information model/diagram.

3. Identify the areas which require international standards.

4. Determine what international standards exist that might suit the requirements and what new or amended standards would be necessary.

5. Create a profile of existing and proposed new standards with a view to interoperability.

6. Decide on how best to 'commission' the drafting of any new standards in a manner which would lead to international standards.

7. Decide whether funding is desirable or necessary to assist standards drafting and if so, identify the source and secure commitment.

8. Commission the drafting of new or amended standards to a timetable determined by policy makers.

9. Agree the means for testing interoperability of standards within the standards profile for the chosen application.

10. Agree the means for piloting the application utilising the standards.

11. Feed back and amend standards as appropriate.

A meeting of policy makers and standards makers could take place some time after step 3. The EU commission DG Enterprise and DG SANCO should be involved and the way the organisation integrating the Healthcare Enterprise (IHE) operates could be a model for testing interoperability.

E.3 Questionnaire results

Questionnaires returned from respondees who were asked to list the top 3 to 5 priorities for the application of ICT to health as expressed in their national strategies or policies enabled a definitive view to be obtained for the following countries: Austria, Belgium, Bulgaria, Czech Republic, Denmark, France, Germany, Netherlands, Norway, Sweden and UK. The results are summarised in the Table Two.

TABLE TWO

Priorities for the application of ICT to business areas from Questionnaires

Priority	Number of countries
Electronic patient/health records including medication	**XXXXXXXXXX**
e-Transfer of prescriptions	**XXXXXX**
e-Prescribing	**XX**
Security and data protection	**XXXXXXXX**
▪ PKI and electronic signatures	XXXXX
▪ Access control	XXXXX
▪ Patient identification	XXX
Health data messages	**XXXXXXX**
▪ Between primary care and hospitals	XXXXX
▪ Between professionals and between hospitals	XX
Data Cards	**XXXXX**
▪ Patients	XXX
▪ Professionals	XXX
▪ Health insurance card	XX
▪ Universal card reader	X
Continuity of care: health, community, social services	**XX**
Delivery highly specialised care	**X**
Quality of health information on web for public	**XXX**
Terminologies	**XXX**
▪ Care related	X
▪ Medicines labeling	X
▪ Health ontology/reference terminology	X
Electronic booking: GPs to hospitals	**X**
Data sets	**XX**
▪ Out of hours services for GPs	X
▪ Resource groupings	X
Standard architectures	**X**
Interoperability test bed	**X**

Table Two demonstrates that for the countries covered the top priorities were:

- electronic patient/health records including medication;
- security and data protection with emphasis on PKI, access control and patient identification;
- health data messages particularly between primary care and hospitals;

- data cards particularly for patients and professionals and for access control and identification.

This confirmed the results form the EHTEL reports.

E.4 Reducing clinical errors

A number of countries in the EU and elsewhere including Australia, Canada, Denmark, The Netherlands, New Zealand, Sweden, UK and USA and have published reports on the high levels of adverse incidents in hospitals [13] [14] [15] [16] [17]and elsewhere which have caused harm to patients. A priority is to reduce such events/errors and the use of ICT has been identified as a powerful means of doing so in some areas. This is particularly so for medication errors where the use of e-prescribing systems with decision support has been shown to be particularly effective

E.5 Conclusions on priorities

The top priorities for the application of ICT to health identified from national strategies and policies appear to be:

- health/patient records including medication records;
- transfer of prescriptions;
- communications between hospitals and primary care particularly results requests and reports and referrals;
- protecting personal information (e.g. using Public Key Infrastructure and professional data cards);
- reducing clinical errors (e.g. through use of e-prescribing systems with decision support).

Business areas in the middle rank of priorities appear to be:

- support for public/patients re access to quality health information;
- support for clinical processes through telemedicine;
- support for clinical decisions;
- epidemiology/statistics;
- support for professionals re access to quality health information and evidence, and for learning(e.g. web access to knowledge bases and e-learning);
- hospital imaging (e.g. PACS/RIS);
- ensuring semantic meaning.

Annex F

Analysis of EU strategies and policies on priorities for application of ICT to health

F.1 eEurope 2005

The EU Commission is actively engaged in promoting an 'eEurope'. Its first action plan eEurope 2002 ran from 2000 to 2002 and has been succeeded by eEurope 2005 [3**]**. Key targets are:

- connecting public administrations, schools, health care to broadband;
- interactive public services, accessible for all, and offered on multiple platforms;
- provide on-line health services;
- removal of obstacles to the deployment of broadband networks;
- review of legislation affecting e-business;
- creation of a Cyber Security Task Force.

Many of these targets are well in hand within the EU e.g. through Directives and individual national initiatives. In the area of e-business, legislative steps are in train in EU countries as a result of a series of EU Directives such as those for electronic signatures [26]; contracts at a distance [27] and e-commerce [28] all of which have an impact in areas of e-Health.

The Europe 2005 Action Plan [3] includes three proposed actions particular to e-Health namely:

- electronic health cards: a European health insurance card will replace paper based forms needed for health treatment in another Member State. The Commission intends to support a common approach to patient identifiers and electronic health record architecture through standardization and will support the exchange of good practices on possible additional functionalities, such as medical emergency data and secure access to personal health information;
- health information networks: by end 2005, Member States should develop health information networks between points of care (hospitals, laboratories and homes) with broadband connectivity where relevant. In parallel, the Commission intends to set up European-wide information networks of public health data and co-ordinate actions for Europe wide rapid reactions to health threats;
- online health services: by end 2005, Commission and Member States will ensure that online health services are provided to citizens (e.g. information on healthy living and illness prevention, electronic health records, teleconsultation, e-reimbursement). Some of the health and related preventative services (e.g. air and water quality online information) could be expanded to a trans-European level through the *e*TEN programme. The Commission will monitor actions taken by Member States to make health information as accessible as possible to citizens as well as initiatives to implement quality criteria for web sites.

F.2 Ministerial Declaration 22 May 2003 [4]

Ministers of EU Member States, Acceding and Associated countries, as well as EFTA countries issued a declaration after their meeting on 22nd May 2003 in the framework of the *e-Health* 2003. Below is a selection of quotations with some significant passages underlined:

- **Promoting quality of and enhancing efficiency in health care through e-Health Applications**

  The Ministers recognised that efficient national planning and evaluation of health policy, as well as cost effective delivery of health care, require speedy, accurate and comprehensive exchange of data.

  Ministers noted that the accessibility to appropriate health information can be enhanced through the use of secure shared e-Health applications, such as those described in the objectives of the eEurope 2005 Action Plan [3], and agreed in the Council's Resolution [29] of 18 February 2003 on the implementation of the eEurope 2005 Action Plan.

  Ministers reiterated their commitment to the developing of an information system for the early warning, detection and surveillance of health threats, both on communicable diseases and on non-communicable diseases.

  The Ministers acknowledged that *e-Health* applications can enhance efficiency and bring added value to health care by avoiding duplicate or unnecessary diagnostic or therapeutic interventions, by supporting the continuity of care, by improving communication between healthcare establishments and by widening access to health knowledge and evidence-based medicine.

  Ministers welcomed the initiative on the European Health Insurance Card announced at the Barcelona Council[3] and endorsed by the Seville Council as part of the eEurope 2005 Action Plan. Ministers encouraged the Commission to explore further initiatives in developing European Electronic Health Cards also taking into account the recent Communication from the Commission (COM (2003)73) [12] on the European Health Insurance Card.

- **Facilitating citizen involvement through access to high quality information**

  The Ministers shared the view that citizens' needs must be at the centre of attention in the development of high quality health related information services. Ministers noted the potential for citizen empowerment through widespread availability of high quality appropriate health information on the internet. Ministers welcomed the Commission Communication on Quality Criteria for Health related Websites [22] and encouraged the Commission to explore the possibilities of EU level Quality Seals [30]

  The Ministers expressed concern about the possible exclusion of sectors in society that do not enjoy easy access to the internet. Ministers acknowledged the need to widen the provision of public access points to the internet to facilitate wide citizen accessibility to appropriate health related information. Ministers noted that such access points and publicly supported health related websites should comply with

guidelines on Web Accessibility [30].

- **Implementing and sharing best practices of *e-Health***

  Ministers agreed to share experiences on the utilisation, efficiency and impact of *e-Health* applications, and to assist the Commission in further dissemination of information on best *e-Health* practices.

  Ministers supported concerted actions to address particularly the development of standards enabling interoperability of diverse systems and services and to especially explore the possibilities of open source applications for achieving this objective.

- **Looking to the future**

  The ministers recognised that full exploitation of e-Health goes beyond local information systems and Internet based provision of information to integrated or linked e-Health systems, that serve the needs of citizens, patients, healthcare professionals, health service providers as well as policy makers. Ministers welcomed the Commission's initiative to explore the possibilities to promote co-ordination at a European level, in order to meet the targets and objectives laid down in the eEurope 2005 Action Plan and the Programme of Community Action in the Field of Public Health (2003-2008), and liaising with other Community initiatives as appropriate.

  Ministers encouraged Member States, Acceding and Associated countries as well as EFTA countries, to take, as appropriate, effective legislative, executive, administrative and other measures, to promote the adoption and use of e-Health applications.

  Ministers noted that the full exploitation of the benefits of e-Health technologies requires continued commitment to the development and use of a robust, secure and interoperable infrastructure, as well as to wide availability and use of broadband communications to maximise the efficiency of e-Health systems and applications. Ministers acknowledged the importance of continued commitment to the implementation of e-Health applications, as agreed to by the Heads of State through the eEurope 2002 Action Plan and noted that benchmarking of such implementation will be carried out under the eEurope 2005 Action Plan.

F.3 e-Health - Making healthcare better for European Citizens: An Action Plan for an European e-Health Area COM (2004)356 [5]

eEurope has spawned a variety of initiatives within the e-Health context in order to pursue the key targets of eEurope 2005. In its latest action plan COM (2004)356 the Commission envisages a European e-Health Area "as a framework built on a wide rage of European policies and initiatives". It seeks to face the challenges of:

- rising demand for health and social services, due to an ageing population and higher income and educational levels. In particular, by 2051, close to 40% of the Union's population will be older than 65 years old [31] ;
- the increasing expectations of citizens who want the best care available, and at the same time to experience a reduction in inequalities in access to good health care;

- increasing mobility of patients [6] and health professionals [32] within a better functioning internal market;
- the need to reduce the so-called 'disease burden', and to respond to emerging disease risks (for example, new communicable diseases like SARS);
- the difficulties experienced by public authorities in matching investment in technology with investment in the complex organisational changes needed to exploit its potential;
- the need to limit occupational accidents and diseases, to reinforce well-being at work and to address new forms of work-related diseases;
- management of huge amounts of health information that need to be available securely, accessibly, and in a timely manner at the point of need, processed efficiently for administrative purposes;
- the need to provide the best possible health care under limited budgetary conditions.

Actions proposed for the period to 2010 are in the Table below with significant phrases underlined.

Action	Time	Responsibility
Issue 1: Addressing common challenges		
The Commission Communication on patient mobility [6] is presented as part of an overall strategy on health care. Work is already underway to improve information on patient mobility and mobility of health professionals at European level and is being taken forward in particular through the health systems working party under the information strand of the public health programme.	2004	Commission
By mid 2005 the Commission should produce a summary of European best practices as guidance for Member States.	Mid 2005	Commission
By end 2005, each Member State is to develop a national or regional road map for e-Health. This should focus on deploying e-Health systems, setting targets for interoperability and the use of electronic health records, and address issues such as the reimbursement of e-Health services.	End 2005	Member States
By end of 2006 Member States in collaboration with the European Commission, should identify a common approach to patient identifiers. This should take account of best practices and developments in areas such as the European Health Insurance Card and identify management for European citizens.	End 2006	Member States Commission
By end 2006, Member States, in collaboration with the European Commission, should identify	End 2006	Member States, Commission

and outline interoperability standards for health data messages and electronic health records, taking into account best practices and relevant standardization efforts.		
By end 2006, a collaborative approach should be undertaken among Member States to supporting and boosting investment in e-Health.	End 2006	Member States
By end 2007, Member States should adopt conformity testing and accreditation schemes following successful best practices.	End 2007	Member States
During the period 2004-2008, Member States should support deployment of health information networks for e-Health based on fixed and wireless broadband and mobile infrastructures and Grid technologies.	2004-2008	Member States
By end 2009, the European Commission, in collaboration with Member States, should undertake activities to: Set a baseline for a standardised European qualification for e-Health services in clinical and administrative settings. Provide framework for greater legal certainty of e-Health products and services liability within the context of existing product liability legislation. Improve information for patients, health insurance schemes and providers regarding the rules applying to the assumption of the costs of e-Health services. Promote e-Health with a view to reducing occupational accidents and illnesses as well as supporting preventive actions in the face of the emergence of new workplace risks.	End 2009	Commission Member States
Issue 2: Pilot actions: accelerating beneficial Implementation		
By end 2005, a European Union public health portal will give access to European level public health information. Health portals shall offer dedicated information on safety at work and health risks in the workplace. By end 2005, there will be a strengthening of early warning, detection, and surveillance of health threats through enhanced information and communication technologies tools.	End 2005	Commission
Promoting the use of cards in the health care sector. Adoption of implementation of an electronic *health insurance card by 2008*.	2008	Commission Member States
By end 2008, the majority of European health	End	Member States

organisations and health regions (communities, counties, districts) should be able to provide online services such as teleconsultation (second medical opinion), e-prescription, e-referral, telemonitoring and telecare.	2008	
Issue 3: Working together and monitoring practices		
In 2004, a high level e-Health forum will be established, the role of which will be to support the Commission services. It should involve all necessary stakeholders, including at national, regional, or local hospital authority levels, thereby enhancing the understanding of the Commission services with regard to the current and planned status of development of e-Health in Member States. Its task should be to follow up the various roadmaps, and to identify further actions including a strong focus on users and access for all to e-Health, as well as to develop a strong evidence basis for the case for e-Health. The work of the e-Health forum will also be closely associated with the implementation of the Community Public Health Programme.	2004	Commission
By the start of 2005, Member States, in collaboration with the European Commission, should agree on an overall approach to benchmarking in order to assess the quantitative, including economic and qualitative impacts of e-Health.	Start 2005	Member States Commission
By the end of 2005, the European Commission, with contributions from Member States, should establish an effective way of disseminating best practices and supporting actions within the European e-Health area.	End 2005	Commission Member States
An assessment of e-Health developments should be completed ahead of the second part of the World Summit to be held in Tunis in 2005.	2005	Commission Member States
During the period 2004-2008, Member States with the support of the European Commission will organise special events such as high level conferences in order to disseminate best practices.	2004-2008	Member States Commission
During the period 2004-2010, every two years, the European Commission will publish a study on the state of the art in deployment, examples of best practices, and the associated benefits of e-Health.	2004-2010	Commission

F.4 Patient mobility between countries

The EU Commission is actively engaged on a number of initiatives to support patient mobility between countries and to support the provision of health care to citizens of one country in that of another within the EU.

Whereas patients will wish to benefit from high quality health care as close to home and as quickly as possible, this may not always be practicable for example because:

- an individual is taken ill whilst on holiday or business abroad;
- the necessary treatment is not available within a reasonable time in the patient's home country;
- the necessary treatment is not available, at the necessary quality, in the patient's home country.

When patients are taken ill whilst abroad in an EU country, arrangements exist for payment of costs through the so-called E111 form and associated provisions (the E111 is to be replaced with an Electronic Health Insurance data-card). However there remains the matter of access from abroad to a patient's health records particularly where they are in electronic form residing on a web site.

