ISSS-FG/eHealth/030
2004-07-23

eHealth Standardization Focus Group

Report from the

CEN/ISSS eHealth Standardization Focus Group

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

Draft V3.1

with amendments by Francois Mennerat, Gunnar Klein and Peter Jensch

Contents

1 Preface

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

The full terms of reference of the Focus Group are in Annex A.

Its objectives were

- To consider, with all the relevant stakeholders, priorities and objectives for eHealth 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/TC 251, ISO/TC 215, ITU, DICOM and HL7;
- To consider the standards implications of the Ministerial Declaration of 22 May 2003, following the Commission/Presidency eHealth 2003 Conference;
- 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-organized Open Meeting;
- To finalise the report in the light of public comments and the Open Meeting discussions.

Its scope was to cover the concept of eHealth 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.

Membership of the Focus Group was opened to all interested parties through a public web announcement. A membership list is in Annex B.

2 Executive summary

To be written by Ray Rogers after meeting on 26 July

3 Introduction

Evolution of ICT in health – the critical stage

Many nations have reached a critical and challenging stage in the application of ICT to health and many other nations are fast approaching the same position. Within these countries most healthcare organisations have already computerised at departmental level, and many of these, whilst partially integrated across the enterprise, have reached the most difficult stage of completing that enterprise integration by implementing an electronic patient record including applications such as decision support, clinical pathways and protocols, e-prescribing. Furthermore enterprises in the nations which are most advanced are facing the challenge of applying ICT to communications and integration between healthcare organisations and are doing so on a large scale – regional or national. For some, this means the creation of electronic health records to be shared between organisations and perhaps fully accessible to patients including, in some cases, data input.

Integration between organisational entities requires agreement between the collaborating parties on common standards: integration without such agreements is not possible. Integration within a single organisation requires agreements simply between the relevant departments and can be achieved relatively easily without necessarily any reference to the outside world. That can also be achieved reasonably easily between a few collaborating healthcare organisations. However, when integration is being attempted on a large scale, particularly nationally, then central national organisation becomes essential to create the means for agreeing the standards to be used. This is the point that many nations have now reached and these countries are actively deciding on the standards that are to be used.

The mechanisms for reaching agreement on such standards varies from country to country but typically ICT policy makers in Ministries of Health (or equivalent) decide the priorities for the application of ICT and then delegate the responsibility for choosing the standards to a body of experts. The latter may be the formal national standards body (i.e. the National Member Body NMB of CEN /ISO) but more frequently it is not.

Choosing standards

Those nations in the process of nationally integrating are about to spend many € billions on ICT over the next five to ten years against extremely tight and ambitious timetables. They need to agree, pilot and implement standards quickly and be certain that they interoperate in the environments and culture of their national health systems. Where will they find the standards they require?

Member States of the EU and EFTA have obligations under EU Directives and the World Trade Organisation (WTO) to use international standards in procurements where such standards exist. These obligations primarily derive from the objective of reducing barriers to trade. Vendors who market their products across the EU and more widely will see these obligations as important – no vendor will wish to have to design its product to different standards for each country in which it is marketed. However, to date, there are few EU-based vendors of health ICT products who market pan-European. Many ICT health products derive from the USA and the latter exercises significant influence on standards within the vendor community. This influence derives substantially from USA influence on standards for integrating ICT in hospitals (standards from the USA-based organisation

HL7). If international health ICT standards are defined as those from CEN TC251 and ISO TC215 (as many believe is the case in EU Directives and WTO agreements) then the commitment by ICT policy makers and their advisors to utilise them is weak amongst those nations who are most advanced with committed schedules. Reasons are varied but include:

- ignorance of CEN TC251 and ISO TC215 existing standards and those in the work programme;
- perceived lack of successful implementations of a suite of interoperable standards and lack of complete profiles of standards which will enable a whole application;
- weak vendor commitment and lack of products on the market which comply with TC251 and/or TC215 standards.

Many nations when seeking out standards for their priority applications realise that there are gaps both in the standards required to achieve a complete suite and in the means to test interoperability where standards do exist. In some areas such as messaging there are competing and conflicting standards and often the challenge is the bringing together of standards from a variety of standards development organisations and getting them to inter-work.

In some areas, the most influential standards in the vendor community derive from bodies which have achieved an international influence and authority outside the formal International/European standards bodies e.g.
;

- the USA based HL7 inc. for messaging;
- DICOM for imaging;
- IEEE for medical device communications.

Some nations are looking more to these bodies for their standards needs than to CEN TC251 and ISO TC215. That having been said CEN TC251, ISO TC215, HL7, DICOM, IEEE and other bodies engaged in standards development such as WHO, are increasingly collaborating as witnessed by the recent formation of an e-Health Standardisation Coordination Group, under the auspices of the ITU (International Telecommunications Union).

However where schedules are tight and high profile, some nations have resorted to creating their own national standards. Whereas the latter may in due course provide an input to international or European standards development organisations that is usually not the prime objective. In ideal circumstances it could be argued that, where a nation identifies a need for standards it should, through its national member body, turn to CEN or ISO to meet its needs and actively engage in the necessary development. The reaction to that proposition tends to be:

- CEN or ISO are too slow and bureaucratic;
- involvement in CEN and ISO involves too many compromises;
- CEN and ISO standards compete and conflict with strong vendor-led standards development organisations such as DICOM, HL7, IEEE;
- there is no mechanism to provide assurance that CEN and/or ISO standards will inter-work between themselves or with those from other standards development organisations.

Whilst these reactions had firm foundation in the past and still have justification at present, circumstances are changing and improving very rapidly. Those changes are not always evident to national ICT policy makers, for example:

- ISO TC215 now has formal agreements for the adoption of HL7 and IEEE standards and is moving towards an agreement with DICOM;
- CEN TC251 has a Memorandum of Understanding with HL7 and has adopted the policy of basing its standards on the HL7 Reference Information Model (RIM);
- new mandatory schedules have been adopted by CEN and ISO for the faster development and publication of standards.

However in a Europe which is seeking close integration at all levels, and an EU which is expanding and promoting increased mobility of citizens and access to cross-border healthcare, this position is unsatisfactory. This report makes recommendations to improve the international standards environment with the aim of achieving a greater commitment by Member States to international standards and their development and testing. By international standards is here meant the output from the many bodies which are involved not solely CEN TC251 and ISO TC215. Whereas achieving that greater commitment may not be practicable in the short term for those nations who are already committed to expenditures and tight timetables, there are many Member States at a less advanced stage that, it is believed, could benefit form the report's recommendations. Such benefit would be reinforced if those Member States who are most advanced were actively to input their experience into the improved processes which this report envisages.

The report structure

It would be impossible for this report to analyse all the strategies, policies and plans across Europe and to address all the ICT applications involved in health and all consequent standards requirements. This report therefore:

1. Identifies priority strategies and policies which appear common to a number of countries in Europe and elsewhere and identifies the top priority ICT applications required to meet those strategies and policies.
2. Identifies priority ICT applications from the viewpoint of stakeholders (Chapter 6)
3. Identifies priority ICT applications within EU policies and Commission Communicators (Chapter 7).
4. Concludes the overall priority applications required from the combined national, EU and stakeholder viewpoints (Chapter 8)
5. Examines the world of standardisation and relationships of the many bodies involved (Chapter 10).
6. Examines and lists existing standards and work in progress (Chapter 11).
7. Considers the challenge of achieving interoperability (Chapter 12).
8. Analyses the requirements of priority strategies and policies, applications and infrastructure in the context of standards requirements (Chapter 13).
9. Considers what needs to be done and makes recommendations (Chapter 14).

4 Methodology

Overall approach

The overall approach adopted by the Focus Group was to:

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

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) and as expressed in EU policy documents;
- WP2 reviewed any known existing national and EU policies on standardisation in e-health;
- WP3 defined of priority requirements from the perspective of stakeholders;
- WP4 reviewed and classified existing standards and work programmes;
- WP5 addressed the analysis and recommendations.

5 Priorities for the application of ICT to health: National strategies and policies

Identifying priorities

National priorities for the application of ICT to health were ascertained by

- Examining existing documents particularly the European Health Telematics Association (EHTEL) reports **[Ref 9,10]**
- A questionnaire survey.

Results

A full analysis is given in Annex C.

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

- health / patient records including the medication record;
- 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. PAC / RIS);
- ensuring semantic meaning.

6 Priorities for the application of ICT to health: Stakeholders views

The members of the Focus Group itself provided the stakeholders' view on the priorities for the application of ICT to health. They supported the priorities identified from national strategies and policies in Chapter 5 and those identified as EU priorities in Chapter 6. With some exceptions the general view was that priorities should be concentrated on intra-organisation processes for the applications of ICT rather than inter-organisation.

The main priority areas identified were:

- Health/patient records (including medication record)
- Transfer of Prescriptions (including the contribution of prescription data to the medication record)
- Communication of service requests and reports for laboratory investigations and patient referral
- Imaging and associated service requests and reports
- Security and access control
- Quality and safety
- Support of patient mobility
- Terminologies for clinical records and medicines

NOTE It is proposed that during the period of public comment particular effort is made to validate this chapter. This might include the European Organisation for Medical Specialists (UEMS) as suggested by Kees Smedema

7 Priorities for the application of ICT to health: EU strategies and policies

Annex D analyses EU strategies and policies in the context of:

- eEurope 2005 **[Ref DD]**;
- the Ministerial Declaration of 22 May 2003 **[Ref 1]**;
- e-Health - Making healthcare better for European Citizens : An Action Plan for an European e-Health Area COM (2004)356 **[Ref HH]**;;
- initiatives regarding patient mobility between EU Member States COM (2004)301 **[Ref JJ]**;
- Community action in the field of public health (2003-2008) **[Ref 7]**.

It concludes that the following should be considered amongst the priorities 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 for the public/patients and healthcare professionals.
- 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".

8 Electronic trading of healthcare goods

This notion of 'health care goods' may encompass the purchasing, distribution, and delivery of a variety of proper goods, as well as of services. Examples of this 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 it 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 health care 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 regulations, 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, although not limited to, message formats to comply with specific requirements.

This seems to be currently the only area where standardisation may respond to actual needs, with a degree of urgency which depends heavily on the moves taken or not by public authorities to better focus the regulations to the evolution of the citizens' common behaviour, and of the resulting market.

E-pharmacy currently appears as the domain where standards are the most urgently needed.

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 nor to make recommendations concerning it.

9 Priorities for the application of ICT to health: Conclusions

Priorities identified from national strategies and policies

Chapter 5 concluded that the following should be considered as top priorities for the application of ICT to health:

- health / patient records including the medication record;
- transfer of prescriptions;
- communication between hospitals and GPs/primary care;
- protecting personal information (with emphasis on Public Key infrastructure and professional data cards);
- reducing clinical errors (particularly through e-prescribing with decision support);
- improving efficiency.

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

- 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.

Priorities identified by stakeholders

Chapter 6 concluded that the main priorities from a stakeholders' point of view were:

- Health/patient records
- Transfer of Prescriptions
- Communication of service requests and reports for laboratory investigations and patient referral
- Imaging and associated service requests and reports
- Security and access control
- Quality and safety
- Support of patient mobility
- Terminologies for clinical records and medicines

Priorities identified from EU documents

Chapter 7 concluded 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.

Additionally it was identified that the above 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”.

Conclusions on priorities

The top priorities identified from the above and the analyses in Annexes C and D are a mixture of strategic aims, applications and infrastructure. They are:

Strategic aims
- improving access to clinical records
- enabling patient mobility and cross border access to healthcare;
- access to quality information on health for patients and professionals;
- reducing clinical errors and improving safety;
- improving access to quality health information;
- improving efficiency of healthcare processes;

Applications
- electronic health / patient records including health record architecture;
- electronic transfer of prescriptions;
- electronic health data messages between hospitals and primary care particularly communication of service requests and reports for laboratory investigations and patient referral;
- digital imaging and associated service requests and reports;
- e-prescribing with decision support;
- core data sets e.g. for public health;

Infrastructure
- management of patient identification including:
  - EU Health Insurance Card perhaps containing an medical emergency data set and controlling access to data in a patient’s country of residence;
  - A common approach to patient identifiers;

    - Access control and authentication;
- protecting personal information (with emphasis on Public Key Infrastructure and data cards for professionals and citizens/patients);
- terminological systems for clinical records and medicines;
- data cards.

As indicated in Chapter 12 and Annex E an overall priority is to achieve interoperability.

10 The world of standardisation and standardisation policies

written by Francois Mennerat and amended by Gunnar Klein

10.1 Needs for standardisation and standardisation policies of the EU

The goals of standardisation
The overall objective of standardisation is to facilitate the production, handling, or use of products or services. In the framework of free trade and free market, the best possible satisfaction of both users and suppliers is at stake.

The role of standards has repeatedly been highlighted by the European Union official policies, e.g. the Council Conclusions 1999[1]:

"THE COUNCIL OF THE EUROPEAN UNION,

EMPHASISING the role of European standardisation as a means to meet specific needs of the European market, to serve the public interest, in particular in support of European policies, to provide standards in new domains, to implement international standards in a coherent way and, while respecting the independence of national standards bodies, to facilitate mutual understanding between Member States' standards bodies and the preparation of coherent positions in international standardisation;"

and further more recently in the Council Resolution 2002[2]:

"THE COUNCIL OF THE EUROPEAN UNION,

reaffirms the important role of standardisation for the internal market and its growing contribution to different policies and actions such as governance in the EU, e-Europe, the strategy for sustainable development, and global trade"

The operational goal of standardisation is to provide sets of consistent specifications — called "standards"— to be shared by all parties manufacturing the same products, or providing the same services, and form the basis for further developments. The ISO/IEC and CEN definition is:

standard
document, established by consensus and approved by a recognized 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 [ISO/IEC Guide 2:1996]

NOTE: Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits.

[1] OJ 2000/C 141/01
[2] OJ 2002/C 66/01

In order to be useful, and attract as many actual users as possible, standards shall have the following characteristics:

- They are easily available: they are well publicised, they can be obtained at the lowest possible cost; on the economic ground, to make them successful, it must prove cheaper and quicker to rely on standards than to make new developments from scratch to cover (entirely) the same needs.
- They represent a sufficient consensus: they reflect the state of the art at their time of publication, meaning that the area of knowledge they cover is reasonably stable. 'Reasonable' stability does not bar any progress from being ever made. Standards evolve, and this raises the issue of the backward compatibility of resulting products. While standards are meant to introduce a certain degree of order in the production, the 'versioning' intends to manage the relationship between the successive versions of standards.

Standards may derive from various processes:

- Standards in most cases result from a voluntary process initiated by important actors in a domain, to bring order and clarity, to establish a common base for market development. Typically it involves both suppliers of products and its customers. Standardisation in many sectors has been dominated by suppliers but increasingly, the development of standards is under pressure from the end users (the 'consumers'), or even initiated by them. This is particularly the case nowadays for ICT in health.
- Public authorities on a national or European level may also trigger the development of standards, and try to stimulate interested parties to find consensus. In some cases especially related to health and safety of the citizens, public authorities may use standards as part of regulation where technical standards detail how to meet legal requirements e.g. for safety of a product. In the European Union this has been called the New Approach directives (although now over 15 years).
- De facto standards may also appear somehow spontaneously, often as the result of a success story, with various interested parties stating that they are definitely willing to share the same characteristics for their products. This involves a whole range of different situations from one market leader actually owning the specification and decides on possible changes to various more or less formal consortias or for a that adapt a rule set resembling that of formal standards bodies. The long term maintenance of such specifications is sometimes a problem. In the ICT area there are over 250 such informal bodies that publish standards and are more or less open.
-

What role for public authorities? *De jure* and *de facto* standards

Whatever the perspective taken, the development of standards is of public interest. Thus the relationship between standardisation and the political power cannot be played down.

The European Council highlighted this in the conclusion on standardisation 2002[3]:

"the Council
reiterates the need for public authorities to acknowledge the strategic importance of standardisation, in particular by maintaining a stable and transparent legal, political and financial framework, in which standardisation can further evolve, and for national standards bodies to continue to support the functioning of the European standardisation infrastructure and the attainment of common European objectives;"

[3] OJ 2002/C 66/01

How far can the use of standards be left dependent on the actors' goodwill, and when does it become necessary to mandate it? There are countries where the mandatory status of those specifications is settled by law, either as a generic principle, or for a precise domain.
Whatever initiative is at the origin of standards —from the suppliers, from the users (customers), or from the public authorities, all with different agendas in mind— if they are to become part of officially acknowledged regulations, they need to be endorsed by some official body. At this point, they are granted the status of *de jure* standard.
The scenery of industrial competition is not always as attractive as outlined here above.

