

#### **Authors:**

Mountford, N; Kessie, T; Quinlan, M; Maher, R; Smolders, R; Van Royen, P; Todorovic, I; Belani, H; Horak, H; Ljubi, I; Stage, J; Lamas, D; Shmorgun, I; Perälä-Heape,M; Isomursu, M; Managematin, V; Trajkovik, V; Madevska-Bogdanova, A; Stainov, R; Chouvarda, I; Dimitrakopoulos, G; Stulman, A; Haddad, Y; Alzbutas, R; Calleja, N; Tilney, M; Moen, A; Thygesen, E; Lewandowski, R; Klichowski, M; Oliveira, P; Machado da Silva, J; Loncar Turukalo, T; Marović, B; Drusany Staric, K; Cvetkovic, B; Luque, E; Fernandez Luque, L; Burmaoglu, S; Dolu, N; Curcin, V; McLaughlin, J; Caulfield, B;

Copyright 2016 The Authors.

This report is based upon work from COST Action (ENJECT TD1405), supported by COST (European Cooperation in Science and Technology). cost.eu

University College Dublin, July 2016 ISBN: 978-1-910963-05-0

The authors would like to thank Jennifer Kelly and Deirdre Clayton for their assistance in the compilation of this report.

### **Table of Contents**

Introduction	2
Executive Summary	3
Methodology	6
Section 1: The Policy Environment	7
Introduction	7
Evaluation of Healthcare Services	7
Connected Health (CH) Strategies Across Europe	13
Connected Heath Activities	15
Privacy and Security	20
Political Instruments/Statements that Guide Connected Health Policy-Making	25
Section 2: Education	29
Educational Connected Health/eHealth Programmes for Future Healthcare Professionals	29
Programmes to Create eHealth/Connected Health-Informed Care-Givers and/or Patients	30
Programmes to Improve the Health Literacy iIndex	32
Section 3: Business and Health Models	35
Organisational Structure	35
Financing and Health Insurance	36
eHealth Models	38
System Organisation	39
Section 4: Interoperability	41
Getting to Interoperability: The Process	42
Section 5: Person	49
Digital Literacy/ICT Literacy Standards to Guide Patient Involvement	49
Section 6: Conclusion	51
An Agenda for Future Research in Connected Health for Europe	52
Appendices	55



## INTRODUCTION

The European Network for the Joint Evaluation of Connected Health Technologies (ENJECT) is a COST action that brings together an international consortium, including business and revenue modellers, clinicians, technologists, engineers, economists, ethnographers, and health researchers to help society to answer one question – how to connect therapies, patients, and care-givers to deliver optimum health results in an era of stretched resources and increasing demands.

ENJECT aims to improve our understanding of Europe's varied health systems, markets, and demographics through access to commercial players, datasets, market knowledge, and policy makers across the continent. It is seeding cross-border, interdisciplinary teams and partnerships leading to new collaborations, improved training and professional development opportunities, knowledge and staff exchange, and a European communication platform for Connected Health research.

ENJECT includes collaborations with higher education institutions (HEIs) and organisations based internationally in Belgium, Bosnia & Herzogvina, Croatia, Cyprus, Denmark, Estonia, Finland, France, Macedonia, Germany, Greece, Ireland, Israel, Lithuania, Malta, Netherlands, Norway, Poland, Portugal, Serbia, Slovakia, Slovenia, Spain, Sweden, Turkey, and the UK.

This paper presents the results of an ENJECT survey that was completed in 19 European countries covering such topics as technical integration, eHealth strategic planning, patient engagement in research, and the patient journey.

There is no doubt that the survey results raise more questions than they answer, but in doing so, they form a basis for future research concentration in Europe – both within and beyond the ENJECT research network. Our hope is that it will provide a collaborative platform for such research endeavours, and that together, we can help Europe's healthcare system to better respond to the demographic and resource-contraint challenges it now faces.

**Prof Brian Caulfield** 

## **EXECUTIVE SUMMARY**

The European Network for the Joint Evaluation of Connected Health Technologies (ENJECT) is a COST action that brings together an international consortium, including business and revenue modellers, clinicians, technologists, engineers, economists, ethnographers, and health researchers to help society to answer one question – how to connect therapies, patients, and care-givers to deliver optimum health results in an era of stretched resources and increasing demands. This report, which has grown out of an ENJECT survey of 19 European countries, examines the situation of Connected Health in Europe today. It focuses on creating a clear understanding of the current and developing presence of Connected Health throughout European healthcare systems under five headings: The Policy Environment, Education, Business and Health Models, Interoperability, and The Person.

Quality, privacy, and safety, major elements of Connected Health, were evident policy concerns in the Connected Health context. Attention is paid as to how the healthcare systems are evaluated. Evaluation methods and responsibilities range from macro state-level evaluation to more dispersed local evaluation. The constant evolution of European healthcare is reflected in the changing methods of evaluation in countries such as Norway, Greece, Malta, and Serbia.

The vast majority (almost 80%) of respondent countries have eHealth strategies in place or are working on implementing such strategies. In general, e-prescribing and Electronic Health Records are the most common forms of Connected Health activities throughout Europe. There is a clear distinction between patient and consultant usages of these forms of Connected Health. A major issue, especially with the creation of Electronic Health Records, has been ensuring that they are safe and secure and that privacy is attainable. Health Insurance companies also make use of electronic patient records for the storage of and quick access to patient records.

Privacy is recognised as an important factor in the development of accessible patient databases. While two thirds of respondent countries rely on national data protection legislation to protect such databases, others have been more proactive and generated eHealth-specific legislation. Croatia, Germany, Slovenia, the UK, and Macedonia have all begun to recognise the need to draw up legislation which prioritises the protection of patient information recorded through these types of technologies. Public statements and political instruments directly address the topic of Connected Health, helping to protect patients while increasing their awareness of the Connected Health options. Websites and manifestos dedicated to health related activities in various countries are at the centre of this public awareness. Additionally, political parties in some of the respondent countries identify eHealth and Connected Health as an area for improvement in their own manifestos.

Of the nineteen respondents to the survey, fifteen countries contributed specific information on university-based programmes that help to ensure that healthcare professionals are aware of and in a position to utilise Connected Health. While few of the programmes focus solely on Connected Health, its inclusion in health and biomedical informatics courses ensures that it will be a part of these future healthcare providers' understanding of the provision of healthcare. Awareness of Connected Health and the development of health literacy is not solely a concern at third level. Health literacy is a challenge across Europe as a whole. Ad hoc health literacy programmes have been proven to work in some countries, but the public's infrequent exposure to these forms of literacy, such as television and poster campaigns, means that their benefit is often not fully felt in the long term. The role that Connected Health can play in the improving health literacy does not seem to have been realised, with most countries still relying on leaflets and information booklets to improve patients' understanding of medical and health related issues. For those countries who actively and regularly promote health literacy, this is done through school systems and specific research communities.

Presenting the business and health models of the healthcare systems in each of the ENJECT respondent's countries helps to develop an understanding of the level of priority placed upon Connected Health. The majority of European healthcare systems are organised through cooperation between private and public bodies. Their funding and finances primarily come from the public sector, with revenue created through direct and indirect taxes. eHealth models within these healthcare systems' business models vary significantly across the region and are gradually becoming an accepted part of a healthcare system's general business models.

To attain an understanding of its healthcare model and patient care pathways, each country has provided a case study of common illnesses. The difference in each country's method of treatment of the same illness shows how each of the systems operate, with a clear focus on the funding of the treatment in each of the instances.

eHealth Records and digital prescriptions top the list of technically integrated systems at national and regional levels enabling electronic systems to work across a variety of healthcare contexts. The unification of language and classification systems emerged as a major issue when considering the interoperability of eHealth.

Generally, the level of patient involvement in the design, delivery, and development of health related research programmes is on the increase. With 30% of the respondent countries having a system in place which encourages the inclusion of patients in the design and development of healthcare, this can be seen as a clear starting point for creating even more connected healthcare systems throughout Europe.

In summary, confusion abounds in the area of Connected Health – around wording, application, models, and systems. It involves a complete transformation of the healthcare system in a long-term play that requires dedicated resources and political will. Many of these elements are difficult to capture with data points being largely qualitative and non-comparable. Different countries are at different stages of readiness in terms of Connected Health – both in terms of its research and its implementation. The evaluation criteria employed in different circumstances and different geographies across Europe are neither clear nor standardised. The majority of states and regions are so engaged in the process of ensuring interoperability at a regional or national level that they have little time or attention left to focus on the thorny issue of international interoperability.

We recommend an agenda for future research in Connected Health for Europe that creates a shared language around health records and a database that would facilitate the development of a Connected Health or eHealth scorecard. We would support a common evaluation framework for Connected Health implementations that is multi-faceted, ranging from technology robustness to regulatory compliance, from economic sustainability to user acceptance, and including both qualitative and quantitative measures. There is evident confusion as to the application of existing rights in the context of Connected Health. We recommend an approach specific to eHealth that helps citizens, researchers, companies, and healthcare providers to understand how we live safely and privately in an era of healthcare data. We suggest that studying how some of the ENJECT countries have done this and distilling learnings and best practice from their experience could help to better design future guidelines and interpretations.

## **METHODOLOGY**

The findings presented in this paper are based on the results of a survey conducted with members of the ENJECT group, which aimed to capture the presence of and readiness for Connected Health (CH) in their region. The survey was developed collaboratively between the members following a one day workshop in Porto, Portugal in March 2015. In order to conduct a survey on the presence of Connected Health in their region, it was first necessary to agree on a definition of the concept. The workshop agreed on the following shared definition of Connected Health:

"Connected Health is a paradigm shift looking after the individual and community health in a process that speaks to the health journey of the person, through the entire lifespan, leveraging a variety of technologies to do so."

The workshop went on to identify key areas for Connected Health research and implementation. It began the process of developing questions for the survey that would be both answerable, and at the same time illuminating, for Connected Health companies, policy makers, researchers, and users across Europe. The questions were subsequently refined in an iterative process lasting six weeks. A comprehensive review of existing white papers, reports, and analyses ensured that the ENJECT survey did not set out to duplicate information that was already compiled in a useful format elsewhere. So, for example, the consortium chose to pull from the WHO European Observatory on Healthcare reports for the health and business models section of this investigation rather than replicating this work.

Once the survey was finalised, it was circulated throughout the ENJECT network. Members were asked to come together and complete one survey response on behalf of each representative country. From a sample of 21 European countries, a total of 19 complete responses were received. These responses represented The UK, Spain, France, Macedonia, Serbia, Greece, Poland, Malta, Slovenia, Portugal, Israel, Finland, Croatia, Germany, Norway, Turkey, Belgium, Ireland, and Lithuania (see map below).

The responses were analysed, and the following report summarises the high level findings. It uses case studies supplied by the respondents to illustrate these findings, where possible.

## SECTION 1: THE POLICY ENVIRONMENT

#### INTRODUCTION

This section presents an overview of Connected Health policy in Europe. Specifically, it focuses on its development and implementation stages, whether and to what extent a formalised approach is being employed, and a more detailed breakdown of individual activities taking place under the Connected Health policy umbrella. It deals with the evaluation of healthcare services within the European countries surveyed and tackles the thorny issues of privacy and security on which many Connected Health proposals and implementations find themselves foundering.

#### **EVALUATION OF HEALTHCARE SERVICES**

## Quality Assurance Defined National Institute Rates Medical Performance Quality and Safety Strategy Checks Agencies Initiatives Activities Regular

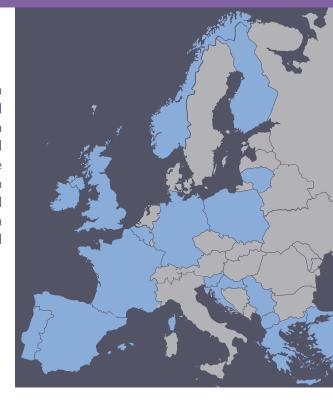


FIGURE 1: MAP OF ENJECT SURVEY RESPONDENTS

**EVALUATION RESPONSES** 

Expectedly, quality and safety were key drivers in evaluation policies and strategies across the surveyed countries. However, other metrics do feature. In Turkey, for example, the speed of care, reliability of care, hygiene, and economics are all considered.

The mechanisms by which oversight and evaluation are conducted vary, however, both within individual countries as well as from country to country. They range from macro level evaluation to dispersed systems for evaluating healthcare. In addition, the system for evaluating healthcare is under transition and reform.

#### **MACRO-LEVEL EVALUATION**

In some instances, such as Lithuania, evaluation is relatively contained within one responsible organ of the state – in this case, the Ministry of Health and the State Health Care Accreditation Agency on its behalf, enacting Article 16 of the Law on Health System of the Republic of Lithuania<sup>1</sup>. This article limits the right to engage in health activities to institutions that have physicians or other qualified healthcare professionals on staff. Since February 2010, the Lithuanian E-Health System Development Program for 2009-2015 aims to balance existing and newly appearing information and communication technologies with healthcare needs (immediate and in the future) by consistently improving the quality of healthcare services.

<sup>&</sup>lt;sup>1</sup> Official Gazette, 1994, No. 63-1231; 1998. No. 112 3099

This macro-level approach is echoed in Belgium where regular evaluation of care is conducted by the Federal Knowledge Institute (KCE) and by The Scientific Institute of Public Health (WIV). Such an approach is complemented by regular assessment of the performance of health care professionals and hospitals, based on well-defined indicators. In Israel, two groups within the ministry of health conduct spot checks for quality of clinical care and audits of HMOs to ensure they provide the required services. National clinical indicators exist to measure process outcomes.

Citizens of Macedonia also enjoy a relatively streamlined process of healthcare evaluation and oversight. Medical treatment is based on an evidence-based medicine approach allied with a set of treatment protocols defined by the Ministry of Health and published in the Official Gazette<sup>2</sup>. Additionally, there are clinical pathway procedures for the treatment of people with malignant diseases<sup>3</sup>. The quality of health services is evaluated through these protocols and procedures.

Healthcare evaluation in Finland is co-ordinated by Valvira, the National Supervising Authority for Social Welfare. Valvira supervises and guides healthcare professionals and medical facilities in both private and public sectors. Supervision of healthcare is divided into four sections:

- 1. Ex-post monitoring of individual cases, for example, handling patient complaints after serious treatment injuries
- 2. Plan-based supervision (supervision following national- or municipal healthcare supervision plans or internal supervision of medical facilities)
- 3. Guidance and advice for healthcare professionals and medical facilities
- 4. Issue of requested statements consisting of official documents to other authorities and courts of justice (including medical statements on causality of injuries for use by insurance officers)

Valvira cooperates with six regional administrative agencies that have primary responsibility for supervising social care in their own region. These agencies have similar duties but differ in geographical scope of jurisdiction. Valvira handles welfare-related supervisory cases when they are of nationwide importance and matters of principle; other complaints are handled by the six regional agencies. Where Valvira handles a case, its decision acts as a precedent for regional administrative agencies to follow in processing similar cases. Among Valvira's responsibilities is the guidance and supervision of social welfare throughout the country. With the agencies, Valvira prepares different national supervisory programs on how welfare should be used, for example, in elderly welfare, child welfare, and substance abuse care.