Where a patient seeks treatment in an EU country other than his/her own, because of the quality and/or timeliness of services in his/her own country, a number of issues arise which the EU Commission is actively addressing [6]. That the EU provides freedom for citizens to seek health care in other Member States has been confirmed by the European Court of Justice and the latter has clarified the circumstances under which costs may be reimbursed [11]. In essence a patient may seek in another Member State:

- any non hospital care to which a patient is entitled in his/her own Member State and the patient will be reimbursed up to the level of reimbursement provided in his/her own Member State;
- any hospital care provided for which the patient has authorisation from his/her own health system. That authorisation must be given if a patient's own system cannot provide the care within medically acceptable time limits considering the patient's condition. Again, reimbursement would be at least up to the level of reimbursement which the patient would receive from his/her own health system.

The Commission has proposed a Directive on Services in the Internal Market that will clarify the authorisation of reimbursement of medical costs incurred by a patient in another Member State.

Patients are already seeking medical treatment in countries other than their own in the EU and elsewhere (e.g. India and Africa) and the practice is likely to increase.

Such mobility again raises the issues such as:

- access to a patient's electronic medical records from another country and their incorporation into, or handling within, the electronic medical record systems within the other country's healthcare provider;
- access to current prescriptions which may be held on a data base in the home country.

F.5 Health data cards

Within the EU, the intention is to replace the E111 paper form with an EU Health Insurance Card [12]. This commenced, 1 June 2004 in 13 EU countries including Belgium, Ireland, Spain, Estonia and Slovenia. Germany intends to issue a patient data card to all its citizens within the next few years and they are in extensive use in France.

It is envisaged that the EHIC will be a chip card and facilitate connection to a health insurance data base in a patient's home country. Such a data base could contain; name, address, next of kin, any unique identifying number, and perhaps basic medical information such as an emergency data set. Security might be afforded by a pin number (so called 'chip and pin' system).

The EU Commission obviously sees data cards as having a substantial role in health in the near future and far beyond a basic health insurance card.

F.6 Community action in the field of public health

In a Decision 23 September 2002 [7], the European Parliament and Council committed themselves to promoting and improving health, preventing disease, and countering potential threats to health, with a view to reducing avoidable morbidity and premature mortality and activity-impairing disability. It adopted a programme of Community action to run from 2003 to 2008. One of its strands is health information and knowledge on which a consultation paper was published March 2002 [33].

It seeks to create a health information and knowledge system as follows.

- Health information and knowledge for citizens and patients aimed at supporting the national efforts to inform the public on health issues and at making available topical health information with direct relevance to the Community dimension.
- Health information and knowledge for professional audience aimed at providing a timely, accurate and comparable description of the health situation, health determinants and health policies in the EU and candidate countries.
- Health information systems required by and supporting the application of the Community legislation are implemented to fulfil the legislative needs. These systems need to be integrated, where appropriate, into the system for the professional audience.

Part of this work will be “Defining the data and information needs, data and indicator definitions, quality development of data collection” and defining “a core dataset”.

F.7 Implications for priorities for the application of ICT to health

The above initiatives and policies imply that the following should be considered amongst the priorities for the application of ICT to health pan-EU.

- electronic health cards including health record architecture;
- Health Insurance Cards for proof of entitlement but perhaps containing an medical emergency data set and controlling access to data in a patient’s country of residence;
- promoting the use of health cards generally in the healthcare sector.
- health data messages

- management of patient identification including:
  - a common approach to patient identifiers;
  - access control and authentication.
- online services such as:
  - teleconsultation (second medical opinion);
  - e-prescription;
  - e-referral;
  - telemonitoring;
  - telecare;
- support of patient mobility;
- core data for public health.

These would need a supporting infrastructure including in particular:

- data definitions to allow “accurate and comprehensive exchange of data between Member States” including in the area of public health;
- development of “a secure and interoperable infrastructure”;
- “setting targets for interoperability”;
- “interoperability standards for health data messages and electronic health records”;
- “conformity and accreditation schemes”;
- “quality criteria for health related websites and possibly EU level Quality Seals”.

Annex G

Structure and work of key standardization bodies

This Annex considers in detail the work and structure of a number of key standardization bodies. A full classified list of standards is available in Annex H. It is obvious that national initiatives to introduce interoperability will not be able thoroughly to review this high number of standards as a whole let alone be conformant. This constitutes a major barrier for interoperability.

G.1 CEN/TC251 “Health Informatics”

CEN/TC251 is the sectoral Technical Committee of CEN for Health Informatics. It was instituted in 1990 with the first immediate aim of transferring into the corpus of European standards the biggest possible part of the technical specifications resulting from Health Telematics "pre-competitive" projects co-funded by the European Commission DG-XIII (now DG-INFSO) through the successive Framework Programmes for Research and Development, or at least those that remained in the public domain. Subsequently CEN/TC251 addressed a variety of other relevant work items. To date, CEN/TC251 has produced over 50 technical documents (standards, pre-standards, and reports).

Starting in 1989, the then DG-XIII had subsidised several projects within the "Advanced Informatics in Medicine" programmes (AIM-0, and AIM-1). Part of the specifications delivered as the outcome of these projects were left in the public domain, and the interest of all contributing parties proved that they could be made openly available to all interested parties, particularly to the industry. During this first phase, CEN/TC251 produced no full standard, but pre-standards (and CEN reports) only. Later, with the revision of these pre-standards, full standards began to emerge. European pre-standards (now known as Technical specifications) are only valid for three years before they are revised. They do not override national documents dealing with similar subjects. Therefore, they were regarded as purely indicative, and without any constraining value. Conversely, full European standards are systematically incorporated within the corpus of national standards of Members States, and they definitely supersede any similar work taking place at the national level. The resulting flow of publications has been impressive: leaving apart a number of many valuable strategic studies: 25 pre-standards (including 2 multiple-part), and 4 CEN reports.

In a second phase, CEN/TC251 has addressed entirely new issues responding to new needs appearing due to the starting implementation of computerised information systems in the domain of health care. During that second phase, however, 1 standard, 12 pre-standards, now technical specifications (including 6 multiple-part), and 4 CEN Reports have been published so far.

Until 1997, the topics (work items) addressed were spread between 7 working groups, then reduced to 4:

WG-I	Information Models
WG-II	Terminology and knowledge representation
WG-III	Security, safety and quality
WG-IV	Technology for interoperability

From the beginning, the methodology used in CEN/TC251 based the development of messages on preliminary modelling. Progressively, however, the need to relate specific domain models within a generic Reference Information Model arose, and this has been achieved within HL7 with its development of the Reference Information Model (RIM).

CEN/TC251 has established a Memorandum of Understanding with HL7, in order to foster collaboration and harmonisation between the approaches of both organisations.

Published CEN/TC 251 standard documents:

EN 1064:2004	Health informatics - Standard communication protocol - Computer-assisted electrocardiography
ENV 1068:1993	Medical informatics - Healthcare information interchange - Registration of coding schemes
CR 1350:1993	Investigation of syntaxes for existing interchange formats to be used in health care
ENV 1613:1995	Medical informatics - Messages for exchange of laboratory information
ENV 1614:1995	Healthcare informatics - Structure for nomenclature, classification, and coding of properties in clinical laboratory sciences
EN 1828:2002	Health informatics - Categorial structure for classifications and coding systems of surgical procedures
ENV 12017:1997	Medical Informatics - Medical Informatics Vocabulary (MIVoc)
ENV 12018:1997	Identification, administrative, and common clinical data structure for Intermittently Connected Devices used in healthcare (including machine readable cards)
EN 12052:2004	Health informatics - Medical Imaging Communication (MEDICOM)
CR 12069:1995	Profiles for medical image interchange
CR 12161:1995	A method for defining profiles for healthcare
EN 12251:2004	Health informatics - Secure user identification for health care - Management and security of authentication by passwords
ENV 12264:1997	Medical informatics - Categorical structures of systems of concepts - Model for representation of semantics
EN 12381:2004	Health informatics - Time standards for healthcare specific problems
ENV 12388:1996	Medical Informatics - Algorithm for Digital Signature Services in Health Care
ENV 12435:1999	Medical informatics - Expression of the results of measurements in health sciences
ENV 12443:1999	Medical Informatics - Healthcare Information Framework (HIF)

ENV 12537-1:1997	Medical informatics - Registration of information objects used for EDI in healthcare - Part 1: The Register
ENV 12537-2:1997	Medical informatics - Registration of information objects used for EDI in healthcare - Part 2: Procedures for the registration of information objects used for electronic data interchange (EDI) in healthcare
ENV 12538:1997	Medical informatics - Messages for patient referral and discharge
ENV 12539:1997	Medical informatics - Request and report messages for diagnostic service departments
CR 12587:1996	Medical Informatics - Methodology for the development of healthcare messages
ENV 12610:1997	Medical informatics - Medicinal product identification
ENV 12611:1997	Medical informatics - Categorial structure of systems of concepts - Medical devices
ENV 12612:1997	Medical informatics - Messages for the exchange of healthcare administrative information
ENV 12623:1997	Medical Informatics - Media Interchange in Medical Imaging Communications (MI-MEDICOM)
CR 12700:1997	Supporting document to ENV 1613:1994 - Messages for Exchange of Laboratory Information
ENV 12922-1:1997	Medical Image Management - Part 1: Storage Commitment Service Class
ENV 12924:1997	Medical Informatics - Security Categorisation and Protection for Healthcare Information Systems
ENV 12967-1:1998	Medical informatics - Healthcare Information System Architecture (HISA) - Part 1: Healthcare Middleware Layer
ENV 13606-1:2000	Health informatics - Electronic healthcare record communication - Part 1: Extended architecture
ENV 13606-2:2000	Health informatics - Electronic healthcare record communication - Part 2: Domain term list
ENV 13606-3:2000	Health informatics - Electronic healthcare record communication - Part 3: Distribution rules
ENV 13606-4:2000	Health informatics - Electronic healthcare record communication - Part 4: Messages for the exchange of information
ENV 13607:2000	Health informatics - Messages for the exchange of information on medicine prescriptions
ENV 13608-1:2000	Health informatics - Security for healthcare communication - Part 1: Concepts and terminology
ENV 13608-2:2000	Health informatics - Security for healthcare communication - Part 2: Secure data objects

ENV 13608-3:2000	Health informatics - Security for healthcare communication - Part 3: Secure data channels
ENV 13609-2:2000	Health informatics - Messages for maintenance of supporting information in healthcare systems - Part 2: Updating of medical laboratory-specific information
CR 13694:1999	Health Informatics - Safety and Security Related Software Quality Standards for Healthcare (SSQS)
ENV 13728:2000	Health informatics - Clinical analyser interfaces to laboratory information systems
ENV 13729:2000	Health informatics - Secure user identification - Strong authentication using microprocessor cards
ENV 13730-1:2001	Health informatics - Blood transfusion related messages - Part 1: Subject of care related messages
ENV 13730-2:2002	Healthcare Informatics - Blood transfusion related messages - Part 2: Production related messages (BTR-PROD)
ENV 13734:2000	Health informatics - Vital signs information representation
ENV 13735:2000	Health informatics - Interoperability of patient connected medical devices
ENV 13939:2001	Health informatics - Medical Data Interchange: HIS/RIS-PACS and HIS/RIS - Modality Interface
ENV 13940:2001	Health Informatics - System of concepts to support continuity of care
ENV 14032:2001	Health Informatics - System of concepts to support nursing
CEN/TS 14271:2003	Health informatics - File exchange format for vital signs
CR 14300:2002	Health Informatics - Interoperability of healthcare multimedia report systems
CR 14301:2002	Health informatics - Framework for security protection of healthcare communication
CR 14302:2002	Health informatics - Framework for security requirements for intermittently connected devices
CEN/TS 14463:2003	Health informatics - A syntax to represent the content of medical classification systems (CIaML)
CEN/TS 14796:2004	Health Informatics - Data Types
EN 14484:2003	Health informatics - International transfer of personal health data covered by the EU data protection directive - High level security policy
EN 14485:2003	Health informatics - Guidance for handling personal health data in international applications in the context of the EU data protection directive
EN ISO 18104:2003	Health Informatics - Integration of a reference terminology model for nursing (ISO 18104:2003)

EN ISO 18812:2003	Health informatics - Clinical analyser interfaces to laboratory information systems - Use profiles (ISO 18812:2003)
EN ISO 21549-1:2004	Health informatics - Patient healthcard data - Part 1: General structure (ISO 21549-1:2004)
EN ISO 21549-2:2004	Health informatics - Patient healthcard data - Part 2: Common objects (ISO 21549-2:2004)
EN ISO 21549-3:2004	Health informatics - Patient healthcard data - Part 3: Limited clinical data (ISO 21549-3:2004)
EN 14720-1:2005	Health informatics - Service request and report messages – Part 1: Basic services including referral and discharge

CEN/TC 251 current projects are:

Deliverable/ Project reference CNS Candidate (Candidate Harmonised Standard - Yes/No)	**Document title**	**Current stage** Track FV CORR = Formal vote per correspondence TCA = TC approval BTA = BT approval VA = Vienna Agreement with ISO, CEN or ISO lead AC = Corrigendum
prEN 13609-1	Health informatics - Messages for maintenance of supporting information in healthcare systems - Part 1: Updating of coding schemes	Track: ENQ+FV
(prCEN/TS)	Health Informatics - Mapping of hierarchical message descriptions to XML	Track: FV CORR
prEN 13606-1	Health informatics - Electronic health record communication - Part 1: Reference model	Track: ENQ+FV
prEN 13606-2	Health informatics - Electronic health record communication - Part 2: Archetype model	Track: ENQ+FV
prEN 13606-3	Health informatics - Electronic health record communication - Part 3: Methodology for clinical domain modelling	Track: ENQ+FV
prEN 13606-4	Health informatics - Electronic health record communication - Part 4: Security	Track: ENQ+FV
prEN 13606-5	Health informatics - Electronic health record communication - Part 5: Exchange models	Track: ENQ+FV
prEN 14822-1	Health informatics - General purpose information components - Part 1: Overview	Track: ENQ+FV

