**Promoten van Normalisatie van Informatica-
en Telematicatoepassingen in de Gezondheidszorg**

Wetenschappelijk ondersteuningsprogramma
voor de normalisatie

deel III

Eindverslag

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1   INTRODUCTION

This document, entitled 'Promotion of Healthcare Informatics and Telematics Standards in Belgium', has been produced with the support of DWTC/SSTC in the framework of the Programme of 'Scientific Support to Standardisation, Stage 3: Promotion of Standardisation and Certification' (contract number NO/E8/20; NO/10/21, Federal Office for Scientific, Technical and Cultural Affairs of the Belgian Prime Minister's Office).
The authors thank all those people who have, directly or indirectly, contributed to the completion of this work.

In its document 'Europe and the Global Information Society' (Recommendations to the European Council), the Bangemann Group proposed an Action Plan of concrete initiatives to carry Europe forward into the Information Society. One of the areas (Application Seven) in which action is still needed, is interconnection of networks and interoperability of services and applications in Healthcare.

The environmental context in which healthcare informatics and telematics are evolving is characterised by the following key factors:
- rising cost of healthcare,
- changing patterns of disease (long-term, expensive care),
- increasing utilisation of new technologies,
- change of organisational structure of healthcare delivery,
- political pressure leading towards harmonisation and integration.

Cost-benefit analyses have been conducted and seem to justify expenditures on Telematics within the constraints of scarce resources and competing demands in healthcare. Consequently, healthcare organisations have already started to communicate electronically at both local and national levels.
National and Regional Healthcare Information Infrastructures and Telematics Services are already becoming essential parts of healthcare business strategies and of day-to-day healthcare provision. Providing a high-quality service to patients today involves all healthcare sector actors having the right information at the right place at the right time.

At present, there is also overwhelming recognition that the timely development of healthcare informatics and telematics standards is necessary for improvement of the interoperability of systems within these Healthcare Information Infrastructures.

The scope of this study therefore is to promote standardisation in the domains of Healthcare Informatics and of Healthcare Telematics. The sector of healthcare represents an important market and is (cf. healthcare reforms around the world, particularly in Europe and in the US) also now subject to rationalisation: in the healthcare reforms new Information and Communication Technologies (ICT). Standards have been broadly recognised to be key-promoting factors for achieving more efficient health information management and better healthcare systems.

The general philosophy of this project is also the recognition of the interdependency between activities in Research and Development (R&D) programmes, in Standardisation and in

Industrial Exploitation. It also considers the necessity of alignment between R&D and Standardisation efforts at national level and corresponding initiatives at European level.

Common goals and strategies have to be defined by actors such as Healthcare Policy Makers, Industry and Users (in this case patients and healthcare professionals). Interaction between those parties will ensure the quality and implementation of the adopted standards.

As such, this domain can serve as a paradigm for other sectors and can be considered as an unique opportunity thanks to the evident Belgian expertise and leadership in this field of standardisation.

Standards will also help provide vendors (primarily Small and Medium Enterprises, SMEs) with a more stable environment for product development, allowing economies of scale and access to this important market.

The general objectives of this project were:
- to reduce the gap between the world of standards and the industry (including SMEs) active in the field of healthcare informatics/telematics in Belgium; this should reduce the risk for misfits and misinvestments;
- to reduce the gap between ongoing research and standardisation efforts on the one hand and between supply and demand on the other;
- to reach consensus between all different sector actors (healthcare authorities, industry and the users) for voting on final drafts, for proposing priorities regarding the content of new work programmes and for defining strategies;
- to facilitate the implementation of European Standards by translating or adapting them to the national situation (cf. organisational, legal issues and other eg. security); to prepare pilot projects in order to test and to validate standards;
- to support and to reinforce the European and Belgian impact on international standardisation activities (cf. CEN/TC 251, ISO/TC 215, IMIA/WG 16 on Healthcare Informatics).

The project will therefore:
- support, together with BIN/IBN, the activities of a forum (the Belgian Mirror Group of CEN/TC 251) in order to bring all sector actors and stakeholders together; this mirror group will function as local point for access to information (including tutorials) and as consensus group to protect national interests;
- establish, together with the Ministries of Health and Social Affairs, the National Health Telematics Standards Committee, by issuing a Royal Order in the framework of the Belgian Health Laws; this Committee of experts will produce guidelines, referring to existing standards, with impact on accreditation in the healthcare informatics sector;
- install and maintain a data-base/inventory on standards in medical informatics using already available equipment (NT server) and tools (Internet WWW sites of CEN/TC 251, ISO/TC 215, IMIA/WG 16 on Healthcare Informatics).

By virtue of its members, who all have been successfully involved in past international research-, standardisation- and exploitation initiatives, the consortium was in a strong position to capture know-how and experience in the field, to carry this forward to the future and to serve as a catalyst for new initiatives.

1.1 Rationale and Importance of this Study

Transpositie en spreiding van informatie in verband met brandveiligheid in gebouwen.

1.1.1 Impact of ICT-Standardisation in the Sector of Healthcare

In conventional sectors of industry, standards are well known for increasing companies' market opportunities and for lowering the cost of equipment and services to users.
The same arguments hold for the field of healthcare informatics, where European industry currently supplies, to a fragmented market, products which have a short life cycle and are over-customised and therefore expensive to develop, to buy or to maintain. Agreement on common requirements will reduce the cost of healthcare information systems and open up the market.

In a Global Information Society access to information is - thanks to technology (e.g. Internet, World Wide Web) - not anymore limited by location but only by the very existence, availability and quality of the information itself.
'Information' implies and will always imply a certain organisation of the data and this exactly is where standards in the field of healthcare enter into the scene and why they are of crucial importance: common message descriptions, common formats, standard definitions of medical concepts as well as standard codes are desperately needed for better healthcare information management.

The successful exchange of information, both clinical and administrative, between different information systems therefore is one of the major challenges for healthcare at present. Unfortunately, there is today a proliferation of heterogeneous and incompatible exchange solutions. As a result, linkage of systems by standard interfaces has now been broadly recognised as a must (cf. Open Systems Environment Standards).
Especially in Europe, where information (e.g. administrative patient information) crosses management boundaries and in many cases regional and national boundaries, agreement on structures and information content of messages is necessary.

Like in the rest of Western Europe, Belgium is on the edge of making its next evolutionary step in Healthcare Informatics and Telematics - that of integration of information organisation-wide and nation-wide.

Today's challenge for realising the potential of information management and technology in healthcare is:
?   to link organisations together to allow care-providers to share information and to access remote care through telematics and telemedicine;
?   to integrate medico-administrative systems within organisations to increase efficiency;
?   to bring integrated systems to bear on clinical processes;
?   to provide access to knowledge and decision support for evidence-based decision making, for maintenance of skills and for education;
?   ultimately to facilitate a secure, shared, multimedia distributed clinical record held electronically in summary form by all citizens.

Much of this could materialise in the next years.
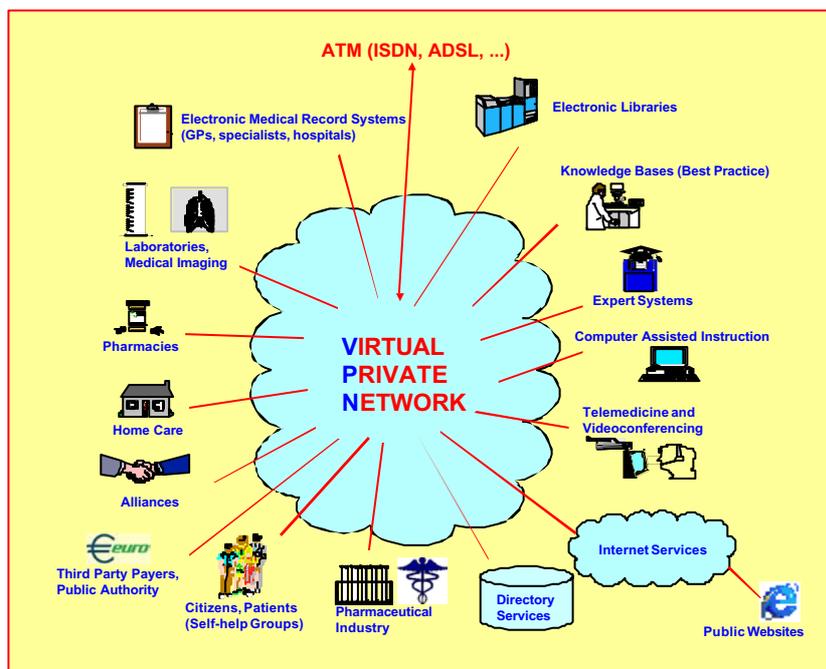
fig 1: Telematics Scenarios in Healthcare

By improving the ability of public administrations, of research centres studying medical effectiveness and of healthcare professionals to share critical information, standards in healthcare telematics and informatics will indirectly contribute to the health of individual patients.

Whilst the potential for substantial improvement in efficiency and effectiveness through automating processes, sharing information and access to knowledge, is enormous, it will not be realised without interconnection and interworking between administrative and clinical systems within and between organisations through telecommunications.

This cannot happen without agreed standards. The incompatibility of systems through absence of higher level standards is creating barriers to progress. These barriers are becoming more and more impeding as healthcare organisations endeavour electronically to communicate with others and seek to share and access knowledge remotely. Already there are signs of cross-national healthcare communications where the barriers are even greater.

To co-ordinate the development of standards in Healthcare Informatics and Telematics in Europe, CEN created the Technical Committee 251 (CEN/TC 251) on Healthcare Informatics in 1990.
CEN/TC 251 is an open forum where participants develop standards through activities within Working Groups, Project Teams and National Mirror Groups (about 2000 experts have

contributed so far in these efforts). Meetings have been attended by delegations, which represent industry, users and authorities in each country.

Based upon the same principles and with the a similar structure as CEN, the homologue Technical Committee in ISO (ISO/TC 215) was set up in 1998.