Like Finland, the UK has a hierarchical evaluation model containing both national and regional bodies. Nationally, the Care Quality Commission (CQC) is responsible for inspecting and approving all healthcare providers<sup>4</sup>. In addition, a variety of 'dashboards' and quality indices are made available to the public via the website 'NHS Choices'. This pulls together a variety of metrics including mortality figures, public ratings, CQC reports, and the 'friends and family test' (a staff self-rating score)<sup>5</sup>. NHS Health and Social Care

<sup>&</sup>lt;sup>2</sup> http://zdravstvo.gov.mk/upatstva/

<sup>&</sup>lt;sup>3</sup> http://zdravstvo.gov.mk/klinichki-pateki-za-maligni-zaboluvanja/

<sup>4</sup> http://www.cgc.org.uk

<sup>&</sup>lt;sup>5</sup> http://www.nhs.uk/Pages/HomePage.aspx

Information Centre publish regular statistics on quality and process<sup>6</sup>. Regionally, NHS England Area Teams and Clinical Commissioning Groups (CCGs) also rate individual providers according to a wide range of routine metrics, including the GP Quality and Outcomes Framework, vaccination rates, hospital readmission, Accident and Emergency waiting times etc.

#### **DISPERSED EVALUATION**

Other countries demonstrate a more dispersed approach to evaluation with one or more key evaluation agencies taking a more prominent role. For example, while Germany has a range of evaluation activities in health, the national 'Institute for Quality and Efficiency on Health Care'<sup>7</sup> (IQWiG) is one key implementer of this.

Ireland demonstrates a similar, multi-party approach to the evaluation of quality of care and health services. This evaluation takes place at numerous levels, by various bodies using diverse guidelines, codes of practice, investigation process, and resulting recommendations. Quality assurance and verification is conducted by several organisations: two HSE Directorates, namely the 'Quality Improvement Division' and the 'Quality Assurance and Verification Directorate', the Clinical Indemnity Scheme, the National Office for Clinical Audit, the National Clinical Audit Effectiveness Committee, the Health Information and Quality Authority, the Mental Health Commission, the National Standards Authority, and potential others unnamed here.

There is no obligatory national or regional policy for evaluating quality of care or health services in Poland. However, some voluntary programs, such as accreditation, do exist. However, the Ministry of Health and the national public payer have issued detailed obligatory requirements concerning quality and quantity of medical personnel as well as infrastructure. Health care providers must adhere to these requirements to access public financing. Substantial activities have been undertaken in the area of quality control, including HTA and the introduction of accreditation standards for hospitals and primary care. Nevertheless, standards of care are still missing in many areas of care (e.g. rehabilitation), making it difficult to assure and monitor the quality of care being provided. The increasing shortage of health care personnel poses another threat and may require complementing the ad hoc interventions practised so far with a more strategic approach.

France employs a range of evaluation strategies which include:

- CE marking
- The National Security Agency of Medicine and Health Products
- assessment of professional practices
- accreditation for particular practices (surgery, cardiology, echography)
- IPAQSS publicly delivered by the High Authority for Health (Indicators for Improving the Quality and Safety of Care)
- peer Certification of health institutions i.e. health professionals (care givers and managers)
- The High Authority for Health: good practices and recommendations, quality approach

<sup>6</sup> http://www.hscic.gov.uk

<sup>&</sup>lt;sup>7</sup> www.iqwig.de

This latter entity maintains a quality of care repository in order to assess expected and effective quality of care, gaps in care, and delivery of care via conformity checks. Regional Health Agencies implement recommendations adopted by the High Authority for Health.

Portugal also locates its evaluation activities with a number of entities. The Directorate-General of Health (DGS)<sup>8</sup>, a public body of the Portuguese Ministry of Health, regulates all activity in the healthcare field including evaluation activities in line with the National Strategy for Quality in Health (ENQS) (Order No. 5739/2015)<sup>9,10</sup> such as:

- issuing clinical and organizational guidelines
- guiding and developing programmes: Public health; Improved healthcare; Total clinical and organizational quality management
- · coordinating and assuring national epidemiological surveillance
- preparing and publishing health statistics
- monitoring the National Health Service Contact Centre
- preparing and assuring the execution of the National Health Plan <sup>11</sup>
- regulating and monitoring compliance with safety and quality standards of blood, tissues and organs

The Portuguese National Health Units Accreditation Programme<sup>12</sup> aims to recognize the quality of healthcare organizations and promote continuous improvement across the National Health Service. The Entidade Reguladora da Saúde (Health Regulating Entity) is responsible for the Sistema Nacional de Avaliação em Saúde (SINAS, National System for Health Evaluation), which performs regular evaluation of Portuguese healthcare units. The Sistema Nacional de Incidentes e Eventos Adversos (SNNIEA, National System of Incidents and Adverse Events) reinforces patient security through interaction between professionals and users of the healthcare system<sup>13</sup>. Portugal has permanent delegates and participates in international Health Committees and projects involving indicators and monitoring systems such as the Health Care Quality Indicators Project and the System of Health Accounts (SHA)<sup>14</sup>. At a local level in each institution, procedures and specific strategies are established and outcomes evaluated after clinical episodes.

#### **EVALUATION IN TRANSITION**

Other countries are evidently in transition with evaluation initiatives underway in Norway, while Malta finalised its National Health System strategy in September 2014, specifying quality of care as one of the main pillars. A Health Strategy performance assessment framework has been developed, and the first report documenting this published online. Healthcare provider level KPIs (Key Performance Indicators) have been identified and will build on currently monitored areas such as re-admission rates for hospitals, length of stay, customer care feedback, and mortality rates.

<sup>8</sup> http://www.dgs.pt/directorate-general-of-health.aspx?v=b5ef3dfe-6f5f-4ce3-8e86-fabad33830bf

http://pns.dgs.pt/files/2013/05/3\_3\_Strategic-Axis-Quality-In-health.pdf;

<sup>&</sup>lt;sup>10</sup> https://www.dgs.pt/departamento-da-qualidade-na-saude.aspx

<sup>11</sup> http://pns.dgs.pt/nhp-in-english/

<sup>&</sup>lt;sup>12</sup> http://www.acss.min-saude.pt/DepartamentoseUnidades/UnidadePlaneOrganiza%C3%A7%C3%A3odeServi%C3%A7osdeSa%C3%BAdePrim%C3%A1rios/Qualidade/tabid/784/language/pt-PT/Default.aspx

 $<sup>^{13}</sup>$  http://www.sep.org.pt/~seporg/index.php?option=com\_content&view=article&id=5552:porto-snniea-sistema-nacional-denotificacao-de-incidentes-e-eventos-adversos&catid=52&Itemid=57

<sup>&</sup>lt;sup>14</sup>These include "Health Accounts for Portugal" and "Health Care Quality Indicators" (OECD online)

Greece, too, is changing the way it evaluates care. Until recently, reporting was done at a regional level that included yearly reports on financial activity, health indices, staff, and technical activities. Despite the obvious positive effects of such a process, a clear evaluation mechanism and a strictly standardised procedure were not in place. In recent years, the web based system BI forms<sup>15</sup> was established by the Ministry of Health as a systematic means to collect financial and functional health services related data in detail at a national level.

Like Greece, Serbia is also emerging from a period of change in relation to healthcare evaluation. In the past 15 years, the quality of health care services, and capacity-building in this regard, have risen to the top of the health care system agenda. This has culminated in the Strategy for Continuous Improvement of Quality of Health Care Services and Patient Safety of 2009<sup>16</sup>. Health care quality is also part of the Health Care Law and related Bylaws, the most important of which for the evaluation of the quality of care is the Bylaw on Health Care Quality Indicators of 2007<sup>17</sup>. All public health care institutions (providers) must collect and return data on indicators relating to:

- the provision of care (by type of care provided)
- · the management of waiting lists
- patient safety
- patient satisfaction
- employee satisfaction

The Institute of Public Health evaluates, compares, and reports results to the Ministry of Health and Health Insurance Fund. Furthermore, every health care institution has its own Commission for Quality Improvement to oversee and manage continuous health care quality improvement in related health care institutions.

Croatia's National Health Care Strategy 2012-2020<sup>18</sup> locates the majority of quality management implementation (regulated by legal framework) in the Agency for Quality and Accreditation in Health Care and Social Welfare:

- granting, renewing, and withdrawing accreditation
- · designing and implementating measures for improving patient care quality and safety
- participating in health technology assessment processes
- · training in quality assurance, improvement, and promotion in the field of social welfare

A voluntary accreditation process for hospitals commenced in most Croatian hospitals by March 2012. A relevant by-law is expected to support the implementation of this process while accreditation standards are in the process of international validation. To date, Croatia has published 60 clinical guidelines (31 in the journal Liječnički vjesnik and 29 at Croatian Medical Association's web sites) which are implemented in practice. Requirements also exist for additional staff in order to improve the system of health care quality measurement and analysis and health technology assessments.

<sup>15</sup> http://bi.moh.gov.gr/login

<sup>&</sup>lt;sup>16</sup> http://www.zdravlje.gov.rs/downloads/Zakoni/Strategije/Strategija%20Za%20Stalno%20Unapredjenje%20Kvaliteta%20Z dravstvene%20Zastite%20I%20Bezbednosti%20Pacijenata.pdf

<sup>&</sup>lt;sup>17</sup> http://www.zdravlje.gov.rs/tmpmz-admin/downloads/zakoni1/Pravilnik\_pracenje\_kvaliteta.pdf

<sup>&</sup>lt;sup>18</sup> https://zdravlje.gov.hr/UserDocsImages/dokumenti/Programi,%20projekti%20i%20strategije/National%20Health%20 Care%20Strategy%202012-2020.pdf

Spain is also experiencing change in this area. Recent reforms by the conservative government mean that, at a national level, the Agency for Health Technology Evaluation<sup>19</sup> sits under the Instituto de Salud Carlos III. This means it belongs to the Ministry of Industry rather than the Ministry of Health. While Health Services are evaluated by the Ministry of Health, most competences are held in regions which have their own evaluation bodies for care and health services.

Slovenia's National Strategy on Quality and Safety in Health Care 2010-2015 places quality assurance and safety measures at its core. The strategy emphasises continuous quality improvement of services and safety through systematic stakeholder engagement. Formally arranged inspection and supervision, together with better access to relevant medical data, are instrumental for the success of the strategy goals, which include:

- · developing a formal, systemic model for quality and safety management
- improving the existing general culture for better safety and quality care for patients
- establishing a formal system for educating and training professionals in the field of health quality and safety
- · developing schemes to improve the efficiency and effectiveness of health treatment

Arising out of the strategy, 'The Manual on Quality Indicators in Health Care' defines measures of quality for all health care service providers across a range of diseases. The indicators give providers a constant overview of the quality of their services, allow continuous assessment and quality control by relevant national bodies, and offer patients information on the safety and quality of specific treatments. Health services can be compared over time, and the current quality of health services between similar health care institutions can be assessed.

The manual emphasises the need for further development of IT infrastructure. Currently, the National Institute for Public Health (NIJZ) collects and monitors data on hospital and non-hospital medical treatments at the national level. The NIJZ is currently preparing for patient level monitoring that will connect existing health related databases to a single secure and supervised central registry of patient data. It will enable data collection from various novel systems that are based on new paradigms, such as data streaming from various levels of disease management, and will enable future development of new therapeutic strategies. The system will facilitate accurate measurement of the quality indicators and will support the security and anonymization of medical data and patient registries.

<sup>&</sup>lt;sup>19</sup> Agencia de Evaluación de Tecnologías Sanitarias

#### CONNECTED HEALTH STRATEGIES ACROSS EUROPE

Respondents were asked whether or not their region or state had in place a strategy dealing with Connected Health or eHealth. Where there was such a strategy, we asked them to provide a link to an electronic version of that strategy. The complete list can be found in Table 1 below.

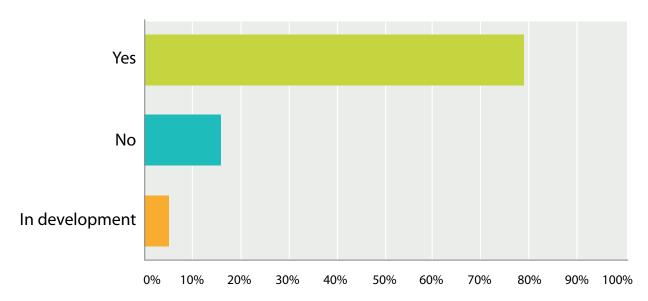


FIGURE 3: IS THERE A LOCAL/REGIONAL CONNECTED HEALTH/EHEALTH STRATEGY?

The vast majority of respondent countries (almost 80%) had an eHealth strategy in place with another 5% in the process of developing such a strategy. The table below offers links to the relevant strategy documents:

TABLE 1: CONNECTED HEALTH STRATEGY DOCUMENTS ACROSS EUROPE

Country	eHealth Strategy Document	Link
Belgium	Action plan e-Health	www.riziv.fgov.be/nl/themas/zorgkwaliteit/e-gezondheid
Croatia	Strategic Plan for eHealth Development 2014	https://zdravlje.gov.hr/UserDocsImages/dokumenti/Programi,%20projekti%20i%20strategije/Strate%C5%A1ki-plan_razvoja_eZdravlja.pdf
Finland	ehealth and eSocial Strategy 2020	www.julkari.fi/bitstream/handle/10024/125955/URN_ISBN_978-952-00-3575-4.pdf?sequence=1
France	Various documents	Connected Health: http://esante.gouv.fr/services/sante-connectee Telemedicine: http://esante.gouv.fr/services/reperes-juridiques/ledecret-du-19-octobre-2010-relatif-a-la-telemedecine PHR: http://esante.gouv.fr/services/espace-dmp/dmp-compatibilite Digital Care: http://social-sante.gouv.fr/systeme-de-sante-et-medicosocial/e-sante/sih/territoire-de-soins-numerique/article/leprogramme-territoire-de-soins-numerique-tsn
Germany	German eHealth Law	www.gematik.de
Greece	eHealth Strategy	https://www.antilope-project.eu/wp-content/uploads/2014/05/ Greek-eHealth-Strategy-under-public-consultation-Mina-Boubaki- Ministry-of-Health-Greece.pdf www.moh.gov.gr/articles/ministry/grafeio-typoy/press-releases/3953- prwth-synedriash-ethnikoy-symboylioy-diakybernhshs-hlektronikhs- ygeias
Ireland	eHealth Strategy for Ireland	http://health.gov.ie/blog/publications/ehealth-strategy-for-ireland/
Israel	HMO individual eHealth strategies	Links not available
Lithuania	HMO individual eHealth strategies	http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=306637
Macedonia	IT Strategy for Health	http://zdravstvo.gov.mk/wp-content/uploads/2015/06/ IT_strategija_IZIS.pdf
Portugal	Health Data Platform	https://servicos.min-saude.pt/utente/ http://spms.min-saude.pt/en/ http://www.arsnorte.min-saude.pt/portal/page/portal/ARSNorte
Serbia	Serbian Government eHealth Strategy (2009)	http://www.rfzo.rs/download/uredbe/Ezdravlje.pdf
Turkey		https://enabiz.gov.tr/Giris.aspx

#### **CONNECTED HEATH ACTIVITIES**

E-prescribing appears at the top of the Connected Health activity agenda with all respondent countries either having such a system in place (63%) or actively working towards one (37%). While Electronic Health Records (EHRs) also boasted a 100% commitment, the proportion with active EHRs was lower with 58% already in place while 42% were still a work in progress. This may reflect the challenges associated with the breadth of players and data types that must be integrated to form an EHR. Personalised medicine appears to pose the greatest challenge in eHealth with only two countries stating that they have active personalised medicine programmes in place. Six respondent countries did not even feature personalised medicine on their eHealth planning horizon. The slightly larger focus on EHRs over Personal Health Records (PHRs) may reflect a Europe which is leaning towards the health professional and health system as information curators and controllers, rather than the patient or citizen as their own health data manager. To balance this point, it should be noted that respondents articulated a wide range of available Citizen Services which are discussed in more detail below.

