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## ANNUAL WORKSHOP ON INTEROPERABILITY ISSUES

### POSITION PAPER ON EHTEL THEMATIC WORKING GROUP “HEALTH INFORMATION SOCIETY EUROPE”

### THE APPLICATION OF ICT STANDARDS PHASE ONE: DEFINING PRIORITIES

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## EXECUTIVE SUMMARY

This report covers Phase 1 of a project on behalf of EHTEL Thematic Group T1, to ascertain how the requirements of policy makers can be better linked with international standards making, and how the take up and implementation of international standards in health informatics might be improved.

This Part 1 comprises a baseline study to determine:

- the priority business areas for the application of ICT and for standardisation and
- what international standards exist to serve those priorities.

The study was conducted by questionnaire (Annex A). The main target was members of the EHTEL A1 Working Group who represent national authorities and thereby policy makers. The A1 Working group represents 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, Finland, France, Germany, Norway, Russia, Slovenia, Sweden and UK. EHTEL A4 Working Group representing patients was also contacted and they provided a consolidated response. The questionnaire was mailed to about 100 suppliers but 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;
- communications (with emphasis on e-prescriptions);
- protecting personal information (with emphasis on Public Key infrastructure and professional 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 cards. The views of suppliers were also closely aligned but in this case there was a greater emphasis on continuity of care in integrating systems across organisational boundaries.

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 PAC / RIS;
- ensuring semantic meaning.

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 PKI);
- 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 and suppliers except that A4 and suppliers identified patient identification more strongly and suppliers gave significant priority to training / e-learning.

Part D of the questionnaire sought opinions on the roles of national authorities such as the Ministry of Health in the area of standardisation. 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 TC 251 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 is to ascertain whether there are international standards to support those priorities. Annex C comprises a list of existing international standards (CEN, ISO, HL7, DICOM, IEEE, WHO).

Annex C demonstrated that there clearly are standards which on the face of it align with the business area priorities. 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, is undergoing substantial revision but nevertheless is regarded as having high potential. In the case of messaging there are many CEN and HL7 standards including for e-prescriptions and the problem is 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 is a Public Key Infrastructure and associated smart cards or equivalent for professionals, the ISO standards on PKI and health cards are only now about to be published. In the context of terminological standards, there are framework and structures standards but ISO and CEN have 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 is awaited, but issues of licensing and translation is creating barriers to uptake. Several respondents identified a need for a classification for medicinal products suitable for electronic records and prescriptions: none that exist appear suitable or are international.

In conclusion this report on Phase 1 has set a baseline for Phase 2 which it is proposed will involve face-to-face meetings and telephone contact to:

- clarify matters arising from Phase 1 e.g. the meaning and scope which respondents attached to priority areas such as electronic records and e-prescribing;
- allow a second iteration of priorities and views in the light of Phase 1;

- explore views on how the requirements of policy makers might be better reflected in international standards development;
- explore how awareness of existing standards might be improved;
- ascertain the extent to which existing standards are being piloted in real applications;
- consider the need for guides on application of standards in priority applications and how drafting might be facilitated;
- take views on means for better European collaboration in piloting of standards and international interoperability testing;
- in particular, in the light of the high priority for electronic records, messaging (e-prescriptions), protecting personal information (PKI and health cards) to ascertain the extent to which Europe as a whole can maximise use of the following standards:
  - the electronic patient record CEN standard EN 13606 (now under active revision);
  - the ISO PKI Technical Specification (just published);
  - the multipart ISO standard on health cards (publication imminent);
  - the CEN standard for electronic prescriptions;
  - for messaging in general, to investigate how Europe can be better involved in HL7 Version 3 and how collaboration in the use of XML might be achieved.

The next step is to present EHTEL with a detailed proposal for Phase 2.

## **INTRODUCTION**

### **Perceptions**

Common perceptions relating to standards, whether justified or not, are that:

- the development process is too long;
- standards which exist are unknown to key players;
- standards are too complex and difficult to understand;
- implementation is difficult and the standards process does not include testing or piloting;
- there are too many standards and they do not inter-operate;
- standards are not application orientated;
- there are insufficient guides or profiles of standards which are 'packaged' and tested for complete applications;
- suppliers are not fully engaged;
- standard making priorities are not tied to business priorities.

This report covers Phase 1 of a study to examine some of these perceptions with the aim of creating practical recommendations for improving the relevance and the application of international standards to priority business objectives.

### **Study rationale**

To examine whether existing standards (plus those in draft) can meet business priorities it is first necessary to understand:

- what the business priorities are and;
- what standards exist to serve them.

This study comprises the first phase in that process.

### **Getting at the business priorities**

In a number of countries the business processes which are a priority for the application of ICT are being determined on a national basis usually led by the government department responsible for health. In some cases these priorities are stated in a national ICT strategy or plan.

National strategies may be underpinned by a formal standards advisory body or organisation charged with selecting and/or piloting and/or developing standards for meeting strategic business objectives. Such bodies tend to draw on international standards and to be involved in the activities of the formal national and international standards bodies. However formal national standards bodies per se, are rarely an inherent component of national strategies.

EHTEL Working Group A1 members represent the policy makers who determine national business priorities for the application of ICT. It was therefore they who were consulted on business priorities. A number of other key players were also contacted.

## Identifying standards

In pursuing the second aspect of this study i.e. identifying what international standards exist, this report acknowledges the UK National Health Service Information Authority's standards database, access to which was facilitated by Pat Village, and the content of the British Standard "Guide to Health Informatics Standards".

## Study process

A questionnaire was designed and cleared with Working Group A1 members (see Annex A). It was sent to:

- members of EHTEL WG A1;
- EHTEL WG A4;
- some heads of delegations to CEN TC 251 who clearly had responsibilities in their countries at a national strategic level;
- to a number of suppliers of health informatics products.

## Responses

EHTEL A1 members represent 12 countries from which responses were obtained from 8 namely, Denmark, Finland, France, Germany, Netherlands, Norway, Sweden and UK. There was no response from Belgium, Eire, Italy or Spain. However a detailed response was received from the President of the Belgium Commission on "Norms for Telematics in the Healthcare Sector", which was created by Royal Decree in 1999. A reply from Austria indicated that a national response was not appropriate at this time because efforts to create a national strategic approach were not complete. For some countries authoritative responses from experts other than A1 were received i.e. from France, Finland, Netherlands, Russia and Slovenia.

Members of EHTEL Working Group A4 representing patients provided a single consolidated response.

In order to get a cross section of opinion from industry about 100 suppliers were mailed. It is regrettable that only 9 responses were received. Whether this reflects the difficulty in answering the questions or apathy towards standards is unknown.

In summary authoritative responses were obtained from the following countries (in some cases from more than one respondent).

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

- UK.

Additionally there was a consolidated response for EHTEL Working Group A4 and 9 responses representing industry.

### **The questions**

The questions posed are in Annex A. Most respondents completed the entire questionnaire. However a few found it easier to answer the substance of the questions via an email response.

The questions were deliberately 'open': that is they allowed the respondent to reply in his/her own words without constraint. A set of structured questions to be answered by a 'tick box' were considered but it was felt that this would constrain and somewhat bias the answers and thereby hide differences in context and opinion.

The downside of open questions is the complexity of identifying common views and differences, and in consolidating responses. However it is intended that Phase 2 of this study will involve face-to-face meetings with key respondents. This will provide the opportunity to explore views further in the context of the findings of Phase 1. For example there were references to inter-professional messaging without necessarily any indication of the nature of messages or of the professions which were the priority. Similarly references to the electronic patient record and electronic health record did not usually indicate the meaning and scope of such terms. Nevertheless, in so far as responses indicated that such matters were priorities, this was sufficient for Phase 1. Detailed meanings and implications can be explored in Phase 2.

**VIEWS CONCERNING PRIORITY BUSINESS AREAS  
(Questionnaire Part A)**

Table One comprises a list of business areas which, although not claiming to be totally comprehensive, is a reasonable spectrum of areas which respondents might have chosen as priorities for the application of ICT. Against each is indicated the number of times each was mentioned as a priority by policy makers, EHTEL A4 Patients Working Group and suppliers.

