

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

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

Part 1: Main Text

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Background documents and records of the Focus Group work can be found at the web-site: www.CENeHealth.org

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 a draft of that report for public comment.

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

Its objectives were

- To consider, with all relevant stakeholders, priorities and objectives for e-Health standardization and interoperability and how the CEN system and others can contribute;
- To overview the existing achievements and current programme of work of CEN/TC 251, 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 (eHSCG) 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 e-Health 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-organised 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 e-Health as defined in the context of eEurope – the application of information and communications technologies (ICT) across the whole range of functions and services which, one way or another, affect the health of citizens and patients, specifically:

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

Membership of the Focus Group was opened to all interested parties through a public web announcement. A membership list is in Annex B. The methodology followed is outlined in Annex C. The Focus Group decided not to address the electronic trading of healthcare goods for the reasons given in Annex D.

There are many organisations involved in standardization and standards development some formally multinational such as CEN, ISO and ITU and many with an international authority or engagement often with international affiliates or equivalent such as WHO, HL7, IEEE and DICOM. The Focus Group chose to use the term Standards Development Organisations (SDOs) to cover all such bodies.

2 Executive summary

The goals for the European Community in health are to:

- maintain a sustainable health care for all;
- improve safety of healthcare delivery and reduce the number of errors;
- support secure authorised access to patients' relevant health documentation anytime, anywhere;
- support the mobile citizen in seeking high quality care throughout Europe.

In Europe the demand for care (quality and quantity) is growing while the resources remain limited. Europe needs to improve and refine the supporting processes of health care to gain resources for future demand. e-Health has the potential to improve the quality and effectiveness of healthcare services. This view has recently been endorsed by the Council for Employment, Social Policy, Health and Consumer Affairs, which "Recognises that electronic health cards, electronic health dedicated national and regional networks and the use of other information technology tools can achieve significant improvements in the quality and safety of the health care that is delivered to patients in an environment of increasing pressure on healthcare systems, while contributing to cost savings in the longer term."

Many countries of Europe are increasing their attention on the use of ICT in the health domain. Some have a declared national or regional policy and others have adopted ambitious strategies for the next five to ten years.

The EU Commission is also looking to ICT to realise many of its health-related objectives and is working with Member States in encouraging a range of trans-EU e-Health services.

The most challenging of the services and work practices to which ICT is being directed involve many, and often diverse, organisational entities sometimes located in different countries. Successful application of ICT in these circumstances will not be achieved unless all the organisations concerned agree a set of common standards. Where the services extend between countries, perhaps across the whole EU, those agreements will need to be trans-national. In considering these matters the Focus Group came to the following conclusions.

Health informatics standards are essential to achieve the goals of e-Health in Europe for:

- interoperability between systems and patient information exchange between health organisations;
- market efficiency by providing increased understanding between all players in that market through a common technical framework and terminology for e-Health application development, procurement and implementation;
- meeting non-functional requirements to ensure safety, security and legal requirements e.g. protecting the privacy of the citizens;
- establishing a representative set of multinational interoperable, coordinated and open eHealth services based on a common business and service architecture
- managing eHealth services.

Many health informatics standards from CEN, ISO and other bodies such as DICOM, HL7 and IEEE exist, or are being finalised, to meet many of the requirements but:

- their existence is not well known, (this statement applies particularly to formal standards);
- they are not used enough;
- their interoperability is often not proven;
- they rarely explicitly take account of whether their requirements are suitable for small enterprises;
- some of them conflict.

European or whenever possible global standards (as opposed to no standards or conflicting national standards) are essential for an open market to:

- allow suppliers to market throughout Europe or globally without designing for each country;
- assist buyers in specifying exact requirements with assurance;
- facilitate cross-border communications and applications;
- meet the obligations of EU Directives and World Trade Organisation (WTO) principles.

Standards activities need positive and active support from:

- Member States in pursuing their national or regional strategies and policies and particularly in regard to their obligations to EU Directives and WTO agreements;
- the Commission in promotion and in financial support;
- healthcare professionals and other users in participation in standards creation and requirements specification;
- suppliers in participation in standards development and implementation of standards in products.

Moreover there is a lack of guidance on where and how to use standards.

Commitment to European and global standards is generally weak in the health domain and there is an increasing tendency for Member States to create national standards. This is despite:

- EU Directives and Commission Communications making clear the advantages of using European or global standards;
- obligations on EU Member States to use such standards in national applications and procurements;
- obligations not to create national standards where European or global standards exist.

The Focus Group was commissioned to address these matters and to make recommendations for actions that should be taken in the area of standardization to enable health policies and strategies to be efficiently realised at local, regional, national and EU levels.

It would not have been possible, or useful, for the Focus Group to have attempted to consider all the features of all policies and strategies across Europe or all the many

applications of ICT to health services which are being pursued. Instead the Group determined to identify and concentrate solely upon those matters and issues which appeared to have a high level of commonality and priority within the countries of Europe in the context of:

- those strategic aims and policies which have high commonality;
- the highest priority ICT applications needed to achieve such aims;
- the highest priority ICT infrastructure elements to underpin those applications.

The key strategic aims identified were:

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

ICT has great potential to assist the achievement of these aims. An analysis of national and EU priorities, stakeholder concerns and a number of case studies demonstrated that there are some particular ICT applications and infrastructure elements that are critical to meeting all or a number of these objectives. The Focus Group concluded that these should be the priorities to pursue.

Critical applications for achieving strategic aims:

- electronic health/patient records including health record and business architectures;
- electronic transfer of prescriptions;
- electronic health data messages between hospitals and primary care particularly communication of service requests and reports for laboratory investigations, discharge summaries and patient referrals;
- digital imaging and associated service requests and reports;
- e-prescribing with decision support;
- core data sets e.g. for public health and assessing quality of clinical care.

Infrastructure to underpin applications:

- management of patient identification including:
 - EU Health Insurance Card perhaps containing a 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 identifying and authenticating professionals and citizens/patients);
- terminological systems for clinical records and medicines;
- data cards and portals.

The Focus Group considered what would need to be done if these priorities are to be supported by the necessary standards with assured interoperability. It was conscious of the fact that the world of standardization is complex and comprises many different standards development organisations which often overlap and conflict. The Main Text lists

the bodies involved, the standards available and those in work programmes. There is a variety of co-ordinating and collaborating mechanisms in place but their effectiveness varies.

Whereas there are many standards available from these organisations which might meet the needs of applications, there can be no guarantees that standards will inter-work unless proven in practical applications and/or pilots. Even where two vendors have implemented the same standard, there are similarly no guarantees that their products will inter-operate without adequate interoperability tests due, for example, to allowable options within the standard. There are bodies such as IHE (Integrating the Healthcare Enterprise) and its regional chapters whose aim is to specify focused profiles based on standards and to test interoperability. They often take standards from different 'stables' in order to build a complete set and can provide an essential feed back to standards developers. Nevertheless the amount of such interoperability testing and its scope needs to be expanded. At present scope is centred on workflows inside hospitals although new profiles include exchange of documents across enterprise borders. The Main Text addresses the challenges to achieving interoperability and the critical need to address them.

In an ideal world health ICT policy makers, stakeholders including in particular health professionals, vendors, patient organisations/representatives and standards developers would come together within Europe and

- define the priorities for the application of ICT to health;
- establish the business requirements;
- identify the areas where standards are required;
- establish what existing standards might fulfil the needs;
- identify gaps in the standards required and determine how they might be filled and by what body (or bodies);
- develop standards for the gaps to an acceptable time-table;
- bring the standards together for interoperability tests and prove the application through pilots;
- promulgate the results.

This ideal is, at present, far from reality, not least because of the lack of a strong, authoritative European position on the minimal requirements for interoperability and quality for European e-Health systems and a formal EU organisational structure which would bring together all the major players at a senior level.

In that context, the "Open method of co-ordination" needs to be employed where the Commission, together with the recently established High Level Group on Health Services and Medical Care, should help those responsible for health systems to work together at European level [34]. The "open method of co-ordination" will contribute to involving the many actors in this sector particularly health professionals and their associations as well as patient representatives whose role is becoming ever more important

The Focus Group considered these matters at length and its most important recommendation is as follows.

Focus Group Main Recommendation

Establishing an Interoperability Platform

The Member States, with the Commission, should establish a permanent platform with a mandate, and the necessary resources to promote e-Health interoperability based on standards and to facilitate co-operation between Member States.

This eHealth interoperability platform should:

- pursue the implementation of the recommendations made in this report;
- establish a Europe-wide view on the requirements for standardization and its implementation in specific domains, in collaboration with standards organisations, based on input from relevant stakeholders communities;
- encourage and promote an environment for detailed specifications testing, evaluation or certification, to achieve interoperability of systems based on standards;
- establish a means for tracking and promoting good practice, and foster pilot implementations in compliance with the aforementioned environment;
- encourage agreements across national borders and between professional groups;
- encourage the further development of an appropriate European legal and regulatory framework;
- promote the establishment of infrastructure services such as for the creation and maintenance of terminology systems and knowledge repositories.

This eHealth interoperability platform should report to the High Level Group on Health Services and Medical Care set up by the EU Health Council.

This eHealth interoperability platform should be driven, at a senior European level

- by relevant stakeholders at a senior level, including patients/consumers, vendors, health professionals, and other experts in the domain of interoperability in health working with standards organisations both in ICT and health care generally;

Other recommendations¹

Note: *When the phrase "The Member states and the Commission should" is used in the recommendations below, it is intended that the high level interoperability platform to be established should become involved in the evaluation and pursuing of the actions needed.*

Recommendation 2: Improving access to records

The Member States, with the Commission, should give significant momentum to national and Europe-wide secure access to clinical records and to achieving full semantic interoperability of personal health data and information through strong support to existing and emerging European standards for electronic health record communication.

Recommendation 3: Reducing medication-related errors and e-prescribing

In order to reduce medication-related errors, the Member States, with the Commission and the eHealth interoperability platform, should implement technical measures to:

- uniquely identify and link the patient, the medication administered, the prescriber, the dispenser and the administrator of the medication (in order to achieve this, a common European identification of medicinal products is deemed necessary);
- formalise and present medical and procedural knowledge, such as medicinal product characteristics in relation to clinical findings, rules, clinical practice guidelines, clinical order sets;
- promote means for creating and distributing such knowledge using appropriate high quality, evidence-based, peer-reviewed content libraries including tools for creating and managing their content;
- facilitate the widest use of prescribing decision support software, based on interoperable data structure;
- trigger the development of representative practice models for a number of business cases.

In relation to these measures, the Commission should mandate the European Standards Organisations to develop the necessary relevant standards, in co-operation with ISO/TC 215 and other organisations.

