

Creation and implementation of the National eHealth Centre in the Czech Republic

SRSS/S2018/006

Component I.2

Study of European eHealth Strategies and National eHealth Competence Centres (NeHCs) in Europe

Version 1.1 of 28 June 2018

Author: Rachelle Kaye

Co-authors

Alexander Kollmann, Christian Rupp,
Stefan Sauermann (Austrian part)

Jan Petersen, Jakob Uffelman (Danish part)

Michaela Laktišová, Jan Tomášik (Slovakian part)

Support team: Marc Lange, Stephan Schug, Diane Whitehouse

(in alphabetical order)

Foreword and Acknowledgement

The report was written to give an overview of the European best-practice examples of NeHCs, basis for the SRSS project to create and implement a NeHC in the Czech Republic. The project is currently in the implementation phase and is funded by European Union via the Structural Reform Support Service (SRSS) of the Commission.

The project is split in two parts. First, the core framework for the NeHC and the options for its design will be set-up. Second, the NeHC supported by international experts – all in accordance with the Czech National eHealth Strategy and action plan – will be implemented.

The study, as basis for the decision finding for an adequate model for a Czech NeHC, was drawn up within 4 months from May to June 2018.

First of all, we would like to thank SRSS for enabling the project by financing it and also for its continuous support during the entire process.

Special thanks go to the main author of the study Rachelle Kaye from EHTEL for her intense research and preparation of the report. In addition, we would also like to thank the co-authors Alexander Kollmann, Christian Rupp and Stefan Sauermann for their contribution to the Austrian part of the study, Jan Petersen and Jakob Uffelman to the Danish part and Michaela Laktišová and Jan Tomášik to the Slovakian part.

Last but not least we would like to thank Marc Lange, Stephan Schuh and Diane Whitehouse from EHTEL for their support and efforts of the preparation of the study.

Without the collaboration and cooperation of all involved experts it would not have been possible to write this report. Thank you all for your valuable work!

Purpose and Limitations

The purpose of this report is to review national and international examples and studies on eHealth strategies and NeHCs to be taken into consideration as a sound basis for the project of Strengthening of the capacity of the Ministry of Health in the Czech Republic in its effort to set up a National eHealth Centre. This project is supported by the Structural Reform Support Service (SRSS) of the European Commission that has agreed to assist in the implementation of a Czech NeHC in response a request submitted to the SRSS by the Czech government.

This study is part of Component 1 of the project whose objective is to “set-up the core framework of the NeHC (framework development) and set-up options for the design of the NeHC (scenario optimization), specifying budget and human resource needs as well as define a Road Map to implement the chosen set-up option of the NeHC based on national legislation and on best international practices”. It aims to review best practices in the area of eHealth strategy and the establishment of national eHealth competence centres that can support the decisions that will need to be made by the Ministry of Health in the Czech Republic.

This report will focus on eHealth Strategies and NeHCs in the European Union only and will not include examples beyond the EU.

Background

There have been several attempts to introduce a functioning eHealth system in the Czech Republic in the past (2009, 2012). These attempts failed due to difficulties concerning the lack of a societal and professional consensus on how to address the issues of implementing eHealth solutions in order to link between patients and providers and between different providers. At present, and compared to other EU members, the introduction of eHealth is delayed in the Czech Republic. The Czech government is now making a renewed effort to solve these problems. In November 2016, the Czech government adopted a National eHealth Strategy. The establishment of the NeHC is an integral and basic part of this strategy. The strategy proposes to base the NeHC on European best practices following generally accepted European models and standards. In addition, the government has committed through a government's decision to adopt a law on a national eHealth system in the first half of 2018¹. (See Annex for the full report on the Czech eHealth Strategy and Proposed NeHC).

¹ The Czech Ministry of Health decided to develop the National eHealth Strategy (NeHS; http://www.nsez.cz/En/Soubor.ashx?souborID=29549&typ=application/pdf&nazev=National_eHealth_Strategy_v0.2_EN.pdf) in 2013 in accordance with the Government Resolution No. 318 of May 2, 2013.



Table of Contents

Purpose and Limitations	2
Background	3
1 eHealth Strategies in the European Union	8
1.1 European Commission Communication on eHealth – a Starting Point	8
1.2 Summary of the study by empirica commissioned by the European Commission in 2010	8
1.3 Progress Since 2010	11
1.4 Updating eHealth Strategies and Policies	11
1.5 Analysis of the evolution of eHealth Strategies Over the Years	22
1.5.1 2004-2010 – All about Infrastructure	22
1.5.2 2011-2013 – Still About Infrastructure but Moving Beyond	22
1.5.3 2014 – “Digitalisation” of Healthcare	22
1.5.4 2015- 2018 – Digitally enabled Service Transformation	22
1.6 New drivers for Strategic Change in eHealth	23
1.6.1 MHealth	23
1.6.2 Digital Single Market and digital transformation of health and care	24
1.6.3 Implications for future eHealth Strategies	26
2 Implementation of eHealth Strategies – Some Achievements	28
2.1 EHR Implementation has Progressed but There are Still Significant Gaps	28
2.2 Some examples of significant advances in eHealth implementation	30
2.3 Countries Still Facing Major Challenges in eHealth	32
3 National eHealth Competence Centres in Six Countries	35
3.1 England – NHS Digital	35
3.2 Finland – THL	39
3.3 Germany – Gematik	47
3.4 Lombardy Italy – Lombardia Informatica	55
3.5 Luxembourg - Agence eSanté	61
3.6 Netherlands – Nictiz	69
3.7 Comparison and Analysis of Similarities and Differences	75
3.7.1 Health Systems	75
3.7.2 eHealth Strategies	76
3.7.3 Organization	76
3.7.4 Functions	77

4	In-depth Studies of Austria, Denmark, Slovakia – Potential Models for the Czech Republic NeHC	78
4.1	AUSTRIA	78
4.1.1	The Austrian healthcare system	78
4.1.2	Brief description of the national/ regional eHealth Strategy	79
4.1.3	ELGA GmbH as the eHealth centre in Austria	87
4.1.4	Normative mandate – authority and responsibilities	87
4.1.5	Goals, objectives and responsibilities of the ELGA GmbH.....	88
4.1.6	Governance of ELGA and the ELGA GmbH.....	89
4.1.7	Organizational structure and staffing of the ELGA GmbH.....	91
4.1.8	Relationship with stakeholders	94
4.1.9	Financing and Budget	95
4.1.10	Actual accomplishments.....	96
4.1.11	Limitation, challenges, barriers (and how they have been overcome).....	96
4.2	DENMARK	120
4.2.1	The Danish Healthcare system	120
4.2.2	Brief description of the national or regional eHealth strategy	121
4.2.3	Description and role of the eHealth Centre as defined in the Strategy.....	123
4.2.4	MedCom as a part of the Danish eHealth Centre	126
4.2.5	Sundhed.dk, the Public National eHealth Portal, as a part of the Danish eHealth Centre	128
4.2.6	Governance of the eHealth Centres	129
4.2.7	Organizational Structure and Staffing.....	131
4.2.8	Relationship with stakeholders	131
4.2.9	Financing and Budget	132
4.2.10	Actual accomplishments.....	133
4.2.11	Limitations, challenges, barriers and how they have been overcome	137
4.2.12	Lessons learned.....	138
4.3	SLOVAKIA	140
4.3.1	Brief Description of the Healthcare system.....	140
4.3.2	National Centre of Health Information	143
4.3.3	Organizational structure and governance over the eHealth project.....	144
4.3.4	Financing and budget.....	145
4.3.5	Actual Accomplishments	145
4.3.6	Relations with stakeholders.....	147
4.3.7	HICs.....	148
4.3.8	Limitations, challenges and barriers	151

4.3.9	5-years eHealth Strategy.....	152
4.3.10	Strategic goals	153
4.4	Some additional lessons learned from Austria, Denmark and Slovakia	154
5	Challenges and Considerations.....	156
5.1	Challenges	156
5.1.1	Achieving the right balance between consensus building and decision-making.. ..	156
5.1.2	Achieving the right balance between privacy and sharing clinical information for better patient care	156
5.1.3	Engaging Physicians When and How	157
5.1.4	eHealth is a means to an end – not an end in itself	157
5.2	Considerations in Establishing an NeHC	157
5.2.1	Legal status.....	157
5.2.2	Budget:	158
5.2.3	Stakeholder engagement	158
5.2.4	Standardisation processes:	158
5.2.5	Mapping	158
5.2.6	Strategy development:	159
5.3	Getting Started.....	159
6	Annex – eHealth in Czech Republic	160
6.1	The Czech Healthcare system	160
6.1.1	Organization and governance	160
6.1.2	Financing	160
6.1.3	Physical and human resources	161
6.1.4	Provision of services	161
6.2	Brief description of the national or regional eHealth strategy	162
6.3	The eHealth Centre as defined in the Strategy	165
6.3.1	Background and requirements to meet the strategic objective.....	166
6.3.2	The impacts of the fulfilment of individual specific objectives within the context of the strategic objective.....	166
6.3.3	Outputs of the fulfilment of specific objectives	166
6.3.4	Indicators of achieving the strategic objective	167
6.3.5	Barriers and risks of implementation (impact of the zero option of strategic objective).....	167

1 eHealth Strategies in the European Union

1.1 European Commission Communication on eHealth – a Starting Point

While a number of European countries began their eHealth journey some years earlier, this report uses the European Commission Communication of 2004² as a starting point for the 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” (eH-AP), Member States of the European Union (EU) committed themselves “to develop a national or regional roadmap for eHealth.” In 2010, empirica GmbH, Bonn, Germany, a private research and consultancy firm, was commissioned by the EC Directorate General Information Society and Media, Directorate ICT Addressing Societal Challenges, ICT for Health Unit, to perform an eHealth Strategies study to analyse policy development planning, implementation measures and progress achieved with respect to national and regional eHealth solutions in EU and EEA. The study was published in January 2011³.

1.2 Summary of the study by empirica commissioned by the European Commission in 2010

The countries surveyed by the empirica team and included in the report included 27 European countries: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, United Kingdom with its four home countries England, Northern Ireland, Scotland and Wales.

The report indicates that at the time of the study, almost all EU countries had detailed documents outlining concrete eHealth goals, implementation measures, and sometimes also already past achievements, in line with eH-AP objectives⁴.

- Patient summary or electronic health record (EHR) - like systems were a priority already in 2006 for all Member States.
- Other solutions high on the agenda were the electronic transfer of prescriptions, the provision of telehealth services and a growing establishment of permanent administrative support structures.

² European Commission (2004). eHealth - making healthcare better for European citizens: An action plan for a European eHealth Area. Brussels: COM(2004)356 final.

³ Karl A. Stroetmann, Jörg Artmann, Veli N. Stroetmann, Denis Protti, Jos Dumortier, Sarah Giest, Uta Walossek, Diane Whitehouse: European countries on their journey towards national eHealth infrastructures: Final European progress report, January 2011, downloaded March, 2018 from www.ehealth-strategies.eu/report/report.html.

⁴ Ibid p.vi.

In terms of implementation, the study found that:

- EHR-like systems had been implemented or were under development in many healthcare provider organisations, and also in various regional healthcare systems. They generally cover patient data from within their own organizational or regional boundaries. Fully-fledged regional EHR systems already existed or were in advanced stages of realisation in some regions like Kronoberg or Norrbotten in Sweden, Lombardy in Italy and in a few Finish regions. The DIRAYA system in Andalusia represented a truly global benchmark, becoming the first true regional EHR system for a significant sized population (over 8 million) fully integrating all patient information from primary to tertiary care including emergency and in-patient care, also connecting all pharmacies, their logistics and billing⁵. However, in larger European countries there were hardly any at the national level. The majority (20 of 34) of European countries surveyed were still at the planning stage.
- Patients rarely had access to their own medication profiles or were able to reorder certain repeat medications themselves, e.g. via the web
- ePrescribing was a key application which 22 Member States mentioned as a part of their national eHealth strategy, fully in line with the eH-AP. A necessary condition for this to occur was the recording of medications in the prescribing doctor's office electronic medical record (EMR) or other system in order to generate an electronic document – i.e. - the medication prescription, to be transferred via communications connections to a specific pharmacy or a regional or national ePrescription repository. At the time of the study only a few countries had implemented a fully operational national system, and these were mainly in primary care, i.e. did not include medications dispensed in hospitals. At the national level, a full ePrescription process was used routinely only in Denmark, Estonia, Iceland, and Sweden⁶.
- The value of Telehealth or telemedicine was emphasized by the EC in its 2009 Communication on telemedicine for the benefit of patients, healthcare systems and society for health system efficiency and the improvement of healthcare delivery⁷. All countries surveyed reported at least small local telehealth or telemedicine experiments or plans to undertake such pilots⁸.
- Stakeholder involvement was mentioned in most strategies and the study found that many countries had set up advisory bodies involving professional associations, patient

⁵ Ibid p. 22.

⁶ Ibid p. 25.

⁷ Telemedicine for the benefit of patients, healthcare systems and society COMMISSION STAFF WORKING PAPER SEC (2009)943 final, downloaded March 2018 from http://www.cupid-project.eu/sites/default/files/Staffworkingpaper_Telemedicineforthebenefitofpatientshealthcaresystemsandsociety.pdf June 2009.

⁸ Stroetmann et al., European countries on their journey towards national eHealth infrastructures: Final European progress report, January 2011, downloaded March, 2018 from www.ehealth-strategies.eu/report/report.html p. 29.

representatives, third party payers or care providers as part of their eHealth governance structures

- Electronic patient identifiers (ID) were an element of eHealth strategies in most countries - 26 at the time of the survey. From an implementation perspective, all citizen cards issued by European countries to be used in an eHealth context were only electronic health insurance cards, not eHealth cards in the proper sense of carrying medical information. eCards as a token for professional ID and as access means to eHealth systems increased.
- In most countries the use of eHealth was being regulated only by the general legal framework, in particular, by laws on patient rights and data protection, and by regulations on professional conduct. Amongst the forerunners in designing a legal framework adapted to the use of eHealth were Denmark, England, Estonia, Finland, France, Norway, Scotland, Slovak Republic and Sweden. Almost all countries that did not have specific regulations with regards to one or more fields of eHealth, such as Austria, Cyprus, Latvia, Malta or Portugal, did have some regulation on health data, if only through the transposition of article 8 of the EU Data Protection Directive.
- Across Europe, the primary sources of funding for eHealth were government or quasi-public sources, e.g. the general budget for health, as well as dedicated ICT budgets or special levies on statutory health insurances. Recurring public budgets dedicated specifically to “the reimbursement of eHealth services” (eH-AP) were still the exception in 2010, whereas there was widespread use of projects-based sourcing.
- Almost all countries had some type of national body directly responsible for eHealth standards development or for overseeing standards development and implementation. Ministries of Health and their respective units play a key role in some countries, e.g., the Directorate of Health in Iceland, the Ministry of Health in Italy, the National Board of Health and Welfare in Sweden, the Department of Health Informatics Directorate (DHID) in England. In others, they complement partially the activities of other actors, like in Belgium, where the Ministry of Health is dealing with content-related standards for several medical professions, and the National Health Insurance Institute with coding schemes related to billing.
- In other countries, national competence authorities or similar agencies had been charged with responsibilities for assuring technical interoperability and harmonised national standards, like ELGA GmbH in Austria, the eHealth Foundation and the Centre for Standardisation in Estonia, ELOT S.A. in Greece, the Quality Agency of the National Health Service of the Ministry of Health in Spain, the Hungarian Standards Institute in Budapest, the Centre for Health Economics in Latvia, the Centre for Information Systems in Healthcare (CSIOZ) in Poland, or the Health Informatics Standards Board in Slovenia. In some countries, a national panel or institutional body was authorised explicitly by law to take decisions about eHealth standards, like the eHealth-Platform in Belgium or the Health Information and Quality Authority (HIQA) in Ireland.⁹ These same

⁹ Ibid p. 37-38.

bodies, in many of these countries, were also responsible for, or partners to eHealth strategy development and their implementation.

The Analysis by empirica as well as the results of a validation workshop in the fall of 2010 in Brussels, which was attended by: representatives of Member States and other European countries, national health authorities and competence centres, stakeholder associations, vendors, and European health policy and eHealth experts, identified seven key success factors:

- Leadership
- Focus on health professional and stakeholder engagement and needs
- Establishment of trust
- Regional rather than national focus
- Reliable infrastructure
- Training
- Impact assessment and evaluation

1.3 Progress Since 2010

Eight years have passed since the completion of the “empirica” study. A review of the situation in all of the EU countries reveals that in many countries, significant progress has been made while in others, eHealth implementation is progressing more slowly.

1.4 Updating eHealth Strategies and Policies

Almost all EU countries published eHealth strategy documents in the years immediately following the EC Communication (2005-2008). Countries that have published new or updated eHealth strategy documents since then are:

- 2010 – Belgium, Luxembourg, Portugal, Spain and Sweden
- 2011 - Italy
- 2012 - Croatia, France, the Netherlands,
- 2013 – Austria, Estonia,
- 2014 – Denmark, Greece, Ireland, England, Malta, Romania, Slovakia
- 2015 – Finland, Wales
- 2018 – Scotland¹⁰

¹⁰ My major source for this information was the WHO Observatory Directory of eHealth policies/national ehealth strategies at <http://www.who.int/goe/policies/countries/en/>. However, it is only updated until March 2016 and therefore I also surfed the web looking for additional information, particularly relative to countries where other sources indicated that eHealth strategies had been recently updated.

Some of the countries that have not published official documents formally updating their eHealth strategies, have nonetheless continued to progress in implementation, as will be reported in the following sections

The following is a brief summary of the updated eHealth strategies by year of publication:

2010

- **Belgium**

La plate-forme eHealth: proposition de stratégie 2011-2013 - Date of publication: 2010

This document provides an environmental analysis, a SWOT analysis and outlines in detail the ten strategic objectives required to successfully implement the proposed eHealth strategy. The objectives include developing a vision and strategy for the provision of services and exchange of electronic information, while respecting the protection of privacy, in close consultation with various public and private healthcare stakeholders. It also outlines the need to determine standards and ICT functional and technical specifications as well as a useful basic architecture for the implementation of ICT in support of this vision and strategy¹¹.

- **Luxembourg**

National Health Luxembourg Roadmap November 2013 – 2016¹² was apparently published in 2010 prior to the decision of the Luxembourg Government in 2010 to create a national agency that would be in charge of implementing its eHealth digital platform). The Healthcare Reform Law passed in December 2010 laid the legal basis for the establishment of Agence eSanté, which became operational in 2012. The Roadmap addresses all of the basic issues including governance, standards, platform services alignment and prioritization of the services of the Platform to the uses and needs of providers of care, data security and privacy.

- **Portugal**

RSE – Registo de Saúde Electrónico, Plano de Operacionalização - Date of publication: 19 February 2010

Portugal's eHealth objectives are embodied in the strategic plan of the central administration unit for health systems (ACSS) published in 2010. This is a follow up to the plan for the transformation and integration of health systems (PTS) that was released in 2007 followed by a comprehensive action plan for implementing electronic

¹¹ WHO national ehealth strategies <http://www.who.int/goe/policies/countries/en/>.

¹² Downloaded in May 2018 from https://www.esante.lu/portal/fr/gallery_files/site/508/509.pdf.

health records in 2008. The ACSS was established in 2007. One of the main goals of ACSS was to develop an information system and the infrastructure needed to support it. Additionally, it also aims to effectively and rationally manage available economic and financial resources. The ACSS made available to all citizens a fair amount of information on hospitals, primary care centres and other NHS institutions and projects¹³.

- **Spain**

ICT in the National Health System 2010 - Date of publication: 2010

This document is an update to the original ICT plan in the National Health System - Healthcare Online programme. It covers the National Health System basic data, progress regarding healthcare centres connectivity, the electronic prescription program, electronic health records and outlines how eHealth fits into the Avanza Plan. The Avanza Plan was an initiative launched by the Spanish government to accelerate Spain's integration into the Information Society, to increase productivity, strengthen the Information and Communication Technologies (ICT) sector, promote R&D and consolidate modern and interoperable public services based on ICT use. Since 2006, all the various Ministries and all the Regional Health Services have been working together on the development of the Online Healthcare program¹⁴.

- **Sweden**

Nationell eHälsa 2010 – strategin för tillgänglig och säker information inom vård och omsorg - Date of publication: 2010

This document is the national eHealth strategy for accessible and secure information in health care. It builds on the National IT Strategy for healthcare that was decided by the Government in 2006 and acknowledges that the work is now entering a new phase. It covers the next steps required, the National strategy focus areas, new conditions for the national eHälsarbetet and how to best monitor progress. It also outlines the Municipalities' implementation of the Strategy and provides an overview of progress in the EU and the international arena¹⁵.

2011

1. Italy

The National eHealth Information Strategy - Date of publication: 2011

¹³ Simões J, Augusto GF, Fronteira I, Hernández-Quevedo C. Portugal: Health system review. Health Systems in Transition, 2017; 19(2): pp. 88-89.

¹⁴ WHO national ehealth strategies <http://www.who.int/goe/policies/countries/en/>.

¹⁵ Ibid.

Produced in 2011, this strategy proposes a new National Health Information System (NSIS) as the national information framework. This system is the reference system at national level for determining quality, efficiency and appropriateness of measures concerning the National Healthcare System (SSN). The NSIS is aimed at allowing the achievement of governance, service and communication objectives at a national, regional and local level. The areas identified as having significant priority are: health services booking system, electronic health record system, online transmission of sickness certificates, ePrescribing, dematerialization and telemedicine¹⁶.

2012

1. Croatia

Nacionalna strategija razvoja zdravstva 2012. - 2020. - skraćena inačica - Date of publication: 2012

The National Health Care Strategy 2012-2020 includes a section on 'Informatisation and eHealth' beginning on pg. 51. The strategy suggests that with more than 17,000 existing users of the Central Health Care Information System in Croatia (CEZIH) and a large number of information systems makes a good basis for informatisation of the entire health care system in Croatia. By introducing e-prescription and e-referral in 2011 millions of electronic referrals and results of laboratory examinations have been exchanged in the system. A solid foundation has been set for the implementation of a central electronic health record for patients which is the next step.

2. France

Projet De Loi portant réforme de l'hôpital et relatif aux patients, à la santé et aux territoires France numérique 2012-2020 - Date of publication: 2012

The national eHealth objectives of France are embodied in a legislative bill regarding patients, health and modernisation of health facilities. The Strategy for the French digital economy 2012 - 2020 also includes a statement of new initiatives supporting the development of eHealth and telehealth. The strategy also describes the elements of interoperability and security required and acknowledges that telemedicine relies on communication networks whose quality must be defined and assessed according to the nature of this activity. The strategy suggests utilizing videoconferencing devices, media exchange data flows teleconsultation, tele-expertise and remote support, the other acts of medical monitoring to achieve the goals of the strategy.

3. Netherlands

¹⁶ Ibid.

Nationale Implementatie Agenda (NIA) eHealth 2012-2015 - Date of publication: June 2012

The Dutch National Implementation Agenda for eHealth was released in June of 2012. It sets out a three years plan centred around self-management by patients and care substitution initiatives'. Other issues addressed include using personal health records, developing data exchange standards, and preparing a long-term research and innovation agenda.

Nationale Implementatie Agenda (NIA) eHealth 2012-2015: website¹⁷.

2013

1. Austria

It is assumed that Austria published an updated Health Strategy document as in the WHO national eHealth strategies website there is reference to “Austria’s ICT Strategy 2014-2018”.¹⁸ In addition, in 2012, the Austrian Parliament passed legislation to introduce the Austrian Electronic Health Record (ELGA). Subsequently, ELGA was included as an operative target in the 2013 health reform, The ELGA web portal gives patients and health providers – including hospitals, ambulatory care providers, pharmacies and nursing care facilities – access to medical information covering prescribed medicines and medicines dispensed by pharmacies (‘e-Medikation’) as well as discharge letters from hospitals, and laboratory and imaging results (‘e-Befunde’). Patients can opt out of ELGA entirely or restrict access to selected information and are able to see who has consulted their individual record.¹⁹

2. Estonia

Eesti infoühiskonna arengukava 2013 - Date of publication: 2013

eHealth objectives in Estonia are addressed through the Estonian Information Society Strategy 2013 which links to the National Health Plan. Broad objectives for eGovernment (including health and social services) are presented along with examples of citizen access portals. Legislation exists in Estonia which obligates health service providers to forward medical data to the national information system as is the use of the national ePrescription system.

¹⁷ Ibid.

¹⁸ WHO national ehealth strategies <http://www.who.int/goe/policies/countries/en/>.

¹⁹ State of Health in the EU: Austria Country Health Profile 2017 p. 15 downloaded from http://www.euro.who.int/__data/assets/pdf_file/0004/355873/Health-Profile-Austria-Eng.pdf?ua=1.

2014

1. Denmark

National Strategy for Digitalisation of the Danish Healthcare sector 2013-2017 - Date of publication: 2014

With this National “Making eHealth work” Strategy, the Danish government, Local Government Denmark and Danish Regions continue their collaboration for digitalisation. The strategy outlines the ambitious and binding common commitment for future work. The strategy comprises five focus areas: healthcare services delivered in new ways; digital workflows and processes; coherent patient pathways; better use of data and governance. Each section provides a brief status on the area, describes challenges, and sets out goals for efforts within the individual area. Each section also contains descriptions of specific initiatives that are to be carried out in the short term in order to realise the strategy²⁰.

2. Greece

Πολιτική για την Ηλεκτρονική Υγεία : Προκλήσεις-Ευκαιρίες-Εμπόδια OR: Policy for Electronic Health: Challenges-Opportunities-Obstacles - Date of publication: 2014

The Greek Ministry of Health referenced the European framework of priorities for the development of eHealth actions and a summary of the proposed strategy and completion of the institutional framework in this area has been produced. It outlines the integration of electronic prescribing, the pilot implementation of Condensed Health History (Patient Summary) and two eHealth related research programs.

Supporting website - Greek Ministry of Health

3. Ireland

eHealth Strategy for Ireland - Date of publication: 2014

The purpose of the eHealth Strategy for Ireland is to provide an outline of eHealth and demonstrate how the individual citizen, the Irish healthcare delivery systems - both public and private - and the economy as a whole will benefit from eHealth. It shows how the proper introduction and utilisation of eHealth will ensure; the patient is placed at the centre of the healthcare delivery system and becomes an empowered participant in the provision and pursuit of their health and wellbeing. The strategy identifies a set of objectives to be achieved and proposes a roadmap for their implementation within an outcomes-based delivery model. It outlines a proposed governance and delivery structure and defines a specific set of actions

²⁰ WHO national ehealth strategies <http://www.who.int/goe/policies/countries/en/>.

that address areas such as funding, resources, stakeholder engagement among others, and also looks at an initial set of priority eHealth projects.

Supporting website - Department of Health

4. England

The power of information: Putting all of us in control of the health and care information we need - Date of publication: 21 May 2012

This strategy sets a ten-year framework for transforming information for health and care. It aims to harness information and new technologies to achieve higher quality care and improve outcomes for patients and service users. Underpinned by the Health and Social Care Act 2012, it covers public health, healthcare and social care in adult and children's services in England. The strategy spans information for patients, service users, carers, clinicians and other care professionals, managers, commissioners, councillors, researchers, and many others. Information and transparency are intended to drive up standards, leading to safer, more integrated care and more effective prevention of ill health²¹.

A new eHealth strategy and Policy was published in 2014 by the National Information Board. Established by the Department of Health, the NIB was a new body which brings together national health and care organisations from the NHS, public health, clinical science, social care and local government, together with appointed lay representatives. It is charged with developing the strategic priorities for data and technology in health and care to deliver the maximum benefit for all citizens and patients and to make appropriate recommendations for investment and action. The NIB helps take forward the ambitions of the Care Act 2014, the Government Digital Strategy (2013), the Department of Health's Digital Strategy: Leading the Culture Change in Health and Care (2012)³ and the proposals in the Department of Health's Power of Information (2012)²².

5. Malta

The National Health Systems Strategy for 2014–2020 was adopted in September 2014, the first since 1995. It sets out key objectives to address the challenges facing the health system, namely: responding to the demands posed by demographic changes and epidemiological trends; increasing equitable access, availability and timeliness; improving quality of care; and ensuring fiscal sustainability.

The vision underlying the Strategy is that of a 'whole of society' approach to health improvement and building sustainable health systems grounded on healthy communities in line with the WHO European Health Policy – Health 2020. The Strategy focuses on

²¹ Ibid.

²² Personalised health and care 2020: A framework for action.

strengthening prevention and primary care, making better use of technologies, harnessing existing resources and further developing health system governance to ensure the development of a sustainable health system that respects the fundamental principle of equitable access for all. The rollout of the myHealth service since 2012 enables patients and doctors to access electronic medical records through a nominated doctor of their choice and an e-ID card, thus strengthening continuity of care for patients. Investment plans have been drawn up for an integrated portfolio of eHealth systems that include the creation of electronic patient records in primary health care, e-prescription services and patient registries²³.

6. Romania

Strategia de e-Sănătate a Ministerului Sănătății - Date of publication: unknown

Romania outlined ehealth requirements in the MOH Strategic plan in 2008. More recently, a strategy was published recommending strategic goals related to implement eHealth nationwide²⁴.

The 2014–2020 National Health Strategy

The key medium-term planning tool in the health sector is the National Health Strategy (Ministry of Health, 2014) which focuses on: public health, health services and system-wide measures, setting key objectives for each. In addition to public health goals, there are also commitments to increase efficiency through eHealth and reduce inequities in access by developing the health care infrastructure. Reforms are expected to reduce pharmaceutical expenditure as well as to improve overall health system funding. Other efficiency-oriented objectives are to implement eHealth solutions, shift resources from hospital-based care towards preventive and primary care; and to centralise procurement procedures²⁵.

7. Slovakia

Health care planning is based on the newly introduced Strategic Framework adopted by the MoH and the Slovak government in July 2014. For the first time the Strategic Framework for Health 2014–30 determines the medium- and long-term direction of Slovak health policy and formulates goals and areas of priority. It furthermore stresses the effective exchange of information (including through the use of eHealth solutions) between hospitals and other

²³ State of Health in the EU Malta Country Health Profile 2017 OECD, European Observatory on Health Systems and Policies p 15. http://www.euro.who.int/__data/assets/pdf_file/0004/355990/Health-Profile-Malta-Eng.pdf?ua=1.

²⁴ WHO national ehealth strategies <http://www.who.int/goe/policies/countries/en/>.

²⁵ State of Health in the EU Romania Country Health Profile 2017 OECD, European Observatory on Health Systems and Policies. Pp. 8, 13.

http://www.euro.who.int/__data/assets/pdf_file/0008/355994/Health-Profile-Romania-Eng.pdf?ua=1.

health care facilities, while ensuring the continuity of health care when transferring patients between different environments (including health care providers, home, etc.).

Although a new law on a National eHealth Information System was adopted in 2013, Slovakia still lacks a credible health information policy and reliable and accessible data. There are several data collection systems that suffer from a lack of systematic and institutionalized data processing capacity. A notable exception is the reference pricing system for pharmaceuticals, which is accessible for all players, while data are transparent and collected systematically. According to the Act on the National Health Information System adopted in 2013, the database for all health information is anchored on four pillars: (1) national health administrative data – the national register of health care providers and the national register of health professionals, (2) the national health registers (see Box 2.2), (3) detection of events characterizing the health status of the population and (4) statistical reports in health care. In accordance with the 2013 legislation, the NCHI is in charge of implementing the eHealth strategy, including authorized electronic communication, electronic prescription, electronic patient records, reporting of medical procedures and systematic data collection²⁶.

2015

1. Finland

eHealth and eSocial Strategy 2020 - Date of publication: 2015

The objective of the Finland eHealth and eSocial Strategy 2020 is to support the renewal of the social welfare and health care sector and the active role of citizens in maintaining their own well-being by improving information management and increasing the provision of online services. To achieve these ends, it is essential to make active use of information related to social welfare and health care services and to refine it into knowledge that will support both the service system and individual citizens.

Additional/supplementary information - Health Strategy and Action Plan of Finland in a European Context

2. Wales

Informed Health and Care: A Digital Health and Social Care Strategy for Wales – date published 2015

This strategy outlines how Wales will use technology and greater access to information to help improve the health and well-being of the people of Wales. It describes a Wales where

²⁶ Smatana M, Pažitný P, Kandilaki D, Laktišová M, Sedláková D, Palušková M, van Ginneken E, Spranger A (2016). Slovakia: Health system review. Health Systems in Transition, 2016; pp. 34-38.

citizens have more control of their health and social care, can access their information and interact with services online as easily as they do with other public sectors or other aspects of their lives, promoting equity between those that provide and those that use services in line with prudent healthcare and sustainable social services. It describes a Wales where health and social care professionals have access to the same digital tools in the workplace as they enjoy at home or would in other industries, so they are able to focus on delivering safe, high-quality, efficient care and plan for workforce and service change based on digitally-enabled approaches,

The Vision has four pillars:

- **Information for you:** People will be able to look after their own well-being and connect with health and social care more efficiently and effectively, with online access to information and their own records; undertaking a variety of health transactions directly, using technology, and using digital tools and apps to support self-care, health monitoring and maintain independent living.
- **Supporting professionals:** Health and social care professionals will use digital tools and have improved access to information to do their jobs more effectively with improvements in quality, safety and efficiency. A 'once for Wales' approach will create a solid platform for common standards and interoperability between systems and access to structured, electronic records in all care settings to join up and co-ordinate care for service users, patients and carers.
- **Improvement and innovation:** The health and social care system in Wales will make better use of available data and information to improve decision making, plan service change and drive improvement in quality and performance. Collaboration across the whole system, and with partners in industry and academia will ensure digital advances and innovation is harnessed and by opening up the 'once for Wales' technical platform allow greater flexibility and agility in the development of new services and applications.
- **A planned future:** Digital health and social care will be a key enabler of transformed service in Wales. Joint planning, partnership working and stakeholder engagement at local, regional and national level will ensure that the opportunities and ambitions outlined in this strategy are prioritised, with planning guidance issued by Welsh Government in 2015

2018

1. Scotland

Scotland's Digital Health & Care Strategy: Enabling, Connecting & Empowering – Date published - April 25, 2018

This is a joint strategy for Scotland across national government, local government and the NHS. The Digital strategy for Scotland sets out to enable Scotland's people and services to fully maximise the potential of digital, by ensuring that digital is at the heart of everything they do. Scotland's overall digital strategy provides the lead for: supporting digital transformation

by delivering public services that meet the needs of the public; effective use of data; developing standards and assurances; improving and extending our broadband and mobile networks; increasing digital participation; making sure Scotland is a world leader in cyber resilience.

Enabling this requires working collaboratively across six key areas, or domains:

- National Direction and Leadership
- Information Governance, Assurance and Cyber Security
- Service Transformation
- Workforce Capability
- National Digital Platform
- Transition Process

By July 2018, Scotland will establish a national decision-making Board made up of Executive representatives of the Scottish Government, Local Government and the NHS, with additional support and advice from industry, academia and the third sector. This Board will drive forward this agenda by:

- Making key national decisions, including on areas such as the standards required to deliver interoperability and information sharing across health and care.
- Agreeing on the financial framework for implementation.
- Identifying priorities for development and improvement.
- Overseeing and coordinating developments to ensure coherence, address risk of duplication, and maximise synergies and efficiencies.
- Reviewing and streamlining existing groups, networks and committees.
- Monitoring and reporting on delivery of this strategy at periodic intervals.
- Overseeing the development of a measurement framework and support for benefits realization and evaluation.
- Establishing appropriate structures to manage individual programmes of work.
- Overseeing adherence to standards, compliance, transition etc
- Sharing best practice and identifying opportunities for collaborative working and embedding new ways of working through appropriate fora.

National and other organisations with responsibility for implementing elements of this strategy will report regularly to the Board on technology and innovation in health and social care²⁷.

²⁷ SCOTLAND'S DIGITAL HEALTH & CARE STRATEGY: ENABLING, CONNECTING & EMPOWERING, Crown copyright 2018, pp. 4-9. www.gov.scot, Downloaded May 2018 from <https://beta.gov.scot/publications/scotlands-digital-health-care-strategy-enabling-connecting-empowering/>.

1.5 Analysis of the evolution of eHealth Strategies Over the Years

While there are significant disparities among countries, as some have moved more rapidly than others in implementing and advancing their eHealth implementation and strategies, there are several trends that stand out that signal both the evolution of eHealth technologies and how they are being adopted and embedded in National and Regional strategies within the EU. The following are brief observations of trends reflected in the eHealth strategies of European Countries during the past decade.

1.5.1 2004-2010 – All about Infrastructure

The strategies that were developed during this period were strongly influenced by the EC Communication on eHealth in 2004 – “making healthcare better for European citizens: An action plan for a European eHealth Area”, Strategies focused on developing the basic infrastructures for implementing electronic health records at the healthcare provider level and exchange of electronic information among providers, electronic identifiers for patients and professionals, electronic prescriptions, telemedicine and telehealth, standards and functional specifications, legal issues, creating governance structures and financing for eHealth

1.5.2 2011-2013 – Still About Infrastructure but Moving Beyond

The strategies published in this period placed emphasis on moving from organizational and regional systems to National Information systems and setting up central electronic health records at a national level. Some countries even enacted legislation mandating providers to forward medical data to the national information system. The movement toward national systems raised issues such as interoperability among existing ICT systems, and data security. Strategies placed increasing emphasis on telemedicine and telehealth, patient portals and Personal Health Records – giving patients access electronically to their own medical information and using eHealth as a self- management tool.

1.5.3 2014 – “Digitalisation” of Healthcare

Strategies published in 2014 began to use new terminology, signalling a change in the way countries were thinking about eHealth. Strategies began to use the term “digitalization of Healthcare” including digital workflows and processes and patient pathways. Strategies also addressed a better use of data including the integration of information from diverse healthcare delivery technology-based systems, leading to a fully integrated digital ‘supply chain’ involving high levels of automation and information sharing. There was increasing emphasis on patient centred care including patients, their carers and their systems and the integration of monitoring devices and sensors.

1.5.4 2015- 2018 – Digitally enabled Service Transformation

The most recently updated strategies put forth a vision that was almost inconceivable in the early 2000s. No longer do we talk only about health care but about health and social care and the integration of the two – supported by digital systems. The focus is even more

strongly on patient -centred care, but also empowering health and social care professionals - using digital tools and apps. Mobile technology is almost taken for granted and, from an infrastructure perspective – the goal is extending broadband and mobile networks. The Digital revolution is perceived as a key mechanism for service transformation – bringing care to the citizen – wherever he might be. Many systems have already developed or are developing comprehensive electronic databases and thus we have entered the era of “big data” and strategies for the effective use of data – for patient care and improving the efficiency of care systems using digitally supported approaches, such as risk stratification and predictive medicine. Cyber security has become a key issue and States are setting innovation leadership objectives for themselves in this “brave new world”.

1.6 New drivers for Strategic Change in eHealth

1.6.1 MHealth

The EC’s Green Paper on mobile Health defines mHealth as: “medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices”. It also includes applications (hereafter “apps”) such as lifestyle and wellbeing apps that may connect to medical devices or sensors (e.g. bracelets or watches) as well as personal guidance systems, health information and medication reminders provided by SMS and telemedicine provided wirelessly²⁸.

Of all the above, the mobile device that has become the most ubiquitous - an omnipresent and pervasive part of our daily lives - is the mobile phone. The number of mobile phone users in the world is expected to pass the five billion threshold by 2019. In 2016, an estimated 62.9 percent of the population worldwide already owned a mobile phone. The mobile phone penetration is forecasted to continue to grow, rounding up to 67 percent by 2019. Most of the mobile market growth can be attributed to the increasing popularity of smartphones. By 2014, around 38 percent of all mobile users were smartphone users. By 2018, this number is expected to reach over 50 percent. The number of smartphone users worldwide is expected to grow by one billion in a time span of five years, which means the number of smartphone users in the world is expected to reach 2.7 billion by 2019²⁹.

Healthcare IT News noted in an article by Jack McCarthy on September 23, 2015 that with some 165,000 health-related apps available, a mere 36 comprise nearly 50 percent of downloads, according to a study by the IMS Institute for Healthcare Informatics that analysed 26,000 apps.

²⁸ GREEN PAPER on mobile Health (“mHealth”) {SWD(2014) 135 final}.

²⁹ Downloaded from “Statista” The Statistics Portal Statistics and Studies from more than 22,500 Sources in June 2018 from <https://www.statista.com/statistics/274774/forecast-of-mobile-phone-users-worldwide/>.

The major reason for this, it seems, is that just 10 percent can connect to a device or sensor while a mere 2 percent sync into providers' systems -a functionality that could greatly improve both accuracy and convenience of data collection.

There is growing interest in the use of mHealth apps for chronic disease management, with almost a quarter focused on this segment. And providers are showing encouraging signs of interest, with more than a third of physicians reporting having recommended an mHealth app to patients³⁰.

In the “EHTEL Response to the Public consultation on the Commission's Green Paper on mobile health”³¹ in July 2014 prepared by the EHTEL Board of Directors based on a consultation with all EHTEL Members, the first recommendation of EHTEL was to differentiate mHealth in clinical settings from mHealth apps belonging to the wellness domain. By clinical settings, EHTEL refers to the use of mHealth technologies in an environment under the supervision of health professionals e.g. to access personal health data in an Electronic Health Record (EHR) residing at the healthcare provider's infrastructure (concept of integrated apps), support health coaching for chronic patients, collect health data remotely for clinical monitoring purposes and support patients in their adherence to medical prescriptions.

It is this use of mobile technology as an integral part of health and social care that is gaining traction in eHealth strategies such as Denmark, Wales, Finland and Scotland among others, and it would appear to have the greatest potential for service transformation. The use of mobile technology within this context will most likely have the most profound effect on eHealth strategies in the near future. As noted in a recent PWC report – Emerging mHealth: Paths for Growth: “If mHealth succeeds in delivering such things as a greater focus on prevention, better monitoring of chronic conditions and patient-centred care, its impact will be dramatic.”³²

1.6.2 Digital Single Market and digital transformation of health and care

The Digital Single Market Strategy for Europe (COM(2015)192 final) was published on 5th May 2015 by the European Commission. It was endorsed by the President of the European Commission, Jean-Claude JUNCKER, with the words:

³⁰ <http://www.healthcareitnews.com/news/how-many-health-apps-actually-matter>.