1.1.2   Links with EU Research and Development

Europe has invested in the past years rather extensively in pre-standardisation through R&D programmes (CEU-DG XIII) and in standardisation in healthcare informatics and telematics (CEU-DG III and CEN/TC 251). Much of the EU healthcare telematics R&D programmes have been aimed at exploring means for integration and sharing of, and access to information. However, realisation of its value both for improving the health of the population and enhancing the commercial strength of the European healthcare industry will founder, unless its outputs can be utilised by others. Without recognised European standards that will not happen: indeed many of the EU projects have been of a pre-standardisation nature for that reason. That pre-standardisation effort will also be wasted if it cannot quickly be translated into European standards.
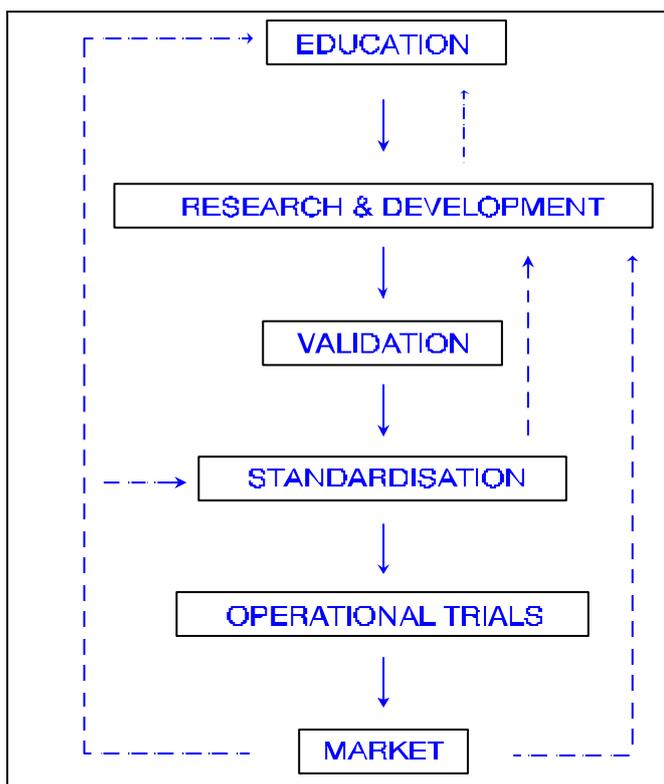
fig 2: The Continuum between R & D, Standardisation and Market

Since an important part of innovation originates from industry directly (without being part of EU sponsored research) those outputs (de facto standards/publicly available specifications) which are suitable for rapid transformation into standards, should also be identified.

From the competitiveness point of view it is essential to maintain and even to reinforce the European impact on international standardisation. If the international standards are drawn

from the European standards, European industry and commerce is more likely to reap rewards in the future. Europe and Belgium have played a leading role at the international level (cf. formation of the CEN/TC 251 and ISO/TC 215 Technical Committees in Healthcare Informatics/Telematics).

1.1.3. Moving Technologies

We are now entering the fourth era of computing. Each of the first three eras lasted just 14 years. The first era ran from about 1954 with the introduction of commercial mainframes to 1968. Around 1968 came the Digital PDP mini-computers, the birth of UNIX, C and MUMPS, and the very first hospital information systems. The third era really started with the IBM PC in 1982, followed by the Apple Mac GUI and the rise of Microsoft Windows. The fourth era (starting in 1996) is typified by the Telecommunications, Internet and WWW, Intranets, Java, software components etc. This fourth (NET-centric) era of computing is very new.

The next table shows the most important and obvious trends in Healthcare Information and Telecommunication Systems:

FROM	TO
Administrative Systems	Medical Systems
Centralised Systems and Mainframes	Distributed Systems Client-Server Computing
Islands	Integrated Systems
Provider Oriented Systems	Patient Oriented Systems
Data-driven	Knowledge-base driven
Text based	Multimedia
Home-made Systems	Vendor-made Systems
Proprietary-driven	Standard-driven
Technology-driven	User-driven
Informatics	Telematics
Regional Context	International Context

fig 3: Trends in Healthcare Information Systems

Standards need to provide an environment in which evolution and development can flourish. Since those active in standardisation are not in the business of dinosaur preservation, the forthcoming standards should focus on the needs of the above mentioned "fourth-era" computing. With moving technologies, success will more than ever depend on dynamism, adaptability and new ideas.

1.1.4.   Industry and SMEs

It should be recognised that the healthcare domain will never be a simple market place. The health policy makers and the citizens of the EU will always expect the quality of healthcare also to be driven by factors other than commerce and would expect that funding for the standards which need to be medically acceptable and on which it relies to derive also from sources other than commerce only. Public authorities and national insurance systems play a highly regulating role and have an enormous impact on this market. It is important for Europe that the healthcare informatics products within this potentially enormous market predominantly come from its own industrial and commercial base.

The forces in this field depend on many different sector actors: healthcare authorities, providers of informatics systems and services, researchers, users with their organisations and other strategic groups. In this sector there is, paradoxically, a growing gap between the standardisation activities in Europe and the solutions provided by industry in member countries, resulting in misfits and in misinvestments. The European and Belgian Health Informatics/Telematics industry, for the largest part Small and Medium Enterprises (SMEs), has a good reputation in the field of healthcare informatics and telematics, but should benefit more from standards to reduce its development and maintenance costs, to maintain its position in the market and to export more products and services (economies of scale).
The existence of standards lowers the risks and costs of market entry, which is particularly important for our SMEs (return on investment).

1.1.5. Role of Authorities and Importance of Directives

The gap between standardisation and industry can be explained for a large part by the fact that the healthcare informatics industry in the EU primarily comprises Small to Medium sized Enterprises, not least because to date the (rather fragmented) market has been dominated by the need for smaller systems. The resources of our SMEs are limited: they have yet to mature and are far from the point where they can realistically provide all the necessary funds for standardisation.
Standards in healthcare informatics and telematics help provide vendors with a stable environment for product development, allowing economies of scale and access to larger markets. The existence of standards lowers the risks and costs of market entry, which is particularly important for our SMEs.

The larger IT and telecommunication companies generally have little, if any, healthcare involvement yet. In many countries, the recognised drivers for IT and the 'superhighway' include health as of major significance. As integration within and between organisations begins to be the market driver, larger companies are now looking to enter the market and SMEs will merge and grow.