Recommendation 4: Safety of health informatics products

The Commission, with the Member States, should consider a EU Directive addressing the need to control the safety of health informatics products in a similar way as for medical devices, and mandate the European Standards Organisations to prepare the safety standards which should be applied.

Recommendation 5: Quality of information - Metadata for knowledge resources

The Commission should mandate the European Standards Organisations to work with ISO through the Vienna agreement to produce a standard on metadata for knowledge resources and guidelines ensuring quality of health information on web sites to be based on guidelines published by the Commission and on work under way in WHO.

¹ The numbering and order of the recommendations does not indicate importance or priority.

Recommendation 6: Efficiency of healthcare processes - Workflow models and clinical pathways

The Commission should mandate the European Standards Organisations to prepare standard workflow models and clinical pathways, which would facilitate the application of ICT and improve efficiency. It will be critical for such development to include the appropriate healthcare professionals.

Recommendation 7: Electronic transfer of prescriptions

Member States, rather than developing national standards, should positively support the collaboration between CEN/TC 251 and ISO/TC 215 to:

- define the business requirements for the electronic transfer of prescriptions;
- identify the necessary standards required to implement the service in full and to identify the standards bodies which should produce them if new or amended ones are required;
- create interoperability arrangements to prove interoperability.

Recommendation 8: Information exchange to support inter-working and the mobile citizen

Member States, with the Commission, should provide the necessary means:

- to establish the paneuropean business requirements for the interworking of health organisations and cross-border communication to support the mobile citizen,
- to exchange interoperable information structures such as for electronic health records extracts, patient referrals, discharge summaries and laboratory results, also integrating point of care medical and test devices;
- to create an inventory of those standards that are necessary to achieve these business requirements;
- to ensure that the appropriate European Standards Organisations are mandated to develop them, in so far as they do not already exist;
- to establish arrangements for testing interoperability based on these standards and to ensure that they are, where appropriate, accounted for in conformance testing, quality labelling and certification processes.

Recommendation 9: Case-mix groupers based on diagnoses and procedures

The Member States, with the Commission, should provide the necessary means for the development of tools for mapping between case mix groupers used in Europe including the underpinning coding systems for diagnoses and procedures.

Recommendation 10: Quality indicators

The Member States, with the Commission, should mandate the European Standards Organisations to develop a standard for communicating the priority indicators of quality of care, based on measurements of health care outcomes and patient safety issues, as well as the definition and matching data elements.

Recommendation 11: Improving availability of standards

The Member States, with the Commission, should consider means for making all e-Health standards available free of charge to users in Europe as well as globally (as recommended by the eHSCG) particularly supporting less resourced developing countries and as has been requested by the Commission in COM 356. It is recognised that the national standards bodies in Europe derive income from the sales of standards, but we suggest that ways be explored as to how to overcome this in order to be able to implement the recommendation.

Recommendation 12: Commission's support to European standardization

The Commission should without delay initiate discussions with the European Standards Organisations concerning the implementation of the relevant recommendations of this report. Implementation of the mandated recommendations will require continuing support to the technical groups concerned. The ESOs should also establish an appropriate and co-ordinated mechanism, possibly under the ICT Standards Board auspices, to address and respond to the requirements emerging from the eHealth Interoperability Platform.

Recommendation 13: Towards an international multilingual reference terminology

The Member States, with the Commission, should:

- ensure the Europe-wide referencing and easy access to the content of existing health coding systems based on registration of such systems by the Eurorec Institute;
- support the international convergence towards a common framework for formal representation, and eventually the development and maintenance of a multilingual clinical reference terminology. This effort should build on existing efforts in formal representation as GALEN, FMA and SNOMED, and be carried out in liaison with the WHO Family of International Classifications
- make the targeted reference clinical terminology publicly available free of charge;
- support a common approach to link national classifications of procedures, to support cross-border reimbursement of health care.

Recommendation 14: Security services

As a step to achieving a secure information infrastructure, the Commission should mandate and fund a study of the Business Requirements for measures and services 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. This study should take into account the many existing community initiatives, as well as standards for inter-sector use, and focus on the need for actions specific for eHealth. The study should include services such as:

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

Recommendation 15: Health cards

Member States should utilise the existing CEN/ISO health informatics standards for health cards and the Commission should, in particular, seek to ensure the use of these standards for the EU Health Insurance Card by member states planning electronic interoperability or multiple applications for the EU Health 'Insurance' Card. Further the Commission should consider data card applications in relation to access through portals to the relevant and actual information.

3 Introduction

3.1 The health policy challenge

Within Europe, and in the rest of the developed world, almost every expression of health policy includes reference to Information and Communications Technology (ICT) whether this be to:

- improve efficiency;
- support clinical decisions;
- improve access to care;
- train professionals;
- provide citizens with health-related information;
- provide care at a distance;
- build repositories of health knowledge;
- address the many other facets of healthcare delivery and health maintenance.

Indeed such policy objectives are becoming increasingly dependent on ICT and, as the public becomes aware of the power of ICT, expectations surrounding its use will grow rapidly as has been witnessed in the use by the public of the internet for health purposes.

The most challenging of the services and work practices to which ICT is being directed involve many, and often diverse, organisational entities sometimes located in different countries and involving health organisations of differing status. Successful application of ICT in these circumstances will not be achieved unless all the organisations concerned agree a set of common standards. This will become more important in future when for many reasons the healthcare focus will shift from hospital-based care to more and more remote care, closer to the needs of the patient and involving increasingly smaller organisational entities.

Whereas this report cannot cover the implications for ICT of all health policies, it has identified five strategic aims which appear to have particular prominence and commonality within Europe namely:

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

Achieving these aims will require electronic means (the e-Health concept): that presents enormous challenges, and demands a variety of different approaches. Many of those challenges will not be technical e.g. they will involve ethics, change management, organisational upheaval, but the technical issues cannot be ignored. Whilst computer technology in the present age seems theoretically capable of meeting any needs, getting it to work in practice is complex. Tackling that complexity inevitably involves the world of standardization.

The world of standardization is a broad church and involves a great deal more than a few experts producing some pages of paper called a 'standard'. It requires:

- ownership and commitment not just by experts but by many stakeholders such as government health ICT policy makers, system developers, vendors, health care providers, patient organisations or representatives, purchasers, academics and, most important of all, users and health professionals;
- an understanding of business requirements and work processes often through complex models;
- sets of standards which will interoperate and the means for demonstrating that interoperability through test beds and real-life pilots;
- in the context of European or global standards, a willingness to work together and, where necessary, to compromise, for the common good.

Implementing standards, although necessary, can involve significant investment of time and money. This can represent a barrier to small organisations, particularly small to medium enterprises (SMEs). They will need reassurance that the standards they choose are the right ones to meet user requirements, any legislative aspects and any regional or national policies. That puts a particular responsibility on purchasers and those such as government health ICT policy makers to make their requirements clear. If the EU's declared aim of a common market is to mean anything, developers will not be required to design their products to different standards for each country in to which it sells its products. For SMEs in particular this can be a major barrier to trade.

This report considers this myriad of issues and makes recommendations.

3.2 Evolution of ICT in health – the critical stage

Many countries have reached a critical and challenging stage in the application of ICT to health and many other countries are fast approaching the same position. Within these countries most healthcare providers, such as hospitals, have already computerised at isolated departmental level. Many of these, whilst partially integrated across the organisation, have reached the most difficult stage of completing that organisational integration by implementing an electronic patient record including applications such as computerised physician order entry, decision support, clinical pathways and protocols, e-prescribing. Furthermore, health organisations in the countries which are most advanced are facing the challenge of applying ICT to communications and integration between health 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 accessible to patients including, in some cases, data input.

Achieving interoperability between organisational entities requires agreement between the collaborating parties on common communication 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 health organisations given a clear business case. 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 countries 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 or may not be the country's formal national standards body - the position varies greatly.

3.3 Choosing standards

Those countries in the process of integrating on a national scale are collectively about to spend many € billions on ICT over the next five to ten years, either centrally, regionally or locally, 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 European or global 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 specifications 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) since the USA represents the biggest market for healthcare ICT products. If European or global health ICT standards are defined as those from CEN/TC 251 and ISO/TC 215 (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 countries who are most advanced with committed schedules. Reasons are varied but include:

- ignorance of CEN/TC 251 and ISO/TC 215 emerging and existing standards (there is a lack of marketing by CEN, ISO and National Standards Bodies);
- perceived deficiencies in, and incompatibilities between, CEN/TC 251 and ISO/TC 215 standards;
- perceived lack of successful implementations of a suite of interoperable standards and lack of complete profiles of standards which will enable a whole application (perhaps in part due to the slowly evolving state of the art);
- weak vendor commitment and lack of products on the market which comply with CEN/TC 251 and/or ISO/TC 215 standards;
- lack of, or weak, support activities for the proper implementation of standards.

Many countries 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-operate.

In some areas, the most influential standards in the vendor and user community derive from bodies which have achieved an international influence and reputation in the market place. They operate outside the formal global/European standards bodies e.g.:

- the USA based HL7 Inc. for messaging;

- DICOM for imaging;
- IEEE for medical device communications.

Some countries are looking more to these bodies for their standards needs than to CEN/TC 251 and ISO/TC 215. That having been said CEN/TC 251, ISO/TC 215, HL7, DICOM, IEEE and other bodies engaged in standards development such as WHO, are increasingly collaborating in many successful co-operations between different standards development organisations based on liaisons delivering common standards. The recent formation of an e-Health Standardization Co-ordination Group under the auspices of the ITU (International Telecommunications Union) and the Interoperability Summit (established 1999) are witnesses to that trend.

Nevertheless where schedules are tight and high profile, some countries have resorted to creating their own national standards. Whereas the latter may in due course provide an input to European or global standards development organisations, that is usually not the prime objective. In ideal circumstances it could be argued that, where a country 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. Whether justified or not, the reaction to that proposition tends to be:

- CEN or ISO are too slow and bureaucratic;
- to date CEN and ISO standards have tended to be pre-standards (ENVs or Technical Specifications) rather than full standards (ENs) albeit some countries have included ENVs in their corpus of national standards;
- involvement in CEN and ISO implies too many compromises;
- CEN and ISO standards compete and partially conflict with strong vendor-led and user-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;
- there is no overview of what standards are required related to healthcare processes.

Whilst these reactions may have had a foundation in the past and may 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/TC 215 now has formal agreements for the adoption of HL7 and IEEE standards and is moving towards an agreement with DICOM (DICOM standards have been included as normative references in ISO/TC 215 standards);
- CEN/TC 251 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.

