

Future Digital Health in the EU

Targeted Analysis

Scientific Annexes

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Authors

Technopolis Group: Peter Varnai, Reda Nausedaite, Dominik Beckers, Theresa Madubuko, Apolline Terrier, Eleonora Zoboli and Katre Eljas-Taal

Experts: Minna Hendolin, Kity Kubo, Mariya Petrova and Mirko Vintar

Advisory Group

Project Support Team: Kadri Jushkin, Ministry of Finance, Piret Hirv, Ministry of Social Affairs (Estonia), Mika Rantakokko, Business Oulu, Maritta Perälä-Heape, University of Oulu, Outi Rouru, City of Oulu (Finland)

ESPON EGTC: Martin Gauk, Laurent Frideres, Ilona Raugze and Teofil Gherca

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The final version of the report will be published as soon as approved.

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Abbreviations

AI	Artificial Intelligence
BaHIS	Base for Health Information System of Bulgaria
CEF	Connecting Europe Facility
CRM	Customer Relations Management
CRPD	Central registry of patient data
DESI	Digital Economy and Society Index
DHR	Digital Health Revolution
DSI	Digital Service Infrastructure
EC	European Commission
ECESA	Electronic Commerce and Electronic Signature Act of Slovenia
EDPR	Europe's Digital Progress Report
EGA	Electronic Governance Agency
EHCIC	Electronic healthcare identity card in Slovenia
eHDSI	European eHealth Digital Service Infrastructure
eHGI	eHealth Governance Initiative
EHF	Estonian eHealth Foundation
EHIF	Estonian Health Insurance Fund
EHR	Electronic Health Record
EHTEL	European Health Telematic Association
EIP on AHA	European Innovation Partnership on Active and Healthy Ageing
ELGA	Austrian Electronic Health Record
EMR	Electronic Medical Records
epSOS	Smart Open Services for European Patients
EU	European Union
EU MS	European Union Member States
ERN	European Reference Network
FinOHTA	Finnish Office for Health Technology Assessment
GDP	Gross Domestic Product
GDPR	EU General Data Protection Regulation
GP	General Practitioner
HDRA	Slovenia's Healthcare Data Records Act
HTA	Health Technology Assessment
HWISC	Estonia's Health and Welfare Information Systems Centre
ICT	Information Communication Technologies
IHIS	Integrated Health Information system of Bulgaria
IoT	Internet of Things
IT	Information Technologies
ITU	International Telecommunications Union
KanTa	Finnish Electronic Patient Record System
KaPA	Finnish National Architecture for Digital Services
Kela	Social Insurance Institution of Finland
LIS	Laboratory Information System
MEC	Finland's Ministry of Education and Culture
MEE	Finland's Ministry of Employment and Economy
MH	Ministry of Health of Slovenia
MS	Member State
MSAH	Finland's Ministry of Social Affairs and Health
MoEAC	Estonia's Ministry of Economic Affairs and Communications
MoSA	Estonia's Ministry of Social Affairs
NCP	National Contact Point
NCPeH	National Contact Points for eHealth
NCPHA	National Centre for Public Health and Analysis of Bulgaria
NeRN	Nordic eHealth Research Centre
NGO	Non-governmental Organisation
NHA	National Health Act
NHIF	National Health Insurance Fund of Bulgaria

NHP	Slovenia's National EHealth Project
NIIS	Nordic Institute of Interoperability Standards
NIIS	National Insurance Institute of Slovenia
NIJZ	National Institute of Public Health
NIPH	Slovenia's National Institute for Public Health
NIVEL	Netherlands Institute for Health Services Research
NOMESCO	Nordic Medico-Statistical Committee
NOSOSCO	Nordic Social Statistical Committee
ODA	Personal Digital Value-added services in Finland
OECD	Organisation for Economic Co-operation and Development
OYS	Oulu university hospital
PACS	Finnish Picture Archiving and Communications System
PAEHR	Patient access to Personal Health Records
PDPA	Slovenia's Personal Data Protection Act
PHR	Personal Health Records
PIS	Personalised Information System
PPP	Public Private Partnership
RENATA	Rehabilitation aftercare program for an optimal transfer into daily life
RHIE	Finnish Regional Data Exchange Systems
RIS	Finnish Radiology and Laboratory Information Systems
RNPHC	Resolution on National Plan of Healthcare of Slovenia
R&D	Research and Development
R&D&I	Research and Development and Innovation
SEGA	State eGovernment Agency of Bulgaria
STM	Finnish Ministry of Social Affairs and Health
THL	National Institute for Health and Welfare of Finland
WHO	World Health Organisation
ZEPEP	Slovenia's Electronic Commerce and Electronic Signature Act

Preamble

This document is the Scientific Annexes, the fourth deliverable (D4) in the framework of a study entitled Future Digital Health in the EU, commissioned by ESPON EGTC from Technopolis Group in December 2017.

Appendices

Appendix A Methodology of the final report

The literature review was designed following the guidelines of a systematic review, however, with some concessions on the breadth and depth of the process. This approach is referred to as rapid evidence assessment. The aim was to identify available evidence to answer the study question regarding digital health solutions and related contextual factors in Europe. The search methodology covered both peer-reviewed literature and 'grey literature' and other data sources on relevant websites. Grey literature, referred to as the literature that has not been formally published, such as government papers, business reports, conference presentations and abstracts, is often included in such reviews to overcome positive result bias and time lag in formal publication. We defined keywords and combined these into search strings to explore databases and create a longlist of publications for review. Data sources included Scopus (Elsevier), GreyNet International, key policy documents from the European Commission and its Agencies, and online repositories and administrative documents of national authorities and networks. We extracted titles and abstracts to assess eligibility and relevance while considering the quality, potential bias and timeliness of the papers. Finally, all relevant documents were saved in a local database and relevant qualitative and quantitative data extracted for further analysis.

The EU-level analysis was followed by analysing specific topics regarding how eHealth is being developed across the EU. These chapters are divided into an overview of the EU-level activities involved in shaping eHealth, international plans and strategies. To achieve this overview at the EU level, the following topics were analysed in separate chapters:

- The chapter on the main eHealth challenges across the EU focuses on the main driving forces/barriers and actors of eHealth development and exploring legislative, governance, technological, ethical challenges. It also discusses how legal concerns are being handled for privacy and protection.
- The chapter "Involvement of institutions and stakeholders" presents the main points about institutions and stakeholders managing eHealth that are present at the EU level or part of the data or communication from international healthcare organisations.
- The chapter "Technology infrastructure facilitating eHealth" focuses on identifying the infrastructure challenges related to supporting eHealth. It provides examples of strategies and programmes that are designed to facilitate digitisation.
- An overview of the economic and social impacts of digitisation services in the health sector in the EU is provided as quantitative evidence. These include: (i) percentage of government spending prior and after adopting eHealth solution; (ii) patient expenditure prior and after adopting eHealth solution; (iii) healthcare provider costs prior and after adopting eHealth solution. The purpose is to develop an understanding what (if any) economic benefits are observable as a result of digitisation in healthcare.

- Lastly, we explore how the practices, challenges, opportunities and benefits of healthcare digitisation are related to other sectors.

For the stakeholder regions it was important to expand the context of healthcare digitisation, particularly employing comparative analysis. Thus, the information collected on the stakeholder regions was contrasted and compared to highlight areas of similarity and, more importantly, areas that could serve as good practice examples to others.

- Healthcare system and institutional structures provides maps for how the infrastructure of eHealth functions in each country, highlighting the main actors, key legislation, services and their relationships. This demonstrates how eHealth is approached by different stakeholders. The chapter is meant to contextualise eHealth within the overall healthcare system.
- Digitisation of healthcare delves deeper into the infrastructure of eHealth, focusing on key managing agencies, funding direction, ICT development. This chapter is important in the discussion of future direction for eHealth and how the stakeholders compare against each other.
- Most prevalent eHealth applications focus on the number of eHealth solutions in use, their design features, interactions to one another and user statistics. It allows analysing how many similar solutions are operable in the stakeholder regions, how they differ, how can they be improved.
- Socio-economic benefits of eHealth show the introduction of eHealth has yielded societal benefits, compares these benefits across stakeholders.

The comparative analysis is made possible by the stakeholder country profiles (which are provided in the Annex). A number of assumptions formed the groundwork for how the analysis of the individual stakeholder regions was performed.

- Elaborated examples to understand the peculiarities behind possibilities and issues that are related to healthcare digitisation. It required a holistic look in terms of what eHealth means in a national context and bring to surface the details about the eHealth services and nuances of their functionality in a national, regional context.
- Impact of healthcare digitisation was to be accurately presented. The expectation was that such indicators would be different across the stakeholder regions, based on eHealth development and data availability. Therefore, instead of a hard-list of indicators, the research group worked on the principle of indicator themes evidence for the input towards developing, managing, maintaining eHealth (costs, time spent, etc.) and the impacts (number of users, extent digital health is used, etc.)
- A point was made for the analysis to look whether examples exists on how the eHealth services and new technological solutions have affected the efficiency of delivering healthcare services.

- For cross-border cooperation evidence was gathered to explore how governments identify the need for cross-border cooperation and the steps taken or to be taken. A critical view was to be applied when judging the potential of these initiatives in terms of their applicability and impact on healthcare quality.

Appendix B Estonia country profile

B.1 Healthcare system and its institutional structures

B.1.1 Legal and financial framework

The health system in Estonia is overseen by the Ministry of Social Affairs (MoSA) and its agencies, which include the State Agency of Medicines (SAM), Health Board, National Institute for Health Development (NIHD), and the Health and Welfare Information Systems Centre (HWISC). The financing of healthcare is mainly organised through the independent Estonian Health Insurance Fund (EHIF). The main healthcare policy document is the National Health Plan (NHP), which integrates sectoral health plans, strategies and development plans into one document.

The fundamental reforms of the early 1990s aimed to move the health system away from a centrally funded and managed system to a decentralised model funded through social insurance. In later years, regulation has been implemented to harmonize laws with EU legislation and to respond to emerging needs. Experience with decentralisation in the 1990s did not result in efficient and accessible health services and a trend towards centralizing planning and regulatory functions has been visible over the last decade.

Estonia is a low spender on health and the level of health expenditure as a share of gross domestic product (GDP) in Estonia has been noted to be below the EU average. By 2015, healthcare expenditure accounted for 6.5% of GDP which was below the EU average of 9.9%.¹ The healthcare system is mainly publicly funded through solidarity-based mandatory health insurance contributions in the form of an earmarked social payroll tax. In fact, a 2017 WHO report noted that around three quarters of healthcare was publicly funded.² In 2017, as the culmination of more than a decade of discussions on the financial sustainability of the Estonian health system, the Estonian government took the historic step of expanding the EHIF's revenue base by including a gradually increasing (until 2022) state contribution on behalf of pensioners. The reform is widely considered to be as important as the initial decision to establish the health insurance system in the 1990s and is expected to make the health system financially more sustainable.

Healthcare provision has been almost completely decentralised since the passing of the Health Services Organization Act which took effect in 2002. Healthcare providers are autonomous entities operating under private law. Primary care is the first level of contact with the health system and is provided by independent family doctors working solo or in groups and practising on the basis of a practice list. More recent reforms aim to strengthen primary healthcare by establishing healthcare centres with a broader scope of services, which is

¹ WHO (2017). State of Health in the EU Estonia Country Health Profile 2017. Available at: http://www.euro.who.int/__data/assets/pdf_file/0010/355978/Health-Profile-Estonia-Eng.pdf?ua=1

² WHO (2017). State of Health in the EU Estonia Country Health Profile 2017. Available at: http://www.euro.who.int/__data/assets/pdf_file/0010/355978/Health-Profile-Estonia-Eng.pdf?ua=1

hoped to improve access, care coordination and management of chronic diseases. Secondary care health services are provided by publicly or privately-owned healthcare providers (hospitals and outpatient care clinics) operating under private law. The EHIF is the main purchaser of healthcare services for insured people. Health services purchasing builds on a contractual relationship with providers as well as financial incentives.

The opportunities for improvements in Estonian health system are considered as overcoming the large health disparities between socioeconomic groups, improving population coverage, developing a comprehensive plan to tackle workforce shortages, better managing the growing number of people with (multiple) noncommunicable diseases and further reaping the benefits of the eHealth, especially for care integration, clinical decision-making and outcome measurement.³

B.1.2 Data management and IT infrastructure

The national health information system is an information exchange platform that connects all providers and allows data exchange with various other databases. The platform also enables patients to access their health data. Healthcare providers are connected to the system and patient health data is stored centrally. All healthcare providers have a legal obligation to send certain health data to the health information system. The obligation applies both to visits covered by the EHIF as well as to those paid by the patient.

In an emergency situation, first-response ambulance personnel compose an electronic first aid card in the ambulance itself. If the patient can be identified during the emergency situation, the first aid personnel already have access to all of the information that is available on the patient in the health information system.

Universal data transfer formats (XML based HL7 v3) are used, regardless of the type of doctor preparing the data or the medical condition described. The ambulatory epicrisis, which contains a summary of a visit or treatment, is what is most often entered. Doctors can also draw up electronic referrals or referral responses. All of the information must be entered into the national health information system within one (ambulatory reception) or five (hospitalisation) working days, as stated by law.

There is a standard in use for data exchange, which means that on one hand, there is an agreement between the state and doctors on what information needs to be uploaded about specific treatment processes and, on the other, the standard work as an information technology language. Thus, the data is comprehensible to the information system and can be processed (i.e. it is machine readable) and, if need be, the data can also be used with other eServices offered by the state.

³ Habicht T, Reinap M, Kasekamp K, Sikkut R, Laura Aaben L, van Ginneken (2018). Estonia: Health system review. Health Systems in Transition, 20(1): 1 – 193 Available at: http://www.euro.who.int/__data/assets/pdf_file/0011/377417/hit-estonia-eng.pdf?ua=1

The system aggregates and standardises healthcare data from different healthcare providers and state registries rather than requiring institutions to use a standard form. The process is organised so that data only needs to be entered once, and each doctor in Estonia uses their own information system – of which there are around 20 being used by Estonian hospitals, general practitioners and specialist doctors. Medical practices that don't have their own information system can use the doctors' portal (Arstiportaal) developed by the HWISC. From the doctors' information systems, the patients' data are transferred via the X-road secure data exchange platform⁴ to the national health information system, where the information is accessible to both the doctor and the patient.⁵

Collected health records are open by default and healthcare professionals can ask for data unless the patient has made their data inaccessible in the system. Access to the data is granted only to licensed medical professionals. Healthcare professionals have the right to ask for data when they have an ongoing treatment relationship with the patient (when the patient makes an appointment or receives first aid care). The treatment relationship ends, in regard to eHealth, when the healthcare professional has finished working with the patient's documents and the information has been entered into the health information system, after being approved. Doctors can also ask for information uploaded by other doctors, regardless of the speciality. Thus, having a complete overview of a patient's condition helps better treatment decisions to be made. With the same reason 91% of citizens consider doctor's access to their entire health records as important.⁶

People have the right to close their data in the health information system (opt out), either completely or one document at a time. Before making this decision, the system informs the user that making data inaccessible may influence the accessibility of the health data relevant to the patient's treatment process. 27% of citizens are aware of the option to opt out and 9% think they would use it.⁷ In practice, since the launch of the health information system in 2008 only 500 people have made this choice. This indicates that the health information system is considered to be useful and secure by the people of Estonia.

As a fundamental principle in Estonian eGovernance, the data belongs to the data subject. Citizens can access and control their own and their children's health data in the national

⁴ e-Estonia (2018). X-Road. Available at: <https://e-estonia.com/solutions/interoperability-services/x-road/>

⁵ EU2017.ee (2017). Estonian Presidency of the Council of the European Union. Available at: <https://www.eu2017.ee/news/press-releases/estonias-unique-e-health-thousands-data-fields-one-personal-health-record>

⁶ KANTAR Emor (2016). Eesti elanike hinnangud tervisele ja arstiabile. Available at: https://www.sm.ee/sites/default/files/content-editors/Ministeerium_kontaktid/Uuringu_ja_analuusid/Tervisevaldkond/arstiabi_uuringu_aruanne_2016_kantar_emor.pdf

⁷ KANTAR Emor (2016). Eesti elanike hinnangud tervisele ja arstiabile. Available at: https://www.sm.ee/sites/default/files/content-editors/Ministeerium_kontaktid/Uuringu_ja_analuusid/Tervisevaldkond/arstiabi_uuringu_aruanne_2016_kantar_emor.pdf

patient portal (web portal). The portal can be securely accessed with a Mobile ID or an ID card. In the portal people can see the same data that healthcare professionals can see and declare their preferences and intentions. Healthcare professionals have an ethical obligation to assess whether making data enquiries is justified. In order to ensure the transparency of the system, people can monitor logs to see who has viewed the health data (and what data) about them in the system.⁸

B.2 Digitisation of healthcare

B.2.1 History, recent developments, future directions

Estonia launched its health information system in 2008, becoming the first country in the world to fully implement such a system nationwide, with records covering an individual's medical history from birth to death.⁹ Ten years later 100% of billing in healthcare and prescriptions, 97% of hospital discharge letters, 60% of ambulatory case summaries, 60% of dental care summaries and 50% referrals are digital. 1.6 million people have documents in the health information system (Estonia has 1.3 million inhabitants) and 34 million different documents are stored in there: 21 million summaries of visits or treatments and discharge letters; 1.7 million referrals; 7.5 million diagnostic study reports and procedures. Every month doctors make 1.9 million queries in the health information system and there are 244,369 unique visitors to the patient portal (15% of the population).¹⁰

The regulatory framework of the health information system is laid down in five major pieces of legislation: 1) The Health Services Organisation Act¹¹, which defines basic principles for processing personal data and for maintaining records of the provision of health services and the health information system as a database belonging to the state information systems where the data related to healthcare are processed, 2) The Statute of the Health Information System¹², which derives from the Health Services Organisation Act and regards patient rights to have access to and allow/forbid access to their medical data, 3) The Regulation on the Documentation of Provision of Health Services and the Conditions and Arrangements for the

⁸ EU2017.ee (2017). Estonia's unique e-health: thousands of data fields, one personal health record. Available at: <https://www.eu2017.ee/news/press-releases/estonias-unique-e-health-thousands-data-fields-one-personal-health-record>

⁹ WHO (2016). E-health in practice. Available at: <http://www.euro.who.int/en/countries/estonia/news/news/016/03/e-health-in-practice>

¹⁰ Novek A. (2017). An Overview of Current Estonian Health Information System Architecture Pitfalls and prospects. Available at: https://sam.lrv.lt/uploads/sam/documents/files/Veiklos_sritys/E.%20sveikata/priedas%20Nr_1_20171013_Estonian%20Health%20Information%20System%20overview.pdf

¹¹ Riigi Teataja (2013). Health Services Organisation Act. Available at: https://www.riigiteataja.ee/en/compare_original?id=512122013005

¹² Riigi Teataja (2008). Tervise infosüsteemi põhimäärus. Available at: <https://www.riigiteataja.ee/akt/13251011>

Retention of These Documents,¹³ which also derives from the Health Services Organisation Act and obliges healthcare service providers to transmit data to the health information system. It defines the list and data content of documents that must be forwarded and the conditions and arrangements for retention of these documents, 4) The Personal Data Protection Act,¹⁴ replaced by the EU General Data Protection Regulation (GDPR) on 25 May 2018, applies to all sensitive personal data protection and processing issues related to eHealth, and 5) The Public Information Act.¹⁵

In 2002 the decision was made to create a nationwide eHealth framework to facilitate the exchange of digital medical documents. In 2005 the first four major eHealth development projects were launched by the MoSA: the health information system, digital images, digital registration and digital prescription. In 2008 the national health information system was launched, and the Estonian eHealth Foundation (EHF) was established by the MoSA, the three largest hospitals, the Estonian Society of Family Doctors, the Estonian Hospital Union and the Association of Ambulance Doctors to operate the system.

However, in 2014 The National Audit Office report¹⁶ revealed that the MoSA should deal with the development of the eHealth system more forcefully, as the initially planned projects had still not completed. Since then several changes have been taken to strengthen the eHealth governance, both the strategic planning and leadership at the MoSA as well as the implementation-level capacity. In the same year the Task Force on the formation of the Estonian eHealth strategy was set up at the Government Office¹⁷. A year later, in 2015 the eHealth vision 2025 and eHealth strategy 2016-2020 was approved by the Government¹⁸ and the responsibility for eHealth at the MoSA was promoted to the deputy-secretary general level. Alongside the three core departments of health, labour and social policy, a new eService and innovation department was created covering eServices across all other departments of the MoSA. The new department is responsible for agenda setting, strategy development and coordination of strategy implementation, and regulating health information system and health registries, as formerly done by the eHealth division within the health

¹³ Riigi Teataja (2008). Tervishoiuteenuse osutamise dokumenteerimise ning nende dokumentide säilitamise tingimused ja kord. Available at: <https://www.riigiteataja.ee/akt/107072011010>

¹⁴ Riigi Teataja (2001). Personal Data Protection Act. Available at: <https://www.riigiteataja.ee/en/eli/512112013011/consolide>

¹⁵ Riigi Teataja (2001). Personal Data Protection Act. Available at: <https://www.riigiteataja.ee/en/eli/512112013011/consolide>

¹⁶ The National Audit Office (2014). Activities of the state in implementing the e-health system. Available at: <http://www.riigikontroll.ee/Suhtedavalikkusega/Pressiteated/tabid/168/ItemId/703/View/Text/amid/557/laenguage/en-US/Default.aspx>

¹⁷ The Government assigned the obligation to establish Task Forces to the Government Office in 2011. A Task Force is being established in the fields that concern several ministries and require cross-sectoral cooperation.

¹⁸ Estonian eHealth Strategic Development Plan 2020 (2015). Available at: https://www.sm.ee/sites/default/files/content-editors/sisekomm/e-tervise_strateegia_2020_15_en1.pdf

department. To co-ordinate the implementation of the eHealth strategy a permanent strategy council consisting of all key stakeholders was formed and the preparation of the national personalised medicine programme was started to hasten the introduction of the novel concept into everyday clinical practice.

The Health and Welfare Information Systems Centre (HWISC) was founded on 1 January 2017. It is a state agency administered by the MoSA, which consolidates the roles and responsibilities of the former Information and Communication Technology (ICT) department of the MoSA and the Estonian eHealth Foundation (EHF). The scope of the HWISC is broader than eHealth, aggregating the eFunctions of health, labour and social policy areas. Tasks of the HWISC include development of information systems, standards, databases and eServices; maintenance of services and infrastructure; providing information security; and data analysis to support policy making, reporting, productivity monitoring and supervision. In eHealth, in addition to the health information system the HWISC became responsible for the three information systems of the Health Board.¹⁹

EHIF as a single public payer of health services has strong levers to influence the eHealth development and deployment. In the past, the EHIF has successfully introduced a digital billing and an ePrescription systems. However, through the healthcare services purchasing model, the EHIF could accelerate significantly more the uptake of ICT in healthcare and stimulate the demand for user-friendly eHealth solutions. Recent changes in the EHIF-related regulation (including creation of preconditions for a healthcare innovation fund) and in the management board (including the recruitment of a Digital Transformation Officer) indicate that the EHIF is expected to strengthen its role in eHealth governance. Despite the longer-term impact of the recent changes in the eHealth governance, the stakeholders interviewed see no remarkable improvement: there is still a lack of strategic leadership by the MoSA, implementation of the eHealth strategy is stagnated, stakeholder engagement and co-ordination is even weakened and the pace of development of eHealth services is slowed down.