**TABLE ONE**

**Priorities for the application of ICT to business areas**

Business area	Number of times referred to as a priority		
	Policy Makers	EHTEL A4 WG	Suppliers
<b>Hospital processes</b>	<b>XX</b>		<b>X</b>
- <i>integrating hospital systems</i>			
- <i>patient records (see later)</i>			
- <i>order communications and results reporting</i>			
- <i>patient administration</i>			
- <i>nursing</i>			
- <i>pharmacy</i>			
- <i>radiology / PACS RIS</i>	XX		X
- <i>pathology</i>			
- <i>medical device communications</i>			
- <i>human resources</i>			
- <i>finance</i>			
- <i>particular specialties</i>			
<b>General Practitioner processes</b>	<b>X</b>		
- <i>electronic patient record (see later)</i>			
- <i>generation of prescriptions</i>	X		
- <i>practice administration</i>			
- <i>hospital booking</i>			
<b>Community processes</b>			
- <i>community nursing</i>			
- <i>health visiting</i>			
- <i>midwifery</i>			
<b>Dentistry</b>			
<b>Ophthalmic Opticians</b>			
<b>Pharmacy / prescribing</b>	<b>XXXXXXXX</b>		<b>X</b>
- <i>administration</i>			
- <i>e-prescribing</i>	XXXXXXXX		X
- <i>drug distribution</i>	X		
- <i>medication management</i>	XX		
- <i>web pharmacies</i>			

Business area	Number of times referred to as a priority		
	Policy Makers	EHTEL A4 WG	Suppliers
<b>Ambulance services</b>			
- administration			
- communications e.g. to base, to hospitals			
<b>Screening</b>			
- breast			
- cervical			
<b>Registers</b>			
- transplant / donors, cancer, cardiology			
<b>Remote clinical processes (through telemedicine)</b>	<b>XXXX</b>	<b>X</b>	
- 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		
<b>Health / patient records</b>	<b>XXXXXXXXXX XXX</b>	<b>X</b>	<b>XXXXXX</b>
- 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		
<b>Continuity of care</b>	<b>X</b>		<b>XXX</b>
<b>Home services and social care</b>	<b>X</b>		
<b>Supporting clinical decisions</b>	<b>XXX</b>		<b>XX</b>
- decision support systems	XXX		
- disease management / clinical pathways	X		XX
- clinical audit / QA feedback	X		
<b>Support for professionals through web</b>	<b>XXX</b>		<b>X</b>
- 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
<b>Support for public / patients</b>	<b>XXXX</b>		<b>X</b>
- <i>web content / quality</i>			
- <i>patient leaflets etc</i>	X		
- <i>access to own data</i>	X		
<b>Epidemiology / statistics</b>	<b>XXX</b>		<b>X</b>
- <i>hospital activity statistics / minimum data sets</i>	XX		X
- <i>population health statistics</i>	XX		
- <i>aggregated health information / health indicators</i>	X		
<b>Reducing administrative costs</b>	<b>X</b>		
<b>Health insurance</b>	<b>X</b>		
- <i>claims</i>	X		
<b>Communications</b>	<b>XXXXXXXXXX XXX</b>	<b>X</b>	<b>XXXXX</b>
- <i>GP / hospital for on-line bed booking</i>	X	X	
- <i>GP / hospital for referrals &amp; discharges</i>	XX	X	X
- <i>GP / specialists communications</i>	X		
- <i>GP / hospital for laboratory tests</i>	XX		X
- <i>GP / hospital images</i>			X
- <i>GP to GP communications</i>			X
- <i>physicians health letters</i>	XX		X
- <i>clinician / patient</i>			X
- <i>professional to professional communications</i>	X		X
- <i>e-prescriptions</i>	XXXXX	X	X
- <i>fees / reimbursement</i>			XX
- <i>hospitals and external providers</i>	X		
- <i>hospitals / community</i>	X		
- <i>with social care</i>	X		
- <i>health network</i>	XXX		
<b>Protecting personal data</b>	<b>XXXXXXXXXX XX</b>	<b>X</b>	<b>XXXXX</b>
- <i>admin / technical measures</i>			
- <i>encryption</i>			
- <i>public key infrastructure</i>	XXXX	X	X
- <i>health professional card</i>	XXXXX		X
- <i>unique patient identification</i>	XX		XX
- <i>access rules / audit trails</i>	XXX		X
- <i>professional directories</i>			X
- <i>electronic signatures</i>	XXX		X
- <i>biometric identification</i>			
- <i>network security</i>	X		
- <i>internet / web based security for sensitive info.</i>	XXX		
- <i>legal aspects</i>			X

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

### Views of policy makers

A glance at Table One reveals four business areas which were clearly top priorities in terms of the number of times they were mentioned i.e:

- health / patient records;
- communications;
- protecting personal information;
- prescribing / drug administration.

Some way behind, in order of the number of times mentioned were the business areas:

- support for clinical processes through telemedicine;
- support for public / patients;
- support for clinical decisions;
- epidemiology / statistics;
- support for professionals (web);
- hospital PAC / RIS;

- ensuring semantic meaning.

Finally the following were referred to only once:

- generation of prescriptions by GPs;
- continuity of care;
- home services and social care;
- reducing administrative costs;
- health insurance.

Some respondents mentioned technical aspects or technologies as priorities particularly:

- health cards or equivalent;
- wireless / mobile applications.

Also referred to were:

- domain / reference models / metadata;
- multi-work stations;
- enhancement of the ICT and medical technology market;
- technical messaging options.

## **Health / patient records**

Not only was this business area in the top two in terms of number of times mentioned, it also was in the top two in terms of how often it was listed by respondents as their first, second or third priority. Considering both these aspects it was the highest priority but only marginally ahead of 'communications' (see below). Germany was an exception in that whilst electronic patient records were mentioned, they were a much lower priority. Respondents used several acronyms to express the electronic record e.g. EPR, ECHR, EHR. It was not always clear whether what was meant was:

- an electronic patient record in the context of a 'patient' in a specific type of health establishment e.g. hospital, GP, community or;
- an electronic health record as a wider concept of a record for an individual irrespective of whether healthy or ill, and without any necessary alignment with a particular type of health organisation (more akin to a birth to death record).

However best judgement indicated that a hospital EPR was the priority most frequently mentioned followed by a multi-user EPR. The EHR birth to death was explicitly referred to only twice albeit one other respondent referred to a GP 'global' record.

There were significant mentions of electronic record architectures or domain models.

## **Communications**

Facilitating communications between organisations and professions, and for electronic prescriptions, was a top priority only marginally below electronic patient records both in terms of number of times mentioned and the number of times it figured as respondents' first, second or third priority.

The highest priority was electronic prescriptions (see later), followed by a variety of communications between hospitals, GPs, community, social services and between professionals.

### **Prescribing / drug administration**

This area had a high priority primarily due to the high priority placed on electronic prescriptions or prescribing. The latter were sometimes allied with medication management, drug distribution or decision support.

It was not clear the extent to which the terms electronic prescription or electronic prescribing were limited to the sending of an electronic message from GP to pharmacist or whether they encompassed more processes in prescribing, such as payments, or even wider to encompass e-pharmacy.

ISO Health Informatics TC215 has examined e-pharmacy and the question of standard needs (available from the project leader Ray Rogers).

### **Protecting personal data**

Issues relating to security, safeguarding confidentiality, authorisation and access were frequently mentioned usually as a third or fourth priority. The most significant issues were public key infrastructure and, in that context, health professional cards as a means of identification for access control. Also of significance were access rules in general, electronic signatures and internet / web based security.

### **Second-level priorities**

The following were ranked about equal in priority in the number of mentions and the level of ranking given by respondents (usually below third).

Support of clinical processes through telemedicine was a top priority in Sweden only, otherwise being ranked below third. Specific applications were not always clear or exclusive but those that figured most were tele-consulting, and tele-monitoring / tele-care in the context of the home and social services.

Support for patients or the public had significant support but little in the way of detail was given in responses.

Support for clinical decision making was supported primarily in terms of decision support but usually without much further elaboration.

Use of ICT to improve statistics gathering in areas such as activity monitoring, population statistics and health indicators had support from a number of respondents.

Support for professionals through e-education had some significant support.

Finally, hospital imaging in terms of PAC and RIS, and ensuring semantic meaning through classification systems both had support from more than one respondent.

## **Views of EHTEL A4 Patients Working Group**

Working Group A4 which represents patients, provided a single consolidated response.

Their top priority was using ICT to aid seamless care which they saw as being assisted through the following applications:

- a single virtual record: the electronic patient record and the electronic health record;
- e-prescribing;
- e-consulting;
- electronic referrals and bookings;

and through an infrastructure including:

- security through a PKI;
- transportable records in the form of smart cards.

Most of these priorities are ranked similarly to those from policy makers e.g. the high priority given to electronic patient / health records, e-prescribing, electronic referrals and PKI for security.

However the high priority given to e-consulting, electronic bookings and smart cards for transportable health records did not align so well in that these were mentioned by only a few policy makers and then usually with middle priority.

The patient group gave as their next priority the use of ICT to create transparency in the quality, availability and cost of services so as to facilitate patient choice and participation in decision making. These matters did not receive explicit mention by policy makers albeit there was significant priority accorded to support of patients in general.

## **Views of suppliers**

The last column of Table One gives the views of the 9 suppliers who responded. This cannot be taken as representative of European industry since numbers are too small and biased to Germany (8 of the 9 responses). Nevertheless priorities align well with policy makers with the top three priorities being the same i.e:

- health / patient records;
- communications;
- protecting patient information.