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 health care, this position is unsatisfactory. This report makes recommendations to improve the European and global standards environment with the aim of achieving a greater commitment by Member States to European and global standards and their development and testing. By European and global standards is here meant the output from the many bodies which are involved not solely CEN/TC 251 and ISO/TC 215. Whereas achieving that greater

commitment may not be practicable in the short term for those few countries 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 from 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.

3.4 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 priorities for the application of ICT to health which appear common to a number of countries in Europe, within the policies of the EU and as seen by stakeholders (Chapter 4);
2. examines the world of standardization and relationships of the many bodies involved (Chapter 5);
3. considers the challenge of achieving interoperability (Chapter 6);
4. analyses the requirements of priority strategies and policies, applications and infrastructure in the context of standards requirements (Chapter 7);
5. presents conclusions and a summary of recommendations (Executive Summary)
6. provides further detail in Part 2 Annexes

4 Priorities for the application of ICT to health

4.1 Identifying priorities

Pan-Europe priorities for the application of ICT were determined by amalgamating priorities as seen from three perspectives:

- those identified from national strategies and policies;
- those identified from EU policy statements;
- the views of stakeholders.

4.2 Priorities: national

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

- examining existing documents such as the European Health Telematics Association (EHTEL) reports [1] [2];
- a questionnaire survey.

A full analysis is given in Annex E.

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, discharge summaries 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 including medication interference alerts).

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

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

4.3 Priorities: EU strategies and policies

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

- eEurope 2005 [3];
- the Ministerial Declaration of 22 May 2003 [4];

- e-Health - Making health care better for European Citizens : An Action Plan for an European e-Health Area COM (2004)356 [5];
- initiatives regarding patient mobility between EU Member States COM (2004)301 [6];
- Community action in the field of public health (2003-2008) [7].

It concludes that the following should be considered amongst the priorities pan-EU:

- electronic health records including health record architecture;
- Health Insurance Cards for proof of entitlement but perhaps containing a medical emergency data set and controlling access to data (through portals) 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 anonymised statistical data for public health and assessing quality of clinical care.

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".

4.4 Priorities: 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 those identified as EU priorities. 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 by Focus Group members as stakeholders were:

- health/patient records including the 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, including hospital admission and discharge letters;
- imaging and associated service requests and reports;
- quality and safety;
- support of patient mobility.

A prerequisite for proper exploitation of these benefits required the basic foundations of:

- security and access control;
- terminologies for clinical records and medicines.

The Focus Group was conscious of the fact that they represented a small and possibly skewed sample of stakeholders and it attempted to gather further views from stakeholders on pan-Europe priorities will be obtained as a result of the Public Comment stage.

4.5 Priorities: Conclusions

The top priorities identified from the above three viewpoints are:

Strategic aims:

- improving access to clinical records;
- enabling patient mobility and cross-border access to health care;
- reducing clinical errors and improving safety;
- improving access to quality information on health for patients and healthcare professionals ;
- 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, discharge summaries and patient referrals;
- digital imaging and associated service requests and reports;
- e-prescribing with decision support;
- core anonymised statistical data for public health and assessing quality of clinical care.

Infrastructure:

- management of patient identification including:
 - EU Health Insurance Card perhaps containing a 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 and portals.

5 The world of standardization and standardization policies

5.1 Standardization requirements and standardization policies of the EU

5.1.1 The goals of standardization

The overall objective of standardization is to facilitate the production, handling, or use of products or services in the framework of free trade and free market to the best possible satisfaction of both users and suppliers.

The role of standards has repeatedly been highlighted by European Union official policies. For example in Council Conclusions 1999 [8] the Council emphasised:

“the role of European standardization 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 standardization.”

Additionally more recently in a Council Resolution 2002 [8] the Council reaffirmed:

“the important role of standardization 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 standardization 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 to form the basis for further developments. The ISO/IEC and CEN definition of a standard [9] is:

“document, established by consensus and approved by a recognised body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context”

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

In order to be useful, and attract as many users as possible, standards need to:

- be easily available, well publicised and obtainable at the lowest possible cost. On economic grounds it must prove cheaper and quicker to rely on standards than to make new developments from scratch to cover (entirely) the same needs.
- represent a sufficient consensus and reflect the state of the art at their time of publication, meaning that the area of knowledge they cover must be reasonably stable. 'Reasonable' stability does not bar any progress from being made. Standards evolve albeit that raises the issue of the backward compatibility of resulting products. It is noteworthy that while standards are meant to introduce a certain degree of order in provision of products, their inevitable successive versions may bring some degree of confusion: while, whenever possible, the evolution of a standard should as much as possible warrant its backward compatibility, the

'versioning' intends to manage the evolution between successive versions by highlighting their relationships.

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 and to establish a common base for market development. Typically it involves both suppliers of products and their customers. Standardization in many sectors has been dominated by suppliers but increasingly the development of standards is under pressure from 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 underpins New Approach Directives (although introduced over 15 years ago).
- Informal standards may also appear spontaneously, often as the result of a success story, with various interested parties declaring their willingness 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 deciding on possible changes, to various more or less formal consortia which may 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.

5.1.2 What role for public authorities? Formal and informal standards

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

The European Council highlighted this in the conclusion on standardization 2002 [8]

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

How far can the use of standards be left dependent on goodwill, and when does it become necessary to mandate them? There are countries where the mandatory status of specifications is embodied in law, either as a generic principle, or within a precise domain. Whatever initiative is at the origin of standards - from the suppliers, from the users (customers), or from 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* standards.

Industrial competition is not always as attractive as outlined above.

- Several suppliers may take a joint initiative to create 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 informal standards. However such specifications may subsequently be challenged by another group of suppliers, so increasing confusion, and impeding 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 player attains so great a share of the market that competitors cannot but comply to its specifications in order to keep selling their goods. If the latter occurs it results in a monopoly and public authorities will need to consider whether to open up the market by endorsing a corresponding *de jure* standard to 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 by consensus the quality of the dominating specifications, and arranging that they be endorsed as a *de jure* standard. This would permit its maintenance to be controlled by more than one party. However, at present, there appears no hint for such a process happening in the European market.

Public authorities have a role also for the financing of standardization activities but this varies between Member States from less than 20% to more than 50% of the costs of the National Standards Bodies. The European Commission and EFTA funding in total covers only 2% of the costs.

The European Council concluded the following in 2002.

"The Council considers however that the viability of the overall standardization 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 standardization, either directly or via support to national standardization; invites the Commission to analyse the costs and benefits of Community financial support to European standardization and how such support could be better targeted in order to contribute to the stability of the financing of European standards bodies."

Much work has been done and is underway within the European Community on the development of systems and standards e.g. the Electronic Health Card/Record project under DG Research, and the ECHI project developed under DG SANCO and its public health programme which includes eHealth as one of its priorities in the Health Information strand of that programme. Work is also underway on improving health information under the auspices of the OECD. The work on development of Cardiology Standards and, in particular, the Cardiology Audit and Registration Data Sets (CARDS) project carried out in 2003/2004, under the auspices of DG SANCO and the European Society of Cardiologists in cooperation with the Irish Presidency of the EU, is a good example of a development driven by specialists in a particular field of health activity and could be a model for development of further standards immediately useful to clinicians.

It is critical that a proper inventory and evaluation of the various existing projects/sources for eHealth standards is carried out at this stage to see which work can be used as a basis for further development of EU wide health information standards leading to the possibility of proper interoperability between systems. Given the investments which have been made in this area it is very important to ensure that work already carried out is not duplicated.

If standards are to be all pervasive then they need to be made readily available in an open manner. Financial assistance to ensure this is highly desirable. Moreover, the cost of creating a standard is less than the cost of implementing it properly on a large scale. Thus additional infrastructure/services should be provided (e.g. facilitating portals).

Recommendation 11

The Member States, with the Commission, should consider means for making all e-Health standards available free of charge to users in Europe as well as globally (as recommended by the eHSCG) particularly supporting less resourced developing countries and as has been requested by the Commission in COM 356. It is recognised that the national standards bodies in Europe derive income from the sales of standards, but we suggest that ways be explored as to how to overcome this in order to be able to implement the recommendation.

5.1.3 New Approach Directives

Recently, the EU “New Approach” to technical harmonisation and the Global Approach to conformity assessment have confirmed the role of standardization 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 options 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: compliance with global standards would be another. In the health sector, the only area to which the New Approach has been applied is in medical devices.

5.1.4 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 in law as part of the legislation for public procurement. Any invitations to tender in the domain it covers must refer to the formal standards, and subsequently bidders have to take it into account in their offers. Although 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 substantially influenced by public choices. In the European Union a set of directives on public procurement makes reference to European or global standards mandatory in the Member States but the interpretation of the meaning of the referral to standards sometimes differs and commitment seems very weak. The public procurement directives are available in several languages at the following web site:
<http://simap.eu.int/EN/pub/src/directiv.htm>.

5.1.5 Rights of use

The issue of patents and intellectual property rights (IPRs) needs to be addressed because the matter of ownership and rights of use of informal standards is crucial, particularly with regard to public procurement. It would not be acceptable that their use be based on the payment of uncontrolled fees to a private organisation. This implies that official and publicly acknowledged standardization bodies need to be granted a prominent role, and it means that all successful specifications should become formal standards so being made freely available as part of the public domain. In order to achieve success of e-Health applications, it should be the role of public authorities to ensure that the market rules are fair and in no way to the pecuniary advantage of any particular private player.

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

5.2 Standardization bodies involved, and their relationships

In a quickly evolving area of technology, standardization aims at helping stakeholders 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.

The question arises: what is the preferable standardization process? What is the quickest, the most efficient, and the most consistent process to design a standard? Channelling it directly through the official standardization bodies from the beginning or letting it be developed, or even triggering its development, within a dedicated group before submitting it to a standardization body for adoption?

Whatever the answers, it is essential for standardization to be based on the combined views of health ICT policy makers and key stakeholders and that the work of standards developers is focused on meeting those needs in an interoperable manner so that policy makers, suppliers and users will wish to implement them. At present health ICT policy makers, users and suppliers are not working closely in a co-ordinated manner and innovative means to achieve this need to be explored.

5.2.1 Official, formal standardization bodies

Official, formal standardization bodies share the following common characteristics:

- a public development process, with an open meeting policy;
- before being approved, new standards have to be publicly commented upon according to a strictly defined process;
- the standards developed are made freely available;
- the adoption and dissemination in the country of the standards approved by the European Standardization Organisations are proactively given a strong support.

The poor awareness of the richness of the formal standards is a matter of concern, since it is one of the major reasons why formal standardization is increasingly jeopardised by an efflorescence of sectoral, unco-ordinated, overlapping, and too often inconsistent initiatives by people unaware of the work already achieved

5.2.1.a National formal standardization

There is a National Standards Body (NSB) in all EU Member States, as well as in other EEA countries (Switzerland, Norway and Iceland). Many 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 receive official support of public authorities). More and more they are seeking to increase their turnover by broadening their domain of activities, which unfortunately may blur their image as bodies dedicated to the public interest.