It is therefore the role of the authorities to act as facilitators for bringing the different sector actors together.

```
                          INDUSTRY

                              ↓

                  Open market for more profit

                              ↑

                 HEALTHCARE  INFORMATICS /
                        STANDARDS

              ↙                              ↘

      Quality and safety              Cost-savings in the
                                      healthcare sector

        ↗                                      ↖

         USERS                          HEALTH  POLICY
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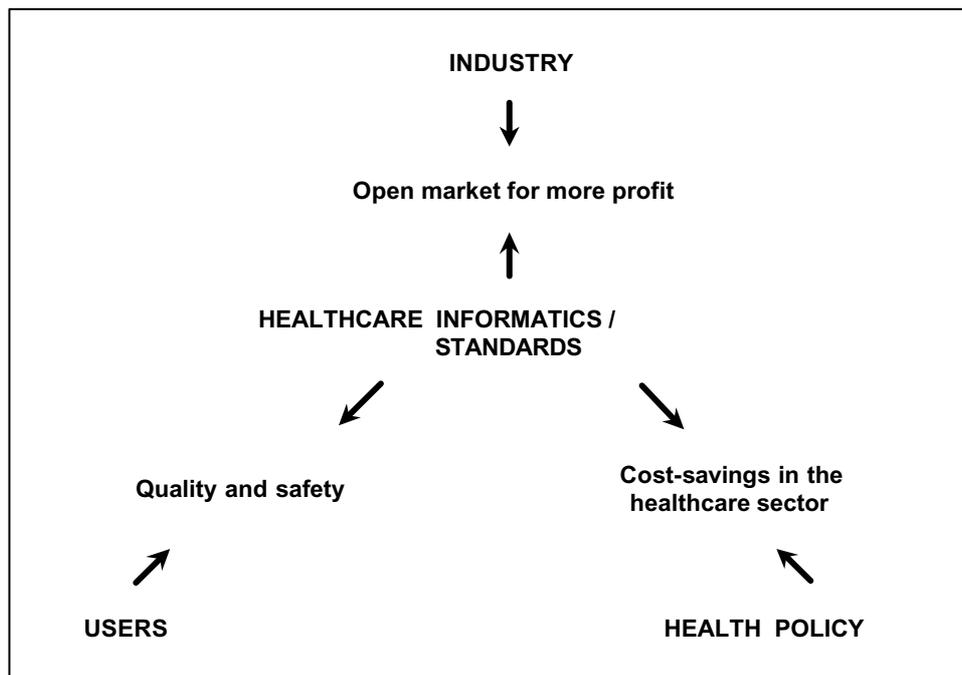
Fig 4: The Benefits of Healthcare Informatics/Telematics Standards

The Belgian healthcare authorities (Ministries of Health and Social Affairs, Third Party Payers in healthcare, …) play a highly regulating role and have an enormous impact on the health informatics market. Health Policy Makers are eagerly looking for better information management and more efficient communication between all actors in the field: electronic data interchange standards are therefore becoming crucial now. A prerequisite for the introduction of standards is strong support from government. Implementations will be facilitated if texts of law clearly refer to standards and their specifications (cf. the Kassebaum-Kennedy Bill, August 19 in the US). Directives should also foresee positive incentives for all stakeholders.

1.1.6. The Users

In the healthcare sector the users are the healthcare organisations and professionals who are the buyers of the informatics and telematics systems. When buying a system or telematics solution, a user is primarily interested in getting stable and interoperable products (and services) and therefore requires standards. Users also play an important role in helping to identify the requirements and priorities and to solve underlying complex problems (e.g. security issues). In medicine and healthcare the users and citizens will always expect the quality of healthcare also to be driven by factors other than commerce only.

1.1.7. New Alliances

As integration within and communication between organisations begins to be the market driver, larger companies (Telecom Operators, Value Added Network Service Providers, Pharmaceutical industry) are now looking to enter the market and to form alliances with SMEs, who will merge and grow.

1.1.8. The Necessity of Fora

Fora are essential in order
* to bring all the sector actors closer to each other,
* to create openness,
* to obtain in a stepwise process the necessary consensus,
* to assist in the co-ordination of existing efforts,
* to reinforce cohesion, to promote adopted standards,
* to act as certification centres and
* to define further strategies.

1.1.9. Implementation of Standards and Pilot Projects

Before implementation, standard solutions should be adapted to national situations (cf. organisational, legal and other issues) and should be tested and validated. Pilot projects should be conducted. One of the highest priorities in Belgium is now the exchange of electronic health records and of referral and discharge letters. The concept of Electronic Episode of Care Summary is in this context an appealing approach as it facilitates the creation of a patient-oriented, longitudinal, virtual and networked electronic health record, for which everybody is waiting.

Potential partners in such pilot projects should be carefully selected (experience in the field and commitment being important criteria) with guidance from the healthcare authorities.

1.2   General Objectives and Tasks of this Study

The general objectives of this project were:

-        to reduce the gap between the world of standards and the industry (including SMEs) active in the field of healthcare informatics/telematics in Belgium; this should reduce the risk for misfits and misinvestments;

-        to reduce the gap between ongoing research and standardisation efforts on the one hand and between supply and demand on the other;

-        to reach consensus between all different sector actors (healthcare authorities, industry and the users) for voting on final drafts, for proposing priorities regarding the content of new work programmes and for defining strategies;

-        to facilitate the implementation of European Standards by translating or adapting them to the national situation (cf. organisational, legal issues and other eg. security); to prepare pilot projects in order to test and to validate standards;

-        to support and to reinforce the European and Belgian impact on international standardisation activities (cf. CEN/TC 251, ISO/TC 215, IMIA/WG 16 on Healthcare Informatics).

Therefore, the project has undertaken three tasks:

1.   to support, together with the Belgian Standards Institute BIN/IBN, the activities of a forum (the Belgian Mirror Group of CEN/TC 251 and ISO/TC 215) in order to bring all sector actors and stakeholders together. This mirror group functions as a local point for access to information (including tutorials) and as consensus group to protect national interests; (see chapter 3),

2.   to install and maintain a data-base/inventory on standards in medical informatics using already available equipment (NT server) and tools (Internet WWW sites of CEN/TC 251, ISO/TC 215, IMIA/WG 16 on Healthcare Informatics); (see chapter 4),

3.   to establish, together with the Ministries of Health and Social Affairs, the National Health Telematics Standards Committee, by issuing a Royal Order in the framework of the Belgian Health Laws; this Committee of experts will produce guidelines, referring to existing standards, with impact on accreditation in the healthcare informatics sector; (see chapter 5).

2.   METHODS

2.1   Approach

In order the achieve the main objectives, the study method consisted of four main steps:
1.   Identification of sector-actors and of all possible information sources
2.   Data collection and interviews
3.   Validation and study of the information collected
4.   Conclusions

There are not so many sectors which are so big and so information intensive as the healthcare sector. The potential for substantial rationalisation and improvement in efficiency through medical informatics standards is enormous. Exact figures of potential savings are lacking but amounts in the order of several per cents of the budgets.

The following list shows the different sector-actors who play a role in the healthcare informatics/telematics domain in Belgium:

A.   The Healthcare Authorities
     A1.   Ministry of Health and Social Affairs
     A2.   Third Party Payers (INAMI/RIZIV and 'Mutualities')
     A3.   Belgische Kruispuntbank van de Sociale Zekerheid/Banque Carrefour Belge des Affaires Sociales.
     A4.   The European Commission and the Council of Europe

B.   The Providers of ICT systems and services
     B1.   Healthcare Information System-Vendors (Hospital Systems, GP Systems, Departmental Systems, …)
     B2.   Telecom-Operators (Belgacom and others)
     B3.   Value Added Network Service-Providers (MediBRIDGE and others)
     B4.   Other Industry-players (Pharmaceutical Industry)

C.   The Researchers
     C1.   Academia and R&D projects
     C2.   Individual Experts from Universities
     C3.   Scientific Societies (MIM, …)

> D.   The Users and their Organisations
>   D1.   Medical Doctors and other Healthcare Professionals
>   D2.   Healthcare Professionals' Organisations
>   (Syndicats, Professional Societies, Hospital Federations, The National Council   of
>   Medical Doctors and of Pharmacists).
>   D3.   The Patients
>
> E.   The Consensus Groups and other Strategic Fora
>   E1.   Standardisation bodies (CEN/TC 251, EBES, …)
>   E2.   PROREC-N.V.
>   E3.   The European Health Telematics Observatory (EHTO).

fig 5: The Sector-Actors in the Healthcare ICT-Domain

2.2   Information Sources

This project has liaised with a number of institutes, organisations and projects, which will contribute as important sources of information.

1.   The Belgian Standards Institute (BIN/IBN)

2.   The European Committee of Standardisation on Health Informatics (CEN/TC 251)

3.   The ISO Technical Committee ISO/TC 215 on Health Informatics.

4.   The International Medical Informatics Association (IMIA) in particular WG16 (the Working Group on Standards in Medical Informatics)

5.   The Belgian Mirror Group of CEN/TC 251 and ISO/TC 215 (BIN/IBN and UCL, Université Catholique de Louvain)

6.   The Commission of the European Union (DG XIII C4 and DG III)

7.   MediBRIDGE N.V. (a Value Added Network Service Provider in Belgium) and Belgacom (the Belgian Telecom operator)

8.   The Belgian PROREC (non-profit) organisation (PROmotion strategy for the European electronic healthcare RECord)

9.   Other research-projects in the OSTC programmes:

-    In 'Pôles d'Attraction Interuniversitaires': 'Télématique Médicale, le point sur les technologies et stratégies développées', D. Dieng, X. Gobert, CITA (Namur, Belgium)
-    In the 'Telematics Programme': SYNAPSIS (CM/XX/A08), 'Healthcare Information Communication Infrastructure', L. Schilders, MediBRIDGE (Brussels, Belgium)
-    In the 'Telematics Programme': MIMSEC (CM/02/005), 'User Requirements and ISPs for Telematics Applications in Medical Imaging (part 1) and Security Recommendations in Health Care Telematics (part 2)', (Gent, Belgium)

10. The European ICT-Standards Board of CEN, CENELEC and ETSI

This work is now to be followed-up in an official Healthcare Telematics Committee, which has been established within the Belgian Ministry of Health and Social Affairs.

2.3   Dilemmas and Problems in Standardisation

The following table lists some of the common dilemmas when standardising. Approaches from the left are not always incompatible with those listed on the right. Often, choices have to be made on a case by case basis.

```
┌─────────────────────────────────────────────────────────────────┐
│                                    ?                              │
│   INTERNATIONAL            ←────────→      REGIONAL, NATIONAL      │
│                                    ?                              │
│   CONSENSUS, (open)        ←────────→      "FORCING", (not open)   │
│                                    ?                              │
│   USER DRIVEN              ←────────→      TECHNOLOGY PUSHED       │
│                                    ?                              │
│   RESEARCH DRIVEN          ←────────→      INDUSTRY LED            │
│                                    ?                              │
│   STATE OF THE ART         ←────────→      DILUTION               │
│                                    ?                              │
│   TOP-DOWN                 ←────────→      BOTTOM-UP              │
│                                    ?                              │
│   MANDATED, FUNDED         ←────────→      VOLUNTARY, ON A PERSONAL│
│                                            BASIS or SPONSORED BY   │
│                                            EMPLOYERS              │
│                                    ?                              │
│   DEJURE, FORMAL           ←────────→      DE FACTO, "P.A.S."     │
│                                    ?                              │
│   DOMAIN EXPERTS           ←────────→      STANDARDS EXPERTS      │
│                                    ?                              │
│   STANDARDS (ENs)          ←────────→      PRESTANDARDS (ENVs)    │
└─────────────────────────────────────────────────────────────────┘
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fig 6: Dilemmas in Standardisation

In addition to the above dilemmas, all those active in standardisation face other common problems in their work. All of these items deserve careful attention. If one of those problems is not solved, a whole standardisation effort or programme may be put in jeopardy.

- Funding of the Standardisation work (Budgets)
- Management (Business-plans)
- Co-ordination (with Research, with Market)
- Maintenance of the standards (Continuity)
- Promotion (Users, Industry, other Sectors)
- International affairs (Competition)

2.4.   Short Description of the Research Group and its Role in Standardisation

The department of Medical Informatics Gent was founded in 1973. It has built over the years an international reputation mainly focusing on medical informatics standards, medical telematics, quality control, medical statistics, medical registration, data protection, computer

aided instruction, linguistic research engineering and medical coding systems. The department's expertise has been built mainly through its activities in the framework of European Scientific Research. Part of the research is co-ordinated through RAMIT vzw. (Research in Advanced Medical Informatics and Telematics), a non-profit organisation established within the University of Gent, with amongst other the following activities:

1. the presidency and secretariat of CEN/TC 251 (European Standardisation Committee, Technical Committee on Medical Informatics) (1990-1996).
2. the secretariat of the Belgian Society for Medical Informatics (M.I.M.) and its presidency (1994 – 1998).
3. spin-off initiatives of research such as the MediBRIDGE electronic mail and data exchange service, covering communication of clinical messages between hospitals and other healthcare organisations and practitioners in Belgium.
4. the chairmanship of IMIA WG16 (International Medical Informatics Association, Working Group 16 on Healthcare Informatics)

The pioneering work undertaken during European research projects has led to the foundation of a separate standards committee (Technical Committee 251, CEN/TC 251) for the healthcare sector, within the framework of CEN (European Standardisation Committee, Technical Committee on Healthh Informatics). RAMIT, being the driving force behind the foundation of CEN/TC 251, was invited to provide for the Technical Secretariat as well as to follow-up the activities of 2000 experts working on standardisation for informatics and telematics in the healthcare sector. The president of RAMIT vzw., Georges De Moor was founder of CEN/TC 251 and chairman from 1990 until 1996. In this period, RAMIT was responsible for the technical secretariat of this TC.

RAMIT staff members continue their leading edge activities in the field of standardisation and development of messages aimed at electronic and structured data interchange within the healthcare sector.

The results achieved from research projects can migrate to products suitable for further commercial exploitation, thanks to the interdisciplinary character of RAMIT's structure (medical science, informatics, telecommunication, marketing, business economics). For this purpose, RAMIT participates in various exploitation companies.