There was somewhat more emphasis on continuity of care probably reflecting suppliers concerns about integrating systems across clinical / organisational boundaries

## **What was not a priority?**

The significance of Table One lies not only in the areas which were selected as priorities, but also in those which were not. Thus no mention was made of dentistry; ophthalmic opticians; ambulance services; health screening; registers such as for cancer, cardiology,

transplants / donors; particular specialties such as gynaecology, oncology, surgery, intensive care; or communications with or between medical devices such as ECGs, EEGs etc. Indeed with the exception of digital imaging (PACS / RIS), no priority was given to particular hospital processes or to administrative areas like finance and human resources. Also despite seemingly significant interest in conferences etc regarding mobile / wireless applications and home monitoring, they received relatively few mentions. That is not to say that respondents necessarily regarded any or all of these areas as unimportant: they simply did not figure significantly even when given the opportunity to list seven top priorities.

## **VIEWS ON PRIORITIES FOR STANDARDS AND INTEROPERABILITY (questionnaire Parts B and C)**

This section deals with the questions on priorities for standards and interoperability and provides a summary of, and observations on, the responses received. Annex B provides details of the responses.

In general one might expect policy makers to identify the business areas which were a priority for the application of ICT, and for them to leave it to suppliers to implement the necessary systems. The latter would determine the standards to apply. Unfortunately life is not that simple.

Leaving suppliers to implement systems in different business areas without coordination will usually result in incompatibilities when attempts are made to interface those different business areas. That becomes particularly evident when attempting to create links between organisational entities or when different organisational entities seek to pursue a common purpose e.g. a shared electronic health record. This is the point which most national health systems have reached at the present time. The problems most are facing in pursuing priority business areas are the incompatibilities built up from the past. A substantial contributor to such incompatibles is different and incompatible standards.

Thus many countries, and indeed the EU as a whole, have recognised the need to formulate national policies and strategies for standards with which suppliers would be expected to conform. Some countries have specific national organisations to which policy makers refer for such detailed standards matters.

Within the EU there are a number of Directives and initiatives on standards. At the heart of these is a general policy that EU member States should utilise international and European standards and look to European and international formal standards bodies for meeting the needs for future standards. National standards should be exceptional and require justification. Some would argue that a range of Directives make such a policy mandatory. However even if that were so, it is being observed in the breach.

Most European countries at government level will formally subscribe to the policy of adopting International or European standards and developing national standards only where unavoidable. However the practice in most countries reflect that policy only very weakly and there is little evidence of a determined drive to get CEN or ISO to produce standards to fulfil future needs let alone a commitment to implement them.

Responses to the questions on priorities for standards and interoperability (Parts B and C) reflected the above. Generally a commitment in principle to ISO and CEN was evident although there was equal interest in HL7 and DICOM. In respect to HL7 this creates problems which the responses highlighted (see later).

One respondent observed that:

- ISO should set frameworks;
- CEN should deal with content standards within those frameworks;
- National standards should be restricted to areas where there are differences in regulations or the practice of health care and even then they should be based on ISO and CEN where practicable.

This appears to be a reasonable observation and was in line with a number of responses although not in accord with current practice.

Policy makers in a number of countries look to particular national organisations to deal with standards matters per se e.g:

- Norway: Norwegian Centre for Medical Informatics (KITH);
- Finland: Finnish National Research and Development Centre for Welfare and Health, STAKES;
- Sweden: Swedish Standards Institute;
- Belgium: advisory commission on standards "Norm for Telematics in the Health Care Sector";
- UK: Department of Health Standards Board.

The extent to which these organisations relate to their formal national standards bodies is not clear but generally there appears to be significant cross membership.

The way in which the questions on standards priorities and interoperability were answered varied markedly. Not unexpectedly, policy makers who were not directly involved in standards making tended to provide general non-specific responses. Conversely the closer the involvement with standards making the more specific the response.

Part A of the questionnaire sought views on business areas which were a priority for application of ICT. Parts B and C sought views on business areas which were a priority for standards. Significant but not exact correlation between answers to these parts would be expected and that was generally the case.

Table Two summarises the replies. Although a significant degree of interpretation and intelligent grouping was involved in producing Table Two, it is nevertheless felt to reflect reasonably the questionnaire responses.

### **Views of policy makers**

The top four priorities for policy makers were:

- communications / messaging;
- security;
- electronic patient / health records;
- semantics.

The first three correlated very well with the business areas which were priorities for the application of ICT. However of significance was the high priority given to semantic matters – classifications and codings etc.

**TABLE TWO**

**Priorities areas for standards**

Priority area	Number of times referred to as priority		
	Policy Makers	EHTEL A4 WG	Suppliers
Communications / messaging (mainly electronic prescribing and relationships between EDIFACT, HL7, DICOM, XML etc)	XXXXXXXX	X	XXXXXXXX
Security (dominantly PKI)	XXXXXXXX	X	XXX
Electronic patient / health records	XXXXXX	X	XX
Semantics, classifications and coding	XXXXXX		X
Patient identification	XXX	X	XX
Telemedicine	XXX		
Integration of systems)	XXX		XX
Smart cards (health and professional)	XX		
Continuity of care	XX		
Health network	XX		
Models (including HL7 Reference Information Model – RIM)	XX		
Insurance	X		
Imaging	X		
Technical interoperability	X		
Epidemiology	X		X
Professional directories			X
Training / e-learning			XXX

**Communications / messaging**

The most significant aspect of responses under this heading was the need for standards for electronic prescribing and the need to resolve difficulties and interoperability matters between EDIFACT, HL7, XML, DICOM etc.

**Security**

The priority matter in relation to security was dominantly the need for standards in the area of a PKI (including cards for professionals).

**Electronic Patient Health Records**

Whereas it was not surprising that standards relating to electronic records was a high priority, it was usually not clear what was meant by electronic patient / health records and thus what the nature of the standards requirement was (albeit mention was made of architecture, core components, interfaces to feeder systems).

## **Semantics**

The need for more and better standards in the area of semantics (classifications and coding systems) figured far more strongly in responses to Parts B and C than in Part A perhaps because semantics was not regarded as a business area per se. Whereas a strong requirement for standards in this areas was evident, there was far less clarity as to the standards bodies which might create them (CEN and ISO have decided not to create content standards in this area). WHO classifications, LOINC, SNOMED CT and various national classification systems were all mentioned.

## **Patient identification**

Policy makers regarded patient identification as a middle priority whereas the EHTEL A4 Patients Working Group ranked it more highly. Patient identification also figured significantly in responses from suppliers. The nature of the requirement in standards terms was not however clear. It is also worth noting that the e-Europe 2005 action plan explicitly commits to support a common approach to patient identifiers and electronic health record architecture.

### **Views of EHTEL A4 Patients Working Group**

The views of the A4 Patients Working Group correlated well with those of policy makers at least in respect to the three top priorities i.e:

- communications;
- security;
- electronic patient / health records.

There was however a high priority accorded to patient identification and no priority accorded to semantics.

### **Views of suppliers**

It needs again to be noted that the number of responses and the bias towards Germany mean that responses cannot be taken as representative of suppliers as a whole. The replies do however indicate a dominate interest in standards for communications overwhelming in relation to matters such as EDIFACT, HL7, DICOM, XML ebXML etc and their interoperability. Security was also of significant concern. Training / learning figured for suppliers but not for others at least in respect of standards priorities.

## ROLES OF NATIONAL AUTHORITIES (Questionnaire Part D)

Part D sought views on the roles of national authorities / agencies such as a Ministry of Health in the area of standardisation. Table Three summarises the responses.

**TABLE THREE**

Role	A1 Members	TC251 heads	A4 responses	Suppliers
None				
Specifying which standards will be national	XXX	XXXX	X	XXX
Sponsoring standards development	XXX	XXXXX	X	XXXXXX
Sponsoring user guides to standards	XXX	XXXX		XXXXXX
Sponsoring pilot implementation of standards	XXXXXX	XXX		XXXX
Sponsoring standards interoperability pilots	XXX	XX	X	XXXXXXXX
Creating an EU legislative environment	XXXXXX	XXXXXX		XX
Roles entered under other:				
Sponsoring national implementation of standards	X			
Creating environment where use of certain standards is de facto or de jure mandatory	X			
Spreading the light	X			
Creating understanding of necessity	X			
Funding national IHE activities				X
Harmonising handling of data on patient cards throughout Europe				X

There was a fairly even split of views on the roles which the questionnaire presented. An additional role emerged namely creating an environment which encouraged the use of standards.

A1 members were clearly of the opinion that the role of national authorities was primarily to sponsor pilot implementation of standards and to create an EU legislative environment. However there was significant support also for other roles.

The opinions of CEN TC 251 heads of delegation, who were contacted, also recognised the role of national authorities in setting an EU legislative environment and not surprisingly looked to national authorities to sponsor the development of standards and of user guides.