³¹ The EHTEL Response to the Public Consultation of mHealth” can be found on the EHTEL website at <https://www.ehtel.eu/references-files/ehtel-briefing-papers-pdf/EC%202014%20mHealth%20consultation%20-%20EHTEL%20response%20v1-0.pdf/view?searchterm=EHTEL%20Response%20to%20the%20Public%20consultation%20on%20the%20Commission%27s%20Green%20Paper%20on%20mobile%20health>.

³² <https://www.pwc.com/gx/en/healthcare/mhealth/assets/pwc-emerging-mhealth-full.pdf>.

“Enhancing the use of digital technologies and online services should become a horizontal policy, covering all sectors of the economy and of the public sector.”

The European digital single market covers three ‘pillars’:

- Better access for consumers and businesses to online goods and services across Europe
 - this requires the rapid removal of key differences between the online and offline worlds to break down barriers to cross-border online activity.
- Creating the right conditions for digital networks and services to flourish
 - this requires high-speed, secure and trustworthy infrastructures and content services, supported by the right regulatory conditions for innovation, investment, fair competition and a level playing field.
- Maximising the growth potential of the European Digital Economy
 - this requires investment in ICT infrastructures and technologies such as Cloud computing and Big Data, and research and innovation to boost industrial competitiveness as well as better public services, inclusiveness and skills.

eHealth was mentioned under the parameters of the third bullet on the growth potential of the European digital economy, particularly in terms of:

- The relationship of eHealth with future (new) technologies, such as the Internet of Things, the cloud, and big data.
- A focus on interoperability and standardisation and revision/extension of the European Interoperability Framework

On 25th April 2018 the European Commission published the Communication on Digital Transformation of Health and Care in the Digital Single Market that identifies three priorities:

- Citizens’ secure access to their health data, also across borders
 - enabling citizens to access their health data across the European Union (EU).
- Personalised medicine through shared European data infrastructure
 - allowing researchers and other professionals to pool resources (such as data, expertise, computing processing and storage capacities) across the EU.
- Citizen empowerment with digital tools for user feedback and person-centred care
 - using digital tools to empower people to look after their health, stimulate prevention and enable feedback and interaction between users and healthcare providers.

As a result of the European Union’s commitment to the Digital Single Market and the digital transformation of health and care, Member States will likely be encouraged to:

- Expect a European Commission review of the role of the eHealth Network in relation to eHealth digital infrastructure, and its operational requirements, and improving the interoperability of patient data and citizen access.

- Follow the text of a (future – as yet undated) Commission Recommendation on the technical specifications for a European electronic health record exchange format.
- Continue to implement relevant European legislation (e.g., the General Data Protection Regulation).
- Work within the eHealth Digital Service Infrastructure to enable new services such as the exchange of electronic health records using the specifications of the European electronic health record exchange format, and the use of the data for public health and research.
- Use funds from the Connecting Europe Facility and Horizon 2020 programmes.
- Consider future collaboration between Member States and between regions on the cross-border exchange of health data and its possible expansion.

1.6.3 Implications for future eHealth Strategies

Both the rapid assimilation of mobile technology into everyday health and social care as well as the activities and ultimately new communications and regulations arising from the Digital Single Market and the digital transformation of health and care will accelerate the existing trends in advancing eHealth implementation in the European Member States and will need to find expression in future eHealth policy and strategy plans and their implementation.

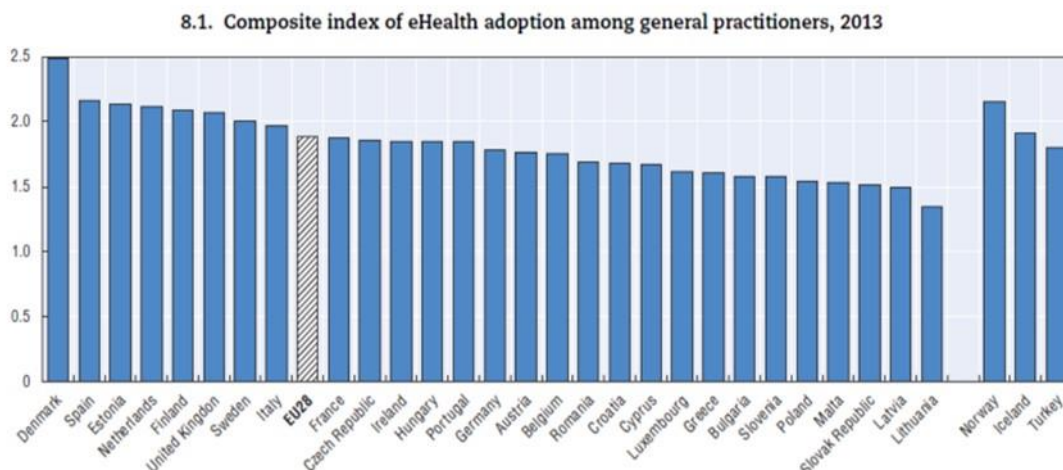


2 Implementation of eHealth Strategies – Some Achievements

Strategy is all about thinking ahead, having a vision, developing goals and planning. But ultimately, the “pudding is in the eating” – plans have to be implemented. We have looked at the evolution of eHealth strategies from 2004-2018, but what has actually been successfully implemented?


2.1 EHR Implementation has Progressed but There are Still Significant Gaps

A 2013 European Commission survey examined the adoption of eHealth in general practice. The following figure shows the composite scores for the surveyed countries:³³



Note: The maximum score for this indicator is 4.

Source: European Commission (2013), “Benchmarking Deployment of eHealth Among General Practitioners”.

StatLink  <http://dx.doi.org/10.1787/888933430057>

Health at a Glance: Europe 2016 State of Health in the EU Cycle. OECD Publishing <http://www.oecd.org/health/health-at-a-glance-europe-23056088.htm>

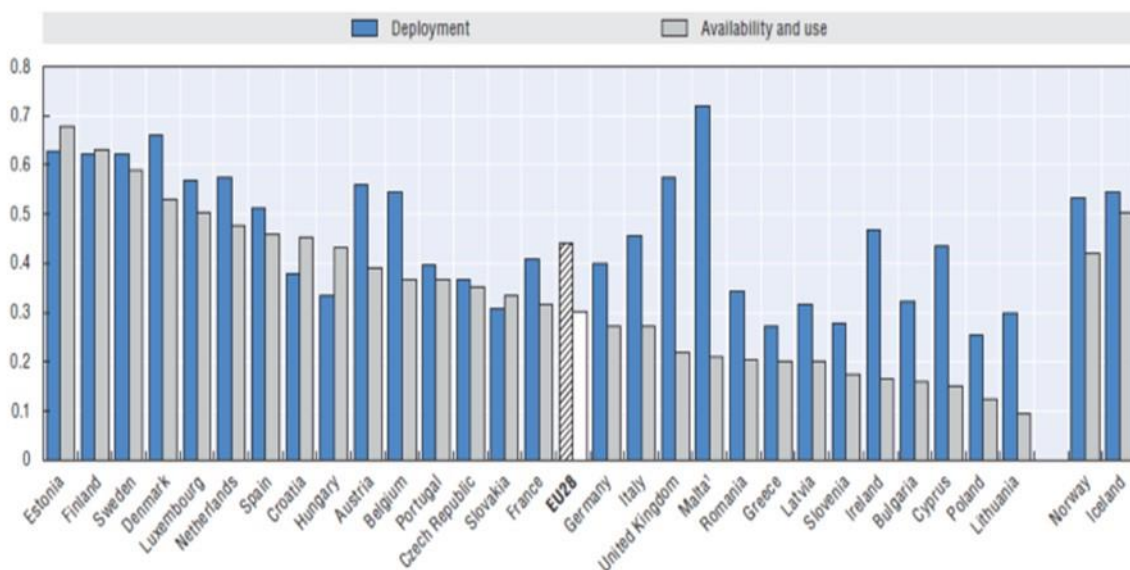
In the analysis of this data, the authors noted that “Denmark achieved the highest score (2.49 out of a possible 4), followed by Spain (2.17), Norway (2.16), Estonia (2.13), the Netherlands (2.12), Finland (2.09) and the United Kingdom (2.07). Lithuania and Latvia had the lowest scores. These results suggest room for improvement in all countries. While basic forms of electronic health records (EHR) are now available to over 90% of GPs on average across EU countries, more advanced features are limited – most notably exchange of health

³³ OECD/EU (2016), Health at a Glance: Europe 2016 – State of Health in the EU Cycle, OECD Publishing, Paris.

information with patients and other providers. Adoption levels for Telehealth and for patient access to their health record remained low.”

A survey of eHealth adoption in European hospitals was also conducted in 2013 with the following results:


8.2. Composite indicators of eHealth adoption in hospitals, 2013



Note: The maximum score for these indicators is 1.

1. In Malta, the data refer to one hospital only.

Source: European Commission (2014), "European Hospital Survey: Benchmarking Deployment of eHealth Services".

StatLink  <http://dx.doi.org/10.1787/888933430069>

Health at a Glance: Europe 2016 State of Health in the EU Cycle. OECD Publishing <http://www.oecd.org/health/health-at-a-glance-europe-23056088.htm>

34

The authors noted that “the averages for EU member states (based on a maximum score of 1) were 0.44 for eHealth deployment, and 0.30 for availability and use. These results also suggest room for improvement as no country was close to the optimal score of 1. Hospitals in

³⁴ For the hospital survey, also conducted in 2013, a representative sample of 1.643 hospitals from EU countries, along with Iceland and Norway, was surveyed. Two composite indicators were generated from the results: 1) Deployment dealing with four “core” eHealth dimensions: digital infrastructure; application and integration; information flows and health information exchange; security and privacy. 2) Availability and Use concerning digital applications and functionalities: the EHR; clinical decision support tools; TeleHealth (European Commission, 2014). The highest possible score for each composite indicator was 1.

the Nordic countries achieved higher scores on both indicators. Hospitals in Eastern and Southern Europe had lower scores.

Larger hospitals and public hospitals recorded higher scores on both indicators. Overall, these results reveal gaps in governance with regard to data security, privacy and interoperability. Only 57% of hospitals reported having a strategic plan for eHealth. There has been a modest increase in many countries' eHealth deployment score compared with the results of a similar survey in 2010 (Deloitte/IPSOS, 2011). Results improved for dimensions related to the infrastructure and integration and, more modestly, to the information flow".

It should be noted that these are 2013 data and eHealth has continued to advance in many countries, so that were this survey to be conducted in 2018, it is likely that the results would be different.

2.2 Some examples of significant advances in eHealth implementation

In the OECD, European Observatory on Health Systems and Policies' – "State of Health in the EU Country Health Profile 2017" series – significant progress in eHealth was noted in a number of countries. The following are the countries that stood out:

Austria: "The ELGA web portal gives patients and health providers – including hospitals, ambulatory care providers, pharmacies and nursing care facilities – access to medical information covering prescribed medicines and medicines dispensed by pharmacies ('e-Medikation') as well as discharge letters from hospitals, and laboratory and imaging results ('e-Befunde'). Patients can opt out of ELGA entirely or restrict access to selected information and are able to see who has consulted their individual record. ELGA is being rolled out step-by-step, starting with e-Befunde in the hospital and nursing care sector: in December 2015, most public hospitals and nursing care facilities in Vienna and Styria were connected to ELGA; other public hospitals and nursing care facilities were added throughout 2016 and 2017; in a next step, ELGA (including e-Medikation) will be extended to include ambulatory care physicians and pharmacies; this will be followed by outpatient clinics, private hospitals and finally dentists"³⁵.

Belgium: "Belgium has strengthened its information infrastructure in recent years to improve health system governance. A new integrated health data system was developed to facilitate data exchange between health care professionals and researchers (www.healthdata.be). The eHealth (eHealth platform) established in 2008, aims to enable safe information exchange between patients, health care professionals and administrative services. All providers and patients are expected to share data on diagnoses, health services and

³⁵ State of Health in the EU Austria Country Health Profile 2017, OECD, European Observatory on Health Systems and Policies, p.14 downloaded from <http://www.euro.who.int/en/about-us/partners/observatory/publications/country-health-profiles>.

treatments. Over the long term, it is expected that this eHealth platform will increase health care quality and patient safety throughout the country, notably through greater control of medication safety risks and reduced duplication of diagnostic tests”³⁶.

Denmark: “The Danish health care system has a first-rate information infrastructure. This includes an electronic health record system that, though not fully integrated, has a large degree of interoperability across settings and sectors and is used by all primary care practitioners. Furthermore, eHealth adoption and use across Danish primary and acute care is among the highest in the EU. Denmark also has a well-established series of disease registries.”

Estonia: “has invested in eHealth and is internationally recognized for its innovations. Most health care providers keep an electronic health record for patients and all health care providers are responsible for sending patient health and health care service provision information to the central health information system. This allows patients to access their health data and providers to access and exchange information with various, relevant databases. The system also allows e-consultations, digital referrals and e-prescriptions – virtually all prescriptions are electronic, and pharmacists increasingly sell on-line. Several new applications are under development, including an electronic immunisation passport, a central digital registration system for outpatient care and, since 2016, a facility to provide access to claims and costs.”

Finland: “invested substantially in eHealth. It introduced a nationwide harmonized electronic patient record, the national Patient Data Repository (referred to as KANTA). This information system includes all public and private health care providers. It also includes mandatory electronic prescription and a health portal allowing citizens to review their own information. These electronic patient records cover all the population since September 2016.”

Greece: implemented “a compulsory, country-wide electronic prescription system to monitor doctors’ prescribing and pharmacies’ dispensing as well as referrals for clinical examinations and tests; and the web-based ESYnet system collects monthly financial, administrative and activity data from public providers for analysis. It was recently integrated with the Business Intelligence System in hospitals that tracks revenue sources and funding flows in a transparent fashion”.

Hungary: the adoption of eHealth among GPs is close to the EU average and among the highest in neighbouring countries. As a result, GPs can more easily access their patients’ electronic health care record, be notified of discharges, follow up with patients and issue e-prescriptions.

³⁶ State of Health in the EU Belgium Country Health Profile 2017, OECD, European Observatory on Health Systems and Policies, p.15 downloaded from <http://www.euro.who.int/en/about-us/partners/observatory/publications/country-health-profiles>.

Italy: “By strengthening eHealth and health information infrastructure in recent years, increased its focus on performance measurement. Following the structuring of the regional recovery plans, the government moved towards a better monitoring of hospital performance to ensure that the Essential Levels of Care are being delivered to the population.

Latvia: “To support greater care coordination, has begun to strengthen its health information infrastructure in recent years with the introduction of an eHealth system and eHealth portal started in 2016. Health care providers can issue ePrescriptions so that patients can purchase their medications at any pharmacy in the country. This will also enable providers to monitor medication safety when multiple drugs are prescribed for patients

Luxembourg: “efficiency improvements mandated by the 2010 health reform included greater care coordination, transparency on hospital activity with the introduction of a national information system for inpatient care, and the creation of a medical expert board that regularly reviews proposed additions and modifications to the benefits basket. In this context the National eHealth agency (eSanté) was created and has been working on the shared electronic health records (DSP) pilot since 2011.”

Malta: “the National Health System Strategy...gives particular attention to the use of information technology and the creation of a Health Care Information System. In particular, the rollout of the myHealth service since 2012 enables patients and doctors to access electronic medical records through a nominated doctor of their choice and an e-ID card, thus strengthening continuity of care for patients. Moreover, investment plans have been drawn up for an integrated portfolio of eHealth systems that include the creation of electronic patient records in primary health care, e-prescription services and patient registries.”

Slovenia: the country “has made substantial efforts to strengthen its health information infrastructure through its national eHealth project. The e-prescription system is widely used by all providers and has improved interoperability and transparency. The e-registry of patient data and patient summaries is being implemented, as is the registry of health care providers, making for easier exchange of information between providers. Other eHealth initiatives are being rolled out, such as an e-referral system, which is soon expected to completely replace paper referrals; the e-booking system, which started in late 2016; and the zVem patient portal (enabling patients to see their own medical data) which launched in January 2017.”

Sweden: “patient records are kept electronically with most primary care providers using electronic patient records for diagnostic data. Moreover, ePrescriptions are used with few exceptions. Efforts are being made towards harmonising patient records across all provider levels. At the national level, there are efforts to integrate various information systems”.

2.3 Countries Still Facing Major Challenges in eHealth

It is perhaps no less important to recognize that there are countries who are progressing in eHealth implementation more slowly. Among the Eastern European Countries, Bulgaria, Lithuania, Poland, Slovakia and the Czech Republic are still lagging behind in eHealth implementations.

In **Bulgaria**, all GPs and most Hospitals use computers, but primarily for reporting their activity as a basis for payment. However, a recent EU-funded initiative aims to develop electronic health records, electronic referral and electronic prescription systems³⁷.

In **Lithuania**, although eHealth development is one of the stated priorities of the national strategy for the development of an information society, the field lacked motivation, leadership and coordination. The National Audit Office of Lithuania (2011a) in its report on the eHealth strategy concluded that progress made over 2008–2011 has been insufficient and the Ministry of Health actions have been inefficient. In response, the ministry cited previous absence of legal arrangements as a major barrier for establishing a countrywide information system that could deliver basic eHealth functions, and it assured that the remaining arrangements should be completed by the end of 2012. Three large public investment projects are currently being implemented in relation to the eHealth system: the development of eHealth services, the electronic prescription service and the medical image exchange system³⁸.

The **Slovak Republic** lags behind many other member countries in implementing unified information standards and health information technologies. As a consequence, diagnostic and treatment procedures are not adequately shared between providers, and the collection of quality and performance data from providers is limited. A new law on a national eHealth information system was adopted in 2013, but implementation is lagging behind, although HICs and private providers are developing their own systems to improve information management³⁹.

In **Poland**, in 2013, eHealth adoption among General Practitioners was fifth lowest in the EU (European Commission, 2013). Similarly, the availability and use of ICT in hospitals was second lowest, behind Lithuania. Several projects, partly funded by European Structural and Investment Funds, to digitalise the health care system and help Poland catch up in the spread and adoption of ICT are currently underway⁴⁰.

In **Czech Republic**, there have also been some more recent advances with projects in the area of quality and safety assurance, such as the adverse event reporting system and the

³⁷ State of Health in the EU Bulgaria Country Health Profile 2017 p. 11

http://www.euro.who.int/__data/assets/pdf_file/0006/355875/Health-Profile-Bulgaria-Eng.pdf?ua=1.

³⁸ Murauskienė L, Janonienė R, Veniute M, van Ginneken E, Karanikolos M. Lithuania: health system review. *Health Systems in Transition*, 2013; 15(2): pp. 77-78.

³⁹ State of Health in the EU Slovak Republic Country Health Profile 2017, OECD and then European observatory on Health Systems and Policies p. 13.

http://www.euro.who.int/__data/assets/pdf_file/0009/355995/Health-Profile-Slovak-Rep-Eng.pdf?ua=1.

⁴⁰ State of Health in the Poland Country Health Profile 2017, OECD and then European observatory on Health Systems and Policies, p. 14

http://www.euro.who.int/__data/assets/pdf_file/0006/355992/Health-Profile-Poland-Eng.pdf?ua=1.

introduction of sectoral safety targets for all health care providers. Nonetheless, without improved transparency these are unlikely to achieve maximum impact. The introduction of a national eHealth programme is intended to address this and aims to tackle the lack of interoperability between health-related data systems; the absence of systematic (quality) performance monitoring; and the link between these and strategic planning⁴¹.

In Western Europe, despite recent progress, **Greece**, **Belgium** and **France** have not advanced as quickly as other countries. The positive achievements of Greece and Belgium have been mentioned above, but both lack a coherent national eHealth system giving providers and patients access to electronic medical record information. In France, since the late 1980s, the health care sector has seen a slow but continuous development of its information technology infrastructure. Recently, development of information technology systems has become a priority on the political agenda, mainly because it is seen as a way to improve the efficiency of the sector. Moreover, in its 2013 National Health Strategy, the government underscored the need to ensure compatibility and interoperability among the information technology systems. Because of the low professional interest in adopting electronic records, incentives have been put into place. There are now P4P incentives for physicians to increase the use of information technologies in ambulatory care, including the electronic transmission of reimbursement claims by SHI and software for following patients and managing prescriptions in the ambulatory, hospital and medico-social sectors of Health⁴².

⁴¹ State of Health in the EU Czech Republic Country Health Profile 2017, OECD and then European observatory on Health Systems and Policies, p. 7
http://www.euro.who.int/__data/assets/pdf_file/0008/355976/Health-Profile-Czech-Rep-Eng.pdf?ua=1.

⁴² Chevreur K, Berg Brigham K, Durand-Zaleski I, Hernández-Quevedo C. France: Health system review. *Health Systems in Transition*, 2015; 17(3): pp. 106-107.

3 National eHealth Competence Centres in Six Countries

In addition to the more in-depth studies of National eHealth competence Centres (NeHCs) in Austria, Denmark and Slovakia in Part IV of this report, six Member States that have established NeHCs have been selected for description and analysis that can contribute to the thinking about the future aims, structure and operations of the planned NeHC in the Czech Republic. The States and NeHCs reviewed in this section will include England, Finland, Germany, Lombardy Italy, Luxembourg and the Netherlands. For each of these countries, there will be a brief description of the Healthcare System, the country's eHealth Strategy and its implementation, a description of the NeHC and its relationship to the eHealth Strategy, legislative support where it exists, and to the extent possible, organizational structure, staffing and stakeholder involvement

3.1 England – NHS Digital

Brief description of Healthcare system

Healthcare in England is mainly provided by England's public health service, the National Health Service, that provides healthcare to all permanent residents of the United Kingdom that is free at the point of use and paid for from general taxation. Though the public system dominates healthcare provision in England, private health care and a wide variety of alternative and complementary treatments are available for those willing to pay⁴³. The National Health Service (NHS) is free at the point of use for the patient though there are charges associated with eye tests, dental care, prescriptions, and many aspects of personal care. The NHS provides the majority of healthcare in England, including primary care, in-patient care, long-term healthcare, ophthalmology and dentistry. The NHS is divided conceptually into two parts covering primary and secondary care with trusts given the task of health care delivery. There are two main kinds of trusts in the NHS reflecting purchaser/provider roles: commissioning trusts are responsible for examining local needs and negotiating with providers to provide health care services to the local population, and provider trusts which are NHS bodies delivering health care service⁴⁴. Primary care is delivered by a wide range of independent contractors such as GPs, dentists, pharmacists and optometrists and is the first point of contact for most people. Secondary care (sometimes termed acute health care) can be either elective care or emergency care and providers may

⁴³ Cylus J, Richardson E, Findley L, Longley M, O'Neill C, Steel D. United Kingdom: Health system review. *Health Systems in Transition*, 2015; 17(5): p. 55.

⁴⁴ "The structure of the NHS" (PDF). Royal College of General Practitioners. Archived from the original (PDF) on 24 February 2007. Retrieved 31 March 2017.

be in the public or private sector, but the majority of secondary care happens in NHS owned facilities⁴⁵.

eHealth Strategy

The National Programme for IT in England had already begun in 2002 and acted as the basis for eHealth deployments. In conjunction with this the 2002 policy paper “Delivering 21st century IT support for the NHS: national strategic programme” was created. A patient summary programme known as the Summary Care Record Programme has been nationally implemented in England since 2008. However, some form of electronic patient record has existed since the mid-eighties due to the high level of computer use in General Practitioners’ (GPs) practices from this time onwards. In terms of ePrescription, England has two programmes for electronic prescribing in existence. One, Electronic Prescription Service (EPS) is directed at the primary care sector, GPs and clinics, and synchronises all steps from the generation to the despatch of the prescription. The other, ePrescribing, is aimed at institutions such as hospitals and includes a decision support component.

Until 2013 England’s eHealth strategy was carried out by the Programme for Information Technology (NPfIT) system in England. It was abandoned in 2013 after being plagued by accusations of being inefficient and not cost-effective – it went considerably over budget and failed to deliver on what had been promised (National Audit Office, 2011).

A new eHealth strategy and Policy was published in 2014 by the National Information Board. Established by the Department of Health, the NIB was a new body which brings together national health and care organisations from the NHS, public health, clinical science, social care and local government, together with appointed lay representatives. It is charged with developing the strategic priorities for data and technology in health and care to deliver the maximum benefit for all citizens and patients and to make appropriate recommendations for investment and action. The NIB helps take forward the ambitions of the Care Act 2014, the Government Digital Strategy (2013), the Department of Health’s Digital Strategy: Leading the Culture Change in Health and Care (2012)³ and the proposals in the Department of Health’s Power of Information (2012)⁴⁶.

National eHealth Competence Centre

The Health and Social Care Information Centre (HSCIC) was formed in April 2013 as an executive, non-departmental public body and the national provider of information, data and IT systems for patients, service users, clinicians, commissioners, analysts, and researchers in health and social care. It works within the framework of the National Information Board (NIB). Its role is to improve health and social care in England by putting technology, data and

⁴⁵ "The structure of the NHS in England - NHS Choices". www.nhs.uk. Retrieved 31 March 2017.

⁴⁶ Personalised health and care 2020: A framework for action
www.gov.uk/government/publications/personalised-health-and-care-2020.

information to work. It provides national technology and information services and is the centre of excellence and leadership in the development and use of technology, data and information.

Its key role is to enable and support the whole health and care system to use technology, data and information to transform its services.

One of the central arguments in the NIB Framework is that local organisations are charged with implementing local systems over time, consistent with a national set of standards. HSCIC takes the lead role, with its partners in the NIB, in orchestrating and delivering all these objectives for the benefit of all⁴⁷.

The HSCIC eHealth strategy set out five objectives for the next five years. The objectives were:

1. Ensuring that every citizen's data is protected
2. Establishing shared architecture and standards. This will be done in collaboration with national partners and with care providers and the software market.
3. Implementing services that meet national and local needs. This involves integration of national systems to create a new information and transaction service for citizens, including service users and carers. HSCIC will also open up access to its core systems, with appropriate safeguards, so that third parties can develop new and innovative services.
4. Supporting health and care organisations to get the best from technology, data and information
5. Making better use of health and care information

In August 2016, HSCIC changed its trading name from the Health and Social Care Information Centre (HSCIC) to NHS Digital to help it better communicate its expanded role. NHS Digital transformed its role in 2016-17, taking on new responsibilities as the lead national delivery partner for the drive to improve the use of data and digital technologies in the health and care system.

- NHS Digital's purpose is to harness the power of information and technology to make health and care better by:
 - designing and building new technology and Systems;
 - running live IT Services and Infrastructure;
 - collecting and Publishing data and information about health and care;

⁴⁷ Personalised health and care 2020: A framework for action
www.gov.uk/government/publications/personalised-health-and-care-2020.

- helping Partners use information and technology securely and effectively.

NHS Digital produces an annual report in which it describes its activities and gives an accounting of its accomplishments as well as its expenditures. From its Annual Report and Accounts 2016-17, we learn that it has maintained as well as upgraded the major eHealth services that form the infrastructure of the English eHealth system including:

- NHS Secure email system which it replaced with NHS mail 2
- NHS e-Referral system
- Electronic Prescription system
- Summary Record system which, in 2016-7 it rolled out to 6000 community pharmacists to assure more accurate dispensation of drugs
- Messaging Exchange for Social Services, a new service initiated in 2016-7⁴⁸

Legislative Mandate

NHS Digital was established in April 2013 as an Executive Non-Departmental Public Body (ENDPB) under the Health and Social Care Act 2012 and its name in statute remains the 'Health and Social Care Information Centre'. The Health and Social Care Information Centre (NHS Digital) is an executive non-departmental government body established under the Health and Social Care Act 2012. The principal activities of NHS Digital are the collection, analysis and dissemination of health data for secondary uses purposes together with the development and contract management of elements of the NHS IT infrastructure. It is accountable to the Secretary of State for Health for discharging its functions, duties and powers effectively, efficiently and economically. The Department of Health actively undertakes this role on his behalf on a day to day basis.

It retains statutory duties to:

- Manage key services that underpin local health and care provision (e.g. the NHS Spine and the e-Referrals service).
- Collect and present national data and publish national statistical reports.
- Publish technical standards and guidance in areas such as governance and security.
- Maintain indicators used to measure the quality of services.
- Improve data quality.
- Advise the Secretary of State for Health on ways to reduce the burdens of national data collections on local organisations.

⁴⁸ Health and Social Care Information Centre (HSCIC) Annual Report and Accounts 2016-17. Presented to Parliament pursuant to Paragraphs 12 (2) (a) of the Health and Social Care Act 2012. Ordered by the House of Commons to be printed on 11 July 2017. Downloaded in May 2018 from <https://www.gov.uk/government/publications>

Organizational Structure and Governance

NHS Digital has a Board of Directors with 5 Executive Directors (including the CEO) and 12 non- executive directors. It has an operating staff organized by activity:

- Health Digital Services
- Clinical services
- Digital Transformation
- Information and Analytics
- Operations and Assurances Services
- Provider Support and Integration
- Workforce
- Finance and Corporate Services

Budget

In 2016-17 Staff costs were £156,198 million and Income form activities was £44,388 million. Remaining staff costs and all other costs are charged to the Department of Health.

3.2 Finland – THL

Brief Description of Health Care System

Finland's health system is complex and decentralised, and care is delivered in municipal, occupational or private facilities. Over 300 municipalities (local authorities) are responsible for the provision of basic services, such as education, health and social care, to their residents. Municipalities fund and organise (often jointly) the provision of primary care, and form 20 hospital districts to fund and provide hospital care. At the national level, the Ministry of Social Affairs and Health is responsible for developing and implementing health reforms and policies, and it extensively relies on a network of expert and advisory bodies in its work. Funding for health care comes through municipalities with taxation right and the statutory National Health Insurance (NHI) scheme, run by the Social Insurance Institution and accountable to Parliament. The NHI is responsible for funding outpatient medications, health care-related travel costs, and sickness and maternity allowances. In addition, it effectively subsidises occupational health care, as in Finland employers are obliged to organise and provide health services for their employees, and the NHI covers about half of employers' health care costs. Furthermore, the NHI reimburses part of services provided in the private sector, mainly ambulatory care. This somewhat unique structure of the health system has been both recognised for being able to adjust to the needs of a dispersed population and criticised for contributing to inequalities and inefficiencies (Couffinhal et al., 2016) A major

reform is under discussion, aiming to establish a more centralised county-based health and social care system with single-payer financing⁴⁹.

Primary care offers multiple services (including prevention and outpatient treatment, dental care, maternity and child health) in health centres and occupational health units. Health centres commonly have General Practitioner (GP)-run inpatient units, largely for chronic and long-term care patients. Secondary care (including specialised outpatient care, inpatient care and day surgery) is mainly provided by hospitals organized in municipality-owned hospital districts. Tertiary care is delivered in five university hospitals. Patients need a referral to access specialist care, except for emergency cases.

EHealth Strategy and Implementation

In 2002, the Finnish Government decided to introduce nationwide electronic patient records by the end of 2007 and the National Health Project Program was launched, including an electronic patient record project. Previously every service provider had its own patient record system which was not usually interoperable. Then, in December 2006, a national EHR archive (eArchive) was introduced in order to enable access and exchange of patient information across organisations. To ensure this, all EHR systems joining the national eArchive use a predefined structure, Finland's eHealth roadmap from 2007 is a follow-up to a national strategy called "Strategy for utilising information technology in the field of social welfare and healthcare in Finland", which was launched by the Ministry of Social Affairs and Health in 1996. Its underlying principle is the development of seamless service chains, which is considered to require the extensive introduction of new technology, the creation of new types of information system architectures, and better compatibility between information systems. From 1996 onwards, the Ministry of Social Affairs and Health has consistently pursued the creation of an implementation chain for the deployment of eHealth with four important landmarks:

- **1996:** Strategy for utilising information technology in the field of social welfare and healthcare in Finland;
- **1998:** Update of the strategy, placing emphasis on several issues, e.g. digital patient records, nationwide interoperability or privacy protection;
- **2002:** Decision-in-Principle by the Council of State for the introduction of nationwide patient records;
- **2007:** "eHealth Roadmap for Finland" is published by the Ministry of Social Affairs and Health.

⁴⁹ State of Health in the EU Finland Country Health Profile 2017 OECD , European Observatory on Health Systems and Policies, European Commission p7 pp 7European Observatory on Health Systems and Policies.

The strategy was supported by Legal acts concerning eHealth development, mainly:

- Personal Data Act from 1999;
- Act on Experiments with Seamless Service Chains in Social Welfare and Care Services from 2000;
- Decree on the Storing of Patient Data from 2001;
- Regulation on the Use of Electronic Social and Healthcare Client and Patient Information from 2007, also called the “Client Data Act”;
- Legislation on the Use of ePrescription from 2007.

The result of the Finnish eHealth strategy was the introduction of a nationwide harmonized electronic patient record, the national Patient Data Repository referred to as KANTA. This information system includes all public and private health care providers. It also includes mandatory electronic prescription and a health portal allowing citizens to review their own information. These electronic patient records cover all the population since September 2016⁵⁰. Citizens can request the renewal of digital prescriptions online, which has decreased visits to healthcare services. Some healthcare organizations have ceased mailing medical case summaries to patients because summaries are available in My Kanta. The service has also made paper archiving unnecessary. Kanta’s most recent feature allows citizens to enter their own data – e.g. data from a mobile application that they use – on their My Kanta page and choose which healthcare professionals can access this information. The Kanta services are under constant development. Some healthcare units are already using the Archive for Old Patient Data, which facilitates the statutory archiving required from healthcare operators. In addition, the Kanta services will also include social services data⁵¹.

The development of Kanta began around 2005, and the first laws concerning the digital service were enacted in 2007. The Kanta Services have been built and continue to be operated cooperatively by several authorities:

- Ministry of Social Affairs and Health (STM) - STM is responsible for the coordination and legislation of Kanta Services.
- Social Insurance Institution of Finland (Kela) - Kela is in charge of the construction and maintenance of the prescription service and the related Pharmaceutical Database, Patient Data Archive database, and the citizen's My Kanta pages service. In addition, Kela takes care of the background support and help services related to the data systems, the technical construction of a national coding service, and coordination of combined testing.
- National Supervisory Authority for Welfare and Health (Valvira) -Valvira is responsible for role and attribute data services, as well as so-called Valvira code sets, necessary in

⁵⁰ Ibid p. 16.

⁵¹ <http://www.finlandhealth.fi/-/finland-s-national-health-data-service-benefits-citizens-healthcare-professionals-pharmacies-and-the-society>.

national data systems. These are based on information from the central register of healthcare professionals (Terhikki register).

- Population Register Centre (VRK) - VRK is responsible for the ID and certification services for data system services. Reliable identification and certification of persons using patient data systems, archive services and the electronic prescription system must be in place. Electronic signature of patient documentation and prescriptions must also be possible. Identification and electronic signatures of healthcare professionals and other personnel employed by healthcare service providers are implemented using PRC's certificate services and management of access rights to operational units.
- **National Institute for Health and Welfare – THL (NeHC – see below)**

Finland has continued over the years to update its eHealth and eSocial Strategy under the leadership of the Ministry of Social Affairs and Health. The most recent strategy is described in the “Health Strategy and Action Plan of Finland in a European Context” published in 2015. The objective of the Finland eHealth and eSocial Strategy 2020 is to support the renewal of the social welfare and health care sector and the active role of citizens in maintaining their own well-being by improving information management and increasing the provision of online services. To achieve these ends, it is essential to make active use of information related to social welfare and health care services and to refine it into knowledge that will support both the service system and individual citizens.

National eHealth Competence Centre

National Institute for Health and Welfare (THL) is responsible for the operational management of electronic data control functions in the social and health services and defines the data contents, conceptual models and data structures supporting the operational processes required to execute the Kanta Services. THL is tasked with providing guidance and advice, as well as producing the material required to allow clients to join Kanta on schedule.

THL participates in specifying areas of responsibility, schedules the phasing of Kanta Services deployments, keeps areas informed on the deployment process and project phasing, produces a deployment handbook, prepares deployment schedules, produces tools, e.g. model plans, testing models, approval criteria, agreement and contract templates, prepares a general training programme, and creates a network of training specialists.

In addition, THL is responsible for code sets and classifications used in the data systems. The national coding server distributes uniform code structures required by the electronic client data systems for social and health services. The code sets are available for national electronic document systems for social and healthcare services free of charge.

It should be noted that THL is not the only driver of eHealth in Finland, nor does it perform all of the tasks often associated with a competence Centre. Responsibility for the eHealth system is shared among a number of different agencies as described above.

In addition, THL has many functions that are not necessarily associated with eHealth per se. It is an independent, expert agency working under the Ministry of Social Affairs and Health

with a number of functions and purposes in addition to its functions in Kanta, THL directs and organise special services within the social welfare and health care sector such as forensic genetics, forensic medicine, forensic odontology, mediation in criminal and civil cases and others⁵².

THL is one of Finland's most internationally networked research organisations. It is a preferred partner in domestic and international research. More than 800 articles by THL are published in scientific journals each year. Half of these are international joint articles. It also studies and monitors - and develops measures to promote - the well-being and health of the population in Finland. It gathers and produces information based on research and statistics. It also provides expertise and solutions, which stakeholders can use in support of their decision-making and other work.

International co-operation is an integral and statutory element of THL's daily expert work and activities. It has close and continuous international contacts in facility monitoring and supervision, health promotion, expert and research collaboration and development projects. Half of THL's scientific research is based on international cooperation

THL is engaged in active collaboration with Nordic countries and the EU on statistics, registers and standardisation. Furthermore, it provides the information it produces as open data. It makes its data available to the public sector, companies and organisations – in support of management, or even the development of new products. In its data policy, THL highlights up-to-date, open data with high visibility; more-flexible licensing processes; and the digitalisation of the entire data management life-cycle. THL promotes wide-ranging use of information resources in the field of social and health care. As part of this objective, THL provides open access to data produced and collated at the institute.

Another major activity of THL, not related to its functions relative to the eHealth system (KANTA) is the THL Biobank. The Biobank is engaged in a new kind of cooperation with the University of Helsinki, Harvard University, Massachusetts Institute of Technology (MIT) and various businesses, to reveal the connections between health and genes

THL produces research information to assist in the development of Finland's social and health service system (so-called SOTE reform) and performs impact assessments in support of policy making.

More in line with its function as an eHealth Competence Centre, THL provides Digitalising services:

⁵² <https://thl.fi/en/web/thlfi-en/services/special-government-services-in-social-welfare-and-health-care>.

- it is involved in the creation of new information management functionality for the reporting and monitoring of the social and health care system, and in making various information systems interactive.
- it is involved in developing the My Kanta (personal health account) service that makes customer and patient data available across organisational boundaries and helps professionals in their everyday work and in accessing information⁵³.

Legislation

The Kanta Services are subject to the Act on Electronic Prescriptions and the Act on the Electronic Processing of Client Data in Social and Health Care Services, among others (noted above):

- Act on the Electronic Processing of Client Data in Social and Health Care Services.
- Under the Act on the Electronic Processing of Client Data in Social and Health Care Services, public healthcare and most private organisations are obliged to enter patient records in a nationally centralised archive. Deployment of the centralised archive is mandatory for private healthcare organisations, if they have an electronic system for long-term storage of patient records. The aim of the Act is to further the data security of patient information Act on the Electronic Prescriptions
- The Act on Electronic Prescriptions provides that introduction of electronic prescriptions is mandatory for pharmacies, healthcare units, and self-employed persons with practices in healthcare units' premises. The aims of the Act on Electronic Prescriptions are to improve patient and drug safety and to make prescribing and dispensing of medicines easier and more efficient. The healthcare unit will tell the patient about the electronic prescription system. The information may be given by e.g. a nurse or doctor. As well as verbal information, a leaflet on electronic prescriptions will be given. At the doctor's appointment, the patient is given a set of patient instructions. It contains details of all the medicines prescribed this time, as well as instructions on how to take them. From the patient's point of view, the information is the same as on a paper prescription. When the electronic prescription is renewed, and no changes made to it, the patient instructions remain the same. The patient instruction sheet should be taken along to the pharmacy, as it speeds up the service. The acts and decrees are available in Finnish and in Swedish only <http://www.kanta.fi/en/lainsaadanto>

Both the Act on the Electronic Processing of Client Data in Social and Health Care Services and the Act on Electronic Prescriptions are being revised in 2017 in order to enable both the healthcare and social welfare services to be included in the Kanta services, in order to support the national health and social services reform as well as to enable a national PHR solution called "Omatietovaranto". It is also suggested that Finland will adopt an opt-out model (Healthcare legal basis) both in the Act on the Electronic Processing of Client Data in

⁵³ <https://thl.fi/en/web/thlfi-en/about-us/what-is-thl->

Social and Health Care Services and for electronic prescriptions and that both the healthcare and social welfare data will be stored in one joint county customer registry. <http://www.kanta.fi/en/lainsaadanto>⁵⁴.

Organization and Governance

THL is an independent, expert agency working under the Ministry of Social Affairs and Health.