Further development of eHealth in Estonia will follow a path outlined in the strategic document eHealth strategy 2016-2020". There are 5 focus areas: 1. High-quality health information and an infrastructure of health data; 2. Citizen-centred healthcare and personalised medicine; 3. Comprehensive case management and cooperation of organisations; 4. Effectiveness of health services and capacity for analysis; 5. Development of remote services.²⁰ Core activities and projects to implement the strategy include improving data capture and quality and the development of a new event-based health information system (health information system 2.0);

¹⁹ HWISC (2017). Available at: https://sam.lrv.lt/uploads/sam/documents/files/Veiklos_sritys/E.%20sveikata/priedas%20Nr_1_20171013_Estonian%20Health%20Information%20System%20overview.pdf

²⁰ Estonian eHealth Strategic Development Plan 2020 (2015). Available at: https://www.sm.ee/sites/default/files/content-editors/sisekomm/e-tervise_strateegia_2020_15_en1.pdf

development of new patient portal, clinical decision support and personalised medicine; development of services for patient logistics, healthcare process coordination and integration of social and healthcare services; analytics for monitoring healthcare services; and development of the platform for telemedicine services.

Secondary use of healthcare generated data in Estonia is low. In 2013 the HWISC launched a statistics module to enable the use of anonymised data in the health information system for statistics and research. One example of the secondary use is the cancer screening register that collects data about the results of cancer screenings and allows the regular assessment of the effectiveness and quality of screening programmes as well as the performance of epidemiologic research.

The development of personalised medicine²¹ is expected to give impetus to the secondary use of data, big data analytics and the use of AI in healthcare. The activities are based on the national programme for 2016–2020 and are co-ordinated by the MoSA. The programme includes two clinical flagship projects in the fields of prevention of breast cancer and cardiovascular disease, creation of data management infrastructure and clinical decision support system, extension of the national genome bank by 500,000 additional data donors, and funding for the development of innovative personalised medicine services and solutions.²²

To enable and ease the secondary use of data, the MoSA has prepared and brought to the Government a concept of Digital Innovation Estonia (DigInEst). DigInEst, foreseen as a state-owned company, aims to provide flexible, practical and professional legal as well as technical framework for R&D cooperation projects utilising the healthcare, social care and other data, which is held and processed by the public institutions of Estonia.²³ For the consent management, HWISC together with the MyData have initiated the creation of a single consent platform where a person can digitally grant and manage third parties access to his/her data, including health data in the health information system. This includes, amongst others, access rights of trustees, various healthcare service options such as organ donation, and consent related to health record access rights. The system will be developed by the Information System Authority.²⁴

The clinical decision support system for healthcare professionals is aimed to assist in making clinical decisions, associating the automatically collected health data of a person (including

²¹ Personalised medicine refers to prevention, diagnosis and treatment of health disorders, based on an individual risk-tailored approach using computational decision support analysis of a person's phenotype and genotype data.

²² Ministry of Social Affairs (2015). The preliminary study of the personalised medicine programme. Available at: <https://www.sm.ee/en/personalised-medicine#Preliminary%20study>

²³ ERR (2018). Sotsiaalministeerium plaanib andmemajanduse riigifirma loomist. Available at: <https://www.err.ee/867518/sotsiaalministeerium-plaanib-andmemajanduse-riigifirma-loomist>

²⁴ Information System Authority (2019). Introduction and structure. Available at: <https://www.ria.ee/en/information-system-authority/introduction-and-structure.html>

genome data) with evidence-based knowledge (clinical guidelines). The procurement of the system is led by the EHIF and will be implemented in co-operation with the HWISC (the system will be hosted by the health information system). The system is planned to be in use by 2020. To start with, the decision support system is developed only for family physicians and the first clinical use cases are decided as breast cancer and cardiovascular disease.²⁵

The eHealth related competence-base is developed at the STACC²⁶, which is the leading machine learning and data science competence centre in Estonia that develops AI solutions, and at the eMed Lab of the Tallinn University of Technology.²⁷

In spring 2018, the Government Office and the MoEAC launched a cross-sectoral project to analyse and prepare the implementation of AI, as well as develop a test environment in Estonia. This project should result in an AI strategy for Estonia elaborating the potential use of AI in the public and private sector, legal challenges, promotion of AI measures, etc. In essence these are the first exploratory steps being taken.²⁸

B.2.2 Cross-border implementation of eHealth

As people become more mobile, the need for cross-border eHealth services becomes more pressing. To enable cross-border health data exchange, Estonia has started bilateral cooperation with Finland²⁹ and actively participates in EU-level projects (epSOS and eHDSI).³⁰ These cooperation efforts are expected to bear first fruits in the nearest future.

The first instance of cross-border data exchange is the ePrescription system and patient summaries for cross-border access to important medical data for patient treatment. Between Estonia and Finland, the cross-border ePrescription service is expected to be launched in 2018, when Finnish ePrescriptions will become valid in Estonian pharmacies. A year later, in 2019 Estonian digital prescriptions will be able to be used in Finnish pharmacies. The opportunity to use ePrescriptions abroad will benefit citizens by making the management of medications treatment easier, while pharmacies benefit from the improved data quality for their activities because digital prescriptions issued in another country will become available in a standardised form and in the local language.

²⁵ Meditsiiniuudised (2018). Otsusetugi valmib aastaks 2020. Available at: <http://www.mu.ee/uudised/2018/07/13/otsusetugi-valmib-aastaks-2020>

²⁶ STACC. About us. Available at: <https://www.stacc.ee/about-us/>

²⁷ TTU (2018). eMed Lab. Available at: <https://www.ttu.ee/institutes/department-of-health-technologies/department-9/structure-16/emed-lab-2/>

²⁸ Riigikantselei 92018). Estonia will have an artificial intelligence strategy. Available at: <https://riigikantselei.ee/en/news/estonia-will-have-artificial-intelligence-strategy>

²⁹ In May 2016, a joint declaration was signed by the Estonian and Finnish Prime Ministers to significantly intensify patient data exchange and e-services between the two countries.

³⁰ epSOS was a large-scale research and development project under the 7th Framework Programme, where a limited amount of test data was exchanged. The eHDSI is a move from a test project to deployment phase of cross-border exchange of health data.

The cross-border eHealth data exchange is not limited with Finland as it will be based on the European eHealth Digital Service Infrastructure (eHDSI), which is provided jointly by the European Commission and the national healthcare systems. The eHDSI is financed by the Member States and the European Union through the Connecting Europe Facility (CEF) programme. It is expected that towards 2019, the EU's cross-border health data exchange will start to be an accepted practice of the national healthcare systems and that an increase in the use of the services will be noticed.³¹ Estonia joined the network with the first wave of countries and intends to realise both ePrescriptions as well as patient summaries. The latter is scheduled to be technically ready for launch by March 2019. In Estonia, HWISC is authorised by the MoSA to act as a National Contact Point (NCP) for eHDSI.

The European Reference Networks (ERNs) is another EU lead initiative, the aim of which is to create cross-border virtual networks of healthcare providers across the EU to tackle rare diseases and conditions.³² From Estonia, two hospitals are involved in ERNs: Tartu University Hospital in rare bone diseases and endocrinology and East Tallinn Central Hospital in rare eye diseases. At the heart of the ERNs is the Clinical Patient Management System, which enables the network to exchange patients' clinical data across borders and hold virtual consultations. The IT system was launched in 2017 and the European Commission will pay ERNs per active use of the system.³³ Experts interviewed see the limited number of national or regional level health information systems and countries' readiness to exchange data according to agreed standards as the biggest barriers in the expansion of cross-border eHealth services in EU.

B.2.3 Pathway integration. Diabetes journey

While Estonia has a basic infrastructure and generic set of eHealth services in place, there is no evidence of condition specific eHealth tools for healthcare professionals and patients, including digital solutions aimed at people with diabetes.

Regarding identification and verification of diabetes, people can find Type 2 diabetes self-assessment tests to find out if they are at risk from websites like kliinik.ee and diabeet.ee. In the care-focused healthcare system, there is not yet the prevention programmes to identify the risk group (using AI and machine learning based algorithms) and prescribe interventions like weight management (supported by the trackers and apps) to reduce the risk of getting ill.

In the diagnosis, treatment and monitoring stages, the main responsibility in the healthcare system relays at the primary care level, while general practitioners are equipped with the

³¹ eHealth Network (2015). Governance model for the eHealth Digital Service Infrastructure during the CEF funding. Available at: https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20151123_co02_en.pdf

³² European Commission (2018). European Reference Networks. Available at: https://ec.europa.eu/health/ern_en

³³ DG SANTE (2017). ERN IT Platform – delivering the virtual link for the Networks. Available at: https://ec.europa.eu/health/sites/health/files/ern/docs/20170309_rt1_04_piha-brand_pres_en.pdf

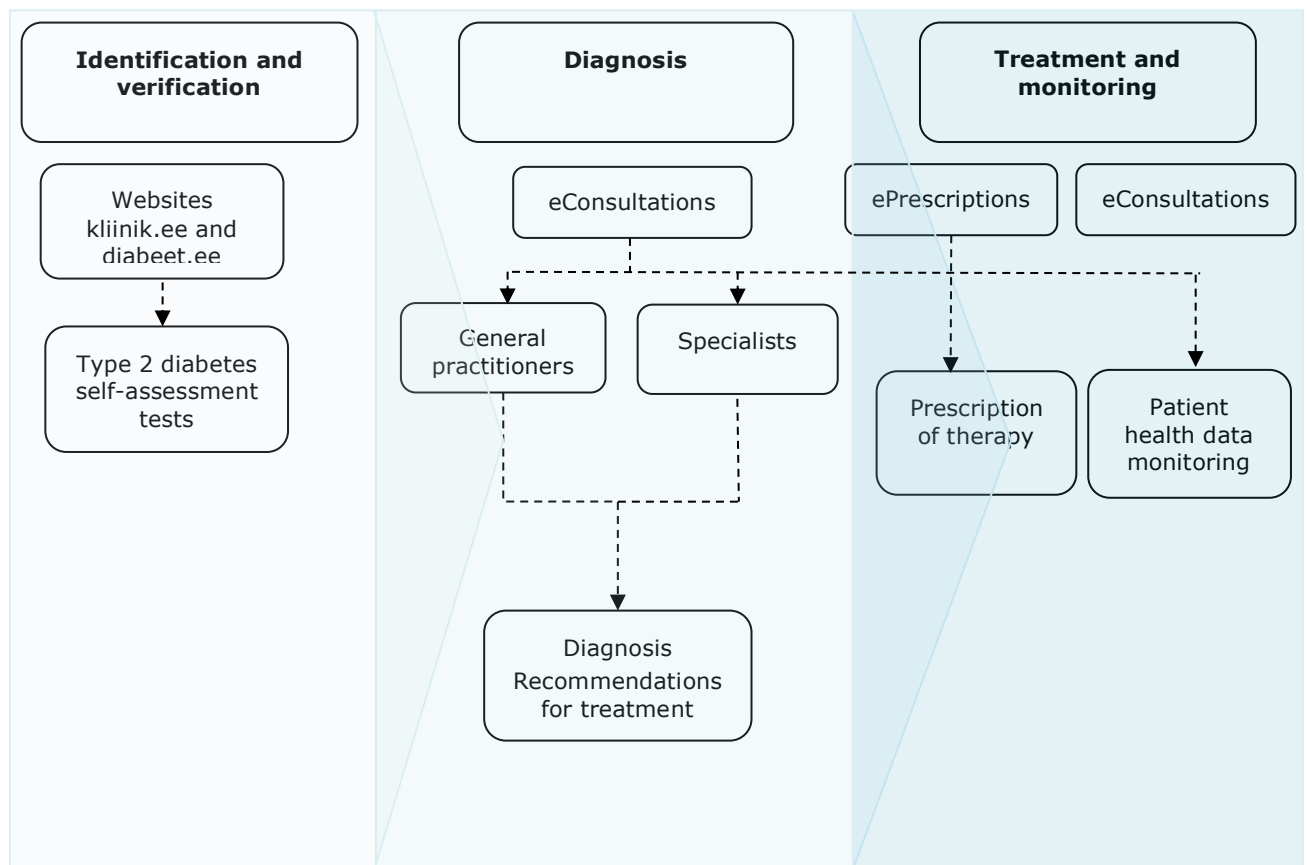
eConsultation possibility, which allows them to consult with the specialist doctors. To improve the monitoring of chronically ill patients (incl. Type 2 diabetes) at the primary care level, this is incentivised financially by the EHIF family physicians' quality system. However, the system is not complemented with the digital tools, which could support caregivers doing the monitoring more efficiently (incl. spending less time) and empowering patients for self-management. For example, the MoSA and the Estonian Diabetes Association commissioned a study³⁴ in 2016 founding out, that at doctor's appointment considerable time goes for the activities, which could be done by the patient in advance (e.g. lifestyle audit, self-assessment of diabetes management) and/or could be solved by using digital solutions (e.g. automated summaries from the patient's diabetes and nutrition eDiaries).

People living with diabetes are free to use different apps and connected devices available in the global market (there are more than 2,000 digital services for diabetes patients available globally³⁵) to manage their condition. However, there are no such solutions adopted to or developed particularly for the Estonian market (incl. available in Estonian and Russian). Even when 63% of people in Estonia would expect their doctor to prescribe them also digital tools, doctors are usually not aware of or do not trust the digital solutions and therefore do not recommend these to their patients. Moreover, the national health information system currently does not allow patients generated self-monitoring data to be sent there and that way share with the doctor. Doctors are also concerned of this new type of data source until they do not have a dashboard-like solution, which could turn the raw data to the information relevant for making better treatment decisions.

³⁴ Mõtus M., Koppel K. (2016). Kroonilise haige jälgimise teenuseprotsessi disain

³⁵ Research2Guidance (2018). Digital Diabetes Care Market 2018-2022. Available at: <https://research2guidance.com/wp-content/uploads/2018/08/R2G-Digital-Diabetes-Care-Market-2018-2022-Ready-To-Take-Off-Report-Preview.pdf>

Figure 1. Identification, verification, diagnosis, treatment and monitoring of diabetes in Estonia using eHealth solutions



Source: ESPON (2018)

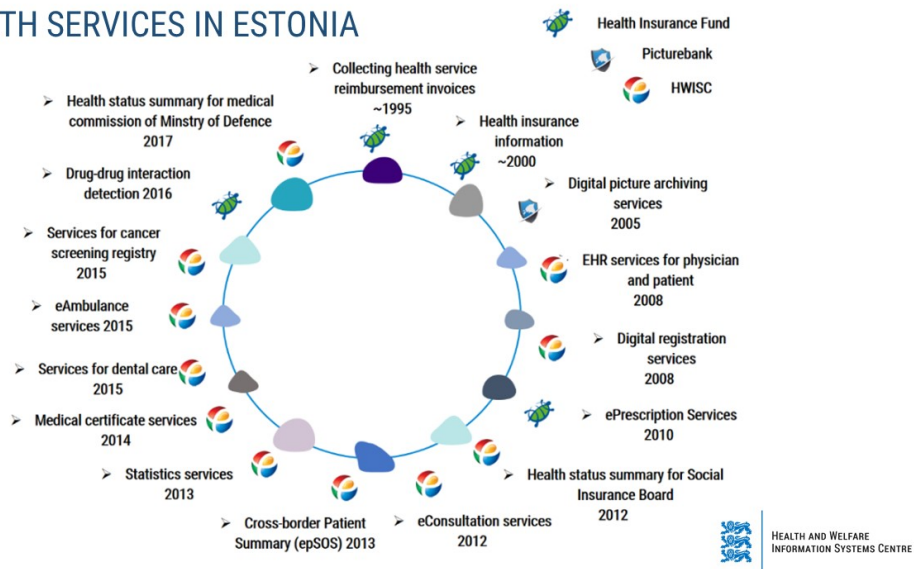
B.3 Most prevalent eHealth applications and their use

B.3.1 eHealth applications directions

eHealth services landscape in Estonia is dominated by the solutions developed centrally by the state and relying on the national health information system.

Figure 2. eHealth services development in Estonia in 1995-2017

E-HEALTH SERVICES IN ESTONIA



Source: The HWISC (2018)

The services described below do not constitute an exhaustive list of eHealth solutions being developed in Estonia. It is a selection of the most and least successful digital health developments in Estonia – that is, according to the opinion of the experts interviewed.

Table 1. eHealth solutions in Estonia

Service	Description
National Health Information System (EHR)	Nation-wide information-exchange platform (acting as Estonians national EHR) was established in 2008. It connects all providers and allows data exchange with various other databases. Healthcare providers are connected to the system and patient health data is stored centrally. All healthcare providers have a legal obligation to send certain health data to the health information system. The system is a backbone for the different eHealth services, e.g. enables patients to access their health data via patient's portal (Digilugu.ee). 1.6 million people have documents in the system (Estonia has 1.3 million inhabitants), there are 34 million different documents stored: 21 million summaries of visits or treatments and discharge letters, 1.7 million referrals, 7.5 million diagnostic study reports and procedures.
National patient portal Digilugu.ee	The national patient portal is a single access point for citizens to their medical data stored in the national health information system. The web-based portal can be securely accessed with a Mobile ID or an ID card. It consists of case summaries, lab results, medical images, prescriptions, dental care documents, immunisations, health certificates and medical bills reimbursed by the EHIF. In addition, the portal allows people to declare intentions and preferences, for example, make organ donor declarations or to assign a representative who can access their health data. In order to ensure the transparency of the system, people can monitor logs to see who has viewed the health data (and what data) about them. In 2017 244,369 unique visitors accessed the portal (15% of the population).
ePrescription	A centralised paperless system for issuing and handling medical prescriptions. To use the ePrescription, a patient needs to present an ID card at the pharmacy. The pharmacist then retrieves the patient's prescription from the system and issues the medicine if it

	<p>has been prescribed to the patient. It is considered the most successful eService as well as eHealth solution in Estonia. It is also the most used public eService (73% of people who have used internet within last two years have also used ePrescription) with the highest citizen satisfaction score (4.8 out of 5.0). 64% of citizens are aware of the possibility to view the prescriptions at the patient portal and 27% have also done so. The service offers extra features, for example the possibility to track the prescriptions history and costs, to compare the prices of alternative products and see the possible savings when choosing the cheapest option.</p> <p>The service was developed by the EHIF and launched in 2010. In 2016 the Drug Interaction Assessment Database was connected to the ePrescription in order to enable physicians to assess drug interaction at the moment when medicinal products are prescribed. The ePrescription covers 100% of used prescriptions, whereas 98% are prescribed digitally and the remaining 2% are entered in the pharmacy. The ePrescription is also the first use case for cross-border data exchange; the service launched in January 2019 between Estonia and Finland, with Finnish ePrescriptions valid in participating Estonian pharmacies, while Estonian ePrescriptions will follow suit later in the year.</p>
eRegistration	<p>A nationwide eRegistration service was one of the very first eHealth projects planned in Estonia already ten years ago (first being discussed by 2005), but not yet realised. Meanwhile, hospitals have developed their own patient portals and offer digital registration and management for the appointments where patients can schedule, pay, reschedule and cancel ambulatory appointments and order SMS and e-mail reminders. Still, currently the HWISC holds a mandate to develop the national system and the EHIF through the financing agreements will make it obligatory for the hospitals to deploy it; the piloting of the system is taking place at the North Estonia Medical Centre.</p>
Information sharing solution(s)	
eConsultation	<p>Through eConsultation family physicians can consult with specialists via the health information system without sending the patient to the specialist care provider. The results of the consultation are forwarded to the health information system by the specialist doctor and may contain recommendations for continuing treatment or invite the patient to attend an appointment. The eConsultation has to follow a standardised format (by specialty), which should better enable specialists to give adequate advice. Patients can see their eConsultations in the patient portal. The eConsultation supports family doctors in assuming more responsibility for patient care and improves cooperation with specialist doctors. In the pilot period the eConsultation was applied to limited number of specialties. After piloting it has expanded gradually and as of 2019 will be in use in 21 specialties. In the 3rd quarter of 2018, 670 family doctors had 4709 eConsultations, which is 50% more than at the same time the year before. Family doctors have stated the eConsultation as the best eHealth innovation of the last few years.</p>
eReferral	<p>eReferral was launched in 2009 and has been used mainly by family doctors linking their patients to the next level of care. In 2017 about 50% of referrals were digital. Patients can see their referrals in the national patient portal. As of 2018, all referrals must be entered digitally via the health information system. In 2013, eReferral was complemented with the eConsultation.</p>

B.4 Healthcare providers

The national health information system is an information-exchange platform that connects all providers and allows data exchange with various other databases. Healthcare providers are

connected to the system and all providers have a legal obligation to send certain health data to the health information system. The set of documents is defined by law, which defines the list and data content of documents that must be forwarded and the conditions and arrangements for retention of these documents. The obligation applies both to visits covered by the EHIF as well as to those paid by the patient. Healthcare professionals have an ethical obligation to assess whether making data enquiries is justified.³⁶

As noted in prior chapters, healthcare providers are obliged to use universal data transfer formats (XML based HL7 v3). All of the information must be entered into the national health information system within one (ambulatory reception) or five (hospitalisation) working days, as stated by law.

B.4.1 Service users

In general, ePrescription in Estonia remains the most widely used eGovernment service and the one with the highest satisfaction rates as well. The national patient portal at Digilugu.ee is a single access point for citizens to their medical data stored in the health information system. In 2017, the portal had 244,369 unique visitors (15% of the population).³⁷ The awareness as well as the use of the portal has improved steadily over time. In 2016, 63% of citizens were aware of the patient portal (compared with 40% in 2014) and 24% had accessed it (compared with 11% in 2014). People mainly accessed the portal to view their medical records (74%), out of curiosity (38%) or to fill in the health declaration (31%).³⁸

B.4.2 Developers

In 2018 €135 million of the state budget has been dedicated to the maintenance and development of the state's ICT infrastructure and services (that is, 1.31% compared with 1.4% in Finland and 2.4% in Denmark). From all ministries, the MoSA €12 million ICT budget is the third biggest.³⁹

The HWISC is financed via MoSA state budget allocations, income from economic activity, allocations from participation in international cooperation projects and EU grants. The budget for 2018 is about €14 million, including €4 million for eHealth. More than half of the eHealth budget consists of project-based funding applied by the HWISC from the EU Structural Funds measures.