CEN/TC 251 was titled 'Health Informatics' and the scope of this Technical Committee is to organise, co-ordinate and monitor the development of standards, including testing standards, in Healthcare Informatics as well as the promulgation of these standards.

CEN/TC 251 decided to constitute seven Working Groups (WGs), which was later reduced up to four:

WG 1.   Information models
WG 2.   Terminology and Knowledge Bases
WG 3.   Security, Safety and Quality
WG 4.   Technology for Interoperability

In most of the member states 'mirror-groups' have been established, following the same structure as the CEN/TC 251 Working Groups. Each Working Group supervises a number of Project Teams. The work in a Project Team is undertaken by specially assigned experts and is funded. Project Teams have to be duly justified. They are small groups of trusted people preparing high quality documents, urgently required.

About 2000 individual experts (representing users, academic centres and industry) are now active in CEN/TC 251 through participation at either the working group level, the project team level or within the national mirror-groups. They constitute a rich network of technically and medically skilled people.

RAMIT actively participated at all levels: TC chairmanship and secretariat, meetings of Working Groups and Project Teams and meetings of the Belgian Mirror Group.

In the context of the formation of the ISO Technical Committee in Health Informatics Standards (ISO/TC 215), Belgium was appointed in December 1996, during an international meeting at ANSI headquarters in New-York, to define a template to collect information on healthcare informatics standards by electronic means world-wide.

3. THE BELGIAN MIRROR GROUP OF CEN/TC 251 AND OF ISO/TC 215

3.1. Introduction

To co-ordinate the development of standards in Healthcare Informatics and Telematics in Europe, CEN created the Technical Committee 251 (CEN/TC 251) on Health Informatics in 1990.
CEN/TC 251 is an open forum where participants develop standards through activities within Working Groups, Project Teams and National Mirror Groups (about 2000 experts have contributed so far in these efforts). Meetings have been attended by delegations which represent industry, users and authorities in each country.
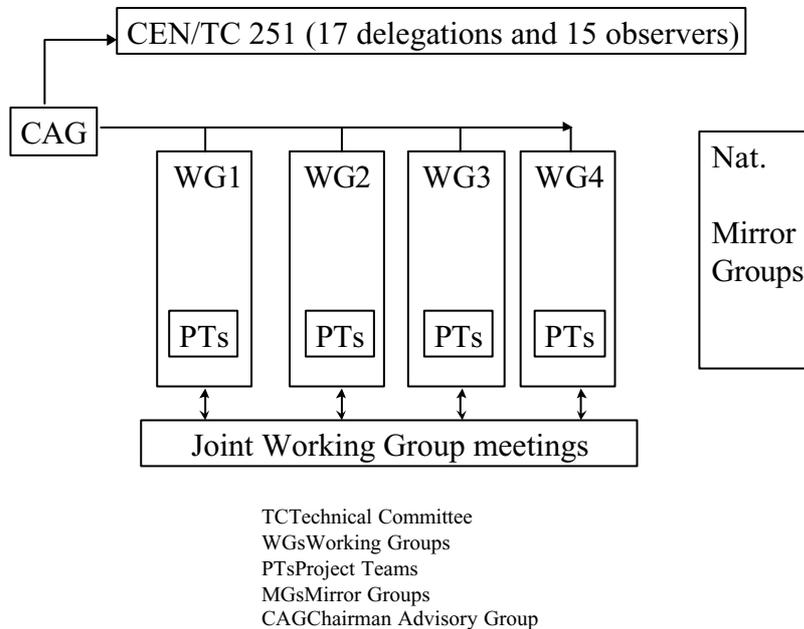
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        ┌──────────────────────────────────────────────┐
   ┌───▶│ CEN/TC 251 (17 delegations and 15 observers) │
   │    └──────────────────────────────────────────────┘
   │
┌──────┐                                              ┌──────────┐
│ CAG  │──────────────────────────────────▶          │  Nat.    │
└──────┘   ┌──────┬──────┬──────┬──────┐              │          │
           │ WG1  │ WG2  │ WG3  │ WG4  │              │ Mirror   │
           │      │      │      │      │              │ Groups   │
           │ PTs  │ PTs  │ PTs  │ PTs  │              └──────────┘
           └──────┴──────┴──────┴──────┘
        ┌──────────────────────────────────┐
        │    Joint Working Group meetings   │
        └──────────────────────────────────┘
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TC   Technical Committee
WGs   Working Groups
PTs   Project Teams
MGs   Mirror Groups
CAG   Chairman Advisory Group

Fig 7: Organisation Structure of CEN/TC 251

The members of CEN are the National Standardisation Bodies (NSB) in each European country. BIN/IBN (the Belgian Standardisation Institute) may send a maximum of three delegates to CEN/TC 251 meetings, and has a duty to ensure that its delegation will convey a national point of view that takes account of all interests affected by the work.

3.2. Definitions and Descriptions

3.2.1. Standardisation; Standards; Consensus; Recognised Standards Body; European Standard Documents

Standardisation describes and provides the quality requirements with which products, processes and services have to conform. It is a systematic activity which creates order, makes selections and formulates rules.

For the purpose of this chapter the following definitions from ISO and IEC (International Standards Organisation and International Electrotechnical Committee, ISO/IEC guide 2 - 1986) apply :

> *'Standardisation* : Activity of establishing, with regard to actual or potential problems, provisions for common and repeated use, aimed at the achievement of the optimum degree of order in a given context'.

> *'Standard* : Document, established by consensus and approved by a recognised body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context'.

Consensus is general agreement, characterised by the absence of sustained opposition to substantial issues by any important part of the concerned interests, and by a process which involves seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments. The standardisation process must be open, so that all parties can be represented.

Consensus requires that all views and opinions be considered, and that concerted action be taken toward their resolution. Consensus means much more than a simple majority, but not necessarily unanimity.

In Europe, the *Recognised Standards Body* for the purposes of healthcare computing is CEN/TC 251. This has the scope and responsibility for the organisation, co-ordination and monitoring of the development of standards in healthcare informatics, as well as the promulgation of these standards.

Publications resulting from the technical work of CEN and made available by CEN are designated European Standards (EN). European Prestandards (ENV) or CEN Reports.

A *European Standard (EN)* is a CEN standard drawn up by consensus of the members and adopted in accordance with a weighted voting procedure. When such a standard is adopted, it must be implemented at national level by being decreed a national standard and by withdrawal of any conflicting national standards. In other words, the national standard adopted will rigorously replicate the European one. Variations are forbidden.

A *European Prestandard (ENV)* is established as a prospective standard for provisional application in technical fields where the innovation rate is high (eg information technology). The standard should not be used where the safety of persons and goods is endangered.

Members must then make the ENV available at the national level and announce its existence. Meanwhile, conflicting national standards may be maintained.

A *CEN (technical) Report (CR)* has to be approved by simple voting in the Technical Board of CEN. CRs are of two types. The first arises when, on a vote on a potential standard, a consensus cannot be reached but it is decided that the information in the document is so useful that it should be made public so as to become available to a wider circle than that involved in creating it. CRs of this type are, in effect, failed standards. The second type are of quite different origin and are not failed standards. These are principally normative documents but were communicated specifically as CEN Reports rather than Standards. An example of a document written specifically as a CEN Report is the report of PT004 'Investigation of syntaxes for existing interchange formats to be used in healthcare'.

A *Harmonisation Document (HD)* is a CEN/CENELEC standard drawn up and adopted in the same way as an EN. In contrast to the EN document, national variations are permitted when existing national regulations or particular technical requirements for a specified transitional period make them necessary. The HD carries with it the obligation to be implemented at national level, at least by public announcement of the HD number and title, and by withdrawal of any conflicting national standards.

Documents (including working drafts) used in the course of elaboration of publications are known as working documents and, at the CEN enquiry and formal voting stage, as prEN, prENV or draft Reports. ENs correspond to ISO standards (IS and ISP), ENVs to ISO Technical Reports, Types 1 and 2.

Public contracting authorities are obliged to require conformance to standards when procuring information technology and telecommunications products in contracts over certain threshold values (100,000/200,000 Ecus, Legislation: IT Standards Decision Revised Supplies Directive).

3.2.2. Informatics; Telematics; (Open) Electronic Data Interchange (EDI and open EDI)

Informatics is a newer word for information science and technology - especially when computers are involved.

Telematics is the use of telecommunications in conjunction with informatics, eg the passing of information from one computer to another via a telephone line or other electronic link.

The basic promises of telematics are obvious: by giving access to any form of knowledge anywhere, it speeds up the diffusion of information, saves time, increases collaboration between individuals and groups, and improves the quality of decisions .
As telematics will allow access to more and more information, it will also generate increasing amounts of new data (the basic threat is also obvious: telematics speeds up the diffusion of inaccurate or false information). New tools for navigation in this sea of data will be required. They already have a name: 'knowbots' or knowledge finder robots. Their development is a major technological challenge.

Medical Telematics is the application of telematics to medicine, eg using telematics to send patient test results from clinical laboratories to general practitioners.

Healthcare Telematics is the wider application of telematics to the whole healthcare environment and involves eg management and nursing, as well as medical, information transfer.

Electronic Data Interchange (EDI) is defined in many different ways. The definition adopted by the International Data Exchange Association is perhaps the most useful: 'the transfer of structured and coded data, by agreed message standards, from computer to computer, by electronic means'.

The data is essentially structured. Unstructured information such as facsimile or free-text electronic mail does not strictly fall into the category of EDI, although such information can be included as part of a message.

The data is primarily intended for processing by computer applications, rather than direct interpretation by human users.

The data is transferred by electronic means, by data transmission using data communications network facilities.

The current EDI standards are really only concerned with the nature of the interchanged data, and cover three main areas:

– a common syntax, equivalent to the grammar in a natural language;
– common data element definitions, equivalent to the vocabulary in a natural language;
– standard messages, which combine data elements and syntax into structured data aggregates suitable for interchange and processing.

Open-EDI: Electronic data interchange among autonomous parties using public standards and aiming towards interoperability over time, business sectors, information technology systems and data types, capable of multiple, simultaneous transactions, to accomplish an explicit business goal. This definition is taken from ISO/IEC JTC1/WG3 'Open-edi Reference Model Standard' (Working Draft 1994-01-24/28). The definition is being further studied by ISO/IEC JTC1/WG3.