- Several suppliers may take a joint initiative for common specifications, in order to permit the interchange, or the inter-operation, of their products, and foster the development of the market. This results in *de facto* standards. But such specifications may subsequently be challenged by another group of suppliers, so increasing the confusion, and impeding actual inter-operation by splitting the market into two (or more) groups of suppliers, with their own customers imprisoned in proprietary non interoperable products. To avoid this, some kind of official process has to take place.
- It may also sometimes occur that one single player gets so big a share of the market that the competitors cannot but comply to its specifications —also then *de facto* standards— to keep selling their goods, as long, however, as those specifications are not protected by patents. If the latter case occurs, which would result in a situation of monopoly, public authorities must take the decision to open up the market by endorsing a corresponding *de jure* standard on which all suppliers would have to align their products.
- A similar initiative may come from the other suppliers —together with, or alternatively from the customers— acknowledging in a consensual move the quality of the dominating specifications, they may manage so that these specifications are endorsed as a *de jure* standard, so permitting its maintenance to be controlled by more than one party.

The public authorities has a role also for the financing of standardisation activities but this varies between member stated from less than 20 % to more than 50 % of the costs of the national standards bodies. The European Commission and EFTA funding over all is only covering 2% of the costs.

The European Council concluded in 2002:

"The Council
considers however that the viability of the overall standardisation system in Europe remains far from secure in the light of a rapidly changing European and international environment and of changes in the traditional sources of income;
…
invites Member States to give constant consideration to the resources provided to European standardisation, either directly or via support to national standardisation;
invites the Commission to analyse the costs and benefits of Community financial support to European standardisation and how such support could be better targeted in order to contribute to the stability of the financing of European standards bodies."

The role of public procurement

In many countries, whenever a set of specifications is accepted, and registered, as a *de jure* standard, it becomes mandatory by law, as part of the legislation for public

procurement, that any invitations to tender in the domain it covers refer to the formal standards, and subsequently bidders have to take it into account in their offers. Though it may sometimes be challenged by circumventing manoeuvres, this proves an effective lever to enforce and generalise the use of *de jure* standards, given that subsequent private procurement is usually much influenced by public choices. In the European Union a set of directives on public procurement directives make such legislation mandatory in the member states but the interpretation of the meaning of the referral to standards is sometimes differ. The public procurement directives are available in several languages at the following web site: http://simap.eu.int/EN/pub/src/directiv.htm.

Rights of use

Beyond the issue of patents, the one of ownership and rights of use of *de facto* standards is crucial, particularly with regard to public procurement: it would not be acceptable that their use be requested, because this would automatically result in the payment of uncontrolled fees to a private organisation. This implies that official and publicly acknowledged standardisation bodies have a prominent role, and imposes that all successful specifications become *de jure* standards to be freely available in the public domain. It is the role of public authorities to guarantee that the market rules are fair, and to secure an income to no particular private player. This does not necessarily precludes that the standards describing documents need to be purchased —though at reasonable prices— from the standardisation bodies, but indeed this differs from the payment of —possibly— recursive fees for the right of use.

These considerations must be kept in mind when screening the existing standards. The willingness of their responsible organisations to protect their income, versus contributing to the public domain to help develop the market is a criterion for choice.

10.2 Standardisation bodies involved, and their relationships

In a quickly evolving context with regard to technology, standardisation aims at helping the various stake holders to keep pace with progress. It is supposed to accelerate technology transition —rather than slowing it down— by readying new techniques for adoption, and providing public validation of their utility.

At this point, a question arises: what is the preferable standardisation process? What is the quickest, the most efficient, and the most consistent process to design a standard? Channelling it directly through the official standardisation bodies from the beginning? Or letting it be developed, or even triggering its development, within a dedicated group — before submitting it for *de jure* standardisation?

Comment: This accreditation of bodies by a national standards body is to my knowledge only an American phenomenon and has no role in Europe.

Official standardisation bodies

National standardisation

Practically, there exists a National Standards Body (NSB) in all EU member states, as well as in other EEA countries (Switzerland, Norway and Iceland). Many have started as a public committee, but their status usually later evolved towards an independent private not-for-profit organisation acting in the public interest, a reason why they get the official support of public authorities. Increasingly, though, they are seeking to increase their turnover by broadening their domain of activities, which unfortunately somehow blurs their image for stake holders.

With slight variations from country to country, the responsibilities of NSBs are:

- the elimination of technical barriers to free trade

- the creation, co-ordination, approval, and promotion of standards that satisfy the national interests of the country in question
- the accreditation of standards development groups
- the monitoring and co-ordination with the standards-developing activities of other national organisations
- the performance of certain test and certification functions
- the accreditation of testing and certification organisations
- the handling of selected standards-testing functions from the standards organisations of other countries
- the provision of information about foreign national standards and international standards
- the creation of standards-based regulations, in relation with governments
- the representation of the country in question in European (e.g. CEN, CENELEC, and ETSI), or international standards bodies (e.g. ISO, IEC, and ITU-T)

European standardisation

In the context of the construction of a formal European unity, this set of missions has had to be reflected at the European level. Thus the *Comité Européen de Normalisation* (CEN - European Committee for Standardization) has been founded as early as 1961 by the national standard bodies in the European Economic Community and EFTA countries to contribute to their objectives with voluntary technical standards which promote free trade, the safety of workers and consumers, interoperability of networks, environmental protection, exploitation of research and development public programmes.

CEN is the major provider of European Standards and technical specifications. According to Directive 83/189 (now revised as Directive 98/34/EC), it is the only recognised European Organisation for the planning, drafting and adoption of European Standards in all areas of economic activity with the exception of electro-technology (in the care of CENELEC - the European Committee for Electro-technical Standardisation), and telecommunication (in the care of ETSI - the European Telecommunications Standards Institute), in a manner similar to what exists at the international level, with ISO, IEC, and ITU. It is registered according the Belgian law as a non-profit making international, scientific and technical organisation. The Members of CEN are the national standards bodies of the EU and EFTA countries. Until the recent enlargement of the European Union, they were 18, and are now 28.

Its mission is to promote voluntary technical harmonisation in Europe in conjunction with other partners in Europe, and world-wide bodies. Since harmonisation diminishes trade barriers, promotes safety, allows interoperability of products, systems and services, and promotes common technical understanding, CEN, as the integrated system for European standardisation, aims to:

- support the achievement of the European Single Market,
- enhance the competitiveness of European players in the global market,
- foster the European economy and the welfare of European citizens under the global concept of sustainable development,
- ensure the most efficient input of Europe to international standardisation activities and co-operation,

through the delivery of standards, other technical specifications and related services needed by interested parties in Europe, working to achieve all sectoral market needs in as close partnership as possible with CENELEC and ETSI.

European Standards are published and disseminated by National Members of CEN as national standards, and draft or experimental standards.

More recently, the 'New Approach' to technical harmonisation and the Global Approach to conformity assessment have confirmed the role of standardisation in Europe. Since 1987 some 25 Directives adopted on this basis have progressively come into force, with the dual purpose of ensuring the free movement of goods through technical harmonisation of entire product sectors, and of guaranteeing a high level of protection of public interest objectives referred to in Article 95 paragraph 3 of the EC Treaty. Innovative features of this legislative technique include the definition of mandatory essential requirements, the setting up of appropriate conformity assessment procedures and the introduction of CE marking. Business and industry are given a wide choice of how to meet their obligations. CEN, CENELEC, and ETSI have the task of drawing up technical specifications which offer one route to complying with these essential requirements.
The New Approach and the Global Approach are based on two fundamental pillars:

1. Council Resolution of 1985-05-07, where a 'New Approach to technical harmonisation and standards' is seen as an essential condition for improving the competitiveness of European industry.
2. Council Resolution of 1989-12-21 on a Global Approach to certification and testing, which states the guiding principles for Community policy on conformity assessment. The Global Approach was completed by Council Decision 90/683/EEC, which was replaced and brought up to date by Council Decision 93/465/EEC. These Decisions lay down general guidelines and detailed procedures for conformity assessment that are to be used in New Approach directives.

CEN/TC 251 is the sectoral Technical Committee of CEN for Health Informatics. It has been set up in 1990, with the first immediate aim of transferring into the corpus of European standards the biggest possible part of those technical specifications resulting from Health Telematics projects co-funded by the European Commission DG-XIII (now DG-InfSo) through the successive Framework Programmes for Research and Development, that remained in the public domain. Subsequently TC251 addressed a variety of relevant work items. To date, CEN/TC251 has produced over 50 technical documents (standards, pre-standards, and reports).

International standardisation

Basically, international standardisation relies on the International Standards Organisation (ISO), the International Electro-technical Commission (IEC), and the International Telecommunication Union (ITU), all three established in Geneva, Switzerland, as parts of the United Nations system.
As for the European standardisation bodies, their members are the NSBs, here of most countries in the world. But while National Standards Bodies of European countries are usually simultaneous members of international standardisation bodies as well as of European standardisation bodies, no hierarchical relationship exists between e.g. ISO and CEN.
An essential differentiating characteristics of international standards, as compared to European ones, is that they are legally less stringent with regard to national standardisation. The agreements between ISO and its member NSBs do not imply that international standards override national ones, as European standards do. The decision of incorporating an international document into a national corpus of standards is left at the discretion of each NSB, with the notable exception of those ISs which are taken as the basis for ENs, or are developed jointly as ENs under the Vienna agreement between CEN and ISO.
This Agreement on technical co-operation between ISO and CEN (Vienna Agreement), was formally approved on 27 June 1991 in Vienna by the CEN Administrative Board, following its approval by the ISO Executive Board at its meeting on 16 and 17 May 1991 in

Geneva. After a decade of experience, the need for the Agreement was confirmed by both ISO and CEN and a simplified version, setting out the principles of the original version, was confirmed by ISO Council Resolution 35/2001 and CEN Administrative Board Resolution 2/2001. The agreement embraces many situations, such as (though not limited to these):

- Co-operation through mutual representation at meetings of committees and working groups
- Adoption by one organisation of available publications from the other organisation
- Co-operation by mutually agreed allocation of work with parallel approval of standards in ISO and CEN
- Decision to carry out parallel approval of a standard in ISO and CEN
- Maintenance of identical ISO and CEN standards

ISO/TC 215 is the sectoral Technical Committee of ISO for Health Informatics, and it has been set up in 1998, after CEN/TC251 proved successful. Since then, besides a few standards which have been developed strictly within TC215, and with a dominating input from European experts, its major achievement has been to channel specifications originated in various US-based organisations as international standards.

The membership of the International Telecommunication Commission (ITU) includes 189 Member States, over 640 Sector Members, and also over 90 Associates. It represents a cross-section of the telecommunications and information technology industry, from the world's largest manufacturers and carriers to small, innovative new players working in new fields like IP networking. Founded on the principle of international co-operation between government and the private sector, the ITU represents a global forum through which government and industry can work towards consensus on a wide range of issues affecting the future direction of this increasingly vital industry. ITU has three sectors: Radiocommunication Sector - ITU-R, Telecommunication Standardisation Sector - ITU-T, and Tele-communication Development Sector - ITU-D.
No ITU health specific standards have been identified, but the growing awareness of the telecommunication needs in this sector have led to the initiation of a study in on eHealth standardization within the Videoconferencing group. ITU also took the initiative to an important international gathering of stakeholders from both the telecommunication and the health sectors, in the Workshop on eHealth Standardisation held in Geneva under the aegis of ITU on 23-25 May 2003 which led to the formation in 2004 of the eHealth Standardization Co-ordination Group.

Other eHealth standards development organisations (SDOs)

DICOM
DICOM (Digital Imaging COMmunication) is a standards organisation creating, and maintaining standards for communication of biomedical diagnostic and therapeutic information in disciplines using digital images and associated data. DICOM is administered by the NEMA Diagnostic Imaging and Therapy Systems Division.
DICOM aims at achieving compatibility and improving workflow efficiency between imaging systems and other health information systems. Connectivity works because DICOM is an international co-operative standard. Every major diagnostic medical imaging vendor in the world has incorporated the standard into their product design and participates in the enhancement of the Standard. DICOM is now used by virtually every medical profession using images world-wide, and participate in its enhancement.
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, TC215 not creating a working group for bio-medical imaging standards, but relying instead on DICOM

Where there are interfaces to standards based on other technologies (such as HL7 V2.x and 3), the focus for harmonisation is on a shared information model.
When specific new technology is required, such as in support of new features such as security and compression, the strategy is to adopt proven international, industry or de facto standards.
All of DICOM specifications have been endorsed as a formal European standard and they will be submitted to become also *de jure* standards in ISO.

HL7, Inc.
HL7 —Health Level Seven,—by reference to the 7th layer of the OSI model— has been founded in 1987 by several vendors of software for the health care industry. Their goal was to develop messages consensual formats to facilitate a better interoperability of Hospital Information Systems (HIS).
In 1994, HL7 has been accredited by ANSI, the American National Standards Institute, the official standardisation body of the United States, as a Standards Developing Organisation (SDO), meaning that HL7 approved specifications are since then channelled into the official standardisation 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 US and several European countries.
An XML-based 'Clinical Document Architecture' set of specifications has been 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 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 message specifications, currently under development, will use a formalised methodology, outlined in a Message Development Framework underpinned by the Reference Information Model (RIM), in order to make messages more consistent than in previous versions.

Current contributors or 'Benefactors' to HL7 include vendors —Siemens, GE Medical Systems, HBOC-McKesson, IBM, Oracle, Microsoft, Philips—, and US or non-US agencies —Veterans Affairs (US), NHS (UK), Centers for Disease Control and Prevention — CDC (US), Standards Australia (Australia), AFNOR (France). Public-private partnerships have also been established with Infoway (Canada), NICTIZ (The Netherlands. Other 'benefactors' include US health care 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 , Germany , Greece , India , Ireland, Italy, Japan , Korea , Lithuania, Mexico, New Zealand, Poland , Spain, South Africa , Switzerland, Taiwan , The Netherlands, The United Kingdom. France is to come soon, while setting up a HL7/USA is sometimes said to be under consideration.

The major focus of interest from other parties in HL7 is undoubtedly the Reference Information Model (RIM). It is noteworthy that this large task of forming an object model of basic building blocks for all Health information is a huge task and it took the HL7 organisation 8 years to agree on a first release. The derived messages from this tool set has not yet been approved.

While the premises of this enormous task can be found in the development previously made in CEN in the nineties, for its messaging pre-standards, it is not challenged that the RIM will be used world-wide as the basis for any future work towards integration or interoperability. The RIM is currently being submitted to ISO for approval as an International Standard.

The only concerns which are expressed are with the responsibility over its maintenance, as well as with its dissemination process. The future relationship between ISO and the HL7 consortium on these matters needs clarification, as will subsequently do the relationships between HL7 affiliates, and National Standards Bodies.
Also, will compliance to the RIM imply that messages are developed uniquely within HL7? Since the use of the RIM as the basis for message development, and the compliance to it will guarantee interoperability —thus easy integration—, an unsolved issue is the degree of freedom which is left to SDOs in developing message formats of their own.
An example of this are the relationships between the future releases of the CDA, and the European standard EN 13606 (EHRcom) now sent for ballot in CEN as well as in ISO, while both claim conformance to the RIM.
Another example regards the development of messages for e-pharmacy, where there are parallel initiatives in the USA, where HIPAA mandates the use of e-pharmacy message standards developed by NCPDP (National Council for Prescription Drug Programs, Inc., an ANSI-Accredited SDO), and outside the US with an initiative started by the Netherlands.
Other areas of potential conflicts may appear in the future, and the relative roles of official and non official SDOs will have to be clearly worked out.

EBI
The European Bioinformatics Institute (EBI) is a non-profit academic organisation that forms part of the European Molecular Biology Laboratory (EMBL).
The EBI is a centre for research and services in bioinformatics. The Institute manages databases of biological data including nucleic acid, protein sequences and macromolecular structures.

The mission of the EBI is to ensure that the growing body of information from molecular biology and genome research is placed in the public domain and is accessible freely to all facets of the scientific community in ways that promote scientific progress.
As the data made available by bioinformatics research will progressively be made available to health professionals, the data bases of EBI will increasingly be searched by field users. This new area of communication will require the use of standards.
Bioinformatics should be accounted for in standardisation activities for e-Health.