The A4 Patients Working Group saw the roles as specifying which standards would be national, sponsoring standards development and interoperability pilots.

The views of suppliers were fairly evenly spread with, not surprisingly, an emphasis on sponsorship of interoperability pilots. It was surprising how few recognised the role of creating an EU legislative environment.

## CEN TC 251 VIEWPOINT

In December 2000, heads of delegations to CEN TC 251 each gave a presentation on health informatics and standards in their country. Notes taken at the meeting and PowerPoint slides were reviewed to gain a view on priorities for standards.

Presentations were made by 13 countries. The main priorities for standards in terms of number of countries that mentioned them are shown in Table Four.

**TABLE FOUR**

**CEN TC 251 viewpoint on priorities for standards from presentations  
December 2000**

Priority area	Number of countries mentioning area
Security	XXXXXXXXXXXX
Communications / messaging (mainly e-prescriptions and health networks)	XXXXXXXXXXXX
Health / patient records (primarily hospital)	XXXXXXXXXXXX
Support for public / patients through web	XXXXXX
Semantics, classifications, coding	XXXXX
Health cards (professional and identity)	XXXXX
Pharmacy (e-prescriptions)	XXXXX
Continuity of care	XXXX
Telemedicine	XXXX
Epidemiology / statistics	XXXX
Health registers	XXX
Professional support (clinical guidelines, e-learning)	XXX

These views, even though two years old, are in line with the questionnaire at least for the top three priorities and to a great extent the middle priorities. The main difference was a higher emphasis on support for public / patients through the internet / web.

## **EXISTING STANDARDS**

Annex C comprises a list of existing standards created by CEN TC 251, ISO TC 215, HL7, DICOM, IEEE and WHO, all of which have an international standing.

The Annex includes CEN TC 251 strategic studies and the current CEN TC 251 and ISO TC 215 work programmes.

Standards are grouped to enable alignment with priority areas identified from responses to Parts A, B, and C of the questionnaire.

Clearly there are in existence a range of standards which do align with priority applications. Indeed, as stated by a number of respondents, the requirement may not be a need for many new standards but awareness, understanding and interoperability demonstrations of existing ones.

## DISCUSSION

### Linking priorities and existing standards

Three areas clearly emerged as priorities for the application of ICT and for standards:

- patient / health records;
- communications / messaging;
- protecting personal information.

It was not clear as to the meaning and scope attached to terms such as electronic patient record, electronic healthcare record and electronic health record, but the impression was that the electronic patient record in the hospital setting was more frequently the meaning than a birth- to-death electronic health record.

In the area of communications / messaging, two aspects stood out:

- electronic prescribing;
- issues surrounding EDIFACT, HL7, DICOM, XML etc.

However there was also significant priority attached to particular message contexts such as referrals and discharges, laboratory requests and results, professional to professional exchanges.

The scope of electronic prescribing was unclear but the most frequent sense appeared to be electronic prescriptions taken to be that between a GP and a pharmacy

The issues surrounding EDIFACT, HL7, DICOM, XML etc are well known in the standards world and an area of substantial controversy, at least in respect of the use in Europe of CEN TC 251 messages / EDIFACT and HL7 Version 2. There were many references in response to HL7 Version 3 and its underpinning Reference Information Model (RIM), and also to XML. The implications were that HL7 V3.0 and XML taken together would create the solutions most respondents were seeking. Not surprisingly there was significant support for DICOM as the standard in the radiological area: indeed it was regarded as THE international standard in this field.

The high priority accorded to protecting personal health information was dominantly related to matters surrounding a Public Key Infrastructure and, in that context, the use of registration authorities and professional cards for controlling access and authentication. There were also concerns surrounding patient identification and health cards (primarily for identification rather than as a vehicle for a medical record).

When asked about priorities for standards a further high priority emerged namely semantics, classification and coding. It was not always clear as to the area of concern but the need for a comprehensive terminological system for clinical terms and for a classification for medicines were explicitly mentioned.

One aspect that clearly underpinned all responses was that concerns were no longer dominated by introducing ICT into particular organisational entities such as a hospital's (departmental systems) or GPs. Today's preoccupations surrounded inter-organisation and inter-professional secure communications and integration, and the secure sharing of records between authorised professionals no matter where located. Whereas it could not

be said that the needs of patients per se were dominant, sufficient mentions were made by respondents to illustrate a shift in that direction.

A glance at the list of standards and ongoing work in Annex C shows that there is a whole range of standards applicable to the top priorities outlined above.

In the area of electronic records CEN TC 251 published the pre-standard ENV 13606 which has had a significant but not an overwhelming impact. It is currently being revised to be a full standard and is regarded by many as having very substantial potential. The questions that arise are:

- Will it meet the needs?
- Will its existence be sufficiently well known?
- Will it be understood? Will there be a guide to its use?
- Will there be pilot implementations to demonstrate its worth?
- Will it interface and inter-operate as required?
- Will national authorities take it on board?
- Will suppliers adopt it?
- Will the wider international community (ISO, HL7) incorporate it into their standards?

In the area of communications / messaging there are many existing standards the majority of which can be demonstrated as having been successfully implemented. This includes electronic prescriptions. The extent, to which the existence of these standards is well known, is unclear but it is suspected that this is not the problem. The problem seems more likely to be uncertainty about which standards to choose, and lack of compatibility between the choices. Whereas HL7 V3.0 and XML may present the solutions these are still some way distant. Additionally European standards developers appear heavily disadvantaged in participating in HL7 Version 3 activities. Some questions which arise are:

- Will HL7 Version 3 plus XML produce the solutions?
- How long will this take and what message environments are the priority?
- How can European national authorities help or speed the process or pilot the results?
- What can be done to greatly increase these endeavours? Can European national authorities help? Should the EU commission provide support?

Protecting personal information is of widespread concern and there are now a range of standards available plus of course the legal infrastructure resulting from the EU Data Protection Directive. However in the area of Public Key Infrastructure an ISO TC 215 Technical Specification has only just been published. Some of the questions that will arise are:

- Will it meet needs?
- Is it understandable or does it need a guide?
- Will there be a pilot implementation with sharing of experience?
- Will there be sufficient awareness of its existence?

Similarly in ISO TC 215 a eight part standard on health cards is in an advanced stage with publication of some parts being imminent. The same questions as for PKI arise.

The problem with semantics classification and codings is not so much standards about structure but about content. ISO and CEN have decided not to address content standards for terminology although there are signs that ISO TC 215 might change its mind. Thus the only content international standards available are those from WHO (the most widely used being ICD) and SNOMED CT a definitive version of which is awaited. With the exception of the UK, the problem with SNOMED CT is one of national licences and translation into European languages and practices. It is rumoured that the USA has failed to negotiate a licence and may go it alone in creating a clinical terminology.

In the area of classification of medicinal products, there are classification, coding and numbering systems but none seem to meet the international needs for electronic records and prescriptions. ISO TC 215 is considering this matter.

Thus although there are demands for international terminological content standards e.g. for clinical procedures, there is no European body in a position to create and maintain them and no funding to support any organisational arrangement suitable for doing so.

Whereas there are international standards available for top priority areas, that is not so for most of the priorities occupying the middle ranks e.g:

- support for clinical processes through telemedicine;
- support for public / [patients e.g. quality criteria for web based information;
- support for clinical decisions;
- continuity of care e.g. definitions of episodes of care and episode linkage.

### **Linking policy makers and standards makers**

Policy makers tend to think in terms of applying ICT to whole applications e.g. electronic health records or pharmacy / prescribing. Applications such as the latter require a range of standards e.g. for architecture, message structure, message content, security, classifications and codes, and a range of web / internet standards. However standards makers, at least in ISO and CEN, tend to think in terms of enabling frameworks, structures, and cross-cutting infrastructure standards such as those for security. Bringing these two outlooks together in practical circumstances requires:

- identification of the nature of the standards required for the application to succeed;
- identification and choice of existing potential standards and filling gaps where no standards exist;
- understanding of standards perhaps through guides and piloting of the application with the chosen standards to test interoperability;
- persuading suppliers to adopt the chosen standards.

It is in these processes that major problems arise even on a national basis let alone on a European level. There are very few arrangements for sharing tasks and sharing experience and for links between standards makers such as those in CEN TC 251 and policy makers seeking to pilot and realise applications.

The one area of collaboration which was highlighted was Integrating the Healthcare Enterprise (IHE). This has been a significant success in terms of demonstrating interoperability. However, despite its ambitions for the future, its work has been mainly in

the radiological domain and it has its critics due mainly to the reliance it is seen to place on HL7 Version 2.

Thus there is much work to do to bring policy makers closer to standards developers and to find mechanisms whereby, in a European collaboration environment, standards can be brought together and piloted to serve whole applications in consort with suppliers.

