eHealth Strategies

Country Brief: Belgium

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European Commission,
DG Information Society and Media,
ICT for Health Unit

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Information Society and Media

About the *eHealth Strategies* study

The eHealth Strategies study analyses policy development and planning, implementation measures as well as progress achieved with respect to national and regional eHealth solutions in EU and EEA Member States, with emphasis on barriers and enablers beyond technology. The focus is on infrastructure elements and selected solutions emphasised in the European eHealth Action Plan of 2004.

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Table of contents

1 Introduction to the report 6

1.1 Motivation of the eHStrategies study 6

1.2 Survey methodology 7

1.3 Outline 8

2 Healthcare system setting 8

2.1 Country introduction 8

2.2 Healthcare governance 9

2.3 Recent reforms and priorities of health system/public health 12

2.4 eHealth setting in the country 13

3 eHealth Strategies survey results 14

3.1 eHealth policy action 15

3.1.1 Current strategy/roadmap 15

3.2 Administrative and organisational structure 17

3.3 Deployment of eHealth applications 18

3.3.1 Patient summary and electronic health record (EHR) 19

3.3.2 ePrescription 21

3.3.3 Standards 22

3.3.4 Telemedicine 24

3.4 Technical aspects of implementation 26

3.4.1 Unique identification of patients 26

3.4.2 Unique identification of healthcare professionals 27

3.4.3 The role of eCards 28

3.5 Legal and regulatory facilitators 31

3.5.1 Patient rights 32

3.6 Financing and reimbursement issues 34

3.7 Evaluation results/plans/activities 35

4 Outlook 36

List of abbreviations 37

5 Annex 39

Annex 1: Compound Indicators of eHealth use by GPs 39

Annex 2: List of SUMEHR contents 39

6 References 41

Executive summary

Belgium has no official national eHealth strategy, but several laws and policy decisions have contributed to the shaping of the general developments towards eHealth use. These laws and official documents do not mention nor refer to the EU eHealth Action Plan, as most of them preceded its publication, but they still address many of its aims. The coordination of the Belgian eHealth approach came from a commission for “Norms related to telematics in support of the healthcare sector“ which was installed in 1999 by Royal Decree. Following that a government agreement in 2004 “BeHealth-platform” was created which was then built upon in 2008 by the founding of a new public organisation called "eHealth-platform", which was created by law. The “eHealth-platform” took over the function and tasks of the above mentioned health telematics commission, and is intended to address and coordinate issues related to eHealth.

In order to consider Belgium’s position regarding eHealth interoperability objectives the following eHealth applications have been examined: patient summaries and electronic health records, ePrescription, standards and telemedicine. In overview Belgium’s situation is as follows::

The official start of dealing with the contents of electronic medical records was marked by the Law on “Social Affairs” in 1999, empowering the king to define minimal (quality/functional) criteria for medical / healthcare software in order for it to be approved for compatibility by the Ministry of Health. The contents of the Belgian patient summary, SUMEHR (Summarised Electronic Healthcare Record), were defined in 2003-2004. Certification schemes for interoperability levels of authorised software systems have been in operation in Belgium since 2002. Since 2005, the certification criteria for EHR systems for general practitioners require them to be able to export the SUMEHR patient summary. Now, more than 80% of all GPs across Belgium use certified EHR systems with this capability.

In Belgium electronic production of printed prescriptions has been available since the early nineties and a decision support facility is available in all primary care EHR applications. However, electronic transmission of prescriptions is so far limited to in-house prescriptions in hospitals. A new ePrescription pilot is currently underway and the first field tests are scheduled for 2011.

The Belgian eHealth-platform, created by law in 2008, has competencies regarding standards. It is mandated to “define ICT related useful functional and technical norms, standards, specifications and basic infrastructure required to support [the eHealth] vision and strategy”. However, the eHealth-platform is not the only institution dealing with standards, the Ministry of Health and The National Health Insurance Institute are also involved. Although Belgium is not a member of IHTSDO it is considering it and international and semantic standards such as ICD10-ICPC2 are in use.

Most telemedicine projects are privately initiated and are generally home care services for elderly people or patients with chronic diseases. Telemonitoring exists in terms of Tele-surveillance or Tele-alarm services and Teleconsultation is used to a limited extent, although services for teledermatology and telepathology exist. There is no specific policy or implementation programme regarding telecare and telemonitoring, but recently the National Health Insurance Institute initiated a call for proposals regarding telemonitoring. Also, a number of mobile monitoring projects are currently being piloted.

List of figures

Figure 1: Important features of primary healthcare organisation in Belgium 12

Figure 2: eHealth use by GPs in Belgium 14

Figure 3: Belgian policy documents related to eHealth 17

Figure 4: Patient summary in Belgium 21

Figure 5: Telemedicine services in Belgium 26

Figure 6: eCards in Belgium 31

1 Introduction to the report

1.1 Motivation of the eHealth Strategies study

Following the *Communication* of the European Commission (EC) on "eHealth – making healthcare better for European citizens: An action plan for a European eHealth Area",[1] Member States of the European Union (EU) have committed themselves to develop and issue national roadmaps – national strategies and plans for the deployment of eHealth applications addressing policy actions identified in the European eHealth Action Plan.

The *2004 eHealth Action Plan* required the Commission to *regularly monitor* the state of the art in deployment of eHealth, the progress made in agreeing on and updating national eHealth Roadmaps, and to facilitate the exchange of good practices. Furthermore, in December 2006 the EU Competitiveness Council agreed to launch the *Lead Market Initiative*[2] as a new policy approach aiming at the creation of markets with high economic and social value, in which European companies could develop a globally leading role. Following this impetus, the Roadmap for implementation of the "eHealth Task Force Lead Market Initiative" also identified better coordination and exchange of good practices in eHealth as a way to reduce market fragmentation and lack of interoperability.[3]

On the more specific aspects of electronic health record (EHR) systems, the recent *EC Recommendation on cross-border interoperability of electronic health record systems*[4] notes under "Monitoring and Evaluation", that "in order to ensure monitoring and evaluation of cross-border interoperability of electronic health record systems, Member States should: consider the possibilities for setting up a monitoring observatory for interoperability of electronic health record systems in the Community to monitor, benchmark and assess progress on technical and semantic interoperability for successful implementation of electronic health record systems." The present study certainly is a contribution to monitoring the progress made in establishing national/regional EHR systems in Member States. It also provides analytical information and support to current efforts by the European Large Scale Pilot (LSP) on cross-border Patient Summary and ePrescription services, the epSOS - European patients Smart Open Services - project.[5] With the involvement of almost all Member States, its goal is to define and implement a European wide standard for such applications at the interface between national health systems.

Earlier, in line with the requirement to "regularly monitor the state of the art in deployment of eHealth", the EC already funded a first project to map national eHealth strategies – the eHealth ERA "Towards the establishment of a European eHealth Research Area" (FP6 Coordination Action)[6] - and a project on "Good eHealth: Study on the exchange of good

[1] European Commission 2004
[2] European Commission 2007
[3] European Communities 2007
[4] European Commission 2008
[5] European Patients Smart and Open Services (epSOS)
[6] eHealth Priorities and Strategies in European Countries 2007

practices in eHealth"[7] mapping good practices in Europe - both of which provided valuable input to the present *eHealth Strategies* work and its reports. Member States' representatives and eHealth stakeholders, e.g. in the context of the *i2010 Subgroup on eHealth* and the annual European High Level eHealth Conferences have underlined the importance of this work and the need to maintain it updated to continue to benefit from it.

This country report on Belgium summarises main findings and an assessment of progress made towards realising key objectives of the eHealth Action Plan. It presents lessons learned from the national eHealth programme, planning and implementation efforts and provides an outlook on future developments.

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1.2 Survey methodology

After developing an overall conceptual approach and establishing a comprehensive analytical framework, national level information was collected through a long-standing Europe-wide network of national correspondents commanding an impressive experience in such work. In addition, a handbook containing definitions of key concepts was distributed among the correspondents to guarantee a certain consistency in reporting. For Belgium, relevant information on policy contexts and health system situation, policies and initiatives as well as examples for specific applications was collected by the overall project lead - empirica in Bonn, Germany.

The key tool to collect this information from the correspondents was an online survey template containing six main sections:

A. National eHealth Strategy

B. eHealth Implementations

C. Legal and Regulatory Facilitators

D. Administrative and Process Support

E. Financing and Reimbursement Issues

F. Evaluation

Under each section, specific questions were formulated and combined with free text fields and drop-down menus. The drop-down menus were designed to capture dates and stages of development (planning/implementation/routine operation). In addition, drop-down menus were designed to limit the number of possible answering options, for example with regard to specific telemedicine services or issues included in a strategy document. The overall purpose was to assure as much consistency as reasonably possible when comparing developments in different countries, in spite of the well-know disparity of European national and regional health system structures and services.

Under Section B on eHealth implementation, questions regarding the following applications were formulated: existence and deployment of patient and healthcare provider identifiers, eCards, patient summary, ePrescription, standards as well as telemonitoring and telecare.

[7] European Commission; Information Society and Media Directorate-General 2009

The data and information gathering followed a multi-stage approach. In order to create a *baseline* for the progress assessment, the empirica team filled in those parts of the respective questions dealing with the state of affairs about 3 to 4 years ago, thereby drawing on data from earlier eHealth ERA reports, case studies, etc. to the extent meaningfully possible. In the next step, national correspondents respectively partners from the study team filled in the template on recent developments in the healthcare sector of the corresponding country. These results were checked, further improved and validated by independent experts whenever possible.

Progress of eHealth in Belgium is described in chapter 3 of this report in the respective thematic subsections. The graphical illustrations presented there deliberately focus on key items on the progress timeline and cannot reflect all activities undertaken.

This report was subjected to both an internal and an external quality review process. Nevertheless, the document may not fully reflect the real situation and the analysis may not be exhaustive due to focusing on European policy priorities as well as due to limited study resources, and the consequent need for preferentially describing certain activities over others. Also, the views of those who helped to collect, interpret and validate contents may have had an impact.

1.3 Outline

At the outset and as an introduction, the report provides in chapter 2 general background information on the *Belgian* healthcare system. It is concerned with the overall system setting, such as decision making bodies, healthcare service providers and health indicator data.