prEN 14822-2	Health informatics - General purpose information components - Part 2: Non-clinical	Track: ENQ+FV
prEN 14822-3	Health informatics - General purpose information components - Part 3: Clinical	Track: ENQ+FV
CEN/TS 14822-4	Health informatics - General purpose information components - Part 4: Message Header	Track: FV CORR
prEN ISO 21549-4	Health informatics - Patient healthcard data - Part 4: Extended clinical data	Track: ENQ+FV (VA ISO Lead)
prEN ISO 21549-5	Health informatics - Patient healthcard data - Part 5: Identification data	Track: ENQ+FV (VA ISO Lead)
prEN ISO 21549-6	Health informatics - Patient healthcard data - Part 6: Administrative data	Track: ENQ+FV (VA ISO Lead)
prEN ISO 21549-7	Health informatics - Patient healthcard data - Part 7: Electronic prescription	Track: ENQ+FV/VA ISO
prEN ISO 21549-8	Health informatics - Patient healthcard data - Part 8: Linkage and reference data	Track: ENQ+FV/VA ISO
prEN 12967-1	Health informatics - Service Architecture - Part 1: Enterprise viewpoint	Track: ENQ+FV
prEN 12967-2	Health informatics - Service Architecture - Part 2: Information viewpoint	Track: ENQ+FV
prEN 12967-3	Health informatics - Service Architecture - Part 3: Computational viewpoint	Track: ENQ+FV
prEN 13607	Health informatics - Messages for the exchange of information on medicine prescriptions (will replace ENV 13607:2000)	Track: ENQ+FV
prEN 1614	Health Informatics - Structure for nomenclature, classification, and coding of properties in clinical laboratory sciences (will replace ENV 1614:1995)	Track: UAP
prEN 12435	Health Informatics - Expression of the results of measurements in health sciences (will replace ENV 12435:1999)	Track: UAP
prEN 12610	Health informatics - Identification of Medicinal products	Track: ENQ+FV
(prCEN/TS)	Health informatics - Categorial structure for anatomy	Track: TCA
prEN-ISO 17115	Health informatics - Vocabulary for terminological systems	Track: ENQ + FV/VA ISO
prEN 12264	Health informatics - Categorial structures for systems of concepts	Track: ENQ+FV
(prCEN/TS)	Health informatics - Clinical knowledge resources – Metadata	Track: TCA
prEN 1068	Health informatics - Registration of coding schemes	Track: UAP
prEN 14463	Health informatics - A syntax to represent the content of medical classification systems	Track: ENQ+FV
prEN 13940-1	Health Informatics - System of concepts to support continuity of care – Part 1: Basic concepts	Track: ENQ + FV

prEN 13608-1	Health informatics – Security for healthcare communication - Part 1 (will replace ENV 13608-1:2000)	Track: ENQ+FV
prEN 13608-2	Health informatics – Security for healthcare communication - Part 2 (will replace ENV 13608-2:2000)	Track: ENQ+FV
prEN 13608-3	Health informatics – Security for healthcare communication - Part 3 (will replace ENV 13608-3:2000)	Track: ENQ+FV
prEN 13729	Health informatics – Secure user identification of healthcare – Strong authentication using microprocessor cards (will replace ENV 13729:2000)	Track: ENQ+FV
prEN ISO 27799	Health informatics - Security management in health care using ISO/IEC 17799	Track: ENQ + FV/VA ISO
prCEN/TS nnnnn	Health informatics - Categorisation of risks from health informatics products (Acronym: CATRISK)	Track: FV CORR
CEN/TC 251 N 96-018 (prCEN/TS)	Health Informatics - Testing physiological measurement software - Part 1: General	Track: FV CORR
prEN 12052	Health informatics - Digital imaging - Communication, workflow and data management	Track: UAP
prEN 1064	Health informatics - Standard communication protocol - Computer-assisted electrocardiography	Track: ENQ+FV
ISO/NP 11073-20301	Health informatics - Point-of-care medical device communication - Part 20301: Application profile - Optional package, remote control	Track: ENQ+FV
prEN ISO 11073-00000	Health informatics - Point-of-care medical device communication - Part 00000: Framework and overview	Track: ENQ+FV/VA ISO
prEN ISO 11073-10101	Health informatics - Point-of-care medical device communications - Part 10101: Nomenclature (ISO/DIS 11073-10101:2003)	Track: ENQ+FV/VA ISO
prEN ISO 11073-10201	Health informatics - Point-of-care medical device communications - Part 10201: Domain information model (ISO/DIS 11073-10201:2003)	Track: ENQ+FV/VA ISO
prEN ISO 11073-20101	Health informatics - Point-of-care medical device communications - Part 20101: Application profiles - Base standard (ISO/DIS 11073-20101:2003)	Track: ENQ+FV/VA ISO
prEN ISO 11073-20202	Health informatics - Point-of-care medical device communication - Part 20202: Application profile - Baseline	Track: ENQ+FV/VA ISO
ISO/NP 11073-20201	Health informatics - Point-of-care medical device communication - Part 20201: Application profile - Polling mode	Track: ENQ+FV/VA ISO
prEN ISO 11073-30300	Health informatics - Point-of-care medical device communications - Part 30300: Transport profile - IrDA based - Infrared wireless (ISO/DIS 11073-30300:2003)	Track: ENQ+FV/VA ISO

prEN ISO 11073-30200	Health informatics - Point-of-care medical device communications - Part 30200: Transport profile - IrDA based - Cable connected (ISO/DIS 11073-30200:2003)	Track: ENQ+FV/VA ISO
CEN/ISO/IEEE 11073-10300	Health informatics - Point-of-care medical device communication - Device specialisation - Framework and overview	Track: ENQ+FV/VA ISO
CEN/ISO/IEEE 11073-10302	Health informatics - Point-of-care medical device communication - Device specialisation - Vital signs monitor	Track: ENQ+FV/VA ISO
CEN/ISO/IEEE 11073-10304	Health informatics - Point-of-care medical device communication - Device specialisation - Pulse oximeter	Track: ENQ+FV/VA ISO
CEN/ISO/IEEE 11073-10305	Health informatics - Point-of-care medical device communication - Device specialisation – Defribrillator	Track: ENQ+FV/VA ISO
CEN/ISO/IEEE 11073-10306	Health informatics - Point-of-care medical device communication - Device specialisation – ECG	Track: ENQ+FV/VA ISO
CEN/ISO/IEEE 11073-10307	Health informatics - Point-of-care medical device communication - Device specialisation - Blood pressure	Track: ENQ+FV/VA ISO
CEN/ISO/IEEE 11073-10308	Health informatics - Point-of-care medical device communication - Device specialisation – Temperature	Track: ENQ+FV/VA ISO
CEN/ISO/IEEE 11073-20102	Health informatics - Point-of-care medical device communication - Application profiles - MIB elements	Track: ENQ+FV/VA ISO

G.2 ETSI/ERM/TG30 "Wireless Medical Devices"

ETSI ERM is a "horizontal" technical committee that is responsible for the standardization of electromagnetic compatibility (EMC) and radio spectrum matters on behalf of all other technical bodies of ETSI. ETSI TC ERM is responsible for 75% of standards being developed under the Radio and Telecommunications Terminal Equipment (R&TTE) Directive (1999/5/EC). The work of ETSI ERM can be considered in three main areas: Electromagnetic Compatibility, Radio Spectrum Matters, and Task Group activities. Task Groups are set up on a short-term basis to deal with particular issues, and are disbanded on the resolution of the task.

ETSI ERM TG30 deals with Wireless medical devices.

Published standards

EN 302 195-1:2004	Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 9 kHz to 315 kHz for Ultra Low Power Active Medical Implants (ULP-AMI) and accessories; Part 1: Technical characteristics and test methods Ultra low power active medical implants operating in the frequency range of 9 kHz to 315 kHz

EN 302 195-2:2004	Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 9 kHz to 315 kHz for Ultra Low Power Active Medical Implants (ULP-AMI) and accessories; Part 2: Harmonised EN covering essential requirements of article 3.2 of the R&TTE Directive Ultra Low Power Active Medical Implants in the frequency range of 9kHz to 315kHz; Harmonised EN

Active Work Items for ERM TG30

prEN 301 839-1	Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 402 MHz to 405 MHz for Ultra Low Power Active Medical Implants and Accessories; Part 1: Technical characteristics, including electromagnetic compatibility requirements, and test methods ULP AMI in the band 402 to 405 MHz	Drafting Stage, WG approval foreseen 2005-02-11
prEN 301 839-2	Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 402 MHz to 405 MHz for Ultra Low Power Active Medical Implants and Accessories; Part 2: Harmonised EN covering essential requirements of article 3.2 of the R&TTE Directive ULP AMI in the band 402 to 405 MHz	Drafting Stage, WG approval foreseen 2005-02-11
prEN	Electromagnetic Compatibility and Radio Spectrum Matters (ERM); Radio equipment in the frequency range 30 - 37.5 MHz for Ultra Low Power Active Medical Membrane Implants and Accessories; Part 1: Technical characteristics and test methods Membrane implants	Drafting Stage, WG approval foreseen 2004-09-24
prEN	Electromagnetic Compatibility and Radio Spectrum Matters (ERM); Radio equipment in the frequency range 30 - 37.5 MHz for Ultra Low Power Active Medical Membrane Implants and Accessories; Part 2: Harmonised EN covering essential requirements of article 3.2 of the R&TTE Directive Membrane implants	Drafting Stage, WG approval foreseen 2004-09-24

G.3 ISO/TC215 "Health Informatics"

The Technical Committee "Health Informatics" of ISO was created in 1998. Its scope is defined as: "Standardization in the field of information for health, and Health Information and Communications Technology (ICT) to achieve compatibility and interoperability

between independent systems. Also, to ensure compatibility of data for comparative statistical purposes (e.g. classifications), and to reduce duplication of effort and redundancies."

The number of participating countries is 25, with 14 Observer countries. In 2004, the total number of ISO standards published under the direct responsibility of ISO/TC215 is 14. ISO/TC215 liaises with several organisations: CEN, DICOM, ICN, IMIA, UN/ECE, W3C, etc. The work of ISO/TC215 is distributed between 6 Working Groups:

WG 1 Health records and modelling co-ordination
WG 2 Messaging and communication
WG 3 Health concept representation
WG 4 Security
WG 5 Health cards
WG 6 Pharmacy and medication business

ISO/TC215 current projects are:

ISO/IEEE DIS 11073-10101	Health informatics -- Point-of-care medical device communications -- Part 10101: Nomenclature
ISO/IEEE DIS 11073-10201	Health informatics -- Point-of-care medical device communications -- Part 10201: Domain information model
ISO/IEEE DIS 11073-20101	Health informatics -- Point-of-care medical device communications -- Part 20101: Application profiles -- Base standard
ISO/IEEE DIS 11073-30200	Health informatics -- Point-of-care medical device communications -- Part 30200: Transport profile -- IrDA based -- Cable connected
ISO/IEEE DIS 11073-30300	Health informatics -- Point-of-care medical device communications -- Part 30300: Transport profile -- IrDA based -- Infrared wireless
ISO/TR 16056-1	Health informatics -- Interoperability of tele-Health systems and networks -- Part 1: Introduction and definitions
ISO/TR 16056-2	Health informatics -- Interoperability of tele-Health systems and networks -- Part 2: Real-time systems
ISO/TS 16058	Health informatics -- Interoperability of telelearning systems
ISO/AWI TS 17090-1	Health informatics -- Public key infrastructure -- Part 1: Overview of digital certificate services
ISO/AWI TS 17090-2	Health informatics -- Public key infrastructure -- Part 2: Certificate profile
ISO/AWI TS 17090-3	Health informatics -- Public key infrastructure -- Part 3: Policy management of certification authority
ISO/DIS 17113	Health informatics -- Exchange of information between healthcare information systems -- Development of messages
ISO/CD 17115	Health informatics -- Vocabulary on terminological systems
ISO/CD TR 17119	Health information modelling framework
ISO/PRF TS 17120	Health informatics -- Country identifier standards
ISO/DIS 17432	Health informatics -- Messages and communication -- Web access to DICOM persistent objects
ISO/CD 18232	Health Informatics - Messages and communication - Length limited globally unique string identifiers - Format

ISO/CD 20301	Health informatics -- Health cards -- General characteristics
ISO/CD 20302	Health informatics -- Health cards -- Numbering system and registration procedure for issuer identifiers
ISO/CD TR 20514	EHR, definition, scope and context
ISO/WD 20856	Health informatics -- Security management in health using ISO/IEC 17799
ISO/AWI 21091	Health informatics -- Directory services for security, communications and identification of professionals and patients
ISO/CD 21549-4	Health informatics -- Patient healthcard data -- Part 4: Extended clinical data
ISO/AWI 21549-5	Health informatics -- Patient healthcard data -- Part 5: Identification data
ISO/CD 21549-7	Health informatics -- Patient healthcard data -- Part 7: Electronic prescription (medication data)
ISO/WD TS 22600-1	Health informatics -- Privilege management and access control -- Part 1: Overview and policy management

G.4 DICOM

Founded in 1983 by the American College of Radiologists (ACR) and the National Electronic Manufacturers' Association (NEMA), the DICOM Standards Committee is acting as an internationally acknowledged SDO. It is now administered by the Diagnostic Imaging and Therapy Systems Division of NEMA in the USA with a solid European representation and participation of users (DRG, SFR, SIRM) as well as manufacturers (COCIR members).

Digital medical image sources, and the use of computers to process them after their acquisition, were introduced in the seventies. In 1983 the American College of Radiology (ACR) and the National Electrical Manufacturers Association (NEMA) formed a joint committee in order to standardise a method for the transmission of medical images and their associated information. In 1985 this committee published the ACR-NEMA Standards Publication No. 300-1985. Version 2.0 was published in 1988. In 1993 version 3.0 marked a major step towards a standard method of communicating digital image information. It also introduced the name DICOM (Digital Imaging and Communications in Medicine).

Since its origin, DICOM has paid much attention to establishing working relationships with other related standard initiatives throughout the world:

- ASTM for its initial version;
- the Internet protocol TCP/IP in 1993;
- CEN in the nineties (this solid co-operation resulting in a number of jointly developed supplements);
- JIRA (the Japan Industries Association of Radiological Systems) for the convergence of a Japanese interchange media format (IS&C) with DICOM;
- ANSI-HISBB in the USA, from which DICOM adopted a harmonised patient name structure;
- HL7 resulting in the creation of a joint DICOM-HL7 working group in 1999;
- ISO/TC215, with which a Type A liaison has been established in 1999, shortly after its creation. ISO/TC215 is not creating a working group for bio-medical imaging standards, but is relying instead on DICOM.

DICOM has 22 Working Groups:

WG-01 Cardiac and Vascular Information
WG-12 Ultrasound
WG-02 Projection Radiography and Angiography
WG-13 Visible Light
WG-03 Nuclear Medicine
WG-14 Security
WG-04 Compression
WG-15 Digital Mammography and CAD
WG-05 Exchange Media
WG-16 Magnetic Resonance
WG-06 Base Standard
WG-17 3D
WG-07 Radiotherapy
WG-18 Clinical Trials and Education
WG-08 Structured Reporting
WG-19 Dermatologic Standards
WG-09 Ophthalmology
WG-20 Integration of Imaging and Information Systems
WG-10 Strategic Advisory
WG-21 Computed Tomography
WG-11 Display Function Standard
WG-22 Dentistry

The current priorities for DICOM are issues relating to security, performance, new modality technology, and workflow management.

G.5 The Institute of Electrical and Electronics Engineers (IEEE)

The IEEE resulted from the merging in 1963 of the AIEE (American Institute of Electrical Engineers) and the IRE (Institute of Radio Engineers), Through its predecessors it dates back to 1884. AIEE, addressed wire communications, light and power systems, while IRE, itself resulting from the merging of two largely local organisations (the Society of Wireless and Telegraph Engineers and the Wireless Institute), addressed wireless communications.

IEEE has undertaken standardization activities in the United States via its subsidiary, the Institute of Electrical and Electronics Engineers Standards Association (IEEE-SA), which develops industry standards in a broad-range of industries, including Biomedical and Healthcare.

Collaboration exists between IEEE, CEN/TC251 and ISO/TC215. Working with ISO/TC215, and in accordance with the ISO/IEEE “Pilot Project”, international representatives can participate in ballots via ‘international co-ordination’. The votes are not binding (i.e. they are not counted in the final tally that determines the result of the ballot). A large suite of standards has been developed and published jointly by IEEE, CEN and ISO

The IEEE Standards efforts in health care are mainly two:

- IEEE 11073, Standard for Medical Device Communications: a family of documents that defines the entire seven layer communications requirements for the 2Medical Information Bus" (MIB). This is a robust, reliable communication service designed for Intensive Care Unit, Operating Room, and Emergency Room bedside devices;
- IEEE 1157, Standard for Health Data Interchange: a family of documents that define the communications models for medical data interchange between diverse systems. This effort has been called "MEDIX". The common data model being worked on by most HISB members is part of this effort.