The Institute of Electrical and Electronics Engineers (IEEE)
The IEEE results 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 standardisation 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. The IEEE Standards efforts in healthcare are mainly two:

- IEEE 1073, Standard for Medical Device Communications: a family of documents that defines the entire seven layer communications requirements for the "Medical 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, CEN/TC 251 and ISO/TC 215. Working with ISO TC 215, 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 are now developed and published jointly by IEEE, CEN and ISO.

American Society for Testing Materials (ASTM)
The American Society for Testing Materials (ASTM) is one of several organisations that develop standards under ANSI, the American National Standards Institute, the official standardisation body of the United States.
ASTM is active in the field of Healthcare Informatics. ASTM/E31 is the committee responsible for healthcare Informatics.
ASTM has for long fuelled a variety of international standards.

Standards supporting initiatives

IHE — Integrating the Healthcare Enterprise
Started by RSNA, IHE subsequently became a joint initiative between HIMSS and RSNA- to improve the integration of systems. it aims at providing a process for a co-ordinated adoption of standards: clinicians and IT staff define needs, vendors develop solutions (a technical Framework) —in 2003, 36 vendors were involved in the USA, and 43 in Europe—, professional societies (HIMSS/RSNA, etc.?) supervise documentation, testing, demonstration, and promotion. Partnerships so exist currently with the American College of Cardiology (ACC), American College of Clinical Engineering (ACCE), HL7, and DICOM.

IHE has no legal status, as it has no proper budget. Participants from the software industry volunteer to contribute to the IHE initiative at their own expense, with the expectation of a return on investment in the form of a commercial advantage.
This initiative aims at speeding up the rate and quality of integration in healthcare environments, fostering communication among vendors, proving that integration is attainable based on standards, and improving the efficiency and effectiveness of clinical practice.
The needs for the IHE initiative comes from the statement that standards are necessary but not sufficient for seamless implementations: they are not "Not plug and play", each interface requires site specific analysis and configuration. Eventually they may be costly to implement and to maintain. IHE delivers integration profiles built on existing standards.
IHE makes it clear that it is not a standards development organisation. It uses existing standards (so far DICOM, HL7, etc.) to address specific clinical needs. Its activity is to be regarded as complementary to SDOs. It has formal relationship with DICOM, and HL7.
IHE is simply a demonstration project, for IHE demonstrations represent only one means to the end adoption of profiles and standards. These demonstrations are backed up by documentation, tools, testing, and publication of information.
The IHE initiative is an intra-enterprise, bottom-up approach supporting a multi-year, standards based, vendor neutral project that creates a framework to seamlessly convey vital information from application to application, system to system, and setting to setting.
The foreseen benefits claimed by the IHE initiative for its participants do not differ from those of standards in general, but the emphasis is put on the practical limitations in the implementation of standards.
An IHE Integration Profile organises a set of coordinated, standards-based transactions between a subset of the functional components of healthcare enterprises in order to address a specific clinical or infrastructure need.
IHE develops such solutions for IT systems integration in a stepwise and pragmatic manner, focusing on the most common integration challenges.
IHE has developed close to 20 Integration Profiles focuses on Radiology, Laboratory, IT Infrastructure (MPI, Security, etc.).It is now expanding to Cardiology, and now starts considering the exchange of clinical documents.
IHE profiles are devised in an intensive process based on a stepwise approach, according to annual cycles.

- the development of profiles is done at the global level, in only one place at a time, by a small group of people;
- the deployment is organised by (world) regions, and by countries, based on national "chapters", and Connect-athons are organised at the "regional" level. National ProRec centres should talk to national chapters.

The EuroRec Institute

The 'European Institute for Health Records' (also dubbed "The EuroRec Institute") had been founded in 2002, and formally registered in 2003 under the French law, as a non-profit association. It represents a new step in the PROREC initiative. The PROREC[4] initiative followed the conclusions of the Concerted Action MEDIREC (1994-1995), and has been developing since 1996 with a strong support from DG "Information Society" (initially DG-XIII), in particular through the PROREC Support Action (1996-1998), and the WIDENET Accompanying Measure (2000-2003).

Its organic tools take the form of a network of national non-for-profit organisations (the "ProRec centres") sharing the same goals, and relying on the same fundamental principles and goals:

[4] Promotion strategy for European health Records

- Building up an awareness of the limitations, shortcomings, and obstacles on the way towards a widespread development, implementation, and use of quality Electronic Health Records (EHRs), and pointing them out. Among a variety of criteria that may outline what quality means in this domain, the ability to communication and interoperability, are outstanding.
- Helping proactively to identify and set up the locally relevant solutions to lift those limitations, shortcomings, and obstacles.

The ProRec national centres gather in a balanced way representatives and opinion leaders from both the users' and the solution providers' categories, while they keep up an ongoing confident relationships with public authorities and decision makers.

To date, 10 national ProRec centres are in existence (Belgium, Spain, France, Slovenia, Germany, Italy, Ireland, Bulgaria, Denmark, and Romania), 2 are currently preparing their registration (Norway, and Cyprus), and promising contacts have been taken in 6 more countries (Portugal, The Netherlands, Hungary, Poland, Sweden, and the U.K.)

The objectives of the Institute are to federate the established ProRec centres, and to develop specifically, according to the principle of subsidiarity, those activities that cannot be handled at the level of ProRec centres. For instance, The application of the European Institute for Health records as the Registration Authority for EN 1068 "Health Informatics — Registration of coding schemes" is supported by CEN/TC251.

Also, the Institute is currently actively investigating with DG "Enterprise" how to implement a quality labelling (or certification) process of electronic health records systems available in members states of the European Union.

It is not in the objectives of the EuroRec Institute to act as a Standards Development Organisation. Conversely, supporting the standards, either already published or in preparation, and raising the level of awareness of their existence and content in the suppliers' and users' communities, is part of its mission, as well as of national ProRec centres, inasmuch their implementation represent a foremost criterion for good quality EHR systems.

The EuroRec Institute co-operates with IHE-Europe to help the development of profiles in the area of EHRs.

EHTEL — European Health Telematics association

The "European Health Telematics Association" (EHTEL) was founded in 1999 under Belgian law as an international non-profit association. It aims at contributing to the implementation of information and communication technologies in the health and social domain, and believes that eHealth tools offer substantial benefits for the improvement of:

- quality of health for patients and citizens
- access to services
- efficiency of care
- cost effectiveness

As a membership driven European association, EHTEL offers a platform to all stakeholders of eHealth in order to exchange information, to identify problems and find solutions for the implementation of the above goals. This is realised through networking between the stakeholders, the organisation of conferences, workshops and specific task forces.

EFMI — European Federation for Medical Informatics

EFMI was conceived in September 1976 at a meeting in Copenhagen, assisted by the Regional Office for Europe of the World Health Organisation (WHO). The representatives of national Health / Medical Informatics societies from ten European countries (Belgium,

Denmark, Finland, France, Federal Republic of Germany, the Netherlands, Italy, Norway, Sweden, and the United Kingdom. Today, the following countries are represented in the Federation - the original ten plus Austria, Bosnia-Herzegovina, Bulgaria, Cyprus, Croatia, Greece, Hungary, Eire, Israel, Portugal, Romania, Slovenia, Spain, Switzerland, and Ukraine) signed a declaration of intent stating:
"The Federation shall be constituted as a non-for-profit organisation concerned with the theory and practice of Information Science and Technology within Health and Health Science in a European context. We declare that the ten delegates here today from the ten national societies shall constitute the preliminary Council of the Federation which thus hereby exists."
Each European country, as defined by the WHO Region, is entitled to be represented in the Federation by a suitable Health Informatics Society.
The term "health informatics" is used here to include all aspects of the use of information management and technology in the fields of health care and health promotion.
EFMI has formal liaison with:

- WHO
- the Council of Europe,
- the International Medical Informatics Association (IMIA),
- the European Commission Research Programme.

EFMI is well known for its Medical Informatics Europe (MIE) conferences, which take place two years in every three (so as not to clash with IMIA's three-yearly Medinfo conferences). The first MIE conference was held in 1978.
EFMI has 13 working groups:

- MCMS - MBDS, Case Mix and Severity of cases
- DPS - Data Protection and Security
- NURSIE - Nursing Informatics in Europe
- IPM - Information Planning and Modelling in Health Care
- EDU - Education in Health Informatics
- PCI - Primary Care Informatics
- NLU - Natural Language understanding
- OIMI - Organisational Impact in Medical Informatics
- MICIT - Medical Informatics in Transition Countries
- EVAL - Assessment of Health Information Systems
- EHR - Electronic Health Record
- MIP - Medical Imaging Processing
- WGCA - Cards

IMIA — International Medical Informatics Association

The origin of IMIA are to be found in Technical Committee 4 (TC4) of the International Federation for Information Processing (IFIP), established in 1967. In 1979, it evolved from this Special Interest Group of IFIP to its current status as a fully independent organisation. In 1989, the International Medical Informatics Association has eventually been established as an independent organisation under Swiss law. IMIA continues to maintain its relationship with IFIP as an affiliate organisation. In 1992, IMIA received official recognition the World Health Organisation (WHO) as a Non-Governmental organisation (NGO).
The basic goals and objectives of the association are to:

- promote informatics in health care and research in health, bio and medical informatics.
- advance and nurture international co-operation.
- to stimulate research, development and routine application.
- move informatics from theory into practice in a full range of health delivery settings, from physician's office to acute and long term care.

- further the dissemination and exchange of knowledge, information and technology.
- promote education and responsible behaviour.
- represent the medical and health informatics field with the World Health Organisation and other international professional and governmental organisations.

In its function as a bridge organisation, IMIA's goals are:

- moving theory into practice by linking academic and research informaticians with care givers, consultants, vendors, and vendor-based researchers.
- leading the international medical and health informatics communities throughout the 21st century.
- promoting the cross-fertilisation of health informatics information and knowledge across professional and geographical boundaries.
- serving as the catalyst for ubiquitous world-wide health information infrastructures for patient care and health research.

Inherent in this mission is to bring together, from a global perspective, scientists, researchers, vendors, consultants and suppliers in an environment of co-operation and sharing. The international membership network of National Member Societies, IMIA Regions, Corporate and Academic Institutional Members, and our Working and Special Interest Groups that constitute the "IMIA family" is uniquely positioned to achieve these goals.
IMIA organises the tri-annual "World Congress on Medical and Health Informatics" (MEDINFO). The first such conference took place in Stockholm in 1974.

Co-operation mechanisms between standardisation bodies

The co-operation mechanisms are varied, and depend on their respective status.

The Vienna Agreement between ISO and CEN
The co-operation between CEN and ISO relies on the Vienna agreement. According to this general framework, work items of interest for both parties can be the subject for occasional agreements meaning that one party may lead the work on behalf of both, and the approval is processed in parallel in both organisations.
However, given the difference between International and European standards with regard to binding the NSBs, careful attention should be paid in European mirror groups to the drafts circulated when they are meant to result in ENs.

ISO Fast Track procedure
International Standards are developed by ISO technical committees (TC) and subcommittees (SC) by a six step process. If a document with a certain degree of maturity is available at the start of a standardisation project, for example a standard developed by another organisation, it is possible to omit certain stages. In the so-called "Fast-track procedure", a document is submitted directly for approval as a draft International Standard (DIS) to the ISO member bodies (stage 4: Enquiry stage) or, if the document has been developed by an international standardising body recognised by the ISO Council, as a final draft International Standard (FDIS, stage 5: Approval stage), without passing through the previous stages.

ISO Pilot Projects
Since 1998, ISO has sought opportunities to work with selected SDOs to speed up the standardisation process for specifications felt as mature for quick adoption as de jure standards. The very first such pilot project concerned the IEEE 1073 series of specifications. Following this process, IEEE keeps responsibility for the maintenance of the documents, and ISO channels them to ISO members.

The issue regarding the ownership of the rights on the standards published also arises with the Pilot Projects.

Bilateral co-operation between bodies

Many of the formal and informal bodies have recognised the need for co-operation and various liaison agreements exists. Thus CEN/TC 251 and HL7 entered an important Memorandum of Understanding in 2000 where it was agreed to exchange expert views and draft standards to explore harmonization and submit results to ISO.

Similarly, CEN/TC 251 and DICOM has co-operated for ten years.

The E-Health Standardization Coordination Group (eHSCG)

The establishment of the E-health Standardization Coordination Group" (eHSCG) was proposed by the Workshop on "Standardization in e-Health" (Geneva, 23-25 May 2003) with representatives of several standards bodies and WHO and endorsed by ITU-T SG16 in May 2003. A formal invitation to join was sent from ITU to WHO, ISO/TC 215, CEN/TC 251, IEEE/1073, IEC/TC 62, DICOM and HL7 and asked for acceptance to joint and nomination of a representative. All except IEC responded and have participated in the planning phase.

The overall objective is to promote stronger coordination amongst the key players in the e-Health Standardization area. The terms of reference of the original invitation are reproduced in the annex here.

The eHSCG is performing informal consultation and coordination on voluntary basis and its recommendations are purely advisory. In particular they do not supersede any official and legal coordination procedures in place at national and international level.

Terms of reference

1. *The eHSCG shall be a coordination group on all aspects of e-health standardization.*
2. *The eHSCG should strengthen the cooperation amongst the SDOs involved, improving information exchange between organizations and avoiding duplication of efforts.*
3. *The eHSCG shall be technical (as opposed to regulatory) in nature taking into consideration regulatory, economic, medical and social issues.*
4. *The eHSCG should consider the requirements for appropriate development paths for health profiles of existing standards from different sources in order to provide functional sets for key health applications.*
5. *The eHSCG shall provide guidance for implementations and case studies.*
6. *The eHSCG shall support activities to increase user awareness of the existing standards, case studies, etc (for example via a specific website).*
7. *The eHSCG should meet regularly, taking advantage of the presence of the experts in e-heath-related technical standardization meetings.*
8. *The eHSCG shall in undertaking the above, always consider the requirements of developing countries as well as the experiences from case studies.*
9. *The eHSCG should establish and maintain a dedicated website with information on e-health standards, e-health case studies, and standardization activities.*

This group had its first meeting in April 2004 and has agreed to compile a list of all available eHealth standards as one first action item. An activity proposed by WHO is also planned to accompany the second World Summit on the Information Society in the fall of 2005 to highlight the importance of standards for eHealth. The first chair of the group is Gunnar Klein, CEN and the vice chair, Yunkap Kwankam, WHO.

The IHE initiative

The IHE initiative is sometimes regarded as a process which specifies the use of selected standards. It is true that IHE benchmarking favours the use of those standards for which implementation 'profiles' have been developed, but it might be damaging that all other standards be ignored following what can be seen as an independent private initiative.

11 Existing standards and work in progress

CEN/TC251 "Health Informatics"

TC251 is the sectoral Technical Committee of CEN for Health Informatics. It was instituted in 1990 in order to transfer 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.

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.

However, during this first phase, TC 251 produced no full standard, but pre-standards (and CEN reports) only. Later, with the revision of these pre-standards, full standards show up. European pre-standards (now known as Technical specifications) are only valid three years before they are revised, and they do not override national documents dealing with similar subjects. Therefore, they were regarded as purely indicative, and without any constraining value. Conversely, 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 flow of publications has been impressive: leaving apart a number of much valuable strategic studies, 25 pre-standards (including 2 multiple-part), and 4 CEN reports.
In a later phase, CEN/TC251 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 later 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 TC 251 based the development of messages on preliminary modelling. It only progressively, however, that the need to relate specific domain models within a generic Reference Information Model arose, and this has been achieved within HL7 which develops the Reference Information Model (RIM).

CEN/TC 251 has established a Memorandum of Understanding with HL7, in order to foster collaboration and harmonisation between the approaches of both organisations.

ISO/TC 215 "Health Informatics"

The Technical Committee "Health Informatics" of ISO has been created in 1998. Its scope is defined as: "Standardisation 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 TC 215 is 14. TC 215 liaises with several organisations: CEN, DICOM, ICN, IMIA, UN/ECE, W3C, ETC. The work of TC 215 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 medicines business

ISO/TC 215 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 telehealth systems and networks -- Part 1: Introduction and definitions
ISO/TR 16056-2	Health informatics -- Interoperability of telehealth 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

DICOM

Founded in 1983 by the American College of Radiologists (ACR) and the National Electronic Manufacturers' Association (NEMA), the DICOM consortium is acting as an internationally acknowledged SDO. It is now administered by the Diagnostic Imaging and Therapy Systems Division of NEMA in the USA.
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.