Chapter 3 presents the current situation of selected key eHealth developments based on detailed analyses of available documents and other information by national correspondents and data gathered by them through a well-structured online questionnaire. It touches on issues and challenges around eHealth policy activities, administrative and organisational structure, the deployment of selected eHealth applications, technical aspects of their implementation, legal and regulatory facilitators, financing and reimbursement issues, and finally evaluation results, plans, and activities

The report finishes with a short outlook.

2 Healthcare system setting

2.1 Country introduction[8]

Belgium is a small, highly developed and densely populated country (approximately 11 million inhabitants). It is one of the founding members of the EU and its capital, Brussels, is also the capital of the European Union. It is a federal state with three relatively autonomous regions: Flanders in the north where Flemish (Dutch) is spoken, Wallonia in

[8] Evidence-based support for the design and delivery of user-centred online public services

the south where French is spoken, and Brussels in the centre which is officially bilingual. As well as the three regions, Belgium is divided into ten provinces: Antwerpen, Brabant Wallon, Hainaut, Liège, Limburg, Luxembourg, Namur, Oost-Vlaanderen, Vlaams-Brabant, and West-Vlaanderen. There are three levels of government: federal, regional and linguistic community, which leads to a complex division of responsibility.

Belgium has a healthcare system based on a compulsory social health insurance model. Healthcare is publicly funded and mainly privately provided. Patients have free choice of provider, hospital and sickness fund. The Federal Government regulates and supervises all sectors of the social security system, including health insurance. However, responsibility for almost all preventive care and health promotion has been transferred to the communities and regions.

In 2007, public health expenditure accounted for 9.9% of Belgium's Gross Domestic Product (GDP). A fixed annual budget for compulsory health insurance and sectoral target budgets are set at federal and community level. Private sole GPs and specialists deliver most primary care. There is no mandatory referral system. The Belgian healthcare system provides comprehensive healthcare to almost all the population while maintaining a wide degree of choice for the insured and the providers. Since the 1980s, the Belgian Government's two main objectives have been cost containment and improving access to healthcare services.

The box below summarises the key facts about the Belgian healthcare system:

Key facts about the Belgian healthcare system:[9]

Healthcare Expenditure as % of GDP: 10.2% (OECD 2007)

WHO Ranking of Healthcare systems: rank 21

Public sector healthcare expenditure as % of total healthcare expenditure: 75.1% (OECD 2007)

2.2 Healthcare governance[10]

Decision making bodies, responsibilities, sharing of power

Since 1980, part of the responsibility for healthcare policy in Belgium has been devolved from the federal Government to the regional governments. It is now shared between the federal Government, exercised by the Federal Public Service for Health, Food Chain Safety and Environment (former Ministry), the Federal Public Service Social Security, the National Institute for Sickness and Disability Insurance, and the Dutch-, French- and German-speaking community Ministries of Health. The federal authorities determine the general legislative framework for the health system by issuing laws and by determining the annual budget. They regulate and finance the compulsory health insurance; determine accreditation criteria; finance hospitals and so-called heavy medical care units, and register and control pharmaceuticals. The regional governments (Flemish

[9] Data from World Health Organization 2000; Health Consumer Powerhouse 2008; World Health Organization 2009

[10] Crainich and Closon 1999; Verhoest and Sys 2006; Corens 2007

community, French community and Brussels) are responsible for health promotion and preventive healthcare; maternity and child health services; different aspects of elderly care; the implementation of hospital accreditation standards; and the financing of hospital investment.

The role of government as a policymaker is situated at the federal level. It is the Minister of Social Affairs, Public Health and the Environment together with the department of Public Health who elaborate the policy towards hospitals. It is also at this level that broad policy goals are translated into concrete objectives, such as the program for hospitals and the accreditation standards. The responsibility for health promotion and most preventive services is situated at the regional level. In the Flemish region it is the Department of Welfare, Healthcare and Family that is responsible for this role of government. It is also this department that grants the licences and accreditations and that supervises the quality standards and accreditation criteria.

The role of government as supervisor of the market is also situated at the regional level. This level is in the first place responsible for supervising the implementation of the different standards and criteria and not for supervising the competition between the hospitals as such. However, by assuring that all hospitals respect the norms, the Department of Welfare, Healthcare and Family at the same time guarantees that there will not be any unfair competition between the different institutions. It is not possible for hospitals to lower price and quality below acceptable norms just to be in a better position to compete with other hospitals.

Finally, government can also in this sector act as an owner, since public hospitals can be owned by an OCMW (a public social welfare institution), an inter-municipal association, a province, a regional community or by the State. However, most public hospitals are owned by the OCMW's. Only a very limited number of hospitals is in the hands of the provinces and municipalities. Moreover, the provinces will have to hive off their hospitals within a couple of years. This means that the possibility of tensions and conflicts between the role of governments as policymaker, government as a supervisor and government as an owner is very limited, since all these different roles are situated at different governmental levels.

Moreover, the OCMW's who own the majority of public hospitals have no regulatory function. The conflicts that did occur at the level of the government were between the federal government and the regional governments. The cause has been mostly the lack of a clear delineation of responsibilities between the two levels.

Healthcare service providers

Healthcare is provided by public health services, independent ambulatory care professionals, independent pharmacists, hospitals and specific facilities for the elderly. Hospital care is provided by either private non-profit or public hospitals. Most medical specialists work independently in hospitals or in private practices on an ambulatory basis. General practitioners (GPs) may only provide ambulatory or primary care. Dentists and pharmacists also work independently, although some pharmacists are employed by pharmacy owners or pharmacy groups. Nursing homes are facilities for elderly people who are chronically ill, but who do not need intensive technical treatment or care.

A striking feature of Belgian healthcare is that it combines a predominantly public funding system with a predominantly private system of healthcare provision. The following kinds of healthcare activities can be found in Belgium: independent health professionals (both generalists and specialists) providing ambulatory care and services, public health services, hospitals, the pharmaceutical industry and social care facilities for the elderly and other groups with special needs.

Primary healthcare (defined as first patient contact) is provided by GPs and specialists. Most physicians (GPs and specialists) used to operate solo practices, frequently without any staff except perhaps a medical secretary. Nevertheless, there is now a development towards (privately owned) group practices. There is no mandatory referral or gatekeeper-system in place, although the government has tried to strengthen the role of GP during the last years.

The number of healthcare professionals has increased in real terms since the 1970s, resulting in a density of physicians per 1000 population clearly above EU average in 2004. Planning for physicians was only introduced in 1996, when the federal Government set up the Committee for Medical Supply Planning and introduced quotas for the accordance of a physician's title for university graduates. This resulted in a decrease of available medical personnel, also partially due to an increasing feminisation of the physicians.[11]

In Belgium, hospitals are private or public non-profit organisations that are classified into acute, psychiatric, geriatric and specialised hospitals. People are free to choose which hospital they attend and public hospitals are obliged to accept all patients. Thus there is no formal referral system between primary and secondary/tertiary care, but in practice, it is usually the GP or the private specialist who decides to send the patient to a hospital. Hospitals can be classified into two categories: general and psychiatric. In 2005, there were 215 hospitals, of which 146 were general and 69 psychiatric. The general hospital sector consists of acute (116), specialised (23) and geriatric hospitals (7).

[11] A higher proportion of female healthcare professionals work part-time or half-time, in addition to parental leave, than their male colleagues.

Figure 1: Important features of primary healthcare organisation in Belgium

Political/administrative unit responsible for primary healthcare	Organisational and regulatory: the Federal Ministry of Health. Regarding preventive care (also part of primary care): the regional health authorities. Financially: the National Health Insurance Institute.
Consumer Choice	Free choice and free access to primary care as well as to specialised and hospital care. There is a financial incentive to select one general practitioner as holder of your global medical record.
Financing	Free compulsive social security system, mandatory to all inhabitants. Largely funded by contributions of the citizens with some taxed-based state contribution for the elderly and social vulnerable persons.
Public or private providers	Self employed primary care providers solely. No publicly employed primary care providers at all.
Gatekeeping function of the GP	Free access to specialists and hospitals. Limited financial incentive for the patient when referred to the specialist.
Integrating health: initiatives for coordination	Public hospitals (large minority) are financially supported by the local authorities of patient's residence. Deficits of those hospitals are covered by patient's local authorities. Limited initiatives for local coordination between primary care and hospital care.

2.3 Recent reforms and priorities of health system/public health

Currently ongoing reforms in the health and social care systems[12]

Although the Belgian health system has not undergone any major structural reforms since the 1980s, various measures have been taken mainly to improve its performance. Reform policy in recent years has included: hospital financing reform; the strengthening of primary care; the restriction of the supply of physicians; the promotion of generic substitution of pharmaceuticals; the increase of accountability of healthcare providers and sickness funds; tariff cuts; and more emphasis on quality of care, equity, evidence-based medicine, healthcare technology, benchmarking with financial consequences and economic evaluations.

These healthcare reforms implemented during the last 20 years have been mainly aimed at containing the system's costs without forsaking its more positive characteristics. The reforms of the Belgian healthcare system, which arose from the need to contain spiralling costs, have been twofold. Firstly, by adapting the financial mechanisms of the system, the reforms have been aimed at devolving responsibility for Belgian healthcare to the system's various stakeholders. Secondly, the Belgian government has implemented reforms which focus on the supply-side of the system. The aim is to limit the supply of medical services.

[12] Crainich and Closon 1999; Verhoest and Sys 2006; Corens 2007

In order to enhance the efficient use of healthcare services, in 2002 a National Council for Health Promotion was set up. It evaluates a provider's prescription practice as compared to indicators of divergence with respect to normal medical practice. The first aim of this reform is to prevent divergent behaviour by providing information and monitoring medical practice. However it also enables the supervisory body to impose sanctions on all establishments and legal persons who carry out unnecessary or unnecessarily expensive services at the expense of the compulsory health insurance with the sole aim of increasing their incomes. Sanctions consist of administrative fines and in the worst case the withdrawal of the accreditation of the care provider in question.

In 2004, the Government decided to abolish the distinction between the health insurance scheme for the self-employed and the rest of the population. As a first step, as of 1 July 2006, minor risks are included in the compulsory cover for those starting self-employment and for the self-employed with the lowest pensions. From 1 January 2008 on, all self-employed were compulsorily insured against minor risks.

Beside this, measures were taken to strengthen the position of the GP as the preferred entrance point for healthcare treatment, while medical professional stakeholders continue to heavily oppose plans for a GP gate-keeping system.