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 European or global standards;
- the creation of standards in support of regulations, in partnership with governments;
- the representation of the country in question in European (e.g. CEN, CENELEC, and ETSI), or global standards bodies (e.g. ISO, IEC)

5.2.1.b European formal standardization

In the context of the construction of a formal European unity, the responsibilities of NSBs have had to be reflected at the European level. Thus the *Comité Européen de Normalisation* (CEN - European Committee for Standardization) was founded as early as 1961 by the NSBs in the European Economic Community and EFTA countries to contribute to their objectives of voluntary technical standards to 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 (the responsibility of CENELEC - the European Committee for Electro-technical Standardization), and telecommunication (the responsibility of ETSI - the European Telecommunications Standards Institute). This is reflected at the global level, with ISO, IEC, and ITU.

CEN is registered, according the Belgian law, as a non-profit making international, scientific and technical organisation. The Members of CEN are the NSBs of the EU and EFTA countries. Until the recent enlargement of the European Union, there 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 integrator for European standardization, 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 global standardization activities and co-operation;

through the delivery of standards, other technical specifications and related services needed by interested parties in Europe. It works to meet the market needs of all sectors in as close a partnership as possible with CENELEC and ETSI.

European Standards are published and disseminated by NMBs of CEN as national standards: the NSBs also publish other CEN deliverables at national level.

CEN/TC 251 is the sectoral Technical Committee of CEN for Health Informatics. To date it has produced over 50 technical documents (standards, pre-standards, and reports).

Recommendation 12

The Commission should without delay initiate discussions with the European Standards Organisations concerning the implementation of the relevant recommendations of this report. Implementation of the mandated recommendations will require continuing support to the technical groups concerned. The European Standardization Organisations should also establish an appropriate and co-ordinated mechanism, possibly under the ICT Standards Board auspices, to address and respond to the requirements emerging from the eHealth Interoperability Platform.

5.2.1.c Global formal standardization

Basically, global standardization 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 for the European standardization bodies, their members are the NSBs, but in this case being most countries in the world. While NSBs of European countries are usually also members of global standardization bodies no hierarchical relationship exists e.g. between ISO and CEN.

An essential differentiating characteristic of global standards, as compared to European ones, is that they are legally less stringent with regard to national standardization. The agreements between ISO and its member NSBs do not imply that global standards override national ones, as do European standards. The decision as to whether to incorporate a global document into a national corpus of standards is left at the discretion of each NSB, with the notable exception of those ISO standards (IS) that are taken as the

basis for a European standard, or are developed jointly as a CEN and ISO standard under the Vienna agreement between CEN and ISO (see 5.3.1).

ISO/TC 215 is the sectoral Technical Committee of ISO for Health Informatics, and was set up in 1998, after CEN/TC 251. Its work programme is now bearing fruit and its first standards have been published.

In the Standardization Sector of ITU, a new work item was recently established to study on a multimedia framework for e-health applications within Question 28(J) of ITU-T Study Group 16.

5.2.2 The United Nations Centre for Trade Facilitation and Electronic Business (UN/CEFACT)

UN/CEFACT is the organisation responsible for the standardization of a syntax in the field of EDI, as well as for the Electronic Business XML (ebXML) initiative. CEN/ISSS is the “European Entry Point” to the UN/CEFACT process. The EDIFACT standard is still widely used.

UN/CEFACT has published the Core Components Technical Specification, as part of the overall ebXML framework, drawn up by a UN/CEFACT-OASIS joint initiative discussed in section 11.8.1 below. This specification is meant to be employed wherever business information is being shared or exchanged amongst and between enterprises, governmental agencies, and/or other organisations in an open and worldwide environment.

This interoperability enabling specification covers both interactive and batch exchanges of business data (e.g. healthcare services) 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.

TBG10 is the UN/CEFACT group dealing with business requirements within healthcare. EEG9 (European Expert Group #9) is correspondingly dealing with healthcare requirements within Europe as a part of CEN/ISSS WS/eBES.

In contrast to HL7 who implemented HL7 standards for message information content using HL7 message syntax, CEN TC251 produced syntax independent standards defining only message content and structure. TBG10 and EEG9 developed and standardised messages types using the EDIFACT message syntax working in close co-operation with CEN TC251. This has been the main implementation of Message standards from CEN TC251. In addition some message types were developed from scratch.

TBG10 and EEG9 have for the last years mainly been involved in the representation of information using XML as well as the definitions of information elements using the techniques of ebXML's Core Component in order to establish semantic interoperability for healthcare related information."

5.2.3 Other e-Health standards development organisations with a global standing

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 an international standards development organisation (liaison A status with ISO/TC 215). Its secretariat is administered by the NEMA Diagnostic Imaging and Therapy Systems Division along with 9 professional societies that assume working group secretariats.

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 they participate in its enhancement.

Where there are interfaces to standards based on other technologies (such as HL7 V2.x and 3), the focus for harmonisation is a shared information model. When specific new technology is required, for example in support of new features such as security and compression, the strategy is to adopt proven European, global, industry or informal standards.

All of DICOM specifications have been endorsed as formal European standards and they will be submitted to become also formal standards in ISO.

HL7, Inc.

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

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

HL7 has 26 international affiliates.

Message specifications ('HL7 standards') Version 1.0 were approved in 1987, and were followed by version 2.0 in 1988. Version 2 still forms the basis for the many HIS systems implemented in the USA and several European countries.

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

improving interoperability beyond messaging, a unified process - the HL7 Development Framework - is currently under development.

Of particular note is an XML-based 'Clinical Document Architecture' set of specifications approved in 2000 (Release 1). Successive releases of the CDA will provide specifications to exchange increasingly structured clinical documents. Release 2 is currently being balloted, and Release 3 is in preparation. The CDA is meant to be used together with version 2, as well as with future message versions, and it is included in the HL7 RIM

A major focus of current interest in HL7 is the RIM. The large task of forming an object model of basic building blocks for all Health information is now complete enough for productive use. The derived messages based on this model are now being balloted. The RIM has been 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.

OMG/CORBA

As part of its open, vendor-independent specification for an architecture and infrastructure CORBA (Common Object Request Broker Architecture), the Object Management Group (OMG) is developing several services for health care. Several CORBA are available:

- Healthcare DTF Roadmap V1.0b;
- Person Identification Service (PIDS);
- Terminology Query Service (TQS);
- Clinical Observations Access Service (COAS);
- Resource Access Decision (RAD);
- Clinical Image Access Service (CIAS).

Others are under development:

- Healthcare DTF Roadmap V2.0;
- Healthcare DTF Toolkit 2.0 release;
- Summary List Management Service (SLIMS);
- Health Information Locator Service (HILS);
- Health Data Interpretation Facility (HDIF);
- Medical Transcription Management (MTM);
- Order Entry/Tracking Service (OE/TS);
- Party Management Facility;
- Pharmacy Interaction Service (PIF);
- Remittance Management Service;
- Charge Capture Management Service;
- Claims Management Service;
- Person Demographics Service;
- Healthcare Relationship Service;
- Health Benefit Plan Management Service;
- Eligibility Service;
- Care Authorisation Management Service;
- Enrolment Management Service.

IEEE (The Institute of Electrical and Electronics Engineers)

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

Collaboration exists between IEEE and ISO/TC 215 in accordance with the ISO/IEEE “Pilot Project” whereby international representatives can participate in IEEE ballots via ‘international co-ordination’ and IEEE standards can be fast tracked through ISO. Through this arrangement a large suite of standards has been developed and published jointly by IEEE, CEN and ISO.

ASTM (American Society for Testing Materials)

ASTM International, formerly the American Society for Testing Materials, was founded in 1898. Today, it is a global forum for the development and publication of voluntary consensus standards for materials, products, systems, and services. Individuals (over 30,000 from 100 nations), rather than entities, are members. ASTM individuals are producers, users, consumers, and representatives of government and academia. It is one of several organisations that develop standards under the American National Standards Institute (ANSI), the official standardization body of the United States. ASTM/E31 is the technical committee responsible for Healthcare Informatics. It has published several useful standards that have fuelled a variety of international standards.

5.2.4 Standards supporting initiatives

IHE — Integrating the Healthcare Enterprise

Started by HIMSS and RSNA, IHE is organised 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 2004, 50 vendors were involved in the USA, 34 in Asia, and 58 in Europe. Professional societies (ECR, BIR, DRG, SIRM, HIMSS/RSNA, etc.) supervise documentation, testing, demonstration, and promotion. Partnerships also exist currently with the American College of Cardiology (ACC), American College of Clinical Engineering (ACCE), HL7, and DICOM. Several individual members take part as well. The European chapter of IHE is also supported by several users' organisations, especially scientific societies (the European Society for Cardiology, SFR, also GMSIH, etc.)

IHE is an independent private initiative that results from a partnership without formal legal status between these vendors and professional societies. They collectively manage its budget. Participants from the software industry voluntarily participate, for a fee, to the testing and demonstration process, with a return on their investment in the form of a reduced installation efforts and a commercial advantage. Of course users' organisations also contribute at their own expense

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 'plug and play' as each interface requires site specific analysis and configuration and 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, Internet, Oasis, etc.) to address specific clinical needs. Its activity is to be regarded as complementary to SDOs. It has a formal relationship with HL7, DICOM, and ASTM.

IHE is not simply a demonstration project, for IHE demonstrations represent only one means to the end of adoption of integration profiles and standards. These demonstrations are backed up by documentation, tools, testing, and publication of information.

The IHE initiative is both an intra-enterprise and cross-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 co-ordinated, standards-based transactions between a subset of the functional components of health organisations 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. It has developed close to 30 Integration Profiles focused on Radiology, Laboratory, IT Infrastructure (MPI, Security, etc.) and Cardiology. It is now considering Nuclear Medicine and the exchange of clinical documents across the borders of an enterprise (e-Health).

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, by an open group of volunteer users and vendors;
- the deployment is organised by (world) regions, and by countries, based on national 'chapters';
- Connect-athons are organised at the 'regional' level (a number of national ProRec centres co-operate with IHE).

IHE has established chapters in France, Italy, Germany, UK, Spain, Netherlands, Denmark, and Norway.

The OpenECG initiative

With almost 350 members, it addresses the issue of "standards from theory to the practice (world market)" in the domain of electrocardiography. Its objective is problem solving, solution of misunderstandings, tutorials, open source SW, tools that are typically requested for facilitating the diffusion of the necessary standards.

The International Telecommunication Union (ITU)

The membership of the International Telecommunication Union (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 Standardization Sector - ITU-T; and Telecommunication Development Sector - ITU-D.