The Institute of Electrical and Electronics Engineers (IEEE)

The IEEE Standards efforts in healthcare are mainly two:

- IEEE 1073, Standard for Medical Device Communications: a family of documents that defines the entire seven layer communications requirements for the "Medical 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/TC 215. 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) originated 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.

The American Society for Testing Materials (ASTM)

The American Society for Testing Materials (ASTM) is one of several organisations that develop standards under ANSI, the American National Standards Institute, the official standardisation body of the United States.
ASTM - is active in the field of Healthcare Informatics, and ASTM/E31 is the committee responsible for healthcare Informatics.

HL7

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

Message specifications ("HL7 standard") Version 1.0 were approved in 1987, and were followed by version 2.0 in 1998.

Versions 2.x
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

CCOW
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 has been 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 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 is now submitted to ISO for approval as an International Standard.

UN/CEFACT

UN/CEFACT is the United Nations Centre for Trade Facilitation and Electronic Business, to be distinguished from EDIFACT, the United Nations Directories for Electronic Data Interchange for Administration, Commerce and Transport
UN/CEFACT has published the Core Components Technical Specification.
This UN/CEFACT ebXML Core Components Technical 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.

eBusiness industry standards consortia

The Electronic Business XML Initiative (ebXML)

ebXML is an international initiative established by UN/CEFACT (see section 0, page 36) and OASIS. The United Nations Centre for Trade Facilitation and Electronic Business (UN/CEFACT) and the Organisation for the Advancement of Structured Information Standards (OASIS) have joined forces to initiate a worldwide project to standardise XML business specifications.

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, international standards and specifications, in effect XML specifications, to be used in a consistent and uniform manner for the exchange of all electronic business data.

For this project UN/CEFACT and OASIS have established the "Electronic Business XML Working Group" (ebXML/WG) to develop a technical framework that will enable XML to be used in this view, as well as eight Project Teams:

1. Business Processes
2. Core Components
3. Technical Architecture Requirements
4. Transport/Routing and Packaging
5. Registry and Repository
6. Technical Co-ordination and Support
7. Technical Architecture
8. Marketing, Awareness, and Education

Membership in the ebXML initiative is open to any group or organisation engaged in developing solutions for the use of XML in EDI, e-Commerce, and e-Business. Industry groups currently working on XML specifications have been invited to participate.

The ebXML initiative is not a commercial undertaking. The results of the Electronic Business XML Initiative will be placed in the public domain on XML.org.

CEN/ISSS eBusiness related workshops

The provision of specifications to facilitate eBusiness has become a core theme in CEN/ISSS. This involvement can be traced back a long way, to the creation of the standards for Electronic Data Interchange (EDI) under the aegis of the UN-ECE. While many multi-national companies and Governments are still using EDI, we are slowly moving towards harmonised solutions for e-business transactions using XML. CEN/ISSS is specifically working to encourage the adoption of specifications using the UN/CEFACT-OASIS ebXML framework. CEN/ISSS has also become active in other areas that are essential to the harmonised introduction of e-business tools that can be used by large and small companies alike, as well as by public authorities.

CEN/ISSS activities in eBusiness are:

- eBES (ebXML) Workshop
- eBusiness Interoperability Forum (eBIF)
- eCataloguing-classification Workshop
- eConstruct Workshop
- eInvoicing Workshop
- eProcurement Workshop

CEN/ISSS is formally the "European Entry Point" to the United Nations e-business standardisation activities, and is a "user" signatory to the ISO/IEC/ITU/UN-ECE Memorandum of Understanding on electronic business standardisation in support of e-commerce. It also collaborates with industry standards consortia in this field.

A full classified list of standards is available in Annex F.

12 Achieving Interoperability

Background

As previously emphasised, standards are the necessary foundation upon which eHealth information access and sharing can be accomplished on a scale that exceeds a few care delivery organizations. Hospitals and large clinics have been actively working at integrating the various specialized IT systems needed to establish such electronic health record system within their walls. Although standards have to been used to some degree, the average experience of the Chief Information Officers who have managed these investments is that, in most cases, healthcare standards have not delivered on their promise. They played a critical role, but did not deliver "actual interoperability" as expected within hospitals. A few will however have noticed that certain domains are exception to this general situation.

Most observers would agree that the rapid adoption of PACS in imaging departments has been facilitated by the use of the DICOM standard where good interoperability has proven possible. Analyzing the root causes for this relative success is a complex subject, but most observers agree that that both the clinical professional community and the vendors of products in this domain have engaged a number of accompanying initiatives such as Integrating the Healthcare Enterprise (IHE) **[See Annex A What is this?]** to facilitate the adoption of the standards and achieve a noticeably higher level of effective information sharing across competing vendors products. This Chapter builds on a number of similar experiences both in healthcare, but also in other domains (e.g. ETSI) **[See Annex B What is this?]** where similar achievements have been realized.

This Chapter proposes a European strategy to fill the gap between published healthcare IT standards and their use to reach effective interoperability. By "effective" is meant:

- Significant integration problems are completely addressed. This often requires the combined use of healthcare IT communication standards and generic IT standards.
- Effective information communication is achieved that includes non-ambiguous interpretation and usage of this information.
- Workflow integration in the scope of the integration problem is addressed and requires minimum customization and results in a reduced cost.
- A significant number of compliant products are available on the market with successful deployment by a number of healthcare delivery organizations.
- A number of supporting services are in place so that interoperable products may be deployed.

Filling this gap is a significant economic challenge as well as a critical success factor. A number of healthcare IT vendors have expressed concerns about the significant increase of the proportion of expenses devoted to performing IT systems integration compared to that of their acquisition costs. Over the last few years these integration costs have increased from 20 to 30%, which represents a trend that needs to be reversed.

eHealth may not be realistically achievable unless interoperability measures are organized alongside the development of the necessary standards. The content, the objective and the approach to ensure that these accompanying measures are put in place, is the subject of this Chapter.

From reactive Integration to proactive integration

Presently interoperability between healthcare IT systems is achieved in a reactive manner. Reactive, because such integration is a significant effort for the IT staff of healthcare institutions and it includes many “adaptations” and “extensions” to healthcare IT systems that have not been designed in a “plug and play” fashion. This requires an understanding of the flows of information and matching them to the network interfaces of the products, and often adapting and extending them to match those of other systems. Even when standards are supported by these interfaces local variants, similar to language dialects, often prevent ‘gluing’ together the various vendors’ implementations of the “standards”. This is ‘after the fact’ or ‘reactive’ integration.

Moving to a proactive integration is the proposed approach to achieve standards-based interoperability. Establishing a common understanding of the workflows, ahead of the actual installation, is certainly something standards designer have attempted to account for in the design of their standards. However it needs to be to recognised that the breadth of the requirements that a standard has to address for broad applicability and the compromises accepted to reach consensus often results in a lack of actual interoperability for the most common usages.

The Five Steps of a proactive integration process

It is critical to recognize the complexity of this integration process where various categories of players are directly involved in the process:

- Health professionals: these include care providers, representing many different medical specialties. Unfortunately they often do not have the time, the interest or the background to be actively involved in the standardization processes.
- IT staff: they play a key role for the larger healthcare institution but are often absent in the smaller care delivery practices. Also they may not be very active in the standards development organisations.
- Healthcare IT vendors: providers of clinical and administrative IT systems and data generating medical devices, e.g. imaging. They span from large multi-national companies all the way to smaller companies focusing on a regional or even national market.
- Administrative staff: they may play a key role for the larger healthcare institution but are often absent for the smaller care delivery practices.
- Health authorities and payers: Government-related structures that oversee the healthcare system and have a variety of relationships with the payers or insurance providers.

Therefore “technical information flows integration” for eHealth needs to account for the variety of stakeholders, in particular, the health professionals who will have their work environment directly impacted by the way in which the eHealth standards are used to support their workflows. Directive processes are therefore unlikely to be successful, and one should look towards collaborative processes. Mandates for applying standards may come into play, but need only to conclude the process rather than to drive it. Five major steps are to be taken to address interoperability:

1. **User Problem Identification.** Clinicians and IT experts, represented by their professional societies at the national or European level, identify common integration

problems in accessing information, and clinical workflow,. As a prerequisite of any interoperability, they define the different roles or actors in a workflow, and the information that needs to be exchanged, in a kind of very high-level architecture. (Many aspects of large public IT projects are for example well described in the German SAGA 2.0 requirements **Reference please**).

2. **Integration Profile Specification.** Healthcare technical experts look for healthcare specific or general IT standards, and the necessary support from the underlying infrastructure that address that need. Specific technical choices are made and documented. The term "Integration Profiles" introduced by IHE will be used to distinguish these specifications from the standards on which they are based. Note that although the starting point for the User Problem Identification is always the use of existing standards, the conclusion maybe that certain standards lack the capability to solve the user's problem. In that case the appropriate standards organization is asked to enhance the standard, and the process stops here until the standard is enhanced. This interaction between User Problem Identification, Integration Profile Specification and Standards Development has proven a very effective process to arrive at practical standards that solve the needs of the clinical community.

3. **Interoperability Testing.** Vendors who seek to implement an Integration Profile relevant to their product scope need a place to test it with other vendors. The IHE has introduced a so-called Connect-a-thon to do this. It is held every year at the European level, but hosted by different countries of Europe. IHE Connect-a-thons are also held in North America and Asia. This allows vendors to assess the maturity of their implementation and resolve very quickly and in a cost-efficient manner issues of interoperability with other vendor products in a supervised testing environment. The results are published and experience has proven this process to be quite effective while avoiding the many complexities and high costs of certification.

4. **Integration Statements and RFPs.** Vendors are highly motivated to publish Integration Statements that document the Integration Profiles supported by their products. This level of specification is such that users (clinicians and IT staff) can understand and reference the appropriate integration profiles in their requests for proposals (RFP), thus greatly simplifying the systems acquisition process.

5. **Success Stories.** The ultimate goal is the successful practical deployment of "Integration profile based" capable systems in multi-vendor seamlessly integrated healthcare solutions. As demonstrated by IHE, such Integration Profiles form the blueprint and guiding implementation roadmap for an effective, efficient, future-proof step-by-step approach to healthcare systems interoperability.

Throughout these five steps, lessons are learned, corrections or gaps in the Integration Profiles specification are addressed, the need for additional integration profiles identified, and most importantly feedback is provided to the standards development organizations for clarifications in existing standards and the need for additional standards.

It is important to note that a broad array of user-driven Integration Profiles will be needed. These can be organized in three categories:

1. **IT Infrastructure**: These Integration Profiles achieve integration at the level of the infrastructure upon which clinical processes and clinical information may be effectively shared. Examples are: Patient Identification cross-referencing, user authentication, cross-enterprise document sharing, information access control, etc.

2. **Health Information**: These Integration Profiles achieve the representation of health information objects so that interoperability can be achieved at a semantic level, i.e. clinical information can be interchanged and understood by different systems. They rely intensively on information models, archetypes and coded vocabulary standards and should be addressed by specialty domains. It is important to note the current lack of consistency in terminology standards. But these issue need to be addressed at the standards development level.

3. **Health Workflow**: These Integration Profiles achieve the active collaboration between healthcare providers and professionals (e.g. Orders/results, referral, scheduling, second opinion). These Integration Profiles generally build upon the above two foundation categories, and provide the visible "value add" to the users.

Supportive Services for Interoperability

(Section to be provides by Gerard)

Organizing Proactive Integration in Europe

IHE has defined over the past 6 years the Interoperability processes as described and used it not only in Europe, but also in North America and Asia with close to one hundred healthcare vendors worldwide that have contributed to, and demonstrated the delivery of, ready-to-integrate products to benefit healthcare enterprises, small and large. Chief Information Officers and clinicians appreciate its positive impact on low-friction multi-vendor integration and low-risk IT investment. eHealth in Europe should leverage this experience.

It is critical to understand that organizing the delivery of Interoperability is a difficult task. For the naive user, it is all about "standards". Howvere the processes necessary and the level at which the various stakeholders need to be involved is quite different. Interoperability needs to be organized with an independent (but related) structure than that of the standards development organizations. The development of interoperability, because it relies on existing standards may proceed on a more time controlled (typically a yearly cycle), with the ability to focus on the primary integration needs. In this process, standards from multiple organizations will be used, requiring at times a selection and sharpening process for the best fit. The development of Integration Profiles and the implementation in products will require a more "industry" driven approach on the technical side, whereas the "clinical community" will have to be involved in making sure that the workflow and information content for their clinical practice is effectively supported.

General Conclusions

Interoperability Support Activities are critical to bridge the gap between existing standards and their interoperable and rapid implementation. From an eHealth point of view, these activities should concentrate on the sharing of health information between care delivery organizations. In order to do so:

- relevant stakeholders need to adopt a collaborative process for the development of interoperability solutions based on existing standards.

- This process needs to be separate from the process of the development of standards, since it will typically involve several standards from different SDOs.
- It needs to leverage the successful process and experience that has been developed in the IHE Initiative in Europe.
- The process needs to include the formulation of technical specifications in the form of “integration profiles” imposed on standards, and a visible verification process.
- Continued education as well as the promotion of achieved interoperability are an integral part of the process.
- A number of interoperability supporting services need to be organised either at the European or the national level.

13 Analysis

Identifying priorities for applications and standards

The priorities listed in Chapters 5, 6, 7 and 9 and the ICT applications standards and interoperability conditions required to support them, derive form highly complex thought processes in national and international settings and by individual stakeholders and the organisations and associations to which they belong. There are often very different starting points, cultural and organisational environments and analytical processes.

Theoretically the process would commence with strategic aims backed by plans followed by identification of how to use ICT to realise those aims e.g. applications. However the process is never that simple. A strategic aim such as 'improving the health of the population' will spawn very many sub-strategies and a multiplicity of plans. Sub-strategies will generate further strategies and so on. Each will lead to conclusions about facilitating ICT applications. The processes are so complex that in practice they are rarely, if ever, fully undertaken or made explicit except for the simplest of objectives: the world of health is too extensive and complex.

Thus national ICT strategies and policies, and those of the EU, are usually presented without the backing of a full explicit analytical procedure. More usually ICT strategies and policies tend to emerge from statements of a limited number of aims with any supporting argumentation either only implied or assumed to be obvious.

That having been said there are a number of key applications which tend to emerge from many strategic policies and aims no matter what the starting point, the cultural or organisational environment or the viewpoint – national, international or stakeholder groups. That this is so is illustrated by the high degree of commonality of ICT priorities that are evident in national ICT policies and strategies across Europe and indeed in the wider world e.g. Australia, Canada and USA. Chapters 5, 6, 7, and 9 are testimony to that.

Identifying the necessary standards to enable priority applications is also complex. For example the application 'electronic transfer of prescriptions' requires not one standard but a set of standards. Such a set would include standards for:

- the message construction;
- the message content;
- medicines terminology;
- object codes: people and places;
- security enhancing technologies (perhaps encryption);
- access control and authentication measures (perhaps a public key infrastructure combined with data cards for patients and professionals).

These standards will need to inter-work. Some standards will also be required for very many other applications e.g. for access control and authentication measures and might therefore be regarded as part of an organisational infrastructure.

The messages may also be required to interface and interoperate with other applications. For example the electronic prescriptions may be the carrier of data for a medication record which in turn may be part of a wider electronic health record. It will be necessary therefore

to ensure the different applicants interoperate. Finally of course there will need to be other technical infrastructures such as a network.

It is not possible for this report to lay out and analyse all the strategic aims which organisations, nations and the EU are following, or might later follow, and thereby derive the enabling ICT priority applications and corresponding standards requirements. For the priority applications this report relies on national and EU views on what they are, together with stakeholder opinions i.e. as in Chapters 5, 6, 7, and 9.

Nevertheless the following is a partial and illustrative analysis supporting the focus groups conclusions.

The illustration is based on Table 1. It takes five strategic aims which appear to be common and of high priority to most nations, most stakeholders and the EU. It examines very broadly the nature of the ICT applications which might be required to support those aims and then examines broadly the nature of the requirements for achieving inter-working within and between applications. Some of the problems and issues are highlighted.

Table 1: Identifying priority applications, standards and interoperability

Strategic aims	Examples: • improving access to clinical records; • enabling patient mobility and cross-border access to healthcare; • reducing clinical errors and improving safety; • improving access to quality health information • improving efficiency of healthcare processes.
Means for achieving strategic aims: ICT applications	Examples: • electronic health records; • electronic messaging; • electronic decision support • electronic access to knowledge bases; • security enhancing technologies • health information web sites.
Achieving inter-working within and between applications	Examples: • standards; • interoperability criteria; • conformance testing; • networks; • common terminologies.