2.4 eHealth setting in the country

This section provides a brief overview of relevant ICT related infrastructure and services data. It draws on earlier studies commissioned by the EC, notably the Indicators eHealth Study . Although the results of this study date from 2007 and may therefore not reflect latest changes, a more recent pan-European survey is not available[13]*.*

In terms of infrastructure, 86% of the Belgian GP practices use a computer. A similar situation can be found in relation to Internet connections: currently 84% of the Belgian GP practices have such a connection. In Belgium, broadband represents the most common form of access to the internet with 80% of GP practices resorting to broadband connections.

Local EHRs are common in Belgium. At least one type of individual data is stored in 84% of GP practices.

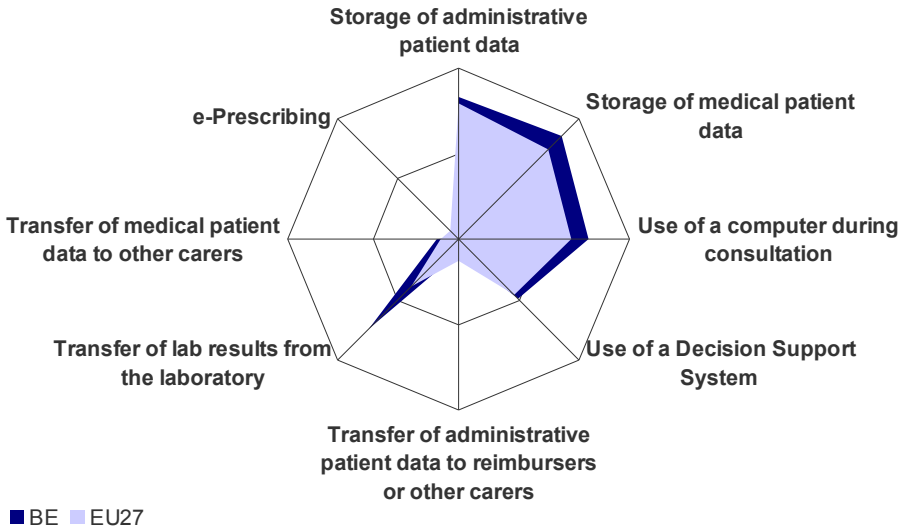
A computer is available in the consultation room of 76% of Belgian GP practices. Here it could for instance be used to display a patient's file to the practitioner, to explain medical issues to the patient by means of a photo or animation but also to run a decision support system helping in diagnosis or prescribing. Notwithstanding the relatively high availability, only about half of the GPs actually make use of a computer in consultation with the patient.

In Belgium the transfer of laboratory results is quite common. 73% of GP practices use a network to receive results from laboratories. Belgium is among seven other countries where rates over 70% are reached. 13% of the Belgian GPs use networks to exchange

[13] ICT and eHealth use among General Practitioners in Europe 2007

administrative patient data with other carers. Primary care is for 90% of the cases provided on the basis of a "fee-for-service", paid by the patient and reimbursed partially to that patient, so electronic communication between GP and insurers is unnecessary.

Figure 2[14]: eHealth use by GPs in Belgium



Indicators: Compound indicators of eHealth use (cf. annex for more information), % values. Source: empirica, Pilot on eHealth Indicators, 2007.

3 eHealth Strategies survey results

The following sections present the results of the eHealth Strategies country survey. In a first section, the eHealth policy actions undertaken in Belgium are presented. This is followed by a presentation of administrative and organisational measures taken. Section 3.3 presents results on key eHealth applications. Section 3.4 focuses on the technical side of eHealth, namely the role of patient and healthcare provider identifiers and the role of eCards. Legal and regulatory facilitators as well as financing and reimbursement issues are presented in the following chapters, 3.5 and 3.6. The report concludes with evaluation activities (3.7) in the country and an outlook (4.).

[14] The notion of „compound indicator" designates an indicator build from a set of other indicators/survey questions regarding the same topic. The compound indicator reflects an average calculated from different values. (see Annex 2) The final results of the study on eHealth Indicators is available at www.ehealth-indicators.eu.

3.1 eHealth policy action

The eHealth strategies of EU and EEA countries are not always labelled as such. Some countries may indeed publish a policy document which refers to the ICT strategy in the healthcare sector. Other countries such as France and Germany have enshrined the central eHealth activities in legislation governing the healthcare sector. In Germany, the relevant law is the law on the modernisation of healthcare; in France the introduction of an electronic medical record is included in a law concerning social security.

Sometimes, also documents from domains such as eGovernment or Information Society strategies may contain provisions which concern eHealth. In cases where the healthcare system is decentralised, i.e. where power is delegated to the regional level, there may even be strategy documents regarding eHealth from regional authorities.

3.1.1 Current strategy/roadmap

Belgium has no official national eHealth strategy, but several laws and policy decisions have contributed to the shaping of the general developments towards eHealth use. The health authorities followed a “de facto strategy” towards data sharing between general practitioners and other health professionals, based on the introduction of quality labelling for EHR systems, including patient summaries and data export as one of the main certification criteria. This “de facto strategy” was not limited to hospitals and primary care centres, but involved also paramedics (home nursing) and preventive care. Financial means like grants and investments were used in order to improve the efficiency of care and care documentation on the one hand and to improve sharing of patient and care related information between healthcare professionals and authorities on the other hand.

Health telematics commission since 1999

The laws and official documents related to eHealth do not mention nor refer to the EU eHealth Action Plan, especially as most of them preceded its publication, but they still addressed many of its declared aims: the introduction of eID, the decision for and the effective set-up of an eHealth backbone infrastructure (Governmental Decision of December 2004, Law of August 2008), the registry of health professionals, a legal initiative on electronic signatures, the labelling of EHR systems for GP's, for dentists, for nurses and for physiotherapists etc.

A commission for “Norms related to telematics in support of the healthcare sector“ was installed in 1999 by Royal Decree. The mission of the commission was to:

(1) advise the Minister of Health on the electronic data exchange of patient related data

(2) promote electronic exchange between the different actors in healthcare

(3) promote the use of the Electronic Health Record by healthcare professionals.

eHealth-platform since 2008

Following up on a government agreement in 2004 planning a “BeHealth-platform”[15], in 2008 a new public organisation, called "eHealth-platform"[16], was created by law.[17] Taking over the function and tasks of the above mentioned health telematics commission, it is

[15] Belgian Federal Government 2008

[16] La plate-forme eHealth 2008

[17] Law of 21 August 2008, published 13 October 2008.

intended to address important issues related to eHealth and to coordinate its development and roll-out. As such, the mission and assigned tasks of this organisation would be the most recent addition to Belgium's "de facto strategy". The (translated) mission statement of the organisation as formulated in the law is: "The eHealth-platform's mission is to optimise quality and continuity of care and patient safety, to favour administrative simplification for healthcare professionals and to support the national health policy. This should be accomplished by offering services and facilitating data exchange between the different stakeholders, with due respect to privacy and data security."

Tasks of the eHealth- platform

The following tasks are assigned to it:

(1) To develop, in coordination with public and private stakeholders, a vision and a strategy for efficient services and electronic data exchange, which are secure and respect patients' privacy.

(2) To define ICT related functional and technical specifications and standards as well as a basic architecture for ICT to support that vision and strategy.

(3) To verify compliance of EHR systems to these specifications and standards, and registration of the compliant systems.

(4) To develop, manage and promote basic ICT services, to be made available without charge, such as:

- a platform for secured electronic data exchange with appropriate access management and logging
- complementary services, such as: encryption services, user- and access management, secured email services for professionals, electronic time stamping, encoding and anonymisation of patient data, data reference services, storage of clinical patient data, subject to prior approval by the patient and the privacy authorities.

(5) To agree on the role of different actors and the quality of the data when collecting, validating, storing and accessing the data exchanged through the platform.

(6) To promote and coordinate projects which intend to realise the defined vision and strategy, using the data exchange and basic services developed by the eHealth-platform.

(7) To manage and coordinate ICT related, organisational, functional and technical aspects of data exchange related to EHR systems and electronic prescriptions.

(8) To provide "Trusted Third Party" services when collecting, processing, coding and anonymising personal data for "public institutions or instances" after approval by the competent privacy authorities.

(9) To promote compliance to the vision, strategy, functional and technical specifications, standards and eHealth basic architecture.

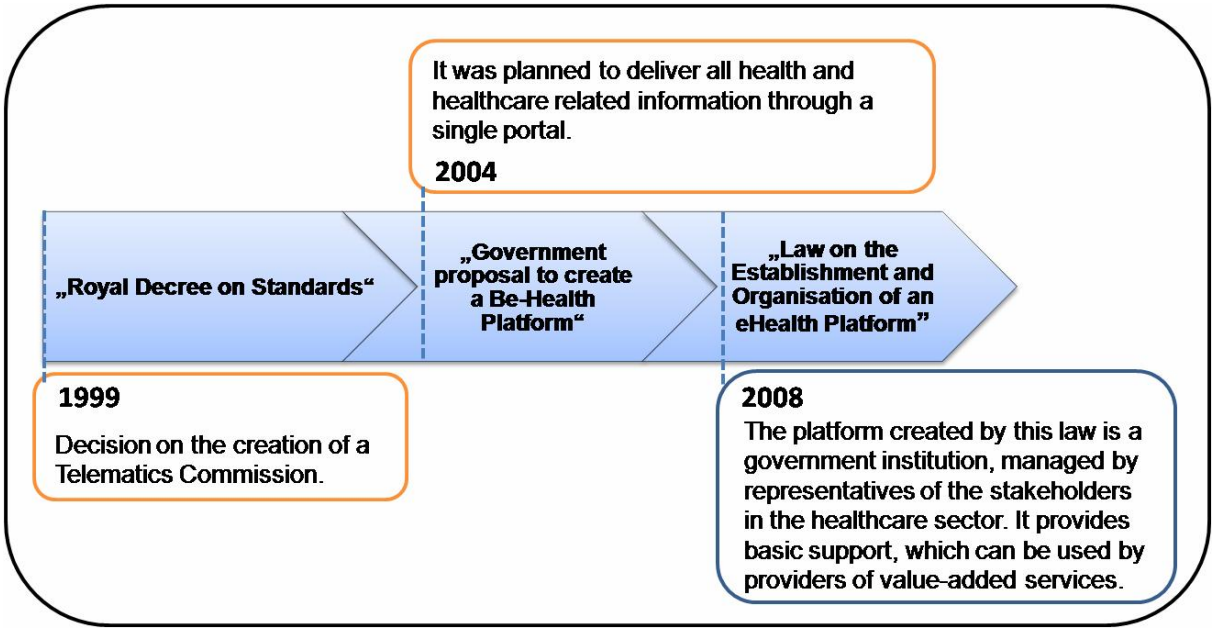
(10) To cooperate with other public agencies involved in coordination of electronic services.