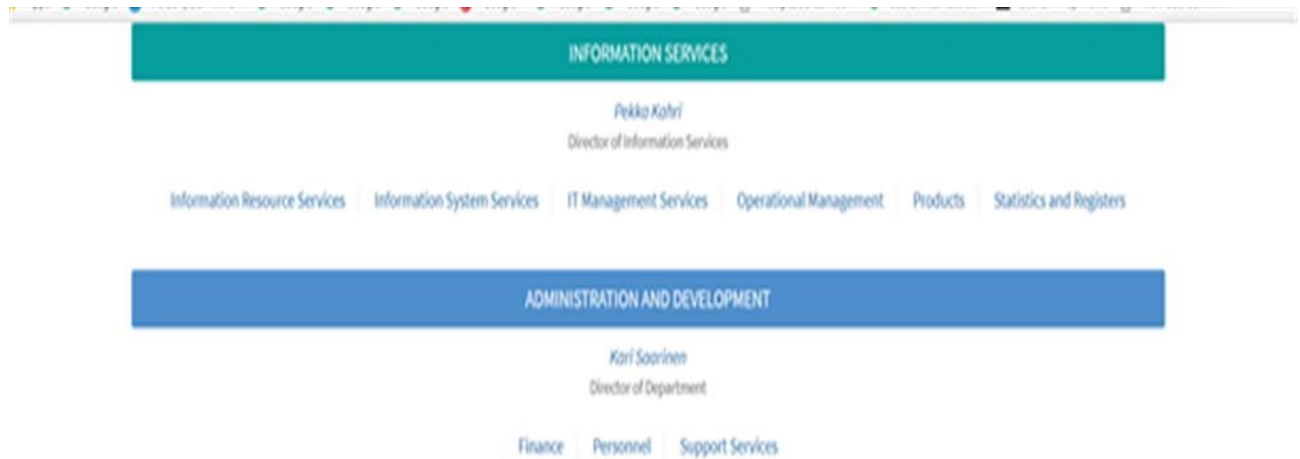
It is headed by a Director General and a Deputy Director General with a support staff for communications, Healthcare and Social Services Evaluation and an International affairs and research support office. Directly under the top management are 7 departments:

- Welfare
- Public Health Solutions
- Health Security
- Health and Social Care Systems
- Government Services
- Information Services
- Administration and Development

The organizational chart is as follows:



⁵⁴ JASEHN DRAFT Report on EU state of play on patient access on eHealth data. Mary Cleary (ICS on behalf of DH), Linda Keane (ICS on behalf of DH), Elise Peters (Nictiz), p. 82.



Of special interest with respect to THL's eHealth functions, Information Services includes the following functions:

- Information Resource Services
- Information System Services
- IT Management Services
- Operational Management
- Products
- Statistics and registers

Staff

THL's staff numbers are equivalent to 969 person-years. Approximately 26% have research qualifications and around 71% are women. A range of professionals work in various tasks. Most THL staff are professionals in the medical and health sciences or have a background in the social sciences. There is also staff with expertise in the bio and environmental sciences and a fair number of information technology experts. Pay at THL is competitive on the labour market and incentivises people to join and commit themselves to the organisation⁵⁵.

Funding

THL's key funding sources include funding from the state budget, co-funded activities and services subject to a fee. The total amount of budget funding in 2017 is EUR 55.4 million (including the transferred appropriation). A total of 62% or most of this is allocated to the wage bill associated with the activities of an expert and research-based organisation. THL's funding from the state budget has been markedly reduced in recent years. Its statutory

⁵⁵ <https://thl.fi/en/web/thlfi-en/about-us/personnel>.

functions have increased during the same period. The budget cuts scheduled for 2017–2019 will require the continuation of adjustment measures over the next few years.

In 2017, a total of EUR 33.4 million has been budgeted for co-funded activities. Co-funded activities involve funding obtained from sources external to THL, free of any obligation to compensate the funding body directly. The Ministry of Social Affairs and Health is the largest funder of co-funded activities.

External funding 2016 - The largest external funders of co-funded activities in 2016 were:

- Finnish Ministry of Social Affairs and Health
- European Union
- Academy of Finland
- Municipalities, cities and others.
- GlaxoSmithKline Ltd
- Prime Minister's Office
- National Institute of Health, USA
- Finnish foundations
- Institute for Molecular Medicine Finland (FIMM) Alko Oy

Budgeted income for services subject to a fee in 2017 totalled EUR 7.1 million. 'Services subject to a fee' refers to the sale of products and services on a competitive market or as statutory services performed at cost price. Such activities mainly consist of laboratory research and analyses, and international projects.

3.3 Germany – Gematik

Brief Description of the Healthcare system

The Federal Republic of Germany is in central Europe, with 81.8 million inhabitants (December 2011), making it the most populated country in the European Union (EU). A fundamental facet of the German political system – and the health care system in particular – is the sharing of decision-making powers between the Länder, the federal government and civil society organizations. In health care, the federal and Länder governments traditionally delegate powers to membership-based (with mandatory participation), self-regulated organizations of payers and providers, known as “corporatist bodies” in the statutory social health insurance (Gesetzliche Krankenversicherung (SHI)) system. These include sickness funds and their associations together with associations of physicians accredited to treat patients covered by SHI. These corporatist bodies constitute the self-regulated structures that operate the financing and delivery of benefits covered by SHI, with the Federal Joint Committee (Gemeinsamer Bundesausschuss) being the most important decision-making body. The Social Code Book (Sozialgesetzbuch (SGB)) provides regulatory frameworks for SHI. Since 2009, health insurance has been mandatory for all citizens and permanent residents, either through SHI or private health insurance (PHI). SHI covers 85% of the

population – either mandatorily or voluntarily. Cover through PHI is mandatory for certain professional groups (e.g. civil servants), while for others it can be an alternative to SHI under certain conditions (e.g. the self-employed and employees above a certain income threshold). In 2012, the percentage of the population having cover through such PHI was 11%. PHI can also provide complementary cover for people with SHI, such as for dental care. Additionally, 4% of the population is covered by sector-specific governmental schemes (e.g. for the military). People covered by SHI have free choice of sickness funds and are all entitled to a comprehensive range of benefits⁵⁶. The 132 sickness funds collect contributions and transfer these to the Central Reallocation Pool (Gesundheitsfonds; literally, “Health Fund”). Contributions increase proportionally with income to an upper threshold (a monthly income of €4050 in 2014). Since 2009 there has been a uniform contribution rate (15.5% of income). Resources are then redistributed to the sickness funds according to a morbidity-based risk-adjustment scheme and funds have to make up any shortfall by charging a supplementary premium.

Sickness funds pay for health care providers, with hospitals and physicians in ambulatory care (just ahead of pharmaceuticals) being the main expenditure blocks. Hospitals are financed through “dual financing”, with financing of capital investments through the Länder and running costs through the sickness funds, private health insurers and self-pay patients – although the sickness funds finance the majority of operating costs. Financing of running costs is negotiated between individual hospitals and Länder associations of sickness funds, Payment for ambulatory care is subject to predetermined price schemes for each profession (one for SHI services and one for private services). Payment of physicians by the SHI is made from an overall morbidity-adjusted capitation budget paid by the sickness funds to the regional associations of SHI physicians (Kassenärztliche Vereinigungen), which they then distribute to their members according to the volume of services provided (with various adjustments).

Payment for private services is on a fee-for-service basis.

eHealth strategy and Implementation

Efforts at introducing an Electronic Health Record and other eHealth services have a long history in Germany. The official German eHealth policy as well as implementation measures were already included in the Law for the Modernisation of Statutory Health Insurance of November 2003. This law contained amendments to the 5th Book of the Social Law on Statutory Health Insurance and provided for the introduction of electronic health cards for patients (“Elektronische Gesundheitskarte”) as the core element of the strategy, electronic health professionals cards (“Elektronischer Heilsberufsausweis”), core and voluntary applications to be supported by these cards, the establishment of a health telematic

⁵⁶ Busse R, Blümel M. Germany: health system review. *Health Systems in Transition*, 2014, 16(2):1–296. P. xxiv.

infrastructure, the establishment of institutions deemed necessary for its successful implementation as well as rules for financing these activities. Various factors related to the federal structure of Germany have so far made progress difficult. Following a change of federal government in autumn of 2009, a reappraisal of the entire eHealth infrastructure and eCard project in Germany was undertaken, focusing particularly on security and, confidentiality issues. A key outcome of this was a restructuring of the implementation process.

Mandatory applications for the German eCard are now the online verification of the insurance status of patients and the online update of insurance data, including the data set of the European Health Insurance Card (EHIC). Technically feasible further services which are however not mandatory include an emergency care data-set for the patient. Future services should include doctor-doctor communication (electronic discharge information). With regard to ePrescription services, discussions on deployment have been put on hold by the Ministry of Health, until proven solutions responding to highest data-protection requirements are found. A recent effort on the level of telemedicine services focused on stakeholder mobilisation. In mid-2010, the Federal Ministry of Health therefore launched the “eHealth-Initiative”, uniting key players of the German healthcare system (doctors, insurers together with the Fraunhofer Gesellschaft and key industry players) around the goal of identifying existing barriers to telemedicine deployment. A set of measures to address these barriers were agreed upon in late 2010⁵⁷.

The present German situation is characterised by a quite long history of planning, preparation for and undertaking implementation work towards realising a comprehensive national eHealth roadmap. The steps towards the present state of affairs can be briefly summarised as follows:

- Initial consensual development of key concepts and planning was accomplished by a so called “Working group on Telematics Applications in the Health Sector” as part of the German national initiative “Forum Info 2000”, 1996 to 1998.
- Its results were further detailed and specified by the “Action Forum Telematics in the Health Sector” (Aktionsforum Telematik im Gesundheitswesen, ATG)²⁸ 1999 to 2004; which became in 2005 the GVG-Committee for “Health Telematics”.
- The Action Programme of the Federal Government “Innovation and New Jobs in the Information Society of the 21st Century” of 1999 had already described, among many other fields of activities, various measures planned to promote and implement eHealth applications.
- This programme was updated and extended in the Action Programme of the Federal Government “Information Society Germany 2006” of 2003 which detailed for the first

⁵⁷ Country Brief: Germany Authors: Karll A. Stroetmann, Jörg Artmann, Sarah Giiest. October 2010, European Commission, DG Information Society and Media, ICT for Health Unit, p. 4.

time in considerable depth eHealth strategic aspects, stakeholders, measures to be implemented and projects to be initiated. Towards the end of 2003, all of this was codified in the Modernising Health Insurance law⁵⁸.

The official German eHealth policy as well as implementation measures are included in the Law for the Modernisation of Statutory Health Insurance of November 2003 that provides for the introduction of electronic health cards for patients as the core element of the strategy. It also includes electronic health professional cards, core and voluntary applications to be supported by these cards, the establishment of a health telematic infrastructure, the establishment of institutions deemed necessary for its successful implementation as well as rules for financing these activities. Together with later amendments and clarifications, it provides for the following strategy components:

- **Goal:** the health policy goal is stated in a rather generic form as “improvement of efficiency, quality and transparency of treatment
- **Patient identifier:** all insurance funds have to maintain a register of their insurees.
- **Electronic health card for patients:** The introduction of an electronic patient card is foreseen with details about its mandatory insurance application as well as requiring capabilities for further (voluntary) eHealth services, also specifying patient and other rights and obligations⁵⁹. Mandatory applications concern the eventual online update of insurance status, recording of mandatory co-payment status, and the data set of the European Health Insurance Card (EHIC). Voluntary applications describe a number of features the Electronic Health Card also “must be able to support” if a citizen gives informed consent to this.
- **Electronic health professional card:** access to electronic patient data stored on the patient card or elsewhere in the public infrastructure is, except for patients themselves, only permitted via an electronic health professional card equipped with qualified electronic signature and secure authentication functionalities.
- **Telematic infrastructure:** the implementation of the necessary information, communications services and security infrastructure is stipulated
- **Competence Centre:** the law initiated the establishment of a Society for [Health] Telematics (gematik - “Gesellschaft für Telematik”) to plan, implement and manage the necessary eHealth infrastructure services (§ 291b).

In addition to the legal details outlined, in July 2005 the Federal Ministry of Health and Social Security summarised its overall position concerning strategic eHealth developments in a paper entitled “The German eHealth Strategy”. It formulated the policy intentions and perspectives of the above mentioned legal provisions implicit in Germany’s eHealth strategy in a non-judicial way and describes the target of the strategy as follows:

⁵⁸ Ibid p. 17.

⁵⁹ Ibid p. 18.

“The healthcare system in Germany is a system with a pressing demand for intensive communication between the different actors with the aim of achieving better collaboration and thus numerous positive results for the health of the citizens, the healthcare system and the State’s economic situation.”

The overall goal of the German eHealth strategy is the modernisation of the healthcare system using information and communications technology, in order to establish more citizen-oriented services, support patient-centred care, improve quality and services, reduce costs, and provide better data for health system management⁶⁰.

National eHealth Competence Centre

As mentioned above, the Gematik Gesellschaft für Telematikanwendungen der Gesundheitskarte mbH, headquartered in Berlin, was founded in 2005 by the leading organizations in the health sector “to plan, implement and manage the necessary eHealth infrastructure services” as defined by the Law for the Modernisation of Statutory Health Insurance of November 2003 - which is the cornerstone of the German eHealth strategy⁶¹.

Gematik is charged with the establishment of the secure, cross-sector, digital networking of the healthcare system. It has overall responsibility for Telematics Infrastructure (TI) and coordinates TI operations. As a service provider to the shareholders, it is the nationwide competence Centre for this purpose. The focus is on establishing an open communication platform for the healthcare sector for the sustainable improvement of medical care, in particular for increasing the quality, transparency and cost-effectiveness in the healthcare sector. The telematics infrastructure implements the applications of the electronic health card but is also an open platform for other already existing or future planned applications of the shareholders or external providers.

Gematik sees itself as a competence Centre and service provider for the healthcare sector. It sets the conceptual framework for the telematics infrastructure as a comprehensive and secure network, coordinates its reliable operation and the market-driven structure. It ensures the functionality and interoperability, i.e. the smooth interaction between the various components, services and applications in the telematics infrastructure, and sets standards in the digital German health care system. In this context, it assumes three central tasks:

- **Specification:** conception, description and definition of the requirements for components, services, providers of operating services as well as other electronic applications of the health care system in the telematics infrastructure.
- **Approval:** it grants authorizations for components, services and providers as well as for their use in the telematics infrastructure. In addition, gematik confirms that other

⁶⁰ Ibid p. 19.

⁶¹ Downloaded from <https://www.gematik.de/ausblick/> April 4, 2018. All of the information on gematik was found on this - the official gematik website.

electronic applications in the healthcare sector are eligible for use in the telematics infrastructure.

- **Operational responsibility:** Gematik defines the framework conditions for the operation of the telematics infrastructure and monitors their compliance.

Strategic fields of action of the Gematik until 2020 are:

- Successful implementation of the specialist projects as a service provider to the shareholders for added value in the TI.
- Building Telematics Infrastructure (TI) for secure, cross-sectoral, digital networking of healthcare as an open and attractive communication platform, ensuring interoperability and compatibility through the use of existing standards and standards.
- Ensuring a viable eGK and TI system operation in the context of overall operational responsibility (including in the areas of licensing, certification, testing and operations).
- Establishment as an efficient and effective service provider for the shareholders as well as a nationwide competence Centre for all topics related to eGK, TI and related specialist applications.
- Development of proposals for the innovative (technical) development of the TI. Enabling competition for a broad, especially medical application landscape.
- Improvement of information and communication to partners, users and other stakeholders.
- Ensuring the efficiency, quality, transparency and efficiency in the implementation of the tasks.
- Development of appropriate and target group-oriented information and communication to the participants.

Legislative mandate

As already mentioned, the Law for the Modernisation of Statutory Health Insurance of November 2003. initiated the establishment of a Society for [Health] Telematics (Gematik - "Gesellschaft für Telematik" to plan, implement and manage the necessary eHealth infrastructure services (§ 291b). it has overall responsibility for Telematics Infrastructure (TI) and coordinates TI operations.

The legislator has put the establishment of an interoperable and cross-sectoral information, communication and security infrastructure (telematics infrastructure) as the basis for a digital and secure networking in health in the hands of the top organizations of the German health care system and these entrusted the implementation of this task to the gematik. As a result, the gematik Gesellschaft für Telematikwendungen der Gesundheitskarte was founded in 2005 in the legal form of a GmbH.

The legal mandate of gematik comprises the introduction, operation and further development of the telematics infrastructure, the electronic health card as well as related specialist applications and so-called further applications for the communication between health professionals, payers and insured persons. In addition, gematik has the following tasks:

- regulation of functional and technical specifications as well as a safety concept;
- defining the content and structure of the records to be used;
- creating and monitoring compliance with the requirements for the secure operation of the telematics infrastructure;
- ensuring the necessary test and certification measures;
- defining the procedures for managing legally regulated access permissions and controlling these accesses;
- approval of components, services and providers.

The following laws form the legislative basis for the activities of gematik:

- § 291 SGB V - Electronic Health Card as proof of insurance;
- § 291a SGB V - Electronic Health Card and Telematics Infrastructure;
- § 291b SGB V - Society for Telematics.

The EHealth Act, which came into effect on January 1, 2016, has once again clarified the requirements for digitizing the German health care system. It sets deadlines for the introduction of specialized applications such as insured person data management, emergency data management, electronic medication plan, electronic patient record and electronic patient compartment.

Organizational Structure and governance of the eHealth Centre

The Gematik is a joint company of the top organizations of the service providers and payers in the German health service (self-government). (See list of shareholders below).

The GKV-Spitzenverband holds 50 percent of the shares and finances the work of Gematik 100 percent with an amount of 1.00 Euro per member of the statutory health insurance. In addition, the Federal Ministry of Health has adjusted this amount in line with the financial needs (needs of funds) of gematik and in consideration of the economic efficiency of the statutory ordinance in recent years. The other 50 percent of the company shares are distributed among the central organizations of service providers.

Decisions on the development, construction and operation of the telematics infrastructure as well as on the electronic health card are made in various committees that constitute the governing bodies of gematik:

- The shareholders' meeting is the supreme body of gematik. The seven shareholders of gematik are jointly making important decisions on the telematics infrastructure and the electronic health card. The chair changes annually between the GKV-Spitzenverband and the service provider side. Together, they set up the management committee, the statutory and accountable body of the shareholders' meeting.
- The Steering Committee is the decision-making body for the strategic management of projects and control until they are put into productive operation

- The Operations Committee is the body for the further development of products from the transfer of the telematics infrastructure into productive operation and already productive products.
- The Advisory Board comments on fundamental issues and advises the company in accordance with § 291b (2a) SGB V. The members of the Advisory Board are the representatives of the federal states, patient, industry, science and the healthcare professions whose leading organizations are not the shareholders.
- Arbitration Board - If a resolution proposal does not receive the required majority in the shareholders' meeting or other committees and 50 percent of the shareholders submit an application, the arbitration board supports the shareholders to find solutions and decides if any differences persist.

Relationship with stakeholders

All of the stakeholders in the German Healthcare System are represented in the above committees.

The shareholders of gematik are:

- German Medical Association;
- Federal Dental Association (DAV);
- German Pharmacists Association;
- German Hospital Association;
- GKV-Spitzenverband;
- Kassenärztliche Federal Association;
- Dentists Federal Association.

The above stakeholders appoint members to represent them in the Steering Committee.

The members of the Advisory Board are:

- Representatives of the federal states: Baden-Württemberg, Bavaria, Lower Saxony, North Rhine-Westphalia, Rhineland-Palatinate, Saarland, and Saxony.
- Representatives of patients: BAG SELBSTHILFE - Federal Working Group Self-help of people with disabilities and chronic illness and their relatives, VdK - Social Association VdK Germany, vzbv - verbraucherzentrale Bundesverband .
- Representatives of the Industry Associations: ADAS - Arbeitsgemeinschaft Deutscher Apotheken-Softwarehäuser, BITKOM - Federal Association for Information Technology, Telecommunications and New Media, bvitg - Federal Association of Health IT, Initiative D21, Steering Group "IT in Healthcare", VDDS - Association of German Dental Software Company, ZVEI - Zentralverband Elektronik- und Elektronikindustrie, the Federal Commissioner for Data Protection and Freedom of Information, and the Commissioner for the interests of the patients (at the Federal Government) .
- Representative of science: Fachhochschule Dortmund - Department of Medical Informatics, Telematics platform for medical research networks, Berlin, Ostbayerische

Technische Hochschule Regensburg - Faculty of Computer Science and Mathematics, Department of Computer Science / EHealth.

- Representatives of the healthcare professions and service providers whose leading organizations are not the shareholders of gematik: BÄK - German Medical Association, BZÄK - Federal Dental Association, DAV - German Pharmacist Association, DKG - German Hospital Association, KBV - National Association of Statutory Health Insurance Physicians, ZBV - Federal Dentist Association.
- Representatives of federal authorities: Federal Ministry of Health, BMWi - Federal Ministry of Economics and Technology, BSI - Federal Office for Security in Information Technology, Federal Commissioner for Data Protection and Freedom of Information (BfDI).
- Representatives of other groups: BPtK - Federal Psychotherapeutic Chamber, Federal Chamber of Pharmacists, German Family Doctors Association, Non-licensed health professionals, GVG - Society for Insurance Science and Design, Commission of the European Communities, Directorate-General for Information Society and Media.
- Representative of the self-government of the GKV.

3.4 Lombardy Italy – Lombardia Informatica

Brief Description of the Health care System

Italy's health-care system is a regionally organized National Health Service (Servizio Sanitario Nazionale, SSN) that provides universal coverage largely free of charge at the point of delivery. At the national level, the Ministry of Health (supported by several specialized agencies) sets the fundamental principles and goals of the health system, determines the core benefit package of health services guaranteed across the country, and allocates national funds to the regions. The regions are responsible for organizing and delivering health care. At local level, geographically based local health authorities (Aziende Sanitarie Locali) deliver public health, community health services and primary care directly, and secondary specialist care directly or through public hospitals or accredited private providers. The National Health Service is largely funded through national and regional taxes, supplemented by co-payments for pharmaceuticals and outpatient care⁶².

Healthcare services in Italy are structured in four layers:

- Primary care, ambulatory specialist medicine, residential, and day care, organised at the level of health districts.
- Secondary care provided in hospitals, organised and managed at the level of Local Health Authorities (LHAs).

⁶² Ferré F., de Belvis AG, Valerio L., Longhi S., Lazzari A., Fattore G., Ricciardi W., Maresso A. Italy: Health System Review. Health Systems in Transition, 2014, 16(4):1–168 p. viii.

- Public hospital trusts, which provide highly specialised tertiary hospital care, have the status of quasi-independent public agencies, and fall under the direct responsibility of regional health departments.
- Health prevention and promotion programmes, which operate within public health divisions.

Primary care is provided by general practitioners (GPs), paediatricians, and self-employed and independent physicians working alone under a government contract. Although primary care physicians are given financial incentives to share clinic premises with their colleagues, they usually work in single practices. These health service providers are paid a capitation fee, based on the number of citizens registered with them. Each citizen is registered with one doctor, and as long as responsibility is not transferred, this doctor is in charge of the citizen and his/her medical information. General practitioners and paediatricians act as gatekeepers for access to secondary services⁶³.

Hospital care is delivered mainly by public and a limited number of private hospitals, which provide both outpatient and inpatient services. LHAs contract services to private hospitals on the same conditions as they reimburse public facilities. Lombardy opted in 1998 for a fully-fledged experiment in which all hospital and specialist services are delivered by hospital enterprises or private providers. The region's main hospitals were converted to hospital enterprises - free to negotiate financing terms with Local Health Authorities (LHA) – although controlled on the quality of services provided – and citizens were given full freedom of choice between LHAs, hospitals and even social care services. Lombardy is the only region that has carried out a complete purchaser–provider split⁶⁴.

eHealth Strategy and Implementation

The Italian eHealth strategy is strongly influenced by the radical change in the relative roles and responsibilities of the state and the regions embodied in the constitutional reform of 2001. Since then, the Italian strategy comprises three interconnected programmes addressing national, semantic, and territorial needs in order to achieve the following key objectives: to improve the efficiency and effectiveness of the healthcare system as a whole, to assure fundamental levels of healthcare services throughout the territory, and to speed up the processes of technological innovation of citizen/patient-centred social and healthcare services.

From a regional perspective, the most important healthcare planning and guideline document issued by the Lombardy region, Regione Lombardia, is the Lombardy Regional Social

⁶³ Alexander Dobrev, Yvonne Vatter, Tom Jones The health information platform SISS in the region of Lombardy Italy: Socio-economic impact and lessons learnt for future investments in interoperable electronic health record.

⁶⁴ Ferré F., de Belvis AG., Valerio L., Longhi S., Lazzari A., Fattore G., Ricciardi W., Maresso A. Italy: Health System Review. Health Systems in Transition, 2014, 16(4): p. 24.

Services and Healthcare Plan, 2007-2009⁶⁵. The plan has two lines of action: the continuous improvement of the quality of the Lombardian healthcare system and the modernisation of the region's healthcare provision. One of the plan's aims is to promote the development of eHealth, telemedicine and tele-diagnostic applications. The creation of a local and regional ICT infrastructure based on the Lombardian eCard, Carta Regionale dei Servizi della Lombardia, the regional service card of Lombardy, and the region's health information system, Sistema Informativo Socio Sanitario, is considered the cornerstones of Lombardy's eHealth strategy. The strategy consists of five objectives, one of which is "to increase health workers' ability to share relevant individual data and give them the easiest possible access to up-to-date medical knowledge from accredited sources". ICT is considered essential in achieving this goal as, on the one hand, it allows for the genesis of high-quality data, and, on the other hand, it offers the key for health professionals to access this high-quality information⁶⁶.

The objectives of the region's health information system, Sistema Informativo Socio Sanitario (SISS) are to:

- Improve healthcare and social services for citizens by simplifying procedures and reducing waiting time.
- Improve the quality of prescriptions, diagnosis, and care by sharing clinical data among healthcare professionals.
- Improve the administration of social and healthcare system costs by enhancing planning and controlling instruments.
- Improve the efficiency of Health Provider Organizations' internal processes through the deployment of new technologies such as digital signature, electronic filing, and electronic prescriptions. The introduction of a local Hospital Information System (HIS) in each hospital and the implementation of a regional network were considered a good basis for meeting these requirements⁶⁷.

Today, the Lombardy network connects over 7,800 GPs, 2,600 pharmacists, 35 hospitals and 320 clinics or private radiology centres, as well as 150,000 stakeholders of the medico-social sector (teachers, professionals in nursing homes and homes for the disabled, etc.) which almost represents the totality of healthcare provision in the region⁶⁸. Thus, since 2004,

⁶⁵ Regione Lombardia Sanità (2008): Lombardy Region Social Services and Healthcare Plan, 2007-2009.

⁶⁶ Alexander Dobrev, Yvonne Vatter, Tom Jones The health information platform SISS in the region of Lombardy Italy: Socio-economic impact and lessons learnt for future investments in interoperable electronic health record.

⁶⁷ Ibid p. 15.

⁶⁸ Statistics of March 2012. Source : EHealth Platform in Lombardy Region The S.I.S.S. Program – Nicola Contardi - Lombardia Informatica/Regione Lombardia <http://mitos.uniurb.it/wp-content/uploads/2012/05/Urbino-FSE.pdf>.

through the “Regional Card of Services”, a patient can access his/her health data compiled in an electronic health record, or ESF (Fascicolo Sanitorio Elettronico), including:

- his/her hospitalisation reports and consultation with specialists;
- the history of his/her medical prescriptions, with the option to also send it directly to his/her pharmacist (e-Prescription);
- his/her x-rays and their analysis;
- his/her discharge documents;
- his/her medical certificates.

The patient has also access to an online appointment application system, which streamlines the management of admissions and consultations. The patient’s health record is now accessible from a mobile device by sending a unique and personalised password via SMS.

The health professional can access a patient’s record after having been previously authorised to do so through a special card (Carta SISS), and within the limits of his/her assigned rights (a nurse in a nursing home does not access the same documents as a doctor for example)⁶⁹.

National eHealth Competence Centre

Lombardia Informatica is a publicly owned IT service company, founded by the Lombardy regional government in December 1981. Lombardia Informatica is primarily involved in the healthcare sector. In charge of the development and design of the region’s IT systems and the maintenance of the already existing ones, it has the overall responsibility for the Regional Service Card and Healthcare and Social Service Information System (Carta Regionale dei Servizi della Lombardia - Sistema Informativo Socio Sanitario, CRS-SISS).

Lombardia Informatica is citizen-oriented and operates as link among the Public Administration, the market of Information and Communication Technology, Citizens and Companies. Lombardia Informatica’s mission is to innovate services and increase the Regional System’s productivity through Information Technology (IT), in order to improve the Citizens’ quality of life and the competitiveness of the Companies in Lombardy. As the IT partner of the Lombardy Region, Lombardia Informatica designs and implements ICT Systems for the Regional Government and represents the unique interface between the Region and the marketplace.

Lombardia Informatica acts as an interface for the requirements of the Lombardy Region and the solutions offered by the Information & Communication Technology (ICT). This is contributing to the growth in demand and investment in ICT in Lombardy, as shown by the

⁶⁹ Lombardy at the forefront of eHealth LE MAG ARTICLE | 24 FEB 2014 <http://esante.gouv.fr/en/the-mag-issue-9/lombardy-the-forefront-eHealth>.



data of recent years. Over 80% of the total income of Lombardia Informatica is placed on the market through public tenders.

The competences of the company are:

- understanding the needs of the Lombardy Region and guiding the Institution in the innovation processes;
- combining ICT technologies with government and legislation aspects;
- managing projects, tenders and contracts while ensuring efficiency, effectiveness and transparency.

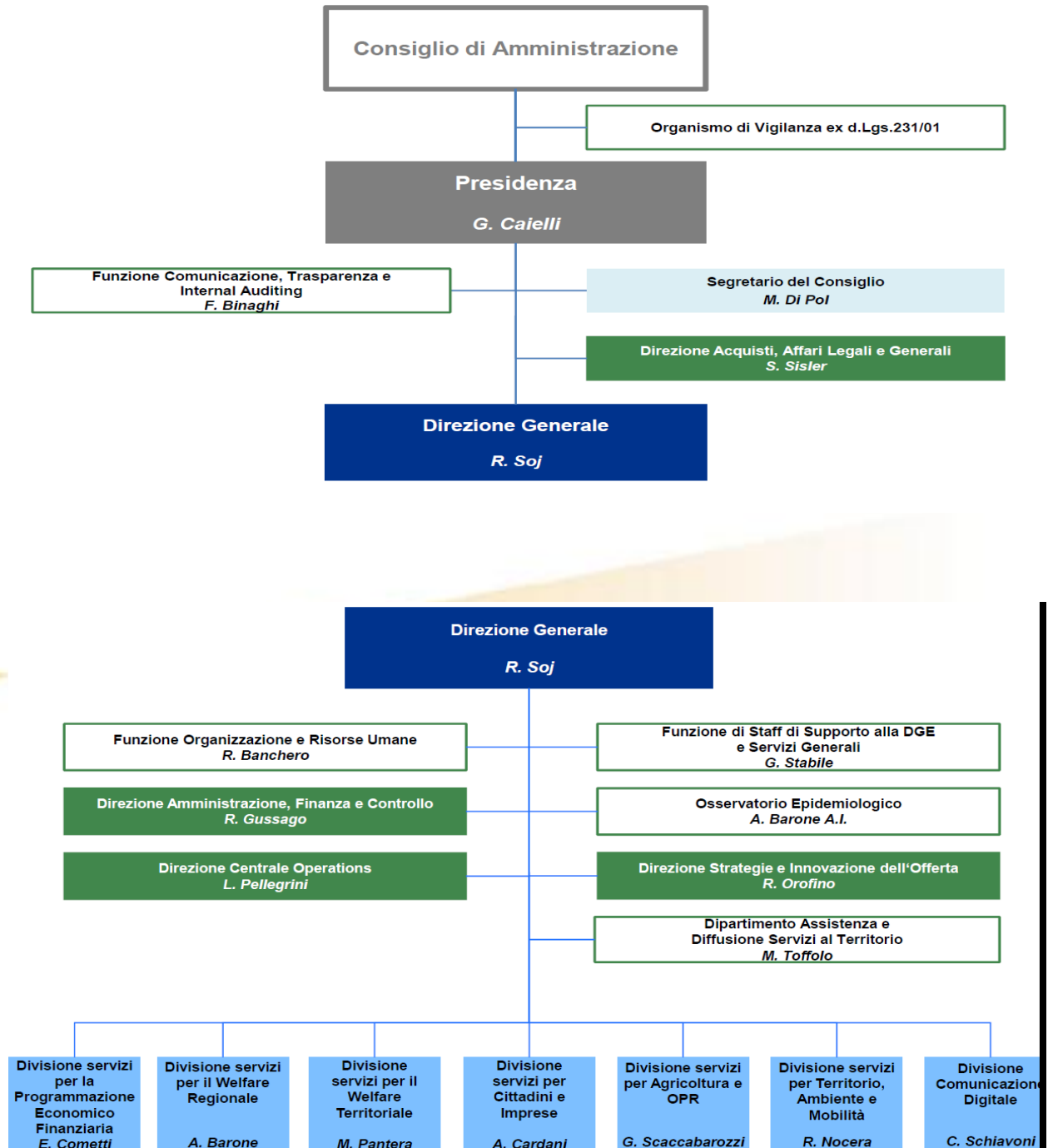
Lombardia Informatica acts as a link between the demand of the Public Administration, the market supply of Information & Communication Technology to citizens and companies who use the services. Lombardia Informatica is an innovative model of a public company, whose mission is to innovate services and increase the productivity of the Regional System, through the use of Information & Communication Technology.

Organization

In February 2005, the Lombardy Region acquired 100% of the control of the capital of Lombardia Informatica. Lombardia Informatica - in compliance with the requirements of the Lombardy Regional Council with resolution n° X / 3718 June 12, 2015 – on November 9, 2015 changed its Statute and left the previous "tier system" in favour of a "traditional system", so specified (so indicated): Governance is provided by:

- the Board of Directors, composed of three members appointed by the shareholders;
- the Board of Auditors, composed of three Effective Members and two Alternate Statutory Auditors appointed by the shareholders.

The following is the Organizational Structure of Lombardia Informatica:



Budget

In the past 20 years, the annual production value of Lombardia Informatica increased from about 50 million to over 180 million Euros in 2014. The Company has about 480 employees. The Shareholders' equity has grown from 10 to over 85 million Euros and fully paid share capital has increased to 25 million Euros. The growth of Lombardia Informatica has enabled innovation and the economic development of the Regional Administration and territory. Over 60% of Lombardia Informatica's turnover is placed on the market for ICT companies through public tenders.

3.5 Luxembourg - Agence eSanté

Brief Description of the Healthcare System

Luxembourg is a representative democracy in the form of a constitutional monarchy. It is a centralized country and is subdivided into 116 communes grouped in 12 cantons. The communes are entities with legal powers⁷⁰. The values and principles of the Luxembourg health system are laid down in Article 11 of the Constitution of the Grand Duchy of Luxembourg dating back to 1868. This is further specified in the Code of Health, the Code of Social Security, with sector-specific legislation as laws as well as regulations, plus Grand-Ducal and ministerial decrees and orders. Key principles of the health system are:

- universal coverage through a compulsory social health insurance (SHI) system, financed mainly by contributions;
- SHI system consisting of three schemes for: (1) health care; (2) accident insurance; (3) long-term care;
- free choice of service providers for patients and direct access to specialist services;
- a central role for self-employed physicians, who are: authorized to provide health services by the Ministry of Health; compulsorily accredited to the National Health Insurance (Caisse Nationale de Santé – CNS); reimbursed according to tariffs as agreed with the CNS national planning of the hospital and pharmaceutical sectors by the Ministry of Health⁷¹.

Regulatory responsibilities are split between the Ministry of Health and the Ministry of Social Security. Both ministries cooperate closely and share responsibility for the organization, legislation and financing of the health system. Health insurance and long-term care insurance are managed by the National Health Insurance (CNS). The CNS was created by law in 2008 and is now the single payer fund for health benefits and long-term care

⁷⁰ Françoise Berthet, Anne Calteux, Michèle Wolter, Laurence Weber, Ewout van Ginneken, Anne Spranger, Luxembourg: HiT in Brief 2015 The European Observatory on Health Systems and Policies p. 3.

⁷¹ Ibid p. 5.

insurance. There is a separation between the primary care sector (dominated by office-based, solo-practice physicians and other health professionals) and the hospital sector, which provides emergency care, specialized ambulatory services and secondary care in Luxembourg. Services in the two sectors differ in the way in which the Ministry of Health plans capacity and in how they are paid⁷². In 2015, 95.2% of the resident population were covered by the compulsory health insurance scheme, with more than half of the population having complementary Voluntary Health Insurance (VHI). Nearly all doctors in the country are self-employed and are paid by fee-for-service, irrespective of whether they practice in hospital or in their own outpatient practice⁷³. The healthcare sector in Luxembourg comprises currently 1544 practicing physicians (2.8/1000 population) 70% of whom are specialists and 30% generalists. About 900 of them are affiliated to a hospital. Currently there are 5 major hospitals for acute care, 4 Laboratories including 1 national laboratory and 3 private laboratory groups⁷⁴.

eHealth Strategy and Implementation

Luxembourg's eHealth action plan, published in 2006, sets out three strategic objectives: improving quality of care; controlling health spending; and enhancing systems interoperability. Recommended actions include establishing a platform for telematic services, reviewing equipment and health information systems, and the implementation of other applications still under consideration, such as electronic health records⁷⁵.

The health reform law of 2010 aimed to improve the efficiency of the health system and contain increasing costs. Efficiency improvements mandated by the 2010 health reform included greater care coordination, transparency on hospital activity with the introduction of a national information system for inpatient care, and the creation of a medical expert board that regularly reviews proposed additions and modifications to the benefits basket. In this context the National eHealth agency (eSanté) was created and has been working on the shared electronic health records (DSP - Dossier de Soins Partagé) since 2011⁷⁶. The pilot phase focused mostly on patients with chronic diseases before being extended to all insured individuals. The DSP contains patient health information relevant to promoting safety, continuity of care, coordination of care and the efficient use of health care services. Patients can access their DSP online and authorized health providers automatically receive key medical data if needed. In addition, patient empowerment was further strengthened by new

⁷² Ibid p. 6.

⁷³ State of Health in the EU Luxembourg Country Health Profile 2017, OECD, European Observatory on Health systems and policies downloaded from http://www.euro.who.int/__data/assets/pdf_file/0011/355988/Health-Profile-Luxembourg-Eng.pdf?ua=1 (p. 7).

⁷⁴ Downloaded from <http://www.sante.public.lu/fr/publications/a/agence-esante-flyer/agence-esante-flyer-20150511.pdf> April 20 2018, p. 2.

⁷⁵ <http://www.who.int/goe/policies/countries/lux/en/>.

⁷⁶ Ibid p. 13.

legislation in 2014, which gave patients the right to receive all available information about their health status, diagnosis, and a plan of examination and treatment options, to help them make informed choices. In line with the European cross-border directive of 2011, patients are now able to access probable treatment costs and options both for Luxembourg and abroad, through the newly established patient information service which is operated by the CNS for questions relating to treatment costs and by the newly established Health Mediator for questions concerning treatments options available within the country⁷⁷. An updated eHealth Strategy: National Health Luxembourg Roadmap- November 2013-2016, was published in 2013⁷⁸. The objective of the roadmap was to identify the priorities for the establishment of the first Health Information System (hereinafter SDSI). The goal of the strategy was to create a platform that will operate the DSP and will integrate, in 2014, a wealth of data that are currently in different formats, mainly paper or informal electronic documents. The main activities to be carried out for effective implementation of the SDSI were defined in five objectives:

- The creation of the framework of governance and management tools.
- DSP & interoperability – establishment of the standards associated with the interoperability framework.
- Platform & services - alignment and prioritization of services from the platform to the uses and needs of care providers.
- Security, protection of data & infrastructure - creation and implementation of the security and privacy policy.
- Support & Development - definition of assessment methods of external projects to the Agency for possible incorporation into its portfolio of projects.

The first priority was governance. The Agency and other stakeholders are to define a complete governance scheme, with the related process. The roles of the different actors will be specified and detailed. Future management of the SDSI bodies will be defined⁷⁹.

National eHealth Competence Centre

Agence eSanté was founded in 2011 as an Economic Interest Group (G.I.E). Its roots go back to 2006, the year in which the Luxembourg government adopted the national Health Action Plan. The first projects launched further to this Action Plan revealed that healthcare professionals needed a platform allowing them to share medical data. Thus, the Luxembourg Government decided in 2010 to create a national agency that would be in charge of implementing this digital platform. The Healthcare Reform Law voted in December 2010 laid the legal basis for the establishment of Agence eSanté, which became operational in 2012 and has since then been in charge of the development of a coherent national eHealth

⁷⁷ Ibid p. 12.

⁷⁸ https://www.esante.lu/portal/fr/gallery_files/site/508/509.pdf.

⁷⁹ Ibid pp. 2-3.

strategy. The eSanté team currently consists of 20 professionals who drive and monitor the various projects that are required for the deployment of the eHealth platform and its services. The interdisciplinary team with its variety of profiles provides the necessary diversity in expertise and also reflects the technological, professional and cultural challenges of this ambitious national project⁸⁰.

The eSanté Platform and its services

The national eHealth platform provides tools that enable the exchange and sharing of health information between health professionals known to the platform, while meeting the requirements in terms of security and privacy protection.

The platform's principal tool to facilitate this information sharing is the so-called "Dossier de Soins Partagé" (DSP), a patient's secure electronic health record allowing authorised healthcare providers, as well as the patient himself, to have access to the latter's relevant health related information. The services offered by the eHealth platform allow a simplified and expeditious use of medical information, and thus support the improvement of prevention, diagnosis, treatment and medical monitoring. As such, they will undoubtedly have a positive impact on the quality of Luxembourg's healthcare, for the benefit of the patient.

Current state of Art:

Agence eSanté has already deployed a first range of services and applications; some others are in the pilot or testing phase, or about to be deployed. Amongst the launched services are the national Healthcare Provider Directory, the application for Secure Messaging, the Document Database, the Collaborative Workspace and the Prevention Datasheet.

Ideomed and IdeoRCP are currently in the testing and alignment phase to prepare a seamless deployment, including training sessions for the concerned institutions and their staff. The DSP, the eHealth platform's key component for medical data sharing, has been launched in a pilot phase (under the name DSP) to a limited group of patients before making it generally available. Thus, the Agence eSanté's services will include all of the following:

- "Secure Messaging" an application for the secure e-mail exchange between the healthcare professionals registered in the national Healthcare provider directory.
- "Collaborative Space", a (virtual) application for project management and theme related exchange between healthcare professionals.
- "Healthcare provider directory" (HPD), the national directory listing healthcare professionals – both individuals and institutions – who are authorised to provide healthcare services in Luxembourg.