³⁶ EU2017.ee (2017). Estonia's unique e-health: thousands of data fields, one personal health record. Available at: <https://www.eu2017.ee/news/press-releases/estonias-unique-e-health-thousands-data-fields-one-personal-health-record>

³⁷ TEHIK (2018).

³⁸ KANTAR Emor (2016). Eesti elanike hinnangud tervisele ja arstiabile. Available at: https://www.sm.ee/sites/default/files/content-editors/Ministeerium_kontaktid/Uuringu_ja_analuusid/Tervisevaldkond/arstiabi_uuringu_aruanne_2016_kantar_emor.pdf

³⁹ Postimees (2018). E-state sitting on ticking bomb. Available at: <https://news.postimees.ee/4470707/e-state-sitting-on-ticking-bomb>

The development of new eHealth services is funded mainly on a project basis from the EU Structural Funds measures for 2014-2020. Information society measures under the auspices of the Government CIO Office at the Ministry of Economic Affairs and Communications have a total budget of €205.5 million (incl. state's co-funding) of which €143.6 million is applicable for the healthcare sector. As of August 2018, eHealth projects submitted either by the MoSA, the HWISC, hospitals or by the Tallinn Social Welfare and Healthcare Board have been funded in the total amount of €3.9 million (incl. state's co-funding and applicant's own financing).⁴⁰

To some extent, the Estonian business support agency Enterprise Estonia as well as the Estonian Research Council finance the development of new eHealth services. They run the EU Structural Funds measures, which provide opportunities for sectoral ministries to apply co-funding based on their specific R&D needs (programme RITA for applied research⁴¹) and for implementation of innovation projects (programme to promote pre-commercial procurement⁴²). In these programmes, eHealth, as one of Estonia's smart specialisation growth areas, has been given a priority. For example, thus far, clinical demonstration projects for piloting the use of personalised medicine in everyday clinical practice implemented by a broad-based consortium led by Tartu University Hospital, and procurement of clinical decision support system for healthcare professionals (total budget €1 million, €0.5 million from the EU Structural Funds and €0.5 million from the MoSA and EHIF combined) have received financing.

Enterprise Estonia's programme for clusters provides EU Structural Funds financing for the Estonian health technology cluster Connected Health⁴³. The cluster is led by the Tallinn Science Park Tehnopol and it connects different stakeholders to co-create needs-based and user-friendly eHealth solutions, accelerate their adoption into the Estonian healthcare system and promote access to export markets. The cluster has grown rapidly: in 2016 it started with less than 40 partners and currently there are more than 80 partners. Health IT companies and digital health start-ups form the core of the cluster, whereas healthcare sector players like MoSA, EHIF, as well as clinics and healthcare practitioners participate in the cluster's activities as "problem owners" and testing ground for the new solutions. In addition to networking services, the cluster provides eHealth demand activation programmes, early-phase funding for prototyping and testing innovative eHealth solutions, and acceleration and facilitation service for collaborative projects between healthcare service providers and digital health companies. The magnitude of the cluster's three years budget (2016-2018) is approximately €1 million.

⁴⁰ MoEAC (2018)

⁴¹ ETAG (2018). RITA. Available at: <http://www.etag.ee/en/funding/programmes/rita/>

⁴² EAS (2018). Innovatsiooni edendavate hangete toetamine. Available at: <https://www.eas.ee/teenus/innovatsiooni-edendavate-hangete-toetamine/>

⁴³ Connected Health (2018). Connected Health Cluster. Available at: <http://connectedhealth.ee/>

The project-based funding and the high dependence on EU Structural Funds have led to the growing number of new eServices, whereas existing eServices and the basic ICT infrastructure these services rely on lack resources for consistent maintenance and modernisation. For citizens, it means eServices that are not user friendly and that may pose security risks. The problem will escalate in subsequent years and peak in 2023 with the gradual withdrawal of EU Structural Funds.

B.4.3 Demand stimulation

The further growth of the usage of the patient portal depends on how convenient it is to use (e.g. at the moment there is only a web portal and no mobile app) and on the availability of value-added and user-friendly services. At the moment, the use of patient portal to access eHealth services has continued to grow (in 2016, 63% of citizens were aware of the patient portal compared with 40% in 2014; in 2016 24% of citizens had accessed it compared with 11% in 2014).

Regarding the eRegistrations developed by individual healthcare providers, analysis suggests that this has not become the preferred option for the patients: a majority of the registrations is still made by using conventional channels like making a phone call or standing in a queue. For family physicians, there is a respective eSolution in the market provided by a private company, the uptake of which is very low. Still, 79% of citizens would like to see the waiting lists across different service providers and for different doctors. (as opposed to using different systems from different providers – an approach that has not shown growth in usage or interest among patients). This interest does suggest that the national eRegistration system (still in development) is of interest to the users.

B.5 Socio-economic benefits of eHealth

The eHealth strategy should contribute to achieving the targets set out in the NHP. One of the eHealth strategy's basic principles is that the eServices developed will create new value, thereby improving the quality of health services and helping to improve the quality of life of people, ensure more years of healthy life, and save time and money.⁴⁴ However, the impacts and benefits of existing and planned eHealth services are not systematically evaluated. So far, the perceived positive impacts of digitisation rather than empirical evidence have driven decisions in eHealth.

Looking for a suitable evaluation methodology, a study was commissioned in 2010. The aim was to develop methodology to evaluate the impact of the implementation of a nationwide health information system. The analysis of potential costs and benefits associated with the implementation of the comprehensive system was carried out on the basis of the PENG method, specially designed to evaluate IT investments. Type II diabetes was used as a test

⁴⁴ Ministry of Social Affairs (2015). Estonian eHealth Strategic Development Plan 2020. Available at: https://www.sm.ee/sites/default/files/content-editors/sisekomm/e-tervise_strateegia_2020_15_en1.pdf

case to validate the methodology and evaluate the benefits for patients, healthcare providers and citizens/society.⁴⁵

An independent evaluation of the ePrescription performed 6 years after its launch found that there is only little empirical evidence available to confirm if the benefits aimed for in the creation of the service were achieved. The service is widely used by citizens, healthcare providers and administrators alike and from a public administration viewpoint, the implementation has led to potential efficiency gains. For example, the costs of paper-based prescription forms bought by the EHIF in 2009-2013 have decreased from €63,668 to €1,628. However, there are gaps in measuring the impact of the service, especially with respect to time savings and enhanced healthcare quality. As a recommendation, future eHealth services should undergo a more rigorous evaluation process during the design and implementation stages.⁴⁶

Currently, the HWISC is making attempts to estimate the potential impact of the new eHealth developments planned in the eHealth strategy 2016-2020 and plans to strengthen the evaluation capacity in the future.

⁴⁵ J. Saluste et al. (2010) Assessing the Economic Impact/Net Benefits of the Estonian Electronic Health Record System. Available at:
<http://www.praxis.ee/fileadmin/tarmo/Projektid/Tervishoid/Digimoju/Digimimpact.pdf>

⁴⁶ L.Parv et al. An evaluation of e-prescribing at a national level (2016). Available at:
<https://www.ncbi.nlm.nih.gov/pubmed/25115948>

Figure 3. Estimated impact by core projects



Source: The HWISC (2018)

Stakeholders interviewed agree with the need for more systemic impact evaluation. As a step in the right direction, the practice was mentioned where new eService development projects applying for co-funding from EU Structural Funds measures owned by the MoEAC must present the information about the potential impact. In order to make impact evaluation a routine in eHealth service planning and implementation, the evaluation methodologies should be agreed on and the capacity to perform the analyses be strengthened. EU-level actions could also be considered to promote the use of already existing evidence and to share the best evaluation practices.

Appendix C Finland country profile

C.1 Healthcare system and its institutional structures

C.1.1 Legal and financial framework

The inflection points of Finland's healthcare system that enabled its transformation to become the entity it is nowadays can be dated back to 1929, when a special committee was charged with an overarching evaluation of Finland's healthcare system. It is in course of this evaluation that healthcare provision has been treated as a municipal responsibility, and publicly funded hospitals have been established. Specifically, these hospitals experienced elevated interest and attention after the second world war, as they continued to function as disseminating instances for medical care and healthcare innovation throughout the entire country.

In its current state the Finnish healthcare system is highly decentralised offering access to universal healthcare. It comprises of a three-level publicly funded healthcare system as well as a considerably smaller private sector. The Finnish Ministry of Social Affairs and Health (STM) is the government institution with the highest national authority, and primarily charged with the management of Finland's welfare and healthcare policy, national eHealth legislation and coordination. The STM is supported by its agencies, the Social Insurance Institution of Finland (Kela) and the National Institute of Health and Welfare (THL). Regional outreach and impact are achieved by the means of regional level planning and prioritisation, carried out via the allocation of project funding and municipalities, which fund healthcare provision. It is specifically this regional level that is of significant importance, as regional or local authorities are ultimately responsible for the provision of healthcare to their respective residents.

Primary care is channelled through local or municipal healthcare centres, which give access to consultation with general practitioners or other day-to-day medical services. General practitioners also serve a filtering role, through referring to secondary or tertiary care levels. Secondary care is dealt with on a municipal level through district hospitals, and complemented by the tertiary level, which is embodied by the five university teaching hospitals in Helsinki, Turku, Tampere, Kuopio and Oulu. These hospitals are primarily funded through municipal authorities, whereas their national counterpart limits its financial support to medical training alone.

In general, funding for the entire healthcare system sources from two major streams, which correspond to the aforementioned typology, and can be captured by municipal and national entities. Municipal funding schemes are based on taxes and their distribution and are primarily channelled to cover primary healthcare costs and services. Municipal authorities have furthermore the right to collect user fees for consultation and primary healthcare services, which are either set to moderate maximum rates for single visits or made dependent on the income of the respective patient for longer illnesses. National Health Insurance, on the other hand, is based on compulsory fees, which are managed so as to fund private healthcare, occupational healthcare, outpatient drugs or sickness allowance. The former

notion, private healthcare, covers a relatively small share of patients in Finland (3-4% of all residents).⁴⁷

This design and structural management, however, is subject to a major healthcare reform that is currently being developed in Finland. One of the major aims is to transfer responsibilities to institutions and entities that are bigger than municipalities, namely counties. Social welfare and healthcare services will be combined to meet these new implementation objectives and trajectories. These structural changes imply a shift from the current national-municipal handling to a national-county-municipal doctrine. More detailed implications are still debated and reviewed, as the planned reform has been exposed to long-lasting and sustained criticism and needs to pass county elections which are scheduled for late 2018.⁴⁸

In numerical terms, Finland's overall total health expenditure reached a volume of €19.8 billion in 2015, which equals a 1.2% increase in real terms. This sum can be translated into a per-capita expenditure of €3,803, or a volume that corresponds to 9.4% of total national GDP in 2015. Of this sum, about €6.9 billion was channelled to primary healthcare, €3.7 billion to secondary healthcare, and approximately €2.5 billion to medicines and other medical consumables.⁴⁹

C.1.2 Data management and IT infrastructure

Finland has been undergoing a process of harmonising national strategies and policies specifically related to eHealth services and the usage of digital health data. Several ministries and government organisations are involved in structuring the eHealth framework and ecosystem in Finland. The Ministry of Health and Social Affairs and the Ministry of Employment and Economy manage the implementation of the National Health Sector Growth Strategy for Research and Innovation⁵⁰ while the Ministry of Transport and Communication is responsible for cyber security, increasing the availability of information and open data and generating new business operations.

On a more overarching level, general legislation on secondary use of data is already in parliament and will be complemented by specific GDPR legislation soon. Legislation concerning storage and access to genetic information and biobanks (6 regional and 4 country-wide institutions that, with the patient consent, store and maintain clinical samples

⁴⁷ NordDRG (2012). Nordic DRG-System. Available at: https://web.archive.org/web/20120426052217/http://www.nordcase.org/eng/nordic_drg-system_/

⁴⁸ Kangas, O. & Kalliomaa-Puha, L. (2018). Finland: The government's social and healthcare reform is facing problems. Available at: ec.europa.eu/social/BlobServlet?docId=18981&langId=en

⁴⁹ Official Statistics of Finland (2017). Health Expenditure and Financing. Available at: <https://thl.fi/en/web/thlfi-en/statistics/statistics-by-topic/finances-in-the-health-and-social-services-sector/health-expenditure-and-financing>

⁵⁰ Ministry of Employment and Economy (2016). Health Sector Growth Strategy for Research and Innovation Activities Roadmap for 2016–2018. Available at: http://julkaisut.valtioneuvosto.fi/bitstream/handle/10024/75145/MEE_guidelines_8_2016_Health_sector_growth_strategy_17062016_web.pdf?sequence=1

and health data for healthcare research)⁵¹ is currently also being reviewed, partly because of the recently introduced EU GDPR directive.

Finland's MyData⁵² aims at strengthening digital human rights while opening new opportunities for businesses, public services or individuals to develop innovative personal data-based services built on mutual trust. In essence, the idea of MyData is to establish a human-centric model to the managing and processing of personal information, which nonetheless remains usable in terms of accessibility and resourcefulness. MyData defines itself as an intermediate actor through which data from segregated units is converted into a far-reaching and unified resource. Furthermore, MyData can be referred to as an infrastructure-level approach targeted at ensuring interoperability and portability, ultimately achieving a decentralised and open, yet secure and responsible surface for data-related issues⁵³.

In general, Finland has reached 100% of digitisation for Finnish healthcare systems, where its counterpart dealing with social affairs is expected to soon follow suit. It is therefore not surprising that ICT and corresponding costs play a significant role in the development of Finnish eHealth. For instance, the median value of ICT costs in hospital districts was about 2.8% of the organisations' total expenditure in 2016. The corresponding figure for healthcare centres and private service providers are 2% and 2.2%, respectively. Moreover, 57% of all hospital districts and healthcare centre organisations estimated that their ICT costs had increased since 2015.⁵⁴

Finland is notable for its efforts in digitising health records being one of the first countries to set up electronic patient records (EPR) that include both, the public and the private sectors⁵⁵. A 100% use of (EPR) by primary healthcare centres and secondary care hospital districts⁵⁶, as well as 100% coverage of EHR in the public, and 80% coverage of EHR in the private sector illustrate this. However, certain issues in Finland's eHealth landscape are observable. Most notably, a multitude of NGOs, patient associations and other interest groups present challenges in formulating common goals and approaches to eHealth.

⁵¹ Suomen Biopankki (2019). Finnish biobanks. Available at: <https://www.biopankki.fi/en/finnish-biobanks/>

⁵² MyData (2018). MyData 101. Available at: <https://mydata.org/mydata-101/>

⁵³ Poikola, A., Kuikkaniemi, K., & Honko, H. (2015). My Data – A Nordic Model for Human-Centred Personal Data Management and Processing. Helsinki: Finnish Ministry of Transport and Communication.

⁵⁴ Reponen, J., Kangas, M., Hämäläinen, P., Keränen, N., & Haverinen, J. (2018). Tieto- ja viestintäteknologian käyttö terveydenhuollossa vuonna 2017: Tilanne ja kehityksen suunta. Tampere: Oulun Yliopisto & Terveyden ja Hyvinvoinnin Laitos.

⁵⁵ Business Finland (2016). Digital Health. Available at: <http://www.finlandhealth.fi/-/digital-health>

⁵⁶ Export.gov (2017). Finland - eHealth/Health IT. Available at: <https://www.export.gov/article?id=Finland-eHealth-Health-IT>

C.2 Digitisation of healthcare

C.2.1 History, recent developments, future directions

Digitisation of the Finnish healthcare sector has proven to be a relatively successful story in an international context. Finland ranks amongst the most advanced countries in the world regarding digitisation efforts and eHealth solutions. The introduction of IT into healthcare can be dated back to the early 1980s, even though no political attention has been spared in the form of targeted policies until the mid-1990s. First advancements were initiated through a strategic document from the Ministry of Social Affairs and Health in 1995, in which rudimentary strategic directions and trajectories were laid out and formulated. One of the core principles was to design a citizen-centred and seamless service infrastructure, which would enable horizontal integration across all levels and sectors. First updates to the initial strategy had been made in 1998, where specifically digital and IT-related advancements were considered. A major inflection point can be marked in 2002, when authorities agreed on developing a nationwide and all-encompassing EHR system by 2007. In course of this decision, Finland carried out a pilot study during 2002-2006, which, however, was stopped because of technical insufficiencies. Nonetheless, gathered findings supported the introduction of EHRs in late 2007. This introduction was enabled by legislative Act 159/2007, which objective was to define the use of electronic social and healthcare and patient information. The specific regulation on the use of electronic prescriptions (Act 61/2007) was launched in that same year, and together with aforementioned Act 159/2007 still serves as the primary legislative document for all eHealth related activities in Finland nowadays.

In its current state, The Finnish approach to digitised eHealth is relatively multifaceted and offers several actors the opportunity to participate in a broad network, which, in its most simplified form, consists of patients, physicians, pharmacies, prescription centres, and the Finnish Electronic Patient Record System KanTa⁵⁷. At a strategic level, the Ministry of Social Affairs is primarily concerned with the conceptual management of the eHealth and eWelfare infrastructure. Operational steering is passed onto the National Institute for Health and Welfare (THL) as well as the Social Insurance Institution of Finland (Kela).

The Ministry of Social Affairs and Health has prepared a new strategy, outlining the two main directions in eHealth development in Finland, represented by the aspirations to make better use of healthcare data, and develop eHealth services for and driven by citizens. The latter notion includes current government flagship projects such as Virtual hospital 2.0⁵⁸ and ODA (Personal Digital Value-added services).⁵⁹ The difference to earlier healthcare digitisation

⁵⁷ Kauppinen, H., Ahonen, R., Mäntyselkä, P., Timonen, J. (2017). Medication Safety and the Usability of Electronic Prescribing as Perceived by Physicians - A Semistructured Interview among Primary Health Care Physicians in Finland. *Journal of Evaluation in Clinical Practice*, 23, 1187-1194.

⁵⁸ Tervetuloa Terveyskylään (2019). Tervetuloa Terveyskylään. Available at: <https://www.terveyskyla.fi/>

⁵⁹ Sitra (2016). ODA-päätös suuri mahdollisuus terveyskeskusjonojen purkamiseen. Available at: <https://www.sitra.fi/uutiset/oda-paatot-suuri-mahdollisuus-terveyskeskusjonojen-purkamiseen/>

projects is that these focus more on practices and processes rather than technological solutions. The prospective Digital Health Reform (DHR), which is expected to be in force by the end of 2018 or beginning of 2019⁶⁰ complements these aspirations. The DHR is a nationwide research project that is coordinated by the Oulu Centre for Health and Technology and funded by Tekes/Business Finland. The objective of this flagship project is to contribute to the change in the control of data in favour of the individual, develop successful personal data movement across systems and services and promote the development of MyData based health business. The aim of the DHR is to thereby create new, increasingly personalised services that respect data privacy standards as set out by the MyData initiative and built an ecosystem around it. In a similar vein, the National Architecture for Digital Services (KaPA) programme's goal is to support the creation of an online infrastructure that will facilitate the interoperability of online services.⁶¹

Financial support and funding opportunities for these applications arise from a multitude of sources: Business Finland (development of projects), the Ministry of Social Affairs and Health STM (development of projects), regional authorities (development, piloting and deployment, infrastructure investments), structural funds (regional projects and investments, other projects), local actors (e.g. cities, universities or hospital districts), as well as EU-wide programmes (e.g. stemming from within the framework of Horizon 2020). Despite the seemingly diverse funding opportunities, certain problems remain. For instance, it is stressed that public funding modalities are not ideal for the kinds of environments and ecosystems eHealth requires, as funding is primarily focussed on individual organisations and projects rather than overarching and far-reaching platforms. A certain exception is represented by KanTa, which could be considered an overarching and hence considerably unified platform.

C.2.2 Cross-border implementation of eHealth

A clear example which demonstrates the potential lying in a more coherent internal and external handling of eHealth-related matters is embodied in cross-border operations. For instance, a study conducted in 2016 noted the potential to develop cross-border data exchange between Finland and its neighbouring countries. Especially the Nordic countries stand out as the most promising initial group of collaborators and co-inventors. A notable example of such Nordic cooperation was the formation of the Nordic eHealth Research Centre (NeRN) of the Nordic Council of Ministers, which was created in 2012⁶². The NeRN's core aspiration is to establish a governance system for the collection of data and formulation

⁶⁰ Please note: different sources indicate different dates. The authors have therefore decided to proceed with a certain time window rather than a specific date

⁶¹ Kangas, O. & Kalliomaa-Puha, L. (2018). Finland: The government's social and healthcare reform is facing problems. Available at: ec.europa.eu/social/BlobServlet?docId=18981&langId=en

⁶² Gilstad, H., Brattheim, B., & Faxvaag, A. (2016). Comparability, availability and use of medication eHealth services in the Nordic countries. *International Journal on Advances in Life Sciences*, 8(1-2), 112-121.

and monitoring of eHealth strategies, thereby manifesting a coherent policy document for the Nordics that is currently absent. NeRN has also been expanding its activities beyond the Nordic countries, as is evident in the gradually increasing collaboration with the WHO over the past years in several projects. An example of this is noticeable in the prospective, but not yet completed, development of an eHealth maturity index. In addition, the internationally operating database “NOWBASE” within the Nordics stands out as one of the most noteworthy recent advancements. NOWBASE is a shared interface for the Nordic Medico-Statistical Committee (NOMESCO) and the Nordic Social Statistical Committee (NOSOSCO), who collaboratively seek to ensure that health and social statistics in the Nordic countries are comparable across borders, gathering statistics in associated fields is feasible and facilitated, and presenting, processing and managing gathered data is promoted and encouraged. However, the database is only compiled and expanded upon specific request of governments of Nordic council members rather than continuously and automatically being updated. NOWBASE is therefore little more than a static accumulation of different data sources, which, however, bears the potential to fundamentally support cross-border data exchange if according measures are being taken⁶³. On a more specific level, cooperation between Finland and Sweden as well as Finland and Estonia should improve healthcare provision, noting the benefits of cross-border eHealth for mobile workers that move between these countries. However, while the Nordic countries have enjoyed similar legal systems which would result in achieving cohesion faster, Finnish and Estonian legal systems were noted to be more different, Estonia having a more permissive approach to legislation.⁶⁴ Despite the differences in legal systems, Finland and Estonia have signed an agreement for joint cross-border cooperation to allow healthcare providers access to healthcare databases in both countries. It is expected that by the end of 2018 both countries will have access to digital prescriptions and by 2019 they will allow access to full patient medical history.⁶⁵ The mutual commitment is represented by the launch of the Nordic Institute of Interoperability Standards (NIIS) in Tallinn in 2017.⁶⁶ Finland’s cross-border cooperation is planned to be extended even further and beyond multiple borders in the next few years. As of 2018, twelve EU MS are expected to begin a project to exchange patient data on a regular basis. The first group of countries include Sweden, Finland, Portugal, Croatia, and Estonia with an additional five scheduled to join the network in 2019, and another group expected for 2020. As part of this project, countries within the network will share ePrescriptions. The need for such a more macro-contextualised approach becomes apparent as the EU experiences the same problems

⁶³ Hyppönen, H., Koch, S., Faxvaag, A., Gilstad, H., Nohr, C., Hardardottir, G., Vimarlund, V. (2017). Nordic eHealth Benchmarking: From Piloting Towards Best Practices. Nordic Council of Ministers.