Additionally there are regional initiatives as the Health Network (Gezondheidsinformatiesysteem, Belgisch Staatsblad 20060907) in the Flanders[18], with

[18] The Regional Decree of March 3rd 2004 created and initiated, as defined in Chapter 5 of the Decree, a regional network of exchange of patient data related to preventive care, involving preventive care health centres (public centres) and primary care professionals. The involvement of the primary care physicians has – until now – not been implemented, due to the lack of preliminary agreement between the "market" and the healthcare professionals. This Decree is only applicable to the Flemish region.

the ambition to centralise all relevant data regarding health epidemiology and preventive care, which are regional competences in Belgium[19].

Figure 3: Belgian policy documents related to eHealth



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3.2 Administrative and organisational structure

Apart from the above mentioned new **eHealth-platform organisation**, one other main actor shaping the Belgian eHealth development is the **Health Insurance Institute,** which was created by law in the 40s. As described in section 3.6 below on Financing and Reimbursement, they are, together with the Ministry of Health, the main providers of finance of public eHealth activities. Most projects and investments need to be approved by the competent professional committees functioning within that institute, e.g. by the representatives of the physicians and the sick funds regarding costs or investments related to primary care or hospital (curative) care.

In Belgium the main federal ministries responsible for eHealth are:

- The Ministry of Health and the Ministry for Social Security,
- The Ministry of the Interior: all matters linked to security.
- The Secretariat of state for administrative simplification (directly under the Prime Minister)
- The Secretariat of state for computerisation, which oversees FEDICT.

Other public services such as justice and public function are also involved but on an ad hoc basis.

[19] Devlies, Thienpont et al. 2006

Belgium is a federal state; thus some eHealth related issues are dealt with at the regional level. The Regions rather than the Communities have been active on the eHealth issues but with important differences from region to region. One can specifically mention the IBBT[20] (Interdisciplinary Institute for Broadband Technology) in Flanders and the CETIC (Centre of Excellence in Information and Communication Technologies) in Wallonia which are both active in e-health R&D.

Following the decision made by the Ministry of Health in 2006 to favour a distributed approach rather than a centralised one, development of regional networks on a voluntary basis has been strongly encouraged sometimes also with financial support from the regional governments. Networks already developed by and for healthcare professionals (in association with a non profit status) which use an open infrastructure include the Wallonia Health Network [21] or GZO in Flanders. Although this was mainly an hospital based initiative, links with the primary care sector have been established in order to have GPs on board.

In 2010, 98% of all Belgium hospitals will be connected to one network. All networks are to be interconnected thanks to the creation of a "meta-hub" managed by the E-health platform. No personal data will be stored in or exchanged through this platform which provides only needed references in order to make possible to retrieve personal information stored at local level. Essential regulatory aspects such as proof of a therapeutic link, management of patient consent and exclusion which were first developed at regional levels.

Private networks such as MediBRIDGE still remain however active. Let's also mention Carenet[22] which was initiated by the sick funds and is used mainly for the transfer of billing data between healthcare providers, insurers and pharmacies.

FEDICT, the Federal Public Service for Information and Communication Technology, has been playing a key role by developing the use of the Belgian smart card (e-ID), the national interoperability framework and supporting all e-government initiatives. Working with all federal entities, it plays an important stimulation role.

3.3 Deployment of eHealth applications

In general, the eHealth-platform is an important backbone for any kind of application deployment in the field of eHealth, as it is being structured as a collaborative framework, which is compatible with all types of healthcare data – also genomic data. As a result, personal medicine is likely to be fully integrated into the services delivered by the eHealth-platform. The key philosophy behind this framework is to avoid centralising information, but to facilitate data exchange between authorised parties, with anonymisation ensured where required.[23]

[20] IBBT

[21] Réseau Santé Wallon (RSW) 2010

[22] CareNet

[23] Eeckloo 2009

3.3.1 Patient summary and electronic health record (EHR)

In this study, the epSOS project's definition[24] of a patient summary was used as a general guideline. There a patient summary is defined as a minimum set of a patient's data which would provide a health professional with essential information needed in case of unexpected or unscheduled care (e.g. emergency, accident), but also in case of planned care (e.g. after a relocation, cross-organisational care path).

Lacking a standard definition, a patient's electronic health record (EHR) is here understood as an integrated or also interlinked (virtual) record of ALL his/her health-related data independent of when, where and by whom the data were recorded. In other words, it is an account of his diverse encounters with the health system as recorded in patient or medical records (EPR or EMR) maintained by various providers like GP, specialists, hospitals, laboratories, pharmacies etc. Such records may contain a patient summary as a subset. As of yet, fully-fledged EHR systems rarely exist, e.g. in regional health systems like Andalucia in Spain or Kronoberg in Sweden, or in HMOs (health maintenance organisations) like Kaiser Permanente in the USA..

It should be noted that in most policy documents reference is made simply to an "EHR" without any explanation of what is meant by it, thereby in reality even a single, basic electronic clinical record of a few recent health data may qualify. As a consequence, this section can only report on national activities connected to this wide variety of health-related records without being able to clearly pinpoint what (final) development stage is actually aimed for or has been reached so far.

The SUMEHR patient summary

The contents of the Belgian patient summary, called SUMEHR (Summarised Electronic Healthcare Record), were defined in 2003-2004. The patient summary is defined as a set of essential clinical care data exported by a general practitioner, who is administrator of the patient's global medical record. The content of the summary is meant to enable other healthcare professionals to provide appropriate care in case of an emergency or unexpected take-over, e.g. in on duty service. Currently, SUMEHR is feasible to be deployed at the ambulatory care level. Certification schemes for minimum quality and interoperability levels of authorised ambulatory care software systems have been developed in Belgium since 2002[25]. Those schemes currently cover GP, nursing and dentist software. The responsibility of the certification scheme has now been transferred to the E-Health platform.

In Belgium, nearly 90% of all lab results have been exported electronically since the late 80's, first on floppy disk and since 1994 by using a secured email service. Imaging reports are also exchanged electronically but to a smaller extent. The same applies for reports from medical specialists. In addition, several condition- or disease specific summaries / records have been developed and are used as an initiative of the National Healthcare Insurance Institute. They focus on specific and – by definition – expensive treatments. These summaries or centralised specialist records are intended to enable cost-efficiency evaluation of these treatments. Examples are arthritis patients treated with anti-TNF medication or some patients with hip- and/or knee-replacements. Another example of centralised reporting of patient data is the National Cancer Register. Most of

[24] European Patients Smart and Open Services (epSOS)

[25] Federal Public Service 2009

these summaries have to be considered as data subsets of the healthcare professionals' EHR system. See Annex 2 for a list of the SUMEHR contents.

The official start of dealing with the contents of electronic medical records was marked by the Law on "Social Affairs" in 1999[26], empowering the king to define minimal (quality/functional) criteria to medical / healthcare software in order to be homologated by the Ministry of Health. This law article applies to medical records as well as to nursing records. It defined the following topics to be addressed:

- the functions of the application
- the internal databases and the possibility to exchange their content (interoperability "avant la lettre")
- the structure of the patient record
- the coding schemes to be used
- statistical capabilities
- diagnostic decision support
- therapeutic decision support and support for the electronic medicinal prescriptions
- the kind of patient data to be exchangeable
- the use of the national social security (identification) card (SIS card)
- the social security "billing" functionality

Subsidy granted for SUMEHR use

The law also defined that a subsidy or bonus can be paid to healthcare professionals registering patient data and transferring (requested) anonymous data to the Ministry and/or the National Public Health Institute in accordance with these legal dispositions. General practitioners using a labelled EHR system, meeting essential quality criteria e.g. regarding the patient summary, are granted at present 810€ per year.

Planned virtual nation-wide access

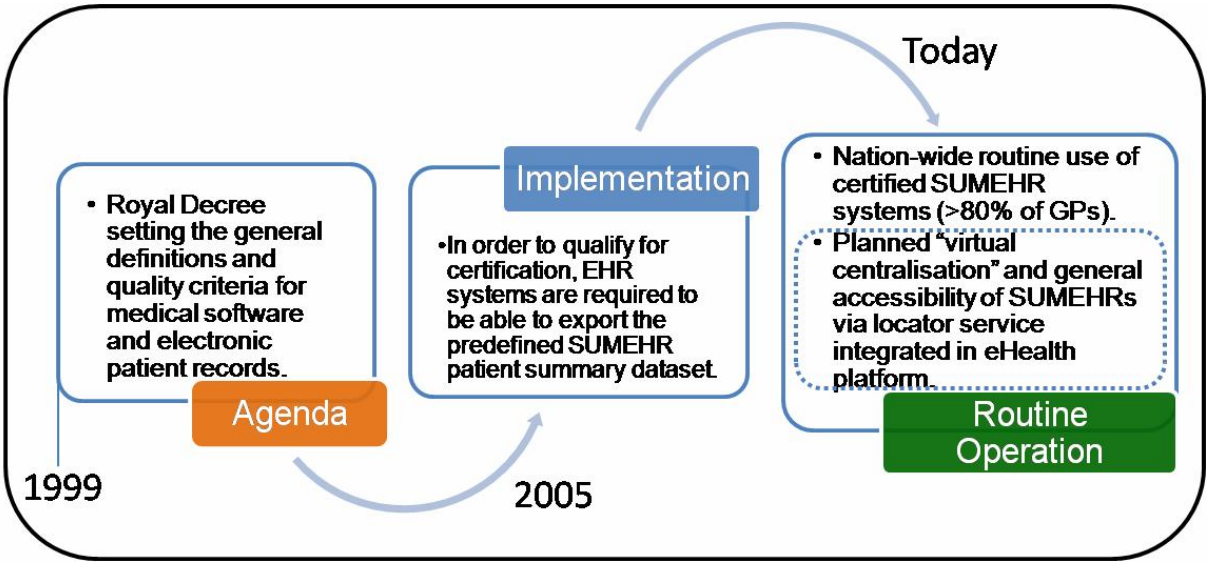
Since 2005, the certification criteria for quality labelled EHR systems for general practitioners require them to be able to export the SUMEHR patient summary.