⁸⁰ Downloaded from <http://www.sante.public.lu/fr/publications/a/agence-esante-flyer/agence-esante-flyer-20150511.pdf> April 20 2018. p. 1.

- “IdéoMed” and “Gecamed”: two patient management IT support systems, put at the disposal of small institutions (who do not have a technical platform) and private professionals respectively.
- “Document database” an on-line database for sharing documents and publications, which are classified by theme. Documents stored in the “restricted” zone can only be accessed by healthcare professionals after due authentication.
- “IdeoRCP”, an application that provides a tool for pluri-disciplinary meetings and concertation, as well as an electronic record designed for medical teams in charge of cancer patients.
- “Prevention Datasheet”, a tool for the evaluation of a number of risk factors that will help the general practitioner determine and provide the patient with the required preventive measures;
- NPS “National Pseudonymisation Service”, a component that allows to communicate pseudonymised data with-out having to communicate the patient’s true identity. It aims to prevent the unauthorised, unwanted disclosure of information about a person by reducing the probability of an individual being associated with the (medical) data.
- “Dossier de Soins Partagé” (DSP), a patient’s secure electronic health record⁸¹.

The three main components of the eHealth Platform being developed are the DSP, the HDP and the MPI:

1. The eHealth platform’s main tool for health information sharing is the “Dossier de Soins Partagé” (DSP), a patient’s personally controlled, secure electronic health record. The DSP allows patients and healthcare professionals to view and share healthcare data that are relevant to an optimally coordinated treatment. It serves as a collaborative tool for healthcare professionals and as such facilitates a better communication between them. Health professionals involved in a patient’s care and who have been granted access to the latter’s DSP, are able to access the information at any time, and thus have the last up-to-date information of the patient’s health. This will help ensure appropriate and fast care. One particular feature of the DSP is that it is under direct control of the patient himself, who controls what information goes into it and who is allowed to access it. At all times he can see who accessed his DSP, when and why (read, write). Furthermore, he can comment on his information in a specifically dedicated virtual space. He can decide to close his DSP any time. The DSP shall encourage people to become active participants in their own healthcare. The DSP complies with the latest international norms and recommendations and applies multi-layer security measures so as to obtain an as high as possible data security and protection degree. The DSP is not a substitute for professional records. The healthcare professional may either continue to work with

⁸¹ Ibid p. 3.

his or her usual business software if it is compatible with the eSanté platform, or with business software provided by the platform⁸².

2. The HPD is the national directory for Luxembourg's healthcare sector. Acting as a central building block to the eHealth platform, it contains valuable and consolidated information about each registered healthcare professional. Being able to authenticate a healthcare professional is a recurrent need for the services of the national eHealth platform, whether for technical, security, or functional reasons. It is an essential component for the secure use of the eHealth services. By way of example, the HPD is used to auto-complete names and emails in the secure messaging service, or to identify a professional and his specialty, and check the latter's assigned access rights to a DSP's document types. It is a directory available to the public on www.eSanté.lu, offering various selection criteria (name, profession/specialisation, place, ...) that will help users find and geo-localise the right healthcare professional.
3. The Master Patient Index (MPI) is a centralised resource for patient demographics. Conceived as a national patients' directory, the MPI delivers trustworthy information about a patient's identity. It will as such serve as referential directory for the identification and authentication of a patient, for all the eHealth services delivered by the eHealth platform. Next to the "basic" identification and authentication function, the MPI also contains a powerful and customised (and customisable) matching algorithm to compare and match identities among different domains, and institutions. For indeed, exchanging and sharing patients' data between different healthcare structure networks requires a complete match of the patient identification data. On top of that, the MPI serves as the operational tool used by Agence eSanté's identity vigilance team to reduce and manage the residual risk on patients' identity.

Standards

The eHealth platform has been developed and built according to the latest and widely used inter-national standards. This alignment simplifies the conception, validation, and delivery process, and therefore has two direct benefits: the services are readily available and the related costs, also the recurrent ones, are lower. Moreover, following international standards gives the benefit of developing and implementing services on the basis of worldwide user experience. Applying standards such as the CDA R2 format and the IHE XDS.b profile, allowed us to quickly connect and integrate external systems into the platform and run the necessary tests. The platform makes use of standards and norms for different purposes. Here a selection of the ones applied: TLS, WS-Security, SSO (security); HTTP and SOAP (transport); SOA and EAI (architecture)⁸³.

⁸² Ibid p. 4.

⁸³ Ibid p. 5.

Data Protection

The eHealth Platform and its component services including the Shared Care File (DSP) have been developed by the eHealth Agency to promote the sharing and exchange of health data in a secure manner between healthcare professionals and patients.

Health data is sensitive personal data that relates directly to a patient's sphere of privacy. Therefore, the processing of these data, essential to promote continuity and good coordination of care, requires a high degree of security and a strong commitment to protect privacy. As such, the experts of the National Commission for Data Protection (CNPD) and eHealth Agency engaged in a working group in an analysis of the components of the platform and its services, to ensure that the means and processes put in place to carry out the processing of these data comply with the requirements for the protection of such sensitive personal data.

Legislation

The law of 17 December 2010 on the reform of the health system gives the eHealth Agency a legal basis through Articles 60.3 and 60.4

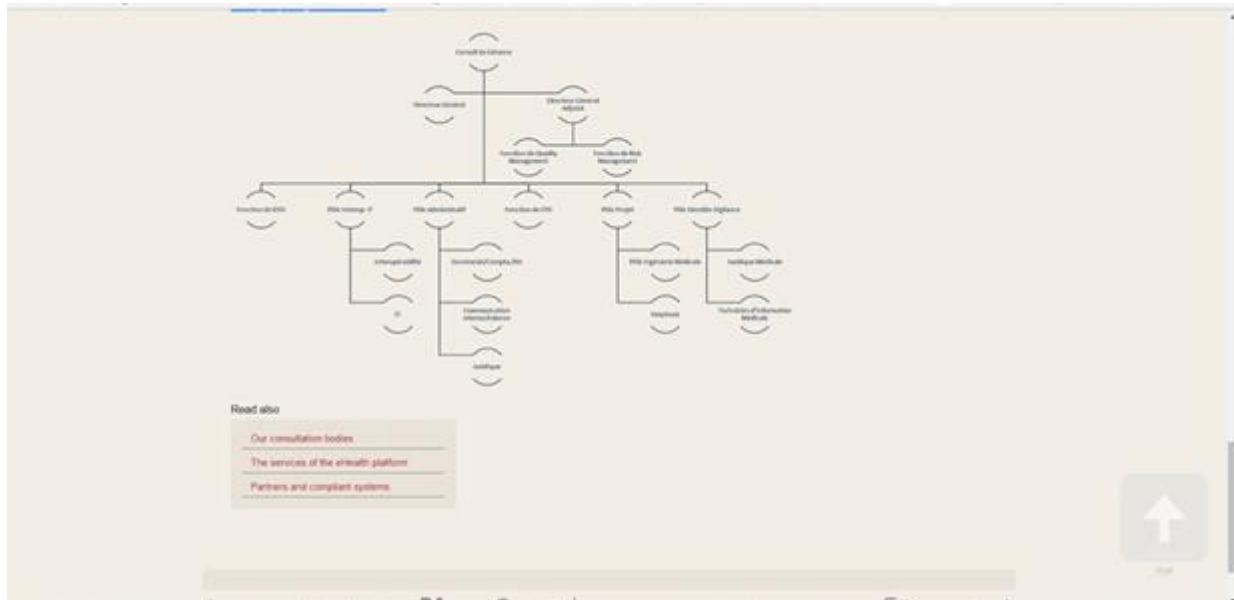
Organization

Agence eSanté is an Economic Interest Group (G.I.E). The governance model adopted by GIE Agence eSanté brings together at the level of the General Assembly and the Board of Managers the relevant health actors, from the public and private domain as well as from the field of healthcare providers, and the representation of patients' interests. Its Board of Managers consists of 15 people representing the following organizations:

- the Luxembourg State, represented by the Ministry of Health and the Ministry of Social Security;
- the National Health Fund (Caisse Nationale de Santé);
- the Joint Social Security Centre (Centre Commun de la Sécurité Sociale);
- the Association of Doctors and Dentists (Association des Médecins et Médecins-Dentistes);
- the Luxembourg Hospital Federation (Fédération des Hôpitaux Luxembourgeois);
- the Association for the Defense of Patients' Interests (Patientevertriebung);
- the Luxembourg association of pharmacists (Syndicat des Pharmaciens Luxembourgeois);
- the Confederation of long term and home care providers (Confédération COPAS);
- the Luxembourg federation of laboratories (Fédération Luxembourgeoise des Laboratoires d'Analyses Médicales).

The task of the Board of Managers is to define and validate the agency's objectives and actions, which have been set out in a 4-year strategic business plan. Broader governance is planned at the level of a General Assembly which will have a representative of each member of GIE Agence eHealth.

The Agency is organized as follows:



Staff

Agence eSanté has a dynamic and multidisciplinary team, currently composed of 20 people, headed by an executive director who carry out the day to day activities of the organization. The diversity of profiles (doctor, caregiver, computer scientist, lawyer, project manager, administrative) and the original mix of members (Luxembourgish, Portuguese, French, German, Belgian, Rwandan, Italian, Romanian, Chinese) of the team reflects the importance of the technological, professional and cultural challenge of the ambitious national project it is carrying out.

Stakeholder Involvement

Constructive partnership and joint reflection are two core values forming an integral part of Agence eSanté's decision-taking process. On a national level this has materialised into a multitude of work groups aiming to gather healthcare stakeholders' input and opinion or seeking their validation. Accordingly, two advisory committees were created in alignment with the agency's articles of association: one focused on interoperability and the other one on ethical and deontological aspects. When required, dedicated thematic work groups are put in place to elaborate one specific topic. The interoperability committee, for instance, set up a dedicated CDA («Clinical Document Architecture») task force, composed of radiology and biological analysis experts, in order to define the implementation framework for the specifications of the CDA-header metadata, and for the structural specifications of the content of radiology reports and biological analysis reports. Likewise, a dedicated LOINC committee was put in place bringing together 17 representatives of the Laboratory domain, with the objective to create a national «Lux-LOINC» register.

Another topic for which the Agence eSanté sought the practical input from the healthcare professionals was the elaboration of the DSP access control matrix, which defines the

access rights of a healthcare professional as a function of his specialty and the kind of information he requires to perform his task in an optimal way. In order to assess the DSP access rights for the 23 officially recognised healthcare professions, Agence eSanté held about 30 meetings with altogether more than 120 healthcare professionals⁸⁴.

3.6 Netherlands – Nictiz

Brief Description of Healthcare System

Before 2006 the Dutch health system was a hybrid system based on social insurance, combined with a long-standing role for private insurance covering the better-off. The 2006 reforms introduced three managed markets for a defined universal health insurance package, plus healthcare purchasing and provision. The government stepped back from direct control of volumes and prices to a more distant role as supervisor of these markets (though planning of medical professionals remains by limiting the number of doctors trained). Both insurers and providers have been consolidating, in part to strengthen their position within the market. Currently, four insurer groups have 90% of the insurance market.

Long-term care was reformed in 2015 in order to contain costs (and was the subject of an EU recommendation through the European Semester). Care at home, preferably by informal carers, is now given greater priority over institutional care, which was seen as having become over-used. Municipalities became responsible for social care – and with a reduced budget, on the assumption that locally organized care will be more efficient. Health insurers took over responsibility for home nursing, with district nurses playing a key role in integrating different aspects of care and support⁸⁵.

Healthcare is principally (72%) financed through the compulsory health insurance contributions from citizens, with an additional 13% from general taxation. Adults pay a community-rated premium to their insurer (the government contributes the premium for children), plus an income-dependent premium into a central fund that is redistributed amongst insurers on a risk-adjusted basis. The basic benefits package includes GP care, maternity care, hospital care, home nursing care, pharmaceutical care and mental healthcare. The first €385 (in 2016) must be paid out of pocket, except for GP consultations, maternity care, home nursing care and care for children under the age of 18. Care that is not covered under the basic package can be insured via Voluntary Health Insurance, such as glasses and dental care.

Health insurers and providers negotiate on price and quality of care, although competition on quality is still in its infancy. For care for which negotiation is not feasible the Dutch Healthcare Authority establishes maximum prices. Healthcare providers are independent non-profit

⁸⁴ Ibid p. 7.

⁸⁵ Kroneman M, Boerma W, van den Berg M, Groenewegen P, de Jong J, van Ginneken E (2016). The Netherlands: health system review. *Health Systems in Transition*, 2016; 18(2):1–239. P xx.

entrepreneurs. Hospitals are paid through an adapted type of diagnosis-related group (DRG) system: Diagnosis Treatment Combinations. GPs are paid by a combination of fee-for-service, capitation, bundled payments for integrated care, and pay-for-performance (focused on issues such as accessibility and referral patterns)⁸⁶.

Public health services are primarily the responsibility of municipalities and include services such as prevention, screening and vaccination.

The gatekeeping principle is one of the main characteristics of the Dutch system and means that hospital care and specialist care (except emergency care) require referral from a GP (or some other primary care practitioners, such as midwives or dentists). Around 93% of all patient contacts with a GP are handled within primary care; only 7% of the contacts result in a referral to secondary care. Extra attention is now being paid to integrated care for chronic diseases and care for people with multi-morbidities, and the shift of care to lower levels of specialization: from hospital care to GP care to practice nurse to self-care⁸⁷.

eHealth Strategy and Implementation

An eHealth roadmap in ICT terms was produced in 2006 entitled “ICT in Dutch Healthcare; An International Perspective”. From a Dutch perspective, eHealth should not be regarded as separate from (regular) health; therefore, no dedicated, encompassing eHealth policy document exists, but there are several multi-focused policies. The focus in the Netherlands from the start was on implementation of an electronic medication record and an electronic general practitioner’s summary. Another important development was the Healthcare Innovation Platform Zorginnovatieplatform, ZIP) Inspiration for Innovation which included development of technologies for chronically ill and older people. In terms of patient summaries in the Netherlands the “Patient Summary Record for the Locum GP” (WDH – Waarneem Dossier Huisartsen) was developed and approved as proof of concept in 2006. It is implicitly considered the patient summary for the entire healthcare system. By the end of 2009 the WDH had been put extensively to use between GPs and GP after hour services. The ePrescription procedure between GPs and pharmacists, within a region, has been routine in the Netherlands for many years now. Information technology plays an important role in the Dutch healthcare system, as it does in society in general. Most Dutch people would welcome the opportunity to contact providers through the internet, but this option is not yet widely offered. Coordination of ICT applications is growing and both users and providers of healthcare services increasingly see benefits⁸⁸.

⁸⁶ P. xxi.

⁸⁷ P. xxiii.

⁸⁸ P. 105.

Most healthcare providers use some form of electronic patient record. Many hospitals are investing in new systems that allow them to share information both within the organization and with partners in care chains, such as GPs, pharmacists and laboratories⁸⁹.

All general practitioners (GPs) use an electronic patient record system; this includes an electronic prescription system. However, the national roll-out of an electronic patient record system to interconnect these practice-based systems failed, mainly for reasons of privacy; a more limited system is being implemented in its place⁹⁰.

All GPs in the Netherlands use an electronic GP information system to record medical data about their patients. The information system is used to manage the care process and for administration purposes. GP information systems are linked to the professional guidelines, which GPs can consult during a patient contact. To optimize the prescription of pharmaceuticals, the Electronic Prescription System (Elektronisch Voorschrift Systeem, EVS) is integrated into the GP information system. The EVS provides GPs with advice on pharmacotherapy and related patient counselling. The introduction of the EVS has improved the quality of prescriptions and the use of electronic medical records and has resulted in a reduction of expenditure on medicines. Since the beginning of 2014 prescribers of medicines may only do so by using an Electronic Prescription System that includes a functionality to monitor unsafe situations.

A national roll-out of the Electronic Patient Record (Elektronisch Patiënten Dossier, EPD) failed after vigorous debate and opposition. The national EPD was not meant to be a central database of patient data, but rather an infrastructure for care providers drawing from local databases of individual healthcare providers. It aimed to reduce the likelihood of medical errors resulting from lack of information, especially in out-of-hours care. Many GPs resisted a central exchange of patient data because they feared unqualified access to the information. Eventually the roll-out was blocked in the Senate because the privacy of patients was insufficiently guaranteed. Currently more pragmatic new initiatives seek to exchange patient data in a more feasible way. A new system called Care Infrastructure (Zorginfrastructuur), which is the new name for EPD, allows care providers to exchange information on patients and the use of pharmaceuticals on a voluntary basis. GPs, pharmacists and medical specialists may only exchange data from patients who have explicitly given consent. It should be noted that the current system does not allow patients access to their medical data. Since 2012, the Association of Care Providers for Care Communication (Vereniging van Zorgaanbieders voor Zorgcommunicatie, VZVZ) has been responsible for Care Infrastructure (<https://www.vzvz.nl/>)⁹¹.

⁸⁹ Ibid p. 37.

⁹⁰ Pp. xx-xxi.

⁹¹ P. 37 (HiT).

In 2012 a number of stakeholders and professional organizations took the initiative to work together to promote the development and use of eHealth. They agreed upon a National Implementation Agenda for eHealth, starting from the observation that there is no lack of innovative ideas and promising applications, but that already developed applications are rarely widely implemented. In 2013 this resulted in the eHealth Governance Covenant 2014 – 2019. This Agenda sets out a three years plan centred around self-management by patients and care substitution initiatives. Other issues addressed include using personal health records, developing data exchange standards, and preparing a long-term research and innovation agenda.

The governmental vision on eHealth, formulated in a letter to the Parliament in June 2012, acknowledged the chances and opportunities offered by eHealth, under the condition of absorption of eHealth by patients and care providers. It was therefore decided that developments and progress in the use of eHealth would be monitored annually⁹².

The first monitoring study, in 2013, among care providers, care users and a number of stakeholders, identified four categories of eHealth:

- searching for health information by healthcare users (e.g. internet use; mobile apps for digital self-tests; tracking health data; or participating in online discussion forums);
- communication between user and care provider (e.g. making appointments or asking questions of care givers; online access to medical files; tele-monitoring);
- medical file management by care givers (e.g. the electronic patient record); and
- communication among care providers (e.g. through electronic referral letters)

The 2015 monitoring study recommended that eHealth should focus on the most promising services, including: online services for healthcare users (such as making appointments; access to health records); information exchange between healthcare providers; and e-care or distant care and dispensing for medicines⁹³.

National eHealth Competence Centre

Nictiz is the Dutch National ICT Institute for Healthcare. Nictiz is an impartial and neutral organization in which all parties involved in the healthcare process take part: healthcare providers, patients, healthcare insurance companies and the government.

It was established in 2002 and is an independent foundation with an independent Board of Directors

The aim of Nictiz is to create the right conditions for the nation-wide provision of information for and about the patient. Part of its task is to combine the strengths of existing IT initiatives.

⁹² P. 116.

⁹³ P. 117.

The ultimate aim is to achieve full accessibility and an efficient exchange of information with the aid of a basic IT infrastructure and a national Electronic Patient Record (EPR). Security and transparency are important considerations in this respect. NICTIZ has chosen to focus on the medication record.

Nictiz is the centre of expertise for eHealth and helps to enable these connections in different ways. As such, Nictiz is conducting research and is involved with large national eHealth programmes. It is also monitoring eHealth trends and interpreting these to help with the establishment of Netherlands national policies of various parties, such as the Ministry of Health, Welfare and Sport, nation-wide umbrella organisations and the Informatieberaad Zorg (national healthcare consultation).

Nictiz is also a partner in national programmes aimed at exchanging information in healthcare such as MedMij. Enabling the exchange of information requires information standards. Nictiz develops and manages these standards and provides advice on their implementation. It provides these information standards and medical terminology via its help centre. Professionals developing eHealth applications can also come with their questions and for advice⁹⁴.

Nictiz's activities are divided into two programs: AORTA and Healthcare Applications⁹⁵.

AORTA

AORTA is the Dutch national infrastructure for the exchange of data between healthcare providers. AORTA uses HL7 version 3 messages and documents as its core mechanism for information exchange. The AORTA program addresses the basic infrastructure linking patients, care professionals and health-care insurers. The infrastructure specifications include a description of both technical, organizational as well as implementation aspects. It also includes data protection measures.

Healthcare Applications:

The focus of this program has been to facilitate the realization of a national EPR. The program addresses the creation of unified information models, terminology systems and the structure of the EPR itself. The EPR is "continuity of care" oriented. The first two implementation areas of the EPR were an Electronic Medication Record (EMR, Dutch acronym: EMD) and an electronic general practitioner's summary file to be used by locum GP's (Electronic Locum Record, ELR, Dutch acronym: WDH).

⁹⁴ <https://www.nictiz.nl/english/>.

⁹⁵ WHO national ehealth strategies <http://www.who.int/goe/policies/countries/en/>.

Organization

Nictiz is a foundation, and has an independent, supervisory board. Nictiz is almost entirely financed by the Ministry of Health, Welfare and Sport. Its annual reports are published on its website⁹⁶.

Nictiz Supervisory Board & management

The Supervisory Board consists of four members. The composition is:

- Peter van Lieshout (chairman): professor of Theory of Care at Utrecht University and former director general of health at the Ministry of Health, Welfare and Sport;
- Marjolein ten Kroode: chairman of the board of GGZ Rivierduinen;
- Wout Adema: member of the board of the St. Antonius Hospital Utrecht / Nieuwegein;
- Hanny Kemna: IT auditor, advisor and director with international experience.

The composition of the management is:

- Lies van Gennip: director;
- Hedde van der Lugt: manager Standards & Implementation;
- Peter Mooren: manager of Expertise Centre.

Stakeholder Involvement

If NICTIZ is to achieve its objectives, it is essential that its activities be supported by as many of the parties involved as possible. Ultimately, NICTIZ needs to be able to rely on the involvement and cooperation of all the players in the IT and health-care field if the plan is to be successful. Care professionals in the care and cure sector, patient organizations, health-care insurers and care sector IT specialists are all closely involved in the activities of NICTIZ. NICTIZ is supported by an Advisory Board which consists of representatives from various sections of the care sector.

In addition, Nictiz is working closely with the Dutch Normalization Institute (NEN). A joint NICTIZ/NEN Programme & Policies Committee will put forward recommendations about the contents of Nictiz's program and the relevant normalization activities within NEN.

Nictiz also works closely with the Health Information Council which is an administrative cooperation between participants from the care field and the Ministry of Health, Welfare and Sport. Together, the members of the Information Council work on a sustainable information system in health care. The Information Council defines, to a large extent, the Nictiz work

⁹⁶ <https://www.nictiz.nl/over-nictiz/>.

plan. The members of the Information Council include the major stakeholders in the Dutch healthcare system:

- the Secretary-General of the Ministry of Health, Welfare and Sport (VWS) as Chairman of the Council;
- the directors-general of VWS and the director-general of the National Institute for Public Health and the Environment as portfolio holder for information provision in the Board of Directors (as DG VWS);
- administrative representatives of the umbrella organizations and client and patient federations;
- Actiz;
- Federation Medical Specialists;
- GGZ Nederland;
- Royal Dutch Society for Physical Therapy;
- Royal Dutch Society for the Promotion of Pharmacy;
- National GPs Association;
- Ministry of Health, Welfare and Sport;
- Dutch Federation of University Medical Centres;
- Dutch Huisartsen Genootschap;
- Dutch Association of Hospitals;
- Patient Federation Netherlands;
- Dutch Care Services Association;
- Dutch Municipalities Association;
- Nurses & Caregivers Netherlands;
- Health insurers Netherlands⁹⁷.

3.7 Comparison and Analysis of Similarities and Differences

There is a great deal of diversity among the six NeHC models.

3.7.1 Health Systems

Three of the healthcare systems – Germany, Luxembourg and the Netherlands are Social health Insurance systems with health insurance organizations charged with assuring that their members receive the benefits and services defined by the National Health Insurance System. They all pay providers (who are generally independent) for services, each in accordance with regulations and procedures defined by each system and these differ among the three systems. The other three systems are National Health Systems although there are significant differences among them. England is a centralized system, Finland is a very decentralized system where health and social care is essentially the responsibility of the

⁹⁷ <https://www.informatieberaadzorg.nl/over-het-informatieberaad>.

Municipalities and Lombardy is a Regional Health System with a great deal of autonomy but functioning within the context of Italy's National Health System. Providers are mixed, some of them are independent, some of them run by the system with salaried professionals and some of them private but still paid by the public system.

3.7.2 eHealth Strategies

The major similarity among the eHealth strategies is the dedication to use ICT for the benefit of patients. The “concept” of sharing medical information among providers is common to all although expressed differently by the strategies in each country – which also affects implementation. England has Patient care summary records but does not really have a national EHR. Finland has a fully integrated EHR to which all providers have access and the patient also has access to his own medical record information (and can now even add patient reported information). Lombardy has a regional information system to which almost all providers are connected, and the patient has access to his own information. In the Netherlands, all of the providers are using electronic medical records but there is still not a national system. Luxembourg is moving strongly in the direction of a national system and its vision is to give the patient control over who has access to his “comprehensive” data (the DSP), although each professional has his own electronic record. Germany has expressed in its eStrategy the goal of shared electronic medical records but has been balked by stringent privacy regulations. The core of the German strategy is the electronic patient card which is essentially an insurance card and has been implemented on a national basis, as well as a professional eCard. These cards are meant to be a part of the basic infrastructure that will enable Germany to move to a shared information system in the future. England, Finland, Lombardy and the Netherlands have ePrescription systems, Luxembourg is moving in this direction, Germany will need to have a national system in place which currently does not exist. Telemedicine is mentioned specifically in the eHealth strategies of Germany and Lombardy. All of the countries address the concept of using eHealth and ICT technology to improve the efficiency of the system, although in Luxembourg, the hope that eHealth will enable better control of healthcare costs seems to be a major motivation

3.7.3 Organization

The organizational nature and structure of each of the six NeHCs is different:

- NHS Digital is an executive non- departmental public/government body with a legislative mandate, accountable to the Secretary of State for Health
- THL is an independent expert agency working under the Ministry of Social Affairs and Health
- Gematik is a joint company (GmbH) owned by its shareholders who are the major actors in the German Healthcare system with a legislative mandate
- Lombardy Informatica is a publicly owned IT Company owned by the Lombardy Region
- Agence eSanté is an Economic Interest Group (G.I.E).with a legislative mandate
- Nictiz is an independent foundation with an independent board of directors

3.7.4 Functions

All of the NeHCs have different functions and responsibilities:

- Only gematik and Agence eSanté have responsibility for guiding eHealth Strategy although final decisions about eHealth Strategy is not in their authority.
- All of them are expected to act in accordance with and facilitate the implementation of the eHealth Strategy adopted by the Country.
- All of them have some involvement in Data Protection and are involved in technology development.
- All of them are involved in some fashion in monitoring what is happening in the eHealth system.
- Only NHS Digital and THL have a formal responsibility for making healthcare data available including publishing reports and statistics on a regular basis.
- Only NHS Digital, Lombardy and Agence eSanté are responsible for running live IT services.
- It would appear that NHS Digital, THL, Agence eSanté and Nictiz are either responsible for or actively involved in setting standards for the ICT systems.
- gematik would appear to have some regulatory responsibilities
- THL – in addition to its functions in supporting the KANTA system – runs other governmental programs and is an internationally respected research Centre.

The differences in functions among the NeHCs studies are due to large degree to their context – that is the nature of the Healthcare system and its internal dynamics, the presence or absence of other agencies and organizations with responsibility and/or authority with regard to eHealth and the decisions of policymakers and politicians at the national governmental level.

4 In-depth Studies of Austria, Denmark, Slovakia – Potential Models for the Czech Republic NeHC

4.1 AUSTRIA

4.1.1 The Austrian healthcare system

The Austrian health care system is characterised by the federalist structure of the country. The major stakeholders in the Austrian health care system are:

- the federal Ministry of Labour, Social Affairs, Health and Consumer Protection [Link];
- the 21 different social insurance funds (“Sozialversicherungsträger”) under its umbrella organisation called Federation of Austrian Social Insurance Institutions (“Hauptverband der oesterreichischen Sozialversicherungsträger”) [Link];
- the 9 federal states (“Länder”);
- professional associations (e.g. the Austrian Medical Chamber, the Austrian Pharmacist Chamber, the Austrian Federal Economic Chamber, the patient advocate, etc.).

The federal government is only responsible for enacting basic laws. Legislation on implementation and enforcement is in the responsibility of the federal states and the federal health funds (“Landesgesundheitsfonds”), respectively. The states are also responsible for the inpatient sector and the care sector. Thus, the states are the main operators of hospitals and care facilities in Austria. Furthermore, in the most states the hospitals are organised in umbrella organisations (e.g. the KAGES in Styria [Link] or the KAV in Vienna [Link]).

In the outpatient sector, but also in the rehabilitation sector health care is organised by the health insurance funds and the Federation of Austrian Social Insurance Institutions on the one hand and the chambers of physicians and pharmacists (which are organized as public-law bodies) and on the other. Beside the public healthcare sector there is also a distinct private healthcare sector in Austria.

In this heterogeneous environment, it is crucial to create interfaces to enable the exchange of distributed information in a standardised way electronically in order to avoid redundant investments and unnecessary efforts for the patients and the health care providers.

Facts & Figures concerning the Austrian Health Care System



- Population: **8,36 Mio** (equipped with e-card)
- Hospitals: **266** (containing 64.000 beds)
- Medical Doctors in hospitals: **21.700**
- Care personnel: **82.600**
- General practitioners: **12.700**
- Specialists: **19.200**
- Dentists: **4.600**
- Doctors in training: **6.900**
- Midwives: **1.800**
- Pharmacies: **2.250** (Public pharmacies and pharmacies in hospitals and with general practitioners)



Source: Die österreichische Sozialversicherung in Zahlen, Hauptverband der österreichischen Sozialversicherungsträger, March 2011, Figures rounded

- Financing by Federal entity, Provinces and Social insurances
 - very complex to balance

June 7, 2016

2

Figure 1: Eisl H. The Austrian Experience in Implementing the electronic health record on national level. IHE World Summit. Amsterdam, June 7, 2016 [Link].

Further information about the Austrian healthcare system can be found here:

- BMGF. The Austrian healthcare system, 2013 [Link]
- SV. Statistisches Jahrbuch der österreichischen Sozialversicherung. 2017 [Link]
- LSE. Efficiency Review of Austria's Social Insurance and Healthcare System. 08.2017 [Link]

4.1.2 Brief description of the national/ regional eHealth Strategy

The use of information- and communication technology in healthcare is an essential part of the Austrian digitalisation strategy [Link]. The Austrian eHealth strategy is mainly defined by the legal framework (e.g. healthcare reform law), the financing, and the political intent on national and regional level. An official, national eHealth strategy for the period after the implementation of ELGA is being worked on.

National

Following international developments in the area of eHealth since the beginning of the millennium, Austria has started the work to foster electronic data exchange and eHealth services in the Austrian healthcare system in 2005 [Link]. The Austrian eHealth Initiative (EHI) was launched in April 2005 as one of several groups to do conceptual work. As a first result the recommendation for a national eHealth strategy was officially unveiled in January 2007 [Link]. The strategy proposed the development of an electronic health record and depicted seven key facets, respectively:

- general aspects of a national eHealth strategy;
- interoperability and standardisation;
- patient identification and archiving;
- network of the health care and social system;
- customer related information systems;
- health care system related information systems;
- telemedicine.

An official working group (ARGE ELGA) was set up in 2006 by the Ministry of Health, together with the Federation of Austrian Social Insurance Institutions, the federal health commission (“Bundesgesundheitsagentur”) and the federal states. The mandate of the ARGE ELGA was to conduct preliminary feasibility studies for the implementation of a national electronic health record in Austria [Link].

Promoting the use of information- and communication technologies in healthcare was already one of the defined priorities in the Austrian Health Reform Act and the Health Telematics Act 2005, respectively [Link]. Based on the conceptual work of the ARGE ELGA and the EHI the public discourse about the legal framework for a national electronic health record started in 2008.

Finally, the legal basis for the standardised, electronic health data exchange in Austria was specified in the ELGA Act in 2012, which constitutes an extension of the Health Telematics Act 2005, the EC Data Protection Directive, the Data Protection Act 2000, Medical Law 1998, Law on Documentation and Federal Law on Hospitals and Cure Facilities, among others [Link].

Main ELGA use cases



1. **Making clinical documentation available**
 - a. „e-Reports“
 - b. Registration of and access to clinical documents
2. **Making medication data available**
 - a. „e-Medication“
 - b. Prescription and dispenses are documented
 - c. List of medication can be retrieved
3. **ELGA in general**
 - a. **Authentication** of health service provider and patient
 - b. **Access control and logging**
 - c. Access to **demographic data** of patients
 - d. Future: Connection to patient's living will and precaution authorisations, Medical Registers, etc.

June 7, 2016

3

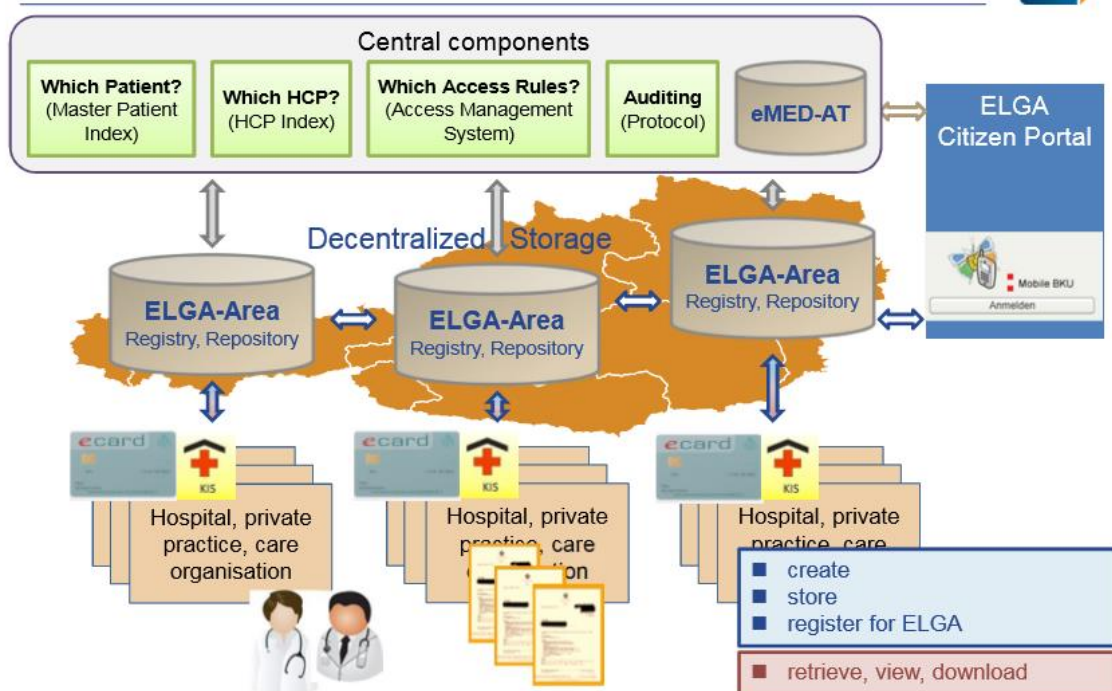
Figure 2: Main ELGA use cases. Eisl H. The Austrian Experience in Implementing the electronic health record on national level. IHE World Summit. Amsterdam, June 7, 2016 [Link].

Today, the Health Telematics Act [Link] provides the basic legal framework for all eHealth activities in Austria. In particular, the Health Telematics Act addresses general definitions, general rules for the secure electronic data exchange in healthcare (chapter 1, 2, and 3) and the core components of the national electronic health record (“Elektronische Gesundheitsakte” - ELGA) including e-medication (chapter 4, this chapter is also called ELGA Act). Thus, ELGA is the only electronic health record scheme in Austria and the basis of the Austrian eHealth strategy. ELGA provides [Link]:

- technical framework for secure and standardised health data exchange on the basis of international standards like IHE, HL7 CDA, LOINC and DICOM [Link]:
 - standardised data formats (Clinical Document Architecture);
 - bringing together information from distributed sources (IHE XDS/XCA);
- formalities on data-hosting institutions (e.g. common security standards, common operations standards, etc.);
- modalities concerning the patient:

- patient consent (central access, authorisation, and logging system);
 - identification (central Master Patient Index);
- identification of health professionals (central Healthcare Professional Index).

ELGA Overview architecture



June 7, 2016

4

Figure 3: ELGA Overview architecture. Eisl H. The Austrian Experience in Implementing the electronic health record on national level. IHE World Summit. Amsterdam, June 7, 2016 [Link].

Standards based architecture for eHealth in Austria

Right from the start, ELGA was designed for flexibility and scalability on the long term. A healthcare record is a substantial effort, in many ways. The goal is to assure the security of these investments by using international standards. In 2007 the basic standards for ELGA were recommended by the "Bundesgesundheitskommission", after a thorough review by stakeholders and standards experts [Link].

The Integrating the Healthcare Enterprise (IHE) IT Infrastructure (ITI) Technical Framework provides an IT protocol specification to share medical records. It includes mechanisms for

node authentication, access logging, sharing document index information, to enable users to register, search, and retrieve medical documents.

The Health Level Seven (HL7) Clinical Document Architecture (CDA) standard is used to describe how medical information shall be encoded into electronic documents, based on the XML standard. Today hospital discharge and care reports, laboratory reports, radiology reports and information about drug prescriptions and dispensation is already recorded and shared in millions of documents in Austria. Figure 3 shows the ELGA registries and repositories, that hold the medical reports. Via their medical information systems (bottom in the image) the health providers submit their reports. The ELGA central components (top in the image) assure consistent identification of patients and health care providers, access rules, and auditing.

With the Health Telematics Act, a new era in the field of eHealth in Austria began. The Health Telematics Act is what could be called a “framework act” which amended several other acts of legislation and opens the door to the Austrian eHealth future. Until today, the framework act has already been supplemented and clarified by ordinances in 05/2015, 11/2015, and 12/2017, respectively.

In 2017, chapter 5 was added to the Health Telematics Act. Chapter 5 provides the legal framework for the development of further eHealth applications in future by reusing already developed (IT-) infrastructure components. Additionally, the Article 15a of the federal constitutional law on the financing and organisation of the health care system provides the legal basis to reuse already developed components for further eHealth services in Austria.

On this legal basis the ELGAplus project was initiated in 2017 by the ELGA GmbH. The goal was to develop a strategic and operational roadmap to extend ELGA to a generic, national IT infrastructure for the Austrian health care system. The basic idea is to reuse already developed components and put new eHealth services and eHealth applications on the top. The key findings of the ELGAplus project were [Link]:

- **strategic goal: protection of investments and innovation**
 - The eHealth roadmap Austria (2018++) was developed (not officially available yet)
 - Development of standardized, highly configurable, and reusable services and products (“blue prints”)
 - New document types: Easy configuration of new CDA document types (at the moment only 5 document types are available)
 - Virtual organization: Easy configuration of networks for cooperation and document exchange between health care professionals (use case: primary health care centres)
 - Generic application container/ interface: Interface for the integration of eHealth applications (like e-medication)
 - Aggregation service: Basic component for collecting medical information from different databases (e.g. patient summary)

- Workflow support
 - Notification services for health care professionals and patients
 - Push standards like IHE and HL7
 - Development of a financial model and “fair use policies”
- **strategic goal: Reduction of development time**
 - Enabling rapid prototyping, proof-of-concepts and pilot trials
 - Enforcement of cooperation in development teams
 - Providing end-2-end testing (test data, test cases, etc.)
 - **strategic goal: Autonomy and low entry obstacles**
 - Providing a feasible governance
 - Making documentation easier to understand

Basically, ELGApus follows the methodology as proposed in the European Interoperability Framework. The framework gives specific guidance on how to set up interoperable digital public services. The European Interoperability Framework acknowledges that interoperability must be addressed on all involved layers:

- Legal interoperability
- Organisational interoperability
- Semantic interoperability
- Technical interoperability

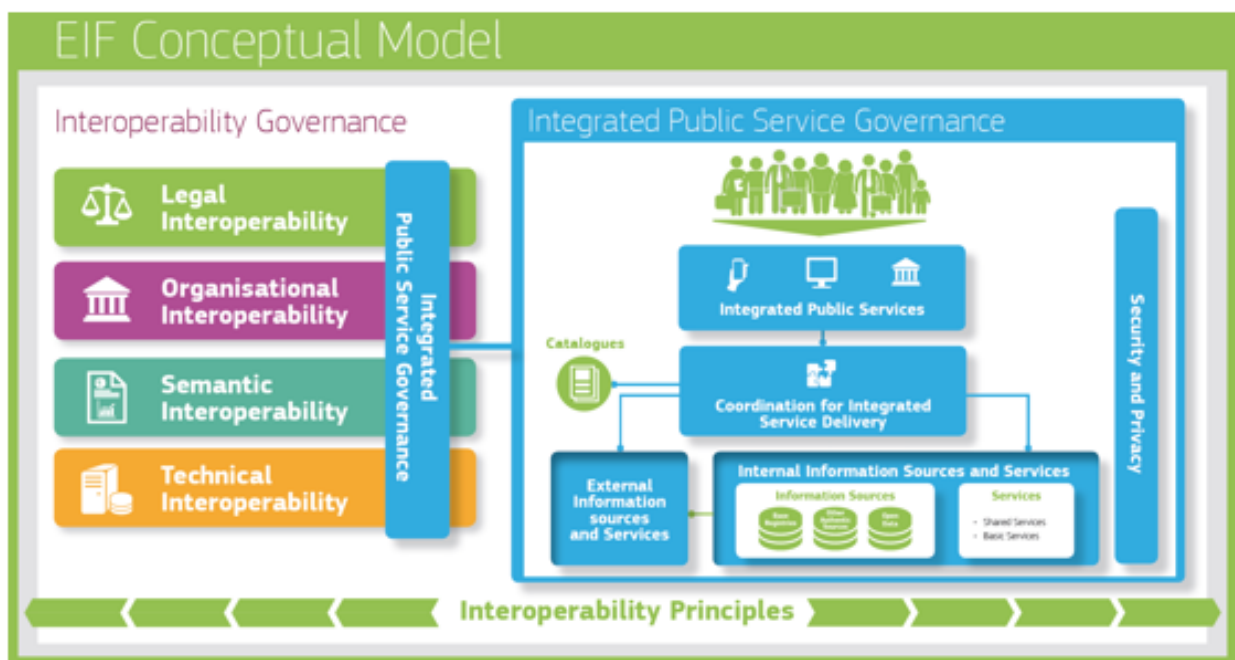




Figure 4: The "European Interoperability Framework (EIF)" [Link]

ELGAplus: Extending the ELGA Architecture for Telemonitoring

Since 2013 work started in Austria to define and implement services and applications to support the care for patients by telemonitoring, for example for chronic diseases. The "Telegesundheitsdienste-Kommission gemäß § 8 BMG" [Link] reviewed clinical evidence and recommended to further explore and implement telemonitoring for diabetes, cardiomyopathy and implant follow up. As one contribution expert groups developed recommendations for implementation, including a standard-based IT architecture.