A collaboration exists between IEEE and ISO/TC215. The ISO/IEEE standards are partitioned into layers that may be combined as necessary to provide the communications appropriate for a given device. These standards are generally broken into three key areas:

1. device data/semantics (ISO/IEEE 11073-1xxxx series);
2. general communication services (ISO/IEEE 11073-2xxxx series);
3. transports (ISO/IEEE 11073-3xxxx series).

Standards from these three primary areas may be combined as necessary to create a full 7-layer communications stack that provides plug-and-play interoperability.

ISO/TC215 has approved seven new work item proposals (NWIPs) originating in IEEE:

11073-10301	infusion devices
11073-10303	ventilators
11073-20101	application profile base standard
11073-20201	polling mode profile
11073-20202	baseline profile
11073-20301	remote control optional package (with CEN/TC251 lead)
11073-30300	infrared wireless transport

Once work is completed on these projects (with international participation) and they pass IEEE ballot (save the –20301 CEN-led project), they will proceed directly to ISO DIS ballot. Within IEEE, two additional ballots should begin very soon: P1073.2.1.1.1 Base Standard, and P1073.1.1.1 Nomenclature. Also, a new project has been approved by the IEEE Standards Board for dialysis devices: P1073.1.3.16.

G.6 The American Society for Testing Materials (ASTM)

ASTM International, formerly the American Society for Testing Materials, is one of several organisations that develop standards under ANSI, the American National Standards Institute (the official standardization body of the USA).

ASTM/E31 is the technical committee responsible for Healthcare Informatics. It has published several useful standards that have fuelled a variety of international standards.

Most recently, ASTM has balloted, and passed, a standard for the Continuity of Care Record (CCR). This is a family of XML-format messages with the original use of supporting electronic patient care referrals among healthcare providers. It is now seen as having archival value within and Electric Health Records repository. Recently, ASTM and HL7 have agreed to harmonise their CCR with the HL7 work on the Clinical Document Architecture (CDA).

G.7 Health Level Seven

HL7 (Health Level Seven, by reference to the 7 layers of the OSI model) was founded in 1987 by several vendors of software for the healthcare industry. Their goal was to develop messages consensual formats to facilitate a better interoperability of Hospital Information Systems (HIS).

In 1994, HL7 was accredited by ANSI, the American National Standards Institute (the official standardization body of the United States) as a Standards Developing Organisation (SDO), meaning that HL7 approved specifications are channelled into the official standardization process, as American National Standards.

Message specifications ('HL7 standard') Version 1.0 were approved in 1987, and were followed by version 2.0 in 1998. Subsequently, version 2 evolved regularly. It still forms the basis for the many HIS systems implemented in the USA and several European countries. An XML-based 'Clinical Document Architecture' set of specifications was approved in 2000 (Release 1). The planned successive releases of the CDA will in turn provide specifications to exchange increasingly structured clinical documents. Release 2 is currently being balloted, and Release 3 is in preparation. The CDA is meant to be used together with version 2, as well as with future messages version, and it is included in the HL7 RIM (Reference Information Model). Various other complementary works have also been approved and published over the years.

Version 3 message specifications, now being balloted, use a formal Message Development Framework methodology, using the RIM, to help make messages more consistently implemented than they are for Version 2.

Current contributors or 'Benefactors' to HL7 include vendors (Siemens, GE Medical Systems, HBOC-McKesson, IBM, Oracle, Microsoft, Philips), USA or non-USA agencies (USA Veterans Affairs), UK NHS, Centres for Disease Control and Prevention (USA CDC), Standards Australia, AFNOR (France). Public-private partnerships have also been established with Infoway (Canada), NICTIZ (The Netherlands). Other 'benefactors' include, amongst others, USA healthcare providers or health insurance funds, such as Mayo Fdn, Duke, Kaiser Permanente.

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

Versions 1x

Message specifications ('HL7 standards') Version 1.0 were approved in 1987.

Versions 2.x

Version 2 followed Version 1 in 1988. Subsequently, version 2 evolved regularly, with v2.1 approved in 1990, v2.2 in 1994, v2.2 in 1997, v2.3 in 1999, v2.4 in 2000, and v2.5 in 2003. It still forms the basis for the major HIS implemented in most countries. In 2000, XML encoding of version 2 messages has been approved.

Specifications of Versions 2.x cover:

- Patient Administration - Admission, Discharge, Transfer, and Demographics;
- Order Entry - Orders for Clinical Services and Observations, Pharmacy;
- Dietary, and Supplies;
- Query - Rules applying to queries and to their responses;
- Financial Management - Patient Accounting and Charges;
- Observation Reporting;
- Appointment Scheduling and Resources;
- Primary Care Referral Messages;
- Medical Record Information Management.

CCOW

In support of visual integration, successive versions of CCOW (Clinical Context Object Workgroup) specifications were also published, with v1.0 in 1999, v1.1 in 1999, v1.2 in 2000, and v1.3 in 2001.

The Clinical Document Architecture (CDA)

A XML-based 'Clinical Document Architecture' set of specifications was approved in 2000 (Release 1). The planned successive releases of the CDA will in turn provide specifications to exchange increasingly structured clinical documents (such as discharge summaries and progress notes). Release 2 is currently being balloted, and Release 3 is in preparation. The CDA is meant to be used together with version 2, as well as with future messages version, and it is included in the RIM.

Various other complementary works have also been approved and published over the years.

Version 3

Version 3 message specifications, currently under development with much the same scope as version 2, will use a formalised methodology, outlined in a Message Development Framework underpinned by the Reference Information Model (RIM). Therefore messages will be much more consistent than in previous versions. The RIM has now been submitted to ISO for approval as an ISO Standard.

G.8 UN/CEFACT

UN/CEFACT is the United Nations Centre for Trade Facilitation and Electronic Business. It is the organisation responsible for the standardization of a syntax in the field of EDI, as well as for the Electronic Business XML (ebXML) initiative. CEN/ISSS is the “European Entry Point” to the UN/CEFACT process. The EDIFACT standard is still widely used. UN/CEFACT has published the Core Components Technical Specification, as part of the overall ebXML framework, drawn up by a UN/CEFACT-OASIS joint initiative discussed in section 11.8.1 below. This specification is meant to be employed wherever business information is being shared or exchanged amongst and between enterprises, governmental agencies, and/or other organisations in an open and worldwide environment.

This interoperability enabling specification covers both interactive and batch exchanges of business data between applications through the use of Internet and Web based information exchanges as well as traditional Electronic Data Interchange (EDI) systems. The specification focuses both on human-readable and machine-processable representations of this information. It represents a methodology for developing a common set of semantic building blocks that represent the general types of business data in use today, and provides for the creation of new business vocabularies and restructuring of existing business vocabularies.

This specification should form the basis for standards development work of business analysts, business users and information technology specialists supplying the content of and implementing applications that will employ the UN/CEFACT Core Component Library (CCL). The Core Component Library will be stored in a UN/CEFACT repository and identified in an ebXML compliant registry.

G.9 eBusiness industry standards consortia

G.9.1 The Electronic Business XML Initiative (ebXML)

ebXML was established by the United Nations Centre for Trade Facilitation and Electronic Business (UN/CEFACT) and the Organisation for the Advancement of Structured Information Standards (OASIS – an industry standards consortium). Open to the participation of any interested parties, ebXML produced in a short time a standard framework of XML specifications for eBusiness.

Following completion of this framework, the initiative was closed, with UN/CEFACT and OASIS agreeing to progress different aspects of the standards within their separate organisations. Some of the OASIS-based specifications have recently been adopted as ISO Technical Specifications under the PAS procedure, and UN/CEFACT has also passed some of its specifications to ISO for processing.

In order to facilitate global business exchanges and to make them a reality for all users, UN/CEFACT and OASIS declared that they strongly support the development and implementation of open, interoperable, European or global standards and specifications, in effect XML specifications, to be used in a consistent and uniform manner for the exchange of all electronic business data.

To some extent, ebXML may be seen as competing with purely commercial eBusiness products, as well as with various industry consortia standardization initiatives. However,

as a global, neutral reference framework, albeit one currently incomplete, it provides more chance of longer-term market uptake than these do. On the other hand, despite availability of the basic specifications for three or more years, software packages have been slow to be produced. There is recent evidence that some Asian markets are beginning to develop implementations in given sectors.

HL7 has recently approved ebXML and web services standards as “draft standards for trial use”.

Further information may be found at http://www.ebxml.eu.org/ (a multilingual site provided by CEN/ISSS) and at http://www.ebxml.org.

G.9.2 CEN/ISSS eBusiness related activities

CEN/ISSS has activities in many of the domains related to eBusiness, both horizontal and sector-specific.

For the horizontal issues that may be relevant to e-Health, CEN/ISSS has active Workshops on eProcurement (supported by DG MARKT), eInvoicing (DG TAXUD) and ‘e’Cataloguing and Classification.

To co-ordinate all activities in a strategic sense, and to contribute at a policy level, CEN/ISSS has created a new group called the eBusiness Interoperability Forum (eBIF).

An additional new activity is seeking to overview standards issues in the context of eGovernment.

A brief description of each activity follows.

eBIF (CEN/ISSS eBIF)

eBIF has been created as a European platform for the consideration of interoperability solutions relating to eBusiness, and make strategic recommendations concerning standardization activities required to achieve this.

eBIF will examine both technical and business-related aspects of interoperability, in a comprehensive approach. Focus of the activity is Europe and its relationship with the other main players in the world on the subject (USA, Japan, China, Korea).

eBIF will not develop standards, but it will provide appropriate guidance and a strategic approach to eBusiness interoperability for the European Commission and the public and private sector.

An open group, the eBIF exploder currently has some 70 registered participants, including ICT vendors, end-users of eBusiness standards, public administrations, industry standards consortia (e.g. OASIS, RosettaNet), representatives of ISO committees, as well as of other CEN/ISSS groups). It already constitutes a centre of expertise for interoperability issues related to standards.

To the extent that e-Health interoperability issues are shared with other domains of standards, eBIF should be in a good position in future to provide advice and guidance to

e-Health practitioners, although this does not obviate any possible requirements for a dedicated strategic standards group in the e-Health area.

eGov (CEN/ISSS eGovernment Focus Group)

This newly formed Group will address the question of standards in the context of eGovernment. It is intended during 2005 to draw up a report concerning the role of standards in:

- the digital provision of services by single and multiple government or public sector agencies, at national, regional and local level, including cross-jurisdiction/cross border issues;

- the "government" of eGovernment, including how the digital provision of services is managed, quality criteria, conformance testing/certification, best practice, etc. and according to what standards and decided by whom.

Care will of course be taken to ensure that the eGOV Group does not address the specific area covered by the eHFG's activities, but simply refers to this Report.

eProcurement (CEN/ISSS WS/ePRO)

This Workshop's objective has been to promote and facilitate the use of inter-operable private and public eProcurement solutions in Europe, based on internationally recognised solutions and standards. It has provided an overview of procurement requirements from a business perspective and recommendations for further standardization activity, related to recent amendments to the EU public procurement Directives to require Member States to recognise electronic procurement. A CEN Workshop Agreement ahs been completed and is publication pending.

eInvoicing (CEN/ISSS WS/eINV)

The general objective of this Workshop as per EU/EFTA mandate M/339 concerns standardization in the domain of electronic invoices in the European Community, with the view to supporting the effective implementation of the related Council Directive 2001/115/EC of 20 December 2001 amending Directive 77/388/EC with a view to simplifying, modernising and harmonising the conditions laid down for invoicing in respect of value added tax (OJ L 15, 17.1.2002, p24) as well as regulations on electronic signatures and EDI.

The Workshop objective refers in particular to the cross-border transmission and storage of electronic invoices, rather than their content. However, since the primary role of an invoice is as a request for payment, the Workshop shall also take due account of requirements concerning payment requests as appropriate. The Workshop may also make recommendations concerning standardization of commercial invoicing issues.

eCatalogues and classification (CEN/ISSS WS/eCAT)

The Workshop deals with strategies for harmonizing electronic catalogues in a multilingual context and product description and classification systems.

The Workshop has already delivered one CEN Workshop Agreement related to Multilingual eCatalogues (CWA 15045: 2004). Work is now focused on harmonization of existing standards for product description and classification in eBusiness, and their use in eCatalogues.

Further projects are under discussion. The intention is to submit completed CWAs to ISO/TC37 for possible adoption as ISO Standards.

eBES (CEN/ISSS WS/eBES)

The eBES Workshop is a focal point within Europe for the standardization of technologies to exchange electronic business data. eBES is the 'European Entry point' for the UN-ECE/CEFACT electronic business standardization process.

Currently its main activity is to participate in the development/maintenance of the ebXML standards and to foster the use of these in Europe. Current activities encompass:

- development of core components;
- ebXML specification testing sessions (a joint interoperability test of ebXML software was recently carried out using the ETSI test infrastructure);
- organisation market surveys and awareness campaigns (a series of seminars is planned in a number of European countries);
- translation of ebXML specifications.

eBES is still involved in the maintenance of UN/EDIFACT i.e. the traditional EDI standards. Pending the full market acceptance of new standard solutions, and to avoid undue migration costs at this stage, multinational industry, governments, etc are continuing to use EDI solutions, which are known to work.

Other relevant activities

CEN/ISSS has a Workshop on Data Protection and Privacy (WS/DPP). This is seeking to standardise principally best practice for industry needing to meet the requirements of the relevant EU Directives. The Workshop has agreed a new programme for 2005/2006.

The ICT Standards Board recently established a new co-ordination function on network and information security (NISSG). Principally with CEN and ETSI participation, as well as that of relevant market players, this will provide the standards interface to the new European Network and Information Security Agency (ENISA) and co-ordinate in a strategic sense European standards activities in this domain. To the extent to which e-Health standards need to take account of the state of the art, NISSG may be a useful interface.