There is now a good coverage of certified EHR systems throughout Belgium (>80% of all GPs), so the main challenge is to make the resulting summaries nationally accessible. So far, some regional and local initiatives have been started to this purpose. The eHealth-platform intends to coordinate these efforts by supporting the rollout of locator services and a patient master index identifying the location of the patient summaries. This way, the Belgian health authorities intend to make patient summaries nationally available by offering a "virtually centralised" medical record. So far, this will only apply to the SUMEHR patient summary, but considering the existing infrastructure, it might be possible in the future to extend the scope of the accessible data.

[26] Law on "Social Affairs" of January 25, 1999 RD (KB/AR), adding an Article 45 to the KB/AR 78. In addition, the Royal Decree (KB/AR) of 3 May 1999 defined the minimal content of a Hospital Medical Record, and was completed by the Royal Decree (KB/AR) of 16 April 2002. Such a record is to contain the following information: Identity of the patient; Personal health history; family health history; Actual diseases or problems or health issues; Data about / from previous patient contacts and hospitalisations; Results of clinical, imaging, lab, functional and histo-pathological test; Reports/advices from consulted health care professionals; Provisional and/or final diagnosis for the actual stay; Treatment. For surgical treatments (16 April 2002): the intervention's and anaesthetist's report; Evolution of the affection; If applicable the report of the autopsy; Copy of the discharge letter; Specific data regarding the use of "blood products".

Further key challenges will be to harmonise the EHR standards (see section 3.3.3 on standards), and to enhance the quality and accuracy of the patient data in the EHR systems, as well as keeping them updated. Training and education in the use of IT applications should help tackling these issues and encourage health professionals to make increased use of the records. Especially the take-up in hospitals is still on a lower level than with general practitioners, although this has begun to change in recent years.

Figure 4: Patient summary in Belgium



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3.3.2 ePrescription

In the framework of this study and following work in the epSOS project[27], ePrescription is understood as the electronic transfer of a prescription by a healthcare provider to a pharmacy for retrieval of the drug by the patient. In this strict sense, only few European countries can claim to have implemented a fully operational ePrescription service. In a wider sense, there are three different aspects of medication management.

Each of them has a different scope, implementation history and roll out in Belgium:

- the electronically produced (paper based) prescription,
- "intelligent" medication management including decision support when initiating a treatment as well as during its follow-up
- and the electronic transmission of an electronically produced prescription.

Electronic production of printed prescriptions is an essential part of all EHR applications on the market since the early nineties. This function was already included in the initial quality certification criteria of EHR systems for general practitioners. Over 80% of all accredited general practitioners use such a labelled EHR system. However, this does not

[27] European Patients Smart and Open Services (epSOS)

mean that all of the EHR system users actually make use of this feature. On average, between 40% and 50% of non-hospital prescriptions are produced by EHR systems.

Integrated decision support for producing prescriptions and follow-up treatment is implemented, at different degrees of sophistication, in all primary care EHR applications, including e.g. allergy and contra-indications management. The same holds true for the selection of medicinal products based on economic or mainly cost related criteria.

Electronic transfer so far only in hospitals

Electronic transmission of prescriptions is so far limited to in-house prescriptions in hospitals, and even there ePrescribing is only used with very limited success due e.g. to the complexity of dosing schemes in hospitals and due to administrative and security related burdens.

A first ePrescription pilot was implemented in the European FP6 ePrescript project, but it was not supported by the authorities, and acceptance by physicians and pharmacists was relatively low. So far, prescribers and patients have not been convinced that ePrescribing might generate any added value. The way ePrescribing was handled in the pilot project involved additional unpaid effort on the side of the prescribers. Furthermore, the absolute freedom of choosing at any time any pharmacy for each prescription hampers the implementation of ePrescribing, at least compared to the situation in countries with one dedicated pharmacy or with non-competing pharmacies. Other issues which would need to be addressed in order to promote ePrescribing are patients' fears of increased compliance control by the health authorities. There were also concerns that so far there is a lack of clear and credible official statements regarding secondary use or misuse of the prescription data.

New project scheduled

For a new ePrescription project funded by the National Insurance Institute (1.350.000€ over 3 years), a tender was issued in October 2009. The best offer was selected in January 2010 and the non-profit organisation Recip-e was founded on the 29th January 2010. The first field tests are scheduled at the earliest in 2011. General rollout of ePrescriptions in the sense of electronically transmitted prescriptions is expected for the end of 2012. The Recip-e pilot is an initiative of the health sector bringing together both public and private partners. Those partners are: the National Insurance Institute, the eHealth-platform, the technical private partner Belgacom-Accenture and several bodies representing the healthcare professionals. In the first phase the project will focus on the testing and national roll-out of ePrescription of medication, but in a second phase the infrastructure will be extended to all prescriptions for care.

3.3.3 Standards

Standards are not only crucial to enable interoperable exchange of meaningful information in the healthcare system; they also ensure secure access to patient records by healthcare providers and citizens. This study aims to identify, among other usage, standards related to the domain of health informatics, such as the SNOMED Clinical Terms or the LOINC terminology.

The eHealth-platform, created by law in 2008, has been endowed with competence regarding standards. It is mandated to "define ICT related useful functional and technical norms, standards, specifications and basic infrastructure required to support [the eHealth]

vision and strategy". However, the eHealth-platform is not the only institution dealing with standards. The Ministry of Health claims historical authority on content related standards, not only for medical care but also for nursing, physiotherapy, dental care and other medical professions. The National Health Insurance Institute claims authority on coding schemes, at least the ones directly or indirectly related to billing. Semantic Standards such as ICD10-ICPC2 had been proposed by the ex Telematica commission for GP practice but institutions kept on choosing or developing standards according to their needs. An initiative has been launched in 2009 in order to analyse the feasibility of a federal "terminology service" which would deal with all terminologies and classifications used in the country through the use of a federal CMV (Controlled medical vocabulary). Definition of responsibilities for the development and maintenance of this service- including links with European and international standardization organizations- are also part of the project deliverables. Specific projects aiming at selecting standards for nursing and physiotherapy practices in 2010 are ongoing. A LOINC based classification will be the official reference for laboratory tests requests and results[28]. Finally, Snomed CT, already in use in a few hospitals is now also being considered, at least as multi-mapping interface.

Challenges for standard use

Belgium is not a member of IHTSDO but is currently considering this possibility. Several technical and syntax standards are in use and a reduction of diversity might be desirable in the future. In general, the lack of free-of-cost availability is seen as detrimental to a wider usage of standards. Other perceived hindrances are the competition between standards, and the fact that often they are not available in all national languages. The usability of some standards is perceived to be limited because they were not specifically developed for clinical environments.

The following standards are officially endorsed in Belgian healthcare:

Official standards in Belgium:

ATC for the active substances of medicinal products

ICPC2 as terminology and classification for use in primary care

ICD-10 as terminology and classification extension linked to the ICPC2

ICD-9-CM still used for reporting to billing authorities and as basis of DRGs in hospitals (ICD-10-CM is recommended to replace ICD-9-CM)

KMEHR (Kind Messages for EHR) as xml based syntax standard, e.g. for electronic prescriptions and for the SUMEHR patient summary – this has been developed by the Belgian Health Telematics Commission.[29]

Furthermore, some other standards like HL7 v.2 are used without being officially endorsed, especially in hospital environments. The Ministry of Health developed an extended terminology (list of terms) that can be used in primary care (and eventually in

[28] Federal Public Service 2010

[29] Kind Messages for Electronic Healthcare Record (KMEHR)

secondary care) for data entry. These terms are coded in compliance with ICPC2 and ICD-10.

3.3.4 Telemedicine

The use of telemedicine applications is recognised as beneficial to enable access to care from a distance and to reduce the number of GP visits or even inpatient admissions. Commission services define telemedicine as "the delivery of healthcare services through the use of Information and Communication Technologies (ICT) in a situation where the actors are not at the same location"[30]. In its recent communication on telemedicine for the benefit of patients, healthcare systems and society, the Commission re-emphasises the value of this technology for health system efficiency and the improvement of healthcare delivery[31].

Tele-monitoring

So far, most initiatives are privately initiated. Telemonitoring is most prominent in the context of home care services for elderly people or patients with chronic diseases. Some specific telemonitoring applications are running for managing particular health conditions as, for example, pregnancy follow-up, and some cardiologic conditions. Two projects are dealing with chronic heart failure. Tele-surveillance or Tele-alarm services, another form of telemonitoring, are largely in use, considering the increasing number of elderly people living alone. The service providers of those PAS (Personal Alarm Systems) are mainly companies specialised in personal assistance (e.g. Touring, Mondial Assistance, IP-Assistance, Telesecours) and home care organisations (e.g. Yellow and White Cross, Telesenior).

Tele-consultation

Teleconsultation between patients and health professionals is still limited to phone contacts, and these consultations are not paid nor reimbursed by the Social Security.

Tele-radiology

Teleconsultation between health professionals is not specifically promoted, considering the relative proximity of specialists in densely populated Belgium. It is easy for healthcare professionals to contact other colleagues in an informal way. Teleconsultation is mostly used to attain a second opinion, especially for complex cases. But because such consultations between health professionals are not reimbursed, these services remain informal and mainly undocumented. A special case of teleconsultation is teleradiology. Belgian physicians offer commercial cross-border services in this field (www.euroradconsult.be). Other clinical teleconsultation services which are in some cases offered in Belgium are teledermatology, and telepathology, for which there exists an established service (www.bvpa.be).

Mobile monitoring

Mobile monitoring is being piloted in a number of running projects, the most important one being the project for the follow-up of patients with chronic congestive heart failure (www.belgium-hf.be). BELGIUM-HF, which stands for Better Efficacy in Lowering Events by General practitioner's Intervention Using remote Monitoring in Heart Failure, aims to cut back the re-hospitalisation rate through an innovative monitoring system for HF patients, with the assistance of general practitioners. The combination of GPs and

[30] Europe's Information Society 2009

[31] European Commission 2008

telemedicine makes this a unique, ambitious clinical trial from both the Belgium and the European perspective.

Call centres for patients exist for specific pathologies, e.g. mucoviscidosis, mostly initiated and maintained by patient organisations. Some of these organisations, e.g. the regional associations for diabetic patients, are granted some subsidies by the authorities. Other service centres are public initiatives as e.g. the "cancer line". There are also call centres of personal assistance service providers, as mentioned under above in the context of telemonitoring, and finally those offered by the pharmaceutical industry, the sick funds and the private insurers.