See [Link]. After thorough review by stakeholders and standards experts and the general public, the Austrian Federal Ministry of Labour, Social Affairs, Health and Consumer Protection published the framework guideline for the IT infrastructure for applications of telemonitoring ("Rahmenrichtlinie für die IT Infrastruktur bei der Anwendung von Telemonitoring: Messdatenerfassung").

This architecture reuses the existing specifications and IT infrastructure of ELGA, and adds specific components to capture, manage and share data from personal health devices and medical devices. It defines a technology platform that receives incoming device data, including the identity of the respective patient. Healthcare providers then can query the platform to search and retrieve device readings of a specific type from an identified patient and a time range. The IT architecture makes use of the "IHE IT Infrastructure" Technical Framework (ITI-TF) [Link] and the Patient Care Device Technical Framework (PCD-TF) [Link]. The Continua Design Guidelines of the Personal Connected Health Alliance (PCHA) [Link] provide specifications for sharing device data, in synergy with the IHE profiles. The HL7 CDA Personal Healthcare Monitoring Report (PHMR) is recommended as an implementation guide for sharing aggregated device data between HCPs. In order to assure end-to-end semantic interoperability, all interfaces use the information models and the nomenclature of IEEE / ISO / CEN 11073, Part 10101, Health informatics -- Point-of-care medical device communication: Nomenclature.

Over the last years, a network of partner institutions has shown strong interest in these specifications. This network may be very valuable in the further work on detailing and finalising the specifications, within Europe and internationally.

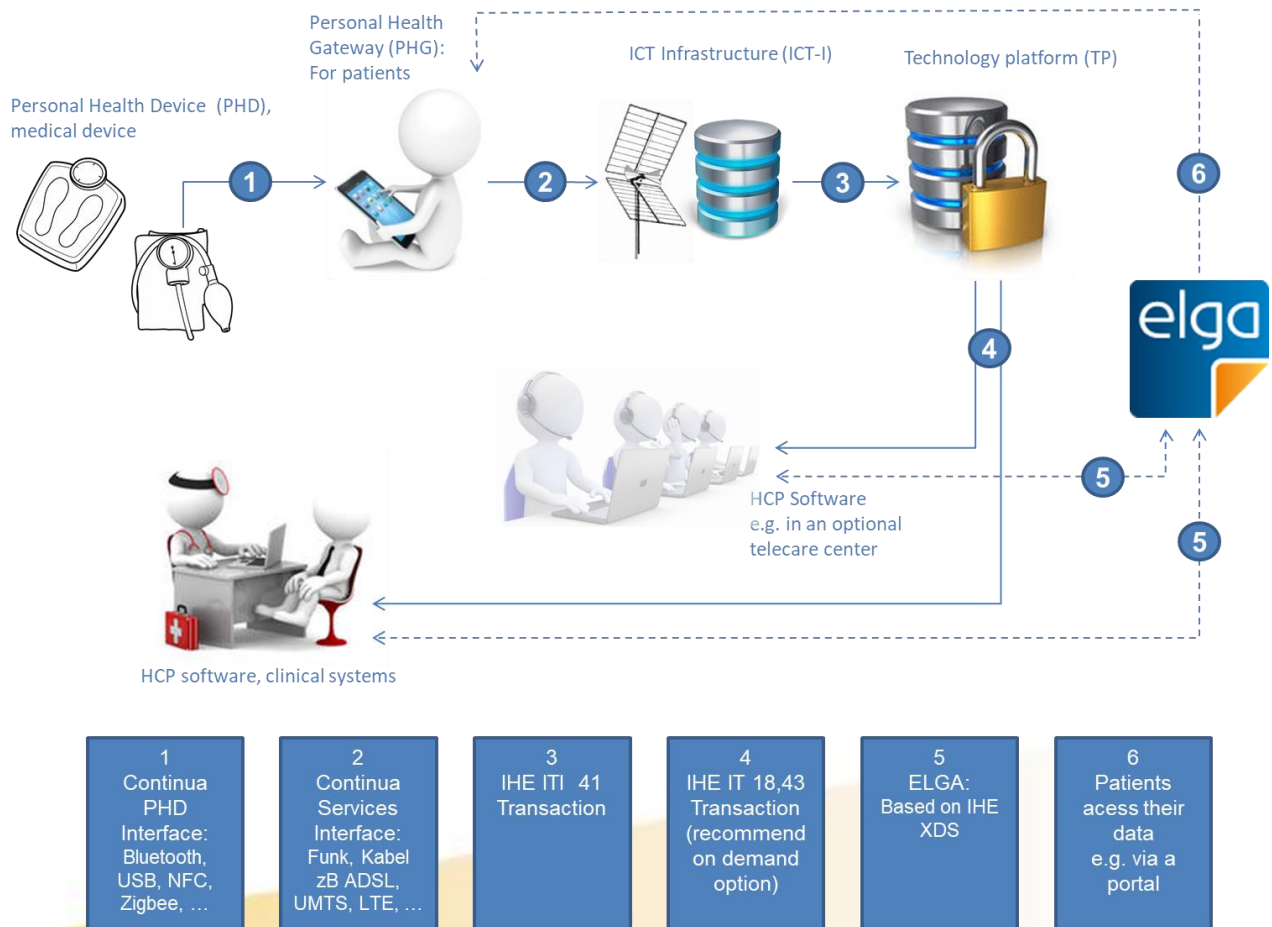


Figure 5: Framework architecture for telemonitoring.

ELGApplus: Extending the ELGA Architecture for Primary Health Care Centres (virtual organisations)

In chapter 5 of the Health Telematics Act, primary health care Centres (PHC) were the first “eHealth applications” which has been addressed. PHCs will use the generic ELGApplus concept “virtual organisation”. Virtual organisation will enable to interconnect health care professionals to exchange health data by reusing ELGA components like the central access and authorisation system, the Health Care Professional Index, the central Master Patient Index, the logging system, etc.

Regional

The Health Telematics Act provides a robust legal framework not only for the implementation of a national electronic health record or national eHealth applications like e-medication but also for the implementation of regional eHealth services as defined in several regional eHealth strategies.

- Vienna: Link

- Styria: [Link](#)
- Vorarlberg: [Link](#)

As already mentioned, the main intention also for regional developments is, to reuse existing (IT-)infrastructure and components and put a new eHealth service on top:

- regional networks for health care professionals (primary health care centres)
- regional eHealth services like x-ray records
- (regional) telemedicine services
- (regional) disease management programs
- ...

4.1.3 ELGA GmbH as the eHealth centre in Austria

The political intention was already manifested in 2008 when the federal entity (Republik Österreich), the nine federal states (Länder) as well as the Federation of Austrian Social Insurance Institutions committed themselves to implement an electronic health record in Austria within the legal framework for the organisation and financing of the Austrian healthcare system.

This commitment was reiterated in a more specific manner in the target control agreement (“Bundeszielsteuerungsvertrag”). Consequently, the ELGA GmbH was founded on the 9th of November 2009 on private law basis to plan, implement, and rollout the electronic health record in Austria in a first step. The ELGA GmbH is owned by the above mentioned governmental partners namely the federal entity (Republik Österreich), the nine states (Länder) and the Federation of Austrian Social Insurance Institutions.

Furthermore, the ELGA GmbH is a non-for profit limited liability company. The syndicate agreement (June 2010) defines the goals, the objectives, the responsibility, the financing, and the governance of ELGA and the ELGA GmbH, respectively [[Link](#)].

4.1.4 Normative mandate – authority and responsibilities

The ELGA GmbH has no official normative mandate but leads and coordinates the standardisation and harmonisation process in Austria. The most important tasks of the ELGA GmbH regarding the standardisation are:

- Requirements engineering and demand management
- Coordination of the technical and legal standardisation activities
- Coordination of goals and milestone of the working groups
- Leading and moderating the working groups
- Editorial work
- Order external experts to support the standardisation process

In 2013 the Austrian “Interoperabilitätsforum” was established to coordinate the technical standardisation process in the standardisation groups [Link]:

- Austrian Standards Institute (Komitee 238 – Medizinische Informatik)
- IHE-Austria
- GS1-Austria
- ProRec-Austria
- HL7-Austria

The Ministry of Labour, Social Affairs, Health and Consumer Protection is responsible for the legal standardisation of the technical standards. For example, CDA implementation guidelines are developed by the HL7 and had decreed by ordinances in 05/2015 and 11/2015, respectively. The software suppliers are responsible to implement the standards accordingly.

It is still an open issue at the moment, who is responsible for the ongoing monitoring and quality assurance of the correct implementation of the defined standards.

Date of actual establishment of the eHealth Centre

9th of November 2009

4.1.5 Goals, objectives and responsibilities of the ELGA GmbH

As the Austrian health system is organised federally using complex mechanisms in planning, guiding and financing, common goals had to be agreed between the different levels of responsibility. This is of particular importance when new technologies are introduced. Thus, the goals, the objectives, and responsibilities of the ELGA GmbH are [Link]:

Goals & objectives

- The goals of the ELGA GmbH, as defined in the syndicate agreement “Syndikatsvertrag” are:
- the coordination and integration of all operative measures regarding the implementation of ELGA in Austria,
- the implementation of system components and support of pilot projects, and
- quality- and acceptance management.

Responsibilities

- Planning, monitoring and evaluation of technical and organisational topics for the implementation and operation of the national electronic health record. In particular, the ELGA GmbH was responsible for the following:
 - “ELGA Master Plan”, which defines the procedure for the implementation of the electronic health record and the necessary schedules. The ELGA Master

Plan monitored the proper and timely implementation of the individual implementation steps and reviews the results.

- integration management and overall coordination of all participating projects.
- “common ELGA IT-architecture”, which specifies the technical framework of the electronic health record, its components, and interfaces.
- the ELGA governance (reporting, decision making, ...)
- preparation of meetings
- preparation of decisions
- evaluation of pilot projects (e.g. e-medication) and review of concepts
- placing and procurement (in cooperation with the Federal Procurement Agency [Link])
- Defining and monitoring compliance with information security requirements. This task includes the definition of data protection measures as well as technical and organisational operational safety measures. This also included the development of an access management, logging and authorisation system for healthcare professionals and patients.
- Development of a quality management system for documents, processes and software products used in the electronic health record. The ELGA GmbH was responsible for:
 - support of the standardisation process. e.g. development of CDA (clinical document architecture) implementation guidelines to guarantee a common structure of data in the documents.
 - recommendations and guidelines for the practical implementation of ELGA in organisations like hospitals, care institutions, laboratories, radiologies, pharmacies and private practices)
 - recommendations and guidelines for the practical implementation of ELGA in software products (including usability guidelines).
 - integration testing of software products
 - check lists for testing ELGA components and software products
 - data quality in several registries and central databases (citizen, healthcare professionals, terminologies, etc.)
- to ensure the interoperability of the various technical components and to ensure compliance with internationally recognized technical standards.
- Balance of interests in the implementation of the ELGA and clarification of any problems that may arise in this context.
 - The ELGA GmbH is commissioned to provide transparency and appropriate knowledge about ELGA through comprehensive information to the stakeholders and the public.
 - If necessary, ELGA GmbH makes also appropriate proposals for the revision of existing or the creation of new legislation.

4.1.6 Governance of ELGA and the ELGA GmbH

Strategic

The corporate bodies of the ELGA GmbH are:

- the Management (with two managing directors)
- the General Assembly.

Furthermore, ELGA GmbH has two advisory boards:

- the Coordination Committee
- the User Advisory Board.

The General Assembly is the supreme body of the company. It makes basic decisions about the content, changes and financial management, appoints the management of the ELGA GmbH and decides the annual economic plan. The members are:

- Austrian Minister of Labour, Social Affairs, Health and Consumer Protection
- 9 federal states' Ministers of Health
- Director and IT-Director of the Federation of Austrian Social Insurance Institutions
- CEO of the ELGA GmbH

All shareholders are represented in the Coordination Committee. Its main task is the preparation and harmonisation of resolutions for the General Assembly. The decisions of the Coordination Committee are made in the form of recommendations to the General Assembly. The members are:

- Division Head of the Ministry of Labour, Social Affairs, Health and Consumer Protection
- Directors of 9 Federal States' Healthcare Funds (incl. deputies)
- IT-Director of the Federation of Austrian Social Insurance Institutions (incl. deputies)
- CEO of the ELGA GmbH
- Division Heads, ELGA chief architect, and ELGA Program Managers ELGA (in case of need)

The User Advisory Board advises the management in technical-organisational as well as in medical-technical matters. The User Advisory Board consists of representatives of all healthcare professions and organisations, patient and advocacy groups, self-help groups organised by associations and hospital stakeholders. It may be extended by additional members by decision of the Coordinating Committee.

Additionally, the Security Advisory Board and the Technology Advisory Board were appointed for the project period. Both boards consist of declared experts from the ELGA GmbH and implementation partners.

During the implementation period till the "go-live" of all ELGA affinity domains a slim Strategic Steering Committee was appointed to fasten the decision making and escalation process.

The committee was nominated by the Coordination Committee and consisted of experts and managers with the authority to decide. The members were:

- Division Head of the Ministry of Labour, Social Affairs, Health and Consumer Protection
- (IT-) directors of 2 Federal States' Healthcare Funds (incl. deputies)
- IT-Director of the Federation of Austrian Social Insurance Institutions (incl. deputies)
- CEO of the ELGA GmbH
- CEO and Division Heads of suppliers (in case of need)
- ELGA chief architect and ELGA Program Managers (in case of need)

Project

During the implementation period all project controlling meetings were declined and an Operative Steering Committee was established. Once a week the CEO of the ELGA GmbH, the ELGA program managers, the project managers, the chief architects, the chief security officer, the chief test engineers, and the chief operations officers came together to report and to discuss upcoming problems and the possible solutions. If necessary, external experts and representatives of the software suppliers were invited. The members of the Operative Steering Committee had the authority to decide for their projects. On demand, working groups and task forces were set up with internal and external experts to find solutions for specific problems (e.g. usability working group) and to advise the Operative Steering Committee.

During the rollout period the Operative Rollout Steering Committee displaced the Operative Steering Committee. The Operative Rollout Steering Committee consists of the responsible ELGA program manager, the project managers of the rollout projects, and managers from the operations.

Operations

The operation of the ELGA (IT-)components is also distributed, as the whole ELGA system is (15+ data centres). Hence, an overall coordination is needed too. As the ELGA GmbH is designed as a "project development organisation" and not as an "operational organisation", the Austrian Federal Computing Centre ("Bundesrechenzentrum") is in charge of the coordination of the operation since the go-live of the first components [Link]. There is also a separate governance for operational issues, which is not described here.

4.1.7 Organizational structure and staffing of the ELGA GmbH

The organisational structure of the ELGA GmbH, the number of the employees, and the key competences of the employees changed continuously during the project phases from initiation of the project, conception, implementation, rollout and operation. The number in the bracket gives a clue on the number of the team members and the corresponding competence levels (S ... senior level/ management, J ... junior level/ legwork, E ... external expert/ consulting).

Initiation and Recruiting Phase (2010)

- Management (2 managing directors)
 - Administration (2J)
 - Legal (1S)
 - Controlling (1S)
- Teams
 - Standardisation & Architecture (1S)
 - Program – and integration management (1S)

Conception & Implementation Phase (2011 - 2015)

- **Management** (2 managing directors)
 - Administration (2J)
 - Communication (1S, 1J)
 - Legal (1S)
 - Controlling (1S)
- **Teams**
 - Standardisation & Architecture (+/- 4S, 4J)
 - development of the common ELGA Architecture
 - development of the CDA guidelines and terminologies
 - setup operations and data security
- **Program and Integration management** (+/- 3S, 4J, 1E)
 - master plan (including governance, reporting, risk management, quality management, project management, decision preparation)
 - integration management (= thematic coordination and coordination of external projects, stakeholders, partners)
 - project lead of the implementation of the access control, authorisation and logging system
- **Test management** (+/- 1S, 4J, 4E)
 - setup test centre
 - regular testing of all new and revised IT-components

Rollout and Stabilisation Phase (2016 – 2017)

- Management (2 managing directors, 1 managing director in 2017)
 - Administration (2J)
 - Communication (1S, 1J)
 - Legal (1S)
 - Controlling (1S)
- Teams

- Program-Management (1S, 1E)
 - reporting and project closure
- Architecture & Operation (2S, 4J)
 - stabilisation and improvement of the technical components
 - support & know-how transfer
- Standards & Usability (1S, 1J)
 - stabilisation and improvement of the CDA documents
 - support & know-how transfer
- Test- and Quality-Management (1S, 4J)
 - testing and release of revised components
 - modification of the test centre
- Project- and Innovation Management (1S, 3J)
 - rollout coordination (including project lead in several rollout projects)
 - project closure and transition from project- to product-management
 - support & know-how transfer

Operation and further development (2017 – now)

- Management (2017: 1 managing director; since 2018 2 managing directors)
 - Administration (1J)
 - Communication (1S)
 - Controlling (1S)
- Teams
 - Program-Management (1S, 1J, 1E)
 - reporting
 - rollout coordination (including project lead in several rollout projects)
 - Architecture & Operation (2S, 4J)
 - advancement of the ELGA architecture to a generic eHealth architecture
 - supporting of the change- and release-management
 - monitoring technical parameters
 - Standards & Usability (1S, 1J)
 - ongoing quality assurance of the implementation of ELGA and CDA in software products
 - support and know-how transfer
 - Test- and Quality-Management (1S, 3J)
 - ongoing quality assurance of software releases

- modification of the test centre
- Project- and Innovation Management (1S, 2J)
 - development of the ELGAplus strategy and the ELGA product roadmap
 - demand management, requirement engineering, and conception of new eHealth services and applications (including project initiation)
 - modification of the software development strategy (→ agile)

4.1.8 Relationship with stakeholders

The implementation of ELGA in the Austrian healthcare system had a lot of contact points to several stakeholders. In the following chapter the most important stakeholders are addressed.

- Implementation partner (Core Components): each component was developed in an entire project (with an external project manager). The ELGA GmbH was responsible for the coordination of the projects. The coordination of the projects took place in weekly coordination meetings. Due to the high impact of the central access, authorisation, and logging system on the overall system, this project was set up as an internal ELGA GmbH project. There is a business relationship between the ELGA GmbH and the supplier of the central access, authorisation, and logging system.
- Implementation partner (Affinity Domains): each affinity domain was ordered and developed in the course of a separate project (with an external project manager). The ELGA GmbH was responsible for the coordination of the projects. The coordination of the projects took place in weekly coordination meetings. There was no business relationship between the ELGA GmbH and the implementation partners of the affinity domain and their software suppliers.
- Implementation partner (User Software): each adoption of the user software to meet the requirements of ELGA was developed in a project and mostly coordinated by the project manager of the affinity domain. The ELGA GmbH was responsible to provide implementation guidelines. There was no business relationship between the ELGA GmbH and the user software suppliers.
- Consulting (external): the ELGA GmbH ordered external consulting services during the project period mainly for quality assurance measures and to get an external, independent view on a specific issue. External consulting services include technical and security reviews of the common architecture, testing and software quality assurance, evaluation of pilot projects, and the overall controlling.
- The Austria eCard system [Link]: The Austrian e-card system is the basis for the electronic administration system of the Austrian Social Security Institutions. Almost each person in Austria will receive such a card. Furthermore, the eCard grants the healthcare professional access to the patient's data in ELGA. For this purpose, the functionality of the eCard system was extended. Therefore, several projects had been set up and coordinated by the ELGA GmbH.
- eGovernment [Link]: The "Austrian citizen card" is a development of the Austrian eGovernment. The citizen card provides a unique identification and authentication of

users, which is necessary to access electronic services like ELGA via the Internet [Link]. In addition to the identification function, the citizen card also offers the possibility of electronic signing of documents in an easily and secure way. For the use in ELGA the functionality of the citizen card was extended. Therefore, several projects (e.g. the adaption of the Online Mandate Service for ELGA [Link]) had been set up and coordinated by the ELGA GmbH.

- professional association [Link], [Link]: The ELGA GmbH provides also an information- and communication platform to capture the user requirements and to obtain user acceptance. In certain cases, the ELGA GmbH was an important escalation level for the concerned parties.
- The Austrian Federal Economic Chamber and user software suppliers [Link], [Link], [Link]: The main task for the ELGA GmbH was to provide implementation guidelines, general information, and know-how for the software developers and the user software suppliers, respectively. There was no business relationship between the ELGA GmbH and the user software industry.
- Standardisation [Link], [Link]: One of the core tasks of the ELGA GmbH is to support the standardisation and harmonisation processes to adapt international standards for the Austrian healthcare system. For this purpose, a distinct team was set up.

4.1.9 Financing and Budget

The federal government, the states and the social security authorities jointly pay the expenses for the construction and operation of the central infrastructure of ELGA in accordance with the corresponding federal agreements. These expenditures were limited to an amount to a maximum of EUR 60 Mio. for the period 2008 – 2013 and 2014 - 2016 [Link]. Furthermore, an additional amount of EUR 41 Mio. were allocated for the period 2017 to 2020 for the operation and the improvement of ELGA and to enhance the developed ELGA IT-infrastructure to a generic eHealth infrastructure for the Austrian healthcare system [Link]. The ELGA budget does not include:

- implementation, testing and operation of the decentralised affinity domains (financed by the states)
- data storage costs (financed by the states/ hospitals)
- costs for the network connection
- adoption of the user software to provide ELGA functionality (adoption is additionally supported financially to a maximum of EUR 1314 [Link] under certain conditions).

The financing of the ELGA GmbH is also an integral part of this agreement and is therefore based on these funds. The prerequisite for this is that the annual economic plan is approved by the General Assembly.

If additional tasks are entrusted to ELGA GmbH, the necessary funds must be provided separately.

4.1.10 Actual accomplishments

According to the responsibilities of the ELGA GmbH the following accomplishments were achieved.

- **Planning, monitoring and evaluation**
 - ELGA master plan and rollout plan
 - ELGA common architecture [Link] and common user guidelines [Link]
 - a working governance
 - operational monitoring
 - ELGA infrastructure is up and running since 12/2015. The nationwide rollout in hospitals is almost finished [Link]. The nationwide rollout of e-medication will be finished by the end of 2019 [Link].
 - 15+ data Centres
 - 14 affinity domains (public and private)
 - +/- 15 Mio. registered documents
 - +/- 4,5 Mio. unique patients with contact to ELGA
 - +/- 3% opt-out rate
 - support and evaluation of the e-medication pilot study [Link]
- **Defining and monitoring compliance with information security requirements**
 - setup of a nationwide information security system for ELGA
- **Development of a quality management system**
 - vast number of check lists, guidelines, submittals, and test plans for software developer and stakeholder [Link], [Link]
 - 99% unique patient identification
 - common project management standards
- **Interoperability [Link]**

Health Telematics Act to ensure legal interoperability:

 - common user guidelines [Link] (“Organisationshandbücher”) and usability guidelines to ensure organisational interoperability
 - terminology server [Link] to ensure semantic interoperability
 - set of technical standards [Link] to ensure technical interoperability
- **Balance of interests in the implementation of the ELGA**
 - thousands of meetings...

4.1.11 Limitation, challenges, barriers (and how they have been overcome)

This chapter addresses the most important limitations, challenges and barriers which have already been solved during the project period. Additionally, there are a lot of lessons learned which are NOT ADDRESSED in this paper.

Limitation, challenges, barriers	How they have been solved
Lack of communication between the stakeholders	The ELGA GmbH enabled a new communication culture by providing structured communication plans, meetings schedules, and coordination services for the stakeholders, the users, and the (project) partners (1 meeting room in 2011 → 3 meeting rooms in 2018)
Unclear responsibilities	<p>The ELGA GmbH was not afraid to take charge of tasks with unclear responsibilities when appropriate to avoid “hot potato shifting”.</p> <p>This means, that the personnel of the ELGA GmbH is highly qualified with a broad knowledge of the (healthcare) system, its (IT-)components and dependencies. The personnel of the ELGA GmbH was also able to provide consulting services for the stakeholder from top-management to expert level.</p>
Missing decisions	The ELGA GmbH established a clear governance for transparent decision making (hundreds of decisions were made, documented and sometimes also withdrawn).
High complexity	<p>The ELGA GmbH introduced a step-by-step and “learning by doing” approach (pilot projects, prototypes, friendly user testing, showcases, click-dummies, ...)</p> <p>The ELGA GmbH introduced also the “keep it simple” paradigm – simple reports, short descriptions, short processes (e.g. short and transparent decision making process).</p>
inefficient project coordination	The ELGA GmbH introduced an efficient governance. E.g. project steering committees

	were merged to ONE operative steering committee.
--	--

Why e-Government and eHealth need to be considered together in many areas especially the digital world

The word e-Government translates literally as "electronic government". However, the term e-Government has established itself worldwide as meaning "the administration of government by means of electronic technology". In general, it means the simplification of work routines and processes through the application of information and communication technologies (ICT) in the areas of information, communication and transaction within and between state institutions as well as between the government and citizens or businesses.

Interaction levels in e-Government – e-Government is classified into the following areas:

- Information: Making information available online, for example, on the Web site of a public authority.
- Communication: The ability to interactively access and exchange information.
- Transaction: The actual carrying out of services, including the signature of application forms and electronic delivery of official documents and notifications.
- Personalisation: Based on personal user profiles, content is adjusted to the different requirements and life situations of people in order to make information as targeted as possible.

E-Government is the set of all electronic public administration services available to everyone in the country.

Austrian E-Government vision 2020

Convenience and simplicity

Citizens and business can communicate with the administration in a convenient, simple, electronic and barrier-free way. The focus here is on citizen orientation and simplicity. Personalisation and regionalisation are offered for identification. The trend towards mobility and the need for unrestricted availability of administrative services are considered.

Increase in efficiency

Where expediently possible, the one-stop-no-stop principle will be implemented electronically. A further increase in efficiency of the administrative processes is achieved in particular through the comprehensive usage of data available in the public administration (for

instance register). An acceleration of the administrative handling results in an alleviation of the burden on the citizens and on business.

Trustworthiness and security

E-Government applications are created and operated in compliance with data protection and state-of-the-art high information security measures. They are perceived by citizens and business as trustworthy and secure. The use of one's own data by the administration is transparent for all involved. The awareness of the citizens and of business for ICT security is actively promoted by the administration.

Transparency and openness

Administrative activities are done in transparent form and are open. Collaboration and Open Government Data are an integral part in the opening up of the administration. E-Government makes an important contribution to freedom of information. As a clear and positive signal, a "right to electronic communication with the administration" is introduced.

Participation

Interactive administrative processes facilitate participation and citizen involvement. The administration encourages citizens and business to contribute ideas and feedback and to collaborate in the organisation of the administrative tasks.

Innovation

The administration acts as a catalyst for society and business and promotes innovations. The administration is open to modern ways of working and technology and makes beneficial use of them.

Business

The intensive usage in administration is an important economic factor for the ICT economy in Austria. At the same time, ICT-optimised administration processes reduce the administrative costs of business. With training offensives, the administration contributes to reducing the lack of specialist ICT staff and thus to safeguarding Austria as a location. The preservation of digital sovereignty is thus also promoted.

National and international convergence and synergies

The Austrian administration is a visionary and pioneer in the international positioning of successful e-Government solutions and is open for European partnerships. Optimum use will be made of international and national convergences and synergies here.

So, to summarize "E-Government is a synonym for a modern and innovative land, in which quality, trust and quickness play a central role."

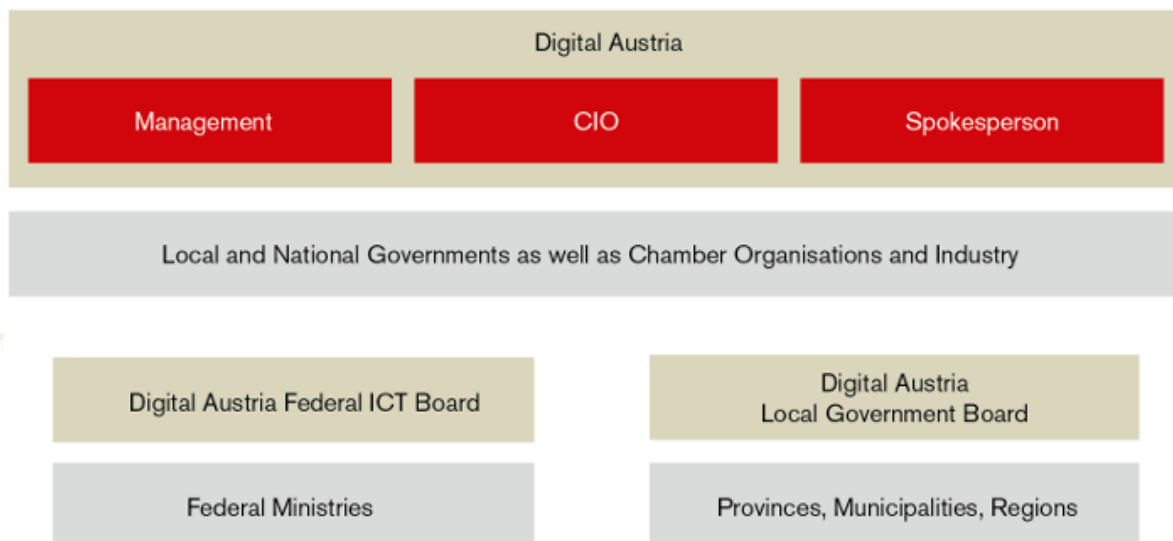
Why should these be different in eHealth?

The aim of eHealth is to improve the medical and social care of patients and citizens through the use of information and communication technology (ICT).

Therefore, the Austrian Government decided that the applications of e-Government and eHealth should not be technologically divergent. Best practices of e-Government shall also be applicable to eHealth and its application. The Federal Platform Digital Austria established in 2006 an EHealth/E-Government working group that deals with these topics.

The Federal Platform Digital Austria, which was created in 2005, is the centre point for coordination and strategy of e-Government in Austria by the Federal Government. All e-Government projects in Austria now run under the Platform Digital Austria designation.

Federal Government



It coordinates the ICT Strategy Group of the Federal Ministries and the Cooperation of Federal Government (Provinces, Municipalities and Communities) as well as the Social Security Agency, the Federal Economic Chamber (as the representative of the industry and businesses) and the Chamber of liberal professions (Chamber of Lawyers, Chamber of Notaries, Chamber of Pharmacists, Chamber of Doctors, ...).

The chairmanship of Platform Digital Austria is held by the Federal CIO. Many members of the Platform Digital are also members of the eHealth strategy group (e.g. ARGE ELGA) from the Federal Ministry for Health.

Within the Platform Digital Austria projects are coordinated with one another so any projects which are too similar can be detected and duplication of effort can be avoided.

Why EHealth and E-Government together?

- no "two worlds" (eHealth services and e-Government services) for citizens (patients);
- harmonized technical and organizational requirements in e-Government and eHealth;
- avoid duplication especially in ICT infrastructure (single sign on (SSO), portal group);
- uniform standards (SSO, eID) and further synergy potentials, e.g. GTelG, eGovG;
- official signatures (z.B. Entlassungsdokumente);
- uniform style guide for e-forms;
- common citizen- and patient register/ databases (including data exchange between the databases);
- access management;
- online mandate service (incl. parents for their children).

Citizen card function (eID and eSignature)⁹⁸

In order to make procedures with public authorities both secure and traceable, public authorities must be able to verify who a person is so that there is no doubt as to their identity. An electronic tool is needed that can uniquely identify citizens and businesses. This electronic identification is the "citizen card".

The term "citizen card" is used to describe a tool in the Austrian identity management concept that makes it possible to provide electronic services for public administration employees and customers in a simple and secure manner. As the electronic identification in the Internet, the citizen card provides unique identification and authentication of users, which is necessary in order to offer certain electronic procedures. In addition to the identification function, the citizen card also offers the possibility of signing documents easily and securely electronically.

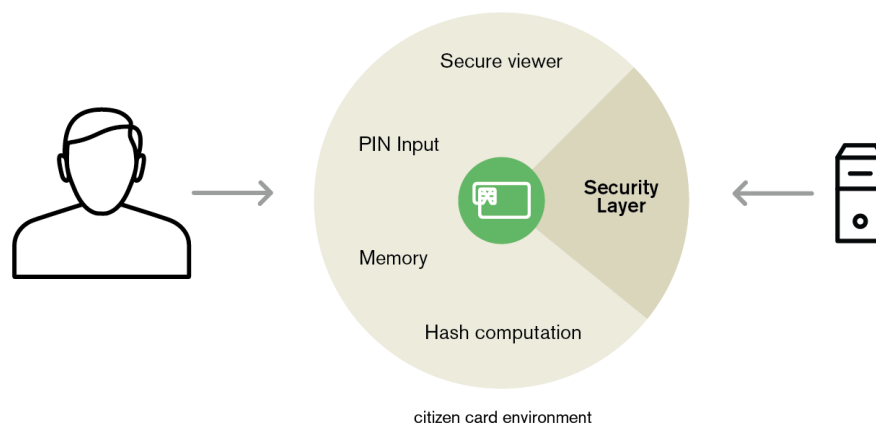
The "citizen card functionality" can be installed on various carrier media. A chip card such as the e-card or the mobile telephone can be used for this. Since the implementation of the mobile phone signature (citizen card with mobile phone function) at the end of 2009, the electronic signature is now very easy to use. In contrast to the use of chip cards with citizen card function, neither card reading devices nor software installations at the local PC are necessary.

Using the citizen card in its different variations means that:

- proving someone's identity securely and electronically saves them having to go to a public administration office in person.

⁹⁸ <https://www.buergerkarte.at/en/index.html>.

- with the help of electronic signatures, users can submit a declaration of intent without any difficulty, which can easily be checked so that there is no doubt as to its authenticity.



The e-card is the key to the health system for approximately 8 million people covered under social insurance. But the e-card offers even more than that: with the citizen card functionality, it also becomes the key to the e-Government and eHealth services for public administration in Austria for more than 17 years now. Since the end of 2009, also mobile phones can be equipped with the citizen card functionality (mobile phone signature) free-of-charge, thereby becoming the key to the steadily increasing number of e-Government and eHealth services. Both the mobile phone signature and the card-based citizen card on the e-card mean secure identification and authentication and are thus a secure replacement for extraneous username/password combinations. New applications are constantly being developed that can be carried out on the Internet with the mobile phone signature and with the card-based citizen card. The number of applications in the economic sector is also increasing.



Mandates

With the help of electronic mandates, individuals can use their mobile phone signature or card-based citizen card to carry out procedures on someone else's behalf. The representative can be either a natural or legal person. This can be the case for natural persons who do not wish or are not able to conduct online procedures with the mobile phone signature or card-based citizen card themselves, and therefore entrust someone to conduct procedures on their behalf.

For legal persons, it is possible to authorize a representative to carry out administrative procedures on their behalf. The electronic mandate makes it possible to uniquely identify the legal person who is being represented.

The specified XML data structure of the electronic mandate contains the identification data for the principal (the person to be represented) and the representative. There are various options for the contents of the mandate: it can be registered without any restrictions, for example with full mandate rights, or it can contain restrictions for the period of validity or transaction limits that can currently be read in an automated manner. Within the scope of eGovernment cooperation, standard text blocks will be defined that can be combined to create complex mandate agreements that still can be checked automatically.

In order to represent somebody electronically, a mandate must be registered in the citizen card environment. This is done using a Web Service from the SourcePIN Register Authority. It allows the principal to prepare the mandate agreement and specify a representative. The form is sent electronically to the representative, who must accept the prepared mandate.

If the principal is a legal entity, the representation information will be automatically drawn from the Business Register, i.e. for companies from the Commercial Register, for associations from the Central Association Register and for other non-natural legal entities from the supplementary register for other parties affected (ERsB). Electronic mandates are created in the course of a registration process on-the-fly by the an online mandate system (OVS) which is operated by the SourcePIN register authority. The mandates get generated on the basis of the representation information stored there, made available to the MOA ID or the application and are only valid within the scope of the registration process.

Identification for Citizens (patients) :

- Citizen Card Function
- SourcePIN Register und Supplementary Register
- authorization concepts on the basis Health Telematic Act (GTelG) and eGovernment Act (eGovG)
- legal Basis for eGovernment and eHealth ("ELGA" (sector-specific personal identifiers (ssPIN)))

Legal basis (eGovG and GTelG)

The eGovernment Act (eGovG)⁹⁹, the centrepiece in Austrian eGovernment law, entered into force on 1 March 2004 and was last amended on 1 July 2016 in particular as a result of the adjustment to the eIDAS Regulation. This law serves as the legal basis for eGovernment instruments and components. Many mechanisms such as the citizen card, sector-specific personal identifiers and electronic delivery are also able to be put to use in the private sector.

Essential regulations:

- **The function “Citizen Card”**

The citizen card is a form of electronic identification for the Internet. People can use it to identify themselves by digital means to a public authority, or as stated in the law - to be uniquely identified and authenticated. A fundamental characteristic of the citizen card is a qualified electronic signature that can be generated with it and that makes it possible to sign forms or contracts which normally require a handwritten signature. While practical for doing business with public authorities, the citizen card can also be put to use in personal matters, for example, in order to guarantee the best possible security during Internet transactions (such as in e-banking). The citizen card is available in many different formats, since it does not depend on a particular type of technology and does not necessarily have to be a "card". In many cases, the carrier medium is a chip card (such as the e-card). It is also implemented as a "mobile phone signature" for mobile phones. It is essential that the citizen card connects a qualified electronic signature and an identity link that contains the respective security data and functions, and also, e.g., serve as a substitute for multitudes of username/password combinations.

- **SourcePIN**

Due to the strict regulations on data protection in Austria, a strongly encrypted and non-traceable derivation of the CRR number is used for SourcePIN computation in place of using the CRR number (number from the Central Register of Residents). For people who are not registered in the central register, the SourcePIN is created using their registration number from the Supplementary Register. The SourcePIN for natural persons may only be stored on their citizen card. For legal persons, the entry number in the Commercial Register (Firmenbuch) or the Central Register of Associations (Zentrales Vereinsregister) or the registration number in the Supplementary Register is used as the SourcePIN.

⁹⁹ https://www.ris.bka.gv.at/Dokument.wxe?Abfrage=Erv&Dokumentnummer=ERV_2004_1_10.

- **Identity Link**

The identity link is used to create a unique link between the citizen card and its rightful owner. The SourcePIN Register Authority verifies with their electronic seal that a link has been established between the citizen card holder and his or her SourcePIN for the purposes of unique identification. The identity link is saved on the citizen card, whereby it is to be pointed out that “the citizen card” is to be understood as a technology-neutral concept here again. Accordingly, the citizen card is a “logical entity”, An “entry in the citizen card” therefore does not by any means mean a physical entry in a certain data carrier.

- **Mandate**

Individuals may authorise another person to submit applications on their behalf. In such cases, a confirmation can be issued by the SourcePIN Register Authority for the representation of non-natural persons or a power of representation for the representation of natural persons.

- **Sector-Specific Personal Identifier**

In order to ensure the protection of data, public authorities are not allowed to save the SourcePINs of natural persons. Within the framework of the citizen card concept, public authorities may identify natural persons only using their sector-specific personal identifier (ssPIN). The ssPINs are derived from the respective person’s SourcePIN. This process is non-traceable and irreversible.

An ssPIN is valid only for the public authority's sector of activity under which the initiated procedure falls. Sector-specific personal identifiers from other sectors may only be used and saved in encrypted form. In order to generate an ssPIN, the SourcePIN is needed. The SourcePIN may only be used to compute the ssPIN - using the citizen card - with the agreement of the person concerned.

Only the SourcePIN Register Authority may generate an ssPIN without the citizen card of the person concerned, and it may do so only in special circumstances with the help of adequate identification attributes.

- **SourcePIN Register**

The SourcePINs required for the unique identification of citizens are calculated from the SourcePIN Register. Technically speaking, the SourcePIN Register is a virtual register, meaning that SourcePINs are only generated when required and are deleted afterwards. The functions of the SourcePIN Register Authority are carried out by the Data Protection Authority.

- **Supplementary Register**

All natural persons who do not have a registered address in Austria and legal persons who do not appear in the Commercial Register or in the Central Register of Associations can register themselves in the Supplementary Registers in order to participate in e-Government. Local and other authorities can register themselves in

the Supplementary Register, e.g. in order to receive documents using an electronic delivery service.

- **“Once Only” principle**

Public authorities are obligated, pursuant to their technical possibilities and in compliance with the requirements stipulated by law, to draw on the available data the person concerned from public registers of a client under public law (not just the Central Register). Thus, certain information (birth certificates, proof of citizenship, proof of residency or documents from the Commercial Register) need no longer be presented by the person concerned but can, with the person’s legal consent or with legal authorisation, be directly requested by the authority from an electronic register. The public authority’s responsibility to enable queries in their registers in no way increases their authority to release information, since they are based solely on existing authorisations.