Strategic aims

Improving access to clinical records

The issue can be expressed as being the possibility for a health care professional in charge of a patient to have access at the point of care to the most relevant information, in the easiest way, and in the smallest possible time.
This is not a matter only for emergency care. It is important for the delivery of the best possible quality health care at any time. For instance, to reduce clinical errors and improve safety, it is of utmost importance in any circumstance for a health professional to base her/his decision on the broadest possible range of data and information.
Actually this issue is twofold:

- the 'relevant' information has to be made available by its authors;
- it has to be easily accessed and retrieved among a mass of irrelevant information, whenever and wherever needed.

This information usually takes the form of documents, whatever their format and the medium used.
As a consequence a secure basic infrastructure must be provided in order to:

- identify and authenticate the persons in question
  - the patient
  - the health care professional
- identify the documents
  - their location, even virtual
  - their topic, and more generally their content
  - their date
  - their author

Accessing the information is not enough. Processing it is paramount.
The most primitive —and noble— manner in which an information is processed, is by reading it. A document must be human-readable in some way.
When it comes to making the most out of modern Information and Communication Technology, the content of a document must also be machine-processable.
Increasingly, the interaction with certified knowledge bases will be part of everyday health care. Decision support software are already mature in several areas such as prescription support, but other development have been experimented for years, though at limited scales. The limiting factor for their current and wide use is the slowness of the process. This limitation should be rapidly lifted with the development and widespread implementation of broadband networks, even in remote areas.
Machine-processability implies that the semantic structure of documents follows standard patterns, in order to make them interpretable independently of the systems in use. This depicts 'semantic interoperability', an inescapable requirement for any Electronic Health Record systems in the short term. From the perspective of the free circulation of the patients within the European Union and its associated non-member states, it is not merely a matter of linguistics. Semantic interoperability implies that the structure of the 'documents' is interpretable, and that their content is understandable. Making this content understandable sometimes requires that the keys for its correct and safe interpretation —such as the terminological systems used— are identified and easily available.
Consistent sets of standards are currently showing, with the aim of providing the satisfying solutions to this issue: their implementation and use must be ranked a top priority, or easy access to clinical records will remain an unattainable goal.

Improved access to clinical records necessitates at least a secure information infrastructure, including patients and providers identification and

authentication, and ubiquitous access to identified terminologies
and the use of acknowledged standards for the semantic interoperability of the records

Enabling patient mobility and cross-border access to healthcare

Whereas patients will wish to benefit from high quality healthcare 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 EU patients are taken ill whilst abroad, in an EU country other than their own, arrangements exist for payment of costs through the so-called E111 form and associated provisions. However there remains the matter of access from abroad to a patient's health records particularly where they are in electronic form residing for example in a hospital, GP practice or 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 [Ref 11]. That the EU provides freedom for citizens to seek healthcare 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 [Ref 12]. 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 within the EU and elsewhere (e.g. India and Africa). The practice is likely to increase.

Such mobility raises the issues of access to a patient's electronic medical records from one country to another and their incorporation into, or handling within, the electronic medical record systems within the other country's healthcare provider. Some of these issues relate to health data-cards. The E111 is to be replaced with an electronic insurance data card (EHIC) [Ref 13]. This commenced, 1 June 2004 in 13 EU countries. 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).

Where a patient's home country has implemented electronic transfer of prescriptions, perhaps holding them on a national data base, a patient may wish to authorise access whilst in another country in order to have a prescription dispensed there.

A complex of standards and interoperability issues arise such as:

- a common electronic health record architecture;
- standards for communication of and/or access to electronic records;
- patient identification management and unique identifiers;
- authentication of, and access control, for professionals;
- security policy bridging between organisations;
- perhaps commonality in data cards;
- semantic understanding;
- language differences.

All these matters require investigation if ICT is to support patient mobility – see Chapter 14 for recommendation.

Reducing clinical errors and improving safety

Reducing clinical errors

Studies in the UK [Ref 14], USA, [Ref 15], Australia [Ref 16]. Canada, Denmark, Italy, The Netherlands, Sweden and New Zealand have reported very high levels of adverse events in hospitals and elsewhere which have led to harm to patients. In the UK, the report "Organisation with a memory", [Ref 14] estimated that about 10% of inpatient episodes in the UK lead to harmful and adverse events. This translates into 850,000 admissions costing up to £3-billion solely for additional bed-days. About half of these events were preventable. Efforts to tackle the reporting, analysis and ultimate reduction of adverse incidents are on an international scale. The WHO has expressed its concerns and has proposed measures to address them [Ref 17].

Amongst the areas which have been specifically identified where action could provide early gains in risk reduction was "examining across the board the potential for computers to reduce the occurrence and impact of errors". Reports recognise that ICT could play a key role here including greater emphasis of its use for electronic patient records to improve the delivery of patient care and improvement of safety. Improving a clinician's knowledge of a patient's medical history through access to an electronic health record will obviously assist in reducing clinical errors.

Access to decision support systems with clinical protocols and care pathways and to a patients electronic care record at the right place and right time, could thus significantly reduce adverse incidents.

Due to historic low reporting of incidents, the true level of medication related adverse events is unknown. Nevertheless, discussions between representative of the NHS in England, Australia and USA [Ref 18] indicate that "medication error accounts for around a quarter of the incidents which threaten patient safety". A breakdown of 30,000 electronic incidents reported to the UK National Patient Safety Agency [Ref 19] showed that whilst

41% of all incidents involved slips, trips and falls nearly 9% were related to medication management and 6% to medical records.

It is widely recognised that greater use of electronic prescribing in hospitals, bar coding technology and robotic dispensing has the potential to reduce significantly the risk of medication errors. Studies in the USA and elsewhere have attributed substantial reductions in errors to the implementation of computerised order entry systems and reductions have also been seen in hospitals which have introduced electronic prescribing with some degree of decision support. Nevertheless despite evidence of the benefits of electronic prescribing in hospitals, take up has not been strong. A survey in 2002 of UK Chief Pharmacists [Ref 20] showed only 3% of hospitals having what could be described as an electronic prescribing system.

Computer generation of prescriptions is the usual practice in many GP surgeries in the EU thus eliminating hand writing and other errors. However prescription details may still required to be manually entered into dispensing pharmacy systems leading to potential transcribing problems.

Bar coding appears to have significant potential for reducing adverse incidents in a number of areas including medication management. For example bar coding of administrative details etc, on a patient's wrist band, plus bar coding of medicines linked into electronic prescribing and decision support and thence to robotic dispensing, would appear to represent a powerful combination for improving the efficiency, effectiveness and safety of patient services.

Most studies on adverse incidents particularly those that are medication related, have concentrated on the hospital sector. However IT and associated decision support systems have the potential also to improve the safety and effectiveness of patient services in non-hospital environments such as primary and community care.

Whereas many GP practices within the EU are computerised and will have some decision support software associated with prescribing, the extent to which such support is used and its impact on medication related adverse incidents is less clear.

Other non-prescribing decision support/expert systems with supporting protocols are available to primary, secondary and community care but again the extent of take-up and the impact they are making, or could make, to safer and more efficacious patient services is unclear.

An important weapon in the battle to reduce clinical errors is to use ICT to support clinicians in collaborating with each other (e.g. video conferencing) to improve training (e-learning) and to facilitate access to high quality knowledge. The COCOON project funded by the EU, is exploring many of these aspects including ICT support of knowledge driven collaborative practices.

Chapter 14 gives recommendations relating to some of these error reducing applications e.g. electronic transfer of prescriptions, electronic prescribing, and electronic health/patient records.

Improving safety
In the past health-related software was primarily applied to relatively non-critical administrative functions where the potential for harm to the patient, as distinct from

disruption to the organisation, was low. Clinical systems were generally unsophisticated often with a large administrative rather than clinical content and little in the way of decision support. Even clinical decision support systems tended to be 'light touch', relatively simple and understandable in their logic and used as a background adjunct to decisions rather than a major influence on which to rely routinely. That has changed and will continue to change substantially. The nature of these changes will increase the potential for risks to patients.

There have been some high profile adverse incidents related to clinical software e.g. in the area of screening and patient call and/or recall where software malfunctions have resulted in failure to 'call' 'at-risk' patients. Such incidents have not only caused anguish for the many patients concerned but may also have led to premature deaths. The trust of the general public has been severely dented. The scope for screening for diseases is increasing significantly and it is in such applications involving large numbers of subjects that there will be heavy reliance, administratively and clinically, on software to detect normals and abnormals and to 'call' or 'process' those deemed to be at-risk. Such software needs to be safe for purpose.

It is increasingly claimed that information systems such as decision support, protocols, guidelines and pathways could markedly reduce such adverse effects. If for no other reasons – and there are others – this will lead, and is leading, to increasing utilisation of decision support and disease management systems which inevitably will increase in sophistication and complexity. It can also be anticipated that, due to pressures on time and medico-legal aspects, clinicians will increasingly rely on such systems with less questioning of their 'output'. Indeed, as such systems become integrated with medical care any failure to use standard support facilities may be criticised on legal grounds.

Economic pressures are also leading to more decision support systems. The area of generic and/or economic prescribing is the most obvious but economy in number and costs of clinical investigative tests is another.

Systems such as for decision support have considerable potential for reducing clinical errors and improving clinical practice. However all such systems also carry the potential for harm. Harm can of course result from unquestioning and/or non-professional use. The potential for harm may equally lie in the system design such as:

- poor evidence base for design;
- failure in design logic to properly represent design intentions;
- failure in logic to represent good practice or evidence in the design phase;
- poor or confusing presentation of information or poor search facilities;
- failure to update in line with current knowledge.

Some of these system deficiencies are insidious and may be invisible to the user.

The safety of medicines and of medical devices in the EU is assured through a variety of legal and administrative measures and is subject to several EU directives [24] [25] [26]. These measures are backed by a range of safety related standards from a number of sources both national and international including CEN, ISO and IEC Software necessary for the proper application of a medical device (together with some software supplied as an accessory for a medical device but necessary for it to meet its purpose e.g. for in vitro devices) is encompassed by these controls e.g. within EU directives and legislation

implementing them including CE marking and certification. However other software applied to health is not covered.

Consideration needs to be given to ensuring the safety of health informatics products in a manner similar to that applying to medical devices. Chapter **14** makes a recommendation on those lines.

Improving access to quality information

Throughout the world there is mounting concern about the quality of health related information being made available to the public. This is particularly so for that accessed through the Internet. Some such information has been shown to be very poor and some positively hazardous to the public. The EU Commission has recently published guidelines for quality of health related web sites **[Ref 27]** and has raised the question of possible quality seals. These initiatives need to be pursued both within the EU and internationally possibly through an international standard based on the Commission's recommendations. Chapter 14 provides a recommendation.

Improving efficiency of healthcare processes

Countries throughout the world are seeking strategies to reduce costs and to improve the efficiency of healthcare processes. ICT has substantial potential to assist such aims. It is not possible to list all the relevant ICT applications but amongst the most significant would be:

- the electronic patient record in hospitals with order communications and results reporting, e-prescribing with decision support plus access to clinical protocols and pathways;
- the electronic patient record in general practice with e-prescribing decision support and access to protocols;
- inter-organisation health data messaging particularly between hospitals and primary care especially communication of service requests and reports for laboratory investigations and patient referral;
- electronic transfer of prescriptions;
- digital imaging.

There are a wide range of telemedicine applications that also appear to have significant potential to reduce costs and improve efficiency. However, because the realisation of substantial benefits often necessitates major organisational change, telemedicine applications have not in general been implemented on a large scale (with a few exceptions).

Reducing costs and improving efficiency is dependent on an understanding of costs and outcomes. This requires high quality data and good quality indicators. A significant tool for understanding resource use and for assigning resources is diagnostic related groups (or their equivalent: there are many grouping methodologies in use in Europe). Similarly there are a wide range of quality indicators used in different European countries. Any understanding at a European level would require some harmonisation in these areas.

Improving public health and thereby reducing costs of healthcare is also dependent on information based upon good data. The EU's public health initiative recognises this and is seeking to create a core data set for public health (see Annex D).

Chapter 14 gives recommendations pertinent to these matters.

Case studies

That these strategic aims are common to many strategies is further illustrated by a number of case studies collected by NORMAPME. The Case studies were the Cocoon project, Belgian Paramedicals, Triamun project, Swiss Medical Association, Dental Technicians, Emergency Aid. These are analysed in detail in Annex G. In essence the findings were as follows.

Improving access to clinical records

Today, many groups in the health care sector, like paramedicals and emergency specialists have no access to patients' files due to privacy restrictions. Although the specialists agree that the definition of the level of access and the definition of the people allowed to access the file is crucial, some kind of additional access via web-based patient information would increase the speed and quality of care for patients. Dental technicians for example receive from dentists mostly only limited information consisting of a written prescription and dental imprints of the patients. The Cocoon project (Italian pilot project to reduce medical errors) identified poor data links among patient data, the lack of best practices and specialised centres for supporting the health care professional and the lack of interoperability amongst different health care systems as the main deficiencies of the current health care system.

The Swiss Medical Association FMH engaged early in eHealth and started with the financing of local eHealth networks and also the HIN project (Health Info Net), as they identified the need for electronic data exchange as one of their future priorities. The Triamun project, a local eHealth pilot project in the Switzerland that is already used by some Swiss doctors, works like an Intranet, where all patient files are stored. The patient is the owner of the files and can allow doctors (single persons or organisations etc) permanent or temporary access to all or a part of the file.

Enabling patient mobility and cross-border access to healthcare

Patient mobility is one of the crucial issues in the European health system. To give a simple but visual example: The organisation of the Swiss health care sector is the combination of 26 health care systems on canton level with a multitude of national and local/regional health insurance providers. Through this system patient mobility even within Switzerland is difficult. Especially in the case of the emergency treatment of foreigners the long time required for information retrieval can be critical. Therefore some eHealth experts think that European patients should carry a minimum of medical information on their person which should be accessible for emergency purposes. Also in the case of custom made devices (CMD), like dental prosthesis, patients have the freedom to buy or repair their medical devices during their stay abroad. The manufacturer of these CMD need all the relevant data defined in the Medical Devices Directive (MDD) 93/42 in order to make them fit properly. This information exchange is often does not happen today.

As barriers to an improved patient mobility, the Cocoon experts identified the lack of interoperability amongst different heath care system sources of information, the lack of medical protocols and weak communication amongst the community of practitioners. On the other hand, whilst the existing e-health system of Triamun is already able to include many different users groups, Triamun experts believe that a Europe-wide system would need to be different and comprise central systems communicating with each other via interoperable solutions.

Most experts agree that even with limited access to patient data, the quality of care could be improved. Interchangeable information over borders can raise the quality of care as the speed of care could be increased in emergencies. In the case of dental technicians, bad fitting, toxic reaction due to incompatible materials and allergic reactions could be minimised by the exchange of information. Of course it should for patients to define the limits of stored and shared data and access levels.

Within the Cocoon project the experts identified as barriers to an improved quality of care: 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.

Reducing clinical errors and improving safety

A recent study of the Italian Patient Right Court shows that at least 14.000 persons die every year in Italy because of medical errors - mostly diagnostic (35%) or treatment errors (18%). Hence, the main objective of the Cocoon project is to minimise medical errors in diagnosis and treatment by supporting knowledge driven collaborative practices in networks of health care professionals.

Experts agree that medical errors can be minimised by better knowledge management within eHealth networks. Electronically enhanced risk management will allow better forms of clinical decision support for the overall patient process e.g. e-prescribing. If authorised doctors and other persons had access to the same, identical patient file, the risk of medical errors due to a lack of patient data would be minimised. In the paramedical sector, the communication of medical data between the paramedical and the doctor often takes quite long and can result in lack and differences of information. For setting up a 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.

Also dental technicians often 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. Additionally, toxic reaction could occur by combining unknown materials. A different point concerns the safety of dental technicians themselves. They often receive no information about the health status of the patient regarding infectious diseases or the disinfection level of dental imprints.

Improving efficiency of healthcare processes

Through the poor coordination of processes, redundant processes and discontinuous processes, eHealth experts see a cost saving potential:

- FMH Switzerland sees savings of 10 – 40 % of total health care costs;
- A UK study indicates 11 % of clinical errors result in extra costs of 3 million bed-days or £1 billion;
- In Italy 14.000 persons die every year because of medical errors.