So far there has been no specific policy or implementation program regarding telecare and telemonitoring, but recently the National Health Insurance Institute (INAMI-RIZIV) initiated a call for proposals regarding telemonitoring. Six different projects (HF, COPD, hypertension and dementia) will be supported from 2010 on[32]. Examples for private or public scientific institutions which are involved in the development of telemedicine solutions are CETIC (www.cetic.be), IMEC (www.imec.be) and IBBT (www.IBBT.be).

A supplementary initiative is currently being considered by the Ministry of Health in order to support hospitals which propose innovative Home Hospitalizations projects. Wider spread legal or organisational initiatives are however not expected in the next few years, unless new options of funding will be made available for reimbursing such services.

Main tele-medicine challenges

Belgium is a small country with a relatively dense population. This means that most of the healthcare services are available "next door", so telecare is not perceived as the most pressing of issues. The main challenges in this sector identified in the i2010 report on Belgium are:

(1) Reimbursement issues: no reimbursement = no large scale implementation

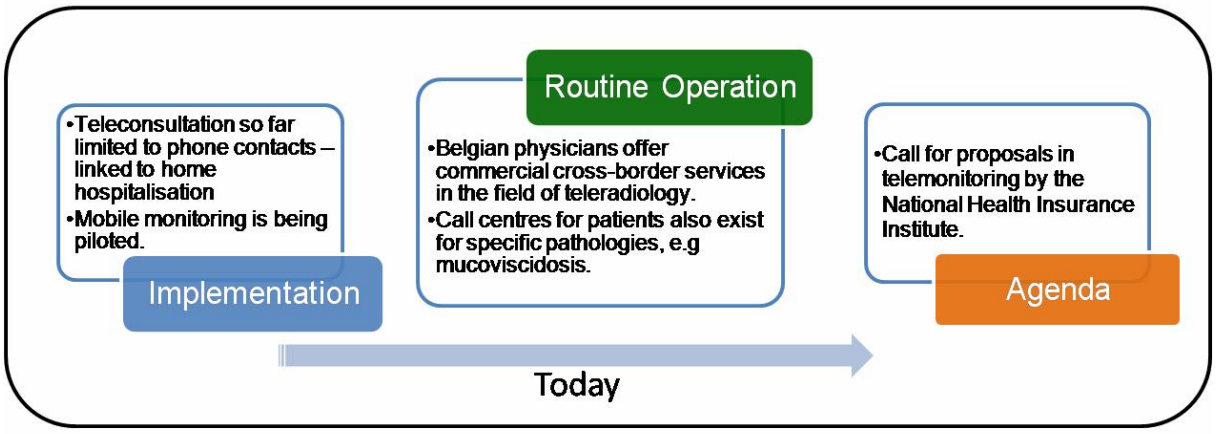
(2) Lack of awareness of possible advantages, politically as well as in the case of the potential users.

(3) Cost efficiency and user friendliness of the solutions.

The key developments in telemedicine services are summarised in Figure 5 below.

[32] RIZIV

Figure 5: Telemedicine services in Belgium



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3.4 Technical aspects of implementation

A key prerequisite for the establishment of an eHealth infrastructure is the ability to uniquely identify citizens/patients and healthcare professionals. This part of the survey deals with identifiers and how they are stored. This section does not deal with the tokens through which identification can or will take place. One such possibility would be via an eCard. This topic is dealt with in the following section. The current section focuses solely on whether or not unique identifiers are in place in Belgium and for which purpose.

3.4.1 Unique identification of patients

National ID number and centralised register

Unique identification of every legal inhabitant is common practice in Belgium. Assigning and using a national identification number (National Unique Identifier) started in 1968 (by the public administrations) and was legally endorsed on 8th August 1983, resulting in a centralised national register of physical persons. The register is maintained by the Ministry of Internal Affairs.

Additionally, every person entitled to healthcare or to social services has a national social security number (INSZ-NISS number – Identificatienummer Sociale Zekerheid – Numéro d'Identification Sécurité Sociale). The national identification number and the national social security number are identical for Belgian residents. Some groups of people are entitled to healthcare without being legal residents in the country. This applies to illegal immigrants, but also to foreigners who work in Belgium without permanent residence, or Belgian citizens living abroad. For these groups of persons, the national Cross-Bank for Social Security generates a specific social security number, the KSZ-BCSS number. KSZ-BCSS are the Dutch and French abbreviations for the national Cross-Bank for Social Security. The use of the National Unique Identifier is – officially – restricted to organisations entitled to do so by Ministerial Decision. The National Unique Identifier is – de facto – more widely used than authorised. The use of the National Social Security

Number has been mandatory since 1986 for data exchange between the hospitals and the payers, the Sick Funds. It is also mandatory for any kind of data exchange via the eHealth-platform. Healthcare enterprises, however, can internally use their own patient identification system. This was common practice until some years ago, but is now disappearing progressively.

3.4.2 Unique identification of healthcare professionals

There are several national registers of healthcare professionals in Belgium:

1. The oldest one is a register exclusively for physicians. It is maintained by the Order of Physicians, which is organised per province and has been created by a law of 25th July 1938. Through this organisation Belgian physicians received and still receive a “visum” and a related number at provincial level. This register is not electronically accessible.
2. The National Health Insurance Institute (INAMI-RIZIV) incorporated that older identifier in an extended unique healthcare professional identifier. This number is assigned to any healthcare professional entitled to provide healthcare services covered by the National Health Insurance. The identifier not only identifies the person as a healthcare professional. It also identifies the exact professional role (physician, nurse, physiotherapist, midwife, pharmacist etc.) and the professional specialisation (general practitioner, dentist, cardiologist, orthodontist etc.).
3. The most recent development in healthcare professional identification is a register set up by the Federal Ministry of Health, based on a law of 29th January 2003. This so called “cadaster” goes beyond payment related activities. It also specifies professional roles, and any professional activities via the eHealth-platform will require identification using that cadaster. The cadaster is, within the Belgian context, identified as a “validated authentic source”.

The next step is to integrate these means of identification into the developing eHealth activities. The eHealth-platform is developing a web service providing "integrated access" to any authorised healthcare provider. This service is not validated yet, but is expected to be routinely available in 2010.

3.4.3 The role of eCards

Citizen eCards

SIS card

At the moment, there are still two types of eCards in use in Belgium, which have relevance to the health sector. So far, the insurance status of a person is documented on the social security card (or "SIS card) which is issued by one of the sick funds in the National Federation of Sick Funds, which is initially chosen by the parents at birth. The management and administration of the cards is assigned to the CBSS – Crossroads Bank for Social Security. The Crossroads Bank coordinates data exchange / data flow between the different social security organisations (Mother and Child, Social Security, Sick Funds etc.).

The SIS card is a passive memory card for offline use, without cryptographic functions. It contains the unique INSZ-NISS patient identification as well as another unique patient identifier based on the patient's membership in one of the many sick funds. The card contains the following displayed information: Surname; First name and second first name; Date of birth; Sex; Social security number; SIS card number; Period of validity.

The following information, which is stored on the chip, is only accessible via validated card readers:

Identification of the Sick Fund of the patient; Membership number within that Sick Fund; Indicator to confirm the right of the patient to get healthcare and their conformity to the rules of health insurance (this means complying with the health insurance regulations, e.g. payment of contribution); Entitlement to third party payment

The SIS card is still required and used, but mainly as an identifying device. This card has been in use since 1998. It will now be phased out, and social security and health insurance status verification will be offered through the eHealth-platform as a value added web service, using the National eID card as access key providing identification. All functionalities related to the SIS card will become integrated into the eID.

National eID card

The national eID card[33] with the national eID number was introduced in 2004, and rollout to nearly all inhabitants of the country, citizens as well as foreign residents, has been finalised in 2009. The national eID cards are issued by the Federal Government in three different versions:

[33] be.ID

1. The standard eID card for each Belgian citizen

This eCard has the following visible content:

Name; Two first names and eventually first letter of the next first name; Date and place of birth; Sex; Nationality (being Belgian for that card); eID card number; Period of validity: in principle five years after being issued (depending on the age); Signature of the card holder; Photo of the card holder; National Unique Identifier (Number at the Register of Inhabitants); Place of issue of the card; Signature of the public servant.

The microchip contains additionally:

The main address of the card holder; Identity- and electronic signature keys; Identity- and electronic signature certificates; Identification of the certification service provider; Information that may be required for the authentication and for the protection of the readable data and certificates; Other legally required data.

2. The KidsID

The KidsID eCard is issued for children younger than 12 years. It includes the same features as the eID card for adults. In addition, the card presents a phone number for emergencies, which is operational 24/7. This number is linked to a code-protected set of personal contact numbers.

3. The eID for non-Belgian inhabitants

Several types of eID cards have been developed depending on the origin of the inhabitant (from inside the European Union or from outside the European Union), depending on the nature of residence (limited in time or permanent) and depending on the status of approval of residence in the country (approved or “under investigation”). The general content of the cards is similar to the eID card for Belgian citizens.

Crypto-graphic and access functions

Each holder of one of these cards has a unique ID number in the National Register of inhabitants mentioned in the section above. The eID card has cryptographic functions and is mainly used for identification purposes. It enables access to public e-services provided by the regions and the local communities (libraries, museum, etc.). Furthermore, it is used for tax purposes (tax-on-web) and for signing e-documents. It is not intended to contain any other information, e.g. emergency data, clinical information or the insurance status of the patient. Information of this kind will be made accessible on secured central servers, termed “validated authentic sources”.

The multipurpose eID card has a pin-protected chip[34]. The card has been personalised with a picture printed on the front of the card, as well as the name of the holder. The cards are produced using state-of-the-art fraud resistant techniques. City administrations act as registration authorities for their citizens, reducing fraud risk. Encryption related information is based on standard options: the public key stored in the chip is RSA 2048 compliant. The private key stored in the chip is RSA 1024 with CRT compliant. The decision not to store any clinical information on the card itself contributes to reducing the risk of damage in case of fraudulent use.

Main eCard challenges

The attention is now shifting towards the creation and availability of value added services accessible by using those eCards. The main challenge is to keep the root certification trustworthy and the root keys protected. Another challenge is the interoperability and ease of access to technical information on how to integrate and use the card. The card and supporting infrastructure have to be kept secure and up to the technical state-of-the-art without burdening third parties which integrate the use of the card in their applications too much with version incompatibilities or excessive changes. Technical problems with the chip on the eID card have been reported, when the chip detached from the card, thereby invalidating the card and introducing security risks should the "lost" chip lead to fraudulent use.