TABLE 2: DO THE FOLLOWING CONNECTED HEALTH/EHEALTH ACTIVITIES EXIST IN YOUR REGION?

Status			
	Planned	Active	Total
E-prescribing	<b>36.84%</b> 7	<b>63.16%</b> 12	19
E-referral between practitioners	<b>38.89%</b> 7	<b>61.11%</b> 11	18
Electronic Health Records (EHR)	<b>42.11%</b> 8	<b>57.89%</b> 11	19
Personal Health Records (PHR)	<b>47.06%</b> 8	<b>52.94%</b>	17
E-scheduling	<b>35.29%</b> 6	<b>64.71%</b> 11	17
Personalised Medicine	<b>84.62%</b> 11	<b>15.38%</b> 2	13
Citizen Services	<b>33.33%</b> 5	<b>66.66%</b> 10	15
Other	<b>44.44%</b> 4	<b>55.56%</b> 5	9

Where respondents had indicated that their country did, in fact, have either an EHR or PHR system in place, they were asked to elaborate on the nature of that system. The analysis of the responses has been broken down into the impact or focus of the services from three perspectives – the citizen or patient; the healthcare provider or health system manager; and the industry or corporate vendor.

#### FOR THE CITIZEN:

In the UK, the PHR rolls out through the citizen services portal, NHS Choices, while the EHR is predominantly web-based and centrally hosted by an external vendor. PHR viewing of the record is also enabled by EHR vendors with patients given a username and PIN.

A Norwegian PHR has been suggested, and some features are already available. These include name and family information, change of GP (General Practitioner, Primary Care), and an overview of hospital admission (from an administrative point of view). However, no clinical information is available to-date.

An mHealth application enables appointment-making in Spain as well as access to health information, change of doctor, etc. It is also planned to add applications which assist patients in the management of chronic conditions (e.g., http://www.palante-project.eu/). Belgians can consent to use of their data online at www.patientconsent.be.

In Ireland, the existing patient-oriented systems are limited and often child-related. They currently rely on predominantly paper-based approaches (e.g. an Oncology passport for Children, held by parents for children) with recent moves towards the use of mobile phone applications. For example, one such app allows parents to track their children's immunisation records.

The Macedonian Ministry of Health has implemented several electronic services for citizens including:

- national system for electronic scheduling of interventions and reviews My Appointment
- electronic referrals (E- Referrals)
- electronic prescription (e-Prescription)
- electronic medical journal (log of medical procedures performed on the patient)

These systems are integrated into the currently developed national system for electronic health records. EHR is not currently used in those e-services. In addition, the Health Insurance Fund of Macedonia has implemented more than 30 e-services for insured people, healthcare professionals, and companies. More than 80% of the services offered by the Fund's branch offices are provided electronically through e-services. For the insured, these include access to data for personal insurance, data on selected physicians, e-submission of forms, and monitoring status of requests.

ePrescription enjoys full nationwide coverage in Croatia, contributing to the country's third place ranking on the EC Digital Agenda Scoreboard<sup>20</sup>. The Croatian PHR is also active. The data for this is delivered by HL7-based messages from the GP office's software application (certified by Croatian Health Insurance Fund) via a secure (VPN, role-based access with smart-card) channel to the Central Health Care Information System

<sup>&</sup>lt;sup>20</sup> http://digital-agenda-data.eu/charts/desi-components

in Croatia (CEZIH). Control for this rests with central Citizen Services: e-Citizens. Other services available nationally include, but are not limited to, an eWaiting List, eOrdering, and a National Prevention Program. In addition, healthcare users will have complete and intuitive insight into their information on the planned Croatian EHR and will be able to see both its use and access history.

The implementation of hospital information systems began in Lithuania in 2008. Currently, one of the major problems is the uncoordinated actions of separate healthcare institutions. This has led to institutions investing in their own information systems. After agreeing to the terms and conditions of the electronic system, patients can obtain information on their laboratory results, operation protocols, images, and other eClinical documents. In the future, patients will also be able to register their body temperature and blood pressure themselves.

While significant efforts have been made to improve the Polish healthcare information system, innovative solutions have been piloted on a small scale. There are, however, Citizen Services concerning administrative matters that are delivered by a range of local and national actors.

The Maltese PHR is provided via a secure online system, which is accessible through an electronic ID. The patient must have an eID and must nominate medical practitioners who hold an eID to view and release their results to them. Patients can view pending appointments and request a change of appointment. They can also view discharge summaries, laboratory results, medical imaging reports, and a list of medications they can obtain free at point of care.

Citizen Services in Portugal include electronic appointment and surgery scheduling, renewal of medication, and requests for fee exemptions. A wide variety of applications have been recently introduced or are under development including physicians support system (SAM), nursing practice support system (SAPE), electronic prescription (PEM), scheduling of medical appointments (CTH and e-agenda), management and disclosure of surgical waiting times (eSIGIC), oral health information system (SISO), and dematerialisation of death certificates. It is intended that the Electronic Health Record (EHR), which currently provides clinical information to health professionals, will eventually be accessible to patients.

In Israel, the EHR is contained within a Health Maintenance Organisation (HMO). The patient can access parts of their records via the internet, using a username and password. However, they cannot ammend the EHR in any way.

In March 2009, Lithuania introduced electronic citizen ID cards. These were financed through the state budget. Each card contains an electronic chip linked to various security mechanisms. However, questions remain around security and data storage, particularly in relation to the viewing and protection of data. Additional concerns include the treatment of HIV and psychiatric treatment data, as well as the financing of such new electronic applications.

#### FOR THE HEALTHCARE PROFESSIONAL/MANAGER:

For Healthcare providers, the Health Insurance Fund of Macedonia e-services include:

- the ability to check the validity of health insurance
- e-submission and e-signature of contracts with the Health Insurance Fund
- · verification of orthopaedic and medical aids
- · e-invoices
- the ability to search for GPs, gynaecologists and dentists
- · monitoring of active/inactive patients and patients who "log off"

The Fund has also implemented an e-treasury system through which all payments from public health institutions toward suppliers and clients are enabled to be performed digitally.

Greece has adopted common medical information coding standards in hospitalization, medication, diagnosis, etc. and is leveraging epSOS initiatives for patient summaries. Centralised e-prescription and e-referral services are currently based on the patient's social security number. Additionally, Greece has implemented a system whereby the patient can access personalised national health services information, such as hospitalisations and diagnosis. Information on a GP's daily availability is accessible, which assists with appointment scheduling, while an e-appointment pilot is in use. In France, the EHR similarly enables ease of scheduling in a select number of university hospitals.

Under Finnish law, all public health care providers within one hospital district may view all patient information from other institutions, provided specific patients have not prohibited this<sup>21</sup>. Current functionalities include access to structured patient information for professionals and citizens, ePrescription (including epSOS), eView, and a Patient Information service for citizens.

The Maltese EHR is provided through a secure online system, accessible using an electronic ID. The locus of control for the EHR is the attending physician who can access summaries, laboratory results, medical imaging reports, and the list of medications that the patient has been authorised to obtain free at point of care. This information is available to both public and private medical practitioners caring for the patient. Public health service practitioners can also request laboratory and imaging investigations online.

In Portugal, services are delivered through a national health number which is centrally controlled<sup>22</sup>. The Portuguese National Commission for the Electronic Health Record (CNRSE)<sup>23</sup> was established in 2011 to coordinate and implement the RSE by the end of 2012. Subsequently, the Committee for Clinical Computerisation (CIC) was created as a successor to the Electronic Health Record Commission to design and implement the Health Data Platform (PDS, PDSi.1). Through the EHR, health professionals may access clinical information archived in healthcare institutions. In the future, patients will also have access to these records.

<sup>&</sup>lt;sup>21</sup> Please note: in effect since May 2011

<sup>&</sup>lt;sup>22</sup> https://servicos.min-saude.pt/utente/Info/Portal/Features

<sup>&</sup>lt;sup>23</sup> Order No. 381/2011, pursuant to the Programme for the Electronic Health Record (RSE)

The Croatian EHR is in development and will be stored in the Central Health Care Information System in Croatia (CEZIH). Each health care user will have a unique Electronic Health Record (EHR) which is completed by their general/family medicine practice, clinical practice specialist, hospital, laboratory, diagnostic unit, private health care institution, and others. Elements of the record must be accessible when an authorized person (e.g. physician) requires it and has patient consent.

In line with legislation, EHRs in Norway are institution specific. The citizen may request the information which is granted as hard copy. Some electronic pilot programs exist. These provide access to discharge letters and carefully selected types of information, most of which are emergency based. This information is stored for 3 years and primarily serves to assist health providers.

In Turkey, applications of the EHR are extensive and provide access to:

- e-Laboratory results<sup>24</sup>
- e-Private doctor talks<sup>25</sup>
- patient information booklets <sup>26 27</sup>
- e-Inpatient directory
- e-Materials required for patients admitted to hospital
- various forms of e-Principles (nutrition in hospitalized and paediatric patients patients)
- e-Patients' rights
- · e-Analysis Request
- e-Infection control program<sup>28</sup>

Ireland has limited focused examples of EHRs and PHRs. While maternity hospitals currently use a patient held paper chart, this is in the process of moving towards electronic record, starting with the Dublin region. The new Irish National Childrens hospital, which is currently at the planning stage, has a stated objective to be Ireland's first paperless hospital. Currently, e-Scheduling is active with relation to phlebotomy. It is planned that personalised medicine will begin in cancer care. Additionally, National Clinical Care programmes are developing integrated models of care in specified areas.

The Lithuanian eHealth strategy describes three stages:

- 1. Pre 2011: the main functions, support facilities and infrastructure of the National electronic health system (NEHS) were being prepared
- 2.From 2011 till 2014: the majority of GPs, institutions, primary healthcare institutions and other healthcare institutions were expected to use the EHR system and have access to the NEHS client services
- 3.By 2016: the universal use of eHealth information tools by patients, GPs, primary healthcare institutions and hospitals is foreseen

<sup>&</sup>lt;sup>24</sup> http://www.erciyes.edu.tr/default.asp

<sup>&</sup>lt;sup>25</sup> http://hastaneler.erciyes.edu.tr/anasayfa.htm

<sup>&</sup>lt;sup>26</sup> http://onkolojihast.erciyes.edu.tr/ana\_sayfa.html

<sup>&</sup>lt;sup>27</sup> http://kalphast.erciyes.edu.tr

<sup>&</sup>lt;sup>28</sup> http://hastaneler.erciyes.edu.tr/anasayfa.htm

In Serbia, the EHR, developed through the EU-IHIS IPA project, was piloted in 12 hospitals during 2015. Later in 2015, the Ministry of Health purchased a new system focused on the electronic scheduling of interventions, reviews, referrals, prescriptions, and an electronic medical journal. It is expected that this system will be implemented in 2016. As of the first quarter 2016, health professionals in general had not been exposed to the new system. It remains unclear how the new system will be integrated with the earlier established electronic services of the NHIF (data about insured individuals, insurance validity, reporting on prescriptions and procedures) that significantly affect the daily work of health providers and professionals. The electronic health card was piloted in 2015, and its replacement on a larger scale is expected in 2016.

#### **FOR COMPANIES:**

The Health Insurance Fund of Macedonia provides e-services for companies including the ability to check health insurance and e-registration for employees and members insured by them, options to request issue of electronic health cards, as well as identification and digital signing of documents, xml files, or service requests.

The Serbian Health Insurance Fund provides a portal where employers may register and investigate employees and their dependents. The Serbian electronic health card was piloted in 2015, and its national rollout is expected to begin in 2016.

#### **PRIVACY AND SECURITY**

# Act Ministry of Health Law Regulation Privacy and Security Information System Health System

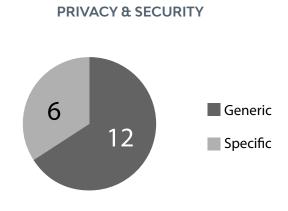
FIGURE 4: WORD CLOUD GENERATED FROM PRIVACY AND SECURITY RESPONSES

Responses varied in relation to privacy and security related to eHealth. Some countries cited over-arching EU regulations as their primary guidance in relation to the use of eHealth. Other respondents stated that they implemented national and eHealth-specific legislation to govern its usage in their country. Additionally, some countries stated that they relied on general data protection legislation to cover the area of eHealth – either general personal data protection legislation, general health data protection legislation, or a combination of both. Where there is a reliance on this type of general legislation, there appears to be a

move towards the development of more specific eHealth-related privacy and security legislation and regulation. This can be seen in examples such as the Irish Health Identifiers Act as a prelude to the introduction of an EHR system and in Lithuania's eHealth strategy implementation process.

## GENERAL DATA REGULATION: PERSONAL DATA, HEALTH DATA OR A COMBINATION

Almost all of the countries (including Finland, who is not otherwise mentioned below) within the study cited European regulations and their translation into law at a national level. However, this referred to general data protection legislation.