Annex H

Classified list of existing standards and work in progress

H.1 Acronyms and abbreviations

H.1.1 Standards development organisations (SDOs)

(Official standardization bodies, as well as dedicated consortia)

ANSI	American National Standards Institute	www.ansi.org
ASTM	The American Society for Testing and Materials	www.astm.org
CEN	Comité Européen de Normalisation	www.cenorm.be/ISSS/
CEN/TC251	Comité Européen de Normalisation Technical Committee 251 "Health Informatics"	www.centc251.org
CORBA	Common Object Request Broker Architecture	www.corba.org
DICOM	Digital Imaging and Communications in Medicine	
EBI	European Bio-Informatics Institute	www.ebi.ac.uk/
ebXML	Electronic Business using eXtensible Markup Language	www.ebxml.org
EDIFACT	Electronic Data Interchange for Administration, Commerce and Transport	
ETSI	European Telecommunications Standards Institute	www.etsi.org
HL7	Health Level 7	www.hl7.org
HIMSS	Healthcare Information and Management Systems Society	www.himss.org/
IEC	International Electrotechnical Commission	www.iec.ch
IEEE	Institute of Electrical and Electronics Engineers	www.ieee.org
ISO	International Organisation for Standardization	www.iso.org
ISO/TC215	International Organisation for Standardization Technical Committee 215 "Health Informatics"	
ITU	International Telecommunications Union	www.itu.int
NEMA	National Electrical Manufacturers Association	http://medical.nema.org
OMG	Object Management Group	www.omg.org
OASIS	Organisation for the Advancement of Structured Information Standards	www.oasis-open.org
Regenstrief Institute	Logical Observation Identifiers Names and Codes	www.regenstrief/loinc/ www.loinc.org
SNOMED	Systematised Nomenclature of Medicine	
SNOMED-RT	SNOMED Reference Terminology	
SNOMED-CT	SNOMED Clinical Terms	
UN/CEFACT	United Nations Centre for Trade Facilitation and Electronic Business	www.unece.org/cefact/
W3C	World Wide Web Consortium	www.w3.org

H.1.2 Supporting organisation and initiatives

EFMI	European Federation of Medical Informatics	www.efmi.org/
EHTEL	European Health Telematics Association	www.ehtel.org/
EuroRec	European Institute for Health Records	www.eurorec.org/
IHE	Integrating the Healthcare Enterprise	www.ihe-europe.org www.rsna.org/IHE
IMIA	International Medical Informatics Association	www.imia.org/

H.1.3 Document types

EN	European Standard	
ENV	CEN pre-standard	must be converted into an EN within 5 years, or withdrawn; now known as a Technical Specification
TS	CEN Technical Specification	a pre-standard, which must be converted into an EN within 5 years, or withdrawn
CR	CEN Report	
CWA	CEN Workshop Agreement	
TS	Technical Specification	
DTS	Draft Technical Specification	
IS	International Standard	
DIS	Draft International Standard	
FDIS	Final Draft International Standard	
TR	Technical Report	
DTR	Draft Technical Report	
WD	Working Draft	
NWI	New Work Item	
NWIP	New Work Item Proposal	
PWI	Preliminary Work Item	

H.2 Grouping of Standards and PAS

H.2.1 Infrastructural specifications

H.2.1.a Security framework

ENV 12251:1999	Health Informatics - Secure User Identification for Healthcare - Identification and Authentication by Passwords - Management and Security
ENV 12388:1996	Medical Informatics - Algorithm for Digital Signature Services in Health Care (revision to EN underway)
ENV 12924:1997	Medical Informatics - Security Categorisation and Protection for Healthcare Information Systems
ENV 13608-1:2000	Health Informatics - Security for healthcare communication -

	Part 1: Concepts and terminology
ENV 13608-2:1999	Health Informatics - Security for healthcare communication - Part 2: Secure data objects
ENV 13608-3:1999	Health Informatics - Security for healthcare communication - Part 3: Secure data channels
CR 13694:1999	CEN Report: Health Informatics - Safety and security related software quality standards for healthcare
ENV 13729:2000	Health Informatics - Secure user identification - Strong authentication using microprocessor cards
CR 14301:2002	CEN Report: Health Informatics - Framework for security protection of health care communication
CR 14302:2002	CEN Report: Health Informatics - Framework for security requirements for intermittently connected devices
EN 14485:2002	Health Informatics - Guidance for handling personal health data in international applications in the context of the EU Data Protection Directive
EN 14484:2002	Health Informatics - International transfer of personal health data covered by the EU Data Protection Directive - High level security policy
CR	CEN Report: Health Informatics - Framework for formal modelling of healthcare security policies
CTS WD	Health Informatics - Security requirements for intermittently connected devices
CR	CEN Report: Health Informatics - Safety procedures for identification of patients and related objects
CTS WD	Health Informatics - Accountability and audit trail mechanism for healthcare information systems
CTS WD	Anonymity user requirements for trusted anonymisation facilities
CTS WD	Access control policy bridging
CEN NWI	Formal security policy modelling
CTS WD	Risk assessment procedures
ISO/TS 17090-1:2002	Public key infrastructure - Part 1: Framework and overview
ISO/TS 17090-2:2002	Public key infrastructure - Part 2: Certificate profile
ISO/TS 17090-3:2002	Public key infrastructure - Part 3: Policy management of certification authority
ISO/TR 21089:2004	Trusted end-to-end information flows
ISO PWI TS 22600	Privilege management and access control
ISO 22857:2004	Guidelines on data protection to facilitate trans-border flow of personal health information
ISO NWIP TS	Security requirements for archiving and backup - Part 1: Archiving of health records
ISO PWI	Framework for health information security

H.2.1.b Security token

H.2.1.c Patients' and professionals' cards

ENV 1387:1996	Machine readable cards - Health care applications - Cards: General characteristics
ENV 1867:1997	Machine readable cards - Health care applications - Numbering system and registration procedure for issuer identifiers
ENV 12018:1997	Health Informatics - Identification, administrative and common clinical data structure for Intermittently Connected Devices used in health care (including machine readable cards)
ENV 13735:2000	Health Informatics - Interoperability of patient connected medical device
ISO WD 20301:2001	Health Informatics - Health cards - general characteristics
ISO WD 20302:2001	Health Informatics - Health cards - numbering system and registration procedure for issuer identifiers
ISO 21549-1:2004	Health Informatics - Patient health card data - Part 1: General structure
ISO 21549-2:2004	Health Informatics - Patient health card data - Part 2: Common objects
ISO 21549-3:2004	Health Informatics - Patient health card data - Part 3: Limited clinical data
ISO WD 21549-7	Health Informatics - Patient health card data - Part 7: Electronic prescription
ISO PWI 21549-8	Health Informatics - Patient health card data - Part 8: Links

H.2.1.d Time-Triggered Protocol services

H.2.1.e Directory services

ISO NWIP TS 21091	Directory services for communications and identification of professional and patient

H.2.1.f Collaboration framework

ISO 6523-1:1998	Information technology — Structure for the identification of organisations and organisation parts — Part 1: Identification of organisation identification schemes
ISO 6523-2:1998	Information technology — Structure for the identification of organisations and organisation parts — Part 2: Registration of organisation identification schemes
EN 12443:1999	Medical Informatics – Health care Information Framework (HIF)
ENV 12967-1:1998	Medical Informatics – Health care Information System Architecture (HISA)- Part 1: Health care Middleware layer
prEN 12967-1:2004	Health Informatics — Service architecture (HISA) — Part 1: Enterprise viewpoint
prEN 12967-2:2004	Health Informatics — Service architecture (HISA) — Part 2: Information viewpoint

prEN 12967-3:2004	Health Informatics — Service architecture (HISA) — Part 3: Computational viewpoint
CR	CEN Report: Health Informatics - Quality of service requirements for health care information interchange
ENV 13939:2001	Health Informatics - Medical data interchange: HIS/RIS-PACS and HIS/RIS - Modality Interface
ENV 13940:2000	Health Informatics - System of concepts to support continuity of care
CR 14300:2002	Health Informatics - Interoperability of health care multimedia report systems
ISO 6523-1:1998	Information technology -- Structure for the identification of organisations and organisation parts -- Part 1: Identification of organisation identification schemes
ISO 6523-2:1998	Information technology -- Structure for the identification of organisations and organisation parts -- Part 2: Registration of organisation identification schemes

H.2.1.g Requirements specifications

CR	Health Informatics - Quality of service requirements for healthcare information interchange

H.2.1.h Modelling and methodology

ISO HL7 NWI	Reference Information Model (RIM)
CR 12161:1995	CEN Report: Health Informatics - A method for defining profiles for healthcare
CR	CEN Report: Health Informatics - General domain model
CR 12587:1996	CEN Report: Medical Informatics - Methodology for the development of healthcare messages
ENV 12611:1997	Categorial structure of systems of concepts - medical devices

H.2.1.i Classifications, coding schemes, vocabularies

prEN 1068:2004	Health Informatics - Registration of coding schemes
ISO 1087-1:2000	Terminology work -- Vocabulary — Part 1: Theory and application
ISO 1087-2:2000	Terminology work -- Vocabulary — Part 2: Computer applications
ENV 1614:1995	Health Informatics - Structure for nomenclature, classification and coding of properties in clinical laboratory sciences
EN 1828:2002	Health Informatics - Categorial structures for surgical procedures
ISO DIS 10241:1992	International Terminology Standards - Preparation and Layout *(currently under revision)*
prEN 12264:2004	Medical Informatics — Categorial Structures of System of Concepts — Model for the Representation of Semantics
ENV 14032	Health Informatics - System of concepts to support nursing
CR	CEN Report: Health Informatics - Vocabulary - Maintenance Procedure for a web-based terms and concepts database
CEN/TS 14463:2002	Health Informatics - A syntax to represent the content of

	medical classification systems (ClaML)
ENV WD	Health Informatics - Clinical knowledge resources – Metadata
ENV WD	Health Informatics - Categorial structure for anatomy
CTS WD	Health Informatics - Categorial structure for documentation of patient findings and problems
CR WD	CEN Report: Health Informatics - Categorial structure for representation of conditions in classifications, coding systems and clinical terminologies
ENV NWI	Health Informatics - Categorial structure for a concept system for imaging procedures
ENV NWI	Health Informatics - System of semantic links in medicine
ISO WD 17115	Vocabulary of terminological systems
ISO/TS 17117:2002	Health Informatics - Controlled health terminology - Structure and high level indicators
ISO 18104:2003	Health Informatics - Integration of a reference terminology model for nursing
ISO PWI	Health Informatics - Terminology expressions in clinical data
ISO PWI	Distribution formats for terminology
ISO PWI	Semantics of terminology
CAP - College of American Pathologists	SNOMED RT - SNOMED Reference Terminology
CAP - College of American Pathologists	SNOMED CT - SNOMED Clinical Terms
Regenstrief Institute	LOINC - Logical Observation Identifiers Names and Codes (primarily pathology)
WHO	ICD 10 International Classification of Diseases - 10th Revision
WHO	ICF International Classification of Functioning, Disability and Health
WHO	International Non-proprietary Drug Names
WHO	ATC - Anatomical, Therapeutic, Chemical classification
WHO	ICMP – International Classification of Medical Procedures
International Council of Nurses	ICNP – International Classification of Nursing Practice
American Psychiatric Association	DSM-IV – Diagnostic and Statistical Manual of Mental Disorders
WONCA / WHO-FIC	ICPC-2 International Classification of Primary Care – 2nd revision

H.2.1.j Data type specifications, message and document formats

CR 1350:1993	CEN Report: Investigation of syntaxes for existing interchange formats to be used in healthcare
ENV 1613:1995	Medical Informatics - Messages for exchange of laboratory information
CR 12700:1997	CEN Report: Supporting document to ENV 1613:1995 - Messages for Exchange of Laboratory Information
prEN 1613:2004	Medical Informatics — Messages for exchange of laboratory information.
ENV 12018:1997	Identification, administrative and common clinical data

	structure for Intermittently Connected Devices used in healthcare (including machine readable cards)
ENV 12381:1996	Health Informatics - Time standards for health care specific problems
ENV 12435:1999	Medical Informatics - Expression of the results of measurements in health sciences
ENV 12537-1:1997	Medical Informatics - Registration of information objects used for EDI in healthcare - Part 1: The Register
ENV 12537-2:1997	Medical Informatics - Registration of information objects used for EDI in healthcare - Part 2: Procedures for the registration of information objects used for electronic data interchange (EDI) in healthcare
ENV 12538:1997	Medical Informatics - Messages for patient referral and discharge
ENV 12539:1997	Medical Informatics - Request and report messages for diagnostic service departments
ENV 12612:1997	Medical Informatics - Messages for the exchange of health care administrative information
CR 13058:1997	CEN Report: Health Informatics - Medical data interchange - Mapping between the models specified in ENV 12539:1997 and NEMA PS3 Supplement 10
ENV 13609-1:2000	Health Informatics - Messages for maintenance of supporting information in healthcare systems – Part 1: Updating of coding schemes
ENV 13609-2:2000	Health Informatics - Messages for maintenance of supporting information in healthcare systems - Part 2: Updating of medical laboratory-specific information
ENV 13730-1:2001	Health Informatics - Blood transfusion related messages - Part 1: Patient related messages
ENV 13730-2:2002	Health Informatics - Blood transfusion related messages - Part 2: Product related messages
ENV 13734:2000	Health Informatics - Vital signs information representation
CTS	File exchange format for vital signs
CR 14300:2001	Interoperability of healthcare multimedia report systems
EN 14822-1:2004	Health Informatics — General Purpose Information Components — Part 1: Overview
EN 14822-2:2004	Health Informatics — General Purpose Information Components — Part 2: Non clinical
EN 14822-3:2004	Health Informatics — General Purpose Information Components — Part 3: Clinical
prEN 14822-3:2004	Health Informatics — General Purpose Information Components — Part 4: Message headers
CEN NWI	Health Informatics — Mapping of hierarchical message descriptions to XML
ISO NWIP	Health Informatics — Framework for emergency data sets
ISO NWIP TR 16056-1	Health Informatics — Interoperability of tele-Health systems and networks - Part 1: Introduction and definitions
ISO NWIP TR 16056-2	Health Informatics — Interoperability of tele-Health systems and networks - Part 2: Real-time systems
ISO DIS 17113:2001	Method for development of messages
ISO/TR 18307:2001	Health Informatics — Interoperability and compatibility in

	messaging and communication standards — Key characteristics
ISO PWI Standard 21090	Health Informatics — Data types for use in healthcare data interchange
ISO PWI TR 22599	Processes for developing and implementing a messaging standard
IEEE 1157	Draft Standard for Healthcare Data Interchange - Overview and framework
IEEE 1157.1	Draft Standard for Healthcare Data Interchange - Information model methods
IEEE 1157.1.1	Draft Standard for Healthcare Data Interchange - Common healthcare objects
IEEE 1157.1.2	Draft Standard for Healthcare Data Interchange - Registration - Admission/Discharge/Transfer
IEEE 1157.1.3	Draft Standard for Healthcare Data Interchange - Laboratory IEEE 1157.2 Standard for healthcare data interchange - interchange format methods
IEEE 1157.2.1	Standard for healthcare data interchange - EDI/EDIFACT interchange formats
IEEE 1157.2.2	Standard for healthcare data interchange - ODA/ODIF/SGML interchange formats
IEEE 1157.2.3	Standard for healthcare data interchange - CMIS/CMIP interchange formats
IEEE 1157.3	Standard for healthcare data interchange - Communication profile methods
IEEE 1157.4	Standard for healthcare data interchange - semantics and knowledge representation of the medical record
IEEE 1157.5	Recommendations for healthcare data interchange - user This standard has effectively been superseded by later standards.

H.3 UN/CEFACT Health care message types

UN/CEFACT has produced message types for health care, such as (among others) MEDPID, MEDRUC, MEDRPT, and MEDREQ.
These message standards are implemented and used by several European countries.

H.4 HL7 Messaging specifications

HL7 is a consortium acting as SDO.

H.4.1 Versions 2.x

Specifications of Versions 2.x cover:

- Patient Administration - Admission, Discharge, Transfer, and Demographics;
- Order Entry - Orders for Clinical Services and Observations, Pharmacy;
- Dietary, and Supplies;
- Query - Rules applying to queries and to their responses;
- Financial Management - Patient Accounting and Charges;
- Observation Reporting;

- Appointment Scheduling and Resources;
- Primary Care Referral Messages.

H.4.2 Version 3

Version 3 message specifications, currently under development with much the same scope as version 2, will use a formalised methodology, outlined in a Message Development Framework underpinned by the Reference Information Model (RIM). Therefore messages will be much more consistent than in previous versions.