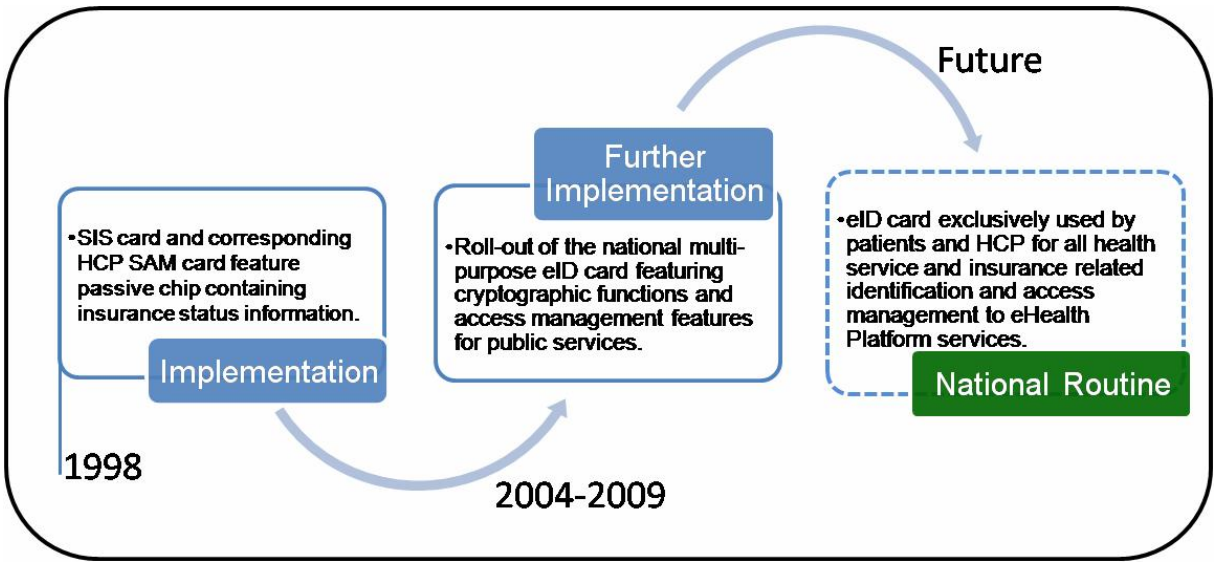
Professional eCard

There are no plans for the introduction of a specific electronic health professional card in Belgium. The Order of Physicians has been issuing a paper based identification card for physicians for several years, without any relation to eHealth. The INAMI-RIZIV issues professional cards (SAM cards) to identify healthcare professionals authorised to read the insurability information on the SIS cards. This approach will disappear together with the SIS cards. Identification of the healthcare professionals and their role in care will be based on the multipurpose National eID card, providing a secured link to the so called “cadaster of healthcare professionals” and to other secured services providing information on their professional roles and titles and on their role regarding the individual patient. The only smartcard project for healthcare professionals running at the moment in Belgium is a pilot for pharmacists.[35]

[34] Validated card readers able and accepted to read the eID are listed on www.cardreaders.be

[35] HPRO Card 2009

Figure 6: eCards in Belgium



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3.5 Legal and regulatory facilitators

Legal and regulatory issues are among the most challenging aspects of eHealth: privacy and confidentiality, liability and data-protection all need to be addressed in order to make eHealth applications possible. Rarely does a country have a coherent set of laws specifically designed to address eHealth. Instead, the eHealth phenomenon has to be addressed within the existing laws on professional liability, data protection etc.

Legislation on medical records

In Belgium, over 225 medical record related Royal Decrees have been issued, between January 1st 1999 and October 31st 2008. 25 of these were specifically dedicated to the "electronic medical record". The official start of dealing with the contents of electronic medical records was marked by the Law on "Social Affairs" in 1999[36], empowering the king to define minimal (quality/functional) criteria to medical / healthcare software in order to be homologated by the Ministry of Health. This law article applies to medical records as well as to nursing records. Another important piece of legislation regarding eHealth was the Royal Decree (KB/AR) of May 3rd, 1999, which created the commission for „Norms related to telematics in support of the healthcare sector." A decree of the same

[36] Law on "Social Affairs" of January 25th, 1999 RD (KB/AR), adding an Article 45 to the KB/AR 78. In addition, the Royal Decree (KB/AR) of 3rd May 1999 defined the minimal content of a Hospital Medical Record, and was completed by the Royal Decree (KB/AR) of 16th April 2002. Such a record is to contain the following information: Identity of the patient; Personal Health History; Family Health History; Actual Diseases or Problems or Health Issues; Data about / from previous patient contacts and hospitalisations; Results of clinical, imaging, lab, functional and histo-pathological test; Reports / advices from consulted health care professionals; Provisional and/or final diagnosis for the actual stay; Treatment. For surgical treatments (16 April 2002): the intervention's and anaesthetist's report; Evolution of the affection; If applicable the report of the autopsy; Copy of the discharge letter; Specific data regarding the use of "blood products".

date also defined the minimal content of a Hospital Medical Record, and was completed by the Royal Decree (KB/AR) of April 16th, 2002[37].

Legislation on ID cards

Legislation which helped prepare national identification registers and cards includes the law of 25th March 2003 on the legal framework of electronic ID cards. It modified the law of 8th August 1983 (organising a national registry of physical persons) and the law of 19th July 1991 (on population registers and identity cards). Additional specifications on the topic were provided by the Ministerial Decree of 26th March 2003 on the format of electronic ID cards, the Royal Decree of 1st September 2004 on the generalisation of electronic ID cards, and the Royal decree of 18th October 2006 on the eID document for Belgian children under 12.[38] Furthermore, the legislation on the electronic signature from 17th March 2003 defined certain legal aspects of information society services.

There is no specific law regarding telemedicine services. In this field, so far the general legal rules regarding care provision and privacy protection apply.

3.5.1 Patient rights

Patient rights, which are here mainly described in relation to medical records, are derived from two Belgian legislative sources: the Privacy Legislation (Law of 8th December 1992, published 18th March 1993, enacted regarding the processing of personal data by the Royal Decree of 13th February 2001, published on the same day[39]) and the law on patient rights[40]. Patient rights legislation has been adopted since 22nd August 2002, (publication 26th September 2002)[41].

Opting-in model for medical records

Patient rights legislation with relevance to the creation of electronic patient records in Belgium prescribes the opting-in model. This means that by law explicit consent is required (except in emergency medicine). However, the forms in which consent can be given are not clearly defined. It does not always have to be in written form. Consent can be implicit if the treating physician can reasonably derive consent from the behaviour of the patient (e.g. patients presenting themselves for a diagnosis and/or treatment). The collection of the data has to be fully in line with the privacy protection legislation of natural persons.

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[37] Please see footnote in Section 3.3.1. on patient summary for details.

[38] European Communities 2007

[39] On 11th December 1998, the Privacy Act was adapted to the European Directive 95/46/EC. The transposition of this directive into Belgian law led to fundamental changes in the Privacy Act, making a new implementing decree necessary. This Royal Decree lays down:

- the conditions authorizing the further processing of personal data for historical, statistical or scientific purposes;
- the conditions for processing sensitive data;
- the way in which a person whose data are processed may exercise his rights (access, rectification, deletion of his data);
- the way in which the automatic processing of personal data has to be notified."

Commission for the protection of privacy,
http://www.privacycommission.be/en/legislation/national

[40] Centre for Biomedical Ethics and Law of the Catholic University of Leuven

[41] In Belgium, there is a difference between the date of adoption of a law and the date of the publication of the law. A law applies at earliest when published in the official Journal. But usually, when indicating a specific the date of adoption is used.

Data access rights for patients

Citizens have a right to be informed of the information contained in their medical records. The information provided has to be clear. However, the patients can also exert their right "not to know" and the physician in charge can invoke "therapeutic exception rules" if he/she thinks that providing the information is detrimental for the patient. Both, patient or treating physician, can decide to involve a trustworthy "go-between" or a custodian. In that case, therapeutic exception can be waved in favour of the custodian. Personal notes made by the physician remain personal and do not have to be communicated, though the legal definition of "personal notes" is not clear.

Generally, the patient has read-only access to his/her patient record. However, according to patient rights legislation patients can demand that "documents" be attached to their medical record, but neither is the sort of document specified, nor is there any provision for patients making any additions themselves. Likewise, the patient cannot directly delete data, but he/she can demand deletion of data, hide certain types of information and bar certain healthcare providers from access to the healthcare record. According to privacy legislation, a citizen can either demand the correction, removal or forbid the use of personal data that is incorrect, incomplete, not fit for the purpose or unlawfully collected or kept (e.g. after expiry of the recording period). These rights are not mentioned in the legislation on patient rights. The patient keeps the right to withdraw his/her consent. Emergency medicine is in the first instance governed by the penal code (art 422bis) where life threatening situations are dealt with, often in a context without recurrence to consent or preferences of the patient and with insufficient time to contact a third party on his behalf.

Data access for patient representatives

A third party, for example parents or other family members or any other person related to the patient, cannot gain access to personal data without consent of the data subject, unless they have legal custody on the data subject (e.g. in case of minors or mentally handicapped persons). According to patient rights legislation, a citizen can consent and even demand that a trustworthy person has access to his medical personal data on this behalf. In the case of therapeutic exception, the treating physician can even propose this initiative himself.

Secondary data use

Secondary use of (patient) data is possible, provided that the rules in the Belgian legislation (which is an instantiation of the EU data protection directive) are followed. If personal health data are concerned, explicit patient consent is required in all cases where it can be obtained.

(Good guidelines are available at the website of the Belgian Data Registrar[42]. There are recommendations that whenever possible totally anonymous data should be used, if not, encoded (i.e. de-identified) data should be used. In a very last instance and under strict conditions, personal data can be used.)

[42] Commission for the protection of privacy

3.6 Financing and reimbursement issues

Alongside the Ministry of Health, the National Health Insurance Institute is the main source of finance of initiatives and projects stimulating the introduction of eHealth in general. The National Health Insurance Institute is funded by employers' mandatory contributions, which are deduced from salaries before taxation, and by the contributions of the self-employed. The State subsidies benefits for the socially weak (disabled, elderly, unemployed, etc…). Final decisions regarding investments and the funding of projects are mostly taken in official decision making bodies including representatives of the different stakeholders within the National Health Insurance Institute. Some stakeholders are less well represented in those committees or working groups than others, especially the actual users of IT solutions. In the past, this has sometimes resulted in a mismatch between their expectations and the options which have actually been decided on.