Greece has aligned with the EU directives, specifically through the Hellenic data protection authority, as the body responsible for data protection.<sup>29</sup> Legislation relevant to this includes patients' rights to access their own health data<sup>30</sup>, the protocol for the use of medical data in a court of law<sup>31</sup>, and the use of medical data for research purposes. <sup>32</sup>

The Lithuanian e-commerce framework is currently based on the general norms of private law, consumer protection law, and data protection law. However, the Lithuanian Parliament has passed a Law on the Services of Information Society. The development of an eHealth legal framework is underway (including a review of the need for new regulations) as part of a continuous process throughout the implementation of the Lithuanian eHealth Strategy. Several national regulations deal with the development of the information society in Lithuania. Many of these are relevant to eHealth but few envisage eHealth specifically. No specific legal provisions on telemedicine, for example, or ePrescribing are issued. The Law on Legal Protection of Personal Data, and several secondary normative legal acts<sup>33</sup>, establish detailed rules and obligations of the parties concerned. Generally, both the Law on Legal Protection of Personal Data and the secondary legislative acts follow the Data Protection Directive 95/46EC. This is also the case for the criteria on the lawful processing of health data. The main legal acts regulating patient rights and duties are the Law on Patient's Rights and Compensation for Health Damages and the Civil Code. Healthcare providers' rights and duties are also regulated through the Law on Medical Practice. However, specific regulations on Electronic Patient Records are not included.<sup>34</sup>

The main Irish law dealing with data protection is the Data Protection Act 1988. This Act was amended by the Data Protection (Amendment) Act 2003 which brought it into line with the EU Data Protection Directive 95/46/EC. The ePrivacy Regulations 2011 (S.I. 336 of 2011) deal with data protection for phone, e-mail, SMS,

<sup>&</sup>lt;sup>29</sup> http://www.dpa.gr/portal/page?\_pageid=33,43560&\_dad=portal&\_schema=PORTAL

<sup>&</sup>lt;sup>30</sup> 2472/1997 and 3418/2005

<sup>31 74/2010</sup> 

<sup>&</sup>lt;sup>32</sup> 46/2004, 47/2004, 16/2005, 32/2006

<sup>&</sup>lt;sup>33</sup> These include, for example, the Resolution of the Government of the Republic of Lithuania concerning the Reorganisation of the State Register of Personal Data Controllers and the Orders of the SDPI on Approval of the Rules on the Requirements for the Description of Data Protection Measures and Procedural Details

<sup>&</sup>lt;sup>34</sup> Other relevant legal acts include: Electronic Signature Law of 11 July 2000, amended on 26 June 2002; Law on Electronic Communications, 2004, amended on 1 September 2007, on 15 November 2008, on 1 January 2009 and on 15 March 2009. Actual wording since 15 March 2009; Law on the Services of Information Society of 25 May 2006

and Internet use and give effect to the EU e-Privacy Directive 2002/58/EC (as amended by Directive 2006/24/EC and 2009/136/EC). Specific to medical/healthcare, the Irish Data Protection Commissioner's website states that:

"The confidentiality of patient records forms part of the ancient Hippocratic oath, and is central to the ethical tradition of medicine and health care. This tradition of confidentiality is in line with the requirements of the Data Protection Acts 1988 & 2003, under which personal data must be obtained for a specified purpose, and must not be disclosed to any third party except in a manner compatible with that purpose. Given the immense sensitivity of health-related information, it is imperative that professionals in this sector be clear about their use of personal data... The Data Protection Commissioner recognises that it would be preferable for comprehensive and carefully thought-through guidelines to be designed by the appropriate representative bodies in this sector, by way of statutory codes of practice."

Most recently this has been addressed in the 2014 Health Information Bill, whose main objectives are to:

- establish a legislative framework to enable information in whatever form to be used to best effect to enhance medical care and patient safety throughout the health system
- to facilitate the greater use of information technologies for better delivery of patient services
- to underpin an effective information governance structure for the health system generally

In Belgium, Poland, and Turkey, this governance comes under the traditional healthcare processes. This is done through the National Health Care service (RIZIV) in Belgium and the Ministry of Health and head of the hospital in Turkey.

More in line with the Irish approach, Portugal leans towards general personal data rather than health data legislation to cover eHealth. Decree-law 12/2005 governs the use of private health data. This law states that health information is the property of the person, who acts as the unit of the health system's trustees of that information. The Portal do Utente (Health Data Platform)<sup>35</sup> activity is regulated by the Comissão Nacional de Proteção de Dados (CNPD) – the National Commission for Data Protection. In technical terms, in web pages where personal data is collected, its transmission is cyphered using the TLS 1.0 (Transport Layer Security) with 256-bit encryption keys. Digital certificates (CDSW) are also used. Similarly in Spain, the main law is the LOPD (Ley Orgánica de Protección de Datos). Although a national law, it can be further regulated with regional laws.

The Serbian national law on the Protection of personal data<sup>36</sup> governs privacy and security. It specifies the possible ways through which personal data may be collected, processed, used, and protected. It is directly linked to related law on free access to information of public significance<sup>37</sup>. Additionally, the protection further relates to the law on Protection of Data Confidentiality.<sup>38</sup> This establishes a unique system for determination and protection of confidential data related to the national and public security, defence, and internal and external affairs. In relation to the healthcare framework, this area is additionally addressed within the

<sup>35</sup> https://servicos.min-saude.pt/utente/TermsConditions

 $<sup>^{36}\</sup> http://www.rfzo.rs/download/zakoni/Zakon\%200\%20zastiti\%20podataka\%20o\%20licnosti-preciscen\%20tekst.pdf$ 

<sup>&</sup>lt;sup>37</sup> http://www.rfzo.rs/download/zakoni/Zakon%20o%20slobodnom%20pristupu%20informacijama%20od%20jz-preciscen%20tekst.pdf

<sup>38</sup> http://www.rfzo.rs/download/zakoni/Zakon%20o%20tajnosti%20podataka.pdf

programme of operation, development, and organization of the Serbian integrated health information system, "eHealth"<sup>39</sup>, and the new Law on Health Records and healthcare-related Statutory Records in the Field of Health Care<sup>40</sup> (adopted in 2014 and postponed until 2017<sup>41</sup>).

In Malta, the Data Protection Act 2001 governs eHealth. This conforms with EU Directive 95/46/EC. It is implemented in practice using the eID framework whereby each end-user has a verified electronic identity. France has also adopted a general data governance framework, namely the National Commission for Information Technologies and Civil Liberties (CNIL), and tailored it to eHealth. This has been done through certification by the Shared Healthcare Information Systems Agency.

Norway may well demonstrate the dangers of a more generalist approach to privacy and security in an eHealth context. Here, focus is now on security and data protection. Although this was not specifically mentioned in other responses, anecdotal evidence would suggest that security and data protection issues may not be uncommon in countries where legislation is not developed specifically for the eHealth sector.

#### SPECIFIC E-HEALTH-RELATED REGULATION

Croatia has very specific eHealth related privacy and security governance that sits alongside the general health and data protection legislation, including the Law on Health Protection<sup>42</sup>; a Compulsory Health Insurance Act<sup>43</sup>; Health Insurance Act<sup>44</sup>; Law on the Protection of Patient Rights<sup>45</sup>; Law on the Protection of Personal Data<sup>46</sup>; Law on Data Secrecy<sup>47</sup>; Regulation on the Method of Keeping, Preservation, Collection and Disposal of Medical Documentation of Patients in the Central Health Care Information System of the Republic of Croatia<sup>48</sup>; Regulation on the Use and Protection of Data Contained in the Medical Documentation of Patients in the Central Health Care Information System of the Republic of Croatia<sup>49</sup>; Regulation on the Method of Keeping of Personal Health Care Files in Electronic Form<sup>50</sup>; and the Regulation on the Data Secrecy and the Right to Information Access in Croatian Health Insurance Fund (internal act), June 2015.

Sanctions for breach of legislation can include dismissal, payment for damages suffered, or other appropriate measures. The Law on Medical Practice prescribes sanctions for medical doctors who do not maintain medical records, while other penalties are set out in the Law on Protection of Personal Data. Croatia also uses the concept of national critical infrastructure - systems, networks, and facilities of national importance that include eHealth infrastructures.<sup>51</sup> The legal framework and regulations on critical infrastructures are handled by the National Protection and Rescue Directorate<sup>52</sup> in the Law on Critical Infrastructures<sup>53</sup>.

```
<sup>39</sup> Official Gazette of the Republic of Serbia no. 55/09
```

<sup>&</sup>lt;sup>40</sup> http://www.uizs.org.rs/wp-content/uploads/Zakon-o-zdravstvenoj-dokumentaciji-i-evidencijama-3533-14.pdf

<sup>&</sup>lt;sup>41</sup> http://www.uizs.org.rs/wp-content/uploads/201512-predlog-izmene-zakona-3314-15.pdf

<sup>&</sup>lt;sup>42</sup> Official Gazette 150/08, 71/10 - 22/14

<sup>&</sup>lt;sup>43</sup> Official Gazette 150/08

<sup>&</sup>lt;sup>44</sup> Official Gazette 150/08, 94/09, 153/09, 71/10, 139/10, 49/10, 22/12, 57/12, 123/12

<sup>&</sup>lt;sup>45</sup> Official Gazette no. 169/04, 37/08

<sup>&</sup>lt;sup>46</sup> Official Gazette 103/03, 118/06, 41/08, 130/11, 106/12

<sup>&</sup>lt;sup>47</sup> Official Gazette 79/07, 86/12

<sup>&</sup>lt;sup>48</sup> Official Gazette 82/10

<sup>&</sup>lt;sup>49</sup> Official Gazette 14/10

<sup>50</sup> Official Gazette 82/10

<sup>&</sup>lt;sup>51</sup> Official Gazette 108/13 (http://narodne-novine.nn.hr/clanci/sluzbeni/2013\_08\_108\_2411.html)

<sup>52</sup> http://www.duzs.hr/page.aspx?PageID=246

<sup>53</sup> Official Gazette 56/13 (http://narodne-novine.nn.hr/clanci/sluzbeni/2013\_05\_56\_1134.html)

The existing risk analysis rules for critical infrastructure businesses<sup>54</sup> require the identification of a central state administration body (in this case, Croatian Ministry of Health). They also demand cooperation with the relevant regulatory agencies (in this case, CHIF and other institutes and agencies) to identify and maintain a database of critical infrastructure, establish sectoral benchmarks for risk analysis of critical infrastructure, and prepare sectoral risk analysis of business critical infrastructure. This is an ongoing process.

In Germany, such issues are specifically dealt with under eHealth law. In France, although the protection rests at a generic level with the National Commission for Information Technologies and Civil Liberties (CNIL), certification by the Shared Healthcare Information Systems Agency ensures a specific focus for eHealth.

Slovenia supplements a generalist, over-arching Personal Data Protection Act with specific eHealth-related regulation. In general terms, privacy and security of personal data is well-defined in an umbrella document from 2013. It is governed by The Ministry of Justice of R. Slovenia<sup>55</sup>. However, the "Healthcare Databases Act" was amended on the 30th of June 2015 with specific reference to privacy in health databases. It addresses the privacy and security of the national health system in the context of contemporary needs. The third Article of the Act designates the National Institute for Public Health and other providers of health services in R. Slovenia as governors of databases in the field of health care.

The UK has merged its general health and data oversight to address eHealth and health data networks. The NHS Health and Social Care Information Centre<sup>56</sup> is ultimately responsible for the privacy and security of the NHS network - known as N3. Locally, however, the Data Protection Act applies to health data. These health data controllers are known as 'Caldicott Guardians' after the Caldicott report.<sup>57</sup>

For Macedonia, this issue is a work in progress. There is recognition that ensuring privacy and security of health information, including information in EHRs, PHRs, and EMRs, is a key component to building the trust required to realize the potential benefits of health information exchange. To that end, privacy and security standards are currently under development with different actors at different stages in the process. The top eHealth supporting regulation is the Law on Health Records and Healthcare-related Statutory Records in the Field of Health Care<sup>58</sup> adopted in 2014. The accompanying regulations should be prepared by the start of its practical enforcement in 2017.

<sup>&</sup>lt;sup>54</sup> Official Gazette 128/13 (http://narodne-novine.nn.hr/clanci/sluzbeni/2013\_10\_128\_2792.html)

<sup>55</sup> English translation can be found on the following link: https://tinyurl.com/ozkhll8

<sup>56</sup> http://www.hscic.gov.uk

 $<sup>^{57}\,</sup>https://www.gov.uk/government/publications/the-information-governance-review$ 

<sup>58</sup> http://www.uizs.org.rs/wp-content/uploads/Zakon-o-zdravstvenoj-dokumentaciji-i-evidencijama-3533-14.pdf

## POLITICAL INSTRUMENTS/STATEMENTS THAT GUIDE CONNECTED HEALTH POLICY-MAKING

Apart from the eHealth strategies dealt with earlier parts in this report, policy-making in the area of Connected Health leverages and gives rise to a variety of public statements and political instruments. Respondents were asked to identify and cite such activities with a view to understanding how important Connected Health is from a political perspective.

## Mentioned Concerning eHealth Acts Health Care White Paper

FIGURE 5: WORD CLOUD REFLECTING PREVALENT RESPONSE TERMS IN CONJUNCTION WITH POLITICAL STATEMENTS/INSTRUMENTS GUIDING POLICY-MAKING

In Lithuania, the 'Strategy of Lithuanian eHealth development for the years 2007-2015' has more recently been followed by a detailed implementation plan. This is titled the 'E. Health System Development Program for 2009 – 2015'. eHealth is also mentioned indirectly in the 'Concept of Electronic Government' from 2002. The main elements of this were transferred to the "Strategy for the Development of Public Administration until the Year 2010". An Action plan for the transfer of public services into electronic space by 2012 was adopted by order of the Minister of Communications on June 14th, 2010. The function of this was to set priority actions aimed at developing public electronic services in Lithuania. In this action plan, several measures are dedicated to the development of eHealth services. Lithuanian local administrations of major cities such as Vilnius, recently took steps to implement eHealth projects. Orders to form work groups or implement public procurements can be found, but there are no legal acts or comprehensive policy documents.

The Turkish Ministry of Health has a website dedicated to its health related activities. The opening introductory sequence and the scrolling images on the main website focus on the people within the Ministry and international visits of note. It should be noted that this is also the website of the EU and Foreign Affairs Directorate. Recent news items as of Quarter 1 2016 do not make any mention of eHealth or Connected Health matters.

In contrast, the website of the German Ministry for Health showcases the eHealth card and states that: "Nowadays, the quality of medical treatment depends to a greater and greater extent on whether the doctor has all of the information necessary to provide his/her patient with the right medical care. If the patient so wishes, the eHealth Card, together with an electronic health care network (telematics infrastructure) that is separate from the internet, will be able to make the health data needed for treatment available safely and rapidly in the future. The aim is to improve the quality of medical care, strengthen the role of patients and reduce costs." <sup>59</sup>

<sup>&</sup>lt;sup>59</sup> http://www.bmg.bund.de/en/health/the-electronic-health-card.html

In Ireland, the appointment of a new Chief Information Officer<sup>60</sup> and the introduction of new Health Identifiers<sup>61</sup> to enable linking up of personal health information across multiple care environments have received top billing in media and government announcements.