H.4.3 The Clinical Document Architecture (CDA)

The successive releases of the CDA will in turn provide specifications to exchange increasingly structured clinical documents (such as discharge summaries and progress notes). Release 2 is currently balloted, and Release 3 is in preparation.

H.5 Devices communications

EN 1064:2004	Health Informatics - Standard communication protocol - Computer-assisted electrocardiography
ISO 11073	Point-of-care - medical device communications
ISO PWI 11703-90100	Analytical instruments - Point-of-care test
ENV 12611:1997	Medical Informatics - Categorial structure of systems of concepts - Medical Devices
ISO EN 13728:1999	Health Informatics - Instrument interfaces to laboratory information systems
ENV 13735:2000	Health Informatics - Interoperability of patient connected medical devices
ENV NWI	Descriptive elements for interoperability of device data file formats and application invocation
CTS	File exchange format for vital signs
CR 14300:2001	Interoperability of healthcare multimedia report systems
CTS WD	Evaluation of physiological analysis systems
ISO 18812:2003	Health informatics - Clinical analyser interfaces to laboratory information systems - Use profiles
ASTM E1394:1997	Standard Specification for Transferring Information between Clinical Instruments and Computer Systems
IEEE 1073.1	Draft Standard for Medical Device Communications - Medical Device Data Language (MDDL) - Overview and framework
IEEE 1073.1.1	Draft Standard for Medical Device Communications - Medical Device Data Language (MDDL) - Common definitions
IEEE 1073.1.1.1	Draft Standard for Medical Device Communications - Medical Device Data Language (MDDL) - Nomenclature
IEEE 1073.1.2	Draft Standard for Medical Device Communications - Medical Device Data Language (MDDL) - Virtual medical device, Generalisations
IEEE 1073.1.2	Virtual Medical Device, Specialised - Domain Information Model

IEEE 1073.1.3.1	Draft Standard for Medical Device Communications - Medical Device Data Language (MDDL) - Medical Device Specialisations - Infusion Device
IEEE 1073.1.3.3-2001	Draft Standard for Medical Device Communications - Medical Device Data Language (MDDL) - Medical Device Specialisations - Ventilator
IEEE 1073.2-1993	Draft Standard for Medical Device Communications - Medical Device Application Profiles (MDAP) - Framework and Overview.
IEEE 1073.2-1994	Standard for Medical Device Communications - Medical Device Application Profiles (MDAP) - Base Standard.
IEEE 1073.2-1995	Standard for Medical Device Communications - Medical Device Application Profiles (MDAP) - Minimum profile
IEEE 1073.2-1996	Standard for Medical Device Communications - Medical Device Application Profiles (MDAP) - Basic profile
IEEE 1073.2-1997	Standard for Medical Device Communications - Medical Device Application Profiles (MDAP) - Extended profile
IEEE 1073.3.1-1994	Standard for Medical Device Communications - Transport profile - connection mode
IEEE 1073.3.1a-2000	Standard for Medical Device Communications - Transport profile - connection mode
IEEE 1073.3.1a-2000	Standard for Medical Device Communications - Transport profile - connection mode
IEEE 1073.3.2-2000	Standard for Medical Device Communications - Transport profile - IrDA Based - Cable Connected
IEEE 1073.4.1-2000	Standard for Medical Device Communications - Physical Layer interface - Cable connected

H.6 Imaging and multimedia communication and archiving

EN 12052:2001	Health Informatics - Digital Images - Communication, ordering and management
ENV 12539:1997	Medical Informatics - Request and report messages for diagnostic service departments
CR 13058:1997	Medical Informatics - Mapping between the models specified in ENV 12539:1997 and NEMA PS3 supplement 10
ENV 12922-1:1997	Medical Informatics - Medical Image Management - Part 1: Storage Commitment Service Class
ENV 13939:2001	Health Informatics - Medical data interchange: HIS/RIS-PACS and HIS/RIS - Modality Interface
CR 14300:2002	Health Informatics - Interoperability of healthcare multimedia report systems
ETG 068	Multimedia medical data interchange

H.7 DICOM

DICOM is a consortium acting as a SDO, administered by the Diagnostic Imaging and Therapy Systems Division of the National Electronic Manufacturers' Association (NEMA) in the USA. Its specifications are now formally accepted as *de jure* standards by ISO and CEN.

DICOM PS 3.1-2003	DIGITAL IMAGING AND COMMUNICATION IN MEDICINE (DICOM) Part 1: Introduction and Overview
DICOM PS 3.2-2003	DIGITAL IMAGING AND COMMUNICATION IN MEDICINE (DICOM) Part 2: Conformance
DICOM PS 3.3-2003	DIGITAL IMAGING AND COMMUNICATION IN MEDICINE (DICOM) Part 3: Information Object Definitions
DICOM PS 3.4-2003	DIGITAL IMAGING AND COMMUNICATION IN MEDICINE (DICOM) Part 4: Service Class Specifications
DICOM PS 3.5-2003	DIGITAL IMAGING AND COMMUNICATION IN MEDICINE (DICOM) Part 5: Data Structure and Semantics
DICOM PS 3.5-2003	DIGITAL IMAGING AND COMMUNICATION IN MEDICINE (DICOM) Part 6: Data Dictionary
DICOM PS 3.7-2003	DIGITAL IMAGING AND COMMUNICATION IN MEDICINE (DICOM) Part 7: Message Exchange
DICOM PS 3.8-2003	DIGITAL IMAGING AND COMMUNICATION IN MEDICINE (DICOM) Part 8: Network Communication Support for Message Exchange
DICOM PS 3.9-2003	DIGITAL IMAGING AND COMMUNICATION IN MEDICINE (DICOM) Part 9: Point to Point Communication Support for Message Exchange
DICOM PS 3.10-2003	DIGITAL IMAGING AND COMMUNICATION IN MEDICINE (DICOM) Part 10: Media Storage and File Format for Media Interchange
DICOM PS 3.11-2003	DIGITAL IMAGING AND COMMUNICATION IN MEDICINE (DICOM) Part 11: Media Storage Application Profiles
DICOM PS 3.12-2003	DIGITAL IMAGING AND COMMUNICATION IN MEDICINE (DICOM) Part 12: Media Formats and Physical Media for Media Interchange
DICOM PS 3.14-2003	DIGITAL IMAGING AND COMMUNICATION IN MEDICINE (DICOM) Part 14: Grayscale Standard Display Function
DICOM PS 3.15-2003	DIGITAL IMAGING AND COMMUNICATION IN MEDICINE (DICOM) Part 15: Security Profiles
DICOM PS 3.16-2003	DIGITAL IMAGING AND COMMUNICATION IN MEDICINE (DICOM) Part 16: Content Mapping Resource

H.7.1 DICOM supplements (2003)

		Status	Applies To
DICOM Supplement 1 Affects part 10	Media Storage and File Format For Media Interchange	Standard	1993
DICOM Supplement 2 Affects part 11	Media Storage Application Profiles	Standard	1993
DICOM Supplement 3 Affects part 12	Media Format and Physical Media Media Interchange	Standard	1993
DICOM Supplement 4 Affects parts 3, 4, 6	X-Ray Angiographic Image Objects and Media Storage	Standard	1993
DICOM Supplement 5 Affects parts 3, 4, 5, 6, 11	Ultrasound Application Profile, IOD and Transfer Syntax Extension	Standard	1993

DICOM Supplement 6 Affects parts 3, 4, 6	X-Ray Flouroscopic Image Object	Standard	1993
DICOM Supplement 7 Affects parts 3, 4, 6	Nuclear Medicine Image Object	Standard	1993
DICOM Supplement 8 Affects parts 3, 4, 6	Storage Commitment Service Class	Standard	1993
DICOM Supplement 9 Affects parts 2, 3, 4, 5, 6	Multi-byte Character Set Support	Standard	1993
DICOM Supplement 10 Affects parts 3, 4, 6	Basic Worklist Management - Modality	Standard	1993
DICOM Supplement 11 Affects parts 3, 4, 6	Radiotherapy Information Objects	Standard	1996
DICOM Supplement 12 Affects parts 3, 4, 6	PET Information Object	Standard	1996
DICOM Supplement 13 Affects parts 3, 4, 6	Queue Management Service Class	Standard	1996
DICOM Supplement 14 Affects parts 2, 5	Standard Extended SOP Classes and Unknown Value Representation	Standard	1996
DICOM Supplement 15 Affects parts 3, 4, 6	Visible Light Image Object	Standard	1998
DICOM Supplement 16 Affects parts 3, 4, 6	Postscript Print Management	Cancelled	
DICOM Supplement 17 Affects parts 3, 4, 6	Modality Performed Procedure Step	Standard	1996
DICOM Supplement 18 Affects parts 11	Media Storage Application Profile for CT and MR Images	Standard	1996
DICOM Supplement 19 Affects parts 11	General Purpose CD-R Image Interchange Profile	Standard	1996
DICOM Supplement 20 Affects parts 11	X-Ray Cardiac (1024) Media Application Profile	Standard	1996
DICOM Supplement 21 Affects part 11	Nuclear Medicine Media Application Profile	Cancelled	
DICOM Supplement 22 Affects parts 3, 4, 6	Presentation LUT	Standard	1996
DICOM Supplement 23 Affects parts 3, 4, 6, 10	Structured Reporting Object	Standard	1999
DICOM Supplement 24 Affects parts 3, 4, 6	Stored Print	Standard	1996
DICOM Supplement 25 Affects part 11	New Ultrasound MOD	Standard	1996
DICOM Supplement 26 Affects parts 3, 4, 16	Ultrasound OB-GYN Procedure Reports	Standard	2003
DICOM Supplement 27 Affects part 12	New 90mm and 130mm MOD Formats	Standard	1996
DICOM Supplement 28 Affects part 14	Grayscale Standard Display Function	Standard	1996
DICOM Supplement 29 Affects parts 3, 4, 6	Radiotherapy Treatment Record and Media Extensions	Standard	1998
DICOM Supplement 30 Affects parts 3, 5, 6, 11	Waveform Interchange	Standard	1999
DICOM Supplement 31	Security Enhancements	Standard	1999

Affects parts 3, 6, 7, 8, 15			
DICOM Supplement 32 Affects parts 3, 4, 6	Digital X-Ray	Standard	1998
DICOM Supplement 33 Affects parts 3, 4, 6	Softcopy Presentation State	Standard	1999
DICOM Supplement 34 Affects parts 3, 4, 6	Stored Print of Non-Preformatted Images	Cancelled	
DICOM Supplement 35 Affects parts 3, 4, 6	Retirement of Referenced Print	Standard	1998
DICOM Supplement 36 Affects parts 3, 4, 6	Codes and Controlled Terminology	Standard	1998
DICOM Supplement 37 Affects parts 3, 4, 6	Printer Configuration Retrieval	Standard	1998
DICOM Supplement 38 Affects parts 3, 4, 6	New Print Image Overlay Box	Standard	1998
DICOM Supplement 39 Affects parts 3, 4, 10	Stored Print Media Storage	Standard	1998
DICOM Supplement 40 Affects parts 11, 12	DVD-RAM Media	Standard	2000
DICOM Supplement 41 Affects parts 2, 5, 6, 15	Security Enhancements 2 - Digital Signatures	Standard	2000
DICOM Supplement 42 Affects parts 5, 6	MPEG2 Transfer Syntax	Ballot	
DICOM Supplement 43 Affects parts 3, 4, 6, 10	3D Ultrasound objects	Work	
DICOM Supplement 44 Affects parts 1, 9, 13	Retirement of Part 9,13 and OSI	Standard	2001
DICOM Supplement 45 Affects part 4	Ultrasound Staged Protocol Data Management	Standard	2003
DICOM Supplement 46 Affects parts 3, 4, 6	Basic Structured Reporting SOP Classes	Cancelled (See Supp 23)	
DICOM Supplement 47 Affects parts 3, 4, 6	Visible Light Video SOP Classes	Ballot	
DICOM Supplement 48 Affects parts 3, 4, 6, 11	Intravascular Ultrasound (IVUS)	Standard	2000
DICOM Supplement 49 Affects parts 3, 4, 6	Multiframe MR Object	Standard	2001
DICOM Supplement 50 Affects parts 3, 4, 6	Mammography CAD	Standard	2000
DICOM Supplement 51 Affects parts 3, 4, 6, 10, 11, 12	Media Security	Standard	2000
DICOM Supplement 52 Affects parts 3, 4, 6	General Purpose Worklist	Standard	2000
DICOM Supplement 53 Affects parts 3, 6, 16	DICOM Content Mapping Resource	Standard	2000
DICOM Supplement 54 Affects parts 11, 12	DICOM MIME Content-Type	Standard	2001
DICOM Supplement 55	Attribute Level Confidentiality	Standard	2001

Affects parts 3, 4, 6, 10, 11, 12			
DICOM Supplement 56 Affects parts 3, 4, 6	Ultrasound Waveform	Work	
DICOM Supplement 57 Affects parts 3, 4, 6	Revised Secondary Capture Objects	Standard	2000
DICOM Supplement 58 Affects parts 3, 4, 6	Enhanced CT Image Storage SOP Class	Standard	2003
DICOM Supplement 59 Affects parts 3, 4, 6, 16	Key Object Selection SOP Class	Standard	2000
DICOM Supplement 60 Affects parts 3, 4, 6	Hanging Protocol Object	Work	
DICOM Supplement 61 Affects parts 3, 5, 6	JPEG 2000 Transfer Syntaxes	Standard	2001
DICOM Supplement 62 Affects parts 11, 12	4.1 Gbyte MOD Medium format and use in CT/MR profiles	Standard	2001
DICOM Supplement 63 Affects parts 3, 4, 5, 6, 16	Multi-dimensional Interchange Object	Work	
DICOM Supplement 64 Affects part 2	Revised Conformance Statements	Standard	2003
DICOM Supplement 65 Affects parts 3, 4, 6, 16	Chest CAD SR SOP Class	Standard	2001
DICOM Supplement 66 Affects parts 3, 4, 6, 16	Catheterisation Lab SR SOP Classes	Standard	2003
DICOM Supplement 67 Affects parts 3, 6, 15	Configuration Management	Ballot	
DICOM Supplement 68 Affects parts 3, 4, 6	Retire Storage Commitment Pull Model	Standard	2001
DICOM Supplement 69 Affects parts 11, 12	640 MB and 1.3 GB 90mm MOD Medium format and use in USA profiles	Standard	2001
DICOM Supplement 70 Affects parts 3, 6	Clinical Trials Identification	Standard	2001
DICOM Supplement 71 Affects parts 3, 4, 16	Vascular Ultrasound Procedure Reports	Standard	2003
DICOM Supplement 72 Affects parts 3, 4, 16	Echocardiography Procedure Reports	Standard	2003
DICOM Supplement 73 Affects parts 3, 4, 6, 16	Spatial Registration Storage SOP Classes	Standard	2003
DICOM Supplement 74 Affects parts 3, 4, 6, 16	RT Worklist Extensions and Calculation Service Model	Work	
DICOM Supplement 75 Affects parts 3, 4, 6, 16	Relevant Patient Information Query Service Class	Ballot	
DICOM Supplement 76 Affects part 16	Quantitative Arteriography and Ventriculography Structured Reports	Work	
DICOM Supplement 77 Affects parts 3, 16	IVUS Structured Reporting	Comment	
DICOM Supplement 78 Affects parts 3, 16	Fetal and Pediatric Echocardiography SR	Work	
DICOM Supplement 79	Breast Imaging Report Templates	Ballot	