## NEXT STEPS

The purpose of this Phase 1 baseline study was to:

- explore views, primarily of national policy makers as represented by EHTEL A1 members, on priority business areas for the application of ICT and for standards;
- identify existing international standards for health informatics.

The study has achieved this at least in the context of Phase 1.

The outline proposal for Phase 2 envisaged more detailed work involving face-to-face meetings and telephone contacts to:

- clarify matters arising from Phase 1 e.g. the meaning and scope which respondents attached to priority areas such as electronic records and e-prescribing;
- allow a second iteration of priorities and views in the light of Phase 1;
- explore views on how the requirements of policy makers might be better reflected in international standards development;
- explore how awareness of existing standards might be improved;
- ascertain the extent to which existing standards are being piloted in real applications;
- consider the need for guides on application of standards in priority applications and how drafting might be facilitated;
- take views on means for better European collaboration in piloting of standards and interoperability testing.
- in particular, in the light of the high priority for electronic records, messaging (e-prescriptions), protecting personal information (PKI and health cards) to ascertain the extent to which Europe as a whole can maximise use of the following standards:
  - the electronic patient record CEN standard EN 13606 (now under active revision);
  - the ISO PKI Technical Specification (just published);
  - the multipart ISO standard on health cards (publication imminent);
  - the CEN standard for electronic prescriptions;
  - for messaging in general, to investigate how Europe can be better involved in HL7 Version 3 and how collaboration in the use of XML might be achieved.

Face-to-face / telephone contacts envisaged would be:

- EHTEL A1 members;
- EHTEL A4;
- EHTEL T1;
- IHE;
- key CEN TC 251 members;
- EU commission;
- key supplier organisations.

The next steps will therefore be to present a detailed proposal for Phase 2 based on the above and on reactions to this Phase 1 report.

### **ANNEX A**

## **A QUESTIONNAIRE ON PRIORITIES FOR THE APPLICATION OF INFORMATION AND COMMUNICATION TECHNOLOGIES AND PRIORITIES FOR STANDARDS AND INTEROPERABILITY**

### **A project under the auspices of EHTEL Task Group T1**

EHTEL is the European Health Telematics Association ([www.ehtel.org](http://www.ehtel.org)). The objectives of EHTEL Task Group T1 is "to support and promote the concepts and connectivity for health informatics in Europe to promote development of a Health Information Society in Europe".

This questionnaire will assist T1 by questioning key players about the priorities accorded to the application of information and communications technologies in health informatics and to requirements for standards and interoperability. Results will be used to inform standards-makers of perceived priorities and to ascertain the extent to which existing or planned standards match those priorities. Respondents will receive a copy of the report.

**Please enter your details in the box below**

Name:	_____
Position:	_____
Employing Organisation:	_____
Address:	_____ _____ _____
Country:	_____
Telephone:	_____
Fax:	_____
Email address:	_____

**THANK YOU FOR YOUR HELP**

**RETURN QUESTIONNAIRE TO PROJECT CO-ORDINATOR RAY ROGERS**

**EMAIL: [ray.rogers@ntlworld.com](mailto:ray.rogers@ntlworld.com)**

**Fax +44 (0) 1483 858489**

Group (for project administration use):

## HOW TO COMPLETE THE QUESTIONNAIRE

**Part A** seeks views on areas which you think are the top priorities for the application of information and communication technologies (ICT). You are asked for seven in ranked order but if you feel that a lesser number better reflects priorities then give fewer. Please be as explicit as practicable with reasons. As an example you may have health records as a priority. In that case it would be useful to know whether you have in mind hospital patient records, GP patient records, birth-to-death health records, some other form of records or all of these. In Part A you are not being asked about priorities for standards: that is for Part B. Thus an electronic birth-to-death record may, in your view, require many standards of different types or, even though the area is a priority, you may feel that no standardisation is required and that suppliers and users should be left to self regulate themselves.

**Part B** seeks views on areas where you feel that standardisation is a priority. You are asked for seven in ranked order but if you feel that a lesser number better reflects priorities then give fewer. You are not asked to identify particular standards in that a priority area such as prescribing may require a number of standards such as an e-prescription messages, security standards, a medicines classification system etc. Nevertheless if you can be specific that would be useful. Please be as explicit as practicable with reasons. For example if a priority area is security, is there a particular application of maximum concern such as encryption, authentication through electronic signatures, certification schemes for the issue of encryption keys, security for smart cards etc.

If you feel that new or amended standards are required, please give views on which standards bodies might best produce the standards in your priority areas with reasons. If you feel the standards would best be produced nationally please indicate whether you mean by your formal standardisation body or by some other agency.

On the other hand if you feel that, in a priority area for a standard, the problem is not producing new or amended standards but the utilisation of existing standard(s) then please say so.

**Part C** recognises that one of your priorities may not be new standards but the interoperability of existing ones. If so give views here.

**Part D** seeks your views on the role which national authorities such as a Ministry of Health should play. By 'sponsorship' in Part D is primarily meant financial support.

**Part E** asks you to add any comments which might make clearer your views in Parts A and B. For example you may have general views on the standards making process that determine your outlook on what bodies are best in a position to meet your priorities for standards. You may feel that there are sufficient standards around but the problem lies in choice, understanding them and interoperability.

If there is a national body other than your national standards organisation explicitly tasked with deciding or advising government on standards to be implemented nationally in health informatics please give details.

## **PART A: Priorities for the application of ICT**

Please list or describe below the seven areas which you believe have the highest priority in your country for the application of ICT over the next five years. If you can list them in order of priority (the first being the highest) that would be appreciated.

## **PART B: Standards Priorities**

Please list or describe below the seven areas which you believe have the highest requirement in your country for a standard. Please indicate, *but only if you can*, whether the standard would best be national (not necessarily your formal national standards body), European CEN, International ISO, HL7, DICOM or other industry standard. If you regard the problem in a priority area as one of utilising existing standards rather than developing new or amended ones please say so.

## **PART C: Interoperability**

Please enter below those applications which you believe are a priority for demonstrating the interoperability of existing standards.

## PART D: Roles

Please mark with an 'X' which roles, if any, you believe that national authorities/agencies such as a Ministry of Health, should play in the area of standardisation.

Role	Mark with 'X' those applicable
None	
Specifying which standards will be national	
Sponsoring standards development	
Sponsoring user guides to standards	
Sponsoring pilot implementation of standards	
Sponsoring standards interoperability pilots	
Creating an EU legislative environment	
Other enter below:	

## PART E: Comments

Please enter below any comments which would help to make your views clearer.

If there is a national body other than your national standards organisation explicitly tasked with deciding or advising government on standards to be implemented nationally in health informatics please give details.

--

## ANNEX B

### VIEWS ON PRIORITIES FOR STANDARDS AND INTEROPERABILITY

#### Policy Makers

The way in which the questions on standards priorities and interoperability (Parts B and C) was answered varied markedly. Not unexpectedly, policy makers who were not directly involved in standards -making e.g. through formal standards bodies, tended to provide a general non-specific response. The closer the involvement in standards-making the more specific the response. Thus one policy maker, (from **Netherlands**), reasonably declined to answer the question on the basis that decisions on what standards to deploy was a matter for ICT experts. Another (from **Germany**) simply expressed the view that the problem was "improving the knowledge about existing standards established by national and European bodies rather than integrating the different industrial 'communications standards' in different sectors". A second policy maker (from **Germany**) observed that international (and open) standards are to be preferred and talk of technical standards / interfaces should not obscure the need for content standards e.g. nomenclatures. That having been said the development of a public key infrastructure including registration authorities for health professionals was crucial as was the development of a legal framework for private contracts for trans-international telemedicine applications. As to interoperability, initiatives such as IHE seemed promising.

One might expect policy makers to identify the business areas to which they wished to apply ICT and then look to systems experts to realise their business aims. The systems experts would then select whatever standards were necessary.

Thus in **Sweden** the top business priorities for policy makers is the application of telemedicine / telecare. The government strategy is therefore to investigate the need for and the use of standards in this area through the Swedish Standards Institute. This is to be approached in an international context first and then from a Nordic point of view in collaboration with other Nordic countries. The focus is to be on ISO standards provided there are no compelling European standards.

In **Norway** policy makers turn to the Norwegian Centre for Medical Informatics (KITH) as the advisory body on standards.

The policy representative for **Finland** noted that interoperability was the crucial issue in Finland. Now that most of the national infrastructure was in place, the problem was interoperability between different standards, different versions of standards and between applications from different vendors. Under active consideration is the need for a nationally defined structure for the core of the EPR, or a nationally defined common interface with which all products would have to communicate. However as to specific standards matters reference was made to the Finnish body STAKES from which a separate response was obtained (see below).