⁶⁴ Ministry of Finance (2016). Cross-border Information Exchange and Digital Services Between Governments. Available at: vm.fi/dms-portlet/document/0/426868

⁶⁵ e-Estonia (2016). Estonia and Finland to start sharing patient data. And that’s just the start. Available at: <https://e-estonia.com/estonia-and-finland-to-start-sharing-patient-data-and-thats-just-the-start/>

⁶⁶ Nordic Institute for Interoperability Standards (n.d.). Available at: <https://www.niis.org/>

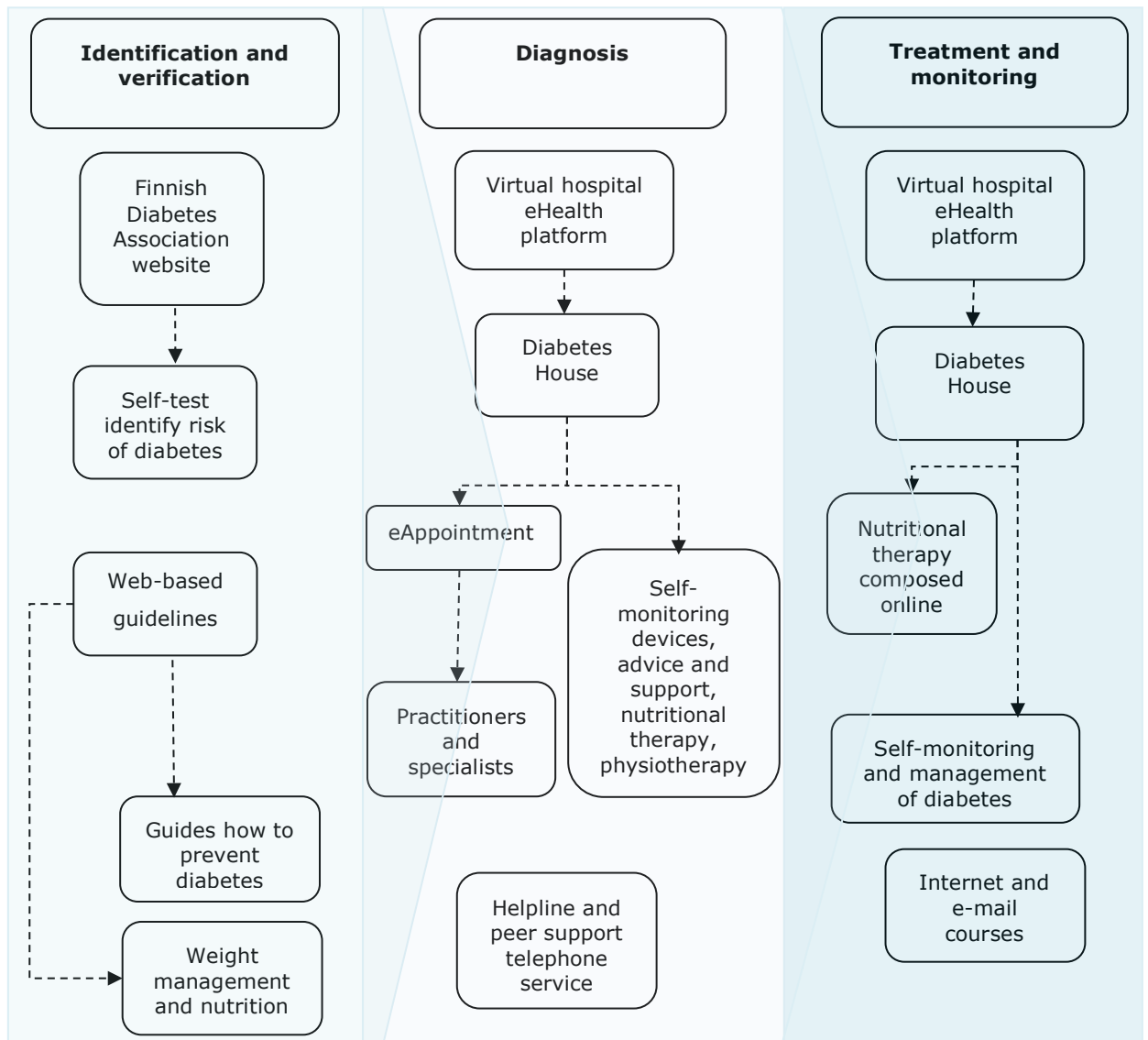
amongst its member states as Finland amongst its regions, as it has not formulated a clear and coherent legislative alignment either. The EU seems to currently not fully realise its opportunity to promote and support certain standardisation measures, which is a general problem that cross-border data exchange finds itself exposed to. Finland's participation in the EU-funded epSOS project⁶⁷, where cross-border exchange of electronic prescriptions was tested, does not fundamentally change this perception. The need for better integration is therefore obvious, and especially expressed by professionals in the healthcare sector.

C.2.3 Pathway integration. Diabetes journey

The availability of eHealth services in Finland for patients diagnosed with diabetes or looking to verify such suspicions is quite considerable. In fact, it is possible for a patient to use eHealth entirely from first identifying symptoms of diabetes all the way through diagnosis and treatment. While the system is not without flaws (particularly due to limited geographical availability of diagnosis) it does present a comprehensive approach of how eHealth can be applied throughout all stages of treatment.

⁶⁷ European Commission (2014). Cross-border health project epSOS: What has it achieved? Available at: <https://ec.europa.eu/digital-single-market/en/news/cross-border-health-project-epsos-what-has-it-achieved>

Figure 4. Identification, verification, diagnosis, treatment and monitoring of diabetes in Finland using eHealth solutions



Source: ESPON (2018)

Before the actual patient journey begins, people can use a web-based self-test to identify their personal risk of getting diabetes. They can access the test on the Finnish Diabetes Association website. There are also web-based guidelines and recommendations on how to prevent diabetes, particularly related to weight management and nutrition.

Once the diabetes has been diagnosed, there are several support services available. These start with helpline and peer support telephone services, social media groups, web-based and e-mail courses aimed at recently diagnosed patients.

One of the most developed eHealth platforms in Finland is the Virtual Hospital. It was launched in 2018 and it covers several diseases, one of which is diabetes. The Diabetes House at the Virtual Hospital offers a wide range of services including eAppointments, ordering self-monitoring devices and materials, advice and support, nutritional therapy,

physiotherapy, mouth, foot and eye health, mental health and psychotherapy, and intoxicant services. Most of these services are available via eHealth applications, and the ones that require traditional appointment, examinations or treatments are integrated through the eHealth platform. Furthermore, the Diabetes House offers a wide range of support material and services for self-monitoring and -management of diabetes.⁶⁸

Currently, only diabetes patients from the 5 hospital districts jointly developing the Virtual Hospital platform can access the Diabetes House fully after they get a referral from their local healthcare unit. Most of the content of the Diabetes House is openly available for anyone interested. The user can also register to the platform after which such services as messaging, calendar, symptom diary, and permission requests become available.

The concept of the Virtual Hospital is very new, so awareness of it and its offer are still limited and closely linked to the healthcare units of the 5 hospital districts. However, it offers a shared platform where new and more extensive eHealth services and applications can be developed. Further development of the platform facilitates better and more extensive integration across healthcare units, which is currently not as seamless as it should be.

Other hospital districts offer similar eHealth services for diabetes patients, but the range and quality vary between regions and healthcare service providers across Finland. There are many web-pages and applications aimed at diabetes patients. However, their user friendliness, quality and interoperability vary a lot and diabetes patients may find it difficult to select which ones are the best for their individual purposes. This emphasises the need for support from the local healthcare provider professionals.

Replacing or complementing traditional healthcare services with eHealth services and applications often require significant changes in day-to-day practices, both among healthcare units and professionals as well as patients. However, the economic potential is high, as can be illustrated e.g. by the weight management support services for diabetes patients: the cost of delivering these services via the Virtual Hospital platform is only one third compared to traditional ways of delivering the same services.

C.3 Most prevalent eHealth applications and their use

C.3.1 eHealth applications directions

Finland has employed a multitude of different approaches, systems and structures to manage and direct digitisation efforts in healthcare. The most crucial element of such efforts is to ensure a stable and mutually-inducing link between patients, professionals and further managing instances (especially those concerned with data gathering and management). To ensure the viability of these linkages, several applications, interfaces and further digital

⁶⁸ Mobi Health News (2018). Inside Health Villages, Finland's multimodal digital push to bring healthcare to the home. Available at: <https://www.mobihealthnews.com/content/inside-health-villages-finlands-multimodal-digital-push-bring-healthcare-home>

solutions have been set up. The following overview provides a snapshot of the most prevalent solutions which both, have emerged in course of an intensified pursuit of eHealth but also distinctively fostered its advancement in Finland.

Table 2. eHealth solutions in Finland

Service	Description
Electronic Health Records (EHR)	Launched in 2007, the documentation of patient data in Finland is almost exclusively carried out by electronic means. The infrastructure in place for EHRs is not entirely uniform and differs between healthcare providers. Yet, certain trends that indicate standardisation can be seen, as the count of EHR trade names has decreased over the past years. Different rates and levels of coverage can be identified according to the nature of healthcare provider. For instance, while public primary healthcare centres and specialised healthcare hospitals uniformly and exclusively rely on EHRs (saturation rate: 100%), private healthcare service providers' saturation rate can be numerically approached by about 80%. ⁶⁹
eAccess: KanTa and My KanTa	Launched in 2007, the central instance and most noteworthy application in the healthcare sector is embodied by KanTa. This interface functions as a centrally managing entity charged with the processing of patients' information. KanTa is complemented by My KanTa, which is the user interface through which patients can access information on healthcare providers, referrals, treatment summaries, patient consents and any log data. One of the intended key features of this design is to give all actors that are relevant during a patient's treatment easy access to necessary data and a convenient opportunity to manage such. Accordingly, My KanTa enables patients to access their medical records and other digital healthcare services (i.e. ePrescriptions) on demand or by default, for instance. In addition to providing patients with access to their medical data, the system also allows users to monitor and manage which organisations access their personal information. ⁷⁰ However, patients cannot deny healthcare providers from accessing the data that they have produced if the provider is currently in a medical relationship with the concerned patient. In order to access their medical records through KanTa, patients have to have a Finnish identity number; however, the data from patients outside of Finland is still recorded and stored in the Electronic Patient Record system. Non-Finnish patients who receive medical treatment in Finland cannot access the KanTa service as their data is not directly electronically stored in KanTa. In the event that Finnish citizens receive medical treatment in another country (or from a healthcare provider who is not registered in the Finnish Electronic Patient Record system), it is the patients' responsibility to ensure that their medical data is submitted. Healthcare data can usually be provided to patients in Finnish and Swedish allowing for greater language flexibility (as well as flexibility when treating people from abroad). If the patients submit their medical data, it is equally their responsibility to ensure that the information is submitted in the language requested by the healthcare provider. ⁷¹

⁶⁹ Hyppönen, Hämäläinen, & Reponen (2015). E-health and e-welfare of Finland - Check point 2015. Available at: <http://www.julkari.fi/handle/10024/129709>

⁷⁰ Korhonen M. (2016). How Finland became a leader in eHealth adoption. Available at: http://healthaffairs.ucd.ie/wp-content/uploads/2016/03/MarittaKorhonenMSAH_National-eHealth-Summit-2015.pdf

⁷¹ Choosehealthcare.fi (2018). Medical records in Finland. Available at: <https://www.choosehealthcare.fi/healthcare-in-finland/medical-records-in-finland/>

ePrescriptions	ePrescriptions were launched in Finland in 2007. The vast majority of physicians operating in Finland have electronic patient record applications and prescriptions that are generated electronically within the nationwide KanTa system. The concerned database is hosted by Kela and can be accessed by physicians and pharmacies alike. Once a prescription has been uploaded it cannot be deleted and will be kept within the ePrescriptions database for 30 months before being transferred to the eArchive. Prescriptions themselves can be viewed by physicians (after consent has been clarified) and are complemented by entire patient histories to minimise the risk of incompatibilities or side-effects. Finnish ePrescribing is fully incorporated with different EHRs and the Centralised Drug Database so as to ensure a complete, secure and up-to-date gathering of patient information and its management. ePrescription services also offer the patient the possibility to request prescription renewals or inquire information on dispensation.
Tervetuloa Terveyskylään (Virtual Hospital)	The Tervetuloa Terveyskylään which launched in 2018, is a collaborative effort by 5 hospital districts jointly developing the Virtual Hospital platform. At the moment the platform is composed of 5 virtual "houses" each of which focuses on a different area (disease) for patients to receive help. These "houses" focus on mental health, weight management, pain management, women, rehabilitation and rare diseases. However, only patients from the 5 hospital districts that have developed the platform can currently access the services.
Information sharing solution(s)	
eArchive	The eArchives, implemented in 2007, function as long-term memory for prescriptions and medical records of patients. It functions as data storage and a legal archive, which allows for the secure sharing of healthcare data between healthcare providers. This archive stores prescription details and data for as long as ten years. eArchives are integrated into KanTa.
Picture Archiving and Communication Systems (PACS)	The introduction of PACS began in 2000 and by 2007 PACS adaptation was nears 100% amongst most of healthcare service providers. Film imaging has been almost entirely replaced and made redundant. Similar to EHRs, PACS are offered by several different providers and market actors. In most scenarios, gathered images (i.e. x-ray scans) and recordings are seamlessly embedded in EHR interfaces.
Radiology and Laboratory Information Systems (RIS)	RIS introduction coincides with the development of PACS and is implemented during the period of 2000-2007. RIS enable the controlling and managing of the operations of radiological units through software-based solutions. The interface gives access to an overview of referral letters and appointment orders, and facilitates the management of work flow, reports or further operational activities. Hospital districts rely on this system and have entirely incorporated the according technology amongst all of its 21 representations. Healthcare centres follow suit and demonstrate a level of coverage of about 90%.
Laboratory Information System (LIS)	LIS introduction coincides with the development of PACS and is implemented during the period of 2000-2007. This software-based solution supports the identification and management of laboratory tests and their results. For instance, laboratory tests can be ordered, and gathered results sent back to the physician who initially ordered the examination. LIS are integrated into EHRs and form a vital part of their scope.
Hospital/Medical institutions	
Regional Data Exchange Systems (RHIE)	Since 2010, regional systems have been popular amongst healthcare organisations and institutions. In fact, many of these actors make use virtual private networks (VPN). Even though RHIE can exchange a multitude of data, their primary use lies in transferring narrative texts
Terveyskylä.fi: Virtual Hospitals	A project launched in 2016 sees Finnish university hospitals jointly develop a national virtual hospital, which is intended to support

present infrastructure and specifically improve quality of and access to specialist care. Currently, multiple divisions (so-called "houses") are in place, expected to be expanded to more than 30 by the end of 2018.

C.3.2 Healthcare providers

In its current state the Finnish approach to digitised eHealth is characterised by multiple healthcare actors developing their own solutions. Regional Data Exchange Systems (RHIE) are one example healthcare organisations developing internal in-house interfaces or virtual private networks. Such networks have primarily been enabled by the Healthcare Act 1326/2010, which specifies the management and handling of public healthcare to build common patient registries for both, specialised and private care in each of the 21 hospital districts. Even though RHIE can exchange a multitude of data, their primary use lies in transferring narrative texts.⁷²

Besides aforementioned RHIE, several regional platforms that serve a broader purpose and function in an accordingly broader sphere can be identified. On a regional scale, cities such as Oulu and Hämeenlinna have been the initial drivers of digital efforts in healthcare in Finland. In 1991, the society for telemedicine, which is now called the Finnish Society of Telemedicine and eHealth, was formed, upon which the city of Oulu developed its Omahoito (self-help) platform. The platform experienced a significant growth of registered users from 12,000 in 2011 to more than 104,000 in January 2018, where the monthly count of log-ins reached 16,000. Most commonly used services have been booking appointments, contacting healthcare professionals, pre-natal services, renewal of prescriptions, and inquiring laboratory results. Two thirds of all users are women and the most active user group has been identified to be people over 65. The city of Oulu invests €1.5m annually in eHealth development through OuluHealth (one of the Oulu Innivation Alliance ecosystems which sees public and private stakeholders collaborating in healthcare research and innovation)⁷³ and has calculated that over €4m were saved during 2015-2017 because of the eHealth platform. Furthermore, the Oulu Innovation Alliance has developed a common piloting and deployment environment together with the Oulu university hospital (OYS), called OuluHealth Ecosystem. At the core of this environment is a platform – a "sandbox" – which uses a replica of EHRs and offers interfaces to IoT and mobile applications, as well as user interfaces for professionals and users. This environment allows for the piloting of new eHealth solutions and services in real-life healthcare context. For instance, the city of Oulu campaign, which was launched in early-/mid-2017, increased the use of eHealth in the region by staggering figures, some even going

⁷² Hyppönen, Hämäläinen, & Reponen (2015). E-health and e-welfare of Finland - Check point 2015 Available at: <http://www.julkari.fi/handle/10024/129709>

⁷³ OuluHealth (2018). About OuluHealth. Available at: <http://ouluhealth.fi/about-ouluhealth/>

as far as 70% in 2017 alone. In a similar vein, a pilot enabling school children to discuss and inquire about health-related issues with professionals through an online chat application, was too successful to simply be discarded and has now been adopted by all schools in and around Oulu.⁷⁴ A general key to further and sustain success will be to make the entire eHealth process more user-driven and allow for intensified involvement in the design, management, and application process of according systems, which appear to be predominantly designed according to top-down rather than bottom-up principles. In addition to regional initiatives, several companies, like IBM Watson, seem to enter the field with their artificial intelligence concepts, which claim to enable more efficient and effective access to the Finnish health and social care market.

C.3.3 Service users

In general, eHealth services and solutions have become increasingly popular in Finland especially over the past decade. The use of the My KanTa interface⁷⁵, for instance, has experienced exponential and significant growth, making it one of the most commonly used public eService applications amongst Finnish residents. This progress can be documented despite the fact that KanTa or My KanTa have not been promoted to residents through any systematic campaigns, which rather focused on professionals, instead. Abovementioned security measures have furthermore contributed to a seemingly high level of trust by users in digitised healthcare services in Finland - only about 1% of all users effectuated their right to limit access to their electronic health records. Transparency certainly plays a key role in this respect and is exemplified by the feature that patients can review whether a newly appointed doctor or any medical- or health-related actor had accessed the concerned person's medical records prior to first contact from the My KanTa website.⁷⁶ The most eagerly embraced tool within the My KanTa system is represented by ePrescriptions, which allows electronically issuing and renewing prescriptions, HIS mental health support and remote or eAppointments.

C.3.4 Developers

Most patient information systems were originally developed over a decade ago. The need to renew these is as evident as the potential that lies in entirely new applications and improved communication strategies, which have already proven to have considerably fostered and intensified the use of eHealth solutions in Finland. Generally, it can be stated that most actors involved in the health and social care domain show interest in redesigning and changing the entire governance of according systems. However, the mere expression of interest has too rarely been followed up by further actions and actual implementation. In fact, the current situation in the health and social care domain can be described as being rather reserved.

⁷⁴ Gilstad, H., Brattheim, B., Faxvaag, A. (2016). Comparability, availability and use of medication eHealth services in the Nordic countries. *International Journal on Advances in Life Sciences*, 8(1-2), 112-121.

⁷⁵ Kanta (2019). My Kanta Pages. Available at: <https://www.kanta.fi/en/my-kanta-pages>

⁷⁶ My KanTa serves as KanTa's online access platform

Accordingly, intensified planning work can be noted, however, actual investments in and grounded implementation of reforms and innovations remain unsatisfactory. This situation creates a vicious circle, in which actors within the system tend to prefer being responsive because of an unclear governance structure, and authorities do not seem to be able to formulate an effective legislative framework because of the sparse and dispersed response and acceptance dynamics prevailing in Finland.⁷⁷ A substantial part of this dilemma is the aforementioned highly decentralised healthcare system in Finland.

A potential field that might serve as a testbed and competitive advantage alike is represented by Artificial Intelligence (AI) and data analytics. In fact, AI and big data are representative of current issues on the application and development side, and therefore together form one of the core priorities of the Finnish government. As indicated, at the current state AI and big data analytics can only be used in a limited manner in eHealth, as current legislation on secondary use of generated data foresees the granting of permissions on a case-by-case basis, where data from e.g. KanTa can only be accessed per patient and for treatment purposes only. The corresponding law concerning secondary use of healthcare data is currently in preparation. It is expected that this legislation will extend the possibilities for secondary use of healthcare data for the purposes of scientific research statistical analysis, development, innovation, education and information management, and thereby replace the currently effective government Act on the Electronic Processing of Client Data in Social Healthcare Services (159/2007). It therefore does not come as a surprise that several ongoing projects and activities in the area of AI and big data can be noted. Kela's AI-based chat robot giving advice to customers, the detection of cancer cells using AI are only some of the most prevalent examples. The Finnish Medical Society "Duodecim" also engages in this subject and uses AI in its decision support system, which checks the compatibility of different medications using ePrescriptions and EHR data based on an interface through which both, citizens and professionals, can access health-related information. Moreover, KanTa already possesses a feature that would allow individuals to generate, collect, store and feed in their personally generated health data through IoT equipment or mobile applications that are approved by the Kanta services. However, this function is still in its trial phase and the user-generated data is currently for their own personal use only. Notably, in the future it is planned to provide users with the option of allowing their generated wellbeing data to be visible to social welfare and healthcare professionals.⁷⁸ An interesting point of view that offers an appropriate overview and understanding of the intertwined nature of the entire matter is provided by a study centred

⁷⁷ Suomi, R., Nykänen, P., Vepsäläinen, T., & Hiltunen, R. (2017). Green Turning Brown - Domain Engineering for Social and Health Services in Finland. MEDINFO 2017: Precision Healthcare through Informatics, 803-808.

⁷⁸ Kanta (2019). My Kanta Pages Personal Health Record. Available at: <https://www.kanta.fi/en/web/guest/wellbeing-data>

on Finnish eHealth start-ups⁷⁹. The emergence of such indicates the attractiveness of the entire sector, however, more importantly potentially paves the way for intensified network and system sophistication, improved quality and diversity of healthcare, and the sustainability of eHealth solutions.