ITU, through its Development Sector, has since 1995 been very active in the implementation of Telemedicine Pilot Projects. Even though no ITU health specific standards have been produced yet, many standards supporting e-Health application exist, such as videoconferencing systems, security, public key infrastructure, video and image coding (e.g. ITU-T Rec. T.81/JPEG). Recently, the growing awareness of the telecommunication needs in this sector has led to the initiation of a study in on e-Health standardization within the multimedia study group of ITU-T (SG 16). ITU also took the initiative to convene an important international gathering of stakeholders from both the telecommunication and the health sectors, in the Workshop on e-Health Standardization held in Geneva under the aegis of ITU on 23-25 May 2003. This led to the formation in 2004 of the e-Health Standardization Coordination Group.

The EuroRec Institute

The 'European Institute for Health Records' (also dubbed 'The EuroRec Institute') was founded in 2002, and formally registered in 2003 under French law, as a non-profit association. It represents a new step in the PROREC initiative. The PROREC [10] initiative followed the conclusions of the Concerted Action MEDIREC (1994-1995), and has been developing since 1996 with 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:

- 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). Among a variety of criteria that may outline what quality means in this domain, the ability to communicate and interoperability, are prominent;
- helping proactively to identify and set up locally relevant solutions to overcome those limitations, shortcomings, and obstacles.

The ProRec national centres encompass, in a balanced way, representatives and opinion leaders from both users and solution providers, while maintaining ongoing 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). Two are currently preparing their registration (Norway, and Cyprus), and

promising contacts have been taken in 6 more countries (Portugal, The Netherlands, Hungary, Poland, Sweden, the U.K. and Greece)

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. 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 but to support standards, either already published or in preparation, and to raise the level of awareness of their existence and content in the supplier and user communities. This is also part of the mission of national ProRec centres.

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 e-Health 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 e-Health in order to exchange information, to identify problems and to 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 assisted by the Regional Office for Europe of the World Health Organisation and representatives of national Health/Medical Informatics societies from ten European countries.

Each European country, as defined by the WHO Region, is entitled to be represented in the Federation by a suitable Health Informatics Society.

EFMI has formal liaison with:

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

EFMI has 13 working groups across the whole spectrum of health informatics: all have an interest in standards but do not develop them:

Additionally EFMI Special Topic Conferences regularly take place.

IMIA — International Medical Informatics Association

In 1989, the International Medical Informatics Association was established as an independent organisation under Swiss law and in 1992 received official recognition from 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;
- 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.

It has an interest in standards but does not develop them.

5.3 Co-operation mechanisms between standardization bodies

5.3.1 The Vienna Agreement between ISO and CEN

The Agreement on technical co-operation between ISO and CEN (the Vienna Agreement), embraces many situations, such as:

- 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.

Co-operation between CEN and ISO relies on the Vienna agreement. It means that one party may lead the work on behalf of both, and approval is processed in parallel in both organisations. Given the difference between global and European standards with regard to binding the NSBs, careful attention needs to be paid in European NSBs to drafts circulated when they are meant to result in ENs.

5.3.2 ISO Fast Track procedure

Global Standards are developed in ISO by a six step process. If a document with a certain degree of maturity is available at the start of a standardization 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 can be submitted directly for approval as a Draft International Standard (DIS) to the ISO member bodies or, if the document has been developed by an international standardising body recognised by the ISO Council, as a Final Draft International Standard (FDIS), without passing through the previous stages.

5.3.3 ISO Pilot Projects

Since 1998, ISO has sought opportunities to work with selected SDOs to speed up the standardization process for specifications felt to be sufficiently mature for quick adoption as ISO standards. The first such pilot project concerned the IEEE 11073 series of specifications. Following this process, IEEE retains responsibility for the maintenance of the documents, and ISO channels them to ISO members.

5.3.4 Bilateral co-operation between bodies

Many of the formal and informal bodies have recognised the need for co-operation and various liaison agreements exist. 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 harmonisation and submit results to ISO.

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

5.3.5 The e-Health Standardization Co-ordination Group (eHSCG)

Establishment of the e-Health Standardization Co-ordination Group (eHSCG) was proposed by the workshop on "Standardization in e-Health" (Geneva, 23-25 May 2003) by 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/11073, IEC/TC62, DICOM and HL7 and sought nomination of a representative. All except IEC responded and have participated in the planning phase. Subsequently OASIS formally joined the group.

The overall objective is to promote stronger co-ordination amongst the key players in the e-Health Standardization area. The eHSCG is performing informal consultation and co-ordination on a voluntary basis and its recommendations are purely advisory. In particular they do not supersede any official and legal co-ordination procedures in place at national and international level. The terms of reference of the original invitation are reproduced below.

1. The eHSCG shall be a co-ordination group on all aspects of e-Health standardization.
2. The eHSCG should strengthen the co-operation amongst the SDOs involved, improving information exchange between organisations 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-Health-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.

At its first meeting in April 2004 it was agreed to compile a list of all available e-Health standards. A website with the latest developments will soon be available at www.ehscg.org.

5.3.6 The Interoperability Summits

The initiative for an Interoperability Summit dates back to 1999. It resulted in two meetings (December 2001 and June 2002), sponsored by the HR-XML Consortium, OASIS, the Object Management Group (OMG), UN/CEFACT, the XBRL organisation (eXtensible Business Reporting Language), and the Open Group. The meetings led to an understanding that a multi-dimensional approach to e-business standards was required and that no one group could or should try to control the entire e-business standards landscape.

At the first summit, participants sought to identify barriers that prevented co-operation among standards groups. At the second, participants learnt about ways that some organisations try to achieve interoperability, as well as the need for interoperability in particular industries. The summit revealed that more e-business standards groups are willing to collaborate and demonstrated various ways they could do so. It also illustrated the difficulty of the task ahead and highlighted the need for more concrete action and urgency in achieving the interoperability goal.

5.3.7 The ebXML initiative

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

Following completion of this framework, the initiative was closed, with UN/CEFACT and OASIS agreeing to progress different aspects of the standards within their separate

organisations. Some of the OASIS-based specifications have recently been adopted as ISO Technical Specifications under the PAS (Publicly Available Specification) procedure, and UN/CEFACT has also passed some of its specifications to ISO for processing.

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

6 Achieving Interoperability

6.1 Stating the issue: what interoperability is, and what it is not

A primary goal of standardization is to make interoperability and integration possible. It is the major theme of this report. Avoiding confusion in terms or concepts is essential.

The distinction between interfacing, integration and interoperability is extremely important. The CEN Report CR 14300:1999 "Interoperability of healthcare multimedia report systems", and the CEN/TC 251 "Short Strategic Study: Health Information Infrastructure", published in 2000 consider these three concepts, as well as the following definitions:

interface: a boundary at which interaction occurs between two systems, processes, etc. [35]. According to OMG (1991) an interface defines how to access an object.

integration: combination of diverse application entities into a relationship which functions as a whole

interoperability: a state which exists between two application entities when, with regard to a specific task, one application entity can accept data from the other and perform that task in an appropriate and satisfactory manner without the need for extra operator intervention.

This definition of interoperability, in its mention of a specific task, usefully distinguishes interoperability from integration. It also brings precision and operational meaningfulness to the IEEE [36] and ISO [37] definition of interoperability namely "the ability of two or more systems to exchange data, and to mutually use the information that has been exchanged".

6.1.1 Interfacing

Interfacing is the most basic way of enabling two systems to work together. However, when the number of systems increases, the task becomes difficult or even impossible. The number of binary interfaces between systems to be developed and maintained follows a well-known mathematical law resulting in 15 interfaces for 6 systems, 435 interfaces for 30 systems, 1225 interfaces for 50 systems, etc.

This raises practical issues and represents a significant economic challenge. When dealing with integration in hospitals, healthcare IT vendors increasingly express concerns about the tremendous increase of the proportion of expenses devoted to performing IT systems interfacing, as compared with their acquisition. Over the last few years these interfacing costs have increased from 20% to 30%, a trend that needs to be reversed. Undoubtedly better interoperability of their products would improve the situation.

6.1.2 Integration

Where a customer wants a variety of components to work together in a seamless way, as if a single system, integration techniques have to be used. These sometimes appear as the ultimate achievement in bringing together several subsystems. Indeed, integrating subsystems may theoretically rely on stepwise interfacing, but undoubtedly the use of fully interoperable components greatly facilitates the integration process.

In health care many entities (private surgeries, outpatient clinics, community networks, hospitals, etc.) collaborate to deliver health care. Some function as integrated

organisations, or should do so: hospitals may represent a good example. Nevertheless, on the whole, it will never be possible to envisage an entire health 'system' as a single fully integrated organisation, even in countries such as the UK, where national health systems are established. Most partners in any health system will work together only temporarily, and will work with a changing set of partners, depending on the patient for which they are responsible. There may be permanent agreements between partners but each has his own unavoidable constraints in terms of time schedules, organisational patterns, status (professional, etc.), which prevent their collaboration being a single fully integrated organisation.

6.1.3 Interoperability

Interoperability is the only sustainable way to help partners acting in various locations, with different expertise, perspectives, statuses and agendas, possibly cultures and languages, and using distinct information systems from different vendors, to collaborate harmoniously to deliver quality health care.

At the very top of an 'interoperability scale' are three levels, each one subdivided: functional, syntactic, and semantic. Full sharing of information requires that the two top levels of interoperability are reached [38]:

1. functional and syntactic interoperability: the ability of two or more systems to exchange information (so that it is human readable by the receiver);
2. semantic interoperability: the ability for information shared by systems to be understood at the level of formally defined domain concepts (so that the information is computer processable by the receiving system).

However, semantic interoperability is not an 'all-or-nothing' concept. The degree of semantic interoperability depends on the level of agreement between sender and receiver regarding the terminology, and the content of archetypes and templates to be used. Semantic interoperability is essential for automatic computer processing to underpin real value-added EHR clinical applications such as intelligent decision support, care planning, etc. Indeed, healthcare delivery deals dominantly with information and knowledge management. What is at stake here is not only exchanging data and information but re-using and processing them i.e. semantic interoperability is the objective.

From the preceding it is clear that standards form the basis for both integration and interoperability, though the standards to be used may differ for both perspectives. The development of e-Health throughout Europe, within and between Member States, requires well tailored standards aimed at facilitating interoperability between local, regional, and national information systems, and the availability of "out-of-the-box" components of information systems. However, in a number of domains, it is extremely difficult to find on the shelves standards that can be used in part or in whole, without further developments. Hence, whereas lessons can be learnt from the IHE and OpenECG initiatives, adaptations will be necessary as there is a shift from integration to interoperability. Some kind of interoperability initiative for e-Health appears necessary at the European level.