Affects parts 3, 16			
DICOM Supplement 80 Affects parts 11, 12	DVD Media Application Profiles	Standard	2003
DICOM Supplement 81 Affects parts 3, 4, 6	XA Non-Cine Image SOP Class	Cancelled	
DICOM Supplement 82 Affects parts 11, 12	2.3 GB 90mm MOD Medium format and use in US profiles	Standard	2003
DICOM Supplement 83 Affects parts 3, 4, 6, 11	Enhanced XA/XRF Image Storage SOP Class	Work	
DICOM Supplement 84 Affects part 3	Clarification of Ultrasound Region Calibration	Standard	2003
DICOM Supplement 85 Affects parts	Web Access to DICOM Objects (WADO)	Ballot	
DICOM Supplement 86 Affects parts 3, 16	Digital Signatures for Structured Reports	Work	
DICOM Supplement 87 Affects parts 11, 12	USB and Flash Memory Media Application Profiles	Comment	
DICOM Supplement 88 Affects parts 3, 4, 6	Media Creation Management SOP Class	Comment	
DICOM Supplement 89 Affects part 4	Worklist and Performed Procedure Step Use Cases	Work	
DICOM Supplement 90 Affects parts 2, 3, 4, 6, 7, 8	SOP Class Relationships Negotiation	Comment	
DICOM Supplement 91 Affects parts 3, 4, 6, 16	Ophthalmic Photography SOP Classes	Comment	
DICOM Supplement 92 Affects part 11	Media Application Profile for Dentistry	Comment	
DICOM Supplement 93 Affects parts 3, 4	Instance Availability Notification	Comment	

H.8 Basic services specifications

H.8.1 Identification services

ISO 6523-1:1998	Information technology — Structure for the identification of organisations and organisation parts — Part 1: Identification of organisation identification schemes
ISO 6523-2:1998	Information technology — Structure for the identification of organisations and organisation parts — Part 2: Registration of organisation identification schemes
ISO DIS 17120	Country identifier mechanism in healthcare

H.8.2 Terminology services

prEN 1068:2004	Health Informatics - Registration of coding schemes
CR	CEN Report: Health Informatics - Vocabulary - Maintenance Procedure for a web-based terms and concepts database
ENV 13609-1:2000	Health Informatics - Messages for maintenance of supporting information in healthcare systems – Part 1: Updating of coding schemes

ISO PWI	Distribution formats for terminology

H.8.3 Policy services

ISO/TS 21667:2004	Health Informatics - Health indicators conceptual framework
ISO WD TR 17119	Health Informatics - Profiling framework
ISO NWIP	Definitions, attributes and relationships

H.9 Prioritised Applications

H.9.1 Electronic health records

ENV 13606-1:1999	Health Informatics - Electronic healthcare record communication - Part 1: Extended architecture
ENV 13606-2:2000	Health Informatics - Electronic healthcare record communication - Part 2: Domain Term List
ENV 13606-3:2000	Health Informatics - Electronic healthcare record communication - Part 3: Distribution rules
ENV 13606-4:1999	Health Informatics - Electronic healthcare record communication - Part 4: Messages for the exchange of information
CR	CEN Report: Electronic Healthcare Record Communication – Domain Model
ISO/TS 18308:2004	Health Informatics — Requirements for an electronic health record architecture
ISO TR 20514:2004	Health Informatics — Electronic Health Record Definition, Scope, and Context
HL7 CDA	The Clinical Document Architecture – Release 1
prEN 13606-1:2004	Health Informatics — Electronic Health Care Record Communication Part 1: Extended Health Care Record Architecture
prEN 13606-2:2004	Health Informatics — Electronic Health Care Record Communication Part 2: Domain Term List
prEN 13606-3:2004	Health Informatics — Electronic Health Care Record Communication Part 3: Distribution Rules
prEN 13606-4:2004	Health Informatics — Electronic Health Care Record Communication Part 4: Messages for the exchange of information
prEN 13606-5:2004	Health Informatics — Electronic Health Care Record Communication Part 5: Messages for the exchange of information
prEN 13606-6:2004	Health Informatics — Electronic Health Care Record Communication Part 6: Messages for the exchange of information
ASTM E1238	Standard Specification for Transferring Clinical Observations Between Independent Computer Systems
ASTM 1394	Clinical Laboratory Instruments to Computers
ASTM E1467	Standard Specification for Transferring Digital

	Neurophysiological Data Between Independent Computer Systems
ASTM E1384	Standard Guide for Content and Structure of the Electronic Health Record

H.9.2 Medications

ENV 12610:1997	Medical Informatics - Medicinal product identification

H.9.3 ePrescription

ENV 13607:2000	Health Informatics - Messages for the exchange of information on medicine prescriptions
HL7	HL7 Messaging Standard Versions 2 and 3 (see later)

Annex I

Case Studies

This collection of case studies, assembled by NORMAPME (Normalisation association of PME (SMEs)) shows the diversity of fields where e-Health is already impacting or could impact on the healthcare sector. The cases follow the structure in Chapter 7. Each case thus covers the fields:

- improving access to clinical records;
- enabling patient mobility;
- quality of care;
- reducing clinical errors;
- improving efficiency of healthcare processes.

The case studies cover a sample of typical cases. Although many more can be imagined, they provide a good indication of opportunities (or deficiencies) within the European healthcare system and how they could be advanced by the use of e-Health solutions.

I.1 Case Study "COCOON Project" – Reduce Medical Errors

The COCOON project is an Italian project, co-financed by the EU Commission, with over 20 different partners, combining healthcare institutional bodies at regional, national and EU level as well as organisations of healthcare professionals and private companies. The project seeks to develop web-based tools to reduce medical risks by building knowledge driven and dynamically adaptive network communities within European healthcare systems.

The main objectives of the project are the reduction of deaths by preventable adverse events, reduction of disability by preventable adverse events, reduction of demands for compensation of damages, cost savings for the healthcare system of the regions involved in the project due to optimisation of resource usage, increasing the transparency of the diagnosis and treatment process for citizens as well as patients.

I.1.1 Improving access to clinical records

The project identified that poor data links between patient data, best practices and specialised centres for supporting the healthcare professional, as one of the main deficiencies of the current healthcare system. The project saw as a priority the need for linking patient data with relevant best practice, protocols and other relevant sources of information (such as hospital and specialised centres to which patients might be referred for further diagnosis, operation or treatment). An enhanced web service could be a possible solution, according to the COCOON experts.

Also the lack of interoperability between different healthcare systems is seen as a second major problem towards risk reduction. COCOON experts felt also that in this field an enhanced web service linking different healthcare system sources of information could increase the success rate of treatment.

I.1.2 Enabling patient mobility

Although patient mobility is not in the focus of the COCOON project, the experts identified several problems hindering the mobility of patients: lack of interoperability amongst different heath care system sources of information; lack of medical protocols (definition and acceptance); and weak communication amongst the community of practitioners. The proposed solutions include web-based data sharing and web-services as well as the development of relevant protocols/software/applications etc. This will allow multiple site and remote control of data.

I.1.3 Quality of care

The COCOON project also outlines the main problems leading to the increased level of medical errors and therefore affecting the quality of care in the European healthcare sector and developed solutions for those deficiencies. Problems identified were: the lack of risk management software; the lack of statistical data for risk management and applications (for delivering best practices and data sharing) as well as weak communication and weak knowledge-sharing (lack of best practice sharing) within the health sector; and poor links between patient files. The proposed solutions include web-based data sharing and web-services as well as the development of relevant protocols/software/applications etc and good access tools for the paramedical sector.

I.1.4 Reducing clinical errors

The health sector is an information-intensive area where it can be almost impossible to quickly assimilate and relay information and make decisions in time-critical situations. Most medical errors are not caused by incompetence but occur due to an overload of information within a complex and inefficient medical system. A recent study of over 1000 records in two emergency hospitals in the UK found that almost 11% of all patients experienced an adverse event, over half of which were deemed preventable according to ordinary standards of care. A recent study of the Italian Patient Right Court, showed that at least 14.000 persons die every year in Italy because of adverse events. The deaths due to medical errors occur mostly in the field of orthopaedy (16,5%), oncology (13%), gynaecology (10,8%) and general surgery (10,6%). Most errors are diagnostic errors (35%) or treatment errors (18%).

Hence, the main objective of the COCOON project is to minimise medical errors in diagnosis and treatment (reduction of deaths and disability for preventable adverse events) by supporting knowledge driven collaborative practices in networks of healthcare professionals.

I.1.5 Improving efficiency of healthcare processes

The adoption of the COCOON solution within the healthcare system in Europe could improve the efficiency and cost effectiveness of the sector, as adverse events directly affect quality of care and the number of medical errors directly impact healthcare cost levels.

Greater public awareness of clinical errors combined with rapidly increasing litigation and insurance costs has created a pressing need for proper risk management in hospitals to improve patient safety and reduce all the related costs.

Avoiding “system errors” by health professionals (which represent the vast majority of errors in medical care) could immediately cut costs, whether they be directly or indirectly related to medical errors.

I.2 Case Studies “Belgian Paramedicals”

The paramedical sector in Belgium (represented by INTERBOR) has no access to patients’ files due to privacy restrictions. Only doctors can access the patients’ files and/or exchange this information.

Today, paramedicals have to rely on the information given to them by a doctor. This strict separation tends to be based on the assumption that most paramedicals are not as well trained as doctors and could not handle patients’ files correctly. This is a simplification and could be solved by access level definition.

I.2.1 Improving access to clinical records

According to INTERBOR, the definition of the level of access and the definition of the people allowed to access the file is crucial. However in the case of emergency aid some kind of additional access via web-based patient information would increase the speed and quality of care for patients. Experts stress that access to patient files should be blocked for user groups which might abuse patient information.

I.2.2 Enabling patient mobility

Especially in the case of the emergency treatment of foreigners the long time necessary for information retrieval can be critical.

I.2.3 Quality of care

The change to a new better system from another could create more paperwork in the short term, but would reduce medical errors and improve the quality of care in the long run.

I.2.4 Reducing clinical errors

Since the communication of medical data between the paramedical and the doctor takes too long and can result in lack of information, this creates a health risk for patients.

I.2.5 Improving efficiency of healthcare processes

In Belgium there already exists an electronic billing and logistics system within the healthcare sector, which allows cost cutting within the Belgian paramedical field. The main cost saving nevertheless accrues to the big organisations and an analysis of how better to share those savings between the different players could further increase the efficiency of the system.

I.3 Case Study “Triamun Project” – e-Health Pilot Project

The Triamun project is a Swiss pilot project, combining a Swiss healthcare professional organisation and private IT companies. The project that connects patients with doctors was started in 2000 and launched in 2003. The web-based solution works like an Intranet

where patient data is stored and to which patients and doctors have access, but where the information flow is administered by the patients themselves.

I.3.1 Improving access to clinical records

The system works like an Intranet, where all patient files are stored. The patient profile is defined on the basis of name, place of living, health history, prognosis/diagnosis, etc. To gain access to the system, the user needs a login.

The patient is the owner of the files and he can allow certain doctors (single persons or organisations etc) permanent or temporary access to all or a part of his/her files (this could be done either by an intranet web-based solution, or by an application service provider solution). The authorisation is given by the patient directly dialing his login and pin code on a certain website (or with the help of his e-Health card), or at the doctors, if the doctor has an access to the internet.

All accesses are recorded through their digital signature in a specific histography file within each patient file. The patients and authorised persons have access to the histography of the file. The histography cannot be changed or deleted.

The IT administrators of the patient data within the system cannot read the data as the data are encrypted. Therefore data protection is good.

The system presently has no restrictions on the in/output of various data (patient information, information about chronicle disease, etc.), but it is technically possible to include restrictions.

I.3.2 Enabling patient mobility

The system can include many different users groups but Triamun experts think that a single Europe-wide system is not the solution but rather different central systems communicating with each other (i.e. managed by national social securities) via interoperable solutions (COCOON project, etc.).

The system is already available in English, German, French and Italian.

In order to introduce a Europe-wide e-Health system, the current bottleneck is that national systems cannot communicate with each other and cannot exchange structured data. This must be solved. Today data can, in most cases, only be ‘read’ by receiving computers but not processed, i.e. only text data can be read by both parties whereas the sending unit which is mostly smaller cannot follow the process of the data in the main computer system and is therefore dependant on the partner for getting information about the data processing.

I.3.3 Quality of care

All changes to the patient file (by persons authorised by the patient him/herself) cannot be reversed. Once data has been input it cannot be deleted from the file. On the one hand this ensures safety of the data recording and a detailed patient record, on the other hand this could cause problems in case of wrong data input.

I.3.4 Reducing clinical errors

As authorised doctors and other persons have access to patient data, the risk of medical errors due to a lack of patient data is minimised.

I.3.5 Improving efficiency of healthcare processes

As the pressure of cutting costs was rising, Swiss healthcare professionals sought for a solution to increase their productivity. This started the Triamun project. The project initiators decided that this could only be done with process integration. The solution was the development of a web-based patient file intranet.

I.4 Case Study "Swiss Medical Association"

The Swiss Medical Association FMH started in 1996 amongst other e-Health initiatives the HIN project (Health Info Net), as they identified the need for electronic data exchange as one of their priorities for the future. Today the Swiss Medical Association supports e-Health pilot projects all over the Switzerland as well as the introduction of TARMED, the national standardised tariff system, for whose participants it will be obligatory to bill electronically.

Today, the main priorities of the FMH in e-Health are quality assessment; secure data management and electronic data exchange, knowledge management and the creation of national standards. Meanwhile the public company HIN offers the leading security platform for the Swiss healthcare sector.

I.4.1 Improving access to clinical records

In 1998 the Swiss started the national project UNIT/Patientendossier 2003 trying to define a common EMR (Electronic Medical Record) for the five Swiss university hospitals, thus creating standards for information management to enable information management within and between hospitals. The project has not yet resulted in unified national standards, but the FMH e-Health experts see the result of the UNIT project in the conceptual shift from product oriented standards to interoperability between systems as a priority for the e-Health field.

Today, there are several local e-Health networks in Switzerland that take the integration of ICT as a precondition for the successful achievement of their objectives The FMH is supporting these local initiatives.

I.4.2 Enabling patient mobility

Today, the organisation of the Swiss healthcare sector is the combination of 26 healthcare systems on canton level with a multitude of national and local/regional health insurance providers. As a result patient mobility even within Switzerland is difficult.

I.4.3 Quality of care

The main importance of e-Health for the FMH expert lies in the possibility of improved quality and efficiency in health care, leading to knowledge management (generating knowledge by coupling of evidence based data and information). Through the statistical and systematic analysis of (anonymous) data (medical and/or economic), the health sector

could consequently gain and disseminate medical, epidemiological and economical knowledge. This helps statistical data treatment.

To ensure the quality of care with respect to data protection, it should be the patient that decides who has (full and/or limited) access to his/her data, counselled by his/her "physician of trust". So, data protection (especially clinical data) against unauthorised users is another priority for the FMH. This can be ensured with a proper authorisation policy (who has access to which data and when) and identification policy (identity management i.e. how to ensure that the authorised persons are well identified before getting access to the data). A practical possibility could be the use of the electronic health card for patients in combination with the electronic health professional card, both used together as an access key and to secure medical processes.

I.4.4 Reducing clinical errors

Medical errors can be minimised by better knowledge management within e-Health networks. Electronically enhanced risk management will allow better forms of clinical decision support for the overall patient process, e-prescribing being only one example.