3.3. National Mirror Groups

Looking at a country's healthcare informatics sector (with its national and regional healthcare authorities, agencies, professional organisations, providers, users and IT industry) and combining its dversity with the scope and depth of the standardisation programmes of CEN/TC 251 and ISO/TC 215, it becomes clear that national delegates need some sort of supportive local organisation if they are to represent national interests properly.

With this in mind, CEN/TC 251 has encouraged NSBs to establish so-called 'Mirror Groups', with membership drawn from interested parties at the national, regional and local levels. The Mirror Group mirrors the activities of the CEN/TC 251 and ISO/TC 215 Technical Committees. It can focus the standardisation programme effectively onto the national healthcare sector and thereby ensures that national interests are taken into account at the Technical Committee (TC),Working Groups (WG) and Project Team (PT) levels. Members of

WGs and PTs take part in the standardisation work as experts in their respective fields, not as national delegates. Nevertheless, national Mirror Groups can be instrumental, through their promotion of the work, in locating the best experts and encouraging them to take an active part in the standardisation process.

3.4. Belgian Mirror Group

The Belgian Mirror Group for CEN/TC 251 and ISO/TC 215 functions as a local contact point for standardisation work in medical informatics and telematics. It enables the work to be influenced so as to protect and promote national interests. It provides a focal point for access to a rapidly growing pole of new standards.

The Belgian Mirror Group is, together with BIN/IBN, instrumental in monitoring and improving the quality of standards in medical informatics/telematics:
– by making proposals regarding the content and execution of the standardisation work programme,
– by disseminating the drafts of new standards and ensuring that these receive proper commenting from a national as well as from a technical perspective,
– by forming the necessary consensus for national voting on final drafts
– by being a channel to inform healthcare society about ongoing activities within CEN/TC 251 and ISO/TC 215, by means of organising tutorials and workshops.

The Belgian Mirror Group, together with the Belgian satellite of the European Health Telematics Observatory, constitutes a pole of information and activity and is a starting point for health informatics/telematics deployment.

3.5. Activities

The Belgian Mirror Group decided that it also has other roles to play as well, for example in connection with implementation of the new standards (which automatically become national standards) or with the co-ordination of healthcare IT projects with parallel standardisation work. Experience is already showing that:
– implementation is far from a trivial task and is best tackled from a national viewpoint,
– costly projects do well to learn from existing standardisation work and thereby minimise the danger of promoting incompatible and unprofitable solutions.

THE FOLLOWING LIST SUMMARISES THE ALREADY ADOPTED EUROPEAN STANDARDS IN THE FIELD:

ENV <u>1064</u> 1993
Medical informatics - Standard communication protocol - Computer-assisted electrocardiography **WG IV**
ENV 1068 1993

Medical Informatics - Healthcare information interchange - Registration of coding schemes (Replaced by ISO/IEC 7826-1 and 7826-2) **WG II**

CR 1350 1993
CEN Report: Investigation of syntaxes for existing interchange formats to be used in healthcare **WG I**

ENV 1613 1995
Medical informatics - Messages for exhange of laboratory information **WG I**

ENV 1614 1995
Healthcare informatics - Structure for nomenclature, classification and coding of properties in clinical laboratory sciences **WG II**

ENV 1828 1995
Medical informatics - Structure for classification and coding of surgical procedures **WG II**

ENV 12017 1997
Medical Informatics - Medical Informatics - Vocabulary **WG II**

ENV 12018 1997
Identification, administrative, and common clinical data structure for Intermittently Connected Devices used in healthcare (including machine readable cards) **WG I**

ENV 12052 1997
Medical Informatics - Medical Imaging Communication **WG IV**

ENV 12251 1999
Health Informatics - Secure User Identification for Healthcare - Identification and Authentication by Passwords - Management and Security **WG III**

ENV 12264 1997
Medical informatics - Categorical structures of systems of concepts - Model for representation of semantics **WG II**

ENV 12265 Withdrawn 1999. Replaced by ENV 13606
Medical informatics - Electronic healthcare record architecture **WG I**

ENV 12381 1996
Health care informatics - Time standards for health care specific problems **WG II**

ENV 12388 1996
Medical Informatics - Algoritm for Digital Signature Services in Health Care **WG III**

ENV 12435 1999
Medical informatics - Expression of the results of neasurements in health sciences **WG II**

ENV 12443 1999
Medical informatics - Medical informatics healthcare information framework **WG I**

ENV 12537-1 1997
Medical informatics - Registration of information objects used for EDI in healthcare - Part 1: The Register **WG I**

ENV 12537-2 1997
Medical informatics - Registration of information objects used for EDI in healthcare - Part 2: Procedures for the registration of information objects used for electronic data interchange (EDI) in healthcare **WG I**

ENV 12538 1997
Medical informatics - Messages for patient referral and discharge **WG I**

ENV 12539 1997
Medical Informatics - Request and report messages for diagnostic service departments **WG I**

CR 12587 1996

CEN Report: Medical Informatics - Methodology for the development of healthcare messages **WG I**

ENV 12610 1997
Medical informatics - Medicinal product identification **WG II**

ENV 12611 1997
Medical informatics - Categorical structure of systems of concepts - Medical Devices **WG II**

ENV 12612 1997
Medical Informatics - Messages for the exchange of healthcare administrative information **WG I**

ENV 12623 1997
Medical Informatics - Media Interchange in Medical Imaging Communications **WG IV**

CR 12700 1997
CEN Report: Supporting document to ENV 1613:1994 - Messages for Exchange of Laboratory Information **WG I**

ENV 12922-1 1997
Medical Image Management - Part 1: Storage Commitment Service Class **WG IV**

ENV 12924 1997
Medical Informatics - Security Categorisation and Protection for Healthcare Information Systems **WG III**

ENV 12967-1 1998
Medical Informatics - Healthcare Information Systems Architecture - Part 1:Healthcare Middleware Layer **WG IV**

CR 13058 1997
Medical data interchange - Mapping between the models specified in ENV 12539:1997 and NEMA PS3 Supplement 10 **WG IV**

ENV 13606-1 1999
Health informatics - Electronic healthcare record communication - Part 1: Extended architecture **WG I**

ENV 13606-2 1999
Health informatics - Electronic healthcare record communication - Part 2: Domain termlist **WG I**

ENV 13606-3 1999
Health informatics - Electronic healthcare record communication - Part 3: Distribution rules **WG I**

ENV 13606-4 1999
Health informatics - Electronic healthcare record communication - Part 4: Messages for the exchange of information **WG I**

ENV 13607 1999
Health informatics - Messages for the exchange of information on medicine prescriptions **WG I**

ENV 13608-1 1999
Health informatics - Security for healthcare communication - Part 1: Concepts and terminology **WG III**

ENV 13608-2 1999
Health informatics - Security for healthcare communication - Part 2: Secure data objects **WG III**

ENV 13608-3 1999

Health informatics - Security for healthcare communication - Part 3: Secure data channels **WG III**

ENV 13609-2 1999
Health informatics - Messages for maintenance of supporting information in healthcare systems - Part 2: Updating of medical laboratory-specific information
WG I

CR 13694 1999
Health informatics - Safety and security selated software quality standards for healthcare **WG III**

ENV 13728 1999
Health informatics - Instrument interfaces to laboratory information systems **WG IV**

ENV 13729 1999
Health informatics - Secure user identification for healthcare strong authentication using microprocessor cards **WG III**

ENV 13734 1999
Health Informatics - Vital signs information representation **WG IV**

ENV 13735 1999
Health Informatics - Interoperability of patient connected medical devices **WG IV**

CR 1999
Health Informatics - Interoperability of healthcare multimedia report systems **WG IV**

3.6. Report on the Belgian Mirror Group Workshop and Conference (see Appendix 1)

3.7. Database of experts in the Belgian Mirror Group (see Appendix 2)

3.8. Inventory of Belgian industrial companies active in ICT for Healthcare (see Appendix 3)

3.9. Minutes of the Belgian Mirror Group meetings (see Appendix 4)

4. INTERNATIONAL DATABASE ON HEALTHCARE INFORMATICS AND TELEMATICS STANDARDS

4.1. Introduction

This database or inventory has to be considered as an intermediate tool to help finding information on existing standards in Healthcare Informatics and Telematics. More information can be found by searching via the references provided in the descriptions.

The template, database and procedures have been kept simple in order to encourage all interested parties to exchange information (a first step in the international co-operation in standardisation).

It is on purpose that the choice of keywords has been left open. The intention is to let standards makers choose the most specific ones for labelling their documents. The task force responsible for this inventory will later explore the possibility of categorising the keywords; the web master will also integrate a user-friendly search engine.

In this stage, the database is open for any standard (official/formal versus de facto/commercial). The quality of the information is under the responsibility of the authors/senders. The task force and the webmaster are not responsible for any possibly irrelevant, false or low quality input.

To submit the description of standards one can choose one of the following methods:

– Using a form on the site. The database update is handled after verification of the information.
– Downloading a word document (or text only) which is conformant with the required template structure. After the data-input, the form can be sent to wg16@ramit.be with 'input inventory' in the subject line.

4.2. History

Belgium has played in the past an important role in medical informatics standardisation. Together with the Belgian Standards Institute (BIN/IBN), RAMIT vzw. proposed in 1990 the formation of TC 251 in CEN. The president of RAMIT (the co-ordinator in this project) was elected the first chairman of CEN/TC 251 and the Technical Secretariat was given to RAMIT via BIN/IBN until 1996 when Sweden took over.
CEN/TC 251 has been widely recognised as being a productive committee and has established contacts with Eastern-European countries, the U.S., Canada, Japan, Australia and South-Africa. A number of these countries have then followed this European initiative and have established committees or boards on healthcare informatics standards, choosing organisation structures which are very similar to the one of CEN/TC 251.

At the Assembly General Meeting of the International Medical Informatics Association (IMIA), Vancouver, July 1995, a new Working Group (IMIA Working Group 16) on medical informatics was formed with again as chairman the president of RAMIT vzw., former chairman of CEN/TC 251.
The trend of drafting "global standards" for medical informatics and telematics is now becoming obvious, as is the case in most other ICT-domains. This explains the underlying

ideas, which lead to the formation of the ISO/TC 215 Technical Committee for the same field. Preparatory meetings for such a TC have been held in New-York (1996), Stockholm (1997) and. London (1997).