C.3.5 Demand stimulation

A recently conducted study concluded that about 2/3 of all respondents were familiar with the My KanTa service, where younger customers showed a higher rate of familiarity. In fact, those aged 75 or above were significantly less likely to know and engage with the system. Respondents with a higher educational level were more likely to be familiar with the service than those with lower educational attainments. ePrescriptions being one of the key features of My KanTa, about 96% of all respondents who had used this specific feature were satisfied with its performance and usability. In total figures, the use of My Kanta and its economic dimensions can be approached as follows: In July 2018 alone, more than 1.1 million log-ins were registered on My Kanta by about 530,000 people. Moreover, the patient data repository's count of documents stored exceeded 1.2 billion in July 2018. Prescriptions issued through KanTa exceeded 61 million in 2017 and dispensing followed suit with a volume of nearly 32 million in the same year.⁸⁰

C.4 Socio-economic benefits of eHealth

Digitised healthcare is a distinctively politicised and politically-steered domain that has therefore also experienced influences and ambitions accordingly. In fact, such ambitions form some of the main political drivers to foster eHealth in Finland. Specifically, access to healthcare and increased quality of healthcare are considered among the most desired and expected socio-economic benefits of eHealth applications. For instance, authorities aim to grant better access to health and medical care especially in remote regions. At the same time, the quality of concerned care is desired to be improved through a streamlined allocation of resources or faster, less complicated and more personalised treatments. In addition, cost savings are anticipated through both, direct (e.g. less in-house visits) and indirect (e.g. better health statuses through improved healthcare) means.

However, the effective identification of socio-economic benefits disseminated by eHealth solutions is as unclear as it is difficult. The main obstacle is represented by a general lack of motivations to monitor the actual economic and social impact of digitised healthcare services in Finland, as the focus has largely been on monitoring the introduction, distribution and use of eHealth services rather than effectively measuring and conceptualising their impact. Some

⁷⁹ Saarela, M., Örtqvist, D., Simunaniemi, A.-M., Muhos, M. (2017). Critical Incidents of Growth in Nordic eHealth Service Start-Ups. *Management*, 12(2), 151-131.

⁸⁰ Kela (2019). Significant increase in the use of Kanta services. Available at: https://www.kela.fi/web/en/news-archive/-/asset_publisher/IN08GY2nIrZo/content/significant-increase-in-the-use-of-kanta-services

(anecdotal) benefits, however, can be generally expressed and anticipated. For instance, many imaging analyses and laboratory tests are often performed in a routine manner. It is assumed that access to real-time electronic health records is likely to reduce the need for these analyses and tests, and thereby reduce the costs of the entire healthcare system. There are also other similar cases, where unnecessary examinations and tests can be eliminated, e.g. by using population health data analysis for screening purposes. Another example is represented by the integrated Finnish ePrescription system, which can detect misuse of pharmaceuticals, monitor the overall pharmaceutical use and detect potential problems arising from combinations of pharmaceuticals, etc. This is likely to not only improve patient safety, but also minimise expenses on pharmaceuticals. Further considerations that particularly stress the improved time-efficiency boosted by eHealth solutions are represented by a (theoretically) streamlined prescription renewal process, or an intensified use and coverage of eConsultations, which reduce relative distances and thereby enable faster consultations for a higher number of patients. Ultimately, economic benefits depend on legislative conditions, the present infrastructure, practice, the harmonisation of these elements, and how well all notions are implemented and used by concerned actors in the healthcare domain. It is also important to keep in mind that comparing public and private healthcare is difficult, if not impossible. The respective business logic is fundamentally different as the public sector aims at reducing the need for healthcare services by optimising the use of its critical resources, whereas the private aims at maximising the number of clients.

Similar to economic benefits, the evidence on social benefits is rather difficult to single out and grasp and therefore disputed. Nonetheless, certain assumptions and educated impressions could be gathered within the scope of this study. For instance, public perception is that the introduction of eHealth improves the quality of healthcare. A crucial element for the positive social response to eHealth (which is also a contributing factor in its effectiveness) is how eHealth use, its benefits, applications is communicated to citizens. Studies conducted in Finland show that if users receive appropriate support in learning how to interact with eHealth solutions, then eHealth supports the sufficient and timely provision of child psychiatric services in remote and sparsely populated areas of Finland. It is especially these thinly populated areas in which an intensified use of eHealth can come along with significant social benefits by increasing patient access to timely healthcare provision.⁸¹

⁸¹ Bykachev, K., Turunen, O., Sormunen, M., Karppi, J., Kumpulainen, K., & Turunen, H. (2017). Booking system, video conferencing solutions and online forms for improving child psychiatric services in the Pohjois-Savo region. *Finnish Journal of eHealth and eWelfare*, 9(2-3), 259.

Appendix D Slovenia country profile

D.1 Healthcare system and its institutional structures

D.1.1 Legal and financial framework

Healthcare system In **Slovenia** is very centralised, uniform across the country and based on the compulsory healthcare insurance system, which includes about 99% of population. Functionally, it consists of prevailing public health care service providers, from local community health care centers to hospitals, while the private initiative in this field still plays more complementary role. Private health care services, prevailing at the secondary level, specialist and consultancy services, which are payable, represent less than 10% of the market. The Ministry of Health (MH) is the responsible authority for the overall national health care system, legal framework, policy design, operation of the health care system and its monitoring. The Ministry is supported by the two main agencies - The National Institute for Public Health and National Insurance Institute of Slovenia.

The National Institute for Public Health (NIPH)⁸² is the key national health policy, professional and monitoring agency in the field of public health, currently also responsible for the development and operation of all eHealth infrastructure, solutions and services.

Next to it is the National Insurance Institute of Slovenia (NIIS)⁸³, in essence a public health care insurance company, whose basic function is to collect all contributions payed by the employees within the compulsory health insurance system and efficiently distribute collected money among providers of health services, i.e. cover the expenses for the services. In Slovenia, this represents more than 90% of funding for public health services. In order to provide some additional funding, there are some voluntary insurance schemes provided by private insurance companies for non-standard, more expensive services or services not covered by the compulsory health care insurance system.

The Ministry of Health is responsible for the legal regulation in the field of eHealth. The fundamental legal act which established the formal framework for the development of e-commerce in Slovenia was 'Electronic Commerce and Electronic Signature Act' (ECESA)⁸⁴ from 2001. The operation and functionalities of the eHealth solutions are regulated by the special 'Healthcare Data Records Act' (HDRA)⁸⁵ from 2000, amended in 2011 and 2015. This act covers the collection, processing, archiving, usage of data and database management in the entire field of healthcare in Slovenia, including all eHealth services, responsible stakeholders and beneficiaries. It clearly specifies responsibilities on the side of service

⁸² NIPH (2018). Nacionalni inštitut za javno zdravje. Available at: <http://www.nijz.si/>

⁸³ NIIS(2018).Zavod za zdravstveno zavarovanje R Slovenije. Available at: <https://www.zzzs.si/>

⁸⁴ ECESA (2018). Zakon o elektronskem poslovanju in elektronskem podpisu – ZEPEP. Available at: <https://zakonodaja.com/zakon/zepep>

⁸⁵ HDRA: Zakon o zbirkah podatkov s področja zdravstvenega varstva – ZZPPZ available at: <http://www.pisrs.si/Pis.web/pregledPredpisa?id=ZAKO1419>

providers concerning the content of collected data, data security and privacy rules, as well as the authorised users of these data. Until 1 December 2015, the National eHealth Project (NHP)⁸⁶ was under the authority of the Ministry of Health of the Republic of Slovenia. After that, the management of information solutions created within the National eHealth Project was taken over by the National Institute for Public Health – NIPH.

According to the HDRA, NIJZ is currently responsible for strategic planning, coordination, development and implementation of an integral national health information system in Slovenia as well as for the development of all nation-wide eHealth services. NIPH has been also authorised as the responsible authority concerning collection, maintenance and use of all medical databases as well as granting access to this data to other stakeholders and commercial users. In the principle, only health care service providers are authorised to access this data.

Further development of health care system in Slovenia, is currently outlined in “Resolution on National Plan of Health Care between 2016-2025” (RNPHC)⁸⁷, passed by the Parliament in 2016. This key national health care policy paper specifies the framework and the key points of further development of eHealth in Slovenia, it specifically states the following general building blocks and services:

- Integration of all existing health information systems in the country.
- Continuation and upgrade of the National eHealth Project until its full implementation.
- Development of all necessary interoperability standards and interfaces to provide reliable and secure data exchange among all eHealth stakeholders in the country.
- Development of m-Health applications, which will provide easier access to health services in the country.

The resolution also specifies some specific tasks and goals:

- The new law on health care data records (until 2021).
- Integration of IT solutions, systems and full operation of EHR/PHR (until 2021).
- Unified standards for health data exchange among all stakeholders in Slovenia (until 2021).

The decreasing accessibility of services, longer waiting times, financial instability of the health care system over the last years, lack of finances for technological and professional development of the whole system are all calling for the profound reforms which are high on the agenda of the new government, in office since September 2018.

⁸⁶ NHP (2018). Nacionalni projekt eZdravje'. Available at: <http://www.ezdrav.si/ezdravje/>

⁸⁷ RNPHC (2016). Resolucija o nacionalnem planu zdravstvenega varstva 2016–2025 »Skupaj za družbo zdravja« (ReNPZV16–25). Available at: <https://www.uradni-list.si/glasilo-uradni-list-rs/vsebina/2016-01-0999?sop=2016-01-0999>

D.1.2 Data management and IT infrastructure

Data management and related eHealth ICT infrastructure in **Slovenia** is centralised, on the national level and managed by the two key institutions. The National Insurance Institute of Slovenia (NIIS) is responsible for all data management, development of respective ICT infrastructure and solutions related to the health care beneficiaries (personal data). Further, they contribute into the public health care system with data related to financial flows (payment of services) between consumers of public health services and health care service providers at all levels of the health system. NIIS also manages all ICT infrastructure related to the issuing, usage and management of 'Electronic health care identity card' (EHCIC) which serves in Slovenia as a digital certificate within the entire public health care system.

Data management and related ICT infrastructure for all other eHealth services, including portal zVem and the telecommunication backbone network zNet is under authority of the National Institute of Public Health (NIPH). In addition to this 'national' infrastructure, all hospitals have their own internal business and medical information systems, their own ICT solutions and related infrastructure, which is not yet fully integrated into the national eHealth system.

The national eHealth architecture is designed around zVem platform which connects health care providers and users, incorporates CRPD (Central Repository of Patient Data with EHR and PHR) and allows data exchange via dedicated network zNet between all stakeholders, relevant databases and also eServices like ePrescriptions, eReferrals etc. All health care service providers are obliged to send relevant data to CRPD. Patients can access their own data via digital certificate. Medical personnel has access to these data via their own professional health eID card restricted according to their privileges.

According to the estimates of the experts, the level of digitisation of Slovenian health care system varies among the institutions, it reaches over 60% in the least digitised hospitals to almost 100% in the most advanced. The most comprehensive information system is the new Paediatric Clinic in Ljubljana, which operates almost paperless. In the rest of the health care system, the level of digitisation varies similarly. Many information systems in the hospitals are fragmented and not yet fully integrated/compatible with the national infrastructure. This is one of the main reasons why CRPD is not yet fully updated on a daily basis and that many documents related to the patient treatment in the hospitals are not yet uploaded to CRPD.

The responsibility for development and maintenance of the eHealth solutions and services in Slovenia is in the hands of management of NIIS, NIPH, management of hospitals and also some smaller community healthcare centres. The eco system in which this development takes place has in Slovenia some specifics. Almost all development was outsourced in the past to some 10-15 private IT companies. Selection is by the rule based on the open public tendering. Selected IT developers must have respective references and be certified for work in the health care sector and management of the sensitive personal data. However, due to the small size of the market and small number of qualified developers even public tendering

brings to the surface for all bigger projects more or less the same IT companies. There are few IT companies who hold the biggest market share.

D.2 Digitisation of healthcare

D.2.1 History, recent developments, future directions

First steps toward computerisation of health care system in Slovenia began in 80s with the establishment of the national electronic register of healthcare taxpayers, which includes nearly 99% of the population. This database has been directly linked to the national population register, which has been created in electronic form even a few years earlier. In 1995, a project aiming to introduce electronic health care insurance card was launched at NIIS and completed in 1999/2000. At that time, all citizens included in the national health care system (99%) received electronic health care identity cards based on smart card technology. The electronic health care identity card contained a digital certificate, data about health care insurance and some important medical data (blood type, data on special diseases, allergies, etc.). All medical service providers were equipped with special eHealth identity card readers. With this card the owners could easily access all health services in the country which means that all health care service providers from GPs, specialist clinics, hospitals to pharmacies are obliged to use this system. The same eHealth identity card is still in use today, but it only serves as a digital certificate for identification of patients and authorisation of payments within the health care system. Since 2008, all other individual insurance and medical treatment data has been stored in the central data base maintained at the NIIS.

In line with the EU initiative, Slovenia launched its first eGovernment strategy in 2001⁸⁸ but this strategic plan did not cover the field of health care. In 2005, Ministry of Health launched comprehensive strategic National eHealth Project (NHP) with three main objectives:

- To establish a unified health information system.
- To establish a central unit for development and implementation of eHealth solutions.
- To redesign and modernise processes, procedures and services of the public health system.

According to the initial strategy, the whole project was to be completed by the year 2015. After a promising start in 2006/2007, the project essentially came to a halt in 2008 due to the global financial and economic crisis. Later on, political instability in the country (frequent changes of the governments), lack of political support, bad project management and lack of funding caused that very little progress was made until 2015. During this period, many stakeholders (in particular larger hospitals) went with development of their own information systems and solutions. This uncoordinated development period that lasted for almost a decade represents one of the most serious barriers to integrate all health information systems and services in the country.

⁸⁸ Vlada Republike Slovenije. Strategija e-poslovanja v javni upravi R Slovenije. Available at: www.vlada.si/fileadmin/dokumenti/si/projekti/projekti.../strategija_e-poslovanja.pdf

Since 2015, the economic recovery of the country has contributed to significant progress in implementing and using eHealth solutions in Slovenia. Observing the dynamics of events since the first promotion of NHP in 2005 it is evident that important progress over the last three years was made. In particular, implementation of vital eHealth solutions like ePrescriptions and eReferrals/eAppointments on a national scale represent a breakthrough in the field of digitisation of health care services in Slovenia. By 2018, most of the services planned as part of NHP were implemented⁸⁹ while the future development of this area is not so clear.

D.2.2 Cross-border implementation of eHealth

According to the EU directive on cross-border health services (Directive 2011/24/EU on patients' rights in cross-border healthcare) national resolution RNPHC also recognises the importance of development of all necessary infrastructure and service in order to stimulate faster development of cross-border health services, in particular with the neighbouring countries. The first step was the establishment of the portal of the National Contact Point (NCP) for information exchange on cross-border health services.⁹⁰ This portal provides all relevant information for Slovene citizens seeking health services in other EU member states and providing relevant health service information for visitors of Slovenia.

There have been several bilateral projects launched in order to develop a framework for cross-border eHealth services. In 2013, a bilateral eHealth project between Slovenia and Italy (named e-HEALTH) was launched as part of the Interreg Programme financed by the EU.⁹¹ Within this project, an interoperability backbone has been developed accessible via a special website, which enables exchange of medical documents between medical institutions on both sides. Since 2014, NIIS uses IT solution, which enables exchange of data referring to expenses of urgent medical treatments of Slovenian citizens abroad and vice versa, with other EU MS. In October 2017, the Republic of Slovenia applied for funding through the Connecting Europe Facility 2014-2020 mechanism (CEF Telecom Call CEF-TC-2017-2). The main objective of this application was to support the establishment of the NCP and related efforts to become a part of a secure peer-to-peer network allowing the exchange of Patient Summaries and/or ePrescriptions with other EU MS, which will pave the way for the following general objectives. The project is approved and will begin in 2019.

D.2.3 Pathway integration. Diabetes journey

Regarding eHealth solutions that facilitate treatment for patients suffering from diabetes, Slovenia does not have any diabetes-specific eHealth services in place (unlike Finland, where

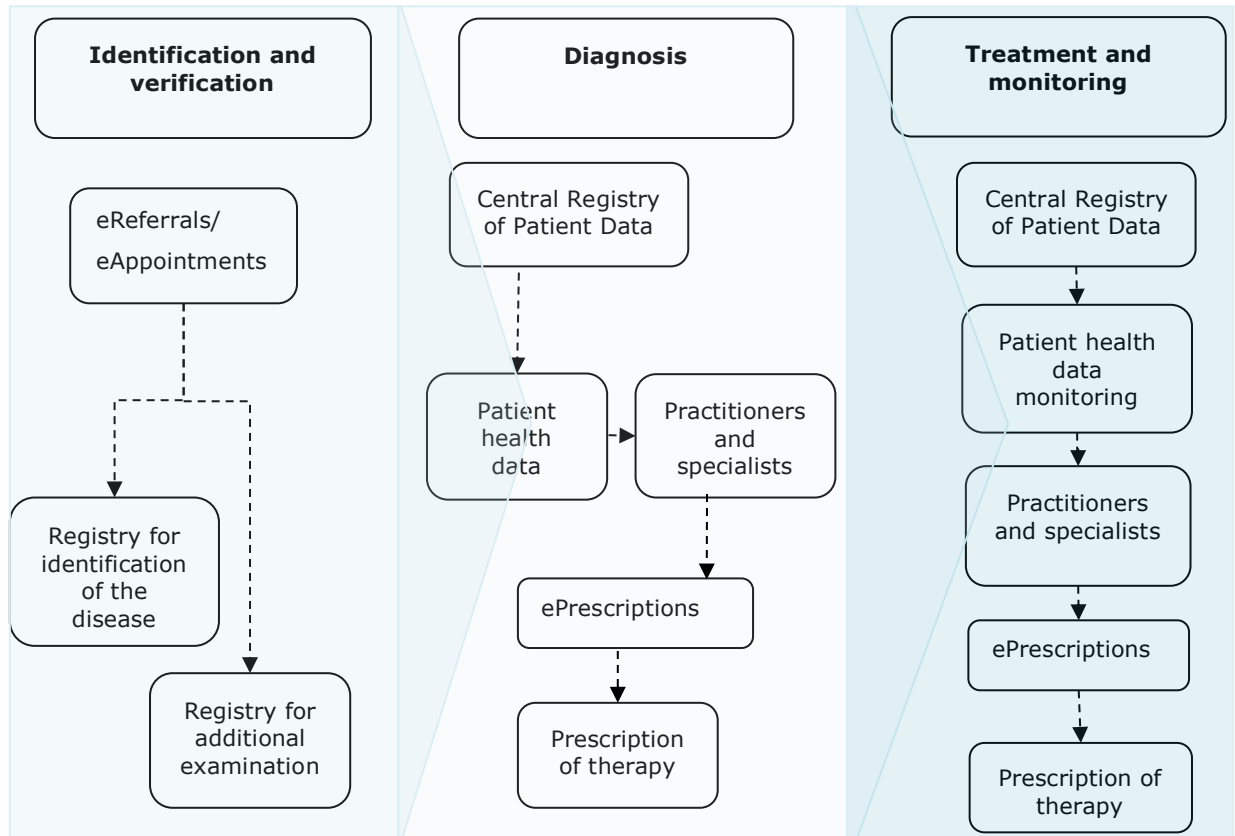
⁸⁹ Rant Živa et al. (2017). eZdravje danes. Uporabna informatika., Št. 3, letnik XXV, 2017

⁹⁰ Republika Slovenija Nacionalna kontaktna točka za čezmejno zdravstveno varstvo (2019). Portal of the national Contact Point. Available at: www.nkt-z.si/wps/vanityurl/NKT-Z_Domov

⁹¹ Parsek (2013). Cross-border clinical healthcare record. Available at: <https://parsek.com/references/cross-border-clinical-healthcare-record>

specific solutions are in place). Therefore, by exploring eHealth solutions available to diabetics we are essentially looking at the general eHealth system of Slovenia. Thus, in the following paragraph we present how a diabetes patient may seek treatment by engaging with the eHealth system that is in place in Slovenia.

Figure 5. Identification, verification, diagnosis, treatment and monitoring of diabetes in Slovenia using eHealth solutions



Source: ESPON (2018)

eHealth system in Slovenia has been designed at the national level as horizontal integral system covering the whole health care system in the country. System integrates and links all three levels of the health care system into an integrated ePlatform, accessible and available to all patients and all service providers in the country. This means in the practice that regardless of entry point, i.e. at the local community GP centre, specialist clinic or hospital the stakeholders have access to the same integrated set of services and via platform zVem also to the same set of patient-related medical documents.

The most used basic integrated services are the eReferrals/eAppointments that integrate primary, secondary and tertiary level of health services. And the CRPD, when fully used, provide via zVem all key documents and information to all stakeholders in a patient pathway across the national health care system.

From the point of view of eHealth services, diabetes patients in Slovenia don't represent any special case and they use all regular eServices. At the moment, the weakest points of the

whole system are numerous internal hospital information systems, many of them not yet fully integrated with the national interoperability backbone and therefore not yet sending all relevant medical documents to the CRPD.

D.3 Most prevalent eHealth applications and their use

D.3.1 eHealth applications directions

In **Slovenia**, the eHealth solution landscape is by large the result of the implementation of the National eHealth Project launched in 2005 and successfully finalised in 2018. NHP has been focusing on the infrastructure, solutions and services, consolidating the fragmented digitisation efforts developed by individual institutions, which represent the backbone of the national eHealth information system in Slovenia. All highlighted solutions and services that were developed on a national level, are now available for the whole state and accessible to all healthcare service providers in the country (of which some, i.e. ePrescriptions, are mandatory for healthcare providers). The list does not include numerous eHealth solutions developed at different hospitals and internally used.

Table 3. eHealth solutions in Slovenia

Service	Description
Central Registry of Patients' Medical and Personal Health Records (CRPD)	Introduced in 2017 the CRPD includes all medical documentation related to a patient (EHR) and a summary of Patient Health Records (PHR). However, CRPD still does not contain all medical data records of the patient, as certain healthcare providers still do not send all documents to the CRPD. Patients can access their personal EHR through the zVem platform using a digital certificate. According to the available data in May 2018 at least 80% of the patients had at least one document in the CRPD and about 36% of patients had summary of their patient records. The trends indicate that the usage of this database is growing very fast.
zVem	The national eHealth platform ⁹² , launched in 2016, which gives all citizens and medical institutions/professionals safe access to information about health service providers, all key eHealth services, waiting times, access to CRPD, i.e. EHR and PHR etc. Access to zVem portal in order to get information about health services, service providers, waiting times etc. is open. Access to CRPD requires relevant digital certificate.
ePrescriptions	Introduced in 2016 on a national level and its use is mandatory for all health service providers in the country. All ePrescriptions are stored in the CRPD and in 2018 more than 92% ⁹³ of all prescriptions issued were digital. Physicians issue paper-based prescription only exceptionally at special circumstances (i.e. visits at home). The main aims of the application were to increase quality of the services for the patient with reducing number of errors, better overview over prescribed drugs individually as well as cumulatively, simplification of the procedures, reduced administrative costs, less visits to the GPs etc. All pharmacies in the country have access to the central database of ePrescriptions.