Several studies in the health care sector prove that eHealth could significantly reduce administration cost by more effective and associated billing procedures, materials and billing reminders, as well as by savings on “hardware” medical record storage and “hardware” medical imaging solutions. For example the dependency of dental technicians on the information provided by dentists and with no links between dental technicians and the patient leads to unusable dental prosthesis and double work.

Also the adoption of the Cocoon solution within the health care system in Europe would improve the efficiency and cost effectiveness of the sector, as the number of medical errors directly impacts health care cost levels. The existing Swiss eHealth projects were a result of rising pressure on productivity, which was achieved by process integration within the Triamun project. In Belgium there is already an electronic billing and logistics system within the health care sector, which also allows cost cutting for the Belgian medical and paramedical field.

Means for achieving strategic aims: applications

To achieve a strategic aim may require a number of interoperating applications. As noted above, some applications will be part of achieving several strategic aims. It is not possible in this document to list all applications which might be pertinent to all applications. However what is evident from the consideration of the few strategic aims discussed earlier is that there are some applications that repeatedly occur.

Amongst these are the applications identified in Chapter 9 as priorities from national, EU and stakeholders points of view namely:

- electronic health / patient records including health record architecture;
- electronic transfer of prescriptions;
- electronic health data messages between hospitals and primary care particularly communication of service requests and reports for laboratory investigations and patient referral;
- digital imaging and associated service requests and reports;
- e-prescribing with decision support;
- core data sets e.g. for public health;

These are explored further to illustrate some of the business drivers, applicable standards, gaps and issues.

Health records including health record architecture

Health records come in a variety of forms, bearing different and sometimes confusing names. Health records are (optimally) orderly repositories of data and information at the disposal of —essentially— health care providers to help them deliver the best possible services. The issue of the ownership of their content finds various responses depending on countries, but the subject's rights over their content are increasingly acknowledged as being part of the patient's/citizen's empowerment.
Health records can be found in private surgeries, in hospitals, in outpatient clinics, as well as in a wide variety of health care delivering facilities. On the patient's side, and in spite of well documented exceptions, they nearly always refer to only one individual. On the providers' side, though, the situation is more diverse. Solo practising physicians manage their patients' records. In hospitals, the rule is rather that more than one professional have access to the record of a patient (which is called the 'patient record'). In group practices, the customs may vary, depending mainly on deontological regulations. There are also other occasions where more than one health care provider is involved in feeding or accessing the record of a patient. Shared care usually implies a shared repository of clinical data and information. Integrated clinical networks made up of distributed providers

and professionals implement virtual network-based shared records, often centred on a common repository.
As a result, the issue is increasingly about exchanging documents and sharing their content, rather than simply storing them in a container reserved to a strictly limited group of users. Team work is actually extending far beyond the limits of local organisations, and the use of computer processable (readable and interpretable) documents, instead of paper ones make it necessary to address new requirements. While human eyes and brains are able to pick up the information that forms the premises of one's decision from more or less any kind of written document or any readable picture, diagram, etc. a machine is designed to follow sets of rules, and in order to communicate two or more machines have to work with consistent rules.
Similarly, those documents to be shared between two or more machines, before they are brought to the attention of human eyes and brains, need to make use of common specifications.
Apparently, the most important issue is what is exchanged, that is sent and received, than what remains static. In other terms, when it comes to getting an information content from another organisation, the messages are more important than the data and information stored, supposedly already in some readable format. What is critical in terms of team work is the ability to understand what the others mean.
However, while it is easy for a system to send out messages, it is much more difficult to process and read what comes in. Therefore, the constraints of being able to read others' messages will have heavy implications on others' machines (rather on others' software) in terms of messaging standards. While the strain is logically put on the messages, this in turn will inevitably bear consequences on the structure of the repositories themselves.
The ease of access and use of the content of a message conveying personal health data defines the requirement for semantic interoperability.

The free circulation of citizens, thus of patients who may have to seek care at any time in any place, requires an easy and quick access to their personal health data. Electronic health records will soon need —and in some occasions they already do so— to be accessed from any place throughout Europe. Accessed means that their content can be read (with human eyes), and understood (with human brains), bit moreover that they can be processed, after the information has been retrieved and forwarded in a message by the remote system.
This requires that the relevant standards be implemented at both ends.

Several developments and experiments are currently taking place throughout Europe, with different levels of requirements with regard to interoperability. Indeed interoperability is not an 'all-or-nothing' concept, and an essential distinction has to be made between structural, syntactical, and semantic levels of interoperability. In a stepwise approach, so far most experiments address syntactic interoperability needs; they still keep very close to electronic management of documents. It must be made clear that while this stage is undoubtedly necessary, no real progress in making personal health data of patients shareable will be effective until semantic interoperability has been reached in actual implementations.

Decision makers should be advised that in this specific domain, in the context of a vast move towards global standardisation for e-health, Europe has gathered an acknowledged considerable experience in the area of EHRs, thanks to the consistency between successful Research and Development projects under the aegis of DG-XIII (now DG-InfSo), and European standardisation. The European works in this area are the most advanced with regard to the architecture of records in the view of interoperability.

Moreover they are definitely meant to fit within other standardisation works which take place internationally, as in the USA with HL7, and they benefit from contributions of international experts. Therefore, the necessary tools are there, and what remains necessary is a strong support to give the necessary momentum for wide scale implementations.

Electronic transfer of prescriptions

The business drivers for electronic transfer of prescriptions include:

- reducing clinical errors;
- improving efficiency and reducing costs;
- contributing to an electronic health record;
- improving services to patients;
- contributing to data bases of prescribing practice to improve services, control costs and facilitate research.

Implementation requires a set of interoperable standards covering, for example, message structure and content, security, terminology. Matters such as security are common to many applications and there are a range of standards available and applicable e.g. from CEN, ISO and HL7. In terms of messages specific to prescriptions there are standards from CEN and from HL7 and a number of standards in use nationally e.g. in Denmark, USA, Australia. Within CEN TC251 the existing standard ENV 13607 is under review. It has been decided not to amend the standard per se but instead to leave the creation of messaging standards in this field to others e.g. ISO TC215, HL7. CEN TC251 will instead create a standard business view for transfer of prescriptions together with a business model. ISO TC215 has also decided to create a Technical Report on the business requirements of e-transfer of prescriptions with the intention of looking to others to develop the necessary messaging standards with an inclination to HL7. CEN TC251 and ISO TC215 have agreed to collaborate.

Comment: This statement, as well as the following ones, does not look exact. Conversely, given that some countries have implemented solutions based on ENV 13607, the decision has been made at the last TC meeting, on 29th June, to revise the pre-standard into an EN. The Netherlands are striving to develop a solution compatible with HL7 v3, but in the USA, there exists a strong reluctance to relinquish the current specifications based on NCPDP work, and mandated by HIPAA. The way would rather be that the revision of the European standard make it fully compatible with the RIM, building upon the previous European experience. Compatibility with the RIM, and with HL7 v3, which guarantees at least structural and syntactic interoperability, does not necessarily mean that Europe has to adopt uniformly hypothetical specifications possibly coming from abroad.

Thus CEN and ISO are taking much the same stance and collaborating and will probably look to HL7 to create messages to meet their business requirements. Such collaboration needs encouragement and the enterprise needs input and commitment from Member States since, whilst some are very advanced and can contribute to solutions, many others are less advanced and could greatly benefit. A test-bed for whole applications to prove interoperability of the necessary suite of standards will be required.

Health data messages

Of particular interest in this area are service requests and reports for laboratory investigations and patient referral. Amongst the business drivers are:

- improving efficiency and reducing costs;
- reducing errors;
- improved services to patients;
- contributing to an electronic health record.

There are existing message standards in CEN TC251 and HL7 and a range of national messaging standards some of which are adaptations of CEN TC251 and HL7 standards. Any health system seeking to implement health data messages may therefore face a choice between implementing or adopting CEN TC251 or HL7 or producing national/local

standards. CEN TC251, ISO TC215 and HL7 are increasingly collaborating in areas such as this with the common intention of basing all future work on the HL7 Version 3 Reference Information Model (RIM). However, full alignment between CEN TC251 and HL7 as manifest in Version 3 has yet to be achieved. It is in the interest of Member States to encourage collaboration with a view to full harmonisation.

Digital imaging and associated service requests and reports

There are several business drivers for digital imaging such as

- departmental efficiency
- ability to process electronically
- enable images to be part of the electronic patient record
- to facilitate transmission electronically to other locations, e.g. remote viewing, second opinion, telemedicine
- supporting quality management, standard reports and sophisticated epidemiology

The majority of imaging modalities create digital data in a primary instance today, non-digital modalities decrease constantly and will vanish in a short time. Furthermore the volume of digital data increases because of new modalities who create multi frame images or movies (e.g. multi-slice CT, endoscopy images) or images with extreme resolution/dimensions (e.g. pathology). Multi-modality imaging is frequently used with functional disorders. It is still common today that many images of different modalities are handled by films or by special workstations, but the handling of standard digital images, high volume images, and multi modality images require **adequate archiving and communication platforms** (locally and globally) and viewing stations. For this we need standards.

Cross-referencing is very important in functional imaging or fusion of images with complicated diseases. Handling of films or the use of different workstations are highly ineffective and require skilled physicians. Electronic cross referencing of images rationalise and ease the workflow and allow the use of other types of **local or remote** health record data if these data are standardised.

Digital imaging is a significant part of a **longitudinal electronic patient record**. Such a record bridges many institutions and patient episodes. Electronic exchange of data (e.g. via Email) with suitable registries (locally or globally) in a standardised way are necessary. Workflows in health care implies a quality management for meaningful reports and epidemiology. This is only possible with standardised electronic means and this will be important in future times.

There is a solid base of available standards:

- DICOM (specific supplements for different modalities)
- DICOM Sup23: Structured Reporting
- DICOM Sup85 / ISO/WD1.14: Web Access to DICOM Persistent Objects
- DICOM Sup31,41,51,55,86,95: Security

- HL7 / CDA
- XMLSig / XMLEncryption in CDA (ongoing work)
- ebXML / SOAP
- T12x Standards (conferencing, document sharing)
- Smart cards (HPC)

Digital imaging is surrounded with other processes. Therefore interoperability with another applications such as departmental, hospital and community systems emphasizes an integrated use. An integration testing with **proof-of-interoperability** provides IHE. Suitable technical frameworks and integration profiles also supports the **harmonisation** of different concepts (e.g. DICOM-SR and HL7/CDA).

e-Prescribing

A key driver for e-prescribing with decision support is the reduction of medication errors. It will however also contribute to increasing efficiency and reducing costs, and can contribute to an electronic record.

An important factor will be the quality of the evidence and logic underlying the decision support if safety is to be assured and potential medication errors spotted e.g. with alerts. A recent study in the UK [Ref 21] of four well established GP systems showed that they exhibited substantial failures in spotting potentially hazardous prescription scenarios and producing alerts for pairs of medicines with similar names.

e-Prescribing within hospitals of combined with bar-coding of medication and robotic dispensing could further reduce medication errors.

This appears to be an important area for investigation given the importance of this application and the apparent slowness in uptake,

Data sets

There are several business drivers for core data sets and quality indicators particularly regarding costs and outcomes.

Core data sets

(Please see an article published in the International Journal of Medical Informatics, 2003, 70 : 215-219, that might be of interest to you : Case Mix use in 25 countries : a migration success but international comparisons failure, by F.H. Roger France)

A hospital inpatients minimum basic data set (MBDS) was defined in 1982 in Europe (with the agreement of DGXIII and DGXII of the EEC, as well as WHO Europe) by the Roger report [Ref 22]. It defined 13 items, including diagnoses, to be coded on a discharge summary for all inpatients stays. It recommended that this be linked with resource data mainly in relation to local (national) financing systems.

The grouping of patients by diagnosis groups in relation to homogeneous costs, through case mix systems such as DRGs (Diagnosis Related Groups) is used in most European countries for hospital financing or management [Ref 23]. Such systems rely on capturing

and coding data of diagnoses and procedures. The quality and comprehensiveness of diagnostic and procedures coding is therefore of great importance for DRGs as it is for general hospital management. However, even if hospitals use the ICD (International Classification of Diseases) versions 9CM or 10 for diagnoses, the coding systems for procedures varies between countries.

Several systems have been developed in most European countries to verify data quality e.g. by statistical checking of the variation of DRGs with time and analysis of MBDS for any containing inappropriate associations of diagnoses and operations. Other tests include estimation of frequencies in hospital MBDS versus other sources (register of cancer, congenital abnormalities etc.)

Quality indicators

Quality of care needs to be assured for the population and be improved continuously.

A systemic approach, which allows the structure as well as the process of care to be modified, appears to be of utmost importance. An emphasis on education as well as financial incentives for quality development are considered the best way to proceed.

The key issue in relation to informatics is to obtain “outcomes measures” for the patient status after care. Agreement needs to be reached in each country on a list of quality indicators, among which some can be taken as outcome measures. Examples are:

- Perinatal mortality rates (mother and child) (there are great differences between Eastern and Western Europe, and with developing countries);
- Cancers due to smoking habits (lungs, larynx, bladder);
- Complications of diabetes (St Vincent declaration);
    - Amputation of foot
    - Cecity
- Nosocomial infections
    - Septicemia
    - MRSA
- Bedsores (to be prevented by early diagnosis)
- Surgical wound (antibioprophylaxy)

A second area of outcomes measurements concerns the degree of patient satisfaction, to be estimated by ad hoc questionnaires.

A third area analyses length of stay by DRG, as well as excess in mortality in some DRGs.

All these measurements are necessary to be able to examine what can be done to improve quality and to create a strategy to modify the situation by better processes and/or a reinforced structures.

In such a systemic approach, a standardised health information system needs to be implemented in all participating countries, with methods to validate recorded data and to respect confidentiality for:

- uniform minimum basic data sets;
- registers of diseases;
- standardised questionnaires.

Thus standards are needed in order to allow comparisons between practices for the measurement of efficiency and quality of care.

There are some standards already available:

- the “European MBDS”
- DRGs, AP-DRGs, APR-DRGs and other case mix systems
- ICD-9-CM and ICD-10 codes

However, the lack of uniformity in procedures codes and the variation in the choice of grouping tools for case mix between countries hamper the possibility of achieving reliable comparisons in hospital care.

Similarly, concerning quality indicators, the level of development of information systems varies widely between countries, mainly through lack of clear objectives.

Greater uniformity in these areas throughout Europe is highly desirable. Chapter 14 makes recommendations.

Achieving inter-working within and between applications and infrastructure

To achieve strategic aims the necessary applications need to inter-work. They will need to do on several levels e.g. physical, logical, and semantic. Achieving interoperability is a complex matter as demonstrated in Chapter 12 and Annex E. There will often also be a need for an underpinning infrastructure e.g. networks, security.

It is not possible in this document to address all these aspects. However Chapter 9 lists a few priorities which arise repeatedly when analysing use of ICT to achieve strategic aims. They are:

- management of patient identification including:
  - EU Health Insurance Card perhaps containing an medical emergency data set and controlling access to data in a patient’s country of residence;
  - A common approach to patient identifiers;
  - Access control and authentication;
- protecting personal information (with emphasis on Public Key Infrastructure and data cards for professionals and citizens/patients);
- terminological systems for clinical records and medicines;
- data cards.

.

Management of patient identification and protecting personal information

The need to manage patient identification and protect personal information is a common requirement of very many applications and is crucially important given the sensitivity of personal health data.

SDOs such as CEN TC251, ISO TC215 and HL7 are very active in this field. CEN TC251 has developed a number of standards and several are approaching their final stages. ISO TC215 has produced standards on Public Key Infrastructure and is producing international

guidance on the application of ISO 17799 to the healthcare sector (ISO 17799 on security management is being widely adopted in all sectors and in health by a number of countries). In this area CEN TC251 and ISO TC215 are working in the closest collaboration with no overlaps or conflicts.

The highest priorities emerging within Member States as and the EU as a whole are:

- ensuring secure patient identification;
- access control to personal health data;
- policy bridging between organisations.

The security of health data may involve a Public Key infrastructure and data cards for patients and professionals.

The challenge is to bring standards together so as to create an infrastructure which will meet all business priority requirements. A review of requirements, the standards needs and their availability and a test environment for interoperability is required (see Chapter 14).