One of the decisions of the above meetings was to create a taskforce to make an international inventory or database of descriptions of already existing healthcare informatics standards (de jure and de facto standards) from anywhere in the world. The leadership of this taskforce has been given to Belgium (RAMIT vzw.). It has been decided to install the data-base on the server with the Internet/WWW site of IMIA/WG 16. The same IMIA/WG 16 has organised its first international conference (Towards Global Co-operation in Healthcare Informatics Standardisation) in September 1997 (Bermuda). The second conference was held in December 1999 (Bruges). It is clear that the establishment of IMIA/WG 16 serves as a signal to the users of standards to demonstrate a certain willingness to co-operate world wide and to organise convergence in the standardisation efforts.

IMIA/WG 16 has also served as a catalyst during the creation of the ISO/TC 215 Technical Committee.

4.3. Objectives

In this work-package, the project has collected and categorised all international standards in the field of healthcare informatics/telematics. This information has been made available in a user-friendly form on the Web.

The objective is to help:
- – user-groups to define their requirements;
- – decision-makers in their choice of standard solutions;
- – and industry to deliver appropriate products.

The data-base or inventory should be considered as an intermediate tool in order to help finding information on existing standards in healthcare informatics and telematics world-wide (de jure and de facto standards). The summary, descriptions and other data in the inventory will point towards other places and sites where more specific information is available.

4.4. Description

The project has used Internet- and World Wide Web- tools to collect, store and disseminate information on standards in healthcare informatics and telematics. The Internet WWW site on Standards has been installed on a server made available by the co-ordinating partner, making use of professional telecom-infrastructure (ISDN) and benefit from an already available fire-wall (cf. security issues).

Guidelines were established and have been distributed to all identifiable information sources, so that they can send their descriptions on standards electronically, using a common template. Standard-makers can choose keywords for labelling their documents. The task force responsible for the inventory has explored the possibility of categorising the keywords. The web-master has also integrated a user-friendly search engine and has provided the system with the necessary external links.

The Inventory will further grow over time, but our goal was to collect as much standards as possible. The definition of the template and the design of the database can change over time as well, depending on feedback and comments received.

4.5. Description of the Internet/WWW site and of the Data-Base

The Web site that has been realised with the standards template, data base of international standards and searching mechanism can be accessed through its address:

   www.ramit.be/imiawg16

*An extract of the database as a list of all European standards can be found in **Appendix 5.***

4.6. Template and guidelines for the information providers

IMIA
WG16

Inventory of Healthcare Informatics and Telematics Standards

With this template you can submit the necessary information on your standard.
More information is available at: http://www.ramit.be/imiawg16/
If you have questions in connection with the interpretation of the fields in the template, please contact:

Mr. Georges Van Maele
Department of Medical Informatics
Gent University Hospital
De Pintelaan 185
B-9000 Gent, Belgium
Tel: +32-9-2402959
Fax: +32-9-2403439
email: georges.VanMaele@rug.ac.be

If you would like to post more than one Standard, please copy the table and append it as many times as needed.

After the data-input, please send it as an attachment to wg16@ehto.be with input inventory in the subjectline.

Fields marked with ' * ' are mandatory

	Please use this column for your data

Title: *	
Acronym, Short Name:	
Identification Number of the Submitter of the Information:	
Keywords (max.7, use commas between key-words):	
Description of the Scope of the Standard: *	
Category:	€Official Standard €P.A.S. €De Facto Standard €Combination
Date of Publication or Expected Date of Publication: *	
Target Groups:	
Standardbody or Producer of the Standard: *	
URL of the Web Site where more Information is Available:	http://
Language(s) of Document:	
Free Text (any other relevant comment):	
Date of submission (year,month,day): *	
Contact info on the Sender of the Description:	

Last Name, First Name:	
Title:	
Organization:	
Phone:	
Fax:	
E-mail	
Contact point for getting more Information on the Standard	
Last Name, First Name:	
Title:	
Organization:	
Phone:	
Fax:	
E-mail:	

This database or inventory has to be considered as an intermediate tool to help finding information on existing standards in Healthcare Informatics and Telematics. More information can be found by searching via the references provided in the descriptions.

The template, database and procedures have been kept simple in order to encourage all interested parties to exchange information (a first step in the international co-operation in standardisation).

It is on purpose that the choice of keywords has been left open. The intention is to let standards makers choose the most specific ones for labelling their documents. The task force responsible for this inventory will later explore the possibility of categorising the keywords; the web master will also integrate a user-friendly search engine.

In this stage, the database is open for any standard (official/formal versus de facto/commercial). The quality of the information is under the responsibility of the authors/senders. The task force and the webmaster are not responsible for any possibly irrelevant, false or low quality input.

4.7. Inventory of Standards for Medical Informatics and Telematics

1. Secure User Identification - Strong Authentication Using Microprocessor Cards
   CEN/TC 251 / PT-037   -   Europe

2. Vital Signs Information Representation
   CEN/TC 251 / PT-021   -   Europe

3. Electronic Healthcare Record Communication - Part 2: Domain Termlist
   CEN/TC 251 / PT-027   -   Europe

4. Electronic Healthcare Record Communication - Part 3: Distribution Rules
   CEN/TC 251 / PT-028   -   Europe

5. Electronic Healthcare Record Communication - Part 4: Messages for the Exchange of Information
   CEN/TC 251 / PT-029   -   Europe

6. Blood Transfusion Related Messages Part 1: Patient Related Messages
   CEN/TC 251 / PT-032   -   Europe

7. Messages for Maintenance of Supporting Information in Healthcare System. Part 2. Updating Medical Laboratory-specific Information
   CEN/TC 251 / PT-033   -   Europe

8. Electronic Healthcare Record Communication - Part 1: Extended Architecture
   CEN/TC 251 / PT-026   -   Europe

9. Secure User Identification for healthcare - Management and Security of authentication by passwords
   CEN/TC 251   -   Europe

10. Security for Healthcare Communication - Part 1: Concepts and Terminology
    CEN/TC 251 / PT-039   -   Europe

11. Security for Healthcare Communication - Part 2: Secure Data Objects
    CEN/TC 251 / PT-039   -   Europe

12. Security for Healthcare Communication - Part 3: Secure Data Channels
    CEN/TC 251 / PT-039   -   Europe

13. Interoperability of Patient Connected Medical Devices
    CEN/TC 251 / PT-035   -   Europe

14. Instrument Interfaces to Laboratory Information Systems
    CEN/TC 251 / PT-036   -   Europe

15. Messages for the exchange of information on medicine prescriptions
    CEN/TC 251 / PT-031   -   Europe

16. Health Industry Bar Code Supplier Labelling Standard
    Health Industry Business Communications Council

17. HL7 Version 2.3, Chapter 12 Patient Care
    Health Level Seven

18. HL7 Version 2.3, Chapter 11, Patient Referral
    Health Level Seven

19. HL7 Version 2.3, Chapter 10 Scheduling
    Health Level Seven

20. HL7 Version 2.3, Chapter 9 Medical Records/Information Management
    Health Level Seven

21. HL7 Version 2.3, Chapter 8 Master Files
    Health Level Seven

22. HL7 Version 2.3, Chapter 7 Observation Reporting
    Health Level Seven

23. HL7 Version 2.3, Chapter 6 Financial Management
    Health Level Seven

24. HL7 Version 2.3, Chapter 4 Order Entry
    Health Level Seven

25. HL7 Version 2.3, Chapter 3 Patient Administration
    Health Level Seven

26. HL7 Version 2.3, Chapter 2 Control/Query
    Health Level Seven

27. The classification of the Electronic Patient Records Systems by JAHIS, V1.1
    JAHIS, Japanese Association of Healthcare Information Systems Industry

28. The standard guidelines of designing security control system for the Electronic Patient
    Records Systems, V2.0
    JAHIS, Japanese Association of Healthcare Information Systems Industry

29. Healthcare Card System Standardisation Manual
    Medical Information System Development Centre (MEDIS-DC)

30. Master file of medical treatment for insurance claim
    MHW   -   Japan

31. Master file of disease and injury
    Ministry of healthcare and welfare (MHW)   -   Japan

32. Pharmaceutical products master of social insurance payment fund
    Ministry of Healthcare and welfare   -   Japan

33. MEDIS-DC Standards for Electronic Filing of Medical Images
    MEDIS-DC   -   Japan

34. The Agreement on Clinical Laboratory Data Communication: JAHIS-DRAFT
    JAHIS, Japanese Association of Healthcare Information Systems Industry   -   Japan

35. Standard guidelines for transfer message between automated analyser and computer
    systems, Ver 1.00
    JAHIS, Japanese Association of Healthcare Information Systems Industry   -   Japan

36. Classification & Coding for Clinical Laboratory Tests, 9th rev. 2nd ed.
    JSCP, Japan Society of Clinical Pathology   -   Japan

37. Medical record image text information exchange
    JAMI   -   Japan

38. Clinical Cancer Management Information Model
    NSW Health Department   -   Australia

39. Ambulatory Care Information Model
    NSW Health Department   -   Australia

40. Personal privacy protection in health care information systems
    Standards Australia   -   Australia

41. NSW Health Standard Technology Products and Acquisition Guidelines
    NSW Health Department, Australia   -   Australia