As well as improving the quality of care delivered to patients, and raising the level of satisfaction of professionals, interoperability standards together with complementary implementation profiles, will result in broadening and smoothing the marketplace for vendors and purchasers.

6.2 Supporting services for interoperability

Stakeholders in health care may be grouped in to:

- citizens;
- healthcare providers;
- payers.

Relationships exist between these three categories, relying on supporting services which can be stratified in three tiers: primary, secondary, and tertiary services. Examples of primary services are: EHR systems, message systems for lab results, etc. Examples of secondary services are: hospital information system, terminology provision, etc. Examples of tertiary services are: network providers, public key infrastructure, etc.

Standards are either already published, or needed, for more or less all the very many functions and data flows in the totality of the health environment. Nevertheless serious interoperability issues still exist at the three levels. They need to be tackled by a proactive process for e-Health interoperability in Europe.

6.3 Leading proactively towards interoperability for e-Health in Europe

e-Health may not be realistically achievable unless interoperability is guaranteed by appropriate measures alongside the development of the necessary standards. The content, the objective and the approach to ensure that these accompanying measures are put in place, are the subject of the following sections.

6.3.1 From reactive interfacing to proactive interoperability

Currently, interoperability between healthcare IT systems is achieved in a reactive manner. 'Reactive', because it requires a big effort from the IT staff to devise many 'adaptations' and 'extensions' to healthcare IT systems that have not been designed in a 'plug and play' fashion: this is interfacing. This requires a full understanding of the information flows and how they match the network interfaces of the products. Even when broad standards are supported by these interfaces, local variants, similar to language dialects, often prevent the 'gluing' together of the various vendors' implementations of the "standards". This represents 'after the fact' or 'reactive' interfacing.

Proactive interoperability is the proposed approach to achieve standards-based integration. Establishing a common understanding of workflows, ahead of an actual installation, is something standards developers have attempted to account for in the design of their standards. However the breadth of the requirements that a standard has to address for broad applicability, and the compromises accepted to reach consensus, often result in a lack of actual interoperability for the most common uses.

6.3.2 The need for 'interoperability functional profiles'

As previously emphasised, standards are the necessary foundation upon which e-Health information access and sharing can be accomplished on a scale that exceeds a few health organisations. However standardization repeatedly implies trade-offs between the breadth of coverage and the detailed level of their provisions. Therefore any actual implementation requires some form of tailoring. If the uttermost importance of semantic interoperability at

the component and system levels is always acknowledged as a common permanent target, and facilitated by appropriate measures, an enormous step forward would be accomplished.

The Healthcare Information framework [39] (HIF) asserts that, where possible, healthcare information interchange ought to focus on utilising existing European or global standards for interchange formats and communication protocols and, in particular, on the specification of 'functional profiles' based upon those standards.

A functional profile is defined as "A set of one or more base standards and, where applicable, the identification of chosen classes, subsets, options, and parameters of those base standards, necessary for accomplishing a particular function". An international standardised functional profile is "An internationally agreed, harmonised document which identifies a standard or a group of standards, together with the options and parameters, necessary to accomplish a function or a set of functions".

Over the last years, several hospitals and large clinics have been actively working at integrating the various specialised IT systems needed to establish hospital information systems within their walls. The experience of many Chief Information Officers who managed these investments is that, generally speaking, the current health informatics standards have not fulfilled their expectations. While often playing a critical part, they were insufficient to deliver integration, as expected.

At the same time, most observers would support the view that the rapid adoption of PACS in imaging departments has been facilitated by the generalised use of the DICOM standard, so fostering an easy integration of the necessary components. Reasons are varied and complex. Nevertheless with initiatives such as Integrating the Healthcare Enterprise (IHE, see Chapter 5), clinical imaging specialists and the vendors of products in the domain have facilitated wide adoption of these standards, and achieved noticeably higher levels of effective information sharing across competing vendors' products. This success story, as well as experiences in health care and other domains (such as ETSI, see Chapter 5) where similar achievements have been realised, provides valuable hints for future action. It illustrates the potential achievements of a European strategy that would aim at filling the gap between published healthcare IT standards, and their actual implementation and use, in order to reach effective interoperability. By "effective" one means that all significant problems are addressed, and solved namely:

- effective communication and data interchange is achieved requiring the combined use of healthcare specific and general purpose IT communication, messaging, and security standards;
- workflow is addressed as part of the interoperability problem requiring minimum customisation at the final stage, and resulting reduced costs;
- all the necessary mechanisms for non-ambiguous interpretation and use of data and information are implemented;
- supporting services are implemented to ease the deployment of interoperable products;
- a significant number of standards-compliant products are available on the market, successfully deployed by a sufficient number of healthcare providers;
- methodologies to assess the implementation of standards, and the effective level of interoperability obtained are available and accessible.

For this, a broad array of user-driven interoperability functional profiles are necessary. They can be arranged into three broad categories:

1. health IT infrastructure profiles: helping to provide secure infrastructures, at local, regional, national, or European levels, upon which clinical data and information may be securely exchanged and shared;
2. health information profiles: aiming at achieving semantic interoperability implying shared information models, archetypes mechanisms, and registration of coding systems;
3. health workflow profiles: built upon the above two foundation categories, and needed to achieve an active collaboration between healthcare providers (for example orders/results, referrals/reports, scheduling, prescriptions, etc.), and providing the most visible added-value to the users.

6.3.3 A proactive, stepwise process towards interoperability

It is critical to recognise the complexity of the process towards interoperability in healthcare delivery, in which various categories of players are directly involved:

- healthcare providers: this category encompasses health professionals, belonging to a variety of professions. Unfortunately, too few have all the necessary characteristics: knowledge and real experience of actual field delivery of healthcare systems including the practical constraints; appropriate skills in computer science and technology; and the necessary time to devote to standardization in health informatics.
- IT and administrative staff: they both play key roles in large healthcare providing institutions, but are often absent in small healthcare facilities. In addition, few are active in standards development organisations.
- health IT suppliers: vendors of clinical and administrative IT systems, and data generating medical devices (e.g. imaging). This category spans large multi-national companies with global objectives to companies of small and medium size, focusing on a market in a small geographic area, or narrow scope.
- health authorities (government-related structures that supervise or manage the health system), and payers (insurers, or the like).
- representatives of consumers and patients: the comments above on health professionals apply to them also.

Therefore, when driving towards interoperability of data and information flows in order to support e-Health, the needs of a variety of stakeholders have to be taken into account. That includes in particular health professionals, whose work environment will be directly impacted by the way standards are used to support workflow in their daily practice. Before considering mandating standards through any official or legal means their acceptability has to be optimised and achieved through collaborative processes.

Ideally four steps need to be taken:

1. identification of the problem from the users' side, by clinicians and IT experts;
2. specification of interoperability functional profiles by health informatics experts (the term 'functional profiles' is used to distinguish these specifications from the standards the implementation of which they should help. Although the starting point is the use of existing standards, some may need to be enhanced by the appropriate standards organisation to solve the problems addressed).

3. interoperability testing (vendors test their products on the basis of the functional profiles developed. For example, IHE holds so-called *Connect-a-thons* for this and ETSI has established an infrastructure for interoperability testing).
4. interoperability functional profiles statements and invitations to tender (vendors document the functional profiles supported by their products by relevant statements, so that both users and implementers can reference the appropriate standards and functional profiles in their invitations to tender).

6.3.4 Building upon significant successful experiences

Triggering interoperability goes beyond publishing standards. There is a need to involve the various stakeholders in a structure which, although relying on existing standards, focuses on the primary interoperability needs, and proceeds on a time controlled (typically one-year) cycle to develop functional profiles. The development of these functional profiles and their implementation in products will require an '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.

Over the past 6 years, IHE has set up an integration process based on world-wide collaboration (North America, Europe, Asia), with close to one hundred contributing health IT vendors. It has demonstrated the possibility of delivering ready-to-integrate products, to the benefit of small and large health organisations. To trigger interoperability for e-Health, Europe should use methods derived from this successful experience.

It should be noted that, in the domain of the Electronic Health Record, the Commission has, since 1994, constantly supported the ProRec Initiative (see Chapter 5). ProRec aims at promoting and facilitating the development, implementation, and use of quality EHRs throughout Europe. Now that EHR standards are close to maturity, this initiative is prepared to play an active role in supporting the development of corresponding functional profiles.

6.4 General conclusion and recommendations

Interoperability support activities are critical to take forward, extend, and complement the specifications provided by standards, in order to help their quick interoperable implementation.

To actually achieve the development of e-Health, these activities should concentrate on sharing health data and information between health organisations. Thus:

- the development of practical and effective interoperable solutions should involve the appropriate stakeholders in a collaborative process starting from publicly available standards;
- this process is likely to rely on standards from several different SDOs, and is distinct from the development of those standards;
- it may build upon the experience gained by the IHE and similar other European initiatives;
- the process suggested will result in the provision of technical specifications in the form of 'integration profiles', superimposed over standards, as well as a visible interoperability verification process. The promotion of achievements in terms of interoperability, through as many channels as necessary, is an integral part of the process;

- a number of interoperability supporting services need to be organised, either at European, or national levels.

Because semantic interoperability is part of such interoperability supporting services and is dependant on appropriate solutions to terminology issues, Member States, through the EU Commission, should support a common European approach as is described further in chapter 7.4.1.

The overriding theme of this report is achieving interoperability. As is evident from this Chapter and Chapters 5, 6 and 7, there are very many bodies involved in standardization and several initiatives to provide liaison and co-ordination across Europe. However there is no single entity which brings together senior representatives of all the key players in Europe and which has the backing, confidence and commitment of Member States, the Commission and stakeholders. Thus the main recommendation from the Focus Group is as follows.

Focus Group Main Recommendation

Establishing an Interoperability Platform

The Member States, with the Commission, should establish a permanent platform with a mandate, and the necessary resources to promote e-Health interoperability based on standards and to facilitate co-operation between Member States.

This eHealth interoperability platform should:

- pursue the implementation of the recommendations made in this report;
- establish a Europe-wide view on the requirements for standardization and its implementation in specific domains, in collaboration with standards organisations, based on input from relevant stakeholders communities;
- encourage and promote an environment for detailed specifications testing, evaluation or certification, to achieve interoperability of systems based on standards;
- establish a means for tracking and promoting good practice, and foster pilot implementations in compliance with the aforementioned environment;
- encourage agreements across national borders and between professional groups;
- encourage the further development of an appropriate European legal and regulatory framework;
- promote the establishment of infrastructure services such as for the creation and maintenance of terminology systems and knowledge repositories.

This eHealth interoperability platform should report to the High Level Group on Health Services and Medical Care set up by the EU Health Council.