⁹² zVem (2018). Portal zVem. Available at: <https://zvem.ezdrav.si/idp/register-start>

⁹³ Nacionalni inštitute za javno zdravje (2018). Uveljavitev eRecepta in eNaročanja v slovenskem zdravstvu. Available at: <http://www.nijz.si/sl/uveljavitev-erecepta-in-enarocanja-v-slovenskem-zdravstvu>
NHP (2018). Nacionalni projekt eZdravje'. Available at: <http://www.ezdrav.si/ezdravje/>

	According to the public opinion surveys, more than 90% of the patients are very satisfied with the service.
eReferrals/eAppointment	Implemented in 2017 on a national level eReferrals/eAppointments are mandatory for all GPs in Slovenia equipped with the application that enables issuing of electronic referrals. All eReferrals are collected in the CRPD in EHR and accessible to health service providers. Healthcare service providers must daily update central database on waiting times and free capacities. In this way, via zVem health portal, patients get information on relevant service providers, waiting times etc. They can select the hospital or clinic, in which they want to be examined or treated and make an appointment via eAppointment service. In August 2018, the percentage of eReferrals exceeded 96% of all referrals issued.
Information sharing solution(s)	
Teleradiology	This system ⁹⁴ enables transmission and exchange of all radiologic data/images between points of examination and all other Slovenian hospitals and/or medical centres included in the system. Currently there are 19 medical centres included in the service, but the usage is low because the financial burden/division of costs is not clearly defined.
Hospital/Medical institutions	
eTriage	Based on the Manchester Triage System, eTriage ⁹⁵ assists medical personnel in cases of large numbers of incoming patients who cannot be treated simultaneously. Its aim is to help identify patients who cannot wait safely and need urgent treatment. Currently only three medical institutions are included in the system, the reason for low usage being weak integration with the back-office systems.
Prevention solution(s)	
Telestroke	This is one of the most successful services within the whole eHealth system in Slovenia in terms of death prevention, since it very efficiently contributes to the successful treatment of stroke ⁹⁶ . The system was introduced in 2015 and works via an audio-visual conference system. It includes 12 regional hospitals in the country, thus covering the whole territory of the state. At the time of reporting (September 2018), more than 2500 patients were treated.
Infrastructure and communication solution(s)	
zNET	Special private eHealth backbone telecommunication network ⁹⁷ , available and in use among all health care stakeholders in the country. It provides secure and reliable exchange of all medical data/documents among all health care entities in the country on the basis of a unique interoperability protocol, which simplifies exchange of data/documents between different users.
Electronic health care identity card (EHCIC)	Represents the key infrastructural element in the whole structure of eHealth services in Slovenia. It is a digital certificate used within the healthcare system compatible with international standards. There are two types of EHCIC, one for the users of the services/patients and 'professional' EHCIC for the medical staff. Introduced nearly twenty years ago, but it is still not clear what the future role of it is going to be. Namely, Slovenia did not yet

⁹⁴ eZdravje (2018). Teleradiologija. Available at: / <http://www.ezdrav.si/category/projekti/teleradiologija/>

⁹⁵ eZdravje (2018). E-Triaža. Available at: <http://www.ezdrav.si/category/projekti/etriaza/>

⁹⁶ Nacionalni inštitute za javno zdravje (2018). Uveljavitev eRecepta in eNaročanja v slovenskem zdravstvu. Available at: <http://www.nijz.si/sl/uveljavitev-erecepta-in-enarocanja-v-slovenskem-zdravstvu>

⁹⁷ zNet (2018). Portal zNet. Available at: <http://znet.ezdrav.si/>

introduce the electronic identity card. In order to access eGovernment services, citizens need 2 separate digital certificates, one for general public services accessible via national eGovernment Portal and another for health care services – the electronic healthcare identity card, both based on a smart card technology.

There are probably two the most serious problems concerning further digitisation of Slovenian health sector. First, is related to a big gap between those institutions/hospitals, which are almost fully digitised and those which are lagging quite far behind. Second is referring to the lack of interoperability between various internal information systems and the central eHealth infrastructural databases. These makes further integration of data and services over the whole health care system in the country very complex. Namely, most of medical data and documents are being stored today in a number of technologically and semantically very diversified health care information systems developed and owned by different stakeholders (mainly hospitals and community health care centres) over the last 15 years.

D.3.2 Healthcare providers

Generally, all eHealth services were introduced at the national level and their usage is mandatory for all stakeholders, GPs, hospitals, medical staff, pharmacies and patients. All service providers are providing all key information relevant to the patients via web sites and are requested to promptly answer to all patients inquires and requests. E-mail has become more efficient communication means with service providers, in particular hospitals, than phone. All health care providers in the country are obliged to use all 'horizontal' eHealth services like ePrescriptions, eReferrals/eAppointments and deliver medical documents to the CRPD. Despite these, some GPs clinics are still reluctant concerning the use and recognition of the advantages of eHealth services. Main problem is lack of financial resources, lack of equipment and lack of incentives in general. Since the use of key services i.e. ePrescriptions and eReferrals is mandatory they complain about the rigidity of the system and administrative burdens. Some providers complain that there is no financial motivation for more active use of these solutions. For some health care providers the 'annoying' factor is the transparency of the services, waiting queues, resources used etc.

D.3.3 Service users

Regarding service user indicators, Slovenia is not among the top-performers in the EU. For example, according to International Telecommunications Union (ITU)⁹⁸ statistics based on the overall ICT development in 2017 Slovenia ranked 22 in Europe while in 2018 the Digital Economy and Society Index (DESI)⁹⁹ ranked Slovenia 15 in the EU for ICT development.

⁹⁸ ITU (2017). Available at: https://www.itu.int/en/ITU-D/Statistics/Documents/.../misr2017/MISR2017_Volume1.pdf

⁹⁹ European Commission (2018). Digital Economy and Society Index Report 2018 Digital Public Services. Available at: ec.europa.eu/information_society/newsroom/image/document/2018-20/5_desi_report_digital_public_services_B5DBE542-FE46-3733-83C673BB18061EE4_52244.pdf

Furthermore, according to DESI Slovenia ranks 16 in the EU for the use of digital public services.¹⁰⁰ According to the Eurobarometer 2017, more than 25% of citizens in Slovenia used health and care services provided on-line in the last 12 months (which is well above the EU average) while in general the usage of online public service in Slovenia is just above 50% (below the EU average)¹⁰¹. Since the usage of ePrescriptions became mandatory in 2016, awareness about benefits of eHealth services spread rapidly which contributed to rapid increase of usage of other eHealth services in particular the portal zVem. Access to eHealth services via zVem portal is enabled via broadband internet using qualified digital certificates but some services, like eAppointments are not yet fully reliable. Access to eReferrals is possible without digital certificate. Appointments for medical treatments via application eAppointments is still restricted to selected number of medical services.

According to the survey made by Slovenian Consumers Association¹⁰² in 2018, most patients support the usage of eServices. More than 80% of users/patients have positive experience with eReferrals and more than 90% with ePrescriptions. Unfortunately, the specialised health care portal zVEM is still rather new and quantitative indicators for the portal and its use are not yet available. However, it is notable that the portal enables access to central database of ePrescriptions, eReferrals/eAppointments to the most secondary and tertiary health services, waiting lists for all medical services in the country, as well as access to the central CRPD (EHR/PHR) database. According to the available data, awareness about eHealth services and functionality of the health portal zVEM is growing very fast. Usage of the portal is growing every month and majority of customers is satisfied with the service. These indicators do suggest that in a few years eHealth services could become the most used public service in Slovenia

D.3.4 Developers

Almost all ICT development in the field of eHealth solutions has been contracted out to the private software companies, which are competing in public tenders. Contracts with selected developer normally include covering the costs for development and testing of a solution as well as maintenance costs for specified number of years. Slovenian market is very small, competition from inside as well as outside of the country became very strong and developers are complaining that they work and compete in a very unpredictable environment, which is not good stimulus for efficient further development. Developers are outlining the following challenges and weaknesses of the current situation in particular:

- lack of long-term strategies and clear vision about further eHealth development.

¹⁰⁰ European Commission (2018). Digital Economy and Society Index Report 2018 Digital Public Services. Available at: ec.europa.eu/information_society/newsroom/image/document/2018-20/5_desi_report_digital_public_services_B5DBE542-FE46-3733-83C673BB18061EE4_52244.pdf

¹⁰¹ European Commission. (2018) Digital Single Market Slovenia. Available at: https://ec.europa.eu/digital-single_market/en/scoreboard/slovenia

¹⁰² ZPS (2018). Slovenian Consumers Association portal. Available at: <https://www.zps.si/>

- weak political support at the national level.
- lack of stable financing.
- market fragmentation which prevents return of investments/development/maintenance costs.
- reluctance of some health care providers in implementation of eHealth services in light of the missing financial incentives from the state.

D.3.5 Demand stimulation

Most health service providers are complaining that there is no incentives and financial compensation for implementation of eServices, which often require additional training of medical staff and additional equipment. National Institute for Public Health is officially responsible for further development of eHealth in the country, but very weak in terms of available staff and 'motivating' instruments of enforcement for the implementation of eHealth policies. For instance, in the last two years when the two key services were implemented (ePrescriptions and eReferrals), there was strong opposition and even obstruction by many service providers who expected additional funding for the necessary additional equipment or some other incentives, which they did not get.

In addition, service providers were aware that digitisation of these important services brings much more transparency into the work of all levels of the health care system, from general practices to hospitals, and enables overview of services planned and delivered, the number of prescriptions issued, the use of drugs per patient etc. Many stakeholders did not like the idea of efficiency (or more appropriately lack of efficiency) becoming visible and measurable. NIPH has neither legal nor financial power nor levers to enforce faster implementation and use of new eServices. NIIS, which is a single public payer of all health services, should have been, at least from the economic perspective, the party most interested in digitisation of the health care system and its efficiency. But so far, it didn't develop any incentives for service providers to make them more interested in the whole digitisation process.

Luckily, the usage of almost all horizontal key eServices (like ePrescriptions and eReferrals) became mandatory immediately after their implementation for all health service providers. Resistance at some health service providers faded out after a few months of testing and implementation. Hence, the promotional activities have been focused mainly on the patients and on those eHealth services, which are still optional, like the usage of portal zVem and CRPD. There are three main instruments in use to raise awareness and stimulate usage:

- Portal zVem offers all relevant information about available eHealth services in Slovenia to the internet users.
- Special leaflets available at all health care centres informing patients about individual eServices and their usage.
- Social networks.

D.4 Socio-economic benefits of eHealth

Despite progress made in the last few years, the future trends and directions of development of eHealth solutions are rather vague. Currently, there are no comprehensive plans,

strategies or action plans whatsoever for the future of eHealth in Slovenia beyond 2018. The already mentioned RNHPC 'is specifying some very general goals concerning future eHealth in Slovenia after 2018 and until 2025. But it lacks in detail. Digitisation of public sector activities and services is generally regarded as the key instrument for improving the quality of public services, accessibility and transparency on the one hand and reducing the costs on the other. In order to achieve all these objectives, digitisation should go hand in hand with profound organisational transformation of respective structures and processes. So far, development of eHealth solutions and services in Slovenia did not strictly follow that trajectory. It did not trigger deeper organisational transformations in the healthcare sector at all. There was no profound renovation of business and medical treatment processes. Processes and procedures in the healthcare system were left by the rule untouched, with almost all redundancies from the past.

Rather than following clear functional, economic and/or social agenda, development of eHealth so far was primarily technology driven. Saying this, it does not mean that there will be no social and economic effects in the healthcare system as a whole, but these will happen more as side effects rather than primary goal.

Comprehensive evaluation of the effects of eHealth solutions in Slovenia on the quality and availability of health services is still missing. What we do have are partial estimations and observations of different experts who were involved in the healthcare system before and between implementation of eHealth services. General opinion among all stakeholders outlines the following expected benefits:

- Easier access to public healthcare services.
- Better quality of services in terms of less paper work for the patients, reduced administrative costs, less unnecessary visits in person to healthcare institutions.
- More efficient use of drugs.
- Better control and overview over the prescribed drugs to the individual patient.
- Higher transparency of the system, which contributes to better use of resources, shorter waiting queues and more just treatment of the patients.
- Better informed patients.
- Better communication between the service providers and the patients.

From the point of view of an average patient, there are two services which affected the availability and quality of health services the most visibly, these are ePrescriptions and eReferrals/eAppointments. ePrescriptions almost completely replaced classical paper-based prescriptions (apart from a few exceptions, for instance when GP visits patient at home) in everyday medical practice. Application linked GPs with pharmacies which have access to all ePrescriptions of the patient via his/hers eHealth identity card. This enabled patients to get some prescriptions without visiting the GPs, for instance in the case of chronic diseases when patient is taking the same drug for a longer period of time. Less visits to the GPs will in turn have positive financial effects for the taxpayers. Nevertheless, the central base of

ePrescriptions is archiving a huge amount of data available and very useful for different medical studies.

Of course, there are high expectations concerning positive effects and impacts on the healthcare system in general. However, reliable qualitative and/or quantitative data in this respect is still scarce. More systematic surveys and evaluation of the whole domain of eHealth is required in the future.

Appendix E Bulgaria country profile

E.1 Healthcare system and its institutional structures

E.1.1 Legal and financial framework

The development of electronic healthcare and the digitisation of healthcare processes is a key initiative and a crucial milestone in the Bulgarian governance action plan since 2008. Despite the number of national strategies devised for it, its implementation to date remains minimal at best, with no pilot projects launched and no tangible results to show even marginal economic or social benefits. In short, within the last 10 years, the Bulgarian government and Ministry of Health have spent over €10 million of the EU funding and has produced 3 largely similar and overlapping National Strategies for the Development of Electronic Healthcare, none of which have been put into practice.

The key document regulating the public eHealth development initiatives in Bulgaria is The Law for Electronic Governance, which provides each Minister, including the Minister of Health, with the power and duty to prepare a sectorial digitisation strategy and to propose it to The National Council of Ministers for approval. The National Healthcare Strategy 2008-2013 (and accompanying Action Plan) was duly accepted and approved in 2008. It planned the creation of a Coordination Committee which was to create an action plan and monitor its implementation and progress. At the end of the planning period and also to present date, the Ministry of Health has not provided any data regarding the creation of such Committee, its members, sessions done, or actions taken leading to the conclusion that by the end of 2013, the National Healthcare Strategy 2008-2013 had no noticeable achievements.

New efforts to introduce digitisation of healthcare services were made with the National Healthcare Strategy 2014-2020. The document was initially rejected by the National Assembly and was later ratified and accepted with corrections in December 2015. In December 2014, one year before the modification and ratification of the final National Healthcare Strategy 2014-2020, the Ministry of Health approved and proposed for public discussion the Programme for the Development of Electronic Healthcare, an implementation plan for the National Healthcare Strategy. Its key goal was the creation of a National Health Information System – a process mapped to cover the 2014-2020 period in three separate stages. By design, the creation and the implementation of the System required the partnership and participation of the National Health Insurance Fund (NHIF). Despite that, the NHIF was neither consulted nor participated in the creation of the Programme, its action plan or its road map. Not surprisingly, the 2016-2017 Healthcare Audit performed by the National Audit Office showed no real progress on the Programme. At the time of the Audit, in 2016, the Ministry of Health prepared and launched a (new) Strategy for Electronic Healthcare, again without the active participation of the NHIF or the National Centre for Public Health and Analysis (NCPHA). By the time the Audit ended in February 2017, the Strategy was not

approved and accepted and there is no further related information to date, meaning that the (new) Strategy for Electronic Healthcare is not yet approved, let alone implemented.

What is more, as the 2016-2017 Healthcare Audit duly notes, the implementation plan of the National Healthcare Strategy 2020 diverges significantly from the Strategy itself. The plan completely omits key eHealth solutions – like the electronic health cards for patients and electronic patient records – and crucial topics – like information security measures and personal data collection. Differences are noticeable even in terminology, with the Plan referring to the eHealth solutions described in the Strategy by using new or modified names and abbreviations. These inconsistencies and gaps in continuity signal an erratic and incoherent governance effort and do not bode well for the future development and implementation of public eHealth solutions.

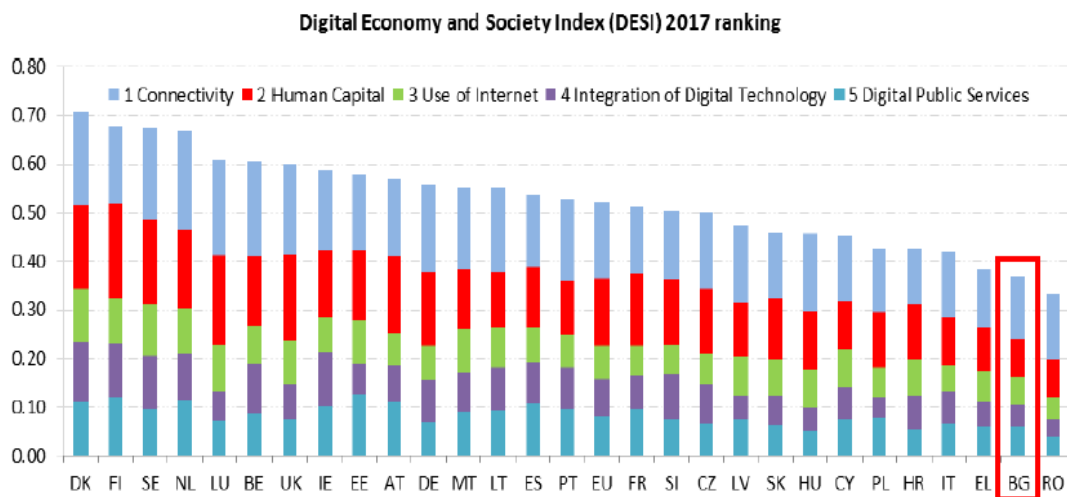
To date, eHealth project funding is predominantly institutional, regulated and based mostly on the EU grants. Funded activities are almost exclusively aimed at solutions development, more specifically at the creation of an integrated electronic healthcare system. After dedicating more than €10 million in funding, no significant progress is made on the matter. Since the integrated system is the base of any further development of eHealth solutions, no funding is dedicated to other developments or solutions. Main obstacles to the development of eHealth are the inadequate management of the process and the lack of will and ability to bring tangible results in a field that is repeatedly stated as a key priority in the governance agenda. The main moving force behind eHealth development (unfortunately) continues to be the availability of EU funding and the national commitments taken as part of the EU's 2020 Strategy.

As a basis for the digitisation of health services, the Ministry of Health has (rightfully) identified the creation of an integrated electronic healthcare system. Between 2012 and 2015 the Ministry has launched three separate tenders for the creation of an electronic healthcare system . Of the three tenders, two were part of the EU Human Resources Development programme and one was under the national sustainable regional development programme. Since there was no preliminary analysis of the existing processes, databases and systems, and consequently no clarity on requirements and expectations regarding the integrated system, all three of the tenders, for a total amount of over €11 million, were unsuccessful and terminated. In 2015, the Ministry launched a much smaller tender for the needed preliminary analysis. It was successful, and the reported results clearly demonstrated that the current processes, data flows and infrastructure in the healthcare systems will not allow a switch to an integrated information system anytime soon. In the beginning of 2017, the Ministry of Health launched a new project for an integrated system. The public tender was discontinued in August 2018.

E.1.2 Data management and IT infrastructure

Despite the increasing foreign and local ICT business investments in the country, Bulgaria remains one of the two less digitised countries in the EU (rivalling only Romania).¹⁰³ While high-speed broadband availability and price remain one of the best in Europe (at least in absolute values), coverage of fixed broadband, mobile data, 4G mobile networks remains far below the EU average, with particularly problematic values in rural areas. A gap in the digital skills and the lack of trust of the population in web-based technologies are obstructing digital development – citizens use their internet access for video calls and social networks rather than media consumption, eShopping or banking, and business rarely rely on eCommerce, digital invoicing or digital services. Public services digitisation is also at an EU record low, with only 20% of Bulgarian internet users interacting with State Administration online. In 2016, the Government launched a number of parallel initiatives, combining the so-far disjointed digitisation efforts in a new State eGovernment Agency (SEGA). The Agency is to regulate, coordinate, monitor and promote all institutional eGovernance efforts, as well as to manage and safeguard collected data, but it is yet to show its value in terms of solutions and services implemented.¹⁰⁴

Figure 6. Digital Economy and Society Index (DESI)



Source: Europe's Digital Progress Report (2017)

According to Europe's Digital Progress Report (EDPR), Bulgaria ranks 27th of the 28 countries in the Digital Economy and Society Index (DESI). While making progress in broadband infrastructure and in open data compared to 2016, the country is still lagging behind in the development digital skills, the digitisation of businesses and the digitisation of

¹⁰³ European Commission (2018). Digital Economy and Society Index Report 2018 Digital Public Services. Available at: ec.europa.eu/information_society/newsroom/image/document/2018-20/5_desi_report_digital_public_services_B5DBE542-FE46-3733-83C673BB18061EE4_52244.pdf

¹⁰⁴ State eGovernment Agency (2016). About the Agency. Available at: https://e-gov.bg/en/about_us

public services. Despite having (newly forged) broadband, eSkills and eGovernment strategies, Bulgaria remains firmly set in the cluster of low performing countries.

E.2 Digitisation of healthcare

E.2.1 History, recent developments, future directions

The first attempts towards the development of electronic healthcare in Bulgaria were made within the National Healthcare Strategy 2008-2013. In the beginning of 2012, the Ministry of Health launched the creation of an Integrated Health Information system (IHIS), as part of the BaHIS (Base for Health Information System) project. The project was part of the EU Operational Programme "Human Resources Development" 2007-2013 and in 2011 was granted approximately €5 million of the EU funding for a duration of 27 months. It was to be carried out single-handedly by the Bulgarian Ministry of Health, without participation from the NHIF of the NCPHA. Despite structural changes in the Ministry of Health, which brought changes in the activities, team members and management of the project, the Ministry launched a number of public tenders in an ill-managed attempt to complete the project successfully.

In the beginning of 2012, the Ministry of Health launched a public tender for the amount of approximately €3.68 million, for the "Creation and Implementation of an Integrated Health Information System under project BaHIS". The technical specification for the tender described only the existing hardware and software solutions used by the Ministry of Health, without as much as mentioning the components and systems used by the NHIF, the NCPHA or any of the healthcare service suppliers – who are all key elements of any integrated healthcare system. Furthermore, the tender did not present the way of estimating the total amount of the order, neither the breakdown of this amount per each stage of the tender.