STAKES is the Finnish National Research and Development Centre for Welfare and Health. Their view on standards priorities and the bodies that might best address them were:

- Electronic patient record
  - heading and metafiles (ISO ongoing activity, also CEN);

- web based EPR including communication standards for expert to expert consultation, client to health care professional (home) services and the administrative data including appointments (ISO, CEN, HL7);
- architecture based on archiving principles (ISO ongoing);
- interoperability between tele-health systems and networks (ISO ongoing)
- Knowledge management
  - terminology and semantics, classifications and coding schemes for the description of health conditions e.g. functioning, disability and health issues (CEN or ISO);
- Logistics
  - the seamless care process including the logistics of all resources needed to accomplish an encounter and an episode in a health care organisation.

In terms of interoperability, priorities are:

- interoperability between coding schemes and semantic models such as UMLS, MeSH, SNOMED-CT and with practices in the Finnish language;
- archiving e.g. security, terminology (heading / metafiles), mobile versus net-based solutions;
- messaging e.g. HL7 / EDIFACT / XML / mobile versus net-based solutions / DICOM.

**Belgium** has created a special advisory commission on standards "Norms for Telematics in the Health Care Sector". Whereas it does not develop standards its remit is to formulate recommendations to ministers to:

- harmonize standards for data exchange;
- protect patient identification, data base access;
- code and convert codes for health data;
- evaluate conformity to norms;
- harmonize national and international standards;
- develop minimal functions for the patient electronic record and health telematics in general.

Its priorities for standards are:

- Develop coherent local health information systems;
  - "Quality labels" for electronic patient records in general practice (national criteria);
  - "Quality labels" for physicians "specialists in health data management" (training, national criteria);
  - "Quality labels" (national) for hospital information services;
  - legal and functional norms (national) for long term preservation of patients records (using XML).
- Develop secure and standardised communication systems;
  - technical recommendations to apply electronic signatures in the health care sector (based on European Directive, existing standards);
  - development of standard messages (in XML) between health professionals, including electronic prescription (use of international standards such as CEN-

- TC 251/HL7/..., selectively or partially, as well as national standards: e.g. CNK (code national code) for drugs, linked to ATC ...);
  - opportunity and implementation of a patient unique identifier (certification, PKI, TTP, ...);
  - modelling electronic data collection for epidemiologic purposes.
- Develop a health network;
  - prototyping;
  - legal recommendations;
  - linkage between records (from general practice, and from hospitals) to the health network.

Belgium has taken CEN TC 251 standard messages for further developments although it applies HL7 for some aspects of interoperability.

In the **UK** a Standards Board has been created within the Department of Health with three sub-committees dealing with clinical, technical and administrative standards respectively. The board is responsible for deciding / accrediting which standards will be adopted as official National Health Service standards. The general philosophy is to adopt existing international standards where they exist before considering national standards but with an overall proviso that successful implementations must be demonstrated. Whereas its procedures are now well documented, few standards have yet been formally accredited. However a significant decision is that the strategic way forward in the area of messaging will be HL7 Version 3. The choice of standards to serve priority business areas such as electronic health records, electronic prescriptions and electronic bookings is actively under consideration but has not been settled. A number of pilot projects are in place. That having been said the NHS is obliged to conform to a wider set of standards laid down for government departments in general (so-called eGIF). The latter covers matters such as internet and browser standards, XML and XML schema etc.

The policy maker's response for **Denmark** listed four priority areas for standards:

- EPR and domain models;
- communications – EDIFACT, XML or HL7 Version 3 and the Reference Information Model (RIM) behind it;
- integration of systems – HISA, HL7 (RIM), IHE (for vendors of radiological systems);
- security and confidentiality including wireless tools.

Interoperability priorities are:

- EPR;
- production systems such as PAS, HIS, RIS, PACS;
- ordering and booking systems to be integrated with human resource systems;
- workflow systems;
- guidelines for good clinical practice, databases;
- quality assessment data;
- aggregated data to be reported to authorities.

The **Netherlands** head of delegation to CEN TC 251 saw standards priorities as:

- interoperability and technology;

- security;
- identification;
- meta information (data dictionary for common components);
- messages, objects;
- minimum data sets;
- ECHR.

The key areas for interoperability were health care identification and message exchange.

The **French** head of delegation to CEN TC 251 listed standards priorities as:

- trustability (CEN);
- clinical terminology (international WHO, CEN and national);
- messages (CEN);
- security (national);
- imaging (DICOM);
- continuity of care (CEN);
- reference information mode (HL7).

On the other hand a general delegate to the **French organisation EDISANTE** listed standards priorities as:

- authentication of healthcare professional - (built on directory and PKI) – first French then European standard (CEN) (for identification schemes in healthcare and directories – for basic authentication protocol and devices such as smart cards, use of international standards is mandatory);
- patient hospital identification and exchange messages - work around national identification process, in accordance with CEN – testing with IHE – convergence to HL7
- hospital movements - work towards HL7 V3 messages, using present model and XML, and IHE methodology and framework
- insurance card - interoperability with other European countries – standardisation process in CEN
- medical information - first stage is to define minimum data set (French, European through CEN) ; simultaneously start EHRCOM implementation and refinement
- medical messaging system - need for implementing the French agreed scheme (from national group for healthcare professional card - GIP CPS) – project must follow international standards for technical basis (such as X509 for certificates) ; then French standards for process, agreement of trusted third party, and conform and promote the European level for these standards ; for the structure of headers and transport architecture, ebXML standard is strongly considered, in relation with HL7
- codes - they are a general requirement, which has to be considered at international level, at least European, for all medical data (for instance biology, pharmacy); what is necessary is a standard way for code identification and localisation and for request and answer to code repositories.

Priorities for demonstrating interoperability were:

- secure messaging between healthcare professionals and institutions belonging to different networks;
- exchange of electronic healthcare record elements automatically between heterogeneous EHR management software;
- access to a secured EHR database in an hospital, from a health care professional not known by the hospital;
- request and results for a laboratory message: or for radiology, between two actors using heterogeneous system, who have not established relation before;
- correct interpretation and treatment of documents for integrating in applications;
- international exchange of documents, international access to knowledge base, international access to EHR with need for translation of requests, international structures for XML schemas etc.

The **Russian** head of delegation to CEN TC 251 saw standards priorities as:

- standard for multilingual dictionary of medical terms (any manufacturer);
- the standard for transfer of medical data (ISO);
- the standard for providing understanding for computers of the semantic value of a term (W3C).

The priorities for demonstrating interoperability were:

- HL7, DICOM, LOINC;
- XML, RDF.

The response from **Slovenia** on standards priorities was:

- medicines classification system - the health insurance institute of Slovenia is renewing the classification of medicines in collaboration with Ministry of health and other relevant institutions at national level;
- implementation of a Public Key Infrastructure - all relevant international standards are applied. At national level there is cooperation with the Slovenian Governmental Certification Authority.
- health insurance card and health professional card: these have been designed on international standards, such as ISO 7618 and CEN, and considering other relevant EU recommendations.

The priorities for interoperability were:

- use of the health insurance cards for attesting the validity of insured persons health insurance in EU;
- medicines classification system as a base for implementing electronic prescriptions;
- emergency medical aid data set (coding and accessing this data on the Health insurance card or patient card);
- the Health Professional Card as an electronic identification document for health care workers in EU.

## **EHTEL A4 Patients Working Group**

The EHTEL Patients Working Group's view on priorities for standards are:

- uniform data standards for patient medical record information [PMRI] - Standard would be best HL7;
- electronic secured exchange - Standard would be best ISO;
- in order to provide patients with freedom of choice about where they receive treatment, Patient Identification, in a cross-border flow, would rely on interoperability between national systems;
- being consistent with Part A, development of a PKI across Europe rely on standards, (X509) but there's still legal issues about electronic signatures;
- in medical digital imaging, DICOM is well known and there is no need to promote another, or newer, standard. In that area, priority would be to promote DICOM use.

The priorities for interoperability are:

- identification;
- medical electronic secured exchange.

## **Suppliers**

Whereas small numbers of respondents and the bias of Germany means that responses from suppliers cannot be regarded as representative, the replies received were broadly in agreement with policy makers and the A4 Patient Working Group.

The highest priority was communications and particularly issues arising around EDIFACT, HL7, XML, DICOM etc.

Security was a concern relating to PKI and there were references to patient identification and professional directories. Training and e-learning had a profile amongst the suppliers which was not reflected by others.

Integrating the Healthcare Enterprise (IHE) was particularly mentioned by several respondents as a very welcome initiative.