- **Official Signature**

Naturally, the authenticity of electronic documents from the public authorities must be able to be relied upon. This means that the documents were really sent by the respective authority. The official signature is an advanced electronic signature (§ 2 Line 3 Electronic Signature Act) or an advanced electronic seal (§ 3 Line 26 Electronic Signature Act) that is electronically affixed to an official notice or document by a public authority. The public authority itself can be identified on the document by the official logo, the official signature and the verification note. This makes it easy to recognise electronic documents issued by authorities. Not only can the authenticity and integrity of the document be verified by means of the official signature, the printed version of a document from a public authority is equivalent to the official certificate.

The same rules and regulations are legally defined also for eHealth in the Health Telematic Act 2012 (GTeIG)¹⁰⁰


- § 14. The use (saving and ascertaining) of ELGA health data is only permitted if the ELGA participants were uniquely identified in accordance with § 18
- § 18. Verification of the identity of ELGA participants
 - Verification of the unique identity (§ 2 Z 2 eGovG) of natural persons in the context of ELGA or other eHealth applications (ssPIN bPK-GH)
 - The data are primarily derived from the data applications of the main association in accordance with § 31 ASVG and the supplementary register pursuant to § 6 eGovG.

¹⁰⁰ https://www.jusline.at/gesetz/gtelg_2012.

- (4) Verification of the identity of ELGA participants (§ 14) must be carried out in electronic form with the participation of the ELGA participant. In this case, the identity data stored in the patient index are to be compared with the identity data determined in the context of the identification. The determination of the identity data can be done by an electronic check of the validity of the e-card and the reading out of data of the e-card by means of the e-card system (§§ 31a ff ASVG) or use of a citizen card (§ 2 Z 10 eGovG) function.

Official signatures in e-Government and eHealth

Public authorities have an electronic signature or “seal” referred to as the official signature, which they can use to sign contracts digitally. The official signature is affixed to documents, to denote them as being official documents from the public authority. The public authority can be identified by means of the official signature. The signature also ensures that the document can be verified.

	Signatory/ Creator of seal	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
	Date/Time-UTC	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
	Verification	Information about the verification of the electronic seal respectively the electronic signature can be found at: https://hierdieURL1.gv.at Information about the verification of the printout can be found at: https://hierdieURL2.gv.at
Note	This document was signed/sealed with an official signature. According to § 20 E-Government-Act a printout of this document has the probative value of an official document.	

The official signature must possess certain attributes, which verify the signature itself and confirm the validity of the document even when a copy is printed on paper. The Austrian eGovernment Act states in §19 that, in addition to the logo and the signature verification information, an indicator must be included that shows that the document was officially signed by the authority. It would make sense for this indicator to have a standard design so that everyone involved in e-Government or eHealth can easily recognize an official signature, whether citizen, business or public authority. The Federal Platform Digital Austria makes software modules available free-of-charge, which can be used to integrate the online application or the citizen card software in the respective IT infrastructure of an authority. Central IT service providers also offer the official signature as a shared service, so that an own internal solution is not necessary within the administration authority.

The former e-Government open-source platform¹⁰¹ of the Digital Austria platform was transferred to the open-source platform Joinup (formerly OSOR)¹⁰² of the European Commission (Department DIGIT). Joinup was created during the course of the ISA program as an open-source platform for cross-sector and cross-border collaboration. The Austrian E-Government is based on freely available software components, the Austrian MOAs (modules for online applications), developed by the Austrian E-Government Innovation Centre (EGIZ) of the Federal Platform Digital Austria. These MOAs can also be easily integrated into the online portals of municipalities and district representations.

The following modules are introduced as examples in the "Infrastructure" chapter: For the purpose of identification, the MOA ID is used. This module enables secure login using the citizen card. Verification of the signature and document is carried out by the MOA SP. The server signature MOA SS creates the official signature for a public authority, such as for a municipal authority, and the delivery module MOA ZS ensures that documents are securely delivered electronically¹⁰³.

When a citizen visits a community Website and e-Government or eHealth service platform and fills out a form, he or she can then sign it using his or her citizen card. The administrative authority checks the signature with help from a MOA and sends the official document either electronically or as a paper hardcopy.

E-Form (styleguide)

The task of designing forms for public administration in Austria lies almost completely in the hands of the individual administration units. The goal is to offer the highest level of uniformity for carrying out electronic procedures in e-Government and provide users with an understandable and easy-to-use interface.

The styleguide for e-forms contains specific measures on structured design, systematic categorisation of content and visual design of online forms. Using a systematic, uniform and user-friendly approach to e-forms, it aims to simplify electronic procedures for citizens and businesses and make them as convenient as possible, to the benefit of both. The specifications of the style guide have already been broadly implemented.

In order to take the technical development in the design of the form into account, the convention is currently being thoroughly revised and extended to include dynamic elements in the form sequence and the description of its behaviour. The updating work of the convention is currently in the finalisation phase so that a framework for a contemporary implementation of e-forms will soon be available.

¹⁰¹ egovlabs.gv.at.

¹⁰² joinup.ec.europa.eu.

¹⁰³ joinup.ec.europa.eu/collection/e-government-innovation-Centre-egiz.

The Convention for Online describes the steps for creating applications using interactive online forms. It contains recommendations on how users should be guided through the form: from accessing the form, entering and changing information, to submitting the data to the proper administrative unit. This process should be uniform and recognisable across the administrative unit. Users should have access to application forms that are simple and easy to understand. This helps to ensure that the electronic input is of high quality, complete, and error-free as possible so that the processing time can be reduced accordingly.

With the new style guide version 3.0, the convention online dialogues are closed as the process and behaviour descriptions are integrated directly into the “style guide for e-forms” due to the increased usage of dynamic elements.

On an increasingly frequent scale, applications are being created by authorities with the goal of also making them available to other authorities. In the process, a major commercial benefit can be gained as the applications do not have to be developed and operated by each partner. This is made possible, among others, by the eGovernment strategies developed in Austria over the last few years (portal group, security and role concepts, etc.) and the technical environment (SSO, common data models, web service interfaces, etc.).

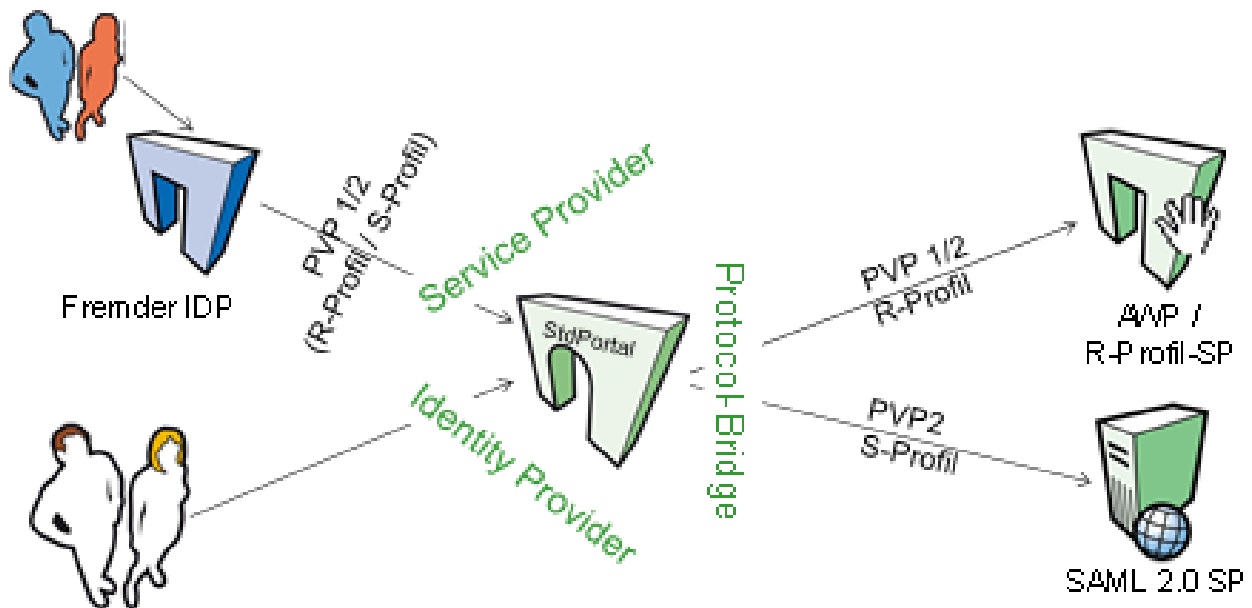
The style guide for web applications (between authorities) is used for newly developed web applications across authorities. The document is aimed at project managers, developers of web applications across authorities and people responsible for style guides of web applications and forms the basis for a structured development of web applications, for a systematic structuring of the content and a uniform external form (layout). The goal is to depict the fundamental components of a uniform operating concept in the form of samples and best practices.

In the process, a greater acceptance and an improved usability as well as a reduced induction time for the users distributed across various organisations.

Austrian Portal Group (e-Government portal, eHealth portal)

eGovernment can only function efficiently when public authorities work closely together and cooperate inter-administratively. This happens when government portals team up with each other to form a portal group and share the existing infrastructure.

The advantage of the portal group concept is that many applications are available from a single entry point. The identity of the user only needs to be verified once on the portal. Users only need to login a single time when they first log on to the portal in order to access various resources, information sources, or “digital offices”. The technical term for only requiring the user to sign in once is called “single sign on”.



Participation in the portal group is governed by the Portal Group Agreement (PVV). This agreement sets out the rights and duties with which the joining partners must comply. This agreement creates an environment of trust between the application providers and the base portal providers, who take care of user management. Communication within the portal group is managed, both technically and organisationally, by the portal group protocol (PVP) and the use of security classes. Application providers determine which of their applications will be available over which portals. Keeping in accordance with all data protection regulations, they specify which administration units and employees are authorised to access which applications and define user roles with corresponding access rights.

In the meantime, there are more than 1300 services available at the portal group, making it an established standard.

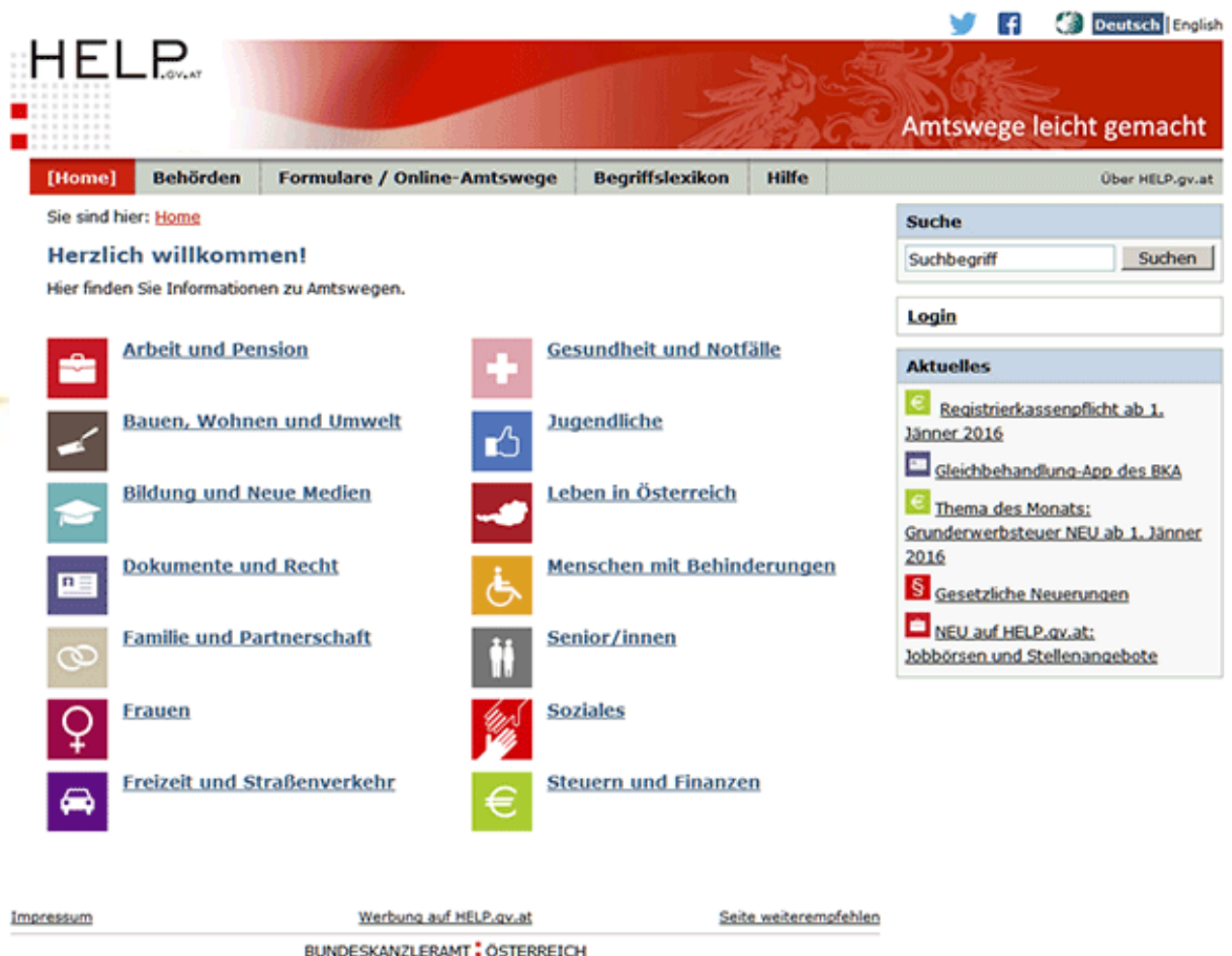
High technical and organizational requirements for data transfer:

- Proof of the identity of the recipient
- proof of the role of the recipient
- Confidentiality of information
- Integrity of the transmitted information
- requires coordinated concepts!

The Citizens Portal – HELP.gv.at information portal¹⁰⁴

The first place to go for questions about public authorities is since 1997 the HELP.gv.at portal. The multiple award-winning portal is not only the first place to go for private individuals, but also for anyone who wants to find out more about public administration in Austria. The HELP Portal is also a useful service point for administration.

The HELP.gv.at website has been offering online services according to the "one-stop-shop" principle since 2001 and continues to successively develop new services. The application of the citizen card as a uniform system of electronic identification in Austria contributed significantly to its success. An electronic appointment reservation system and information offerings adapted specifically for mobile end-user devices are just a few of the numerous additional services at HELP.gv.at.



The screenshot shows the HELP.gv.at website interface. At the top, there are social media icons for Twitter, Facebook, and YouTube, along with language options for Deutsch and English. The main header features the HELP.gv.at logo and the slogan "Amtswege leicht gemacht". Below the header is a navigation menu with links for [Home], Behörden, Formulare / Online-Amtswege, Begriffslexikon, and Hilfe. The main content area includes a welcome message "Herzlich willkommen!" and a search bar. A grid of 16 icons represents various service categories such as Arbeit und Pension, Gesundheit und Notfälle, and Steuern und Finanzen. On the right side, there is a "Suche" section with a search input field and a "Suchen" button, followed by a "Login" section and an "Aktuelles" section with news items like "Registrierkassenpflicht ab 1. Jänner 2016". At the bottom, there are links for Impressum, Werbung auf HELP.gv.at, and Seite weiterempfehlen, along with the text "BUNDESKANZLERAMT ÖSTERREICH".

¹⁰⁴ <https://www.help.gv.at/Portal.Node/hlpd/public>.

The Website is designed with accessibility requirements in mind so that it can be used with ease by those with special needs, older people and those with diminished eyesight. The navigation was designed to be as simple and straightforward as possible so that users do not need to search too long to find the desired topic from the start page. All available content is arranged according to topic into major categories and subjects. Categories such as Education (which includes forms for registering for school), Documents (e.g., for applying for a passport) and Finances (for online tax declaration forms) can be found on the HELP.gv.at platform.

The HELP.gv.at site contains general information on e-Government services but also on eHealth in a compact and comprehensive format and provides links to the corresponding solutions.

The menu item Forms/Online procedures contains an exhaustive list of application forms for all public authorities in Austria, from A to Z. Many of these documents can only be downloaded, filled out and sent to the corresponding authority by regular post or e-mail. However, more and more forms can now be electronically filled out, signed and sent – completely paperless, without changes in the type of media and without any further action being necessary. The number of official deliveries that do not require a change in media format is rising steadily since replies are able to be sent back to citizens using an authorised electronic delivery service.

Austrian Social Security Services

Austrian Social Security (www.sozialversicherung.at) offers services for people who are insured, contract partners, employers and pharmaceutical companies.

For those who are insured:

Application forms (e.g., for retirement, child care allowances, etc.)

- Health insurance data: This service accesses the data stored by the association for social insurance for a given social security number and calculates the amount of services that have been utilised by the insured or family members (up to the date of the application) during the insured periods.
- Health services statement (LIVE): You can look up and print your personal statement of health services that you have utilised online.
- Standard personal retirement account (ePK): For all men and women born after 1 January 1955 with retirement insurance coverage have a retirement account reserved for them, which contains information on all the contributions from the insured periods.
- Prescription fee account: Every person who is insured can look at the maximum fee limit for prescriptions and the number of prescriptions that have been filled in the

current year so far. As an additional service, the number of prescriptions needed to reach the exemption limit is displayed.



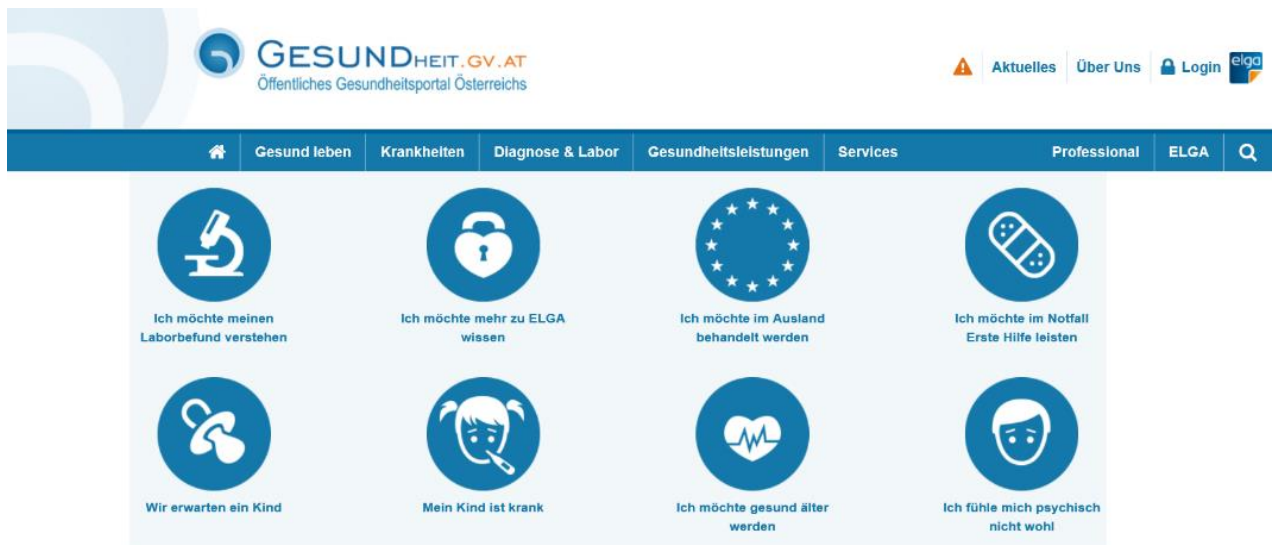
The screenshot shows the top navigation bar of the Austrian Social Security (SV) website. On the left is the SV logo with the text 'Österreichische Sozialversicherung'. The main navigation includes 'SV-TRÄGER', 'Meine SV', and 'LOGIN'. A search bar with the placeholder 'Suchbegriff eingeben' is located below the navigation. A secondary navigation bar contains 'VERSICHERTE', 'DIENSTGEBER', 'GESUNDHEITS-DIENSTLEISTER', 'ÜBER UNS', and 'KONTAKT'. Below the navigation are three large image-based buttons: 'ICH BIN VERSICHERTER' (with a family photo), 'ICH BIN DIENSTGEBER' (with a business meeting photo), and 'ICH BIN GESUNDHEITSDIENSTLEISTER' (with a pharmacist photo).

Social insurance data sheet: The social insurance data sheet contains information on the periods of time that the citizen was insured as well as information on the amount and origin of contributions that have been made so far.

The Electronic Health File (ELGA)¹⁰⁵

With the electronic health file (ELGA), an information system is planned that facilitates a secured, location and time-independent access to important health data (preliminary findings, letters of discharge, laboratory, radiology, drugs). Patients as well as health service providers (hospitals, doctors' practices, chemists, nursing facilities) can access it. Only in the case of medical treatment (and only in this context) does ELGA network already existing health-related data and information relating to a clearly identified person. Data protection has the highest priority here.

¹⁰⁵ <https://www.gesundheit.gv.at/>.



The ELGA citizen's portal (health portal) will in future facilitate a straightforward and secure access to their own findings for citizens. The citizens themselves determine participation in ELGA and access to ELGA data. As a result of the "opt-out" regulation stipulated by law, it is possible to determine as a citizen whether you would like to participate in ELGA at all or in part, e.g. only for the e-medication.

Trust Mark

Indispensable prerequisite for a central health portal on whose contents the citizens is an "official" seal of approval for the contents of the portal - , regularly reviewed or renewed of a central assigned. Analogous to development of other labels such as the Austrian e-Commerce Trust Mark¹⁰⁶ (also a European quality mark for the electronic Purchasing) or the former Austrian e-Government Seal of Approval.



¹⁰⁶ <https://www.guetezeichen.at/>.

ICT Accessibility for e-Government and eHealth?

A health portal that informs citizens in their everyday engagement with the themes of health care, prevention, disease and the Austrian health system in general should be optimally supported, must complement the content structure meet basic design and handling requirements. In order to achieve the highest possible acceptance by the users, the portal must be designed with regard to its structure and its usability, the generally valid quality criteria, Guidelines and standards for Internet applications are sufficient. Every user should just get up can navigate the portal, even for IT inexperienced citizens, the information must be intuitive be findable and provide support in the respective life and needs situation. The portal should be clearly recognizable as an "official" health portal and basic requirements e.g. Regarding recognizability on all sides, similar look & feel, easy navigation etc. fulfilled. Overall, therefore, the structure and the design of the portal from the point of view of "design for a majority".

The same rules for e-Government - public authorities must provide barrier-free access to the web content.

It is not just for the sake of fulfilling legal requirements that makes adhering to international standards, such as the Web Accessibility Initiative (WAI) Guidelines important. Rather, the goal is to build user-friendly Web service offerings that can be used with ease by everyone in the same way, quickly, simply and conveniently.

Web offerings must be able to be used without difficulty and without help from others, in order to be considered truly "accessible". Meeting accessibility requirements for people with special needs poses a particular challenge for information and communication technologies. Due to the diverse nature of disabilities, a multitude of aspects have to be taken into account when developing Web offerings.

Article 7 of the Constitution formulates the principle of equality and also lays down a general ban on discrimination against handicapped people. The Federal Government, the provinces and municipalities must ensure the equal treatment of all people, whether handicapped or not, in all areas of daily life.

As an important result of this article of constitutional law, the Federal Act on Equal Treatment of Disabled Persons (Bundes-Behindertengleichstellungsgesetz, or BGStG) was enacted. The WAI guidelines, especially the Web Content Accessibility Guidelines (WCAG), are used as criteria for offerings on Internet sites.

§ 1, Par. 3 of the eGovernment Act states that public authority Internet presences must implement accessibility features to ensure access for people with disabilities. International standards on Web accessibility should be thereby conformed with and implemented. The need for action is even more urgent for government sites in which accessibility has not been taken into account.

Further specifications are given in § 3, Par. 5 of the Federal Service of Documents Act and § 3, Par. 1, line 10 of the Delivery Service Regulation, which are based on the latest standards for implementation of accessibility for electronic delivery.

The current general terms and contracting conditions of the Republic of Austria for IT Services Software (AVB-IT/SW) demand a detailed and verifiable description to what extent their product can be used by disabled persons without barriers ("Accessibility statement") from the contractor free of charge.

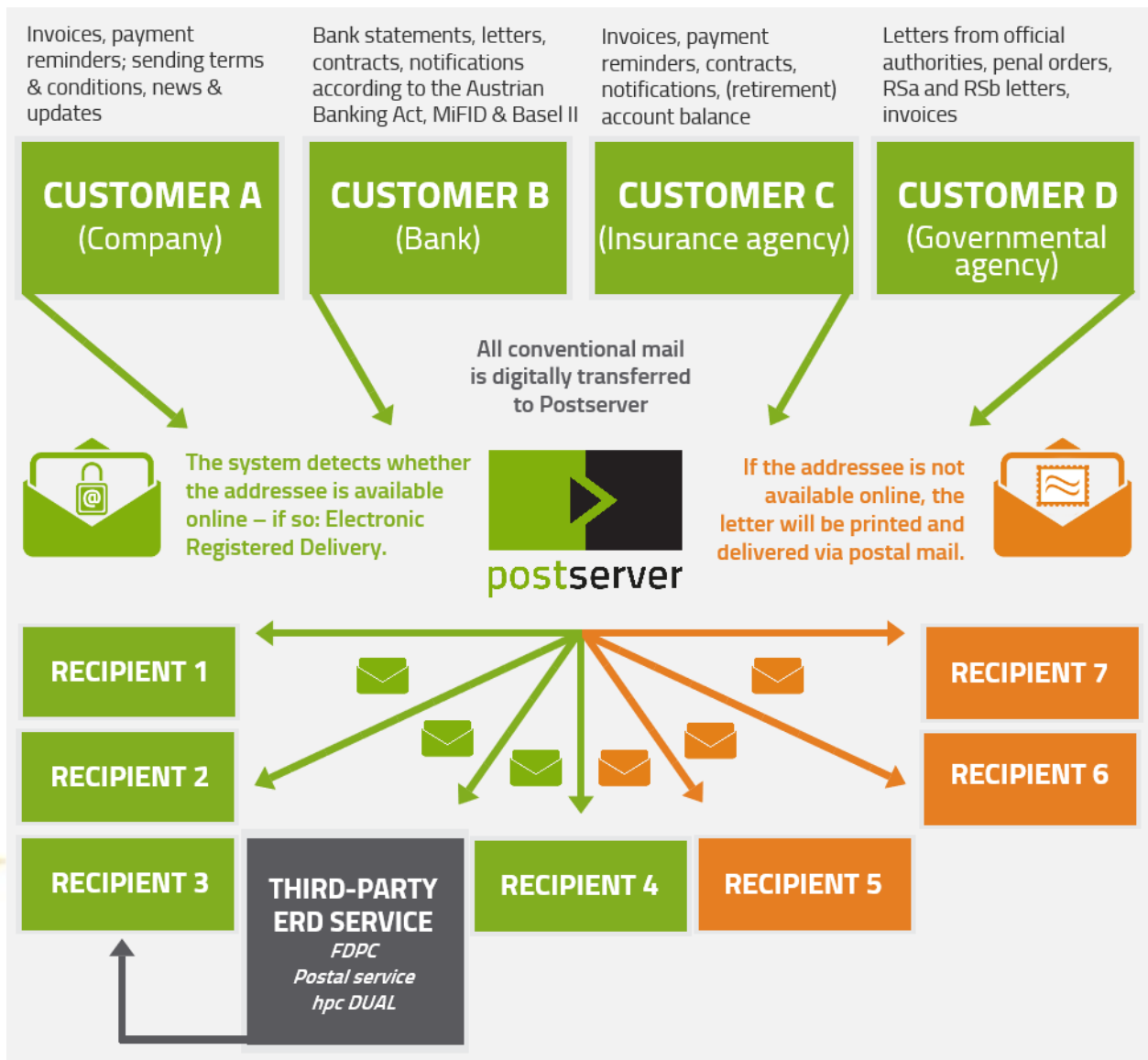
The "EU Directive on the Accessibility of the Websites and Mobile Applications of Public Sector Bodies" was adopted in 2016. The goal of the directive is the creation of a harmonised market for websites and mobile applications of public sector bodies. The directive aims to ensure that the websites and mobile applications of public sector organisations are made more accessible on the basis of joint requirements.

Electronic Delivery (Dual Delivery) in e-Government and eHealth?¹⁰⁷

Citizens can choose to have RSa and RSb letters delivered electronically already today. However, businesses are becoming more and more receptive to this idea as well. In a few years they will be reducing the number of paper documents. Electronic delivery should be seen as an additional service and is not intended to replace delivery of printed documents.

One of the key advantages of electronic delivery is that you no longer need to go to the post office to pick up official letters. After successfully registering with one of the officially approves an electronic delivery service, business employees or their representatives can retrieve documents online from anywhere, 24 hours a day, 7 days a week. Electronically delivered registered mail is held for at least 14 days in the inbox, but this time period can be extended if desired. Just like conventionally delivered mail, holds can be put on delivery for short periods of time, for example, for holiday periods or sick leave. During this time, any mail that has an expiry date attached to it will not be delivered.

¹⁰⁷ <https://www.bmdw.gv.at/Digitalisierung/ElektronischeZustellung/Seiten/default.aspx>.



However, with electronic delivery, it is possible to pick up mail even while on holiday because the Inbox can be checked almost anywhere, thanks to the Internet. In addition to the amount of time saved, electronic delivery also brings further cost reductions. Electronic delivery services can also send non-official documents electronically with proof of delivery.

Even in the age of e-Government, government authorities have two basic possibilities for delivering documents: the traditional paper hardcopy delivery or the new digital one used in e-Government but why not also in eHealth. Electronic delivery of documents saves costs, speeds up delivery time and is more convenient for citizens and businesses. Since electronic delivery can only be used when the person authorized to receive the delivery consents to it, a dual delivery system was developed.

For public authorities, the advantage of the dual delivery system is that it is carried out over a single interface. The delivery can, but does not have to, be carried out electronically. With dual delivery, if the recipient is not reachable over an electronic delivery system, the delivery is carried out by a delivery service that prints the piece of correspondence on paper and sends it to the recipient by post.

Core Register

To carry out the tasks and obligations imposed on them by law, authorities require a lot of various information. A fundamental part of this information is kept in electronic systems, the so-called administration registers.

Registers are the main basis for many e-Government (eHealth) applications. They contain relevant information on the respective governmental purpose and create valid data within the public sector. This makes it possible for the government to provide fast and dependable action. Citizens and businesses also profit from the data in the public registers.

The optimisation of the register landscape constitutes one of the key intentions of the joint ICT strategy of the Austrian administration in order to establish an efficient infrastructure for contemporary administration activities and innovative government services.

A cross-sector working group from federal government, provinces, cities and local communities already carried out the following evaluation with the following insight in 2010:

Improvement in the quality of the registers is a central theme, since only valid data can promote their use in electronic procedures. A core register needs to be defined for natural and legal persons with the necessary attributes and optimal processes for entering and updating the data. Cleaning up, merging and synchronising registers should be drawn up on this basis. Updates must be made to be required by law to ensure that the register basis is kept current. Wherever data privacy allows, the transmission of data must be made legal and automated queries must be made possible. Standardised technical interfaces need to be created to be used for all registers. With the creation of these kinds of automated mechanisms, it should be a duty of the authorities to support queries to the register. This would remove the need for businesses and citizens to submit information which is already saved in central registers (e.g., Central Register of Residents).

Since personal information in particular plays a central role for optimisation for many different procedures, implementing a Central Register of Civil Status (including Births, Marriages and Deaths) should be carried out quickly. This Central Register of Births, Marriages and Deaths would be the key to an optimal procedure flow with the focus on "one-stop".

The evaluation has since formed the basis for a number of specific implementation measures, which contributes to a gradual improvement in the data inventory kept by the administration. Of pivotal importance in this context is particularly the register cores mentioned at the beginning for natural and non-natural persons whose functionality is firstly

provided by the central civil status and nationality register (for natural persons) and secondly by the business register (for non-natural persons).

The central civil status and nationality register is operated by the Federal Ministry of the Interior and contains information on civil status and nationality of predominantly Austrian citizens. Specifically, this means that the responsible civil status and nationality authorities note every single birth, marriage or civil partnership, divorce and death in the database of the register and assign these to the persons concerned.

Through the central filing of civil status and nationality data and the setting up of corresponding query options for individual administration units, in many cases, there is no longer any need, among others, for citizens to present certain documents or certificates (birth certificate, proof of nationality, etc.), which was frequently seen as an irksome task when dealing with authorities.

In addition, the central civil status and nationality register provides all Austrian administration systems with the register core for natural persons that stores the personal core data of all citizens at a central point. A comprehensive linking of the register core to other registers means that the quality and up-to-datedness of the data processed by the Austrian administration authorities is improved and thus the efficiency of the public administration increased in the long term.

Digital Archive Austria

"No document may be lost, either today or tomorrow, and not in a hundred years either." After appropriate preparation, this basic principle is followed by the Digital Archive Austria - a storage system solution, for joint use for countries, cities, municipalities and other bodies, at two locations and a software based on the Open Archival Information System (OAIS) reference model.

The comprehensive use of the electronic file system in the federal administration also requires professional archiving. According to the Federal Archive Act, the Austrian State Archive is not only responsible for the orderly selection, takeover and storage of the electronic original file but also for the long-term (=permanent) legibility of the data. This is ensured by the setting up of a storage system, the Digital Archive Austria, and the corresponding software. In the interest of cost efficiency, a general licence was procured by the Federal Chancellery which makes it possible for all Austrian provinces, cities, municipalities and other public bodies to use this archive solution without their own tendering but with their own client.

4.2 DENMARK

4.2.1 The Danish Healthcare system

Introduction to Denmark¹⁰⁸

Denmark has an area of 43,094 km² and a population of 5.7 million people. The political system of Denmark is that of a multi-party structure where several parties can be represented in Parliament (Folketinget) at any one time. Danish governments are often characterized by minority administrations with one or more supporting parties. Since 1909, no single party has held the majority in Parliament.

The Danish healthcare system is universal and based on the principles of free and equal access to healthcare for all citizens. The healthcare system offers health care services, the majority of which are financed by general taxes.

The healthcare system operates across three political and administrative levels (national, regional and local levels):

- the state
- the regions
- the municipalities

The Ministry of Health

The Ministry of Health is responsible for establishing the overall framework for the provision of health and elderly care. This includes legislation on the organization and provision of health and elderly care services, patients' rights, healthcare professionals, hospitals and pharmacies, medicinal products, vaccinations, maternity care and child healthcare. The legislation covers the tasks of the regions, municipalities and other authorities within the area of health.

The Regions

The five regions are governed by regional councils, elected every four years. The regions are responsible for hospital care, including emergency care, psychiatry, and for health services provided by GPs and specialists in private practice

The Municipalities

¹⁰⁸ Information in this section is based upon the publication: HEALTHCARE IN DENMARK, AN OVERVIEW (MoH).

The 98 municipalities are local administrative bodies governed by municipal councils. The council members are elected in municipal elections every four years. The municipalities are responsible for a number of health and social services. Local health and elderly care services include disease prevention and health promotion, rehabilitation outside hospital, home nursing, school health services, child dental treatment, child nursing, physiotherapy, alcohol and drug abuse treatment, home care services, nursing homes, and other services for elderly people

Financing

In general, all health and social services are financed by general taxes and are supported by a system of central government block grants, reimbursements and equalization schemes.

Approximately 84 per cent of healthcare expenditure is publicly financed (2015). The remaining 16 per cent are financed primarily through patient co-payments.

Important prerequisites for eHealth and standardization in Denmark

To understand how national secure, safe and uncorrupted exchange of health care data is possible, one has to implement a set of prerequisites aiming at maintaining full semantic and technical interoperability:

- Unique Person ID - life-long and multi-purpose (since 1968) – contains all with a permanent residence in Denmark
- National registration of hospital contacts (since 1976)
- Legal authorization registry – all health care professionals are listed – public access
- Health provider registry (since 2006) – all health care providers are listed
- National security services – National service platform – National PKI infrastructure
- National health insurance – a single payer tax financed health care service
- National IT-strategies – covering all sectors
- National classifications and terminology
- National catalogue for exchange interfaces and standards

Nowadays, these prerequisites to data exchange have been implemented with almost 100% penetration.

4.2.2 Brief description of the national or regional eHealth strategy

Denmark has national eHealth strategies since the late 90'. Initially, these strategies focused on digitalization of the health care sector. A lot of the focus in the first years was on development and implementation of EHR (Electronic Health Record) in the hospitals. Nevertheless, EMR (Electronical Medical Records) was introduced in primary care (GP and private practitioner) already by the mid-90's. By the turn of the century the whole Danish health care system was digitalized, thus all health care professionals are using electronic documentation systems, capable of communicating. Over the years, the national strategies were built upon some basic policies:

- A multi-vendor environment – Each health care organization is free to choose and implement eHealth application of its own choice
- All health care organization must adhere to, and implement commonly agreed interfaces, standards, terminologies and classifications in order to maintain both technical and semantic
- Profiles and exchange interfaces for electronical communication in the health care sector are developed in a consensus process
- National standardization is the responsibility of the MoH. The ministry can delegate the operational responsibilities.
- A Coherent and Trustworthy Health Network for All – Digital health strategy 2018-2022

The current Danish national eHealth is covering a period of five years. The strategy focuses on addressing the demographical challenges, the increased demand for health care services and proactive involvement in everyday life – and more self-service.

The strategy has been developed in a close cooperation between the national stakeholders for eHealth – Ministry of Health, Ministry of Finance, Danish Regions and Association of Local Government – and applies to all sectors in the health care system, including private practices, e.g. GP offices, private practitioners, private clinics and hospitals. The URL of an English translation of the strategy can be found in section **Fehler! Verweisquelle konnte nicht gefunden werden.**



The following tasks have been defined and described:

- The doctor in your pocket – A GP app must be developed to meet functional needs in communication and cooperation between GPs and patients
- Ask the patient – Patient Reported Outcome (PROs) - Standardized questionnaires will be developed for use across the health care sector
- Digitally supported rehabilitation - Digitally supported training means that patients use digital aids during their rehabilitation process to support physical exercises.
- A complete presentation of the patient's health data - In a new 3.0 version of the Danish eHealth Portal (sundhed.dk) project, an analysis of the individual sub-deliveries in the project will be conducted
- A guide to health apps - The technical, organizational and legal prerequisites and possibilities must be analysed to establish a comprehensive guide to eHealth apps
- Decision support tools for cancer patients - Digital support tools will be developed for patients with breast cancer, lung cancer and colorectal cancer.
- Digital pregnancy tool - A preliminary analysis of possibilities of development, implementation and dissemination of a digital pregnancy tool will be carried out

- Better, faster and more secure digital communication across the sector - Analyses will be carried out and prototypes of new forms of communication will be established and tested
- A complete overview of a patient's care and treatment - Solutions for a unified patient overview will be developed and tested in the form of new digital services concerning the sharing of appointments, plans and actions, master data and contact details
- Digital workflows at GPs and more targeted communication with other parts of the health care sector - New standards and functions need to be developed in the local IT systems used in general practice: a quick patient overview, better preparation for consultations through questionnaires, an intelligent inbox, and a better framework for cooperation and communication with the hospital and municipal health services.
- Safer medication at residential care centres and substance abuse rehab centres - The Shared Medication Record (FMK) must be technically available in all residential care centres and substance abuse rehab centres.
- Better overview with structured care records in municipalities - To ensure a more structured recording of municipal health care data, it has been agreed to implement The Common Language Platform in all municipalities before the end of 2018.
- Digitally supported early detection in municipal elderly care services - The digital tool has already been developed. Some municipalities will need to purchase the solution. Others are already using it.
- Data-driven technologies for automation, prediction and decision support - There is a need to develop ideas and to test and obtain more knowledge about new technologies in this area
- Digital decision support for prescribing medicine - The project involves the purchase of a decision support system and establishment of a central medication allergy (CAVE) register.
- Further spread of telemedical home monitoring - All 98 municipalities and 5 regions have joined forces to establish common telemedical solutions for patients with COPD. The telemedical solution for COPD will build on existing national infrastructure and common standards.
- Digitally supported care plans for patients with chronic illness - Care plans for patients with COPD will be the first plan developed and rolled out in close cooperation between the parties and their IT suppliers, and will be viewable on the Danish eHealth Portal (sundhed.dk) etc
- Better follow-up on vaccination and cancer screening programmes - The National Health Data Authority and relevant parties will jointly prepare a model for how the necessary data can be made available for use by patients and physicians in an overview of participation in vaccination and screening programmes.

4.2.3 Description and role of the eHealth Centre as defined in the Strategy

The Danish governance and operations of the eHealth rests within several organizations. These organization are responsible for the development and implementation of the efforts

and goal in the national strategy. Each partner has a well-defined span of control. The main organizations are:

Governmental level/Ministry of Health - The Danish Health Data Authority (SDS)

SDS is a governmental body under the MoH. SDS was established in 2015 and have these tasks and obligations:



- Provides health care data regarding activity, resources, and quality for the relevant health care parties
- Provides valid person related Health Care data for patient services and research purposes
- Strengthen the coordination of the overall digitalization of the health care services
- Coordinating the efforts regarding cross-sector exchange of health data through goal setting, strategies, agreements and it-architecture

Regional – Danish Regions - Regional eHealth (RSI)

Danish Regions is the representative organization for the five regions in Denmark. Danish Regions' overall mission is to safeguard the interests of the regions nationally as well as internationally.




The most important tasks of the organization are:

- To safeguard regional government interests within health care, hospitals, special education, regional development, environment and finances
- To act as spokesman on behalf of the regions vis-à-vis national government, the EU, other interest organizations and the media
- To negotiate the annual financial frames of the regions with national government

An RSI section is responsible for coordination common eHealth initiatives and activities on behalf of the five regions.