Israel completed the transition to computerized medical records a decade ago in most care settings. This was done in a spontaneous fashion without government control or standardised settings. Therefore, the current challenge is to convert the information scattered in different systems into organized, visible information and make it available at various levels in health management. The Ministry of Health's solution is to implement a selected information system from a specific vendor at all hospitals and HMO clinics in order to achieve interoperability. The system will allow access to patients' medical records from any location.

The Norwegian government has expressed expectations around eHealth. Consequently, a number of earlier white papers on the subject have been consolidated into one comprehensive white paper – 'Future Health.'62 This paper opens with the following quote:

"The care services crisis is not created by the elderly boom, but by the notion that care cannot be provided in a different way than it is today." (Source Kåre Hagen)

The Maltese government included in its manifesto<sup>63</sup> the following measure: to evaluate the current myHealth system with a view to making it more user-friendly for patients, family doctors, and pharmacists in both the community and Health centres. This is positioned as an important step towards the development of much needed primary care reform and improving communication between patients in acute and community care settings.

As part of its 2014 EU Presidency, the Greek government took the opportunity to highlight the importance of eHealth and to encourage "systematic efforts towards the design, development, and deployment of advanced eHealth services in various healthcare sectors". Its particular focus was twofold: the improvement of health benefits and the creation of high technology jobs. It also showcased a collaborative effort within Greece to develop an eHealth ecosystem amongst the following:

"Commercial, academic, health, well being, and social care stakeholders, decision makers, researchers, government bodies, health professionals, healthcare providers, members of academia, medical associations, patient advocacy groups, and all other key players both in the public sector and the marketplace." 64

In 2010, Portugal established the Grupo Técnico para a Informação no Sistema de Saúde (Technical Group for Information in the Health System)<sup>65</sup>. This is a public enterprise under the instruction of the Ministries of Health and Finance. Its aim is to provide shared services from the areas of purchasing and logistics, financial

<sup>60</sup> http://leovaradkar.ie/2014/12/varadkar-announces-hse-chief-information-officer-to-overhaul-ict/

<sup>61</sup> http://health.gov.ie/blog/press-release/varadkar-lynch-publish-health-priorities-for-2015/

<sup>62</sup> https://www.regjeringen.no/en/dokumenter/meld.-st.-29-2012-2013/id723252/?ch=1

<sup>&</sup>lt;sup>63</sup> http://3c3dbeaf6f6c49f4b9f4-a655c0f6dcd98e765a68760c407565ae.r86.cf3.rackcdn.com/082d10b0fed6c04d78ced4e 7836e1dc11067452380.pdf

 $<sup>^{64}\,</sup>http://ehealth2014.org/wp-content/uploads/2014/02/eHealthForum\_boston\_v\_1-2.pdf$ 

<sup>65</sup> http://spms.min-saude.pt/en/ http://www.softventure.pt/index.php?lang=en https://www.facebook.com/cloudcomputing.pt/photos/?tab=album&album\_id=842526045800731 https://mhealthinsight.com/2014/12/12/mhealth-events-for-2015/

services, human resources and information, and communications systems and technologies to organisations operating specifically in the area of health. This is to "centralise, optimise and rationalise" the procurement of goods and services within the NHS. This group presented recommendations under the headline "Initiative for focused information in System-user Health - Better information. Better knowledge" 66,67

The program of the Government of Macedonia contains a special section devoted to health and health care, some parts of which relate to Connected Health policy<sup>68</sup>.

The two major political parties with the largest number of representatives at the national level in The Croatian Parliament are the Social Democratic Party of Croatia (SDP)<sup>69</sup> and the Croatian Democratic Union (HDZ)<sup>70</sup>. In its 'Declaration on e-Health' (April 2011)<sup>71</sup>, the Academy of Medical Sciences of Croatia identified "eHealth" as the common name for the development, implementation, and evaluation of information and communication technology (ICT) in the healthcare system. The term eHealth relates to the needs of health professionals (routine or professional work, continuous education, and lifelong learning and evaluation of professional work and research) and for all citizens (for their own health: information on the health system and functioning and reliable health information on the Internet). eHealth acts as an umbrella term and is seen to denote the application of ICT in health and medicine (biomedical, medical and health informatics, health portals, medical advice on the Internet, information for patients, computerisation of health care, internetisation of health system, telemedicine).

In France, the National Doctors Council produced a White Paper on Connected Health<sup>72</sup> entitled "From eHealth to Connected Health" (2015). An earlier white paper was also produced by CATEL (2014)<sup>73</sup>. CATEL is a group of almost 20,000 participants from the health, social, training, and personal service that includes health professionals, institutions, regional authorities, industry, associative networks, researchers, and students.

The Spanish Ministry of Industry has published a report on the topic of ICT in healthcare.<sup>74</sup> Additionally, the Spanish Medical Information Association (SEIS) frequently produces reports on eHealth aimed specifically at Spanish policy makers.<sup>75</sup>

The Slovenian National Health Care Plan (2008-2013), titled 'Satisfied Users and Providers of Health Services', includes in its introduction the statement that: the "Resolution on National Health Care Plan... is based on the Law on Health Care and Health Insurance Act... and takes into account as guidance EU's health strategy 'Together for Health: A Strategic Approach for the EU 2008-2013"<sup>76</sup>.

<sup>66</sup> http://www.portaldasaude.pt/portal/conteudos/a+saude+em+portugal/publicacoes/estudos/informacao+conhecimento.htm

<sup>&</sup>lt;sup>67</sup> http://www.portaldasaude.pt/NR/rdonlyres/A5AC67FD-CC3A-4A53-B858-

<sup>81</sup>F5BF61D706/0/RelatorioFinalGrupoT%C3%A9cnicoInforma%C3%A7%C3%A3onaSa%C3%BAde\_20150216\_1300.pdf

<sup>69</sup> http://www.sdp.hr/aktualno/o-ciljevima-zdravstvene-strategije/

<sup>70</sup> http://hdz.hr/vijest/nacionalne/ante-corusic-predocio-nacrt-zdravstvene-reforme

<sup>&</sup>lt;sup>71</sup> http://www.amzh.hr/news%20and%20events.html

<sup>72</sup> http://www.conseil-national.medecin.fr/node/

<sup>&</sup>lt;sup>73</sup>www.catel.pro/documents/LivreBlanc/livre-blanc-version-synthetique.pdf

<sup>74</sup> http://www.ontsi.red.es/ontsi/es/estudios-informes/las-tic-en-el-sistema-nacional-de-salud-edici%C3%B3n-2012

<sup>&</sup>lt;sup>75</sup> http://82.98.165.8/jsp/base.jsp?contenido=/jsp/publicaciones/informes.jsp&id=5.2

<sup>76</sup> https://tinyurl.com/o7go9ng

The Finnish document, 'Information To Support Well-Being and Service Renewal eHealth and eSocial Strategy'<sup>77</sup>, aims to support "the renewal of the social welfare and health care sector and the active role of citizens in maintaining their own well-being by improving information management and increasing the provision of online services."

In the UK, Connected Health is seen as a small subset of the push towards 'integrated care' - i.e. joined up healthcare for people with high health needs.<sup>78</sup>

 $<sup>^{77}</sup> http://www.julkari.fi/bitstream/handle/10024/125955/URN\_ISBN\_978-952-00-3575-4.pdf? sequence=1.0024/125955/URN\_ISBN\_978-952-00-3575-4.pdf? sequence=1.0024/12595/URN\_ISBN\_978-952-00-3575-4.pdf? sequence=1.0024/12595/URN\_ISBN\_978-952-00-3575-4.pdf? sequence=1.0024/12595/URN\_ISBN\_978-952-00-3575-4.pdf? sequence=1.0024/12595/URN\_ISBN\_978-952-00-3575-4.pdf? sequence=1.0024/12595/URN\_ISBN\_978-952-00-3575-4.pdf$ 

<sup>&</sup>lt;sup>78</sup> https://www.gov.uk/government/uploads/system/uploads/attachment\_data/file/198748/DEFINITIVE\_FINAL\_VERSION\_Integrated\_Care\_and\_Support\_-\_Our\_Shared\_Commitment\_2013-05-13.pdf

## SECTION 2: EDUCATION

We set out to understand the exent to which education programmes across Europe are creating the conditions and skills necessary for the widespread adoption of Connected Health. In the first instance, respondents were asked a very specific question around university-based education for Healthcare Professionals. Subsequently, a more open question around programmes in general to create eHealth informed care givers and patients gave more opportunity to include ad hoc and community-based programmes. Further detail was sought on the approach to health literacy education in each region. Case studies were invited across all questions in this section. A small sample are included here as illustration.

## EDUCATIONAL CONNECTED HEALTH/eHEALTH PROGRAMMES FOR FUTURE HEALTHCARE PROFESSIONALS

Medical Informatics	41.18%	7
Data Analytics Biomedical Engineering Data Regulation	35.29%	6
Program	29.41%	5
Degree	23.53%	4
Courses	23.53%	4
Medicine	17.65%	3
MSc	17.65%	3

FIGURE 6: WORDS AND PHRASES USED IN DISCUSSING CONNECTED HEALTH HCP EDUCATION

Fifteen countries supplied specific information on university-based programmes that contribute towards the development of future healthcare professionals who are aware of Connected Health. In total, 42 specific programmes were offered as examples of this type of education, a complete list of which is available in Appendix II.

Of these 42 programmes, just under half have a Connected Health/eHealth dimension. The remainder include either health informatics or biomedical informatics elements that the respondents felt made them relevant to the future of eHealth or Connected Health.

The most popular type of programme was one that contained a health informatics element. Over half (22 out of 42) of the programmes cited have healthcare informatics as a major component. The vast majority of these 22 programmes include the phrase 'health informatics' or 'information management' in their title.

Diploma in Leadership and Quality, Royal College of Physicians, Ireland

Part of the National Quality Improvement Programme, this Diploma guides senior management and clinicians to improve patient safety within their workplaces.

It has helped to build a common language between senior management and clinicians which is vital in inspiring change in healthcare. It is designed for senior level healthcare personnel such as Clinical Directors, Directors of Nursing, Hospital CEOs, Clinical Care Programme Leads, AHP Leads, GPs, Primary and Community Care Leads.

The programme enables multidisciplinary professional teams (i.e. Doctor, Nurse, Allied Health Professional or Management) to increase quality improvement, patient safety, waste, and flow in the workplace.

It provides the insights, skills and practical knowledge needed to provide a safer healthcare service to patients. Staff are trained through eleven inhouse training days with online inter-session learning and mentoring.

## PROGRAMMES TO CREATE eHEALTH/CONNECTED HEALTH-INFORMED CARE-GIVERS AND/OR PATIENTS

Respondents showcased a range of programmes that aim to create more informed care-givers or patients across Europe. This is not an attempt to formulate an exhaustive list but rather to offer a snapshot of different training and education activities across Europe.

Lithuania provides a range of masters-level programmes that are targeted at the business, technical, and healthcare management challenges within the healthcare system. The Master of Applied Mathematics<sup>79</sup> at Kaunas University of Technology, Faculty of Mathematics and Natural Sciences looks at Business, Big Data Analytics, and Connected Health. Klaipėda University offers two relevant programmes – a Masters of Electronic Information System Engineering<sup>80</sup>, dealing with Technical Information Systems Engineering in the context of eHealth, Biomedical & Health Informatics, and Data Analytics; and a Masters of Management<sup>81</sup>, addressing Health Care Management, including both Connected Health & Data Regulation.

While Germany exhibits too many such programmes to even begin to describe, Malta, Slovenia, and Macedonia have yet to design specific programmes that target this audience. This is also, of course, a question of scale. Such courses may not be sustainable in smaller countries, and it is possible that candidates may be going abroad to study these subject areas. Turkey offers a Human Care Science and Postmodern Nursing course<sup>82</sup> through Erciyes University. Israel has focused on the patient with the establishment of patient-group focused courses<sup>83</sup>. Each HMO also has initiatives to support and inform their own patients. Norway, on the other hand, has chosen to focus on the research base with a range of research funding schemes, a Centre for Research based innovation (SFI) dedicated to Connected Care, and professionally-oriented R&D activities.

In Greece, EU-funded research projects employ eHealth, sensors, mobile technology, and analytics to change behaviour of both patients and caregivers. Examples of ongoing programmes at AUTH/CERTH include:

- The Splendid programme<sup>84</sup>: A Personalised Guide for Eating and Activity Behaviour for the Prevention of Obesity and Eating Disorders. This focuses on adolescents, the use of smart devices and mobiles
- The Welcome Programme for COPD and comorbidities<sup>85</sup> is a planned pilot in Greece for patients and carers using wearable and mobile technology to drive patient empowerment
- In-Life: INdependent Living support Functions for the Elderly<sup>86</sup>, is a planned pilot in cognitive impairment patients and their carers (amongst others). The Municipality of Trikala, in collaboration with secondary care, has installed telehealth services for chronic patients<sup>87</sup> to improve their daily life. Vital signs are recorded at home, transferred to the hospital, and reviewed by experts, who then provide the necessary feedback.

<sup>&</sup>lt;sup>79</sup> http://ktu.edu/en/programme/m/business-big-data-analytics

<sup>81</sup> https://web.liemsis.lt/kuis/stp\_report\_ects.card\_ml?p\_stp\_id=777&p\_year=2015&p\_lang=EN

<sup>82</sup> http://watsonibb.erciyes.edu.tr/

<sup>83</sup> See example at http://www.camoni.co.il/

<sup>84</sup> http://splendid-program.eu/

<sup>85</sup> http://www.welcome-project.eu/home.aspx

<sup>86</sup> http://www.inlife-project.eu/

<sup>&</sup>lt;sup>87</sup> Chronic Heart Failure, Chronic Asthma or COPD, Arrhythmias and Hypertension

- An example of much wider coverage is the Vodafone Greece Telemedicine Program, implemented in one hundred areas across Greece, focusing on enabling remote health screening of citizens especially from geographically dispersed areas
- In addition, a series of NGOs and patient associations implement programmes (often nationally or EU funded ) on patient and carer support and involvement<sup>88</sup>

Serbia has worked with the European Union and World Bank since 2005 on a range of programmes<sup>89</sup> that have included staff training alongside the establishment of hospital information systems (HIS). The Integrated Health Information System (EU-IHIS) Project<sup>90</sup> (2012-2015) is a 2.5 million euro project funded through European Union (EU) Pre-Accession Assistance (IPA). Its main goal was to implement and integrate hospital information systems (HIS) in the remaining 19 beneficiary hospitals without HIS and link these systems with the unique, standardized Electronic Health Record (EHR) system. One of the key factors to address during implementation was staff training and technical support, not just in the IT hospital sectors, but with practitioners as end users. The partners were the Ministry of Health (MoH) and the World Health Organization (WHO) with administrative support of UN Office for project Services (UNOPS). Health institutions involved are Clinical Hospital Centre (CHC) Bezanijska kosa, CHC Zemun, CHC Zvezdara, CHC Kragujevac, General Hospital in Pancevo, Sombor, Pirot, Cuprija, Cacak, Krusevac, Prokuplje, Smederevo, Kikinda and Paracin, Institute of Oncology and Radiology of Serbia, University Children's Hospital, Institute for Orthopaedic Surgery Banjica, Specialized Hospital for Rehabilitation and Othopedic Prosthetics, and Institute for Rheumatology Belgrade. Upon the HIS implementation, the project funded training activities of the end user personnel, practitioners, and other medical staff. Apart from these EU funded programmes that included some training, no other programmes exist.