## ANNEX C

### EXISTING INTERNATIONAL STANDARDS

#### Acronyms and abbreviations

CEN	Comité Européen de Normalisation
ISO	International Organization for Standardization
EN	Full CEN standard
ENV	CEN pre-standard (must be converted in to an EN within 5 years or withdrawn). Now known as a Technical Specification
CTS	CEN Technical Specification (a pre-standard which must be converted in to an EN within 5 years or withdrawn)
DTS	Draft Technical Specification
CR	CEN Report
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
HL7	Health Level 7
EDIFACT	Electronic Data Interchange for Administration, Commerce and Transport
DICOM	Digital Imaging and Communications in Medicine
IEEE	The Institute of Electrical and Electronics Engineers
ASTM	The American Society for Testing and Materials
NEMA	National Electronic Manufacturers' Association USA
SNOMED	the Systemized Nomenclature of Medicine
SNOMED RT	SNOMED Reference Terminology
SNOMED CT	SNOMED Clinical Terms
LOINC	Logical Observation Identifiers Names and Codes

#### General

ENV 12017:1997	Medical informatics vocabulary (MIVoc)
EN 12443:1999	Medical informatics healthcare information framework (HIF)

ENV 12967-1:1998	Healthcare Information System Architecture (HISA)- Part 1: Healthcare Middleware layer
CR 12161:1995	A method for defining profiles for healthcare
HL7	HL7 Messaging Standard Versions 2 and 3 (see later)
CR	General domain model

### **Electronic records**

ENV 13606-1	Electronic healthcare record communication Part 1: Reference architecture
ENV 13606-2	Electronic healthcare record communication Part 2: Methodology for clinical domain modelling
ENV 13606-3	Electronic healthcare record communication Part 3: Security requirements and distribution rules
ENV 13606-4	Electronic healthcare record communication Part 4: Methods for the exchange of information
CR	Electronic Healthcare Record Communication – Domain Model
ISO WD 18308:2001	Functional requirements for the Electronic Health Record reference architecture
HL7 CDA	The Clinical Document Architecture
HL7	HL7 Messaging Standard Versions 2 and 3 (see later)

### **Messaging**

ENV 12538:1997	Messages for patient referral and discharge
ENV 12612:1997	Messages for the exchange of healthcare administrative information
ENV 1613:1995	Messages for exchange of laboratory information
CR 12700:1997	Supporting document to ENV 1613: 1995 – Messages for the exchange of laboratory information
ENV 12539:1997	Request and report messages for diagnostic service departments
ENV 13730-1	Blood transfusion related messages - Part 1: Patient related messages
EN 1370-2	Blood transfusion related messages - Part 2: Product related messages
ENV 13609-1	Messages for maintenance of supporting information in healthcare systems

ENV 13609-2	Messages for maintenance of supporting information in healthcare systems - Part 2: Updating of medical laboratory-specific information
EN 12537-1	Registration of information objects used for EDI in healthcare-Part 1: The register
EN 12537-2	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
CR 12587:1996	Methodology for the development of healthcare messages
CR	Quality of service requirements for healthcare information interchange
CR 1350:1993	Investigation of syntaxes for existing interchange formats to be used in healthcare
CEN WD	General purpose components for messages -Part 1: Data types and common classes Part 2: Healthcare agents Part 3: Message header information Part 4: Patient matching information Part 5: Common clinical components
CEN NWI	Mapping of hierarchical message descriptions to XML
ISO DIS 17113:2001	Method for development of messages
ISO TR 18307:2001	Key characteristics for interoperability in messaging and communications standards
ISO NWIP	Framework for emergency data sets
ISO NWIP TR 16056-1	Interoperability of telehealth systems and networks - Part 1: Introduction and definitions
ISO NWIP TR 16056-2	Interoperability of telehealth systems and networks - Part 2: Real-time systems
ISO PWI Standard 21090	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 (see later)
HL7	HL7 Messaging Standard Versions 2 and 3 (see later)

### **Electronic prescription and pharmacy**

ENV 13607:1999	Messages for the exchange of information on medicine prescriptions
ENV 12610:1997	Medicinal product identification
HL7	HL7 Messaging Standard Versions 2 and 3 (see later)

## Security

ENV 12251:2000	Secure user identification for healthcare: management and security of passwords
ENV 13608-1	Security for healthcare communication- Part 1: Concepts and terminology
ENV 13608-2	Security for healthcare communication - Part 2: Secure data objects
ENV 13608-3	Security for healthcare communication - Part 3: Secure data channels
ENV 13729:1999	Secure user identification for healthcare - strong authentication using microprocessor cards
ENV 12388: 1996	Algorithm for digital signature services in health care (revision to EN underway)
ENV 12924: 1997	Security categorisation and protection for healthcare information systems (revision to EN underway)
CR 13694:1999	Safety and security related software quality standards for healthcare (SSQS)
CR	Framework for formal modelling of healthcare security policies
CTS WD	Security requirements for intermittently connected devices
CR	Safety procedures for identification of patients and related objects
CTS WD	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
EN 14485	Guidance for handling personal health data in international applications in the context of the EU Data Protection Directive
EN 14484	International transfer of personal health data covered by the EU Data Protection Directive - High level security policy
ISO TS 17090-1	Public key infrastructure - Part 1: Framework and overview
ISO TS 17090-2	Public key infrastructure - Part 2: Certificate profile

ISO TS 17090-3	Public key infrastructure - Part 3: Policy management of certification authority
ISO NWIP TS	Security requirements for archiving and backup - Part 1: Archiving of health records
ISO NWIP TS 21091	Directory services for communications and identification of professional and patient
ISO PWI	Framework for health information security
ISO WD 22857	Guidelines on data protection to facilitate trans-border flow of personal health information
ISO PWI TS 22600	Privilege management and access control
ISO DTR 21089	Trusted end-to-end information flows

### **Professional/patient health 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	Identification, administrative and common clinical data structure for Intermittently Connected Devices used in healthcare (including machine readable cards)
ISO WD 20301:2001	Health cards - general characteristics
ISO WD 20302:2001	Health cards - numbering system and registration procedure for issuer identifiers
ISO DIS 21549-1	Patient healthcard data - Part 1: General structure
ISO DIS 21549-2	Patient healthcard data - Part 2: Common objects
ISO DIS 21549-3	Patient healthcard data - Part 3: Limited clinical data
ISO WD 21549-7	Patient healthcard data - Part 7: Electronic prescription
ISO PWI 21549-8	Patient healthcard data - Part 8: Links

### **Semantics, classification and coding schemes**

EN 12264	Categorial structures of systems of concepts - model for representation of semantics
EN 1828	Categorial structures for surgical procedures
ENV 13940:2000	System of concepts to support continuity of care

EN 1614	Structure for nomenclature, classification and coding of properties in clinical laboratory sciences
ENV 14302	System of concepts to support nursing
CTS	A syntax to represent the content of medical classification systems
CR	Vocabulary - Maintenance Procedure for a web-based terms and concepts database
CR 1350: 1993	Investigation of systems for existing interchange format to be used in healthcare
ENV WD	Clinical knowledge resources – Metadata
ENV WD	Categorical structure for anatomy
CTS WD	Categorical structure for documentation of patient findings and problems
CR WD	Categorical structure for representation of conditions in classifications, coding systems and clinical terminologies
ENV NW1	Categorical structure for a concept system for imaging procedures
ENV NW1	System of semantic links in medicine
ISO WD 17115	Vocabulary of terminological systems
ISO DTS 17117	Controlled health vocabularies - Vocabulary structure and high level indicators
ISO WD 18104:2001	Integration of a reference terminology model for nursing
ISO PWI	Terminology expressions in clinical data
ISO PWI	Distribution formats for terminology
ISO PWI	Semantics of terminology
SNOMED RT	SNOMED Reference Terminology - College of American Pathologists
SNOMED CT	SNOMED Clinical Terms - College of American Pathologists
LOINC	Logical Observation Identifiers Names and Codes – primarily pathology
WHO	ICD 10 (International Classification of Diseases Version 10)
WHO	ICF International Classification of Functioning, Disability and Health
WHO	ICNP International Classification of Nursing Practice
WHO	ICPC-2 International Classification of Primary Care
WHO	INN – International Non-proprietary Names
WHO	International Classifications of Mental and Behavioural Disorders

## **Imaging and multimedia**

EN 12052:2001	Health Informatics - Digital Images - Communication, ordering and management
ENV 12623:1997	Media interchange in medical imaging communications (MI-MEDICOM) – to be replaced by EN 12052
CR 13058:1997	Mapping between the models specified in ENV 12539:1997 and NEMA PS3 supplement 10
ENV 13939:2000	Medical data interchange: HIS/RIS-PACS and HIS/RIS - modality interface
ETG 068	Multimedia medical data interchange
ACR/NEMA:	DICOM (see later)

## **Diagnostic services and laboratory systems**

EN 12435	Expression of results of measurements in health sciences
EN & ISO 13728	Instrument interfaces to laboratory information systems
ISO FDIS 18812	Clinical Analyser Interfaces to Laboratory Information Systems - Use Profiles
ASTM E1394-97	Standard Specification for Transferring Information between Clinical Instruments and Computer Systems
HL7	HL7 Messaging Standard Versions 2 and 3 (see later)