Local - Local Government Denmark (KL)


Local Government Denmark is the association representing the 98 Danish municipalities. All the 98 municipalities have voluntarily decided to be a part of KL.  The mission of KL is to safeguard common interests of the municipalities, assist individual municipalities with consultancy services, and ensure that the local authorities are provided with up-to-date and relevant information.

Consequently, KL is also overseeing coordination regarding cross sector eHealth initiatives on behalf of the municipalities.

National eHealth organizations

There are two national eHealth centres. Both are governed by the state, regions and municipalities.

Sundhed.dk (Health portal)

Sundhed.dk is the official portal for the public Danish Healthcare Services and enables citizens and healthcare professionals to find information and communicate. The portal facilitates patient-centred digital services that provide access to and information about the Danish healthcare services. 

The purpose of the portal is to:

- Bring together relevant information from all parts of the health service
- Offer a shared platform of communication
- Empower patients by offering maximum insight and transparency in the health care sector
- Offer health care providers easy access to clinical information about their patients' medical history.


Sundhed.dk is a public, internet-based portal and infrastructure platform that collects and distributes health care information among citizens and health care professionals. It is unique in bringing the entire Danish health care sector together on the Internet and providing an accessible setting for citizens and health care professionals to meet and efficiently exchange information.

Additionally, every citizen has a personal page (available upon identification), which reflects the specific situation of this citizen, e.g.:

- view treatments and diagnoses from his/her hospital patient record
- book appointments with his/her general practitioner (GP)
- renew prescription of drugs
- monitor his/her drug compliance
- seek for shortest waiting lists for operations and quality ratings of hospitals
- register as organ donor
- get access to local disease management systems in out-patient Clinics.

Health professionals can also log on and gain secure and controlled access to personal data regarding patients they are actively treating.

MedCom – implementing organization

MedCom facilitates the cooperation between authorities, organizations and private firms linked to the Danish healthcare sector. 
MedCom is financed and owned by The Ministry of Health, Danish Regions and Local Government Denmark.

MedCom's role is to contribute to the development, testing, dissemination and quality assurance of electronic communication and information in the healthcare sector in order to support excellent continuity of care.

Normative mandate - authority and responsibilities

Regarding the implementation and operation of eHealth systems and applications in the Danish health care sector the authority and responsibility follows those of the general governance model for the health care system.

It is therefore the responsibility of each organization to implement and operate health IT-systems. It follows there is a diversity of systems in the health care sector:

- Regions/Hospital: Four different vendor EHRs plus various clinical systems
- Municipalities: Local health care application (EOJ) – three different vendors
- GP and other private practitioners: 10 major vendors and a number of small vendors

The National Board of eHealth is the highest authority regarding eHealth matters. It advises the Minister of Health regarding the IT-strategies and IT-architecture along with national demands and standards for eHealth. The board also initiates and secures the quality of new approaches regarding cross-sector investments.

According to an agreement in 2010 the board was established with this representation:

- The State – 3 members
- The Regions – 3 members
- The municipalities- 3 members

The State holds the chairmanship with a direct reference to MoH.

4.2.4 MedCom as a part of the Danish eHealth Centre

Date of actual establishment

MedCom was established in 1994 as a partnership of authorities, organizations and private enterprise associated within the Danish health sector. In the 1999 financial agreement between the counties and the government, it was decided to make MedCom a permanent organisation, with the following aims:

“MedCom shall contribute to the development, testing, dissemination and quality assurance of electronic communication and information in the health sector with a view to supporting good practice in patient care.”

MedCom develops standards and profiles for exchange of health care related data throughout the entire Danish health care sector. Furthermore, MedCom supervises and monitors the national technical and organizational implementation of the standards/profiles.

Goals, objectives and mandated responsibilities and tasks

By request of the Rigsrevisionen - the Danish national audit office – and the MedCom steering board, MedCom has within recent years developed a vision and a mission:

- **Mission**
To support coherent patient care paths and facilitate cooperation in the health care sector. As a public organization, our mission is to disseminate digital paths of high quality, supporting patient care paths and facilitate cooperation between health care providers through digital communication.
- **Vision**
To work for a secure and timely communication, increased efficiency and increased coherence across the health care sector, focusing on the health care professionals and citizens.

MedCom's span of operation

MedCom's most essential job is to support the local co-operation between regions, municipalities and general practitioners and to coordinate national project plans. This is always in close collaboration with regions, municipalities, the primary sector and IT vendors.

MedCom is a project organisation, running over two-year project periods. Currently we are in MedCom's 11th project period (MedCom11: 2018-2019).

MedCom works within four types of basic ongoing activities:

- **Cross-sector dissemination**
MedCom serves as project coordinator, provides support and information for healthcare professionals, and is involved in various national committees, including the preparation of new initiatives and statistical monitoring of implementation and dissemination. There is a particular focus on telemedicine solutions and exchange of data such as exchanges of journals and electronic referrals.
- **Standards, test and certification**
MedCom's standards are the foundation for exchanges of relevant data between the different parts of the healthcare sector. MedCom is documenting, arranging courses, testing and certify IT vendors' implementation as well as offering support and consultancy. MedCom's standards include EDI letters for message-based data exchange, XML letters for message- or online-based data exchange and Danish profiles of HL7.
- **System management**
MedCom is also responsible for a number of public IT solutions. That involves specifications of requirements, supply and follow-up on contractual agreements,

surveillance and support as well as user groups and future developments. MedCom is the system manager for the Danish Health Data Network (SDN), the joint video infrastructure (VDX) and the national home monitoring database (KIH).

- **International activities**

Application, participation and project-management in relation to EU projects are part of MedCom's international activities. In addition, MedCom also promotes Danish health IT and international standardisation initiatives.

4.2.5 Sundhed.dk, the Public National eHealth Portal, as a part of the Danish eHealth Centre

Sundhed.dk also operates according to an overall strategy and is a part of the national and regional strategies as well as the collective agreements

Sundhed.dk vision and mission

Sundhed.dk is the common public encyclopaedia for citizens, patients and health professionals providing all relevant health related data and information.

It provides a trustworthy and user-friendly access to health information and personal health data. It also contributes to a coherent health system for citizens and health professionals by providing solutions within the national health strategies.

Sundhed.dk span of operation

Sundhed.dk is a public eHealth portal that supplies stakeholders and user in the health system with information, data, infrastructure and applications – all with relevance and user friendliness in focus. Sundhed.dk is a project platform as well as a portal and the main activities are operating the platform with all its infrastructure, web and apps as well as constantly building out the scope of sundhed.dk with new projects.

The strategy of sundhed.dk has 4 key areas:

- **More relevant data for the users**
The portal is always under further development and the request for projects on sundhed.dk is great. As the Danish eHealth system expands, so does the portal as new data must be brought to the citizens and health professionals. Especially telemedicine and disease specific information are growing areas as well as mobility and apps.
- **A better, more user-friendly portal**
Understood in its broadest sense, the need to meet the users and their expectations goes beyond making a web-portal. Today the solutions are made available on multiple platforms and through web, apps and social media where relevant. This

involves working closely with the users, both health professionals and citizens and using disciplines like co-creation and service design.

- **More users for sundhed.dk**
As any internet media, the success must be measured in the number of users. Although sundhed.dk is free of ads or other income generating features based on traffic, the number of users is interesting. The outreach of the information and data on the portal helps to empower patients, support health professionals and create transparency.
Working closely with clinicians, taking culture into account as well as more traditional elements like marketing are important for our work. Sundhed.dk has more than 1.7 million unique users each month.
- **Digital security and trustworthiness**
A key activity of sundhed.dk is taking care of citizens' data and providing a safe, transparent and secure environment for sharing data. IT security is the highest priority and every time the portal is modified, sundhed.dk hires hackers to try to break the system and compromise data in order to keep the highest possible level of security. Also, information security is important and a priority within the organization as well as awareness campaigns both internal and in the population. Sundhed.dk also displays a log of people who accessed a citizen's health data and that log is available to citizens themselves.

Beneath the strategies are the day-to-day operations. Sundhed.dk is employing its own development teams that are possible to scale with external developers. Also, IT operations are located within the organization to get maximum ownership to the solution, architecture and project tools as well as the business knowledge. With more than 120 different data integrations to the portal and platform, sundhed.dk are experts in interoperability in healthcare. It incorporates almost any type of interface/integration/standard which is needed in order to run a platform of this calibre. Developed since 2003, the types of integrations used in the healthcare system have changed many times and this will never be a static picture.

4.2.6 Governance of the eHealth Centres

MedCom

As mentioned, MedCom is a part of the total eHealth governance in Denmark and reports to the National eHealth Board. Through their joint ownership, MOH, Danish Region and KL¹⁰⁹ forms the managing board for MedCom. MedCom's steering board has quarterly meetings. Besides them, the steering board consists of:

¹⁰⁹ www.kl.dk/english.

- The State: MoH (Chairman), The Danish Health Data Authority, Agency for Digitisation (3 seats)
- KL (Vice Chairman), including municipalities (3 seats)
- Danish Regions (Vice Chairman), including regions (3 seats)
- MedCom (1 seat)

Besides these, the board includes observers from The Danish Association of General Practitioners, sundhed.dk and relevant MedCom employees. MoH runs the secretariat for the steering board.

At the start of a new project period, the MedCom steering board shall approve the work program and the two-year budget. At the end of the period the steering board must report the result to the National Board of eHealth.

The MedCom steering board duties is adjusted according to 2015 financial agreement between the counties and the government and includes:

- Receiving on-going status regarding progress for MedCom activities and projects
- Prioritizing activities within the budget frames
- Managing project and activities not governed in other organizations
- Approving and signing the audited annual Financial Statements
- Approving the roadmap for change management, including releases and updating of standards
- Discussing new strategical actions within the framework of the current work program

The MedCom steering board can when needed escalate matters to National Board of eHealth.

The CEO of MedCom has the prime responsibility for the daily operations and management of MedCom.

Sundhed.dk

Sundhed.dk is governed by a board of politicians.

The board is chaired by a politician from the regions and deputy chairman is from the MoH. The regions hold 3 positions, MoH 1 and municipalities 2.

The board is advised by a steering committee with directors from the Healthcare sector, interest organizations and MoH.

The operational level of steering is anchored here, and the project portfolio is owned by this committee. Its chaired by the regions.

4.2.7 Organizational Structure and Staffing

MedCom

MedCom's daily operations are managed by a management group made up of two persons:

- CEO Lars Hulbæk
- Chief Consultant Jan Petersen

They handle the overall strategic, staff related and financial management and external communication.

MedCom has an extended management group which includes the above team and all team leaders. This group focuses on coordinating the current work program and the key activities in MedCom. It also coordinates the representation of MedCom in national steering bodies and committees.

This extended leader group works also on municipality communication, GP and laboratory communication, Standards, testing and certification and System management.

MedCom has a staff of 40 employees. Their professional background includes:

- Health care professionals – nurses, lab. technicians, medical secretaries
- Health information technologists
- Data Engineers, data technicians
- Academic/humanistic candidates
- Sundhed.dk
- Sundhed.dk has 50 employees. Their professional background includes:
 - Academic/humanistic candidates
 - IT developers, IT architects, IT operations specialists
 - Project managers and portfolio specialists
 - Business developers and service designers
 - Legal and economic counsel
 - Communications experts

At any given time, sundhed.dk can be scaled with around 10-15 consultants in various fields e.g. management, IT security, IT development or usability.

4.2.8 Relationship with stakeholders

MedCom

MedCom has a long tradition for developing communication standards and profiles in a close relation with the relevant stakeholders. The most important being:

- IT Vendors – software vendors developing and operating eHealth systems in the health care sector
- Project managers in regions and municipalities
- End users and health care professionals
- Decisions makers within eHealth

Apart from the formal governance and communication already described in above sections, MedCom maintains a broad array of contacts with these stakeholders through project groups, professional reference groups and general MedCom coordination group; all in all, this means more than 30 groups.

MedCom maintains a transparent policy regarding the activity in all steering, project and coordination groups. All meeting material is available on-line from www.MedCom.dk. An essential part of MedCom's modus operandi is indeed to develop solutions through a consensus driven process involving all relevant stakeholders straight from the initial clarification stages and throughout, until the finished deliverable is ready for implementation.

Sundhed.dk

Sundhed.dk has strong ties to the communications employees in healthcare organizations in Denmark as well as Regional IT environments. In the past few years, sundhed.dk has begun working directly with clinicians in hospitals, thus hospitals became strong stakeholders in sundhed.dk. Collaborations with universities and researchers who study evidence has also been initiated.

As an organization exposing data and information to citizens, patient organizations are becoming increasingly important stakeholders.

Sundhed.dk's projects often have ties to national initiatives, so close collaboration with national organizations in healthcare is needed. Therefore, public organizations as well as the interest organizations for Regions, Municipalities, doctors and similar are very important stakeholders too.

As a more project-based organization, sundhed.dk often has a 1 to 1 relationship with stakeholders and vendors unlike MedCom that has a broader coordinating role in some areas e.g. vendors in a specific field like GP systems vendors.

4.2.9 Financing and Budget

MedCom

MedCom has two sources of financial sources:

- Basic financing DKK 21 million per year (approx.. € 2.9 million), of which
- DKK 7 million. from the Government (Ministry of Health)
- DKK 7 million from the Regions

- DKK 7 million from the Municipalities

A few tasks are financed separately:

- Operation of Health Net: this is a cost-neutral financed by its users
- National telemedicine effort: financed by the Welfare Technology Fund
- Ad hoc projects financed by MoH

The overall budget for the MedCom 11 period looks like this in broad terms (please note that it is covering a two-year period): All numbers in DKR 1000:

- Common Costs including management administrations and basic operation: 12.000 DKR.
- Basic activities including dissemination, standards, test and certification, health data network, home monitoring and pro repository : 35.167 DKR.
- MedCom 11 project activities including developing GP, telemedicine international projects: 55.677 DKR.
- Total for MedCom 11 (two years basic and external financing): 102.844 DKR.

Sundhed.dk

Sundhed.dk has a base financing which reflects the split of assignments in healthcare:

- Regions finance 80 %
- MoH finances 14 %
- Municipalities finance 6 %
- The set annual budget for sundhed.dk is DKK 64 million with
- 35 % on operations and maintenance
- 14 % on administration and marketing
- 51 % on development and innovation

On top of this, comes projects with external financing but they only amount to 10 – 15 % on top of sundhed.dk's yearly budget.

4.2.10 Actual accomplishments

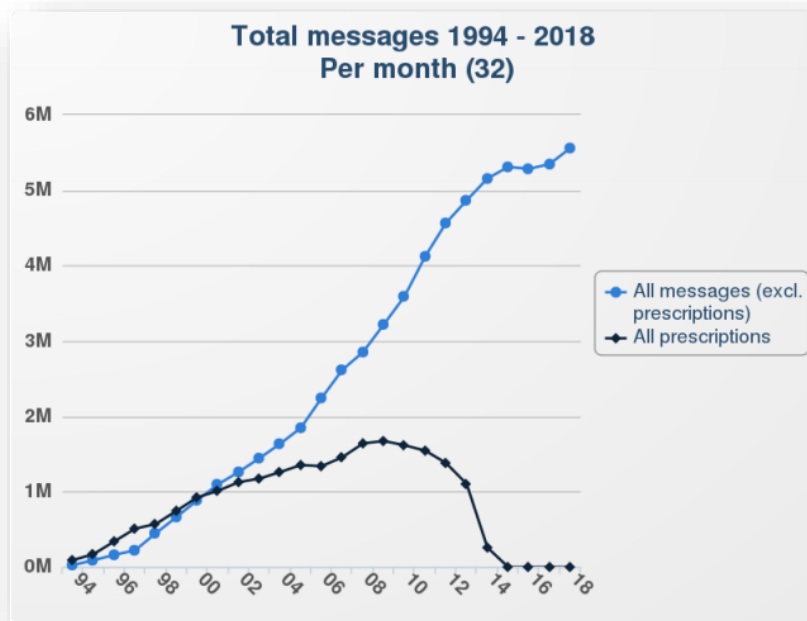
MedCom

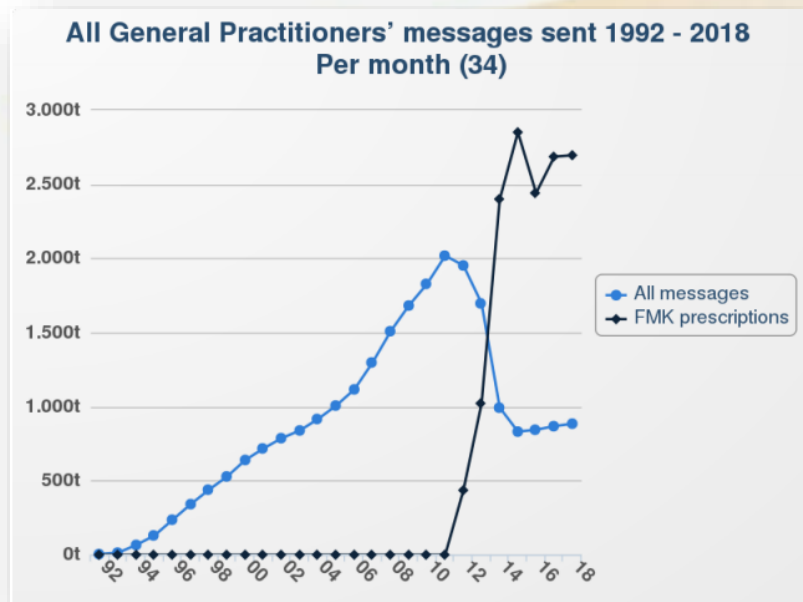
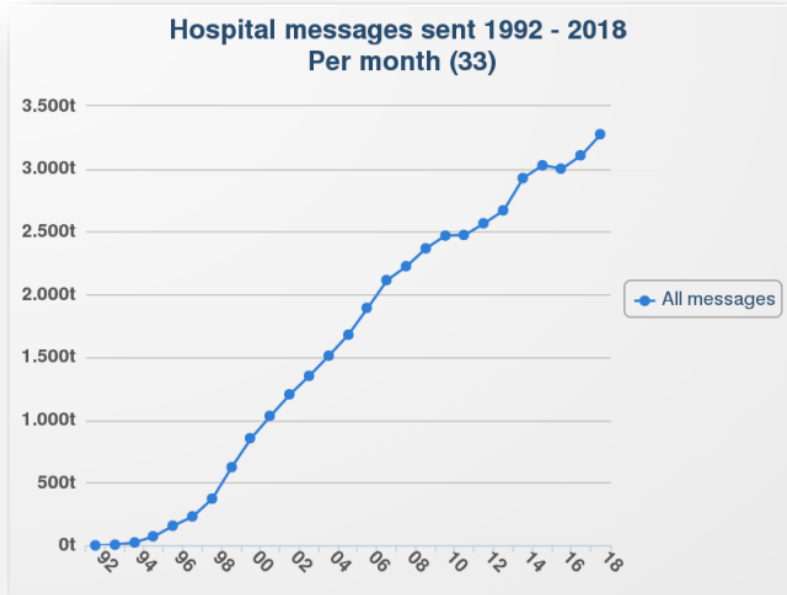
Since its start in 1994, MedCom has developed 194 national standards and profiles for exchanging personnel health care data in the Danish health care sector. These profiles and standards have been built on international standards: N-EDIFACT, OIO-XML, Online webservices, HL7. These standards are listed in the national standard catalogue maintained by the Danish Health Data Authority.

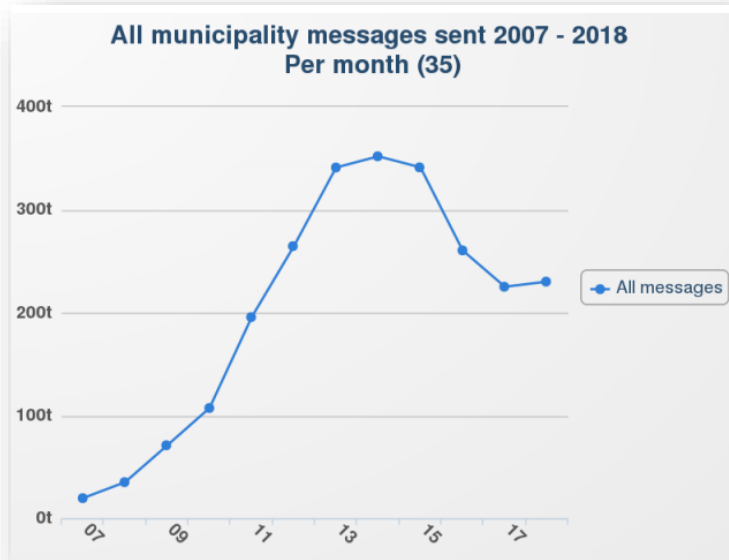
MedCom has developed, disseminated and monitored the use of these standards since the very beginning.

Apart for setting and documenting them, MedCom has tested and certified the implementation in the IT-systems used in the Danish health care sector. 153 IT systems have undergone this testing process, a process which is now ISO ISO9001 certified.

The ongoing monitoring of the accrual use of the MedCom exchange formats enables to monitor the national spread of these standards:







As seen in these graphs, almost 5,5 million messages are sent each month.

An interesting development is the decline regarding some types of messages, e.g. e-prescription and municipality messages. This reflects ongoing transition from messaging to service-oriented communication.

MedCom has been involved in many other activities apart from standard development and dissemination. MedCom had a major role in dissemination of the Common Medication Record (FMK), the development of the National EHR on sundhed.dk, and the management of several telemedicine projects. An overview regarding results and achievements during the last 20 years can be found in the publication: MedCom – 20 years (<https://www.medcom.dk/media/1167/medcom-20years.pdf>)



Sundhed.dk has been in operation since 2003 and has significantly contributed to put eHealth on the agenda for citizens and health professionals. Providing increased transparency and changing culture in the healthcare system, making eHealth available can make a real difference to all the stakeholders.

Examples of ground breaking solutions are the national sharing of EHR data, total coverage of digital laboratory results and the Medicine card, all projects with multiple partners from national and local level and projects where sundhed.dk and MedCom collaborated. In 2013 sundhed.dk launched “Sundhedsjournalen” where health professionals and patients can

access all relevant health data presented in one overview. As a national solution this is unique world-wide.

Sundhed.dk also received a number of prizes throughout the years. Some of the most important are:

- 2004: 1st place, eEurope award for eHealth from the EC (together with MedCom)
- 2005: 1st place, “Bedst på Nettet” – a Danish digitalization award for userfriendly solutions
- 2006: 1st place, Digitalization prize in Denmark
- 2007: 1st place, Computerworld Honors Program, an American award
- 2009: Mentioned as Most Advanced eHealth Portal by Obama administration
- 2016: Among the 6 most advanced eHealth portals in the world (not ranked individually) by Frost & Sullivan
- 2018: 1st place, Digitalization prize for Coherence in Healthcare in Denmark

4.2.11 Limitations, challenges, barriers and how they have been overcome

MedCom

MedCom has over the years evolved as an implementing organisation for national strategies and agreements. While MedCom was very dependent on local participation and engagement in the past, it now works more as a national-driven decision environment.

An ongoing challenge is to coordinate implementation of revised and new exchange interfaces. The multi-vendor policy makes the technical and organisational updates challenging and changes coordination in both IT-systems and health care organisations. It seems that each party (vendors, regions, municipalities and primary care) has its own change management approach.

Healthcare stakeholders do not always have the same ambitions and goals. They are of course primarily concerned with their own business and only then with cross-sector data exchange. This can lead to differences that could create difficulties for a national centre like MedCom. However, with its joint ownership, MedCom has been able to act as a neutral part in the development of the Danish eHealth.

Sundhed.dk

Much like MedCom, Sundhed.dk has also grown into an executing organisation that is integrated into the national strategies.

One of the major challenges over the years have been to get on-board health professionals, especially doctors. This has been a major barrier in the past but in the last few years, we have seen the digital readiness in Denmark become so high that those obstacles are minor now. The tenacity of organisations like MoH, MedCom, Sundhed.dk and the Regions has

helped to turn the tide and now doctors and nurses request digital and mobile solutions to help them in their daily work.

To be able to reach this point, it was needed to change the eHealth perspective from a technical perspective to an organisation/business perspective. We no longer run technical projects but healthcare projects where technical and digital solutions are a common ingredient.

4.2.12 Lessons learned

- Think small – disseminate big – Our experience is that focusing on small well-defined use cases is better than trying to solve the total communication need in one go. You build the general infrastructure as you go along.
- Only one challenge at a time – don't try to solve several complex challenges in the same project. Complexity is a threat to a successful outcome.
- Standardization by demand – Do only standardize and structure data when is demanded by meaningful use.
- If you cannot explain your strategies/plans in plain language – it will probably never work in the real world – Being able to communicate the purpose and the benefits of your project in plain language is often vital for a successful project.
- Technical aspects must be secondary to business and healthcare needs. Every major eHealth project in healthcare is also a cultural and organizational project.
- Don't start with the standards. The world moves faster than you can describe it, so once standards are selected, they are often obsolete. At least every 2nd year over the last 10 years, the recommended standard has changed. In the past 6 years standards in focus in Denmark have changed at least 4 times without any major roll-out of the recommended one.
- Use co-creation with users and don't be afraid to spend time on the specifications and user needs. Your applications and installations will likely be in use for many years.
- Build ecosystems and exchange only the data the business asks for.

List of abbreviations

HIC	Health Insurance Companies
HCSA	Health Care Surveillance Authority
ICT	Information and Communications Technology
IS	Information System
MoH	Ministry of Health
NeIP	National eHealth Implementation Programme



NHIC National Health Information Centre

NHIS National Health Information System – ICT solution for operating eHealth

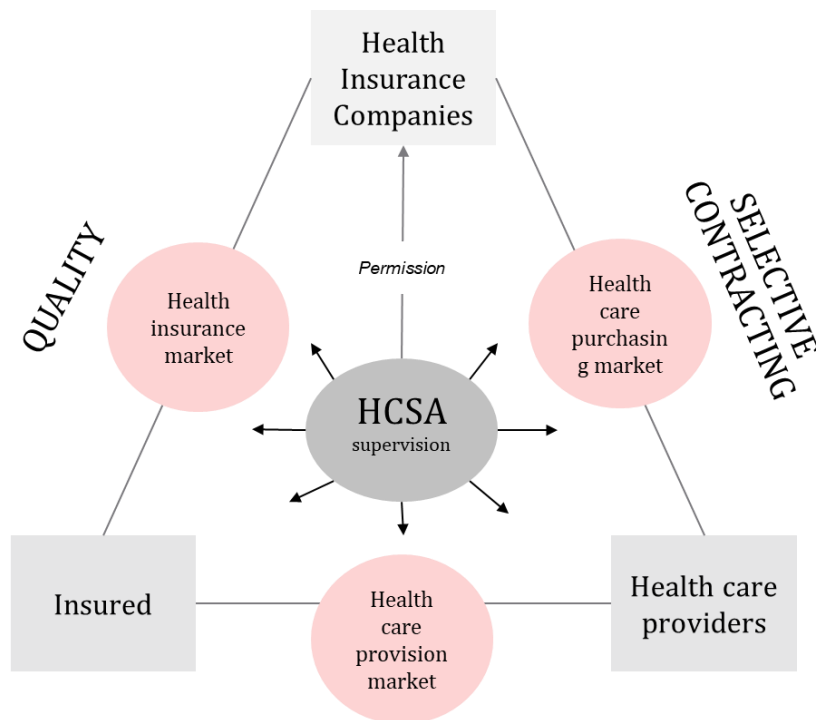
4.3 SLOVAKIA

4.3.1 Brief Description of the Healthcare system

Slovakian healthcare system is based on universal coverage, compulsory health insurance, a basic benefits package and oligopolistic insurance model with selective contracting of healthcare providers and flexible pricing of health services (sometimes perceived as unfair). Healthcare should be provided to insured with no payments. After fulfilling certain explicit criteria, there are no barriers to entry to health care provision and health insurance markets. The Health Care Surveillance Authority (HCSA) is responsible for surveillance over health insurance, health care provision and health care purchasing markets.

The MoH defines the minimum benefit package, the provider network, minimum quality criteria for providers and maximum waiting lists for patients. Furthermore, the MoH owns and operates the largest health care providers, including four university hospitals, eight faculty hospitals, highly specialized institutions and almost all psychiatric hospitals and sanatoria and is the only shareholder in the largest health insurance company¹¹⁰. Then there are only two other HICs, both privately owned, with total insured tribe of 30% of population. Relations between principal stakeholders of healthcare systems can be illustrated as follows:

¹¹⁰ Health Systems in Transition - Slovakia 2016, p. 24.



QUALITY, WAITING TIME...

MoH's direct responsibility over distribution of health care funds to different outpatient and inpatient segments was devolved to HICs. Despite this irreversible measure, its regulatory role is still in pharma policy, education, personal and technical normative or HICs minimal obligations. It is the only authority issuing healthcare laws.

A lack of information sharing across the health system was intended to be tackled by legislation in 2013 establishing a NHIS.

Current state of eHealth

The status of the Slovakia has not been satisfying in terms of successful implementation and usage of eHealth. We are postponed app. ten years in comparison with other EU countries concerning eHealth services.

Formally, as of 2013 the law requires all health care providers (public and private) and all health insurance companies (state-owned and privately owned), as well as the self-governing regions, the Public Health Authority and legal entities under the management of the MoH to provide data in a systematic structure according to standards set by the NHIC. In practice, this requirement has not been fully met due to:

- Poor implementation of unified ICT standards and registries
- Low readiness of IS vendors
- Inadequate capacity at NCHI handle such a robust project

Hence, the data on health expenditures, health status, quality and performance of health care providers do not meet the needs of policy-makers in making profound qualified decisions.

However, during last two years we have intensified efforts, when the roll out of eHealth modules were recovered. Even though the reliability and validity of centralized data are still low, the trend of penetration and thus inputs volume is growing.

Vision

Vision of national eHealth solution/electronic healthcare services is to enable sharing of inevitable and adequate patient health data at the right time, right place and it should serve as guide throughout the all stages of health care provisioning.

Strategy

There were outlined four strategic goals of eHealth:

- to create legislative and standardized frame of eHealth;
- to create secure infrastructure for eHealth vision and message realization;
- to optimize electronic processes and services in Healthcare from public sources;
- to develop innovations in patient management and forms of healthcare services;

Short historic insight

The eHealth Implementation Programme is a strategy aimed to develop electronic healthcare. Up to now, the following components were managed:

- The National Project Electronic Health Services, with goals as the launch of National Health Portal with basic information.
- The development and launch of these applications (only pilot testing): eBook for Citizens, e-Prescription, e-Medication, e-Allocation.
- Creation of conditions for integration of healthcare providers' information systems within national eHealth solution, verifying integration with IS HCP during pilot operation.

The National Project Electronic Health Services-Extension of Functionality and Services covered tasks as:

- Data consolidation of medicine and knowledge database
- Provision of administration and data updating of medicine and knowledge database
- Expansion of mechanisms for the protection of personal data of a specific category with expanded functionality and range of electronic health services
- New functionalities of electronic health services.

Despite the successful completions of both projects in 2015, the functioning outcomes by physicians' visits were still missing, as the integrations of stakeholders into NHIS could not be enforced.

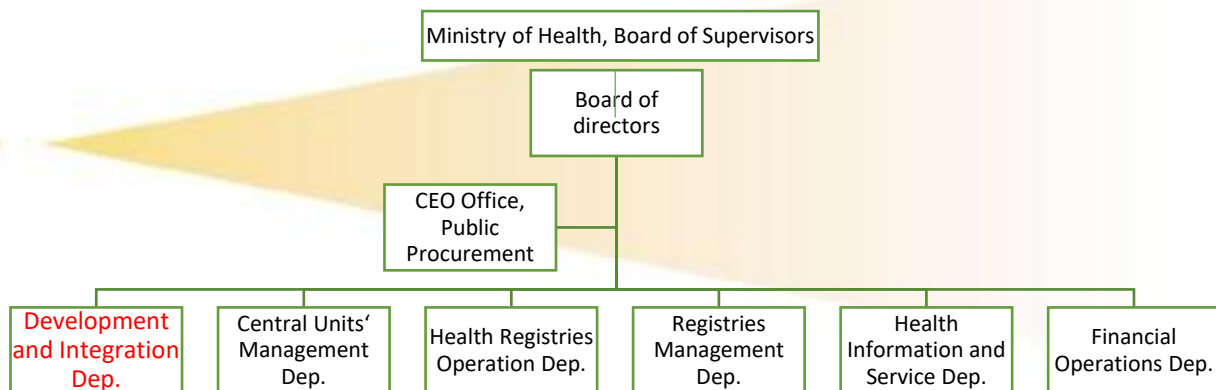
4.3.2 National Centre of Health Information

A brief history

The Ministry of Health established the National Health Information Centre in 2004 as a state contributory organization to cover any electrification issues in the healthcare sector. However, even after quite long settlement period, its activities focus on collection, processing and provision of health publication and statistics for public and internal (mainly MoH) purposes. First years of EU funded project of eHealth NHIC acted as supervisor rather than trendsetter in e-services. This weakened potential was caused by rigid project settings and partially also by not clearly defined competencies between MoH and NHIC leading to mutual blaming of which institution is capable for driving change.

Ambition to act as national authority in management and development of ICT level across sector or at least in state owned hospitals has not been grown up yet.

There are about 200 full time employees and brief organizational structure of NHIC:



Role

The MoH's leading role over the NHIC is governed by Act no. 153/2013 Coll. on the National Health Information System and on Amendments and Additions to Certain Laws.

NHIC performs tasks in the following areas:

- Informatization of health service, administration of the National Health Information System
- Standardisation of health informatics
- Health statistics prepared based on data collection from providers of health care
- Responsibility for National Health Portal

- Administration of national health administrative registries of Healthcare Workers and Providers

National health registries gained by comprehensive, rather manual collection of filled questionnaires, e.g. National Cancer Registry, National Diabetes Mellitus Registry, National Congenital Disease Registry, National Cardiovascular Registry, National Registry of Neurological Disorders etc.

Provision of library and information services in the field of medical sciences and health service

NHIC collaborates with institutions such as the Statistical Office of the Slovak Republic, the Health Care Surveillance Authority, the Public Health Authority of the Slovak Republic, the State Institute for Drug Control, institutes of the Slovak Academy of Sciences, health care providers, chambers and health professional organisations, health insurance companies and medical faculties.

At international level, NHIC collaborates with WHO, EOCED, EUROSTAT and EMCDDA.

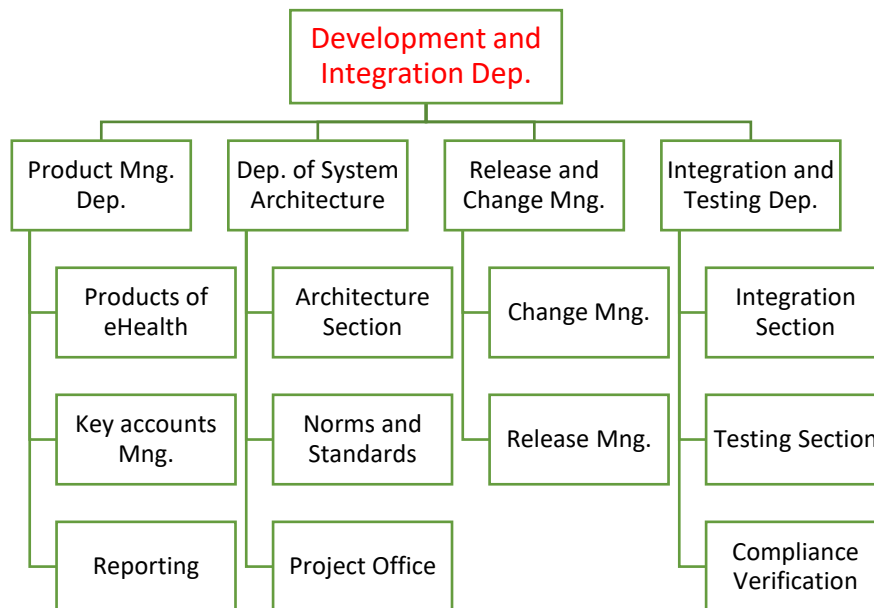
Authority and responsibilities

NHIC is legally autonomous, state contributory organisation. Board of directors consists of three members, out of which one is general director. Board of directors is accountable for its decisions and tasks delivery to minister of Health. Usually, NHIC does nothing above by law stated tasks and rules, that causes quite inflexibility in realizations of different measures.

4.3.3 Organizational structure and governance over the eHealth project

Statutory regulations towards a NHIS were not implemented until 2016. It had been up to health insurance companies to shape eHealth policies that meant the risk of further fragmentation within the health system. Fortunately, under the governance of the new minister of Health, considerable shift towards sustainable operation of the system has been driven.

Central point of eHealth project implementation is Development and Integration Department.



4.3.4 Financing and budget

An amount of 0.41% of contributions into health insurance funds is annually dedicated by HICs to cover all operational costs of the centre, including the NHIS. In absolute numbers, this amount represents app. 16.5 mil €. Fixed initial costs for system development and all the ancillary services were about 100 million €, drawing from EU funds.

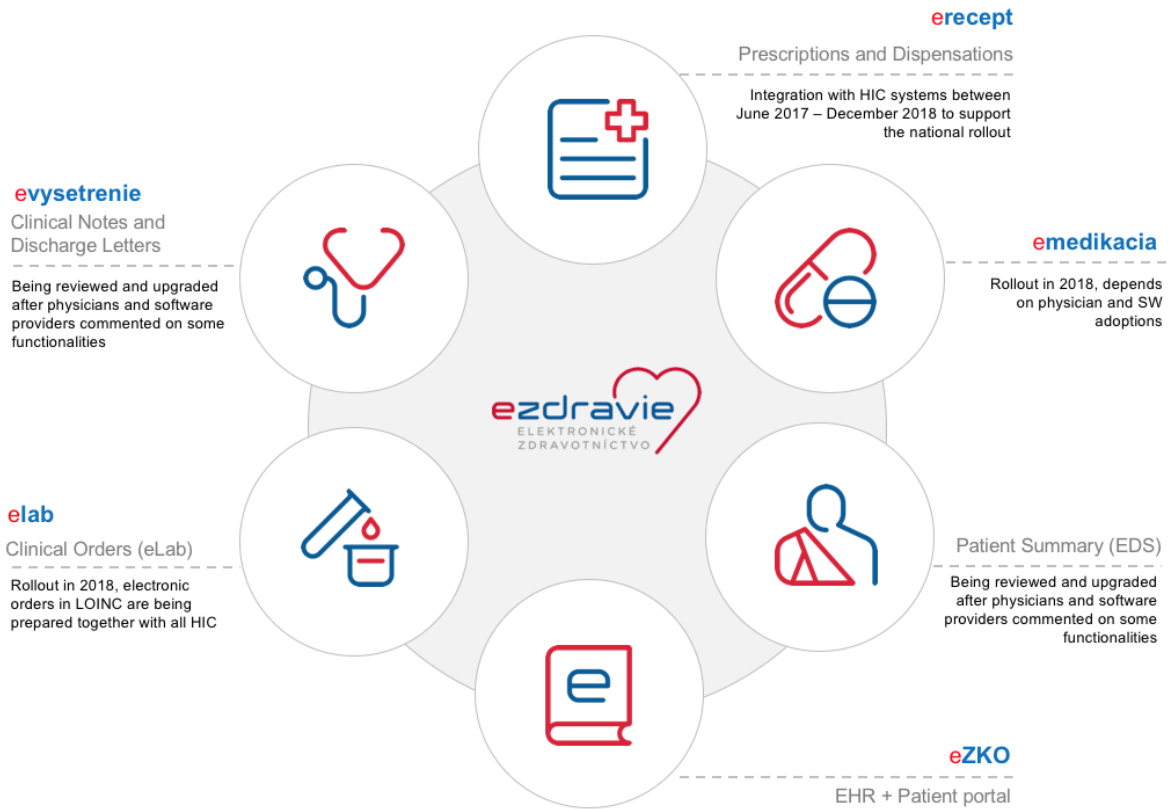
4.3.5 Actual Accomplishments

NHIS went online on January 1st, 2018 after successful integration with all three HICs during June 2017 – December 2018. A number of additional integrational and system tests were performed to assure all functionalities and performance. This was one of the outcomes from pilot operation in 2016. In 2017, a team of 35+ people was dedicated to perform tests and communication with care providers, software vendors on scheduled Connectathon and conferences. Active networking should have started earlier, at least 12 months prior to GO LIVE.

30+ software vendors for healthcare provides have passed the certification process conducted and confirmed by NHIC in 2017. Some vendors haven't been able to pass or implement required functionalities in time, so the certification of their software is a continuous process in 2018.

Discussions and system tests led to a few legislation changes, but still there is several issues on the waiting time list to be solved.