In Portugal, the Doctors Order establishes agreements to provide education on the use of some tools with national entities and companies<sup>91</sup>. Croatia's National Health Care Strategy (2012-2020)<sup>92</sup> advocates an increase in IT literacy among health care workers as a significant precondition of future development and application of new information systems. Since 2006, 17,000 health care workers have obtained basic IT training and used IT applications in their daily work. Informatic Education for CHIF (Croatian Health Insurance Fund) employees was established to raise IT competences of non-IT staff. They work continuously as an internal business process of CHIF without any additional funding. The aims of this programme are to increase employee productivity, reduce support costs, and assist the adoption of higher standards of internal skills.

A public program concerning eHealth introduced by Centrum Systemów Informacyjnych Ochrony Zdrowia<sup>93</sup> exists in Poland. It is directed at healthcare institutions, managers, and medical personnel. Some commercial initiatives with a focus on eHealth also exist<sup>94</sup>.

<sup>88</sup> example list http://www.moh.gov.gr/articles/citizen/c69-xrhsimoi-syndesmoi/352-syllogoi-asthenwn

<sup>89 1.</sup> Serbia Health Project – SHP (2005-2009) 2. Serbia Health Project Additional Financing – SHPAF (2009-2012) 3. Development of a Health Information System for Basic Health and Pharmaceutical Services in the Republic of Serbia - EHR Project (2005 – 2008) 4. HIS IPA 2008 (2010 – 2011) 5. Delivery of Improvement Local Services - DILS project (2009 – 2014) 6. The Integrated Health Information System - EU-IHIS (2012-2015)

<sup>90</sup> www.eu-ihis.rs

<sup>91</sup> https://www.ordemdosmedicos.pt/?lop=conteudo&op=ed3d2c21991e3bef5e069713af9fa6ca&id=5c8e07660e3000f141dda8b83107ed6e https://www.ordemdosmedicos.pt/?lop=conteudo&op=ed3d2c21991e3bef5e069713af9fa6ca&id=cb5f984421c93f1efb42b53a43f83c3a

 $<sup>92\</sup> https://zdravlje.gov.hr/UserDocsImages/dokumenti/Programi, \%20projekti\%20i\%20strategije/National\%20Health\%20Care\%20Strategy\%202012-2020.pdf$ 

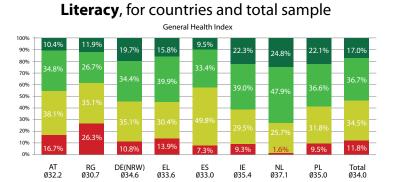
<sup>93</sup> Centre for Health Information Systems http://www.csioz.gov.pl/index.php

<sup>94</sup> e.g. http://silvermedic.eu/

Different technical tools (MOOCs, Apps, Social Media) are used in Spain to improve the patient's care experience. These elements are used for secondary prevention and self-management in multiple diseases (e.g. breast cancer, COPD). Their approach is blended, and digital tools are combined with on-site training for patients. It is also well aligned with the regional health system, especially primary care. The programme is led by the Andalusian School of Public Health<sup>95</sup> which belongs to the Andalusian Health Ministry. The centre recently became a reference point for the WHO in "Integrated Health Services Based on Primary Care"

#### PROGRAMMES TO IMPROVE THE HEALTH LITERACY INDEX

Health literacy has been shown to be a challenge across Europe<sup>97</sup> (see chart below).



problematic HL

>25-33 Points

inadequate HL

0.25 Points

Percentages of different levels of **General Health** 

#### NO HEALTH LITERACY PROGRAMMES

It was noticeable that a significant proportion of respondents were unable to identify any health literacy programmes in their country including Turkey, Norway, Portugal, Macedonia, France, and Finland. Some countries, such as Malta, were in the process of developing programmes having recently carried out a health literacy survey to inform this activity.

sufficient

>33-42 Points

excellent HL

>42 50 Points

An updated policy to reduce children's exposure to advertising practices relating to unhealthy foods has been developed by the Norwegian Government and is now subject to public consultation.

#### AD HOC HEALTH LITERACY PROGRAMMES

Of those countries that did refer to health literacy programmes, the majority of these did not address health literacy for the general population in a targeted fashion. For example, Croatia encountered this problem in completing a study on sound evidence for a better understanding of health literacy in the European Union<sup>98</sup>.

<sup>95</sup> http://www.easp.es/

<sup>%</sup> http://apps.who.int/whocc/Detail.aspx?cc\_ref=SPA-44&cc\_code=spa&

<sup>&</sup>lt;sup>97</sup> Kristine Sorensen; Jurgen M. Pelikan; Florian Rothlin; Kristin Ganahl; Zofia Slonska; Gerardine Doyle; James Fullam; Barbara Kondilis; Demosthenes Agrafiotis; Ellen Uiters; Maria Falcon; Monika Mensing; Kancho Tchamov; Stephan van den Broucke; Helmut Brand; ¼ Health literacy in Europe: comparative results of the European health literacy survey (HLS-EU) The European Journal of Public Health 2015;¾doi: 10.1093/eurpub/ckv043

<sup>98</sup> Final Report, RfS Chafea/2014/health/01, Directorate-General for Health and Consumers Health programme, European Commission, June 2015 http://ec.europa.eu/health/policies/docs/2015\_health\_literacy\_en.pdf

The study inclusion criteria meant that many programmes and activities suggested to the research team were more broadly aimed at patient empowerment or health education but not specific to health literacy (or equivalents of this concept in other languages).

Lithuania has a number of targeted masters-level programmes that address the issue of health literacy from the public health provider and health policy/managment perspectives. They include a Masters of Public Health from Klaipėda University<sup>99</sup> and a Masters of Health Policy and Management from Mykolas Romeris University<sup>100</sup>. Like Lithuania, Poland also primarily targets its national health literacy programme at healthcare institutions, managers, and medical personnel through a programme introduced by Centrum Systemów Informacyjnych Ochrony Zdrowia<sup>101</sup>.

In Belgium, there are some health programmes directed at caregivers, while specific e-learning programmes focused on dementia, obesity, urinary incontinence, and the optimal use of electronic records and EBMPractice NET<sup>102</sup> are available. Furthermore, there are specific websites providing health information to the general public and patients including http://www.gezondheidenwetenschap.be.

There are no specifically targeted programmes to address health literacy in Ireland. However, there do exist patient education programmes surrounding specific diseases that should improve health literacy. One example is the Irish Heart Foundation's Stroke Action's F.A.S.T. Campaign<sup>103</sup>. Posters, leaflets, cards, and television advertising build into a campaign that reuses materials from the UK's NHS. According to research by the Royal College of Surgeons Ireland (RCSI), the F.A.S.T campaign increased awareness of stroke symptoms by 124%. Since the F.A.S.T campaign, the thrombolysis (clot busting drug) rate in Ireland has increased by 500% saving an estimated 150 extra stroke patients a year from death or severe disability. However, the gains made by the Act F.A.S.T. campaign to date could easily be lost. The RCSI research showed that in a matter of weeks, after major bursts of campaign activity, stroke admission rates were falling back to normal levels. A second example is the Health Service Executive Advocacy Unit's Patient Charter developed in partnership with "many interested parties, including patient advocacy groups and individual advocates". One example of an outcome from this process was the development of an information resource, in partnership with patients, to enable them to care for their wounds once they have been discharged from hospital. Feedback from patients highlighted that this resource makes a difference to them as it empowers patients to safely look after their wounds and identify when something needs further attention. The National Healthcare Charter 'You and Your Health Service' is a Statement of Commitment by the HSE describing what patients can expect when using health services in Ireland and what patients can do to help Irish health services to deliver more effective and safe services. The charter is the work of a diverse and dedicated group of people with the common goal of informing and empowering people to actively look after their own health and to influence the quality of healthcare in Ireland. It is based on eight principles: access, dignity and respect, safe and effective services, communication and information, participation, privacy, and improving health and accountability. These principles have been identified through a review

<sup>99</sup> https://web.liemsis.lt/kuis/stp\_report\_ects.card\_ml?p\_stp\_id=2056&p\_year=2015&p\_lang=EN

<sup>100</sup> https://stdb.mruni.eu/ects\_katalogas/programa\_en-6566.html

<sup>&</sup>lt;sup>101</sup> eng. Centre for Health Information Systems http://www.csioz.gov.pl/index.php

<sup>102</sup> http://www.health.belgium.be/nl/e-services/e-learning

http://www.stroke.ie/iopen24/fast-campaign-t-483\_487.html

of national and international patient charters and through wide consultation with the Irish public.

Like Ireland, Spain has a number of ongoing programmes including those mentioned in the previous section, such as the one developed and provided by the Andalusian School of Patients.

Health literacy in Serbia relies mainly on patient communication with doctors in Primary Health Care Centres and through different media campaigns (invitation to screening programmes, raising awareness of AIDS, breast tumour diagnosis, etc.). These types of campaigns are sometimes driven by the Ministry of Health and occasionally by patient associations or other stakeholders. Likewise, Slovenia engages in diverse promotional and public relations activities carried out by the Ministry of Health, the National Institute of Public Health, and various NGOs.

#### TARGETED HEALTH LITERACY PROGRAMMES

In Greece, the health literacy index is used in health promotion training at schools. Various pilots are underway through regional authorities and regional education offices<sup>104</sup>. At a national level, health literacy is promoted by informing the general public about prevention of communicable and non-communicable diseases. This is done through leaflets at hospitals, tv-spots, and campaigns, etc., which rely on hybrid funding. However, the effectiveness of these types of health literacy activities is not proven. In addition to the national campaigns, various self-management projects indirectly aim at improving health literacy, usually through education. Among the first ones, CHS (from AUTH) introduced educational messages for the patient tailored to their condition. These messages were delivered by telephone automation or internet. Sample pilot studies include the DEPLAN study<sup>105</sup> which offered 126 participants, group-based, non-intensive dietary counselling to prevent type 2 diabetes. Another example is a patient education programme using Conversation Maps for people with type 2 diabetes to encourage self-management<sup>106</sup> that compares group and individual teaching methods.

Within the UK, Scotland appears to lead the way in terms of a specific health literacy plan, namely 'Making it Easy - A Health Literacy Action Plan for Scotland'  $^{107}$ . Additionally, there is an active health literacy research community within the UK $^{108}$ .

Israel is also making a national effort to raise health literacy<sup>109</sup> and has included developmental goals on Health Literacy in its 2020 goals and objectives. It has a National Strategic Plan for Reducing Health Disparities and has implemented a Directive for Cultural and Language Accessibility on the Health System (2/2013) that requires:

- · cultural mediators in health services
- all information and signage in 4-5 languages
- simultaneous translation of services
- capacity training for health professionals
- · culturally appropriate health promotion in community
- empowerment and involvement of the community

<sup>104</sup> http://www.ncbi.nlm.nih.gov/pubmed/25843827

<sup>105</sup> http://www.ncbi.nlm.nih.gov/pubmed/21955962

<sup>106</sup> http://www.ncbi.nlm.nih.gov/pubmed/25724879

<sup>107</sup> http://www.gov.scot/Publications/2014/06/9850

<sup>108</sup> http://www.healthliteracy.org.uk

<sup>109</sup> http://iom.nationalacademies.org/~/media/Files/Activity%20Files/PublicHealth/HealthLiteracy/2012-SEP-24/Daine%20LevinZamir.pdf

# SECTION 3: BUSINESS AND HEALTH MODELS

As much work has been conducted throughout Europe to understand the healthcare models pertaining to each state, the ENJECT group were reluctant to replicate work carried out by well-resourced institutions such as the WHO observatories. To interpret the business models and healthcare delivery in a meaningful way, the respondents were requested to extract information from relevant sources, with a particular emphasis on the WHO observatory reports. From the responses, it is possible to form an understanding at a general level of the form these business and health models take. The following sections reflect the extracts provided by the respondents, as well as providing context and commentary from respondents, where relevant.

### **ORGANISATIONAL STRUCTURE**

Generally, healthcare systems across the ENJECT group are characterised by cooperation between private and public sectors. In most of these cases, the public sector, namely the national Ministry for Health or similar government body, takes the majority of responsibility for the coordination of the national healthcare system. These government-run, national bodies are assisted by smaller, private partners. For example, the Lithuanian healthcare system is primarily public, with a small sector of private health and dental care. The public healthcare service providers report to the Ministry for Health and/or the local authorities.

Additionally, Belgium's healthcare is provided through public, private, and independent avenues. Here, there exist independent ambulatory care professionals, independent pharmacists, and private (non-profit) and public hospitals. The majority of medical specialists, dentists, and pharmacists work independently or in private sectors, while general practitioners (GPs) provide ambulatory or primary care.

The provision of healthcare services in Turkey mainly lies with the public body, the Ministry for Health. In addition, there are other public bodies involved such as the Social Services and Child Protection Agency. In each province, the directorates of the Ministry of Health are responsible for ensuring health policies are implemented. Private services also exist in the Turkish healthcare setting, providing care for members of the population with social health insurance.

Greek healthcare services are provided by both public and private bodies including the Greek National Healthcare Service, social insurance funds, local authorities, and physicians privately contracted by health insurance companies. Likewise, in Slovenia, the health system is composed of numerous public and private bodies. These include the public Ministry of Health, the Health Insurance Institute of Slovenia, and private health services and NGOs.

Since the publication of the WHO observatory HiTs, the UK's health system has been completely reformed. A new body, Public Health England, was established under the Department of Health. The healthcare service is coordinated by several hundred clinical commissioning groups, partly run by GPs, and these serve as a major point of access for private service providers.

Malta's healthcare is mainly provided by a publicly funded system. The private sector contributes to the provision of healthcare in the form of organisations, such as the church and other voluntary organisations. Portugal's healthcare system is coordinated by public and private bodies: the universal NHS, special public and private insurance schemes, and private VHI.