## **Medical Devices**

ENV 12611:1997	Categorial structure of systems of concepts - medical devices
ENV 13735:1999	Interoperability of patient connected medical devices
EN 1064: 2002	Standard communications protocol - computer-assisted electrocardiography
ENV 13734:1999	Vital signs information representation
CTS	File exchange format for vital signs
CR 14300:2001	Interoperability of healthcare multimedia report systems
CTS WD	Evaluation of physiological analysis systems
ENV NWI	Descriptive elements for interoperability of device data file formats and application invocation
ISO 11073	Point-of-care - medical device communications
IEEE 1073	Draft Standard for Medical Device Communications - Medical Device Data Language (MDDL) (see later)
ISO PWI 11703-90100	Analytical instruments - Point-of-care test

## Statistics

ISO WD TS 21667:2001	Health indicators: conceptual framework
ISO WD TR 17119	Health informatics profiling framework
ISO NWIP	Definitions, attributes and relationships

## e-Learning

ISO NWIP TS 16058	Interoperability of telelearning systems
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## Other

EN 12381: 1996	Time standards for healthcare specific problems
ISO DIS 17120	Country identifier mechanism in healthcare

## CEN TC251 Strategic Studies

N99-093	Strategic review of Healthcare Message Standards Alignment (Final Report) David Markwell 1999-11-03
N99-079	Annexes to the Draft final report of Strategic review of healthcare Message Standards Alignment David Markwell 1999-08-11
N99-021	Short Strategic Study: Systems of concepts for nursing: a strategy for progress Nicholas Hardiker & others 1999-03-05
N98-061	Short Strategic Study: Enabling Technologies - SGML/XML Andrew Hinchley 1998-07-16
N98-082	Short Strategic Study: Enabling Technologies - UML Tim Benson 1998-05-25
N98-083	Strategic Short Study - Names and Numbers as Identifiers Robin Hopkins 1998-05-18
N98-084	Strategic Short Study - Names and Numbers as Identifiers: Summary of Recommendations

## HL7

### HL7 Version 2

Version 2 covers:

- 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
- Medical Records/Information Management
- Appointment Scheduling and Resources.

- Primary Care Referral Messages
- Patient Care - Problem-oriented records

### **HL7 Version 3**

Version 3 has much the same scope as version 2, but messages are created using a formalised methodology, outlined in the Message Development Framework underpinned by a Reference Information Model (RIM). Messages will thus be more precise with fewer options than version 2.

### **HL7 CDA: The Clinical Document Architecture**

This standard provides an exchange model for clinical documents (such as discharge summaries and progress notes).

### **DICOM**

DICOM is a standards organisation administered by the Diagnostic Imaging and Therapy Systems Division of the National Electronic Manufacturers' Association (NEMA) in the USA.

NEMA PS 3.1 2000	Digital Imaging and Communication in Medicine (DICOM) Part 1: Introduction and Overview
NEMA PS 3.2 2000	Digital Imaging and Communication in Medicine (DICOM) Part 2: Conformance
NEMA PS 3.3 2000	Digital Imaging and Communication in Medicine (DICOM) Part 3: Information Object Definitions
NEMA PS 3.4 2000	Digital Imaging and Communication in Medicine (DICOM) Part 4: Service Class Specifications
NEMA PS 3.5 2000	Digital Imaging and Communication in Medicine (DICOM) Part 5: Data Structures and Encoding
NEMA PS 3.6 2000	Digital Imaging and Communication in Medicine (DICOM) Part 6: Data Dictionary
NEMA PS 3.7 2000	Digital Imaging and Communication in Medicine (DICOM) Part 7: Message Exchange
NEMA PS 3.8 2000	Digital Imaging and Communication in Medicine (DICOM) Part 8: Network Communication Support for Message Exchange
NEMA PS 3.10 2000	Digital Imaging and Communication in Medicine (DICOM) Part 10: Media Storage and File Format for Data Interchange
NEMA PS 3.11 2000	Digital Imaging and Communication in Medicine (DICOM) Part 11: Media Storage Application Profiles
NEMA PS 3.12 2000	Digital Imaging and Communication in Medicine (DICOM) Part 12: Media Formats and Physical Media for Data Interchange

NEMA PS 3.13 2000	Digital Imaging and Communication in Medicine (DICOM) Part 13: Print Management Point-to-Point Communication Support
NEMA PS 3.14 2000	Digital Imaging and Communication in Medicine (DICOM) Part 14: Grayscale Standard Display Function
NEMA PS 3.15 2000	Digital Imaging and Communication in Medicine (DICOM) Part 15: Security Profiles
Supplement 1	Common media storage functions for data interchange - Addenda on Directory, media storage service class and data dictionary
Supplement 2	Part 11: Media storage application profiles - addenda on conformance
Supplement 3	Storage functions and media formats for data interchange
Supplement 5	Ultrasound application profile, IOD and transfer syntax extensions
Supplement 9	Multi-byte character set support
Supplement 11	Basic Work list management (Modality work list management SOP class)
Supplement 15	Visible light image, anatomic frame of reference, accession and specimen for endoscopy, microscopy and photography
Supplement 17	Performed procedure step SOP class
Supplement 30	Waveform interchange
Supplement 31	Security enhancements one
Supplement 33	Softcopy presentation state
Supplement 41	Digital signature
Supplement 50	Mammography Computer-Aided Detection SR SOP Class
Supplement 52	Interpretation work list
Supplement 55	Attribute level confidentiality (including de-identification)
Supplement 61	JPEG 2000 Transfer Syntaxes
Supplement 62	4.1 Gbyte MOD medium format and use in CT/MR profiles
Supplement 65	Chest Computer-Aided Detection SR SOP Class
Supplement 68	Retirement of Storage Commitment Pull Model
Supplement 69	640 Mb and 1.3 GB 90mm MOD medium format and use in US profiles

## IEEE

### IEEE 1073

1073.1	Draft Standard for Medical Device Communications - Medical Device Data Language (MDDL) - Overview and framework
1073.1.1	Draft Standard for Medical Device Communications - Medical Device Data Language (MDDL) - Common definitions

1073.1.1.1	Draft Standard for Medical Device Communications - Medical Device Data Language (MDDL) - Nomenclature
1073.1.2	Draft Standard for Medical Device Communications - Medical Device Data Language (MDDL) - Virtual medical device, Generalizations
1073.1.2	Virtual Medical Device, Specialized - Domain Information Model
10731.3.1	Draft Standard for Medical Device Communications - Medical Device Data Language (MDDL) - Medical Device Specializations - Infusion Device
1073.1.3.3-2001	Draft Standard for Medical Device Communications - Medical Device Data Language (MDDL) - Medical Device Specializations - Ventilator
1073.2-1993	Draft Standard for Medical Device Communications - Medical Device Application Profiles (MDAP) - Framework and Overview.
1073.2-1994	Standard for Medical Device Communications - Medical Device Application Profiles (MDAP) - Base Standard.
1073.2-1995	Standard for Medical Device Communications - Medical Device Application Profiles (MDAP) - Minimum profile
1073.2-1996	Standard for Medical Device Communications - Medical Device Application Profiles (MDAP) - Basic profile
1073.2-1997	Standard for Medical Device Communications - Medical Device Application Profiles (MDAP) - Extended profile
1073.3.1-1994	Standard for Medical Device Communications - Transport profile - connection mode
1073.3.1a-2000	Standard for Medical Device Communications - Transport profile - connection mode
1073.3.1a-2000	Standard for Medical Device Communications - Transport profile - connection mode
1073.3.2-2000	Standard for Medical Device Communications - Transport profile - IrDA Based - Cable Connected
1073.4.1-2000	Standard for Medical Device Communications - Physical Layer interface - Cable connected

## **IEEE 1157**

1157	Draft Standard for Healthcare Data Interchange - Overview and framework
1157.1	Draft Standard for Healthcare Data Interchange - Information model methods
1157.1.1	Draft Standard for Healthcare Data Interchange - Common healthcare objects
1157.1.2	Draft Standard for Healthcare Data Interchange - Registration - Admission/Discharge/Transfer

- 1157.1.3 Draft Standard for Healthcare Data Interchange - Laboratory
- 1157.2 Standard for healthcare data interchange - interchange format methods
  - 1157.2.1 Standard for healthcare data interchange - EDI/EDIFACT interchange formats
  - 1157.2.2 Standard for healthcare data interchange - ODA/ODIF/SGML interchange formats
  - 1157.2.3 Standard for healthcare data interchange - CMIS/CMIP interchange formats
- 1157.3 Standard for healthcare data interchange - Communication profile methods
- 1157.4 Standard for healthcare data interchange - semantics and knowledge representation of the medical record
- 1157.5 Recommendations for healthcare data interchange - user  
This standard has effectively been superseded by later standards.