42. Community Health Information Model
    NSW Health Department   -   Australia
43. NSW Health Enterprise Information Model
    NSW Health Department   -   Australia
44. NSW Health Standards Framework
    NSW Health Department, Australia   -   Australia
45. Implementation of Health Level Seven (HL7) Version 2.2 Part 1: Admission, discharge and transfer
    Standards Australia   -   Australia
46. IEEE 1073 Standard for Medical Device Communications
    IEEE   -   World wide
47. (Australian) National Health Information Knowledge Base
    (Australian) National Health Information Management Group - produced by the Australian Institute of Health and Welfare   -   Australia
48. Tentative agreement on clinical laboratory data communication
    MEDIS-DC   -   Japan
49. Diagnostic Japanese Terminology in accordance with ICD10
    MEDIS-DC (Medical Information System Development Centre)   -   Japan
50. NSW Health Information Privacy Code of Practice
    NSW Health Department   -   Australia
51. CIHI Rehabilitation Minimum Data Set
    Canadian Institute for Health Information   -   Canada
52. Patient Administration System Information Model
    NSW Health Department   -   Australia
53. CIHI Ambulatory Care Minimum Data Set
    Canadian Institute for Health Information   -   Canada
54. Canadian Classification of Interventions/Classification canadienne des interventions
    Canadian Institute for Health Information (CIHI)   -   Canada
55. Canadian Classification of Diagnostic, Therapeutic, and Surgical Procedures/Classification canadienne des actes diagnostiques, thérapeutiques et chirurgicaux
    Statistics Canada   -   Canada
56. Electronic Nomenclature and Classification of Disorders and Encounters in Family Medicine/Codification électronique pour la médecine familiale
    College of Family Physicians of Canada, in collaboration with the Centre for Information Technology Innovation of Industry Canada and CLINIDATA Inc.   -   Canada
57. CIHI National Continuing Care Data Set
    Canadian Institute for Health Information   -   Canada
58. Case Mix Groups
    Canadian Institute for Health Information   -   Canada
59. Day Procedure Groups
    Canadian Institute for Health Information   -   Canada

60. Teleradiology Standard
Ontario Association of Radiologists - Canada

61. Pharmacy Claim Standard
Canadian Pharmaceutical Association - Canada

62. Guidelines for Management Information Systems in Canadian Health Care
Facilities/Guide sur les systèmes d'information de gestion dans les établissements de
santé canadiens
Canadian Institute for Health Information (CIHI) (formerly published by the MIS
Group) - Canada

63. CIHI Discharge Abstract (Dataset for Acute Care)
Canadian Institute for Health Information (formerly produced by the Hospital Medical
Records Institute) - Canada

64. Media Interchange for Medical Imaging Communication
CEN/TC 251 - Europe

65. Standard Communications Protocol for Computerised Electrocardiography
CEN/TC 251 - Europe

66. Medical Imaging Communication
CEN/TC 251 - Europe

67. Medical Image Management - Part 1: Storage Commitment Service Class
CEN/TC 251 - Europe

68. Medical Data Interchange: Information System to Modality Interface - Part 1
CEN/TC 251 - Europe

69. Security Categorisation and Protection for Healthcare Information Systems
CEN/TC 251 - Europe

70. Algorithm for Digital Signature Services in Healthcare
CEN/TC 251 - Europe

71. Identification, administrative, and common clinical data structure for Intermittently
Connected Devices used in healthcare
CEN/TC 251 - Europe

72. Supporting document to ENV 1613:1995; Messages for Exchange of Laboratory
Information
CEN/TC 251 - Europe

73. Secure User Identification for Healthcare - Management and Security of Authentication
by Passwords - Healthcare Oriented IT Security
CEN/TC 251 - Europe

74. Messages for Exchange of Healthcare Administrative Information
CEN/TC 251 - Europe

75. Methodology for the Development of Healthcare Messages
CEN/TC 251 - Europe

76. Registration of Information Objects used for EDI in Healthcare. Part 1.
CEN/TC 251 - Europe

77. Request and Report Messages for Diagnostic Services Departments
CEN/TC 251 - Europe

78. Messages for Exchange of Laboratory Information
    CEN/TC 251   -   Europe
79. Messages for Patient Referral and Discharge
    CEN/TC 251   -   Europe
80. Registration of Information Objects used for EDI in Healthcare. Part 2.
    CEN/TC 251   -   Europe
81. Medicinal Product Identification
    CEN/TC 251   -   Europe
82. Standard Architecture for Healthcare Information Systems
    CEN/TC 251   -   Europe
83. Concept Structure for Nomenclature, Classification, and Coding of Properties in Clinical Laboratory Sciences
    CEN/TC 251   -   Europe
84. The Electronic Healthcare Records Architecture
    CEN/TC 251   -   Europe
85. Structure for Classification and Coding of Surgical Procedures
    CEN/TC 251   -   Europe
86. Structure of Concept Systems - Vocabulary
    CEN/TC 251   -   Europe
87. Categorial Structure of Systems of Concepts - Medical Devices
    CEN/TC 251   -   Europe
88. Expression of the Results of Measurements in Health Sciences
    CEN/TC 251   -   Europe
89. Time Standards for Healthcare Specific Problems
    CEN/TC 251   -   Europe
90. Registration of Coding Schemes
    CEN/TC 251   -   Europe
91. Investigation of Syntaxes for Existing Interchange Formats to be used in Healthcare
    CEN/TC 251   -   Europe
92. Medical Informatics Vocabulary
    CEN/TC 251   -   Europe
93. Healthcare Information Framework
    CEN/TC 251   -   Europe
94. Operating Theatre Information Model
    NSW Health Department   -   Australia

Relevant web-sites:

www.ramit.be/imiawg16/
www.centc251.org
www.astm.org/isotc215/

5 ESTABLISHMENT OF THE NATIONAL HEALTH INFORMATICS / TELEMATICS STANDARDS COMMITTEE

5.1. Introduction

It is widely recognised that the systematic availability of medical care services is a vital component of the social network. Information systems consisting of telecommunication and computing technologies will play a key role in supporting the emerging new healthcare delivery systems. Whilst the potential for improvement in efficiency and effectiveness through ICT, sharing information and access to knowledge is substantial, it will not happen without agreed standards. Telematics and standards together will also allow better evaluation and assessment of healthcare.

The healthcare domain is not a simple market place. There are many actors and different forces. There are factors which constitute an interplay between "centripetal" trends promoting harmonisation and standardisation, and "centrifugal" trends precipitating fragmentation and differential growth. The constant oscillation between these two dynamics is currently generating turbulence in the healthcare domain, a situation which makes future healthcare (telematics) scenarios difficult to predict.

An official committee, supported by the government and ministry, is a prerequisite for the introduction of standards in the field.

5.2. Objectives

The establishment of the official Belgian committee on standards in health informatics and telematics within the Ministries of Health and Social Affairs, with as remit:

- the promotion of electronic information exchange, including patient data, in healthcare;
- the promotion of the use of patient-oriented electronic medical record systems in hospital- and ambulatory care;
- the harmonisation and standardisation of the content, of the interchange formats and of the syntaxes of electronic messages in order to make consistent and automatic integration of data in electronic medical records possible;
- to make technical recommendations on any issue which may affect electronic communication in healthcare, e.g. ICT, security, patient identification, encoding of medical data;
- to propose accreditation criteria in relation to minimal functionalities of electronic medical record systems and medical telematic services.

5.3. Description

Within Belgian Health Law, a Royal Order has been issued, establishing the above Committee (18 experts, a secretary, a chairman and co-chairman). The committee is to meet regularly and give technical advice to the Ministers of Health and Social Affairs.
The Committee will draft and update a strategic plan on the future health information management and use of standards for the Minister of Health and Social Affairs.
The directives will foresee positive incentives for all stakeholders.

5.4. Strategic plan on the future information-management and use of standards in the Belgian healthcare sector

The Royal Order on the establishment of the National Health Informatics / Telematics Standards Committee can be found in **Appendix 6.**

5.5. Committee Meeting reports and Publications (see Appendix 7).

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6. CONCLUSION AND FUTURE INITIATIVES

There is a need for a comprehensive electronic service concerning health informatics/telematics products, related standards, procurement advice and relevant background information. The aim for such a service should be to become self-supporting.

The cost of healthcare is steadily increasing across Europe due, for example, to new expensive technologies and drugs, rising expectations, demographic changes and increased life expectancy. Improved efficiency, enhanced productivity and new modes of operation are essential if costs are to be contained within affordable levels. Information technology and telecommunications are the important tools by which this can be achieved. Examples are:

- Telemedicine;
- Electronic booking of appointments;
- EDI for electronic referrals, requests and results for laboratory and radiological tests;
- EDI for ordering of supplies and electronic submission and payments for item of service claims;
- Access to electronic services and knowledge bases.

Throughout Europe and the developed world investment in health informatics products is increasing. In the UK alone the National Health Service is investing 1.5 billion Euro solely to supporting a new Health Information Strategy. Part of that strategy requires electronic interworking between all organisational entities within the health system and a key objective is the creation of electronic patient records and an electronic health record for every citizen. Such objectives are mirrored across the countries of Europe, with particular emphasis in a number of countries on patient and professional data cards. A number of European states are pursuing national health informatics strategies. Electronic services and knowledge bases can greatly assist the formulation and implementation of such strategies.

As health systems over Europe prepare to invest in health informatics products common standards become of considerable importance for example to ensure;

- Interoperability;
- Interworking;
- Security;
- Cohesion and consistency in all components comprising an electronic health record which may be widely distributed.

Increasingly the applications being pursued to improve health delivery and efficiency such as seamless care, EDI between primary and secondary carers, electronic booking of hospital appointments, involve inter-organisational communications. The latter particularly require compliance with common standards if interworking across organisational boundaries is to be successful.

Additionally compliance with European and international standards is a critical aspect of:

- Reducing barriers to trade;
- Increasing market opportunities;
- Expanding user choice through interoperability of best-of-breed;
- Improving efficiency and reducing costs;
- and, in health applications, improving services to patients.

In all aspects of electronic exchange of personal information security must be assured. In the health sector this is of paramount importance given the sensitive nature of personal health information. Compliance in these matters with standards and good practice guidance is thus of considerable significance.

Interfacing with health system users and procurers, are a wide variety of vendors. Some are substantial companies although not all such companies market their products across all of Europe. However most vendors are small SMEs often focused on the market in one or a few countries. There are however signs of this changing. For example in the UK, about ten years ago, the primary care market for general practice systems was split between about twenty significant but small players. Amalgamations and take-overs have reduced this now to about three to five. As companies strengthen they are increasingly looking to widen their market base. Telecommunication companies are becoming more and more significant in the health informatics sector as inter-organisational communications grow and health Internet applications expand in volume and significance. Large software companies such as Microsoft are also beginning seriously to tackle the health informatics market-place as witnessed by a rapidly growing European user group.