The responsibility for Ireland's healthcare system lies in the public domain of the Government, specifically the Department of Health and Children (DoHC), which is under the direction of the Minister of Health and Children (MoHC). It is coordinated by a public body, the Health Service Executive. A small number of private bodies also input into the coordination of the system.

Israel's healthcare system is defined as a sophisticated public health effort, run by the Ministry of Health, while the Norwegian healthcare system is publically coordinated, with Regional Health Authorities responsible for ensuring its implementation.

In summary, the existence of these differing forms of healthcare organisation throughout the ENJECT group suggests that the evolution of general business models and the associated healthcare delivery is a process which depends on the involvement of several public and private bodies. On the other hand, the organisational structure of other healthcare systems, such as Ireland, Israel, and Norway, suggests that the development of business models and healthcare delivery derives from one centralised source.

### FINANCING AND HEALTH INSURANCE

The organisational structure of the healthcare providers discussed above is directly linked to their financing, healthcare delivery models, and the areas deemed as priorities in each of the healthcare settings.

Across the board, financing of the healthcare sector primarily comes from the public sector, with revenue created from direct and indirect taxes. None of the healthcare sectors within the countries of the ENJECT group members are financed solely by public or private means. While large portions of the funding come from public and private bodies, Voluntary Health Insurance (VHI) and compulsory health insurance structures assist in financing the sector. For example, 72.9% of Lithuania's healthcare funding comes from the public sector, namely the National Budget and the Compulsory Health Insurance Fund, while 27.1% of its funding comes from private insurance companies and Out of Pocket (OOP) payments. A compulsory Health Insurance Fund also operates here.

Belgium's healthcare sector, while having both private and public funding bodies associated with it, is organised through six compulsory health insurance organisations and a National Association Sickness Fund. In Ireland, the healthcare service is funded through public taxes (78.3%), with the remainder coming from private sources such as GP visits, pharmaceuticals, stays in public and private hospitals, and private health insurance providers. Private health insurance accounted for 8% of total health expenditure in 2008.

Israel's healthcare services are primarily financed through payroll and general tax revenue. In 2008, 68% of Israel's total healthcare funding came from the public sector, with the remaining 32% being drawn from private sources. They also offer four National Health Insurance policies to the population.

The Greek healthcare system is funded through public and private investments. Social insurance funds and direct and indirect tax revenues play a role in healthcare at a very basic level (29.1%). Health insurance also provides a significant portion of the budget (31.2%). Private expenses, such as OOP payments, provide the largest percentage of funding for the Greek healthcare system (37.6%), reflecting a certain inequality in healthcare provision.

In Serbia, healthcare is financed by public contributions to a social health insurance scheme. The National Health Insurance Fund finances the system, in addition to mandatory health insurance premiums being placed upon employees salaries.

77% of France's healthcare expenditure is publically funded by Statutory Health Insurance. Other structures, such as Voluntary Health Insurance and publically financed universal health coverage, contribute to the funding of the French healthcare system.

Slovenia is funded by both public and private bodies. Compulsory Health Insurance and state revenues provide the majority of funding to the Slovenian healthcare system with VHI and OOP also contributing. Malta's healthcare system is primarily publicly funded from taxes. Private funding also exists in the form of out-of-pocket payments and VHI.

The Macdeonian system, based on Diagnosis Related Groups (DRGs), was introduced in 2009. Primary care (GPs) is financed through a per capita system out of which 70% is fixed payment while 30% is based on preventive goals. Hospitals are financed through the DRG system for in-patients, but some hospitals (especially university clinics) have conditions placed on part of the finances received that include the treatment of specific diseases and deficient interventions (minimum number of transplantations, treatment for CF, etc.). If they do not meet the condition that is arranged in the fiscal year, their funds might be decreased.

In Portugal, healthcare is funded in several different ways including direct and indirect taxes (public funding), contributions to public and private health subsystems, private insurance premiums, and user charges at time of consumption (private).

It is evident that private and public funds are central to the financial stability of the healthcare sector in all of the countries represented in ENJECT. In addition, health insurance, both compulsory and voluntary, is central to the funding of the system. The division of funding and the importance of privately run health insurance schemes in patient care are evident when the healthcare delivery pathways are examined.

### **eHEALTH MODELS**

The position of eHealth within the healthcare models of each of the ENJECT countries varies. Of the countries that responded in relation to the role of eHealth in their national healthcare business model, the majority are dominated by the improved communication between doctors and patients with regard to their treatment. In addition, eHealth has been activated in an attempt to counter the issues relating to patient satisfaction with the care they receive, with hospital and consultant waiting lists, and with patients access information about their own care. Some countries, such as Belgium and Slovenia, have initiated formal programmes aimed at advancing eHealth. Belgium established the Belgian Health Telematics Commission in 1999 to address issues around standards with relation to the exchange of health information and to advise government authorities on eHealth. The commission is divided into separate working groups relating to data, hospitals, telemedicine, and homologation of (para)medical software. Slovenia is also proactive in terms of its focus on eHealth. In 2005, the Ministry for Health initiated the 'eHealth 2010 strategy,' which, among other elements, focused on assisting healthcare professionals with electronic medical records and other health related databases. However, it has been recognised that the sutainability of the eHealth strategy is a challenge for the Slovenian healthcare sector.

Other countries represented in ENJECT have begun to activate technology to assist in the improvement of healthcare provision. In Norway, eHealth occupies a minor focus, with the introduction of electronic medical records on a national scale. However, the importance of eHealth measures has recently come to the fore on the Norwegian medical agenda.

Croatia is gradually incorporating eHealth into its business model. Since 2001, it has been working on integrating an IT system which would function across the healthcare sector. This began with the introduction of the Central Health Information System of the Republic of Croatia. The Croatian healthcare sector also hopes that the increase in eHealth would assist in the improvement of patient satisfaction. In 2012, the improvement of health IT and development of eHealth was listed as the Government of the Republic of Croatia's main priority in their National Healthcare Strategy 2012-2020.

eHealth features in the Maltese healthcare model. The development of eHealth portals for access to medical records is at the fore of this innovation. An internal eHealth strategy guides innovation in the sector.

In Lithuania, eHealth is financed through public and private funding streams. There exists a very clear system of funding and expenditure in the Lithuanian eHealth model. State investment is mainly provided to hardware and software products for projects applying for EU Structural support. Projects applying for state support to develop information technologies must provide an organisational report on investments into the same over the last 5 years. Healthcare providers that receive or are applying for state support for the development of information technologies must allocate at least 2% of their annual income from the state health insurance fund to maintenance and development

eHealth is gradually becoming recognised in the business models of various healthcare providers. With funding being allocated to the development of eHealth in specific countries, it is evident that the recognition of the role that technology can have in improving the organisation of the healthcare system and the patient experience is increasing.

Data was not provided for Spain, Finland or Germany.

### SYSTEM ORGANISATION

In this section, we felt that it might be helpful to experience the patient journey in a case study context in a number of the respondent countries.

### Ireland: Chronic Hip Pain

A woman suspected of needing hip replacement:

- A local GP consultation will be paid for by the patient unless she is on a medical card or over 70.
   The GP makes a diagnosis and refers the patient to a consultant (public or private, based on whether or not she has health insurance). Waiting times are longer for public referrals but no details on waiting times are available.
- Implications of different surgical options will be explained. The decision is the patient's. If agreement is reached regarding surgery, she is placed on a waiting list for between 1 and 11 months. If she has been waiting longer than three months, she may be offered treatment in a private hospital.
- After surgery, she will be given medication to help relieve post-operative pain. A physiotherapist will help individuals to move freely and will provide advice on exercises. An occupational therapist will advise individuals on how to be independent in daily living and will assess the need for help at home. They might also arrange aids and adaptations to help with daily living activities. Typically an individual would be discharged within 6-10 days.
- At home, a district nurse will change bandages and take out any stitches (sutures).
- An outpatient consultation usually takes place 6-12 weeks after surgery.

### Lithuania: Chronic Hip Pain

A woman suspected of needing hip replacement:

- After a free visit, her GP refers her to a specialist (orthopaedist-traumatologist) at a public hospital.
- She has free access to specialist physicians and hospitals contracted by the NHIF (waiting times for all providers are on the NHIF website).
- If elective surgery is chosen, the physician must inform the patient about waiting lists and reimbursement. The patient chooses a hospital.
   She will either wait in queue (for a free prosthesis) or buy the prosthesis (and get reimbursed at the level of the cheapest centrally procured analogue device after the surgery).
- If she has to wait, she is prescribed necessary medications (the reference prices of those on the positive list will be reimbursed).
- Following surgery and primary rehabilitation at the hospital, the patient could be referred either to inpatient (no later than five days after discharge) or outpatient rehabilitation, consisting of physical therapy with a physical medicine and rehabilitation physician. The need and duration of rehabilitation depends on severity, measured through Bartel and/or Keitel indexes. Outpatient rehabilitation and/or home rehabilitation could follow inpatient rehabilitation if needed.

### Malta: Chest Pain

- An elderly patient contacts the regional primary health centre because of chest pain. A brief telephone call raises the possibility of acute ischaemia. He is transferred to the hospital emergency department by ambulance, which may have ECG monitoring with real-time data transfer to the Emergency department. This reveals an acute myocardial infarction, and on arrival, his transfer to cardiology for further management including primary angioplasty is expedited.
- Once the acute phase is over, he is sent to the rehabilitation hospital for further recovery and is then discharged home under the care of his GP.
- The discharge liaison service engages with the elderly patient from the date of admission to prepare for his eventual discharge back to community. Once discharged, he may receive community health care nursing at home if needed but will be followed up by the specialist at the outpatient clinic or the specialist in internal medicine in the public primary care centre. His discharge summary, imaging, and laboratory results will be accessible online via secure elD login from all public facilities (hospital and regional health centres) by the patient himself and his nominated private general practitioner.

### **Belgium: Diabetes care**

- For all type 2 diabetic patients there is a diabetes passport.
- There is a specific care pathway for the treatment and follow-up of diabetic patients.
- The collaboration between caregivers is described in a care pathway contract that lasts four years.
- Patients get all their consultation fees and specific medication fully reimbursed.
- The patient is seen several times by the General Practitioner and at least once in a year by the diabetes specialist.

### **Greece: Data Integration**

- Nationally funded project pincloud<sup>110</sup> provides a cloud platform for integration of data coming from different collaborating sources.
- Implemented scenarios include a private hospital, a private telemedicine service, and private doctors.
- Doctors and patients subscribe to the service and have controlled access.

### **Greece: Open Care Centre for Elderly**

- Open care centres for the elderly are operated and funded by the municipality of Thessaloniki. They offer basic physiological screening (portable sensors) and support. The patient is interviewed by a nurse and has a teleconsultation with hospital experts.
- · Referral to hospital if needed.
- >600 elders in pilot.
- This combines the social welfare policy of the municipality with the healthcare service of expert centres.

<sup>110</sup> http://pincloud.med.auth.gr/

# SECTION 4: INTEROPERABILITY

The "connected" element of Connected Health relies heavily on its technical infrastructures being able to communicate with each other and data being "open" to being shared – across institutions, specialisms, regions, and countries. Respondents were first asked what integrated infrastructure existed in their region or country. They were then asked to elaborate in terms of the practical experience on the ground. In particular, we sought details as to how easily an application can be produced that communicates with both healthcare professional and personal caregiver/patient populations. In addition, we asked respondents to focus on whether separate organisations are facilitated to work together and whether open data initiatives regarding health exist.

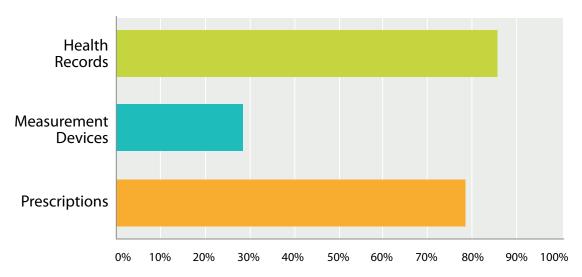


FIGURE 8: WHAT LEVEL OF HEALTHCARE TECHNICAL INTEGRATION IS IN PLACE NATIONALLY/REGIONALLY?

It is clear from the responses that, although cross-border interoperability is on the minds of healthcare actors across Europe, it is not yet certain how this might be ensured. The main issue raised by the stakeholders in Lithuania, for example, is the unification of language and classifiers used in the national systems of the Member States. Furthermore, it is not clear what standards and requirements will be established for national EHR systems regarding their integration into EU level. Greece is, perhaps, typical of European approaches to data sharing where open data initiatives exist only in terms of research projects<sup>111</sup>. In contrast, Macedonia's initiative for Open Government commenced in 2011, and the Ministry of Information Society and Administration, appointed as responsible for the Open Government and the Open Data initiatives, has published the official Macedonian Open Government portal<sup>112</sup>. The law on public sector data use outlines OpenData Rules on technical standards for data format and the manner of publication. Open data published to-date in Macedonia include:

- list of primary care physicians, specialist clinics, pharmacies and doctors in specialist consultative health care who have contracted with the Fund
- other lists of doctors, pharmacists, health care providers and pharmacies
- fees for healthcare institutions for current year
- · list of orthopedic devices

<sup>111</sup> e.g. AEGLE http://www.aegle-uhealth.eu/

<sup>112</sup> http://www.otvorenipodatoci.gov.mk/

- · overview of insured persons
- reports from the scope of operations of the Fund
- the budget of the Fund
- list of appointment dates for each doctor

The Croatian Government adopted the Action Plan for implementation of the Open Government Partnership Initiative from 2014 to 2016<sup>113</sup>. The Action Plan envisages implementation of 16 measures and 46 activities. Until 2016, these actions will be carried out by 20 government agencies within 4 key areas:

- improving the legal framework for realization of rights of access to information
- · proactive disclosure of information and open data
- transparency of public administration, with an emphasis on fiscal transparency
- · public participation in the formulation and implementation of public policies

The Croatian Health Insurance Fund has provided the open data and initiated the implementation of an application (web or mobile) that enables retrieval, viewing, and searching of public information on contractual partners of primary health care (PZZ). Developed using a hackathon process, the winning application "Pametno zdravlje" is freely available for iOS. It allows for easy searching for health institutions (by type) in Croatia, as well as mapping of the public health network and the ability to place phone calls and e-mails directly to the institution, etc.

France also has an open health data initiative<sup>115</sup>, whereas in Spain, it is still very hard to integrate any application unless it has been developed by the health administration. The current plan is to open the API to allow people to integrate a third party app, but the workflow and process are not clear as yet. Finland actively promotes the secondary use of patient data, as well as the MyData ideology in healthcare<sup>116</sup>.