I.4.5 Improving efficiency of healthcare processes

Through eliminating poor co-ordination of processes, redundant processes and discontinuous processes, the FMH e-Health experts see a cost saving potential of 10% to 40% of total healthcare costs. Only through interoperability and integration of all the processes including the whole patient process, can the healthcare sector be significantly optimised and new services developed.

So, the benefit of e-Health, as FMH sees it, is the possibility for both raising efficiency (by rationalisation and resource management) and rising quality of care.

I.5 Business Case “Dental Technicians”

Today, European dental technicians (represented by the FEPPD) do not have a direct link to patients, as the patient only sees a dentist, who takes measurements and prescribes a dental prosthesis. The dental technician will produce a dental prosthesis totally based on the data transmitted by the dentist.

I.5.1 Enabling patient mobility

Today, patients have the freedom to buy a new set of dental prosthesis abroad (e.g. in the new EU accession countries) or to have them repaired during their stay abroad. In order to make them fit properly the manufacture of these custom made devices (CMD) needs all the relevant data, to ensure the production of a high quality and safe medical device in terms of the Medical Devices Directive (MDD) 93/42.

I.5.2 Improving access to clinical records

Dental technicians mostly receive from dentists only limited information consisting of a written prescription and often dental imprints of the patients. Often the patient is only identified by a patient number, therefore sex, medical history or other crucial patient data are not transmitted. This lack of information is a risk for the patient.

Dentist sometimes deny dental technicians access to more patient data referring to the 'medical secret', but today manufacturers of custom made devices have to have certain information as specified under the MDD 93/42 to manufacture CMD. This information must include critical patient information in accordance with the MDD 93/42 (Annex I and VIII).

I.5.3 Quality of care

Even with limited access to patient data, the quality of care could be improved. Bad fitting, toxic reaction due to incompatible materials and allergic reactions could be minimised. However as a main interest of the patient lies in quality of care plus data protection, it should be the patient who defines the limits of stored and shared data and access levels, stresses the FEPPD expert.

I.5.4 Reducing clinical errors

Today, dental technicians do not receive information regarding possible or identified allergies of the patient. This could lead to a medical device that cannot be used by the patient, as allergies are more and more common. Knowledge about the allergic reactions of patients is therefore important because dental prosthesis could contain materials that provoke allergic reactions. Additionally, toxic reaction could occur by combining unknown materials.

A different point is the safety of dental technicians themselves. Today they receive no information about the health status of the patient regarding infectious diseases, like hepatitis, AIDS etc. Dental technicians constantly work with dental imprints, but the disinfection level of those imprints is often missing. Even limited access to such information could reduce the health risk of dental technicians (e.g. cross infections). Also, if a dental technician does not know of the use of possibly hazardous materials, allergic reactions or other damages to the health of the dental technician could occur.

I.5.5 Improving efficiency of healthcare processes

The dependency of dental technicians on the information provided by dentists and the non existing link between dental technicians and the patient leads to unusable dental prosthesis and double work.

I.6 Case Study "Emergency Aid"

Of high importance for the emergency aid specialists (represented by the Belgian emergency specialist of the EFKA and OLVM hospitals) is today the fast communication of crucial information. The format and structure of the stored data as well as the software used in future e-Health networks are of secondary interest to the emergency sector, which focuses mainly on the speed of care.

In order to smooth the functioning of such a network, information needs to have a clear transparent structure. Therefore, the information gathered and produced over the next years should be structured in such a way that it is not dependent solely on software for interpretation, but rather a stand-alone solution, indexed and categorised, to be able to run diagnostics and statistics on the whole of the information contents.

At this point in time, XML seems to be the contender that displays the largest number of possibilities concerning the application of ergonomic, economic and scientific principles in

the gathering, collecting, organising and analysis of patient related information, and its reproduction.

As examples for future e-Health systems are the national initiatives in Belgium and the Republic of Ireland, because of the experience that has already been achieved, and the information that has already been gathered, and the positive reactions that this has caused within and around the medical community.

I.6.1 Improving access to clinical records

A thorough structure and normalisation of the different possible formats of data sets (antecedents, past history/surgery, images, protocols, therapy, names of medical preparations, etc.) could ensure the interchangeability of information on European and international level. A simple format for a one page text file containing the most critical information on the patient, as well as a reference for further information (person or other) contained in pre-defined fields in the document, would outweigh the advantage of waiting for a thoroughly studied very elaborated universal forum or format for interchangeability of complete medical records. All possible e-Health solutions should contain the possibility for future enlargement of their functions.

As a very feasible option, an encoded algorithm could be used to create, and to decipher a 2D barcode, which could contain as many as 2000 letters can be printed on any surface (e.g. on the back of a ID card or health insurance card). Reading of such a barcode would only require a small software key, which could be made available online to those presenting the right ‘credentials’, and the barcode itself could be read with any 2D barcode reader or even a flatbed scanner. A non magnetic, non-electronic carrier of digital information could have certain advantages in the short term over the sending of digital information throughout Europe.

I.6.2 Enabling patient mobility

European patients should carry a minimum of medical information on their person, which should be accessible for emergency purposes. Border-crossing online information sharing should be a goal, but might, in practice, be more difficult in the short term.

The most interesting way to realise this, is to define a format for an information carrier that can carry just enough data to ensure the patient’s safety when admitted or treated in a foreign country of the EU (or beyond), while pursing a low threshold for data accessibility as far as technical needs are concerned.

I.6.3 Quality of care

Interchangeable information over borders can raise the quality of care as the speed of care could be increased in emergencies. e-Health could thus mean for the first time truly sharing of medical information over borders, given that some arrangements on format and structure could be agreed upon.

Access to electronic minimum health records for ‘the mobile European’ could help create an opportunity for widespread use of electronically regulated clinical pathways in health care, thus mapping or tracking consecutive medical events, for individuals, and shedding light on habits and uses versus the patient, and the differences of approaches throughout the entire area could thus be mapped.

I.6.4 Reducing clinical errors

For setting up minimum emergency medical record and also the complete medical record the priorities must be the incorporation of a completely transparent medication order structure, combined with a closely linked drug (and technical procedure) delivery control mechanism.

The records should contain identify the person who administered the drugs (at which time, to whom, in whose order, etc). The Food and Drug Administration (FDA) has already prepared a system in which every dose of medication that is packaged and administered separately in a hospital in the USA must contain a bar code on the reverse side, mentioning the drug and the doses. This not only showed a clear traceability of errors, but also seemed to increase prevention of medication errors in trials, by sheer peer pressure of nurses aware of the error tracking.

I.6.5 Improving efficiency of healthcare processes

Several studies in the healthcare sector proved that e-Health could cut down on administration cost (less need for personnel) and could lead to more effective and associated billing of procedures, materials and billing reminders. Additionally e-Health could help saving on “hardware” medical record storage and “hardware” medical imaging solutions (software instead of real X-rays) as well as savings on telecommunications. Finally, e-Health can cut costs on mail expenses, administration, reduction of errors and thus litigations and compensations and to lower insurance cost because of reduced number of errors.

Annex J

Glossary

ANSI	American National Standards Institute
ASTM	American Society for Testing and Materials
CEN	Comité Européen de Normalisation
CEN/TC251	Comité Européen de Normalisation, Technical Committee 251 "Health Informatics"
CEN/ISSS	Comité Européen de Normalisation, Information Society Standardization System
CORBA	Common Object Request Broker Architecture
CR	CEN Report
CWA	CEN Workshop Agreement
DICOM	Digital Imaging and Communications in Medicine
DIS	Draft International Standard
DTR	Draft Technical Report
DTS	Draft Technical Specification
EBI	European Bio-Informatics Institute
ebXML	Electronic Business using eXtensible Markup Language
EDI	Electronic Data Interchange
EDIFACT	Electronic Data Interchange for Administration, Commerce and Transport
EEA	European Economic Area
EFMI	European Federation of Medical Informatics
EFTA	European Free Trade Association
e-Health, eHealth	*e-Health* refers to the use of modern information and communication technologies to meet needs of citizens, patients, healthcare professionals, healthcare providers, as well as policy makers
EHTEL	European Health Telematics Association
eHSCG	e-Health Standardization Co-ordination Group
EN	European Standard
ENV	CEN pre-standard, must be converted into an EN within 5 years, or withdrawn; now known as a Technical Specification
***e*TEN**	electronic Trans European Network
ETSI	European Telecommunications Standards Institute
EuroRec	European Institute for Health Records
FDIS	Final Draft International Standard

GALEN	Generalised architecture for language, encyclopaedia, and nomenclatures in medicine
HIMSS	Healthcare Information and Management Systems Society
HL7	Health Level 7
ICT	Information and Communication Technology
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronics Engineers
IHE	Integrating the Healthcare Enterprise
IMIA	International Medical Informatics Association
integration	combination of diverse application entities into a relationship which functions as a whole
interface	boundary at which interaction occurs between two systems, processes, etc.
interoperability	state which exists between two application entities when, with regard to a specific task, one application entity can accept data from the other and perform that task in an appropriate and satisfactory manner without the need for extra operator intervention
ISO	International Organisation for Standardization
ISO/TC215	International Organisation for Standardization, Technical Committee 215 "Health Informatics"
ITU	International Telecommunications Union
LOINC	Logical Observation Identifiers Names and Codes
NEMA	National Electrical Manufacturers Association
NMB	National Member Body (a National Standards Body, as a member of CEN or ISO)
NSB	National Standards Body
NWI	New Work Item
NWIP	New Work Item Proposal
OASIS	Organisation for the Advancement of Structured Information Standards
OMG	Object Management Group
PACS, PACS/RIS	Picture Archiving and Communication Systems / Radiology Information Systems
PKI	Public Key Infrastructure
PWI	Preliminary Work Item
RIM	Reference Information Model
RSNA	Radiologists Society of North America
SDO	Standards Development Organisation
SMEs	Small to Medium Enterprises

SNOMED	Systematised Nomenclature of Medicine
SNOMED-CT	SNOMED Clinical Terms
SNOMED-RT	SNOMED Reference Terminology
SOAP	Simple Object Access Protocol
standard	document, established by consensus and approved by a recognised body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context
TR	Technical Report
TS	CEN Technical Specification, a pre-standard, which must be converted into an EN within 5 years, or withdrawn
TS	Technical Specification
UN/CEFACT	United Nations Centre for Trade Facilitation and Electronic Business
XML	eXtended Mark-up Language
W3C	World Wide Web Consortium
WD	Working Draft
WTO	World trade Organisation

Annex K

References

1. Priorities for application of ICT standards: A project report for EHTEL thematic working group T1 Phase One, Ray Rogers, Juergen Sembritzki, Pat Village, Joy Reardon, October 2002

2. The application of ICT standards. A project report for EHTEL thematic working group T1 in collaboration with the actors working group A1 for health authorities, Phase two: Conjoining ICT policy makers in Europe with standards makers, Ray Rogers and Joy Reardon, June 2003

3. eEurope 2005: An Information Society for All – An Action Plan, EU Commission COM (2002) 263 final, 28.5.2002

4. Ministerial Declaration Brussels, 22 May 2003 Final

5. e-Health – making healthcare better for European Citizens: An Action Plan for a European e-Health Area, EU Commission Communication, COM (2004)356, 30.4.2004

6. Follow-up to the high level reflection process on patient mobility and healthcare developments in the European Union, EU Commission Communication, COM (2004) 301 final, 20.4.2004

7. Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008)

8. Official Journal of the European Union, OJ 2002/c 66/01

9. ISO/IEC Guide 2:1996

10. Promotion Strategy for European Health Records

11. The Kohll judgement, Case C-155/96 of 28.04.98, ECR 1998 p. 1-1931Smits et Peerbooms judgement , Case C-157/99 of 12.07.01, ECR 2001 p. 1-05473 Vanbrackel judgement, Case-C368/98 12.07.01, ECR 2001 p. 1-05363 Inzan judgement , Case C-56/01 of 23.10.03, not yet published eichtle judgement, Case-C 8/02 of 18.3.04, not yet published

12. Communication from the Commission concerning the introduction of a European health insurance card, COM(2003) 73 final, 17.02.2003

13. An Organisation with a Memory: Report of an expert group on learning from adverse events in the NHS chaired by the Chief Medical Officer England, 2000, HMSO

14. To Err is Human: Building a Safer Health System, Institute of Medicine, National Academy Press, 2000

15. Quality in Australian Health Care Study (QAHCS) 1995

16. Quality of Care: Patient safety report by the Secretariat, EB109/0, December 2001, WHO

17. UK National Patient Safety Agency Business Plan 2003/04

18. Year 2002 Survey of UK Trust Chief Pharmacists Views on Electronic Prescribing, Association of Scottish Trust Chief Pharmacists (AST CP), 2002 www.show.scot.nhs.uk/astcp

19. Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices

20. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

21. Council Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in-vitro diagnostic medical devices

22. Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions, eEurope 2002: Quality Criteria for Health related Websites, COM(2002) 667 final, Brussels, 29.11.2002

23. Fernando B, Savelyich B, Avery A, Bainbridge M, Horsfield P, Teasdale S, Prescribing safety features of general practice computer systems: evaluation using simulated test cases, BMJ, May 2004; 328: 1171 – 1172.

24. Roger-France F.H. The minimum basic data set for hospital statistics in the EEC. Luxembourg, Office of Publications of the EEC, Document EUR 7162, 152 pp, 1981.

25. Roger France, F H, Case Mix use in 25 countries: a migration success but international comparisons failure, International Journal of Medical Informatics, 2003, 70: 215-219.

26. Directive 1999/93/EC of the European Parliament and the Council of Europe 13 December 1999 on a Community Framework for electronic signatures

27. Directive 97/7/EC of the European Parliament and the Council of Europe, 20 May 1997 on the protection of consumers in respect of distance contracts

28. Directive 2000/31/EC of the European Parliament and the Council of Europe, 8 June 2000 on electronic commerce

29. OJ: C 048, 28/02/2003, p.2-9

30. Communication from the Commission concerning eEurope 2002: Accessibility of Public Web Sites and their Content COM (2001) 529, 25 September 2001

31. J. Braun, A: A. Constantelou, V. Karounou, A. Ligtoet, and J-C. Burgelman (2003) Prospecting e-Health in the context of a European Ageing Society: Quantifying and qualifying needs. Final report, November 2003. IPTS/ESTO: Sevilla, Spain

32. EU Commission Communication, COM (2002) 119 final

33. A concept paper on the implementation of Strand 1 on health information and knowledge in the future action programme on public health, EU Commission, Health and Consumer Protection Directorate-general, 08/03/2002

34. Modernising social protection for the development of high-quality, accessible and sustainable health care and long-term care: support for the national strategies using the “open method of co-ordination”, COM (2004) 304.

35. ISO/IEC 2382-1:1993, Information technology - Vocabulary -Part 1: Fundamental terms.

36. IEEE STD 610.12, and IEEE Standard Computer Dictionary: A Compilation of IEEE Standard Computer Glossaries, New York, 1990

37. ISO/IEC TR 10000-1:1998e, but the more recent ISO TR18307:2001 "Health informatics - Interoperability and compatibility in messaging and communication standards - Key characteristics" now uses the CEN definition.

38. ISO TR 20514:2004, Health Informatics - EHR Definition, Scope, and Context.

39. ENV 12243:1999, Medical informatics – Health care information framework.

40. Com (2002) 499, more research for Europe towards 3% of GDP.

41. Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ: L 281, 23/11/1995, p.31-50).