This eHealth interoperability platform should be driven, at a senior European level

- by relevant stakeholders at a senior level, including patients/consumers, vendors, health professionals, and other experts in the domain of interoperability in health working with standards organisations both in ICT and health care generally;

7 Analysis

7.1 Identifying priorities for applications and standards

The priorities listed in Chapter 4 and the ICT applications standards and interoperability conditions required to support them, derive from 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. 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. Chapter 4 is 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 an electronic prescription 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 applications 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, countries 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 Chapter 4.

Nevertheless the following is a partial and illustrative analysis supporting the Focus Group's conclusions.

The illustration is based on Table 1. It takes five strategic aims which appear to be common and of high priority to most countries, 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 health care; • reducing clinical errors and improving safety; • improving access to quality health information for patients and healthcare professionals • improving efficiency of healthcare processes.
Means for achieving strategic aims: ICT applications	Examples: • electronic health records; • electronic messaging such as for referrals, results reporting and transfer of prescriptions; • electronic decision support e.g. e-prescribing • electronic access to knowledge e.g. health information web sites. • security technologies
Achieving inter-working within and between applications	Examples: • standards; • interoperability criteria; • conformance testing; • networks;

- | | |
|--|--|
| | <ul style="list-style-type: none"> • common terminologies; • data cards. |
|--|--|

7.2 Strategic aims

7.2.1 Improving access to clinical records

The issue of improving access to clinical records can be expressed as being the possibility for a healthcare 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 shortest 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 important, in any circumstance, for a health professional to base her/his decision on the broadest possible range of data and information.

In practice 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 healthcare professional;
- identify the documents;
 - their location, even virtual;
 - their topic, and more generally their content;
 - their date;
 - their author;
- identify the information originating device, component etc.

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 is already mature in several areas such as prescription support, but other developments have been experimented for years, though on limited scales. The limiting factor for their current and wide use is the slowness of the process. This limitation should be rapidly overcome 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 independent 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 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, such as the 5-part EN 13606 "Health Informatics - Electronic Health Record Communication", are currently emerging with the aim of providing the satisfactory 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.

Recommendation 2

The Member States, with the Commission, should give significant momentum to national and Europe-wide secure access to clinical records and to achieving full semantic interoperability of personal health data and information through strong support to existing and emerging European standards for electronic health record communication.

A further recommendation specific to health / patient records is given later in this Chapter (7.3.1).

7.2.2 Enabling patient mobility and cross-border access to health care

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 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 [6]. That the EU provides freedom for citizens to seek health care in other Member States has been confirmed by the European Court of Justice and the latter has clarified the circumstances under which costs may be reimbursed [11]. In essence a patient may seek in another Member State:

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

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

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

Such mobility raises 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 and in some countries this will be an electronic health insurance data card (EHIC) [12]. 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;
- a common set of services and informations;
- 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;
- bridging language differences.

All these matters require investigation if ICT is to support patient mobility and require action by Member States.

7.2.3 Reducing clinical errors

Studies in the UK [13], USA, [14], Australia [15]. Canada, Denmark, Italy, The Netherlands, Sweden, Germany 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", [13] 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 [16].

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 patient's 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 representatives of the NHS in England, Australia and USA indicated 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 [17] 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 [18] 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 (e.g. some systems may alert GPs of drug incompatibilities). Nevertheless prescription details may still need to be manually entered into dispensing pharmacy systems leading to potential transcribing problems. Also, the paper carrying the printed information may be heavily damaged on its way from the physician to the pharmacy.

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. There are other technical means for unique identification which warrant exploration.

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 up-to-date, 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. Decision support through clinical guidelines and other rule – based systems has considerable potential to reduce errors

Recommendation 3

In order to reduce medication-related errors, the Member States, with the Commission, should implement technical measures to:

- *uniquely identify and link the patient, the medication administered, the prescriber, the dispenser and the administrator of the medication (in order to achieve this, a common European identification of medicinal products is deemed necessary);*
- *formalise and present medical and procedural knowledge, such as medicinal product characteristics in relation to clinical findings, rules, clinical practice guidelines, clinical order sets;*
- *promote means for creating and distributing such knowledge using appropriate high quality, evidence-based, peer-reviewed content libraries including tools for creating and managing their content;*
- *facilitate the widest use of prescribing decision support software, based on interoperable data structure;*
- *trigger the development of representative practice models for a number of business cases.*

In relation to these measures, the Commission should mandate the European Standards Organisations to develop the necessary relevant standards, in co-operation with ISO/TC 215 and other organisations.

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.

Another way of reducing clinical error is to establish more well-defined clinical concepts for terms as well as definition of data elements through an agreed semantics.

Within this chapter are recommendations relating to some of these error reducing applications e.g. electronic transfer of prescriptions, electronic prescribing, and electronic health/patient records.

7.2.4 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 open up new mechanisms to do harm 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 significantly increasing 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 systems such as for decision support. 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 [19] [20] [21]. These measures are backed by a range of safety related standards from a number of

sources both national, European or global standards 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. Tools for verification of performances in measurements performed by automatic programs are often not available.

The safety of health informatics products needs to be assured in a manner similar to that applying to medical devices.

Recommendation 4

The Commission, with the Member States, should consider a EU Directive addressing the need to control the safety of health informatics products in a similar way as for medical devices, and mandate the European Standards Organisations to prepare the safety standards which should be applied.

7.2.5 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 [22] and has raised the question of possible quality seals. These initiatives need to be pursued both within the EU and globally. The Commission's recommendations should be internationalised.

Recommendation 5

The Commission should mandate the European Standards Organisations to work with ISO through the Vienna agreement to produce a standard on metadata for knowledge resources and guidelines ensuring quality of health information on web sites to be based on guidelines published by the Commission and on work under way in WHO.

7.2.6 Improving efficiency of healthcare processes

Countries throughout the world are seeking strategies to reduce costs and to improve the efficiency of healthcare processes both administrative and clinical. 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 computerised order entry 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, discharge summaries and patient referral;
- electronic transfer of prescriptions;
- digital imaging;
- non-imaging examinations and their multimedia reporting in electronic health records.

There are many healthcare processes the efficiency of which could be improved through ICT applications. In achieving this, it would be of assistance to system developers and users if they had access to standardised work flow models.

Recommendation 6

The Commission should mandate the European Standards Organisations to prepare standard workflow models and clinical pathways, which would facilitate the application of ICT and improve efficiency. It will be critical for such developments to include the appropriate healthcare professionals.

There are a wide range of telemedicine applications that also appear to have significant potential to reduce costs and improve efficiency. Nevertheless, 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). In addition, they are often not economically advantageous. The issue of reimbursement and a well-founded cost-benefit analysis is missing in many cases.

Reducing costs and improving efficiency is dependent on an understanding of costs and clinical 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 is a wide range of quality indicators used in different European countries. Any understanding at a European level and learning from each other by best-practice-sharing would require some harmonisation in these areas.

Improving public health and thereby reducing costs of health care is also dependent on well-defined data without substantial margins for different interpretation. The EU's public health initiative recognises this and is seeking to create a core data set for public health (see Annex F).

Later in this Chapter are recommendations on data sets and indicators pertinent to these matters.

7.2.7 Case studies

That these strategic aims are common to many strategies is further illustrated by a number of case studies collected by NORMAPME (Normalisation Association of PME (SMEs)).

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 I. In essence the findings were as follows.

Improving access to clinical records

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

The Swiss Medical Association FMH engaged early in e-Health and started with financing local e-Health networks and 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 e-Health pilot project in the Switzerland 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 health care

Patient mobility is a crucial issue in the Europe. For example the Swiss healthcare sector comprises 26 healthcare systems on canton level with multitude national and local/regional health insurance providers. In this system patient mobility even within Switzerland is difficult. In emergency treatment of foreigners, the long time required for information retrieval can be critical. Therefore some experts think that European patients should carry a minimum of medical information on their person for emergency purposes. On the other hand, Triamun experts believe that a Europe-wide system would need to be different and comprise central systems communicating with each other via interoperable solutions.

As barriers to patient mobility, COCOON experts identified lack of interoperability amongst healthcare sources of information, lack of medical protocols and weak communication amongst practitioners. As barriers to quality of care they identified: lack of risk management software, lack of statistical data for risk management and applications (for delivering best practices and data sharing) as well as weak communication, weak knowledge-sharing and poor links between patient files.

Quality of care

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. For custom made devices, like dental prostheses, patients may wish to buy or repair their medical devices whilst abroad. Manufacturers of these need all the relevant data defined in the Medical Devices Directive 93/42 to make them fit properly. This information exchange often does not happen.

Reducing clinical errors and improving safety

A recent study of the Italian Patient Right Court showed that at least 14,000 persons die every year in Italy because of medical errors - mostly diagnostic (35%) or treatment errors (18%).

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 healthcare professionals. 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 patient file, the risk of medical errors due to a lack of patient data would be minimised. In the paramedical sector, communication of medical data between the paramedical and the doctor often takes too long and can result in lack of, and differences in, information. For a minimum emergency medical record and also the complete medical record, priorities must be incorporation of a completely transparent medication order structure, combined with a closely linked drug delivery (and technical procedure) 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. 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 impressions.

Improving efficiency of health care processes

Eliminating poor co-ordination of processes, redundant processes and discontinuous processes through e-Health systems could result in major cost savings:

- FMH Switzerland forecasts savings of 10% to 40% of total healthcare 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 healthcare sector prove that e-Health 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 deficiencies in information provided by dentists to dental technicians and lack of links between dental technicians and patients, lead to unusable dental prosthesis and double work.

Also the adoption of the COCOON solution within the healthcare system in Europe could improve the efficiency and cost effectiveness of the sector, as the number of medical errors directly impacts healthcare cost levels. The existing Swiss e-Health projects were a result of rising pressure on productivity, which was achieved by process integration within the Triamun project.

7.3 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 strategic aims.

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 4 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, discharge summaries and patient referral;
- digital imaging and associated service requests and reports;
- e-prescribing with decision support;
- core anonymised statistical data for public health and assessing quality of clinical care.

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

7.3.1 Health/patient 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 - healthcare providers to help them deliver best possible services. Who is the owner of their content depends on the country, 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 healthcare 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, customs may vary, depending mainly on deontological regulations. There are also other occasions where more than one healthcare 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 for 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, makes it necessary to address new requirements. While human eyes and brains are able to pick up the information 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.

The most important issue for standardization is about what is exchanged, which means sent and received, and how it is exchanged, rather than about what remains static, and how it is stored. In other words, to understand fully the content of information obtained from another organisation, how the data and information are built into the messages so as to retain their entire intended meaning is more important than how they may be stored (in whatever format to be readable locally) in the sender's and recipient's repositories. What is critical in terms of team work is the ability to understand what the others mean.