Terminological and coding systems

Medicines

If applications are to inter-work at the level of semantics then terminological standards will be required. This is also true for coding systems e.g. for identifying organisations.

The priorities in this area identified by Chapter 9 were for terminological standards for clinical records and for medicines. They are essential for such as:

- electronic patient/health records;
- electronic transfer of prescriptions;
- reducing medication errors;
- many inter-organisation electronic messages.

Neither CEN TC251, ISO TC215 nor HL7 has taken on the responsibility for the content of any terminological systems albeit they have, and are, producing standards for example regarding their structure and common concepts.

However ISO TC215 has recognised the need for an international standard for medicines and is producing a Technical Report on the Business Requirements before investigating what further steps might be taken in this direction. There are a number of national terminological systems and several international standards on which to build. However the creation of such an international terminological system requires a body recognised internationally for actually creating a system. This is a matter that needs to be addressed (see Chapter 14).

Clinical records

The major, detailed terminological system for capturing clinical data in patient/heath records is SNOMED CT (Clinical Terms). This is owned, developed and maintained by the Royal College of Pathologists in the USA. The UK has a national licence to use it within its National Health Service and the USA has recently also negotiated a licence. A number of

EU Member States are likewise considering national licences plus the matter of translation from English (a German translation now exists).

Considerable advantages could accrue if SNOMED CT became the standard for the EU as a whole. However this raises questions of licensing, translations and mechanisms whereby EU Member States could influence future SNOMED developments and maybe additions to the terminology (some terms will be peculiar to particular Member States). This is subject to recommendation in Chapter 14).

Data cards

There is a need to implement eHealth applications based on European wide interoperability of eHealth infrastructures. Patient data cards (PDC) and Health Professional Cards (HPC) are important components of these infrastructures. The use of these cards has over the last ten years developed from pure memory media to key elements of a telematics network, which itself is becoming more and more patient oriented. Therefore smart card systems should be seen as an intrinsic component of an information network both using their synergies to enable core functionalities such as:

- Enabling patients and health professionals to collaborate and share patient and other health-related data for continuity of care.
- Enabling healthcare providers, healthcare insurers and welfare institutions to establish reliable and efficient communication processes; hence enabling patient-focused delivery of high quality care and at the same time saving resources by efficient support for administrative procedures.
- Providing a secure and individualised system that allows patients to monitor their personal health.
- Supporting safe mobility by enforcing the provision of emergency care and specifically enabling support for those who may need regular and more intensive healthcare services.
- Supporting increased mobility for business, training, skills dissemination and leisure.
- Supporting continuity of coverage and quality of care for people regardless of their type of (public and/or private) health coverage.
- Improving the availability and effectiveness of intervention by providing mobile communication between carers.

To achieve all this PDCs should include at least the following data (or remote data access pointers):

- Administrative data (i.e. insured ID, name and address, health coverage 'coordinates', period of entitlement, availability period, relevant regulation, etc.).
- Medical data (emergency clinical data, protected private file).

- Security components, possibly including biometrics, e.g. for reliable identification of the person covered and secure access to personal health data of the patient.

Additionally all such systems need, in parallel, Health Professional Cards to assure secure access to patient data stored on PDCs or elsewhere in the system and at the same time allow access to the system itself and trustworthy communication between all parties involved in the health care sector.

International interoperability of these health care systems needs standards regarding the technique, the hardware, e.g. size and thickness of those cards, command sets addressing and managing the cards, and the data stored.

Most of these issues are already covered by standardisation efforts practiced mainly by:

- ISO TC 215 “Health Informatics” (regarding content)
  - WG 4 “Security”
  - WG 5 “Health Cards”
- ISO/IEC JTC1/SC17 “Cards and personal identification” (mainly regarding technique)

In terms of security many standards have been adapted from other domains, e.g. the banking sector, partly modified to health sector needs.

In terms of content, specific standards have been developed, e.g. for emergency data, immunisation and blood group and transfusion data. Many others are on their way, e.g. extended clinical data, identification data, administration data, medication data and the structure of links to data stored elsewhere in the system. It is internationally agreed, that cards are not the storage place for all available data on a patient, but should serve as a kind of directory for relevant medical data.

Standardisation has recognised the necessary domains that have to be worked on in the field of cards. Nevertheless there is a lot to be done in terms of promoting these efforts and ensuring standards are implemented in nationwide applications. A first important step has been taken by the decision to have the E111-replaced electronically on a card. This will stimulate the implementation of card systems European wide. However to achieve the above objectives it is absolutely necessary not to be satisfied with this administrative decision, but to promote the use of the existing standards towards the implementation of a European Health Insurance card, assuring interoperability across all member states health care systems.

Interoperability

Achieving interoperability in its widest sense is a considerable challenge. These matters are dealt with in Chapter 12 and Annex E. Recommendations are in Chapter 14.

14 What needs to be done: recommendations

A. Supporting particular strategic aims

Improving access to clinical records

As discussed in Chapter **13** an essential prerequisite for improving access to clinical records is the creation of electronic clinical records in all healthcare environments and having the means to access them securely. The matter of the electronic health record per se is the subject of a recommendation later in this chapter.

Recommendation

That Member states, with the support of the Commission, co-ordinate their efforts towards the implementation of secure information infrastructures which provide patients' and providers' identification and authentication, and ubiquitous access to identified and registered terminologies.
That the Commission give a significant momentum to national and Europe-wide access to clinical records. That full semantic interoperability of personal health data and information be sought through a strong support to existing European standards for EHR communication.

Enabling patient mobility and cross-border access to healthcare

As indicated in Annex **D**, a key objective proposed by the EU Commission is to facilitate patient mobility and access to cross-border healthcare. If this is to happen effectively and securely arrangements will be required to allow access to a patient's health record form countries other than his/her own. This will be complex and require close collaboration and interworking between Member States and shared standards covering a number of areas.

Recommendation

Member States, with support from the Commission, should commence development of interconnectivity for patients' administrative and health data access and/or transfer between Member States in a manner that will allow its safe use in accord with patient requirements and the needs for reimbursement and statistics.

Reducing clinical errors and improving safety

As discussed in Chapter **13**, medication errors comprise a significant proportion of clinical errors and can be particularly harmful. It has been shown that e-prescribing with decision support can substantially reduce such errors yet take-up has been relatively slow. Error reduction can be further enhanced if e-prescribing is combined with bar coding and robotic dispensing. The use of these systems needs to be encouraged. A recommendation is given later in this Chapter.

As shown in Chapter **13** action needs to be taken to ensure the safety of health informatics products. This might be achieved by bringing such products within controls exerted in the EU over medical devices.

Recommendation

That the Commission consider whether the safety of health informatics products should be encompassed by controls similar to those within the EU for medical devices and if so the safety standards which should be applied.

Improving access to quality health information

International efforts are required to ensure that the public can identify and trust helth related information in the Internet. The Commission has published guidelines for health related web sites and raised the question of quality seals. These initiatives need to be taken forward on an international scale.

Recommendation

That the Commission should mandate TC251 to work with ISO TC215 through the Vienna Agreement to produce a standard comprising guidelines for ensuring the quality of health related information available on web sites: the stndard to be based on the guidelines published by the Commission.

Improving efficiency of healthcare processes

One of the necessary components of improving cost control is to understand how costs arise and to allocate funding in a cost effective way which preserves and enhances the quality of care. Tools for these purposes include patient care groupings such as Diagnostic Related Groups (DRGs or their equivalent) and quality indicators. Later in this Chapter recommendations related to these are given.

Is there any other recommendation to be made under this heading?

B. Particular applications

The following observations and recommendations derive from the conclusions on priorities for the application of ICT to health in Chapter 9.

Electronic patient/health records

Many countries are pursuing electronic patient/health records in one form or another. The form being pursued varies from country to country and the pan-European requirements need to be clarified. As Chapter **13** showed, the need for such electronic records arise from many business drivers. However achieving electronic records and secure access to them is a complex matter requiring a range of standards covering a number of areas. An in depth review is required covering all these aspects.

Recommendation

Member States, through theThe EU Commission and the e-health High Level Group, should fund a study of:

- the pan-Europe Business Requirements for electronic health records;
- the portfolio of standards which are necessary to achieve those business
- requirements;
- how those standards can be created in so far as they do not already exist;

- how interoperability of the necessary standards can be proven;
- the need, if any, for conformity testing or accreditation.

Electronic transfer of prescriptions

As shown in Chapter **13,** the electronic transfer of prescriptions is an objective of a number of countries and will probably be the objective within the strategies of many more in the near future. Those countries which are most advanced are in a position to assist those who are about to start or intend to do so in the future. The business aims vary from country to country and the standards in use vary also. Both CEN TC251 and ISO TC215 are embarking on a collaborative analysis of business requirements so as to clarify needs for those who will create the necessary standards for meeting them including the necessary message standards. These efforts need to be positively supported by Member States.

Recommendation

That Member States each nominate and support an expert to participate

- in the collaboration between CEN TC251 and TC215 to define the business requirements for the electronic transfer of prescriptions;
- in the identification of the necessary standards required to implement the application in full and the identification of the standards bodies which should produce them if new or amended ones are required;
- in the creation of interoperability arrangements to prove interoperability.

This recommendation might be supported by the recommendation later in this Chapter on "bringing ICT policy makers and standards makers closer together".

Electronic health data messages

There are existing standards for health data messages for key areas such as service requests and reports for laboratory investigations and patient referral. Those from CEN TC251 and HL7 are of particular note. TC251 has recently published a revised standard and HL7 is considering moving from its Version 2 standards to Version 3. Both sets of messages are based on HL7 Version 3 but there are differences which may cause difficulties in choice.

Recommendation

That Member States each nominate an expert to participate in a review of the existing standards and work programmes for health data messaging to recommend whether any action is required to ensure full harmony in international messaging standards.

Digital imaging

Digital images with its complementary processes **migrate** from local applications (today) **to remote and groupware** (forthcoming) applications with special emphasises on data security and protection.

Standardisation and proof-of-concept activities needs to be done:

Asynchronous communication

1. Secure **cross enterprise data exchange** of simple messages (e.g. electronic mail – locally, globally and mobile)
2. **Cross-referencing** of distributed data (suitable indexing concepts, virtual organisation, (web)service-orientation – locally, globally and mobile)
3. Simple and complex **query-handling** for quality management and epidemiology ((web)service-orientation - locally, globally and mobile)
4. Secure **cross enterprise document sharing** of large volumes of data (e.g. multi-slice images, movies, extreme resolution images, telemedicine – peer-to-peer or grid concept)

Synchronous communication

5. **Collaboration** protocols (remote pointing, remote control, e.g. joint-annotation, joint-editing)
6. Handling and processing of **federated resources** (e.g. distributed image databases, co-ordinated image analysis – peer-to-peer or grid concept)

Portion of these communications can be proofed by proper IHE technical frameworks and integration profiles. Therefore the development of standards (and its intermediate results) should be associated with integration and interoperability testing.

e-Prescribing systems with decision support

As discussed in Chapter **13**, medication errors comprise a significant proportion of clinical errors and can be particularly harmful. It has been shown that e-prescribing with decision support can substantially reduce such errors yet take-up has been relatively slow. Error reduction can be further enhanced if e-prescribing is combined with bar coding and robotic dispensing.

Recommendation

That Member States, through the Commission, review the use of e-prescribing systems with decision support, and their use combined with bar coding and robotic dispensing, to determine the circumstances which might encourage their further use and the standards required to ensure their interoperability and effectiveness.

Core data sets

Chapter 13 examines the case for more uniformity across Europe in the area of minimum data sets, resource groupings (DRGs or equivalent) and quality indicators. The recommendation below seeks to take steps in that direction. The definition of a core data set for public health appears to be in capable hands (EUROSTAT) and therefore no recommendation is made in this area.

Recommendations

That Member States through the Commission investigate the means and financial provisions for the development of an appropriate case mix grouper tool to be used in Europe that would include a uniform coding system, to be updated yearly, for diagnoses and procedures.

That Member States through the Commission fund a project

- to list the priority quality indicators, based on outcomes of care measurements as well as on patient safety issues, that should be collected in a uniform manner in all countries that agree to participate to quality of care continuous development and
- determine the best means for creating a standard for their definitions and data elements.

Such recommendations will allow comparisons of results between countries, using a similar information system, whilst ensuring that each country remains master of its health delivery systems that can vary widely between countries.

C. Supporting standards development

Bringing ICT policy makers and standards developers together

The EHTEL Report on "Conjoining ICT policy makers in Europe with standards makers" **[Ref 10],** policy makers declared a commitment to international standards but reality demonstrated that the commitment was very weak. One reason was that the links between ICT policy makers in ministries of health or equivalent, and international standards makers, was elusive and very indirect.

The EHTEL project sought to establish whether there were means for bringing together European ICT 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.

This study 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 appeared to be electronic transfer of prescriptions perhaps including PKI and professional and patient data cards. 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, determine what international standards exist that might suit the requirements and what new or amended standards would be necessary.
4. Create a profile of existing and proposed new standards with a view to interoperability.
5. Decide on how best to 'commission' the drafting of any new standards in a manner which would lead to international standards.

6. Decide whether funding is desirable or necessary to assist standards drafting and if so, identify the source and secure commitment.
7. Commission the drafting of new or amended standards to a timetable determined by policy makers.
8. Agree the means for testing interoperability of standards within the standards profile for the chosen application.
9. Agree the means for piloting the application utilising the standards.
10. Feed back and amend standards as appropriate.

A meeting of policy makers and standards makers could take place after stage 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.

Recommendation

It is recommended that the Commission further explore this proposition with EHTEL and the e-Health High Level Group.

Supporting the development of standards

One of the criticisms of standards making is that it can be slow. Undoubtedly the availability of financial support helps to accelerate processes, to engage the best experts and, provided commissioning focuses on the priority standards, ensures that the standards which emerge are relevant to needs.

Below is the recommendation proposed before the last Focus Group meeting. However it was agreed that it is difficult to include it before the TC251 Business Plan had been appraised and results to date have been appraised by the Focus Group. Any recommendation is to emerge from the email group created at the last meeting and facilitated by François Mennerat

Recommendation

The Commission should renew its support to common standardization work within the formal European Standardization system where it is necessary with European level standards. This means in particular political and financial support allowing CEN/TC 251 to continue its highly relevant work to complete formal standards in the 28 member countries for the major priorities.

Special support should be included to assist the new accession countries to engage fully in the European standardization and interoperability processes and assist them to obtain expert knowledge on standards and implementation issues.

The Commission should also support European interests in global standards activities and the promotion of European standards to become International standards, particularly through ISO

Availability of standards

A significant barrier to the dissemination and implementation of standards is their cost. Additionally the modern electronic world is demanding standards in new electronic formats such as data bases which do not align well with sales and pricing mechanisms particularly in the environment of free open source software.

Recommendation

The EU member states and the European Commission should consider making all eHealth standards available free of charge to users in Europe as well as globally (as recommended by the eHSCG particularly supporting less resourced devloping countries and as has been requested by the Commission in COM 356. It is recognised that this would require financial support to the CEN national standards bodies to cover the loss of income from sales of standards.

D. Achieving interworking and infrastructure

Interoperability

This is discussed in detail in Chapter **12** and Annex **E** which set the scene for the following recommendation.

Recommendation

In order to support the development of interoperability processes Member States and the European Commission should:

- consider a mandate and funding of an appropriate European group (e.g. by extending IHE Europe) to manage necessary interoperability processes in close cooperation with the respective stakeholders. This should include processes for supporting, testing, demonstrating and promoting standards-based integration profiles. The Commission should ask CEN/TC 251 to consult this interoperability European group for new work item proposals. This would allow CEN/TC 251 to obtain additional feedback form stakeholders such as healthcare professionals, healthcare IT officers, vendors and regulators.
- should support European interests in global interoperability activities and direct the interoperability European group to ensure consistency with other interoperability initiatives (e.g. IHE North America and Asia).

Peter Bursig suggested the following text and recommendation. Can it be assumed that this can now be deleted in view of the recommendation above

Interoperability activities should concentrate on the sharing of health information between care delivery organizations, based on a limited number of priority issues, e.g. patient record sharing and collaborative workflows (e.g. e-prescribing). These activities should be based on a common set of “critical objectives” that need to be met, e.g. information security, patient safety.

In order to do so, relevant stakeholders should agree on a collaborative process for the development of interoperability solutions based on existing standards. This process needs to be separate from the process of the development of standards, since it will typically involve several standards at a time. It is recommended to leverage the successful process

that has been developed in the IHE Initiative in Europe.