In healthcare Europe represents a complex marketing environment with a wide variety of national organisational models for its delivery. Bringing products to the notice of end users and procurers is expensive and difficult particularly for SMEs. Thus widening marketing bases across European national boundaries is a challenge that few can surmount. The advent of e-commerce could change this markedly.

These barriers to marketing deprive users and procurers of the knowledge of the products and services which European-based vendors can offer. That is particularly the case for products from innovative small SMEs breaking into the market with state of the art technologies. There is in addition a substantial body of good advice and experience documented throughout Europe relating to health informatics, such as the deliverables from EU projects, that could greatly benefit users and procurers. However, whilst many of these are promoted on a variety of web sites, there is no e-portal that brings them together with product information and standards information as a coherent whole. Again here e-commerce can have a real, beneficial impact.

Users widely recognise that getting all the advantages of picking the best-of-breed for different applications requires common standards if they are to be interfaced and that the demands for inter-organisational interworking requires the same. Suppliers also recognise that compliance with common standards is desirable to users and procurers and that such compliance can bring economies in production and sales. Nevertheless, despite this evident need for common standards and the advantages of these being European and international standards, there is a substantial risk that purely national or proprietary non-de facto standards will dominate.

CEN, through its Health Informatics Technical Committee TC 251, has been in existence for about ten years. It has completed 31 ENVs, 7 preENVs and 4 CRs (CEN reports). They cover aspects such as interoperability and communication protocols for patient connected medical devices; clinical messaging structures and content; nomenclature and terminological systems; data structures for patient data cards; medical imaging; security including digital signatures, and security classifications; safety of software; user identification; instrument interfaces for laboratory information systems. A substantial programme of work is in hand. However, despite many attempts, European industry has been only marginally involved in CEN/TC 251.

In 1998 ISO formed a Health Informatics Technical Committee ISO/TC 215. Its work programme is underway with considerable European participation. Its influence is growing rapidly yet, as with CEN, European industry is involved only marginally.

There are also a range of health-related industry de facto standards and Publicly Available Specifications with equivalent international standing for example: HL7 and DICOM. These will be encompassed within the project.

In addition to this standards activity, a large number of EU RTD projects in the health informatics domain have created guidance of great potential value to users and vendors alike. Some is akin to standards and/or of a pre-standard nature, much of which has been fed into the standards-making process.

The exact extent of take-up of standards by the European health informatics/telematics industry is unknown, but all the evidence points to minimal knowledge, and thereby minimal implementation and low interest.

A major factor in the take-up of standards by industry is the extent of insistence on standards compliance by users and procurers - public and private. Again the exact extent to which European buyers are insisting on standards is unknown but evidence again points to marginal engagement and little awareness.

One major reason for this circumstance is ignorance of what standards exist and little understanding of what they mean and the circumstances in which they might best be applied. This extends to both industry and users. A new initiative should look to diminish this ignorance and raise awareness by bringing procurers and industry closer. It should assist procurers to understand what standards are available, what they mean and the extent to which products comply. It will help industry to understand the importance of standards and provide a platform for them to advertise to procurers their compliance with them. It should assist standards-makers to appreciate the take-up of their work and gaps and priorities for future endeavour.

Bringing products to the attention of users and procurers is the essence of successful marketing. Knowing what products are available with their characteristics and having reference sites with which to consult is a prerequisite for successful procurement. Having available good advice and guidance is an important part of successful implementation and utilisation.

Inherent to such success is compliance with standards. Insistence on compliance with standards in procurement is the key to increasing the uptake of standards by industry. Knowledge of the extent to which industry is implementing a standard is critical if standards makers are to be able to gauge success, learn lessons and focus awareness activities. Awareness of standards, and an understanding of how any particular standard applies to the procurement and implementation of particular applications, is a prerequisite to take up.

The future self-supporting service should be aimed at:

– Forging close electronic links between product vendors, service providers and users
– Enhancing knowledge of availability of products services;
– Increasing awareness and understanding of standards and their applicability;
– Providing direct access to standards and other documentation which impact on the procurement, implementation or utilisation of health informatics / telematics products.

Such eService should be delivered through closely inter-linked European databases and a dynamic portal web site comprising:

- A database of products and services from European based suppliers with hyperlinks to their web sites and an email enquiry service;
- A database of standards (European, international and industry de facto);
- A database of information relating to products and procurement
- A portal through which to order electronically relevant documents including standards;
- Electronic newsletters covering 'What's New' in standards and other matters.
- There should be strong links between the web site's input and output and the databases, particularly that for standards.

7. BEKNOPTE SYNTHESE IN HET NEDERLANDS

De algemene objectieven van dit project waren de kloof in België tussen standaardisatie in het domein van ICT voor de gezondheidszorg enerzijds en industrie anderzijds te verkleinen, de banden tussen de onderzoeks- en ontwikkelingsactiviteiten te versterken, consensus-fora to organiseren ten behoeve van alle belanghebbende actoren, de implementatie van Europese standaarden en richtlijnen te bevorderen en de impact van België en van Europa op de internationale normalisatie in dit domein te vergroten.

Hiertoe werden de volgende drie taken tot een goed einde gebracht :

– het in stand houden van de officiële Belgische spiegelgroep van CEN/TC 251 en ISO/TC 215 (zie hoofdstuk 3) en bijlagen;

– het ontwikkelen en onderhouden van een dynamische web-site met een database van internationale standaarden (zie hoofdstuk 4);

– het oprichten van de Commissie Telematica Standaarden in de Gezondheidszorg via Koninklijk Besluit (Staatsblad 30/7/1999 – Ministeries van Volksgezondheid en Sociale Zaken) (zie hoofdstuk 5).

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9. LIST OF ACRONYMS

ACOSTA	Accompanying Measure on Consensus Formation and Standardisation Promotion
ACR	American College of Radiology
AFNOR	Association française de normalisation
AIM	Advanced Informatics in Medicine (CEC-DG XIII programme)
ANSI	American National Standards Institute
ANSI-HISB	American National Standards Institute, Healthcare Informatics Standards Board
AOW	Asia and Oceania OSI Workshop
ASN.1	Abstract Syntax Notation One (ISO)
ASTM	American Society for Testing and Materials
ATC	Anatomical Therapeutical and Chemical Classification (WHO)
BC	Bon de Commande (Contract between CEC and CEN)
BCD	Binary Coded Decimal
BSI	British Standards Institution
BSR	Basic Semantic Repository
BT	Technical Board (Bureau Technique)
CCITT	Comité Consultatif International Télégraphique et Téléphonique
CEN	Comité Européen de Normalisation
CENELEC	Comité Européen de Normalisation Electrotechnique
CEU	Commission of the European Union
COCIR	Comité de Coordination des Industries Radiologiques et Electromédicales
COST	Cooperation Européene Scientifique et Technique
CR	Computed Radiography
CT	Computer Tomography
DICOM	Digital Image Communication in Medicine
DIN	Deutsches Institut für Normung e.V.
ECG	Electrocardiogram
EDI	Electronic Data Interchange
EDIFACT	Electronic Data Interchange for Administration, Commerce and Transport
EFMI	European Federation for Medical Informatics
EFTA	European Free Trade Association (Austria, Finland, Iceland, Norway, Sweden, Switserland)
EN	Europaïsche Norm (European Standard)
ENV	Europaïsche Norm Vorausgabe (European Prestandard)
EPhMRA	European Pharmaceutical Market Research Association
ETSI	European Telecommunications Standards Institute
EU	European Union
EUCLIDES	European Standard for Clinical Laboratory Data Exchange between Medical Information Systems (AIM project)
EUREKA	European Research Coordination Agency
EWOS	European Workshop for Open Systems
EWOS/EG MED	EWOS/EG MED Expert Group Healthcare
GMD	General Message Description
GP	General Practitioner (in medicine)

HCD	Healthcare Coding Scheme Designator
HD	Harmonisation Document
HIS	Hospital Information System
HL7	Health Level 7 (US)
ICD	International Classification of Diseases
ICT	Information and Communication Technologies
IEC	International Electrotechnical Commission
IEEE	Institution of Electrical and Electronics Engineers (USA)
ISDN	Integrated Services Digital Network
ISO	International Organization for Standardization
ISO-IAeG	ISO Inter Agency edi Group
ISP	International Standardised Profile
IT	Information Technology
IT&T	Information Technology and Telecommunications
ITU	International Telecommunications Union
JTC	Joint Technical Committee (ISO/IEC)
LIS	Laboratory Information Systems
MEDIX	Medical Data Interchange Committee (IEEE P1157)
MHS	Message Handling Systems
MITI	Ministry of Trade and Industry (Japan)
MoH	Ministry of Health (Japan)
MRI	Magnetic Resonance Imaging
NCPDP	National Council of Pharmaceutical Distributors and Producers (US)
NEMA	National Electrical Manufacturers' Association
NIST	National Institute for Standards and Technology
ODA	Open Document Architecture(ISO 8613)
OIW	Open Implementors' Workshop(USA)
OOA	Object Oriented Analysis
OPENLABS	Application of Advanced Informatics and Telematics for Optimisation of Clininical Laboratory Services (AIM project)
OSE	Open Systems Environment
OSI	Open Systems Interconnection
PACS	Picture Archiving and Communication System
PT	Project Team (CEN)
RIS	Radiology Information System
SI	Système Internationale
SOGITS	Senior Officials Group for Information Technology Standardisation
SPAG	Standards Promotion and Application Group
TC	Technical Committee (CEN)
TEDIS	Trade Electronic Data Interchange System
TR	Technical Report(see also CEN Report - CR)
UN	United Nations
UN/ECE WP4	
	United Nations Economic Commision for Europe, working party on trade facilitation
UNSM	United Nations Standard Message
US	Ultra Sound

WCC	Wetenschappelijk Comité voor Classificatie en Terminologiëen (Nationale Raad voor Volksgezondheid - Nederland)
WEEB	Western Europe EDIFACT Board
WEEB/MD 9	Western Europe EDIFACT Board, Message Development Group 9 for Healthcare (now CEN/EBES/EG 9)
WG	Working Group
WHO	World Health Organisation
WI	Work Item (CEN/TC 251 workprogramme)
X.400	CCITT (1984 and 1988) Message Handling System