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 messages from others will have heavy implications on others' machines (or rather on others' software) in terms of messaging standards. Nevertheless, 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 mobility of citizens and thus of patients who may have to seek care at any time in any place, requires easy and quick access to their personal health data. Electronic health records will soon need to be accessed from any place throughout Europe. In some instances they already can be. Accessed means that their content can be read (with human eyes), and understood (with human brains), but 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, most experiments so far 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 standardization 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 standardization. European work in this area is the most advanced with regard to the architecture of records in respect to interoperability. Moreover the European work is intended to fit within other standardization work which is taking place internationally, as in the USA with HL7, and benefits from contributions from international experts. Therefore, the necessary tools are there, and what remains necessary is to give strong support to the necessary momentum for wide scale implementations.

7.3.2 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 anonymised data bases of prescribing practice to improve services, control costs, planning supplies 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, HL7, ITU (for PKI). In terms of messages specific to prescriptions there are standards from CEN, UN/CEFACT (MEDPRE)" and HL7, and a number of standards are in use nationally e.g. in Denmark, USA, Australia. Within CEN/TC 251 the existing standard ENV 13607 is under review. CEN/TC 251 will instead create a standard business view for transfer of prescriptions together with a business model. ISO/TC 215 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. CEN/TC 251 and ISO/TC 215 have agreed to collaborate.

Thus CEN and ISO are taking much the same stance and collaborating. 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.

Recommendation 7

Member States, rather than developing national standards, should positively support the collaboration between CEN/TC 251 and ISO/TC 215 to:

- *define the business requirements for the electronic transfer of prescriptions;*
- *identify of the necessary standards required to implement the service in full and to identify the standards bodies which should produce them if new or amended ones are required;*

create interoperability arrangements to prove interoperability.

7.3.3 Health data messages

Of particular interest in this area are service requests and reports for laboratory investigations, discharge summaries, patient referral and communication with point of care medical devices. Amongst the business drivers are:

- improving efficiency and reducing costs;
- reducing errors;

- improving services to patients;
- contributing to an electronic health record.

There are existing message standards in CEN/TC 251 and HL7 and a range of national messaging standards some of which are adaptations of CEN/TC 251 and HL7 standards. Any health system seeking to implement health data messages may therefore face a choice between implementing or adopting CEN/TC 251 or HL7 or producing national/local standards. CEN/TC 251, ISO/TC 215 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). Despite this, full alignment between CEN/TC 251 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.

Communication with point of care medical devices such as vital signs systems and the wide range of equipment in mobile and acute care requires special attention e.g. because of the need for plug and play solutions and real time support. There exists a very good global co-operation between CEN, IEEE and ISO in this field and a number of standards have been finalised, more will be finalised in 2005 for such communication (see further part 2). these standards are being rapidly taken up by new product developments and it is important that they are specified by health care procurements.

Recommendation 8

Member States, with the Commission, should provide the necessary means:

- *to establish the pan-European business requirements for the inter-working of health organisations and cross-border communication to support the mobile citizen;*
- *to exchange interoperable information structures such as for electronic health records extracts, patient referral, discharge summaries, and laboratory results , also integrating point of care medical and test devices;*
- *to create an inventory of those standards that are necessary to achieve these business requirements;*
- *to ensure that the appropriate European Standardization Bodies are mandated to develop them, in so far as they do not already exist;*
- *to establish arrangements for testing interoperability based on these standards and to ensure that they are, where appropriate, accounted for in conformance testing, quality labelling and certification processes.*

7.3.4 Digital imaging and associated service requests and reports

There are several business drivers for digital imaging such as:

- improved image quality;
- reduced radiation exposure due to increased sensitivity of detector systems;
- increased access rate to almost 100% throughout place and time instead of the rate of loss associated with film-based documents;
- increased departmental efficiency;
- the ability to process electronically;
- enabling images to be part of the electronic patient record;

- facilitating transmission electronically to other locations, e.g. remote viewing, second opinion, telemedicine;
- supporting quality management, standard reports and sophisticated epidemiology.

Today the majority of imaging modalities primarily create digital data in their primary mode. The proportion of non-digital modalities is decreasing constantly and will vanish in a short time. Furthermore the volume of digital data increases because new modalities 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 for images of different modalities to be handled by films or by special workstations. 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. Because of this there is a need for standards.

Cross-referencing of image data sets 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 is necessary. Workflows in health care mandate quality management for meaningful reports and epidemiology. This is only possible with standardised electronic means and this will become even more important in the future.

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;
- EN 14720
- HL7 v2.x and v3
- XMLSig/MLEncryption in CDA (ongoing work);
- ebXML/SOAP;
- T12x Standards (conferencing, document sharing);
- Smart cards (HPC).

Digital imaging is surrounded by other processes. Therefore interoperability with other applications such as departmental, hospital and community systems emphasises the requirement for integrated use. IHE provides integration testing with proof-of-interoperability. Suitable technical frameworks and integration profiles also support the interworking of different concepts (e.g. DICOM-SR, ebXML and HL7/CDA). Digital images with their complementary processes are migrating from local applications to remote and forthcoming groupware applications with special emphasises on data security and protection.

Standardization and proof-of-concept activities need to be undertaken for:

Asynchronous communication

1. Secure cross-organisation 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-organisation 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)

Some 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.

7.3.5 e-Prescribing

A key driver for e-prescribing with decision support is the reduction of medication errors. It will also contribute to increasing efficiency and reducing costs, and can provide input 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 [23] 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 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.

Recommendation 3

In order to reduce medication-related errors, the Member States, with the Commission, should implement technical measures to:

- uniquely identify and link the patient, the medication administered, the prescriber, the dispenser and the administrator of the medication (in order to achieve this, a common European identification of medicinal products is deemed necessary);*
- formalise and present medical and procedural knowledge, such as medicinal product characteristics in relation to clinical findings, rules, clinical practice guidelines, clinical order sets;*
- promote means for creating and distributing such knowledge using appropriate high quality, evidence-based, peer-reviewed content libraries including tools for creating and managing their content;*
- facilitate the widest use of prescribing decision support software, based on interoperable data structure;*
- trigger the development of representative practice models for a number of business cases.*

In relation to these measures, the Commission should mandate the European Standards Organisations to develop the necessary relevant standards, in co-operation with ISO/TC 215 and other organisations.

7.3.6 Data sets

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

Core data sets for hospitals

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-France report [24]. 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 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 [25]. 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. Nevertheless, even if hospitals use the ICD (International Classification of Diseases) versions 9CM or 10 for diagnoses, the coding systems for procedures vary 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.).

It is highly desirable that a means of mapping between systems used in different countries is developed to allow pan-European comparisons.

Recommendation 9

The Member States, with the Commission, should provide the necessary means for the development of tools for mapping between case mix groupers used in Europe including the underpinning coding systems for diagnoses and procedures.

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);
- amount of blood consumed during specific surgeries;
- duration of surgeries;
- survival rates on staged cancers.

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/resource group, as well as excess in mortality in some DRGs/resource groups.

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 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.

None the less, 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.

Recommendation 10

The Member States, with the Commission, should mandate the European Standardis Organisations to develop a standard for communicating the priority indicators of quality of care, based on measurements of health care outcomes and patient safety issues, as well as the definition and matching data elements.

This recommendation 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.

Core data set for public health

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.

7.4 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 6. 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 4 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 and portals.

7.4.1 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 4 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;
- helping overcome language diversity.

Neither CEN/TC 251, ISO/TC 215 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.

Nevertheless ISO/TC 215 has recognised the need for an ISO 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 European or global standards on which to build. Unfortunately, for the achievement of interoperability, a number of national and international bodies appear to be embarking on new terminology systems. However the creation of such an international terminological system requires a body recognised internationally for actually creating a system.

Clinical records

The major, detailed terminological system for capturing clinical data in patient/health records is SNOMED CT (Clinical Terms). This is owned, developed and maintained by the College of American Pathologists (CAP), 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 for maintenance whereby EU Member States could influence future SNOMED developments and maybe additions to the terminology (some terms will be peculiar to particular Member States).

Recommendation 13

The Member States, with the Commission, should:

- *ensure the Europe-wide referencing and easy access to the content of existing health coding systems based on registration of such systems by the Eurorec Institute;*
- *support the international convergence towards a common framework for formal representation, and eventually the development and maintenance of a multilingual clinical reference terminology. This effort should build on existing efforts in formal representation as GALEN, FMA and SNOMED, and be carried out in liaison with the WHO Family of International Classifications*
- *make the targeted reference clinical terminology publicly available free of charge;*
- *support a common approach to link national classifications of procedures, to support cross-border reimbursement of health care.*

7.4.2 Management of patient identification and protecting personal information

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;
- e-Health 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. processor based ID data cards);
- access control including:
 - policy bridging between organisations;
 - role definition;
 - audit trails.

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

SDOs such as CEN/TC 251, ISO/TC 215 and HL7 are very active in this field. CEN/TC 251 has developed a number of standards and several are approaching their final stages.

ISO/TC 215 and ITU (X.509) have produced standards on Public Key Infrastructure and ISO/TC 215 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/TC 251 and ISO/TC 215 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 processor-based identity 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.

Thus for realising a trustworthy environment for communication and co-operation using personal health information, Member States, through the EU Commission, need to establish a framework of policies and standard-based solutions for guaranteeing appropriate identity and privilege management for authorisation and access control of all those involved in patient care; controlled by patients and, depending on their level of access, by professionals who are given such authority by patients or by their function/role.

Recommendation 14

As a step to achieving a secure information infrastructure, the Commission should mandate and fund a study of the Business Requirements for measures and services 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 services such as:

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

7.4.3 Data cards

There is a need to implement e-Health applications based on European wide interoperability of e-Health 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 'co-ordinates', 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 healthcare sector.

International interoperability of these healthcare 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 standardization 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.

Standardization 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 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 card², assuring interoperability across all Member States healthcare systems.

The use of data cards to authorise access to data will access through portals.

Recommendation 15

Member States should utilise the existing CEN/ISO health informatics standards for health cards and the Commission should, in particular, seek to ensure the use of these standards for the EU Health Insurance Card by member states planning electronic interoperability or multiple applications for the EU Health ‘Insurance’ Card. Further the Commission should consider data card applications in relation to access through portals to the relevant and actual information.

7.4.4 Interoperability

Achieving interoperability in its widest sense is a considerable challenge. These matters are dealt with in Chapter 6.

7.5 Conclusions

The Focus Group's main conclusions and all the recommendations are presented in the Executive summary in chapter 2.

² The adopted terminology "Health insurance" for cards replacing E111 as evidence of entitlement to statutory social security schemes does not imply economic activity of insurance