In the end of 2012, the first public tender for the BaHIS project was discontinued and a second tender was launched. This time a breakdown of the amount for each stage and activity was provided, but without any specification of how it was calculated and what method was used in estimating its cost. Furthermore, as in the first tender, no preliminary analysis was made in order to assess the existing hardware and software solutions and systems, the processes and exchanges of data between systems and key players, and the technical, social and economic conditions under which the services subject of the tender were to be rendered. On the contrary - this initial analysis was included as a stage in the tender and was expected to be carried out by the winning supplier. Needless to say, without this preliminary information the Ministry of Health was unable to define the software and hardware requirements for the completion of integrated healthcare system, or their estimated value. This, in big part, rendered the tender and its expected results undefined and unclear, which ultimately led to its termination by the Ministry. The project was discontinued, and the dedicated EU funding remained unused.

In 2014, as part of the Programme for the Development of Electronic Healthcare (and its main goal of creating a National Health Information System), the Ministry of Health launched a new project for the “Creation of a National Health Information System”. The project was approved for funding under the national public investment programme for “Growth and Sustainable Development of the Regions” and granted a budget of approximately €6 million. The public tender for the project repeated almost all of the mistakes of the previous two tenders, lacking any preliminary analysis or clear methodology of cost estimation, and was also terminated, leaving the dedicated part of the national budget unused.

In 2015, after three unsuccessful public tenders for the realisation of a health information system, the Ministry of Health launched and completed a 28-thousand-euro tender for the “Analysis of Information Processes in the Bulgarian Healthcare System – key players, responsibilities, systems, flows and legal framework”. The final results of the analysis described the main challenges in the creation of an integrated healthcare systems, grouping them into four categories: strategic, standardisation, legal and technical.

In short, the project demonstrated that the existing healthcare processes and organisation are very far from ready for a switch to an integrated system:

- Key local information systems were (and still are) outdated, offline or non-digitised (with some still filled-in, collected and archived on paper).
- Local systems were built ad-hoc and not suitable for an integration in a larger system; many systems are not updated, administered and maintained properly and regularly.
- There are no stipulated standards on how to process, store, maintain, archive and backup data (on neither national, nor local level).
- No standards on what data is collected by whom and in what formats, so exchanging or merging data sets is not possible.
- No legal framework that specifies what data is to be collected and administered by each type of healthcare service provider or how are they to store, share and safeguard it.
- There are no standards or general requirements for the creation of an IHIS, clarity on existing code ownership and licensing, testing or quality assurance processes or criteria for the evaluation and acceptance of the technological solutions.

Facing a multitude of challenges and organisational and technological gaps on different levels, the Ministry of Health decided to discontinue the pursuit of a one-off implementation of an integrated system and to implement the integration on stages, building the system in modules or parts. The results of the 2015 analysis were taken into consideration in the National Strategy for Electronic Healthcare 2016-2020 and are most probably the reason why its implementation plan is rather less ambitious than the strategy itself, omitting many of the eHealth solutions and their implementation.

Within the new National Healthcare Strategy 2020, the Ministry launched a new project under EU Operational Program “Good Governance” 2014-2020. The related public tender, for an approximate amount of €6 million, was discontinued recently, in August 2018, without any further data or justification provided.

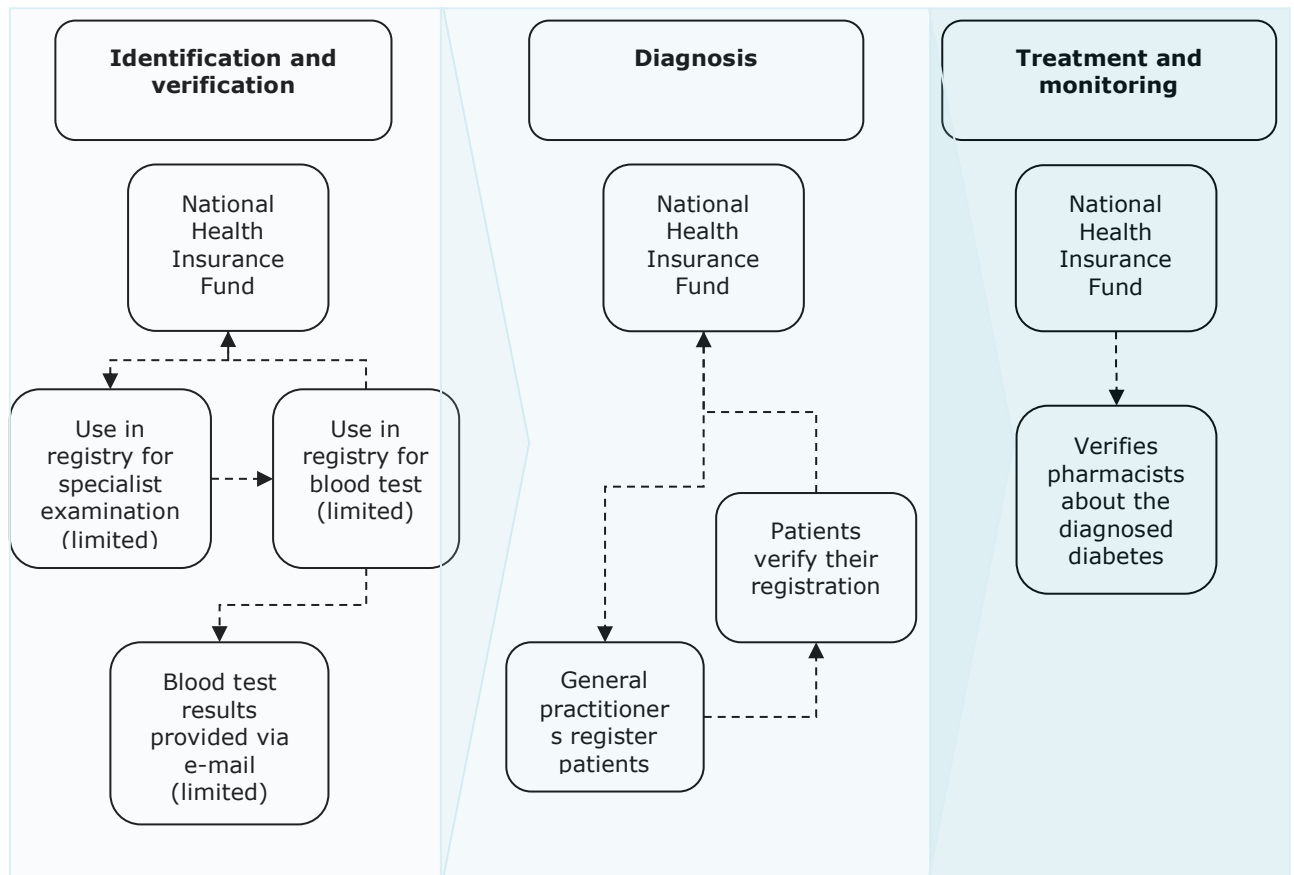
E.2.2 Cross-border implementation of eHealth

Given that there is no integrated healthcare information system, cross-border exchange of information is not currently implemented and seems a remote opportunity. As the National Audit Report 2016 duly notes, due to limited automation and often manual and offline processing of information, there are often delays in checking the status and issuing European Health Insurance Card for Bulgarian citizens abroad, as well as delays cross-border health-insurance status confirmations and healthcare cost reimbursements. In 2008, with the admission to the EU and rising levels of cross-border mobility for both study and work in EU, the national administration made an important step to reduce such times and launched the issuing of electronic health insurance cards. Similar to an ID, the cards are a personal document that certifies that the owner is health insured in Bulgaria. Despite that the cards could not be used directly by foreign healthcare providers – they still needed to contact a national contact point to verify the insurance and confirm cross-border reimbursements – the cards were communicated as obligatory and a must for Bulgarians staying abroad for longer periods and there was a massive effort from both citizens and administration to issue a lot of cards as quickly as possible. Although the cards allowed quicker identification of patients and their insurance status and facilitated the communication between the foreign provider and Bulgarian NHIF, they did little in terms of reimbursement or exchanging healthcare information between states. Currently, the initial enthusiasm around it is largely forgotten and the eCard is rarely used, since it ultimately did little to facilitate the processes of treatment and reimbursement.

E.2.3 Pathway integration. Diabetes journey

Given that there is currently no integrated healthcare system, much of “patient journey” still involves doctor visits and use of document largely in paper format with multiple trips to different institutions. The following figure highlights areas where digitisation is being applied in Bulgaria; however, these instances are much fewer than in other stakeholder regions.

Figure 7. Identification, verification, diagnosis, treatment and monitoring of diabetes in Bulgaria using eHealth solutions



Source: ESPON (2018)

If a patient is concerned about having diabetes, they have to visit his/hers personal General Practitioner (GP). Observing the symptoms, if the GP has doubts that patient is suffering from diabetic disease. He registers the exam in the NHIF system and directs the patient to a specialist (Endocrinologist). The direction is registered in the NHIF system and also printed out and handed to the patient to bring on paper.

Following this the patient visits the hospital, registers for an appointment and presents the direction papers provided by the GP. After waiting his turn, he is admitted for an exam with the Endocrinologist, who takes the direction papers and registers them in the hospital software, which sends them daily to the NHIF. At this point the initial registration of the direction done by the GP may or may not be already noted in the system. In any case, the two registrations are done separately and independently. The patient is examined by the specialist and receives a direction for blood tests in the laboratory. Depending on the types of tests, the chosen laboratory and on whether the laboratory has a contract with the NHIF, the direction for testing is either registered and later reimbursed or the patient is required to pay for the tests. The test results are provided to the patient in either paper format or via email or access to a web platform. In both cases the patient is the one to bring them back to the specialist

(with some exceptions when the laboratory is in the same hospital and is connected with the hospital's patient register).

After the endocrinologist considers the results of the blood testing and the performed examination, a diagnosis is made and the patient receives their diagnosis documentation together with a protocol for hospitalisation (in the case of diabetes "hospitalisation" envisions the monitoring and regular checks that must be performed by the GP). Patient has to bring these documents to his personal GP. In turn, the GP registers them in the NHIF system and assigns the patient as hospitalised with him/her. Finally, the GP notes this procedure in a second protocol and gives it to the patient.

Following this procedure, the patient visits the local NHIF office, hands in the (second) protocol that certifies his hospitalisation and assignment to the GP. The NHIF office ratifies it and registers it in their system – the patient is now registered as a hospitalised diabetic patient in his insurance profile. After the patient brings back the NHIF-ratified protocol to the GP they also buy a personal recipe booklet from the stationary store. The GP writes down a prescription for insulin and blood sugar testing strips, notes it in the recipe booklet and fills in the patient information in it and signs it.

The patient can then proceed to visit a local pharmacy that has a contract with the NHIF, presents his recipe booklet and the GP's prescription. The Pharmacist checks in the NHIF system if the patient is insured, verifies the validity of the paper documents (recipe booklet and prescription) and (depending on the rate of reimbursement) either sells or provides free of charge the prescribed insulin and test strips.

It is apparent that the process is rather complicated and mostly relies on the patient bringing information in paper format from one provider or institution to another. The opportunity for savings and simplification is considerable, especially if an integrated system updated in real-time is envisioned connecting all key players. Such a solution would not only facilitate and shorten the process, but also bring a much-needed transparency.

[E.3 Most prevalent eHealth applications and their use](#)

E.3.1 eHealth applications directions

Bulgaria is lagging far behind the other EU countries in the digitisation of public services. Through a combination of unimplemented, but regularly renewed strategic documents and a series of unsuccessful public tenders, the Government has realised only one eHealth solution – an electronic register of medical services and interventions reimbursed by the NHIF for each patient. Although the platform - Personalized Information System – works similarly to an electronic patient register, its implementation and the processes of filling-in and updating its contents present challenges that severely limit its use for healthcare purposes (see User Adoption and Perception). Apart from this solution, the Ministry of Health has made a number of attempts to create an integrated healthcare information system, but due to lack of analysis, clear requirements and standards, as well as technological base and knowledge, its initiatives

so far have been without successful results. The newly formed State eGovernment Agency (SEGA) seems to be a step in the right direction, but since its establishment in 2016 it has not brought to light any implemented eHealth solutions.

With state initiative struggling for a lift-off, many private healthcare supplier and health-related businesses and start-ups have opted for smaller private solutions and applications, either as an optimisation of internal or external processes or as a new business and revenue models. Some prominent examples include the pregnancy and child-care information portal and mobile app of FEIA.bg, the medical advice platform that connects patients and doctors also through a mobile app - medichome.com, the online appointment and medical specialist catalogue of superdoc.bg, and the platform and mobile app of healthykid.eu that connects parents to paediatric specialists and hospitals according to location proximity and symptoms. Although all of these applications have their valuable uses and niche target audience, they target well-defined audiences and needs and usually resolve simple information problems related to search, access of specialised information and advice. We are yet to see a larger-scale investment and coverage and more complex functionalities like electronic patient records, remote monitoring, self-managed apps, etc. What is more, since most private applications rely either on subscriptions or advertisements, most solutions do not share a common data format or information standards, so there is no interoperability or possible exchange of data.

E.3.2 Healthcare providers

Given the lack of integrated healthcare information system, healthcare providers usually use their own internal systems for tracking patients and activities. In terms of public healthcare solutions, they use the bare minimum – the providers that have reimbursement contracts with the National Insurance Fund Software use the NHIF system to register activities directly and ensure timely reimbursement. Since hospital software is typically not connected or integrated with the NHIF system, this brings a higher administrative workload and redundancy.

E.3.3 Service users

The National Health Insurance Fund (NHIF) created a solution that, for a lack of better description, can be compared to an electronic healthcare record. The Personalised Information System (PIS) was created with the main goal of informing health-insured patients on the interventions and services received and reimbursed by the NHIF. The project was launched in 2010, saw very low participation and satisfaction rates and encountered severe hardware and software problems in 2012 due to lack of any maintenance during the two-year period after its launch. After a number of unsuccessful and terminated public orders for its repair and maintenance, it continues to function to this day through partial automation – many of the activities are brought out of the system and are done manually and offline.

A root cause for its low adoption rate is the fact that the PIS, by design, is not a proper system for electronic patients' records. First, the PIS does not cover all patients, but only those that

are covered by the obligatory health insurance. Given that this insurance applies to all Bulgarian citizens and citizens of comparable status, this is not a major setback – it covers approximately 6.25 million health-insured citizens. Second, it does not cover all medical interventions – the PIS tracks only services, pharmaceuticals and medical materials that are covered and reimbursed by the NHIF – meaning that any interventions, drugs, laboratory results and images not covered by the insurance are not parts of the electronic record. Third, it focused on reimbursements and not on patient history, meaning that key information like blood type, allergies, vaccinations, previous illnesses and interventions were almost always missing, partially or entirely, from the record, thus rendering it useless for medical or diagnostic purposes.

Even in its purpose of a crowd-sourced control mechanism, the PIS failed spectacularly. The 2017 Report of the National Audit Office duly states, a multitude of shortcomings of the system and setbacks. First, the system does not update information in real-time – while hospitals submit reimbursement data on a daily basis, general practitioners (GPs) submit it on a monthly basis, while private practices working with the NHIF can submit it in a period slightly shorter than 2 months. This makes tracking of activities almost impossible, for both patient and system operators – it is common, for example, that the information from a GP who examined and directed a patient to a specialist in a hospital reaches the system only after the report from the examination by the expert.

Second, as the enquiry and report of the National Audit Office clearly stated, even when inconsistencies were discovered between the electronic record and actual interventions done, the slow procedural speeds and the legal timeframes for complaints and waivers, precluded the NHIF from acting accordingly and even from editing and correcting the incorrect information in the records. Two examples illustrate well the inadequacy of the PIS as a control mechanism: a) the Audit Office discovers an inconsistency between a PIS record and the hospital's patient record – an intervention that was not done is wrongly (intentionally or not) registered in the PIS; they file a complaint with the NHIF and, after few weeks of waiting for an electronic reply, visit the local NHIF office to receive the official reply in paper form; the reply informs them since the official 7-day period for complaints and waivers on services reimbursed by the NHIF to suppliers has expired before filing the complaint, no further enquiry was made with the supplier; given the speed with which information is updated in the PIS, the chances of filing a complaint on time are rather limited; b) one of the patients in the sample analysed the Audit Office had a condition registered in the PIS that he has not suffered from; upon inquiry with the NHIF, the Office was informed that the patient has filed a request for sick leave in order to take care of an ill family member; the illness of the relative, being the cause for the requested absence, was registered in the electronic record of the user, severely distorting his health information; despite this being a systematic error in the PIS, the report mentions no corrective actions undertaken by the NHIF to fix it.

E.3.4 Developers

Due to the numerous tenders on behalf of the Ministry of Health for an integrated electronic healthcare system, many of the Bulgarian system developers and IT development providers are well aware of the eHealth projects. Due to the lack of clear requirements, budgeting and analysis of current software and hardware systems, the tenders were unsuccessful, with limited participation and interest. Furthermore, as usual with public tenders in Bulgaria, the methodology of the tenders is based on best priced offered and not on a price-quality ratio offered. Usually adopted for all infrastructure projects, this approach reduces the risk of complaints or appeals of the tender and, in theory, speeds up the tender assignment process. However, it proves unsuitable for the task of software development and even more so for the development of integrated systems. The lack of knowledge and clarity about standardisation, system modules, system functionalities and quality of code by the Ministry precludes the participation of renowned private IT companies who are unwilling to invest time, people and resources on a project of considerable size but low potential margins and uncertain outcome.

While big or specialised IT development companies shy away from the sizable but risky public tenders, a number of local players with a positive track record of winning and delivering public tenders of various size and complexity, mostly related to research, analysis and creating policy recommendations and frameworks, often take up public projects for software development. Like with the shortcomings of the Personalized Information System (see User adoption), the results often speak for themselves and demonstrate the lack of experience and expertise of such players in software development, testing and maintenance.

With no integrated healthcare records system in place, no further eHealth solutions are being funded or developed. Medium and small IT development companies focus on private projects for independent software for small clinics, private hospitals, private practices or targeted user applications. Common examples of such software functionalities are the recording, submission to NHIF and reimbursement of interventions and pharmaceuticals, tracking stock and availability, scheduling appointments, publishing and sharing laboratory test results and imagery, etc. Some private companies choose to rely on advertising revenues and develop end-user applications like the pregnancy app FEIA.bg or online professional social network platforms like Credoweb.

Despite these private initiatives, the eHealth solution landscape remains small, fragmented and dominated by the governmental initiative, pushed by EU and state funding and struggling to define the processes and functionalities that are needed to be digitised and connected.

E.3.5 Demand stimulation

The main driving force behind the development of institutional eHealth solutions in Bulgaria continue to be EU grant programs like Operational Programme “Human Capital Development” and Operational Programme “Good Governance”. To date, there have not been registered any local or national initiatives aimed at increasing awareness or usage among medical professionals or patients, including for the launch of the NHIF’s PIS system. For hospitals and

private practices, the main reason for using the NHIF's registration and reimbursement software is still the speed and facilitation of the reimbursement. However, the use of these systems is a challenge rather than a facilitation – doctors have to use both their private software, as well as the NHIF system, often fill-in data both on paper and online, and spend as much as 2/3 of their working time in administrative activities (especially in the case of general practitioners).

In terms of trend and usage statistics, the majority of citizens is not even aware of the existence and functionality of existing eHealth solutions, as well as with the very notion of electronic healthcare. The analysis of the user adoption and satisfaction rates PIS carried out by the National Audit Office in regards to the PIS provides us with important insights.¹⁰⁵

- 56% of all respondents are not familiar with the term “electronic healthcare”
- 94% of all respondents declare to not being informed on the benefits of electronic healthcare
- 5% of the respondents familiar with eHealth are aware that the monitoring and control of the development of eHealth are responsibility of the National Center for Public Health and Analysis
- Out of all eHealth aware respondents, 40% cannot decide if they are satisfied, 33% are not satisfied, 19% are partially satisfied and only 8% declare to be personally satisfied with the institutional actions for the implementation of electronic healthcare in the country
- 92% of all respondents do not have access to their “electronic health record” (their record in the PIS); of the remaining 8% that have such access, 2% find the information incorrect and 3% find it not useful; leaving only 3% of all respondents to use the service and actually find it worth something
- 5% of respondents declare full trust in the safeguarding of their personal data used in the electronic health record; 22% declare partial trust in NHIF regarding it
- Less than half percent of the potential user base (0.498%) have actually used the service at least once

E.4 Socio-economic benefits of eHealth

As demonstrated in the User Adoption and Perception paragraph, there is a lot more to be desired from the Ministry of Health's communication and awareness building activities regarding eHealth. The implemented solutions to date (PIS) have done little to convince users of the benefits and usefulness of electronic healthcare processes – the PIS, apart from being the only realised solution, remains widely unknown and unused and, where adopted by users, perceived as marginally valuable or outright useless. Given the increasing administrative workload for medical practitioners and the growing scarcity of medical staff and professionals, any well-implemented and well-designed solution have the potential to vastly improve the situation for all - patients, medical personnel and institutions. A good example is the PIS, which, despite being a noted disappointment as an electronic medical record and crow-

¹⁰⁵ Bulgarian National Audit Office (2016). За извършен одит на изпълнението „Електронно здравеопазване“ за периода от 01.01.2012 г. до 30.06.2016 г. Available at: <http://www.bulnao.government.bg/bg/articles/dokladi-128>

sourced control mechanism, facilitated significantly the process of choosing and assigning the personal general practitioners to patients. Given that the process was rather complicated (allowed only twice per year within a limited timeframe during summer and Christmas holidays), the ability for the patients to do it online through the PIS was a well-appreciated improvement. Given the very limited use of the PIS, however, this benefit remained largely uncommunicated and unused.