Main sources of eHealth funding:

National Health Insurance Institute

Ministry of Health

Project support through EC Structural Funds

eHealth-platform 5-year budget: €80m

For the funding of the first five years of the eHealth-platform, a budget of 80 million Euros has been agreed on. In 2009, the National Health Insurance Institute spent 9 million Euros on work on the eHealth-platform. Together with the Ministry of Health it hands out subsidies to the users of the certified EHR systems. The Ministry of Health pays mostly for infrastructure initiatives and interoperability. International funding happens mainly through EC Structural Funds supporting the participation of Belgian industry and research organisations in European eHealth projects.

The following eHealth related items were included in the public health budget of 2009:

Federal Ministry of Health

- 420.000€ for development of infrastructure and infostructure initiatives (semantic interoperability, regional networks, coding schemes) (Annual)
- 1.116.000€/year for telematic protocols and interconnectivity,[43] mainly between hospitals and primary care (Annual)
- 16.219.000€ for the promotion of Integrated EHR in Hospitals (Annual)

In cooperation with the National Health Insurance Institute

- 18.912.000€ subsidies for users of labelled EHR and/or practice management systems (GPs, home nursing, physiotherapists ...): Annual grant of 810€ per user of a system.
- 1.300.000€ to improve efficiency and mobility of nursing home care (2007-2011)

National Health Insurance Institute

- 1.350.000€ for ePrescription: project definition and initial deployment (2009-2012)

[43] Resident Assessment Instrument, a scale measuring invalidity in homes.

- 9.000.000€ eHealth-platform (7.000.000€ for specific IT investments)
- 300.000€ for the RAI[44] registration (disabled persons and elderly)
- 500.000€ for development and maintenance of a National Database of Medicinal Products for Ambulatory Care (all products that are not specific for hospitals): Annual
- 500.000€ telemedicine projects (2009)
- 5.000.000€ pilot projects cooperation / exchange with sick funds

One should however add funding made available by regional governments and funds allocated by public institutions to support electronic (mostly web-based) registration of data for secondary use purposes.

3.7 Evaluation results/plans/activities

From a public policy perspective, evaluation is a key activity in the policy-cycle. It provides insights into the success or failure of a policy or project and leads to new policy goals and new methods of implementation. The need for evaluation of eHealth policies and projects has been stressed time and again by the EC, not least in order to further the spread of eHealth in the process of healthcare delivery.

Evaluation activities in Belgium are not assigned to any specific institute. Generally, the Ministry of Health is competent to evaluate all activities related to the general provision of care, but it does not cover the complete set of activities. The regions are responsible for all aspects related to preventive and personal care. The eHealth-platform is expected to play an important role in the future, providing continuity in the policy and evaluation approach specifically regarding eHealth. In 2007, The National Health Insurance Institute had been conducting a survey targeted at GPs and specialists in order to evaluate main barriers to wider EHR use[45]. Extensive evaluations remain however currently projects-based: See for example, the Vinca project which aims at supporting mobility in home nursing care [46],

Ministry of Health is competent to evaluate

So far, some evaluation activities have been initiated for EHR systems and their accessibility via regional servers. Since the introduction of quality certification for EHR systems in 2005, several aspects of these systems have been under evaluation. The technical evaluation of the labelled EHR systems guarantees that all of them are able to export “validated” patient summaries, based on the Belgian standard definition SUMEHR. Such technical certification-related evaluation was conducted by a team of experts working under the supervision of the ex Telematica commission until 2007. Competence regarding certification moved to the eHealth-platform as defined in the law of August 21st 2008. Effective testing will be done by an independent organisation based on a tender issued in December 2009.

[44] Sam Delye 2010

[45] Institut national d'assurance maladie-invalidité [National Institute of Disability Insurance] 2010

[46] Federal Public Service 2010

Technical and functional evaluation at server level is ongoing for three regional servers (Réseau Santé Wallon, Abrumet and Gents Ziekenhuis Overleg). Access management is an essential part of that evaluation. This partially depends on developments at the level of the eHealth-platform, linking patient identification, care provider identification, patient consent and care team management. The latter is supposed to be based on a database of so called "therapeutic links" to be accessed through the platform. Those links are created according to a set of pre-defined rules[47]. Developing the validated authentic sources takes more time than initially expected, as does the process of making them accessible.

4 Outlook

Belgium has already achieved a good infrastructure foundation for further eHealth development. The government has legally established the quality criteria for certified EHR systems which are able to export a patient summary (SUMEHR) following a dedicated syntax standard (KMEHR). By now, over 80% of GP practices are equipped with these systems, although hospital usage is not yet up to this level of penetration. The next step forward would be to create nationwide accessibility of these patient summaries. The eHealth-platform organisation, which was installed by law in 2008, is in a good position to attain this goal by providing locator and index services via their internet platform services. For the five years following its creation, the eHealth-platform has been assigned a 80.000.000€ budget; this is complemented with investments in research and deployment projects by the National Health Insurance Institute and the Ministry of Health . The eHealth-platform is mandated by law to design a strategy and vision for eHealth data exchange, EHRs and ePrescription.

The use of certified EHR systems is being subsidised by the Ministry of Health and the National Institute of Health Insurance. An extension of these systems' SUMEHR functionality towards systems providing accessible full EHRs as well as an ePrescription option would be in line with the tasks of the eHealth-platform and can be facilitated by the most recent Belgian national identification solution. Unique identification and authorisation for the eHealth-platform services are foreseen to be handled through the national eID cards which have completed rollout in 2009. These multipurpose eCards feature cryptographic and electronic signature functionalities and can provide identification for access to a wide range of eServices via certified card readers and "Authentic Source" service providers through the eHealth-platform.

The combined assets of a dedicated, legally mandated eHealth organisation, secured funding earmarked in the next few years' budgets, a fully rolled-out ID system and a broad penetration of standardised EHR systems may contribute towards further implementation of the EU eHealth Action Plan's objectives in the coming years.

[47] eHealth platform 2010

5 List of abbreviations

CMV	Controlled Medical Vocabulary
DRG	Diagnosis Related Group
EC	European Commission
EEA	European Economic Area
EHR	Electronic Health Record
EMR	Electronic Medical Record
EPR	Electronic Patient Record
epSOS	European patients Smart Open Services
ERA	European Research Area
EU	European Union
FEDICT	Federal Public Service for Information and Communication Technology
GDP	Gross Domestic Product
GP	General Practitioner
HCP	Healthcare Provider
HL7	Health Level Seven International (authority on standards for interoperability)
HPC	Health Professional Card
ICT	Information and Communication Technology
ID	Identification (e.g. number, card or code)
IHTSDO	International Health Terminology Standards Development Organisation
INSZ/NISS	National Social Security Number
IT	Information Technology
KMEHR	Kind Messages for Electronic Healthcare Record [Syntax Standard for Patient Summary]
KSZ-BCSS	Kruispuntbank van de Sociale Zekerheid; Banque Carrefour de la Sécurité Sociale [Crossroads Bank for Social Security]
LSP	Large Scale Pilot
OCMW	Openbare Centra voor Maatschappelijk Welzijn [public social welfare institution]
OECD	Organisation for Economic Co-operation and Development

PAS	Personal Alarm System
PHS	Personal Health System
R&D	Research and Development
SIS card	Social Security Identification Card
SUMEHR	Summarised Electronic Healthcare Record
WHO	World Health Organization

6 Annex

Annex 1: Compound Indicators of eHealth use by GPs

Compound indicator name	Component indicators	Computation
Overall eHealth use	- Electronic storage of individual medical patient data - Electronic storage of individual administrative patient data - Use of a computer during consultation with the patient - Use of a Decision Support System (DSS) - Transfer of lab results from the laboratory - Transfer of administrative patient data to reimbursers or other care providers - Transfer of medical patient data to other care providers or professionals - ePrescribing (transfer of prescription to pharmacy)	Average of component indicators
Electronic storage of individual medical patient data	- A2a - Symptoms or the reasons for encounter - A2c - Medical history - A2c - Basic medical parameters such as allergies - A2d - Vital signs measurement - A2e - Diagnoses - A2f - Medications - A2g - Laboratory results - A2h - Ordered examinations and results - A2i - Radiological images - A2j - Treatment outcomes	Average of component indicators
Electronic storage of individual administrative patient data	- A1 - electronic storage of individual administrative patient	A1 value
Use of a computer during consultation with the patient	- B2 - Computer use during consultation	B2 value
Use of a Decision Support System (DSS)	- B3a - Availability of DSS for diagnosis - B3b - Availability of DSS for prescribing	Average of component indicators
Transfer of lab results from the laboratory	- D1e - Using electronic networks to transfer prescriptions electronically to dispensing pharmacists?	D1e value
Transfer of administrative patient data to reimbursers or other care providers	- D1a - Using electronic networks to exchange of administrative data with other healthcare providers - D1b - Using electronic networks to exchange of administrative data with reimbursing organisations	Average of component indicators
Transfer of medical patient data to other care providers or professionals	- D1c - Using electronic networks to exchange medical data with other health care providers and professionals	D1c value
ePrescribing (transfer of prescription to pharmacy)	- D1d - Using electronic networks to transfer prescriptions electronically to dispensing pharmacist	D1d value

Dobrev, Haesner et al. 2008

Annex 2: List of SUMEHR contents[48]

SUMEHR contents	
Date of creation	
Author	
Patient identification	
Patient presentation	* Family name
	* Forenames
	* Sex
	* Birth date

[48] Federal Public Service, Health, Food Chain Safety and Environment, http://tiny.cc/RUPol

	* Usual language
Contact person	
Risks	* Allergies
	* Adverse drug reactions
	* Social factors
	* Other factors
Relevant personal antecedents	* Standardisation: IBUI and ICPC-2 and ICD10
	* Begin date
	* End date
	* Text
Actual issues list	* IBUI and ICPC-2 and ICD10
	* Begin date
	* Text
Relevant medications	* CNK (Code National(e) Kode) or other Id (if no available CNK)
	* Administration information
	* Instructions for patient
	* Begin date
	* End date
	* Text
Vaccination status	* Administrated
	o CNK and/or ATC (Anatomical Therapeutic Chemical-code)
	o Date
	* To be administrated
	o CNK and/or ATC
	o Date
Contextual comment	

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