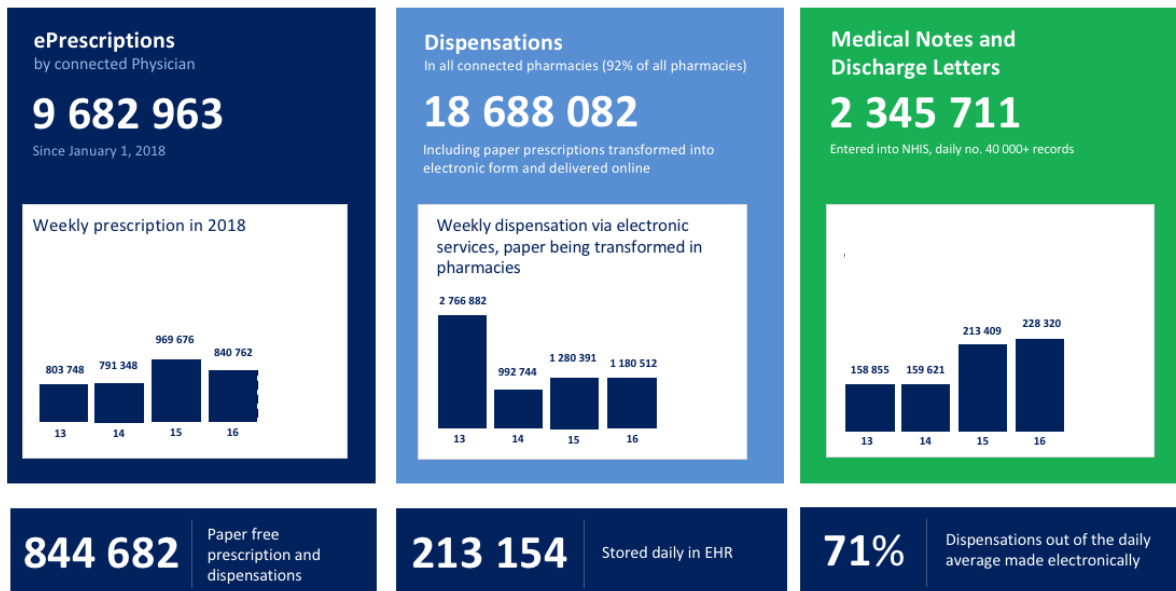
Graphical summary of active modules implemented as of January 2018, and some of them with planned releases, looks like this:



After a very slow growth in terms of connections and electronic records flow during the first three weeks in January, healthcare providers and physicians started to use their software to create and send electronic records through NHIS services; ePrescription (eReceipt), reached 92%+ penetration in March 2018 confirming the fact that the direct integration with HICs was a good decision. HIC had changed motivation criteria for care providers to support electronic prescription. We expect to save 10 – 20 million EUR a year due to electronic prescription and paper free process (administration costs and fees in pharmacies, some paid by patients).

Not all software vendors were ready to upgrade their software or support the national rollout due to lack of the resources, mainly experts to support to installations and consultation with physicians. Some vendors could not perform remote upgrades so they needed to visit each location. Proof of progress for e-Prescription and e-Examination is documented in recent statistics:





Scheme: e-Prescription and e-Examination (Clinical Notes and Discharge Letters overview), January 1 – April 20, 2018.

4.3.6 Relations with stakeholders

In general, legal acts and IT solutions itself are not sufficient for project implementation. Especially in public environment is a sort of interactive approach with all relevant stakeholders often not the priority. We adopted internationally well-known format of regular organisational and technical meetings – Connectathon. Its goal is to create a communication platform between NHIS project team and vendors of IS for healthcare providers, including pharmacies.

Vendor of national solutions

The development of the national eHealth solutions had suffered from government changes throughout the years 2007 – 2018. In such a project its always better to GO LIVE with smaller parts of the systems rather than use a BIG BANG approach. Environment is not ready to absorb such a huge change.

This was the main reason to change the approach in 2017 and prepare GO LIVE for authentication modules, ePZP cards for health care professionals, prescription and discharge letters and clinical notes, leaving clinical orders and other functionalities to a step-by-step rollout.

National solution was developed by consortium of NESS and MICROSOFT with 4 main subcontractors Asseco, Lynx, Anext, BSP. Current SLA is signed with Asseco. Still there is a

lack of coordination and effective cooperation between all subjects providing the services under one service level agreement.

Health care providers

Structure and numbers of health care provider in Slovakia (end-points from the NHIS point of view):

- Total number of care providers is 13.160:
 - Primary care) - 2846
 - Specialists - 6120
 - Inpatient - 140 - general, specialized (faculty, regional, private, public hospitals)
 - Pharmacies - 2112
 - Hemato-transfusiology - 11
 - Other - 1721

An average patient visits physician 12.6 times a year. There is 19 000+ physicians.

EHealth, probably as any national wide project, focuses on homogenous coverage of main stakeholders concerned. As few exceptions as possible. Reality, however, is sometimes different from the sample of users we have assumed is the whole target group of built concepts. E.g., we have to face unsolved role of non-certified physicians in eHealth who are not eligible to write discharge letters by the law, but most of them do so in fact. Then there is role of nurses that should be redefined due to the need of access to patient medication history when preparing prescription in cooperation with physician (a.k.a. assisting physician with administrative tasks).

In general, there are not unified roles and competencies in current health laws with accustomed daily routine.

4.3.7 HICs

NHIC depends on financial resources received from HICs. There are three HICs in Slovakia (VŠZP with appx. 69% market share, private Dôvera with 26% and 5% Union).

HICs cooperate with National Health Centre in rollout and certification process. Some services of national solutions are supported by HICs which has created a front-end for NHIS. Services where data from agreements between HIC and care providers are needed to process requests, prescriptions, orders, etc. are directed through HIC, which validates the inputs and accepts or rejects request for a service. HICs support the rollout by motivating care providers with a price differentiation for selected services provided to patients if performed and documented by electronic way.

Pharmacies

There are 2112 public pharmacies in Slovakia. Since January 1st, 2018, only electronic prescription is legitimate, so many pharmacists had to overcome interesting process change. Except the use of pharmacist ePZP card, e-Prescription is the only module applicable for them.

In cooperation with HIC an expert system for drug interactions is provided. Patient is identified by eID or HIC card. After 2022 only eID will be accepted for patient authentication before drugs are disposed.

Major software vendors (4 companies) have been able upgrade respective versions of their SW in time, having implemented eID identification and all other required functionalities. Discussions from Connectathon held in 2017 led to a number of fine-tuning functionalities implemented and rolled-out before December 31st, 2017.

Patients

Few years ago, was signed contract for special eID to be distributed for patients designated only for eHealth authentication and access to own e-Book. Despite it was too expensive (joke), we reassessed this intention and nowadays we use standard eIDs of citizens with electronic certificate. After inserting to card reader, it is used by care providers and by dispensing medicines in pharmacies.

Released modules

The initial vision of electronic health services, thus sharing medical data to improve quality and efficiency of healthcare services has been slightly fulfilled. The launch of the system January 2018 means historically the greatest qualitative change in healthcare provisioning. EHealth is the central repository of the patient's health records and is a source of important information about the patient's health condition that can save his life.

Obviously, inevitable precondition of functioning system is the mechanism of users' integrations. There had to be ensured accesses of patients via electronic citizen card – eID, instead of electronic patient card. App. 100 doctors, nurses and other workers use their electronic card of medical worker for authentication into system.

e-Prescription

From the financial perspective, this module is magic tool for ensuring the minimizing of redundant, duplicate and sometimes unsafe pharmaceutical consumption. Physicians make prescriptions in their internal software and background controls verify this ordination with all currently administered active substances and their dosage. Every physician is entitled to view prescription history entered by other physicians treating same patient.

From the HICs perspective, this domain integrates their individual systems into one central dealing with electronic prescriptions.

Requirements of this module are:

- Prescription of medicine, medical devices, dietetics'
- Dispensation of medicine, medical devices, dietetics'
- Repetitive prescription for up to 12 months without necessity of doctor's visit
- Blocking rules
- Prescription cancelation
- Substance interactions control
- Debt check of patient's contributions
- e-Examination
- This module enables the users to create and read following records:
 - Specialized examination
 - Clinical notes
 - Discharge letter
 - Imaging and radiologic diagnostics
 - Urgent health care provided

Moreover, it manages to create an exchange letter for recommended specialized examination, including the inserting of record the conclusions from this specialized examination.

e-Lab

This service consists of creating the record from laboratory analysis and enables to add a link with results into e-Examination form.

e-Book for Citizens

Electronic health book primarily serves patients to have a private overview of provided healthcare services. Since 2013, in the preparation phase of e-Book implementation, HICs are obliging to share their datasets with NHIC to prepare a patient's record history by the moment of eHealth launch. Centralized database contains very detailed tables of outpatient, inpatient, transport, diagnostic services and pharmaceuticals paid by HICs at individual level.

A side effect is that MoH uses these anonymous data for analysing expenditures, diagnosis, regional distribution and almost any kind of matrix concerning health status of population.

Patient summary

The patient's summary is part of e-Book and contains, if known:

- the blood group and Rh factor
- active implantable medical device with its further specification
- custom-made dental medical device
- allergies

- vaccination carried out, with its further specification
- capitated general practitioner
- personal data regarding closest relatives
- Mandatory fields are:
 - date and time of the last update of the patient summary
 - dispensed and administered medicines and medication history for the last six months
 - codes of stated diagnosis
 - e-Medication

Nowadays, medication in hospitals is rather manual process, weakly supported by IS platforms. Physicians write attributes like medicine, dosage, form, period of administration in plain text within the daily patient record. Neither their habits nor the absent structured electronic forms for medications in inpatient IS are a reliable precursor for successful extension of this eHealth module.

The lack of guidelines or described patient workflows designed and monitored on a national level, the rollout won't be an easy process. NHIC should prepare and provide such guidelines in cooperation with MoH to navigate physicians, nurses and other staff members through the whole transformation process. In Slovakia, these guidelines and instruction were prepared on-the-fly. It's important to stress out the facts and changes in day-to-day tasks for physicians and nurses. In fact, they use the same software, which should send or retrieve data on the background; of course, some interaction with user is required. The need for more structured data has the main impact on physicians.

4.3.8 Limitations, challenges and barriers

Long-term preparation phase accompanied by repetitive legislative and technical delays led to successful implementation of several eHealth modules beginning 2018. It is namely e-Prescription, e-Examination and e-Book for Citizens. Modules like e-Medication, e-Lab and Patient summary will be updated this summer.

Parallel electronic and paper worlds

Parallel paper documentation is still required by some legacy methodologies and requirements. Care providers are motivated to create and send electronic documents so the eHealth database server to its main purpose. Citizens, especially 60+, are afraid to leave physician office without the paper. NHIC will launch campaigns to empower patients to use, precisely demand, electronic documentations. HICs will change (or already had changed) rules and motivation criteria for care provides. Those connected will receive higher payments for their services.

NHIC has chosen repetitive receipt as an example of electronic service that will help both patient and physicians. Once the drug is prescribed for a period up to 12 months, patient is not required to visit physician each time he or she needs to refill the drugs. Those could be

picked up at any pharmacy showing only eID or HIC card. This functionality will save some time to physicians and nurses where examination before prescription is not necessary.

Transition to a paper free or simply electronic world will never be 100%, there is a small group of health professionals that may use the paper. In other cases where computer systems are not present or it is not practical to use computer at the point of care, health professionals must enter electronic records within 24 – 72 days depending on situation.

Software solutions are tested and certified to comply with the above mentioned rules.

The main focus in 2018 – 2019 is to have almost all ePrescriptions and Discharge Letters in electronic format.

Implementation in hospitals

Dedicated teams of project manager were active during the year 2017 planning and supervising the software upgrades in all hospitals in Slovakia. MoH was in charge of connecting state owned hospitals.

Major software vendors (6 companies) have been able upgrade respective versions of their SW in time only for two modules e-Prescription and e-Examination. One of major vendors could not manage the upgrade due to technology obstacles and internal problems. Some hospitals with own in-house development were ready between January and March 2018.

4.3.9 5-years eHealth Strategy

The mission of NHIC is to use every possible health IT as a tool to support health care transformation into a new digital era.

5-year strategy is being prepared within the core product team in NHIC. The main goal for 2018 is to connect as much care providers as possible to all modules, 2019+ will be the years for continuous development and improvement.

NHIC will insist on process improvement and patient security during the care processes. Each change, new module or even a small feature must comply with the most of these requirements:

- Help to collect and share structured data
- Define workflows to manage and measure care provided to patients
- Care quality must be measured and managed online
- Focus clinical staff on a patient management to achieve the best care outcomes
- Development of online analytics over the collected (big) data in EHR
- Use of predictive alerts for clinical staff and patients (also within preventive care and self-care)
- Reduce deviations in clinical processes

- Integrate and coordinate care between providers (right data in time at the point of care)
- Increase reputation of project which attracts more users (physicians, nurses, patients)

In terms of healthcare providers' ISs NHIC will empower and help vendors to upgrade and transform their solution from data collecting applications (mainly for billing) and plain text typewriter-like software to more advanced systems benefiting from structured data and seamless integration in real-time. To do so, NHIC will keep the pace of Connectathon on a monthly basis and will prepare the criteria and hints for a software to get the certificate. This will allow us to share the processes in forthcoming years.

Goals and Objectives

Implementation of the national eHealth programme was one of the biggest IT projects in Slovakia, literally with impact on every and each person in state. We do not expect the environment to change in terms of its structure, it will be heterogeneous (264 care providers such as hospitals, clinics, 12K+ GPs and specialists, more than 100K+ doctors, nurses and other medical staff, 73 software vendors).

4.3.10 Strategic goals

eHealth as a set of IT tools and processes must help to achieve these goals:

- Increase patient safety in every possible way (small steps towards the improvements)
- Highest possible penetration of users
- Trust of patient that their data are securely centralized and processed
- Unify clinical processes, reduce deviations in care delivery (at least in state owned care providers)
- Change mind-sets of a clinical staff to a patient centric and cooperative setup
- Paper-less operation
- Online benchmarks and monitoring of KPIs
- Physicians focused on care sharing documentation and clinical results
- Skilled non-medical workforce able to perform repetitive, predictive and mostly administrative tasks
- Personalized approach to the patient needs
- Innovations introduced on a regular basis
- Decision support becoming a day-to-day standard for all clinical staff
- Operational goals

Besides the system development itself, there are some inevitable ancillary services for nationwide rollout:

- compliance verification of IT systems of 70+ vendors operating across ambulatory, inpatient and pharmacy sector
- access of healthcare workers

- access of patients, provide mobile application for PHR

4.4 Some additional lessons learned from Austria, Denmark and Slovakia

The experiences of Austria, Denmark and Slovakia have, as to be expected, some similarities and differences from the six countries reviewed in Part 3 which has provided a good context for viewing them.

Some of the main lessons learned are:

1. It is important to start – to put together a working team that begins to get things done. In Austria, ELGA started out as working group several years before there was any legislation and the establishment of ELGA as a GmbH. Likewise, in Denmark, MedCom was established as a temporary partnership of authorities, organisations and private enterprise associated with the Danish health sector. It only became a permanent organisation 5 years later thanks to a financial agreement between the counties and the government.
2. Another important lesson, also seen in Austria and Denmark, was to start slim. The working group, and following that, the initial ELGA GmbH, were composed of a small group of competent people.
3. A major key to the success of the Arge ELGA Working Group and later the ELGA GmbH is that they had the authority to make decisions and were not afraid to make decisions.
4. MedCom has pioneered and successfully managed a consensus process for the development and implementation of standards which can serve as a model for the Czech NeHC. MedCom has never had the authority to dictate or impose any of its-solutions on the health care providers. MedCom has always acted by demand from the owners (State-region-municipalities). Through mutual agreements and common needs MedCom has developed, documented, disseminated, tested, certified national interface specifications. The process has been conducted through consensus building and practical testing (piloting). Only when the specifications/standards/infrastructure has proven beneficial and working in the clinical setting, have the standards been made mandatory through financial agreements or legal regulations. The overall approach has been: ‘standardisation by demand’, building on focused clinical use cases.
5. Both ELGA and MedCom had a clear view of their main function as a project coordinator rather than a direct operator of technology systems. They coordinated all of the necessary organizations and stakeholders in order to assure that the job got done.
6. In both Austria and Denmark, we see the importance of starting small, focusing on a limited number of initial projects and then moving forward step-by-step. This was a clear lesson in Slovakia as well.
7. There are some important differences between Austria and Denmark that will raise questions about what is the most appropriate for the Czech Republic:
 - ELGA in Austria is a Project Coordinator and responsible for setting standards

- In Denmark, the MOH sets standards for the healthcare system, while MedCom sets the technical standards for data exchange;
 - Sundhed.dk is responsible for managing the data and providing intelligent and user-friendly access to patient data for clinicians as well as patients, MedCom is responsible for the data exchange profiles that enable getting the data to Sundhed.dk
8. Cooperation and collaboration with the key stakeholders is critical to success, whether it be Health Insurers as in Austria and Slovakia, or the Regions and municipalities in Denmark.
 9. The Ministry of Health is a key player in all countries reviewed and without its full support there is no start.
 10. Another key stakeholder without which it is impossible to move forward are the physicians. It is the doctors who ultimately supply the medical data, without which there can be no system. This was clearly highlighted in all of nine countries reviewed.
 11. The flexibility of the organizational structure of the NeHC and its ability to adapt its structure and its staffing at each stage of system implementation is another key success factor.

5 Challenges and Considerations

5.1 Challenges

The lessons learned from all of the 9 countries reviewed reveal some major challenges with which the Czech Republic will have to contend – as did all of the Countries reviewed.

5.1.1 Achieving the right balance between consensus building and decision-making

While this challenge has arisen in all of the countries, perhaps a comparison between Germany and Austria best illustrates this point. There are many similarities although there is a big difference in population size – Germany having the largest population in the EU with 81 million people whereas Austria has a relatively small population – 8.6 million people. eHealth systems of both are relatively expensive with total health expenditures in Germany at 11.2% of GDP and in Austria 10.3%.

Both have Bismarkian Health care systems wherein National government sets policies and passes legislation, but coverage of care delivery is the responsibility of non-profit health insurers. These set fees for paying providers by collective negotiations with professional organizations. Both have a not-insignificant private sector. In both countries, there is free choice of physician and the GP is not a gatekeeper, although Germany has been trying to create incentives for patients to see the GP as point of first contact.

In both cases the NeHC was established as a GmbH, gematik in 2005 and Elga in 2009 – although its precursor, ARGE ELGA, an official working group established by the Ministry of Health, was set up in 2006. Despite the similarities, there is a significant difference in achievements. Germany has finally achieved national roll out of its eID Card and has yet to implement a national system for clinical data exchange among providers and ePrescriptions whereas Austria has made very significant advances in implementing the ELGA system.

A key factor would appear to be achieving the right balance between collaboration and consensus building and decision-making with clearly predefined deadlines for implementation. As the Czech Republic similar to both Germany and Austria, has a Bismarkian system where Health Insurers are key players, it would be worthwhile to compare and analyse in depth the processes in Germany and in Austria in order to understand better the critical success factors in Austria's implementation.

5.1.2 Achieving the right balance between privacy and sharing clinical information for better patient care

This is another major issue that has been confronted – and not always successfully, in many countries. Progress in Germany has clearly been hampered by its privacy legislation and regulations. The Netherlands failed to implement a shared medical record system for the same reason and are now working on an alternative solution. Finland, on the other hand seems to have dealt with this issue rather successfully and has moved to an opt out policy. This means that by default data is shared across the health care sector without asking for

patient consent. In the next stage it is planned to include the social care sector in this scheme. Luxembourg is trying to deal with the issue by placing access control of the DSP in the hands of the patient

5.1.3 Engaging Physicians When and How

Engaging physicians is a crucial success factor but is complex. Doctors tend to be very conservative and reluctant to change the way they practice medicine. Many countries have faced the resistance of doctors to using electronic medical records – France is now providing financial incentives – and even where doctors have been working on electronic records for years, they resist sharing medical records and/or clinical data exchange, as we have seen in the Netherlands.

However, without them, there is no data to share. While this is a challenge that is never “solved” and must be overcome every time there is a change in technology or a new function, Denmark and Finland have done a good job of physician adoption of eHealth.

There is sometimes a tendency to think that it makes sense to wait and to engage the doctors only when you have a polished, easy to use and finished product, but experience has shown that in most cases, this is not the successful approach. The English Spine almost failed and had to be seriously revised because it was built top-down by IT people instead of bottom-up with the doctors as full partners from the very beginning to assure that the solution supported their work processes instead of trying to superimpose a whole new way of working.

5.1.4 eHealth is a means to an end – not an end in itself

When embarking on a journey to establish an eHealth system with all of its technical platforms, it is easy to forget that technology is not the goal. The overarching goals are indeed to improve the health care of patients (the clinical objective) and to make the operation of the health care system more effective and efficient (the managerial or administrative objective). IT and eHealth are enablers that are meant to support and help actualize the goals.

Both the Danish and Austrian system got it right and their NeHC was and is the project coordinator, determining what needs to be developed and how to serve what ends, while IT companies are subcontractors with specific tasks. The tendency for IT to dominate is another challenge that must be managed and overcome.

5.2 Considerations in Establishing an NeHC

The study has identified a number of issues, both structural and process, that need to be considered in order to have a successful National eHealth Competence Centre.

5.2.1 Legal status

From a long-term perspective and if the legislation of Czech Republic allows it, it is important to consider establishing the eHealth Centre as a legal entity distinct from the Ministry of

Health, working under the regime of private law but owned by the public authorities that will fund it. Such a structure would offer the flexibility needed to recruit staff according to market rules and to contract suppliers. Typical example of this are ELGA in Austria, gematik in Germany, Agence eSanté in Luxembourg, Lombardy Informatica in Italy, Nictiz in the Netherlands, MedCom in Denmark.

5.2.2 Budget:

To secure means and engagement, the eHealth Centre should be financially supported by funding from key stakeholders; in the context of Czech Republic, this would include the State, the country's health insurers, and the regions. Most of the cases studied in this report have indeed implemented this approach. While the budget will vary at the different stages of implementation of the eHealth system, it is crucial to make sure that the budget is sufficient to get the job done. Along with budget comes accountability and both NHS Digital and Nictiz, in the publication and public availability of their annual reports on their websites are excellent examples of the transparency required to assure trust of all of the stakeholders and financial sustainability.

5.2.3 Stakeholder engagement

Involving all stakeholders at an early stage of the set-up process – and not only the key ones who will finance the centre – is essential. The objective of such engagement should be to balance the top-down approach with a bottom-up one. This should be done both in a formal and informal way, and in any case in a neutral and transparent way to create trust and engagement. An example of this is the creation of thematic advisory committees, but there are also other ways, such as having centre staff members who can bring stakeholder perspectives to bear in the day to day decision making. Most of the cases studied in this report have indeed implemented this approach. In all cases, in this study, the doctors have been pivotal to the success of implementing eHealth and they need to be on board from the very beginning.

5.2.4 Standardisation processes:

Working with standardisation organisations and collaborating with all stakeholders (i.e. demand and supply side) for building consensus on the definition of the national eHealth infrastructure and related national standards and profiles is also a key task of an eHealth Centre. This should however be complemented by the development of business plans/project plans as an incentive for vendors integrating standards in their solutions. The experience of Nictiz and MedCom can be underlined here.

5.2.5 Mapping

The mission of the National eHealth Centre should include mapping and coordinating existing stakeholder representative organisations and eHealth projects to:

- Ensure their alignment to the National eHealth Strategy
- Facilitate stakeholder engagement,

- Create consensus on the architecture of a national eHealth infrastructure.

In the Czech Republic, as in all of the countries studied, we are not starting from scratch. There are already many projects running and many of the stakeholders are already using ICT. All of these systems and projects need to be identified and analysed and plans need to be devised to align them in order to create a coherent system.

5.2.6 Strategy development:

The National eHealth Strategy needs to evolve continuously to stay in line with the changing needs of the health care system as well as the evolution of supporting technologies. The eHealth Centre should be in charge of or at least an essential partner in developing and modifying strategy on an ongoing basis.

5.3 Getting Started

In accordance with the project contract and based upon this study, the workshops and the site visits, there is a consensus that there is a need to make and implement an Action Plan. This should include at least the following:

1. A working team needs to be set up (whether as a department in the MOH or elsewhere, whatever can be decided upon and implemented quickly) with a small group of skilled people, fully supported by the Ministry of Health, with a small number of clearly defined objectives and deadlines that must be met. This group will require strong leadership capable of quickly making and implementing decisions.
2. This working team must have a clearly allocated budget and staff along with an office and all of the other organizational supports and amenities to enable it to get its job done.
3. The key stakeholders need to be involved with this “working group” from the beginning – first and foremost the doctors. If the doctors “buy in” – it will be much easier to engage the collaboration of the health insurance companies and the hospitals.
4. The team will need to develop an action plan with clearly defined operational objectives and tasks and deadlines.
5. One of the key tasks of the team will be to define what the NeHC will be, both from a structural and process perspective. However, the working team will need to begin to implement, on an initial basis, some of the tasks that will become a part of the NeHC’s mission.

6 Annex – eHealth in Czech Republic

6.1 The Czech Healthcare system

6.1.1 Organization and governance

The Czech Republic has a system of statutory health insurance (SHI) based on compulsory membership of a health insurance fund, of which there were seven in 2014. The funds are quasi-public, self-governing bodies that act as payers and purchasers of care. The core health legislation of the Czech Republic was adopted in the 1990s and has changed only marginally since then. The Ministry of Health's chief responsibilities include setting the health-care policy agenda, supervising the health system and preparing health legislation. The Ministry also administers certain health-care institutions and bodies, such as the State Institute for Drug Control (SÚKL), which is the main regulatory body for pharmaceuticals.

The 14 regional authorities (kraje) and the health insurance funds play an important role in ensuring the accessibility of health care, the former by registering health-care providers, the latter by contracting them. Czech residents may freely choose their health insurance fund and health-care providers. The health insurance funds must accept all applicants; risk selection is not permitted (though there is risk equalization between the funds, see below). The use of information and communications technology (ICT) is generally underdeveloped in the Czech Republic; for instance, plans to implement national eHealth capacities have not been realized. Similarly, efforts to develop approaches for health technology assessment have not yet materialized into an infrastructure for using HTA in practice.

6.1.2 Financing

Following a rapid increase in the early 1990s, total health expenditure in the Czech Republic as a share of GDP has remained relatively low (7.7%) compared to the EU average of 9.6% in 2012. Health expenditure as a share of GDP rose temporarily following the financial crisis because of the fall in GDP but fell back due to restrictions in expenditure. Health expenditure from public sources as a share of total health expenditure remains relatively high at just under 85% (the EU average is 75.9%), with the balance made up through out-of-pocket expenditures (private insurance plays only a marginal role).

However, the system as a whole has had constant financial problems since the establishment of the current system at the start of the 1990s, reflected in solvency problems with health insurance funds; although insurers had built up reserves towards the end of the last decade, following the financial crisis the largest insurer required a €62m loan, which was partially repaid in December 2014. Population coverage is virtually universal, and the range and depth of benefits available to insured individuals are broad; in principle insured individuals are entitled to any medical treatment aiming to maintain or improve their health status, though in practice there is a range of limitations. The SHI system is financed through compulsory, wage-based contributions and through state contributions on behalf of economically inactive people, such as children and the unemployed. A risk-adjustment

formula based on age, gender and ex-post compensation of 80% of costs above a set limit is used to redistribute funds between the insurers.

Since 2007 hospitals have been paid for inpatient care using a combination of a diagnosis-related group (DRG) system, individual contracts and global budgets. Since 2009 hospital outpatient care has been reimbursed using a capped fee-for-service scheme. GPs in private practice are paid using a combination of capitation and a fee-for-service payment system, the latter being applied mostly for preventive care. Non-hospital ambulatory care specialists (e.g. Self-employed physicians or dentists) are paid using a capped fee-for-service scheme.

6.1.3 Physical and human resources

During the 1990s changes made to the structure of inpatient facilities in the Czech Republic were driven primarily by an excessive number of beds in acute care and an insufficient number of beds in long-term care. In the past two decades the number of acute beds decreased continuously while the number of long-term beds increased, though at 470 acute care hospital beds the Czech Republic is still well above the EU average of 385 per 100 000 population in 2011.

Furthermore, the lack of capacity in the social care system is a bottleneck for the hospital system. Since 2007 over €480m from EU Structural Funds were invested to improve ageing physical resources additional to national efforts. However, many psychiatric institutions, long-term care and nursing facilities for the elderly are out-dated and in need of modernization.

By European standards, the number of physicians in the Czech Republic is relatively high, with 3.6 physicians per 1000 population in 2012 (the EU average is 3.5), though the ageing profile of primary care physicians represents a potential human resources problem in the near future. The nurse-to-population ratio is above the average for the EU (8.5 per 1000, as compared to 8.4 per 1000 for the EU as a whole). Though some health professionals move to work elsewhere in the EU, precise numbers are lacking.

6.1.4 Provision of services

The Czech Republic has an extensive public health network responsible for a range of services, including epidemiological surveillance, immunization logistics, quality analyses for consumer and industrial products, and monitoring the impact of environmental factors on health status.

Approximately 95% of primary care services are provided by physicians working in private practice, usually as sole practitioners. Patients register with a primary care physician of their choice but can switch to a new one every three months without restriction. Primary care physicians do not play a true gatekeeping role; patients are free to obtain care directly from a specialist and frequently do so. Secondary care services in the Czech Republic are offered by a range of providers, including private practice specialists, health centres, polyclinics, hospitals and specialized inpatient facilities.

Almost all pharmacies in the Czech Republic are run as private enterprises, and at the time of writing there is a trend towards the establishment of pharmacy chains, especially in urban areas. The target for emergency care is 20 minutes after an emergency call, with a wide range of services involved in provision; there are some cooperation initiatives in border regions with Germany and Poland. The systems of long-term health care and long-term social care in the Czech Republic have traditionally been separate in terms of organization and funding, which has led to frequent complications, especially in the reimbursement of services.

The 2006 Act on Social Services was aimed at improving the coordination between the two systems by providing individuals with a flexible care allowance, allowing cross-funding between the two systems. However, the transfer of patients between social care and health-care facilities is still imperfect and there are strong financial incentives for patients to try to remain in health-care facilities even if it is unjustified by their medical condition. The flexible individual care allowance has also enabled some patients to pay for care by family members or volunteers.

6.2 Brief description of the national or regional eHealth strategy

eHealth strategy is an umbrella document for computerisation of electronic healthcare of the Czech Republic in the medium term of at least five years. In certain areas, the document is very specific, on the contrary, it only sets out the basic rules, principles and vision of the future state in other areas. This is a very complex issue and the environment in which many influences operate and the state has just limited resources to enforce even the useful measures.

The presented strategy had to deal with the absence of any general documents of a longer horizon, covering the area in the Czech Republic (e.g. policy or concept). It includes accepted Set of objectives and measures which structurally sets targets for the overall direction of the area in the long-term and determines the basic principles and character of the objectives set. This Set of objectives and measures is partly elaborated into outputs and indicators for the period until 2020, without pretensions to implementation of the entire set within a limited time.

Priorities are set sequentially and are influenced by a number of factors which cannot be effectively detected in the scope of a single strategy document. An important and fundamental task of a strategy is to find such a concept for further development that would provide a common denominator, common shared services and cooperating (interoperable) environment to all the concerned areas. An environment that would allow individual participants to share information in a defined manner and would effectively boost the development of the health system in the context of computerisation of public services.

Strategy does not delegate the burden of building the informatics services and the creation of a central system to the state, which should be compulsorily used by health workers and ultimately by citizens. This solution, although it is sometimes applied in countries with

different healthcare system and the organisation, is not acceptable in the context of the Czech healthcare system. The area where the strategy considers an irreplaceable role of the state lies in creating preconditions and fundamental building blocks on which the developed computerisation can rely. Parallels to these basic building blocks are the Basic registers of the Czech Republic which present a prerequisite for unambiguous identification of citizens and organisations and allow or facilitate the effective sharing of information across the public administration. The state will not create any megalomaniac centralist project but will provide the basic building blocks of computerisation which allow the gradual establishment and implementation of purposeful subprojects coordinated with strategic objectives and the principles set out in this strategy.

The Ministry of Health will deal exclusively with the preparation of projects that are a priority for the health sector where the role of the state is irreplaceable and which present a necessary prerequisite for meaningful development of computerisation of healthcare. Therefore, the National Strategy for eHealth opens up the ample scope to all researchers of existing and future projects of electronic healthcare to ensure that their solutions could be mutual purposefully aligned to support both the vision and goals of the strategy and support to serve the healthcare of citizens. Only such projects can apply for state aid. Examples of key projects are National register of health professionals and providers, ePrescription, etc. (these projects resulted from the preparatory work on the Strategy and from the conclusions of the working groups, some arose from events such as a legislative change). Therefore, any subject may apply for the public support if it agrees to the demands of strategies of defined goals, objectives, rules and standards and meets the architectural requirements contained in the publicly published principles of Enterprise architecture computerisation of healthcare. All projects' implementors will have to meet well-defined requirements for data security and transfer at least on the level required by the system of public administration (eGovernment).

The preference aim of the strategy is the maximum use of existing information systems, provided that they meet quality, safety and other requirements for interoperable electronic healthcare systems, namely the requirements for input/output data format and modularity, i.e. the individual information systems can be developed independently, but they will be able to mutually transmit the data, as their structure will be defined. Achieving mutual interoperability of existing electronic healthcare solutions is the investment protection as well and it is the use of the current potential operating applications. Selected key projects shall always be focused on meeting the goals and indicators set out in this strategy. Proposers of individual projects will follow the guidelines and principles defined by Enterprise architecture computerisation of the health sector in accordance with the overarching principles of building eGovernment.

Enterprise architecture of the solutions will be processed for each project based on the methodology prepared for the computerisation of electronic healthcare by the Ministry of Health and therefore, its interconnection with other projects will be ensured. Interoperability with new solutions, including the use of existing services sector and ICT eGovernment services will be also guaranteed. Implementation plans for each upcoming project will be established in stages. The first stage specifies the plans of priority projects and will be

completed by the end of 2016. In this first stage, the deadlines for processing other implementation projects will be determined as well.

The role of the state in defining the concept and priorities of electronic healthcare, particularly in the coordination of its development, is indispensable. The state did not fulfil this role in the long term, besides other reasons due to lack of the necessary experts and expertise of professionals in the field of ICT and the inability of the government in attracting them. The consequence of failed projects of computerisation is great mistrust in the computerisation of medical workers and its benefits, which are accompanied by mistrust in the ability of government to improve the dismal state.

National strategy for eHealth had been created for two years in working groups and workshops with experts in a wide representation. The Czech MoH approached representatives of organisations working in healthcare and those from other areas with a request to nominate their representatives to the team for strategy creation and support working groups and delegated representatives then participated in making strategies. The common outputs of the team and working groups were presented and opposed. It was based on the international recommendations for the creation of national electronic healthcare strategies and on foreign experience. To avoid tendentious solution without the participation of public health, the following procedure was respected:

One of the main principles of the National Strategy for eHealth creation is openness and involvement of the widest possible professional and non-professional public among users of electronic healthcare. MoH hereby declares the clear intention to gradually reconcile mutually uncoordinated activities of the state, of the self-government, the commercial sector, health insurance companies and healthcare providers towards fulfilling the vision of the National Strategy for eHealth interoperability and create a familiar environment for all implementors of electronic healthcare services.

However, the National Strategy for eHealth, based on Czech and foreign experience, and using the principles promoted by the Czech Medical Association of J. E. Purkyně gives precedence to the six principles:

- 1) The primary objective of the development of electronic healthcare must be beneficial to patients and to the quality of healthcare.
- 2) Patient's right to ensure the welfare, protection of personal dignity and privacy must not be weakened by means of introducing electronic healthcare, but rather strengthened.
- 3) Doctors and other professionals in the healthcare sector must be involved in projects already in the process of preparing plans, during the planning and during solutions drafting. The opinions of the experts must be actively sought within the framework of projects and adequately taken into account.
- 4) Before the introduction of new tools and services of electronic healthcare into practice, their usefulness, quality, stability and performance must always be adequately verified and evaluated.

- 5) Electronic healthcare introducing based on broadly defined responsibilities is fundamentally not acceptable. When introducing new services and electronic healthcare tools, it is necessary to use positive motivation in particular and to introduce new technologies gradually and prudently so that the continuity and safety of the operation is not jeopardized, the patient is not endangered, nor the working conditions of health professionals are deteriorated.
- 6) It is necessary to utilize wherever possible and appropriate for creating new solutions all available scientific knowledge and proven technologies, including standards for the exchange and display of medical information. An example of fundamentally incorrect procedure when introducing electronic healthcare was a course of the project of the electronic prescription implemented in isolation as a partial service, entrusted to an institution whose mission is not computerisation of medical services for citizens. Legislation does not allow even in its current form for implement electronic prescribing the most desirable benefits, especially for citizens, doctors and pharmacists – the main users of this system. The project lacked a responsible guarantor of the whole process of computerisation of prescription medications, so called electronic prescriptions, and could not rely on the concept and architecture of computerisation department, nor on the necessary infrastructure of computerisation of healthcare.

The Cabinet Office of the Czech Republic evaluated the state of the digital development of the Czech Republic in a prepared updated Action plan for the development of the digital market (July 2016) as highly unsatisfactory and states: "Digital technologies are fundamentally and at a rapid pace changing the economy and form of companies around the world. Changes, that the digital revolution brings, will inevitably affect the life of each of us. Even healthcare cannot fall behind in computerisation anymore because information and communication technologies can contribute substantially to improving the accessibility and quality of healthcare throughout the company, contribute to greater involvement of the citizen in his own health and help to reorient health systems towards the citizen.

6.3 The eHealth Centre as defined in the Strategy

The strategic goal of computerisation of Health is to improve the availability and transparency of health services, increase the efficiency and transparency of public administration and support of the program Health 2020, through the tools of electronic health as a specific part of eGovernment. Introducing elements of electronic health must be carried out in compliance with legal and technical conditions and needs of all partakers in the system, especially on the part of patients and health care providers. Computerisation of selected processes of health system will be systematically promoted in order to motivate patients and providers to implement and use new processes, systems and applications. In addressing electronic health documentation patient should be able to choose a manager for their data without worrying about privacy breaches and data loss. The infrastructure development will create a basic technical and safety framework which defines authentication principles and mutual compatibility and interoperability of different systems and solutions. An important consideration when building electronic health services and will be technical solution to work

ergonomics in electronic health environment. This can be a significant factor in choosing ways to implement electronic health services so that they deliver the expected effects.

6.3.1 Background and requirements to meet the strategic objective

Electronic health will be built on the basis of Czech and foreign experience and will be based on the following principles:

- The primary objective of the development of electronic health must be contribution to patients and quality of health care.
- Patient's right to ensure the welfare, protection of personal dignity and privacy must not be weakened by means of introducing electronic health, but rather strengthened.
- Doctors and other professionals in the health sector must be involved in projects already in the process of preparing plans, the planning and drafting solutions. The opinions of the professional public must be within projects actively sought and adequately taken into account.
- Before the introduction of new tools and electronic health services into practice their usefulness, quality, stability and performance must always be adequately verified and evaluated.
- Introduction of electronic health based on generally established responsibility is fundamentally wrong. When introducing new services and electronic health tools we need to use mainly positive motivation and introduce new technologies gradually and prudently so as not to jeopardize the continuity and safety of operation, endanger the patient or deteriorate the working conditions of health professionals.
- Wherever possible and appropriate, it is necessary to utilize all available scientific knowledge and proven technologies during the creation of new solutions, including standards for the exchange and display of medical information.

6.3.2 The impacts of the fulfilment of individual specific objectives within the context of the strategic objective

Electronic health management system must ensure an efficient, controlled and coordinated introduction of computerisation in accordance with national interests and priorities expressed in national strategies. To fulfil this task, it is necessary to establish a body fitted with responsibility for the management system of electronic health and equipped with the necessary powers, the professional capacity and adequate financial resources. This entity will be managed and controlled by MoH with the involvement of other key organizations.

6.3.3 Outputs of the fulfilment of specific objectives

The strategic objective consists of three specific objectives and corresponding actions:

- 1) **Development of infrastructure for sharing and provision of health services**
 - optimisation and creation of authoritative registries - authoritative data sources,
 - rise (of safe) infrastructure for health information exchange at regional and national level,
 - introduction of a system providing services system management agendas according to eGov model,

- consolidation of health, hygiene and other registers as tools of electronic health,
- authorisation, authentication and management of providers' authorisations,
- management of approvals and accesses,
- easy and accurate patient identification and retrieval of patient data.

2) Standards and interoperability

- clinical terminology and classification,
- interoperability and data access,
- data structures and sets, EHR, EMR, PHR,...

3) Management and Infrastructure of electronic health

- leadership, policy and strategy for electronic health;
- legislative and regulatory framework;
- privacy, policy, quality and safety;
- cooperation of stakeholders at national and EU level;
- promoting the adoption and use of standards.

6.3.4 Indicators of achieving the strategic objective

The primary identifier of achievement of this objective is the provision of the body responsible for the management of system of electronic health (National Centre for Electronic Healthcare – NCEH). Another two indicators are shown in the relevant specific targets.

6.3.5 Barriers and risks of implementation (impact of the zero option of strategic objective)

The main risk is not finding a political consensus on the creation of the National Centre and its provisions. If it fails to be created, the state will not be able to fulfil the goals of the strategy or the commitments to Action Plan No. 11 Health System Computerisation, National Health Strategy 2020. Electronic healthcare system will be very critically evaluated in terms of potential leakage or misuse of sensitive personal data, especially of patients' data, but also data of physicians and other participants in the system. Therefore, the issues of cybersecurity and privacy shall be carefully considered and tested repeatedly throughout the life cycle of implementation of measures since their design, implementation to operation and change management. Patients' roles in decisions about their own privacy must be not only respected by the system but shall be strengthened at the maximum possible extent. The intention of the strategy is the establishment of the National Centre for Electronic Healthcare (NCEH), which will be responsible for the preparation and development of computerisation of health care, however, the outputs of the centres will depend on the involvement of many experts, mostly IT professionals who actually will establish eHealth and then maintain it. On the Czech market, there is a long-term shortage of IT professionals, the competition with the private sector is high, therefore the issue of attracting and retaining human resources poses a risk and one of the main barriers to the implementation of Strategic Objective 4 Electronic healthcare infrastructure and management. The basic prerequisite for coordinated and successful development of electronic health is consistent processing of the complete

Enterprise Architecture (EA) MoH and the related sub-system architecture (SA) of individual information systems, which have a major impact on the implementation of the objectives of the proposed strategy. Therefore, it is necessary that the architects and the creators of new ICT systems and services respect the existing environment, knowing what new business roles and services they create and who will be the user. At the same time the architecture must clearly specify the requirements for technical solutions to applications and data sharing, capacity and performance characteristics of sub-components and the necessary secure infrastructure.



The work can be freely published, distributed and modified under the assumption of quoting this work.

Copyright remains to aed - Agency for Economic Cooperation and Development

This document was produced with the financial support of the European Union via the Structural Reform Support Service of the Commission. The views expressed herein can in no way be taken to reflect the official opinion of the European Union.



European Union

© 2018 aed all rights reserved