Appendix F eHealth mapping

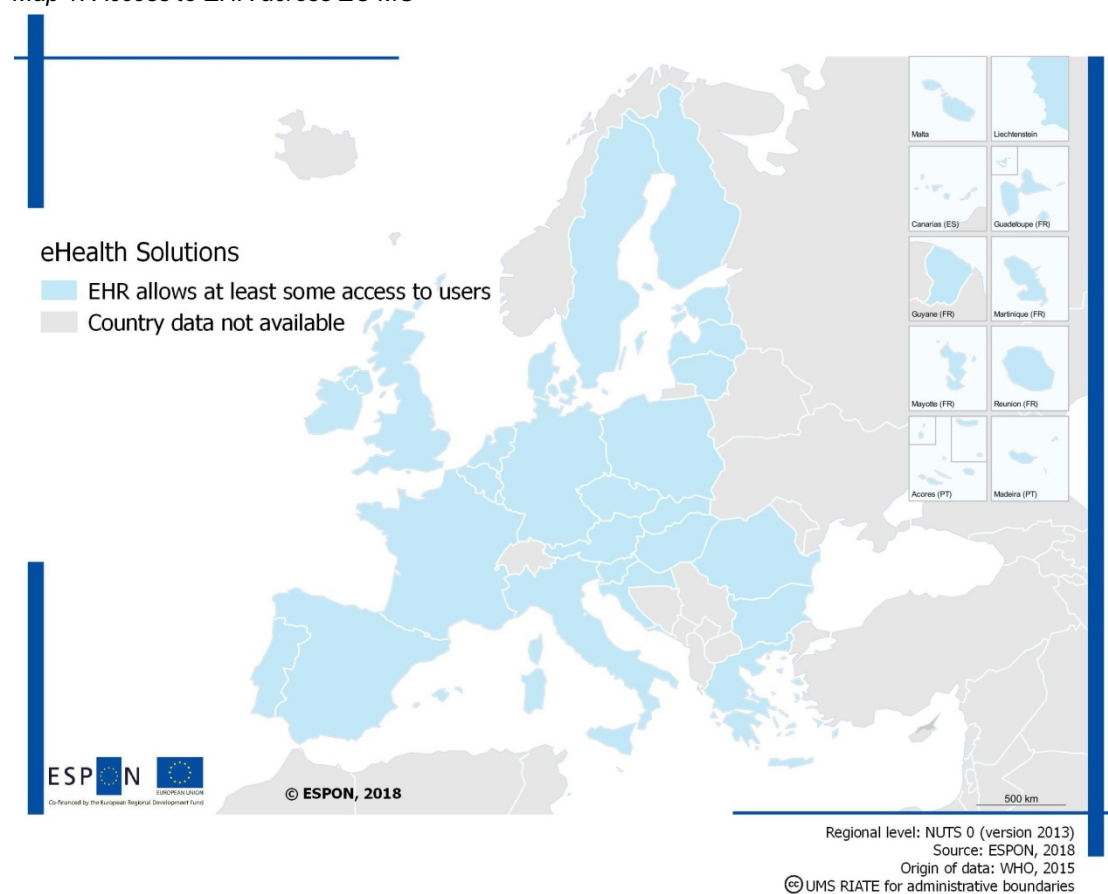
The following is an overview and status quo of implementation of main eHealth solutions across EU28. The findings are primarily based on data from World Health Organisation to provide a common ground to compare and contrast individual EU MS. The data presented in the following chapters focuses on the existence of certain eHealth solutions; however, only allowing for a broad overview.

F.1 Mapping of implementation of Electronic Health Records

Electronic Health Records are a digitised form of patients' health records allowing information to be available instantly and securely to authorised users across healthcare providers and countries. We analysed three key dimensions related to EHR: access, privacy protection and sharing of patient data across healthcare providers. Subsequently we mapped this information across the EU.

Access is defined as the degree of control individuals have over their health-related data stored in EHR. This includes (i) electronic access to data held in EHR; (ii) demand of data removal from EHR; and (iii) specification of data that can be shared with health professionals of their choice.

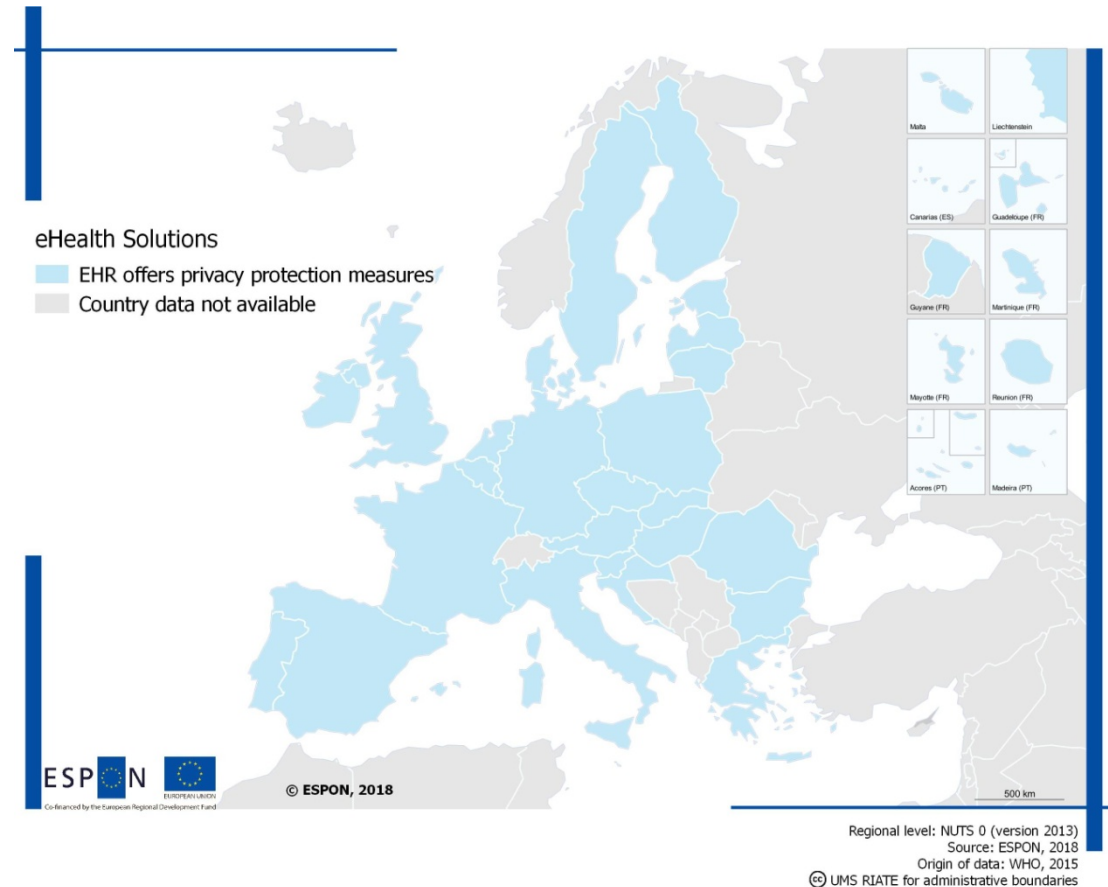
Map 1. Access to EHR across EU MS



Source: ESPON (2018)

Privacy of health-related data is aimed at protecting individual. We analysed the extent to which EU MS have adopted privacy protection of personally identifiable data of individuals irrespective of whether it is in paper or electronic format.

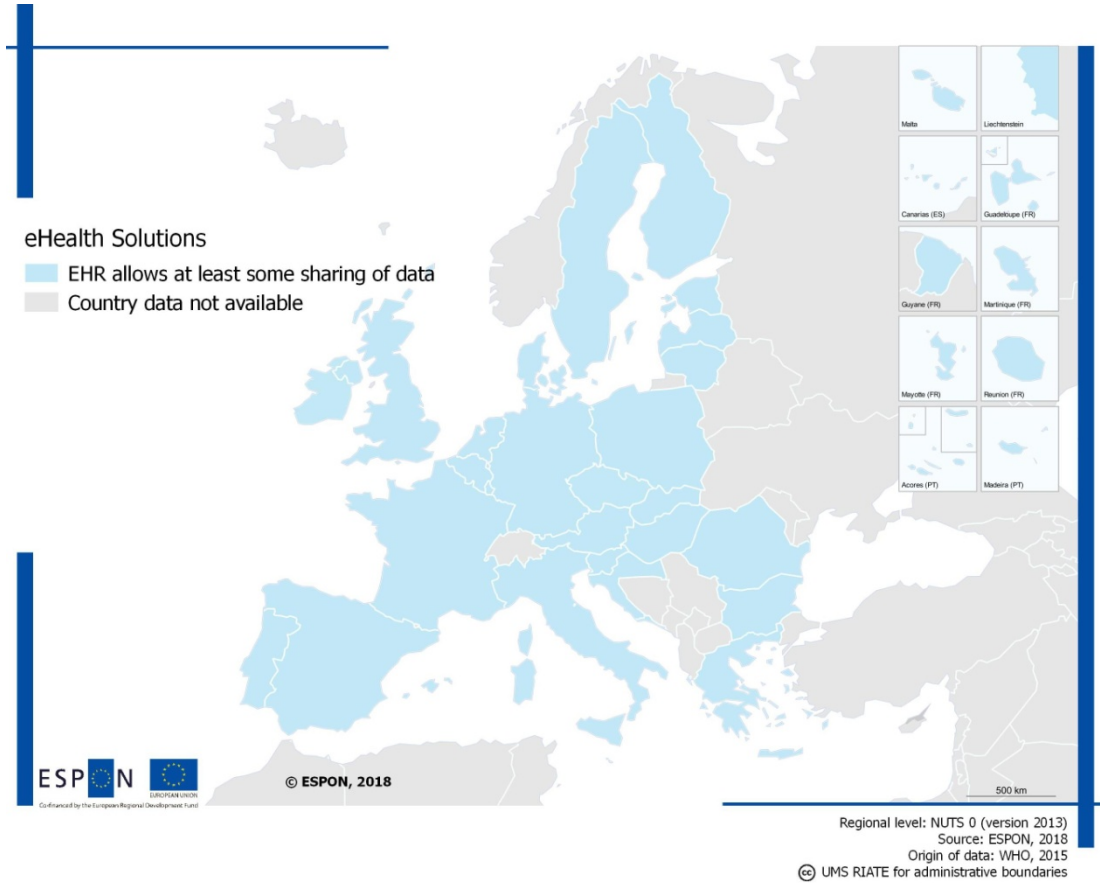
Map 2. Implementation of privacy protection in EU MS



Source: ESPON (2018)

Sharing of health-related data stored in EHR include the following options: (i) sharing of data between health professionals in *other health services in the same country*; and (ii) sharing of data between health professionals *in health services in other countries*. The following map illustrates whether any of these options are available to healthcare providers in EU MS.

Map 3. EHR data sharing in EU MS

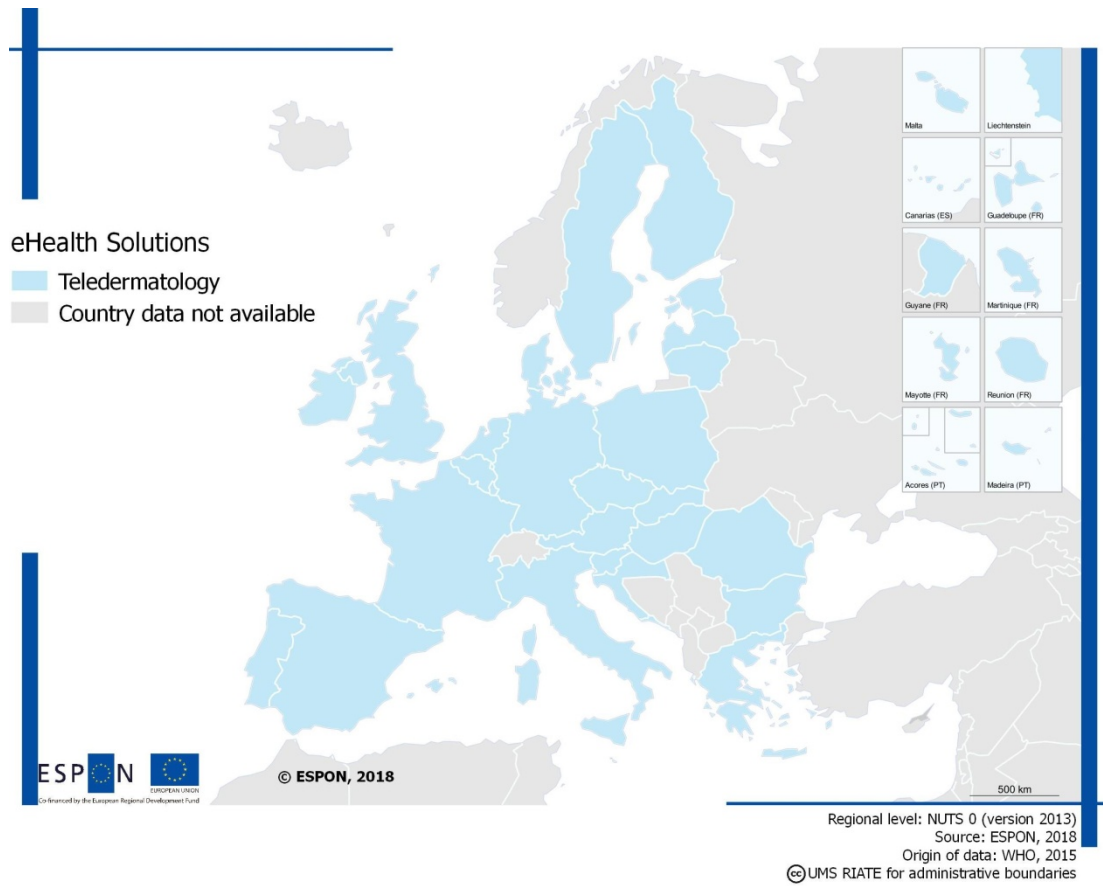


Source: ESPON (2018)

F.2 Mapping of telehealth services

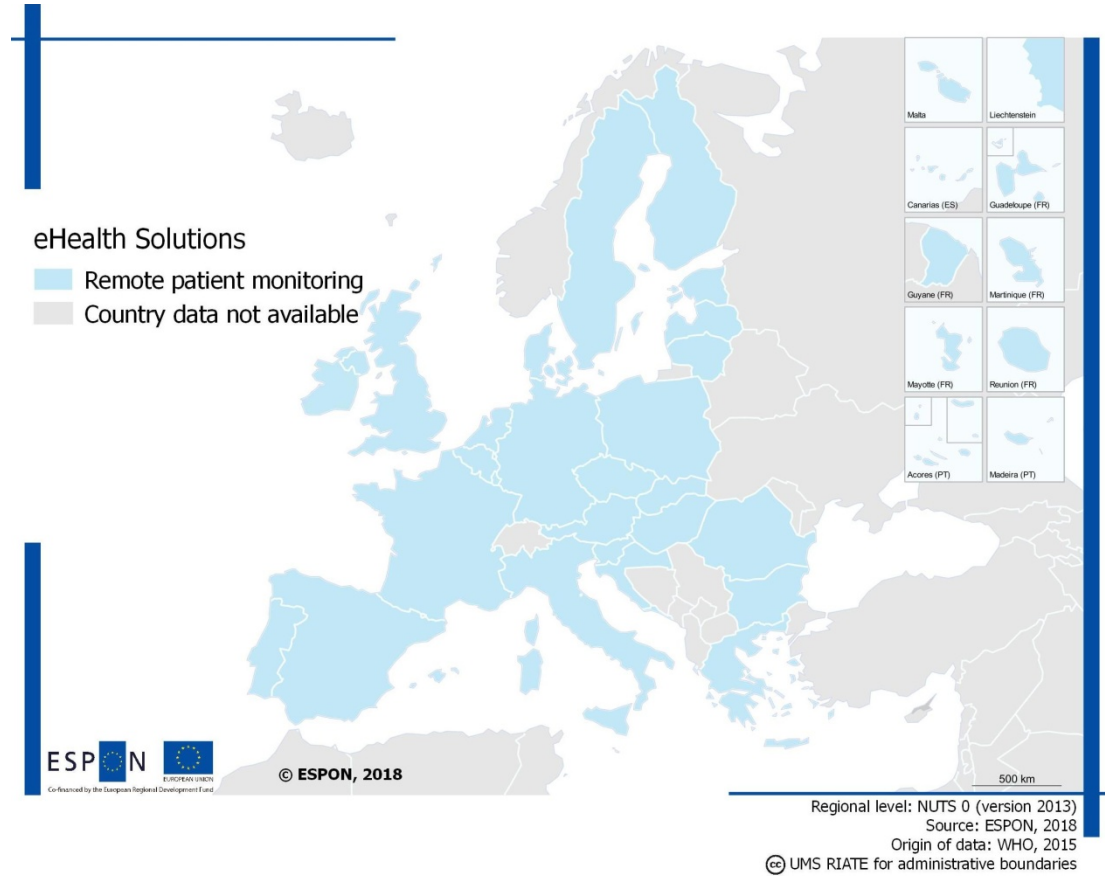
Telehealth is the delivery of healthcare services remotely by healthcare professionals using ICT for the exchange of health data for prevention, diagnosis, or treatment. Specific telehealth services were analysed in EU MS: (i) teledermatology; (ii) teleradiology; (iii) telepathology; (iv) telepsychiatry; and (v) remote patient monitoring. The analysis revealed that the most commonly available services across EU28 were teledermatology and remote patient monitoring. The maps below indicate the EU MS where these services are developed.

Map 4. Availability of teledermatology in EU MS



Source: ESPON (2018)

Map 5. Availability of remote patient monitoring in EU MS

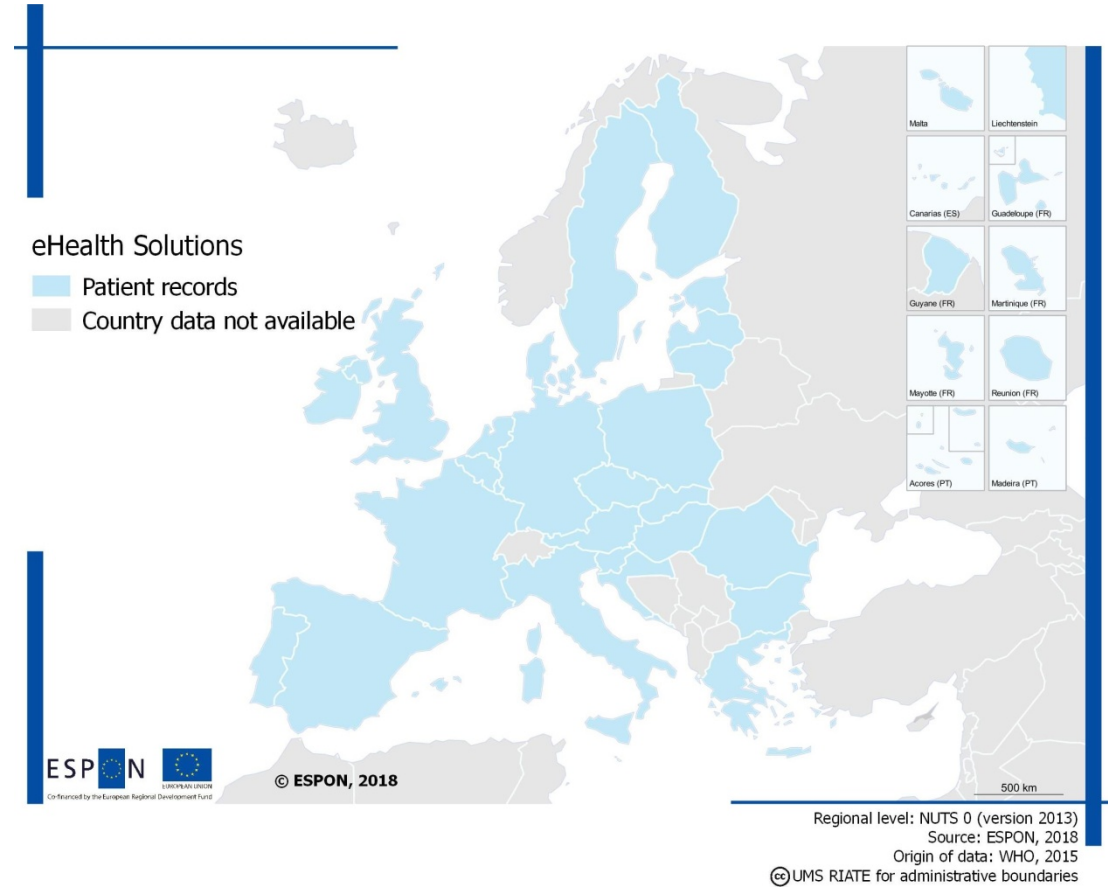


Source: ESPON (2018)

F.3 Mapping of mHealth services

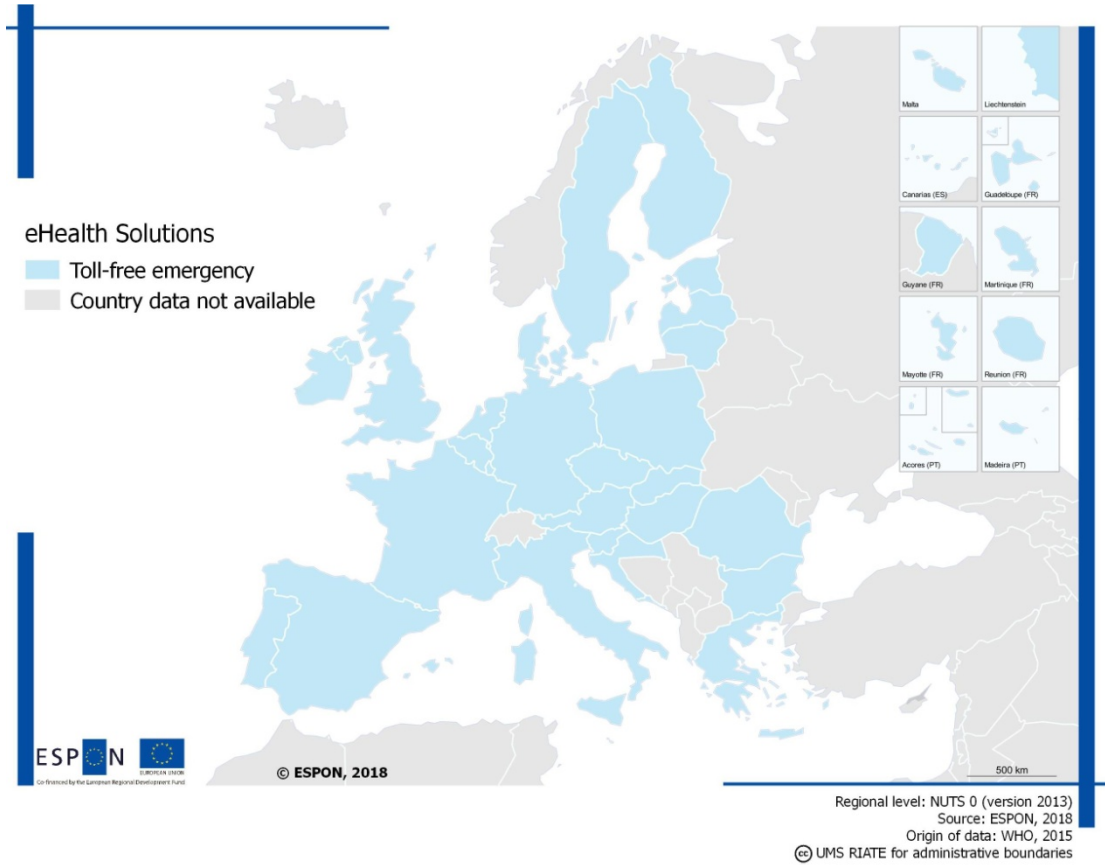
mHealth or mobile health is defined as medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, and other wireless devices. We analysed the availability of the following mHealth services: (i) Toll-free emergency telephone services; (ii) Health call centres; (iii) Appointment reminders; (iv) Access to information, databases and tools; (v) Patient records; and (vi) Patient monitoring. The most widely applied services across EU28 were those providing access to patient records and toll-free emergency calls.

Map 6. Availability of patient records via mHealth services in EU MS



Source: ESPON (2018)

Map 7. Availability of toll-free emergency calls via mHealth services in EU MS



Source: ESPON (2018)