The process should include the requirements for interoperability, the technical specifications in the form of an “integration profile” and a visible verification process. Continued education as well as promotion of the achieved interoperability are an integral part of the process.

Successful implementation, use and exploitation of interoperability solutions requires accompanying structures (e.g. registries of care deliverers, data security components etc), taking local/regional/national requirements into account. This includes
The other important element are appropriate incentives for users, industry and other stakeholders to support the deployment and use of the interoperability solution.

Recommendation

In order to support the development of interoperability processes the European Commission and Member States should consider to mandate appropriate groups to manage such processes in close cooperation with the respective stakeholders.

Gunnar Klein proposed the following. Can it now be deleted?

Member States through the EU Commission should provide

- support to interoperability demonstrators
- support to the building of a certification system

Terminological systems

Achieving semantic understanding within and between applications is a very difficult challenge and requires standards for terminology and particularly content standards as compared with standards on, for example, required structures. Chapter **14** identified the need for such content standards for clinical records and for medicines. Below are recommendations towards those aims.

Recommendations

Member States, through the EU Commission, should examine the business case for negotiating an EU-wide licence for the EU to use SNOMED CT. The business case should consider support for a small coordinating EU classification centre to provide a channel for EU input into SNOMED.

Member States should each nominate and support an expert to participate in the collaborative work between CEN TC251 and ISO TC251 in identifying the business requirements for an international terminology for medicines and the means for its production and maintenance.

Management of patient identification, access control and security

The identified priorities for the application of ICT to health such as:

- health/patient records
- electronic prescriptions

- messages between care providers
- access to records by professionals and patients
- eHealth Insurance Cards

lead to security requirements relating to:

- ensuring secure data exchange
    - common interpretation
    - data integrity
    - safe and secure systems
    - secure communication
- patient and professional identity management (e.g. data cards)
- access control including:
    - policy bridging between organisations
    - role definition
    - audit trails

A comprehensive interoperable set of standards will thus be required if such priorities are to be successfully and safely realised.

Recommendation

That member States, through the EU Commission, fund a study of the Business Requirements for measures to support the management of patient identification and access control to patient identifiable data by patients and by professionals with patient authority, and to delineate the set of standards required to support those Business Requirements. The study should include aspects such as:

- ensuring secure data exchange
    - common interpretation
    - data integrity
    - safe and secure systems
    - secure communication
- patient and professional identity management (e.g. data cards)
- Public Key Infrastructure
- access control including:
    - policy bridging between organisations
    - role definition
    - audit trails
- identifying a suitable means for testing interoperability.

Data cards

To be written Juergen

15 Summary of recommendations

The Focus Group has agreed that less than 10 recommendations would be too few and more than 20 would be too many. This Chapter will be completed when the recommendations are agreed.

Annex A

Terms of Reference for the CEN/ISSS eHealth Standardization Focus Group

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.

2 Objectives

- To consider, with all the relevant stakeholders, priorities and objectives for eHealth 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/TC 251, ISO/TC 215, ITU, DICOM and HL7;
- To consider the standards implications of the Ministerial Declaration of 22 May 2003, following the Commission/Presidency eHealth 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-organized Open Meeting;
- To finalise the report in the light of public comments and the Open Meeting discussions.

3 Scope

The activities of the CEN/ISSS eHealth Focus Group should cover the concept of eHealth as defined in the context of eEurope[5] – 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.

[5] http://www.europa.eu.int/information_society/eeurope/2005/all_about/ehealth/text_en.htm

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.

5 Working methods

The CEN/ISSS eHealth 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 coordinated 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 organize 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.

6 Expected deliverable(s)

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

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 health care delivery.

Ministers welcomed the eHealth 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 eHealth 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 eHealth applications, such as those described in the objectives of the eEurope 2005 Action Plan[1], and agreed in the Council's Resolution[6] 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 Council3 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)[7] on the European Health Insurance Card.

---

[1] COM (2002) 263
[6] OJ: C 048, 28/02/2003, p.2-9

[7] Communication from the Commission concerning the introduction of a European health **insurance card, COM (2003)73 final, 17 February 2003**

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[8] and encouraged the Commission to explore the possibilities of EU level Quality Seals[9].

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[10].

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.

Looking to the future

The ministers recognised that full exploitation of eHealth goes beyond local information systems and Internet based provision of information to integrated or linked eHealth 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

---

[8] **COM (2002) 667 final**

[9] Decision N° 1786/2002/EC of the European Parliament and the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008) - Commission

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

EFTA countries, to take, as appropriate, effective legislative, executive, administrative and other measures, to promote the adoption and use of eHealth applications.

Ministers noted that the full exploitation of the benefits of eHealth 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 eHealth systems and applications. Ministers acknowledged the importance of continued commitment to the implementation of eHealth 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[11], ensuring steady advancement of European eHealth technology applications that meet European demands for confidentiality[12], data security and interoperability.

Ministers noted the successful collaboration on issues related to eHealth 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 eHealth developments at the second eHealth Conference in 2004.

[11] **Comm (2002) 499 more research for Europe towards 3% of GDP**

[12] 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)

Annex B

Membership

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

List of members here

Karin Kajbjer to be responsible

Annex C

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

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 eHealth;
- from some countries it has not proved possible to gather any information;
- 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

EHTEL studies

Priorities for the application of ICT

EHTEL undertook a 2-phase study **[Ref 9,10]** 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 standardisation and
- 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 PAC / 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*	XXXXX	X	X
- *fees / reimbursement*			XX
- *hospitals and external providers*	X		
- *hospitals / community*	X		

- *with social care*	X		
- *health network*	XXX		
Protecting personal data	**XXXXXXXXXXX**	**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**

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 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.

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 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.

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 e-Europe 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 stage 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.

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 specialized 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**

The Table 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.

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 [Refs 14,15,16,17,18]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

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. PAC / RIS);
- ensuring semantic meaning.

Annex D

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

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 [Ref DD]. 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 [Ref EE]; contracts at a distance [Ref FF] and e-commerce [Ref GG] all of which have an impact in areas of eHealth.

The Europe 2005 Action Plan [Ref DD] includes three proposed actions particular to eHealth 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 standardisation 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.

Ministerial Declaration 22 May 2003 [Ref 1]

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 eHealth 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 eHealth applications, such as those described in the objectives of the eEurope 2005 Action Plan **[Ref DD]**, and agreed in the Council's Resolution **[Ref 2]** 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) **[Ref 3]** 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 **[Ref 4]** and encouraged the Commission to explore the possibilities of EU level Quality Seals **[Ref 5]**
  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 **[Ref 6]**.

- **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 eHealth goes beyond local information systems and Internet based provision of information to integrated or linked eHealth 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 eHealth applications.
  Ministers noted that the full exploitation of the benefits of eHealth 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 eHealth systems and applications.
  Ministers acknowledged the importance of continued commitment to the implementation of eHealth 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.

e-Health - Making healthcare better for European Citizens : An Action Plan for an European e-Health Area COM (2004)356 [Ref HH]

eEurope has spawned a variety of initiatives within the eHealth context in order to pursue the key targets of eEurope 2005. In its latest action plan COM (2004)356 the Commission envisages a European eHealth 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 [Ref II] ;
- 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 [Ref JJ] and health professionals [Ref KK] 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 [Ref JJ] 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 eHealth. This should focus on deploying eHealth systems, setting targets for interoperability and the use of electronic health records, and address issues such as the reimbursement of eHealth 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 and outline interoperability standards for health data messages and electronic health records, taking into account best practices and relevant standardisation efforts.	End 2006	Member States, Commission
By end 2006, a collaborative approach should be undertaken among Member States to supporting and boosting investment in eHealth.	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	2004-2008	Member States

networks for eHealth based on fixed and wireless broadband and mobile infrastructures and Grid technologies.		
By end 2009, the European Commission, in collaboration with Member States, should undertake activities to: Set a baseline for a standardised European qualification for eHealth services in clinical and administrative settings. Provide framework for greater legal certainty of eHealth 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 eHealth services. Promote eHealth 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 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.	End 2008	Member States
Issue 3: Working together and monitoring practices		
In 2004, a high level eHealth 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	2004	Commission

enhancing the understanding of the Commission services with regard to the current and planned status of development of eHealth 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 eHealth, as well as to develop a strong evidence basis for the case for eHealth. The work of the eHealth forum will also be closely associated with the implementation of the Community Public Health Programme.		
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 eHealth.	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 eHealth area.	End 2005	Commission Member States
An assessment of eHealth 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 eHealth.	2004-2010	Commission

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 healthcare 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 [Ref JJ]. 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 [Ref LL]. 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 health care provider;
- access to current prescriptions which may be held on a data base in the home country.

Health data-cards

Within the EU, the intention is to replace the E111 paper form with an EU Health Insurance Card [Ref ZZ]. 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.

Community action in the field of public health

In a Decision 23 September 202 **[Ref 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 **[Ref 8]**.

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”.

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 E

Interoperability

This Annex may not be needed

Annex F

List of existing standards and work in progress

Acronyms and abbreviations

Standard designing organisations (SDOs)

(Official standardisation 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/TC 251	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	
FSF	Free Software Foundation	www.gnu.org/
HL7	Health Level 7	www.hl7.org
HIMSS	Healthcare Information and Management Systems Society	www.himss.org/
IEC	International Electro-technical Commission	www.iec.ch
IEEE	Institute of Electrical and Electronics Engineers	www.ieee.org
ISO	International Organisation for Standardisation	www.iso.org
ISO/TC 215	International Organisation for Standardisation 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	
TOG	The Open Group	www.opengroup.org/
UN/CEFACT	United Nations Centre for Trade Facilitation and Electronic Business	www.unece.org/cefact/
W3C	World Wide Web Consortium	www.w3.org

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/

Document types

EN	(Full) CEN standard	
ENV	CEN pre-standard	must be converted into an EN within 5 years, or withdrawn; now known as a Technical Specification
CTS	CEN Technical Specification	a pre-standard, which must be converted into an EN within 5 years, or withdrawn
CR	CEN Report	
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	

Grouping of Standards and PAS

Infrastructural specifications

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/TS 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

Security token

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

Time-Triggered Protocol services

Directory services

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

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

Requirements specifications

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

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

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

Data type specs, 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 telehealth systems and networks - Part 1: Introduction and definitions
ISO NWIP TR 16056-2	Health Informatics — Interoperability of telehealth 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.

HL7 Messaging Specifications

HL7 is a consortium acting as SDO.

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

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 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.

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

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

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: Greyscale 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

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 Affects parts 3, 6, 7, 8, 15	Security Enhancements	Standard	1999
DICOM Supplement 32	Digital X-Ray	Standard	1998

Affects parts 3, 4, 6			
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 Affects parts 3, 4, 6, 10, 11, 12	Attribute Level Confidentiality	Standard	2001
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	Catheterization 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 US 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 Affects parts 3, 16	Breast Imaging Report Templates	Ballot	
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	

Basic services specifications

Naming services

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

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

Query services

Classification services

Pointer services

Archiving and backup services

Access services

Authorisation service

Access control services

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

Prioritised Applications

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

Medications

ENV 12610:1997	Medical Informatics - Medicinal product identification

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)

Non-healthcare specific technical basic specifications

UN/CEFACT

Technical security specifications

Categorisation of Standards and PAS

Mandatory specifications

Recommended specifications

Specifications under consideration

Annex G

Case Studies

This still requires some editing

This collection of case studies, assembled by NORMAPME, shows the diversity of fields where eHealth is already impacting or could impact on the health care sector. The cases follow structure in Chapter 12. Each case thus covers the fields:

- Improving access to clinical records,
- Enabling patient mobility,
- Quality of Care,
- Reducing clinical errors
- Improve efficiency of healthcare processes.

The Case studies cover a sample of typical cases. Of course many more can be imagined. However they provide a good indication of opportunities (or deficiencies) within the European health care system and how they could be advanced by the use of eHealth solutions.

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 health care 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 by compensation of damages, cost savings for the health care 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.

Improving access to clinical records

The project identified that poor data links between patient data, best practices and specialised centres for supporting the health care professional, as one of the main deficiencies of the current health care 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 reffered 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 health care systems is seen as a second major problem towards risk reduction. Cocoon experts felt that also in this field an enhanced web service linking different health care system sources of information could increase the success rate of treatment.

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.

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 health care 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.

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 diagnostics 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 health care professionals.

Improve efficiency of healthcare processes

The adoption of the Cocoon solution within the health care 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 health care cost levels.

Greater public awareness of clinical error 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.

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.

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 stresses that access to patient files should be blocked for user groups which might abuse patient information.

Enabling patient mobility

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

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.

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.

Improve 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.

Case Study "Triamun Project" – eHealth Pilot Project

The Triamun project is a Swiss pilot project, combining a Swiss health care 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.

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 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 dialling his login and pin code on a certain website (or with the help of his eHealth card), or at the doctor, if the doctor has an access to the internet.

All accesses are recorded through their digital signature at 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.

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 eHealth 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 mostly smaller 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.

Quality of care

All changes to the patient file (by persons authorised by the patient himself) cannot be reversed. Once data has been input it can not 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.

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.

Improve efficiency of healthcare processes

As the pressure of cutting costs was rising, Swiss health care 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.

Case Study “Swiss Medical Association”

The Swiss Medical Association FMH started in 1996 amongst other eHealth 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 eHealth pilot projects all over the Swiss 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 eHealth are quality assessment; secure data management and electronic data exchange, knowledge management and the creation of national standards. Meanwhile public company HIN offers the leading security platform for the Swiss healthcare sector.

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 eHealth 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 eHealth field.

Today, there are several local eHealth networks in the Switzerland that take the integration of Information and Communication Technologies (ICT) as a precondition for the successful achievement of their objectives The FMH is supporting these local initiatives.

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.

Quality of care

The main importance of eHealth for the FMH expert lies in the possibility of improved quality and efficiency in healthcare, 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 data, counselled by his "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 = 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.

Reducing clinical errors

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

Improve efficiency of healthcare processes

Through eliminating poor coordination of processes, redundant processes and discontinuous processes, the FMH eHealth experts see a cost saving potential of 10 – 40 % of total health care costs. Only through interoperability and integration of all the processes including the whole patient process, can the health care sector be significantly optimised and new services developed.

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

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.

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.

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)

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. But 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.

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.

Improve 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.

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 a future eHealth 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 eHealth systems are the national initiatives in Belgium and 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.

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 outway the advantage of waiting for a thoroughly studied very elaborated universal forum or format for interchangeability of

complete medical records. All possible eHealth 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.

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.

Quality of care

Interchangeable information over borders can raise the quality of care as the speed of care could be increased in emergencies. eHealth 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 healthcare, 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.

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 US 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.

Improve efficiency of healthcare processes

Several studies in the health care sector proved that eHealth 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 eHealth 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, eHealth 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 H

Glossary

To be compiled

References

The strange numbering will be sorted out when all references are in the document

DD e-Europe 2005 : An Information Society for All – An Action Plan, EU Commission COM (2002) 263 final, 28.5.2002

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

FF 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

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

HH 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

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

JJ 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

KK EU Commission Communication, COM (2002) 119 final

LL The Kohll judgement, Case C-155/96 of 28.04.98, ECR 1998 p. 1-1931
Smits 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
Leichtle judgement, Case-C 8/02 of 18.3.04, not yet published

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

1 Ministerial Declaration Brussels, 22 May 2003 Final

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

3 Communication from the Commission concerning the introduction of a European health insurance card, COM (2003)73 final, 17 February 2003

4 COM (2002) 667 final

5 Decision N° 1786/2002/EC of the European Parliament and the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008) – Commission

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

7 Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September2002 adopting a programme of Community action in the field of public health (2003-2008)

8 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 & Consumer Protection Directorate-general, 08/03/2002

9 Priorities for application of ICT standards: A project report for EHTEL thematic working group T1: Phase One, Ray Rogers, Juergen Sembtritzki, Pat Vilage, Joy Reaerdon, October 2002

10 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

11 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

12 The Kohll judgement, Case C-155/96 of 28.04.98, ECR 1998 p. 1-1931
Smits 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
Leichtle judgement, Case-C 8/02 of 18.3.04, not yet published

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

15 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

16 To Err to Human: Building a Safer Health System, Institute of Medicine, National Academy Press, 2000

17 Quality in Australian Health Care Study (QAHCS) 1995

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

19 UK National Patient Safety Agency Business Plan 2003/04

20 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

21 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.

22 Roger 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.

23 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.

24 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

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

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

27 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