### **GETTING TO INTEROPERABILITY: THE PROCESS**

The "Strategy of Lithuanian eHealth development" specifies the need for a basic patient summary and electronic health record but allows for a gradual development of the electronic health record. The introduction of hospital information systems commenced in 2008, with further key decisions on functionalities and data inclusion being made in 2010. In countries such as Israel, we can see that, although full integration does exist at a regional level, integration is lacking at the national level with an absence of integration of information across providers. In Malta, inter-application communication in health is facilitated through HL7 messaging. Separate organisations within the public service are typically not only facilitated to work together but incentivised through central government policy direction as to the elements that should feature in a public service director's performance plan. Indeed, the process is always an ongoing one. In France, although technical integration is made through certification with ASIP Santé within the Health Information Systems Interoperability Framework, this will change with the forthcoming Health Bill. After

<sup>&</sup>lt;sup>113</sup> https://udruge.gov.hr/UserDocsImages/UserFiles/File/Akcijski%20plan-POV-8-7-2014-final.pdf http://www.opengovpartnership.org/files/action-plan-ogp-8-7-2014-final-engpdf/download

<sup>&</sup>lt;sup>114</sup> http://zipzg.com/en/posts/seetech-hackathon-organized-by-hamag-bicro-held-in-zip/

<sup>115</sup> https://www.data.gouv.fr/fr/topics/sante-et-social/

<sup>116</sup> http://www.lvm.fi/julkaisu/4440204/mydata-a-nordic-model-for-human-centered-personal-data-management-and-processing

that, the certification system will be managed by the Employees Health Insurance National Fund (CNAMTS)<sup>117</sup>.

#### **DEFINING STANDARDS**

The Lithuanian eHealth strategy defines three levels of interoperability: semantic, data, and technology. It envisions a new tool to aid the exchange of standardised data. Lithuania is also a member of the International Health Terminology Standards Development Organisation (IHTSDO). By the end of 2006, the technical health ICT standards such as HL7 CDA, HL7 V3, EN 12251:2004 were planned to be adopted and implemented. The relevant decision-making body is the Ministry of Health, which also carries out some specific initiatives related to semantic interoperability. The coding and classification system for health ICT applications<sup>118</sup> is TLK 10 and is managed by the Ministry of Health and the Lithuanian health information centre. No form of conformity testing or accreditation scheme for eHealth systems and applications is available. The development of interoperability standards for EHR was included in the eHealth Strategy.

In Malta, standards are ensured by the Chief Information Officer of the Ministry and a governing central IT policy agency. As all applications to be developed must be cleared by this office, this ensures that the same standards are used throughout.

Certification of software solutions for primary health care providers in Croatia (general/family practitioners, pediatrics, gynecology, dentistry, school medicine, etc.) is regularly conducted by the Croatian Health Insurance Fund. All specifications needed for new implementation or upgrades of software solutions are openly available at www.cezih.hr. Part of primary health care provider income is based on the content of messages sent to the Croatian eHealth system. Therefore, the goal of the last year's recertification<sup>119</sup> was to raise the quality of message content with a focus on reports after the visit, preventive panels, panels for patients with chronic conditions, overall updates, and completeness of the codebooks. ProRec is expected to increase its activities in Croatia during 2015.

Finland lacks a centralised approach to national best practice or regulation. While some municipalities have on line self-management systems in place, regional IT systems are independent.

### **HEALTH RECORDS**

Although the development of interoperability standards for EHRs was included in their eHealth Strategy, currently there is no common EHR architecture available at a national level in Lithuania. However, the ESPBI IS system<sup>120</sup> is planned as one centralised database. Legislation provides that the exchange of data between internal healthcare institutions and ESPBI will be carried out using indicated standards and data protocols. In Turkey, an application is available that communicates with both healthcare professional and personal caregiver/patient populations.

In Portugal, electronic health records are widely implemented at a national level and supervised by the Ministry of Health. They are publicly funded and cover all clinical and disease areas<sup>121</sup>.

<sup>117</sup> http://esante.gouv.fr/services/espace-dmp/dmp-compatibilite

<sup>&</sup>lt;sup>118</sup> Used in primary care and hospital care at both regional and national levels since 1996

<sup>&</sup>lt;sup>119</sup> conducted from 08/2014 to 10/2014

<sup>&</sup>lt;sup>120</sup> State Electronic Health Services and Cooperation Infrastructure Information System

<sup>121</sup> https://www.sns.gov.pt/

In Ireland, although the majority of primary care practices have an electronic record within their practice management software, these are not connected, and electronic records are largely absent at the hospital care level. One example of an effort to integrate records across primary and hospital care is the ARCH Technology Centre's Dementia Platform in collaboration with universities, industry partners, hospitals, and GP practices. Using an off-the-shelf platform customised for the project, it provides common two way information platform for hospital-based consultants, General Practitioners, patients, and informal care-givers. The platform had to be used alongside existing GP electronic practice management systems and hospital paper-based systems. It was funded through the Enterprise Ireland technology centre model as a common platform project for a group of Irish companies and rolled out to 40 patients. While the trial was not long enough to establish clinical outcomes, the uptake of the platform and engagement with the platform was extremely positive, and both patients and clinicians were reluctant to part with it at trial completion. More recently, eHealth Ireland, charged with delivering an Electronic Health Record (EHR) for Ireland, announced three 'Lighthouse Projects' aimed at building understanding of the benefits of an EHR in the Irish healthcare system. These projects are in the clinical disciplines of Epilepsy, Hemophilia, and Bipolar Disorder and will be carried out over a 12 month period with specific deliverables. eHealth Ireland will be working in collaboration with a number of organisations to deliver these projects (see individual projects). eHealth Ireland will also be working with ARCH across all three projects to research the implementation of a flexible and re-usable EHR model.

In Norway, health information exchange is message based and restricted to selected areas. As the message exchange goal is to assist health providers, system vendors do not appear to place a priority on increasing access to this information.

In Malta, health records are not available as open data, but registers hosted within a secure environment have been actively maintained and used for intelligence generation for the past 20 years. Record-level data is, nevertheless, available for research upon clearance by the relevant data protection authority and the Director of the section owning the data being requested.

Serbian Health Records are integrated within one Primary Healthcare Centre (PHC) or, in some pilot programmes, multiple PHCs with some Hospital Centres (HC). Data exchange at the system level exists for checking insurance<sup>122</sup>, electronic invoices<sup>123</sup>, making specialist appointments in the hospital<sup>124</sup>, connection of Lab Information System (LIS) with Hospital Information System (HIS)<sup>125</sup>, and connection of Radiology Information Sysem with HIS<sup>126</sup>. An integrated view of patient summaries and individual contacts was implemented and tested in 12 EU-IHIS beneficiary hospitals<sup>127</sup>. To date, no applications communicate with both patient and healthcare professionals in Serbia apart from some pilot projects listed above.

 $<sup>^{\</sup>rm 122}$  All healthcare institutions with Health insurance Fund (HIF)

<sup>&</sup>lt;sup>123</sup> All healthcare institutions with HIF Pilot components

<sup>&</sup>lt;sup>124</sup> All PHC Centers in Kolubara district with Valjevo hospital, PHC Center Novi Sad with Children's Hospital, PHC Vozdovaac Belgrade with Clinical hospital centre "Dragisa Misovic - Dedinje"

<sup>&</sup>lt;sup>125</sup> All PHC Centers in Kolubara district with Lab in Valjevo hospital

<sup>&</sup>lt;sup>126</sup> PHC Vozdovac Belgrade with Clinical hospital centre "Dragisa Misovic - Dedinje"

http://www.eu-ihis.rs/docs/news39/EU-IHIS\_Final%20Conference\_15%20jun%202015\_EN.pdf

The Croatian National Health Care Strategy 2012-2020<sup>128</sup> requires data from the insured person's personal Electronic Health Record to be electronically submitted to the Central Health Care Information System in Croatia (CEZIH) which has more than 17,000 users. Currently, all general, paediatric, gynaecological, and dentistry practices, as well as pharmacies, primary health care laboratories, school medicine offices, out-of-hospital specialist-consulting health care, and the information system of the Croatian Health Insurance Fund, are connected to CEZIH. Data is sent in real time, and advanced reports on the operation of the health care system emerge from that database<sup>129</sup>. The architecture of the CEZIH allows doctors to view both the medical and the personal data of their patients. Communication between practitioners and other institutions is ciphered, and the medical data is completely separated from the administrative data. Furthermore, only authorised personnel from the institutions (CHIF, CPHI, Ministry of Health, etc.) have access to the data stored in CEZIH. They can then only use the data to create reports which are needed based on the legislation or to make statistical analysis with the medical data. The physician must keep precise, detailed, and dated medical documentation according to procedures of managing medical documentation of patients for up to 10 years.

In Poland, Electronic Health Records (EHR) and Personal Health Records (PHR) are under development. Since early 2015, providers have been obliged to maintain Electronic Health Records (EHR) for their patients. The next stage will entail the exchange of health data across practices. Although pilot projects are planned, there is no experience of implementation in this regard yet.

In Spain, health records are integrated regionally. For example, currently there is a PHR/HIS for the entire region of Andalusia. At a national level in Finland, the national PHR and Kanta services allow healthcare professonials to easily share patient information which will be expanded to MyKanta, which promotes nationwide communication between healthcare professonals and patients.

### IT AND MEASUREMENT DEVICES

"IT standardisation in Lithuania is one of biggest problems for Lithuanian IT companies: long term IT standardisation policy and plans, interoperability framework for IT systems (e-services) development and operation are lacking. Because of that, plenty of closed (proprietary) systems are developed and used, having low competition possibilities, and high development/usage cost". A single set of national eHealth standards is missing and common standards and minimum data sets have still to be agreed upon. These standardisation problems increase the risk of different actors in the eHealth system misunderstanding each other. Therefore, the Lithuanian eHealth strategy defines three levels of interoperability, which have to be addressed: 1) semantic (e.g. terms, information models); 2) data (e.g. records, documents); and 3) technology (databases, protocols). To solve the interoperability problems in all three fields, the strategy foresees the development of new tools in order to exchange standardised data between different information systems and a minimum data set.

<sup>128</sup> https://zdravlje.gov.hr/UserDocsImages/dokumenti/Programi,%20projekti%20i%20strategije/National%20Health%20 Care%20Strategy%202012-2020.pdf

<sup>129</sup> http://www.cezih.hr/dokumentacija.html

#### **PRESCRIPTIONS**

eTransmission of prescription to pharmacies is part of the Lithuanian eHealth strategy. There were plans to develop an information system with electronic prescription functionality by 2011, but its implementation has failed to-date.

The Greek nationwide e-Prescription system has been deployed by the Ministry of Health and is accessible by authorized users only (physicians and pharmacists). Prescriptions contain patient's social security number, diagnosis (encoded in ICD-10), medicines (quantity, dosage) and patient's participation share of payment of each drug, etc. The system is based on interoperability and security standards (HL7 CDA, IHE ATNA, respectively) and interconnects with pharmacies information systems through a CDA based RESTFul API<sup>130</sup> in order to automatically dispense electronic and hand-written prescriptions.

ePrescribing was identified in the National eHealth Strategy (2013) as a key priority for Ireland. Following discussions and after reviewing the documentation available, it was decided that the best way to build and test a National ePrescribing solution in a useful and safe manner is to do it in incremental steps. Two initial pilots with two different vendors are currently underway. Approval has been given to proceed in 2016 with an initial phase that will facilitate the electronic transfer of prescriptions by utilising HIQA standards developed to date and the national message broker, HealthLink. The collaborative initiative 'ePrescription' will ensure a standardised transportation mechanism and supporting infrastructure for the safe electronic transportation of a prescription from a prescribing site system to a dispensing site system.

In Portugal, ePrescriptions are widely implemented at national level and supervised by the Ministry of Health using web technology. They are publicly funded and cover all clinical and disease areas<sup>131</sup>.

In the case of the Macedonian prescriptions service interoperability, the following data flow is envisaged: a citizen visits their physician who uses the REST<sup>132</sup> based web service to complete the prescription which is then available for retrieval in all pharmacies. When pharmacies confirm service, this is logged in the centralised database. Pharmacies can also check the status of the citizen's health insurance as citizens with active state insurance pay only a small fraction of the medicine cost. The Ministry of Health uses web services to check the statistics of prescribed medicine by region, hospitals, physicians, etc. The infrastructure is built on web services, so it is easy for third party developers to develop services for different institutions involved in the process (health insurance fund, Ministry of Health, Public and Private health providers, pharmacies).

### **TELEMEDICINE**

At present, telemedicine in Lithuania is limited to teleconsulation and videoconferencing between health professionals. However, plans for telemedicine services to be expanded are included in the eHealth framework. In the past, Lithuania has been involved in cross-border teleradiology pilots, and the Telemedicine Centre of Kaunas University of Medicine also introduced some telemedicine services.

<sup>&</sup>lt;sup>130</sup> Application Programming Interface

<sup>&</sup>lt;sup>131</sup> http://spms.min-saude.pt/en/product/38716/

<sup>&</sup>lt;sup>132</sup> Representational State Transfer

Slovenia offers an example of good practice implementation in a regional telemedicine network at the General Hospital Slovenj Gradec (GH SG) called CEZAR. The CEZAR network provides tele-medical support to patients with Diabetes Mellitus type 2 (DM2) and/or patients having Congestive Heart Failure (CHF). Currently, the services are available in the Carinthia region covering 1.300 km2 with over 100.000 inhabitants with ambitions to become available for the whole country. The technological and organisational infrastructure was set-up in 2014, and the centre now provides support to 370 DM and 130 CHF patients living at home or in residential houses (DM only). The patients receive tele-medical support as a part of the existing long-term care programme, enabling them to continue with their daily/weekly disease measurements at home. Their standard medical devices were replaced by modern equivalents containing a Bluetooth interface. The DM2 patients measure their whole blood sugar profile weekly (6 measurements), and the CHF patients measure their weight, blood pressure, heart rate, and blood oxygen saturation on a daily basis. Patient data is now automatically sent to the hospital server where it is monitored through the telemedicine programme. If an intervention is required, the operator contacts a corresponding medical specialist who decides on further action - e.g. a change in therapy or an invitation for a visit to the hospital. The patient receives an oral report over the phone by the centre operator and a written report by post on every change in the therapy. The medical specialists also periodically examine patients' data, and where there is a need for patient advice or a change in therapy, a written report is prepared and sent to the patient. The national compulsory health insurance system does not yet cover the service. The patients are for the moment not charged for the service as the costs are covered from an EU project. A model for financial contribution from the patients has been considered.

# SECTION 5: THE PERSON

With the patient being at the very core of the concept of Connected Health, the ENJECT members felt it necessary to understand and reflect the level of involvement that the patient has in the practical development of healthcare in their country. It was also important to examine and account for the regional or national digital literacy standards that enable or constrain a patient's involvement in the management of their own healthcare.

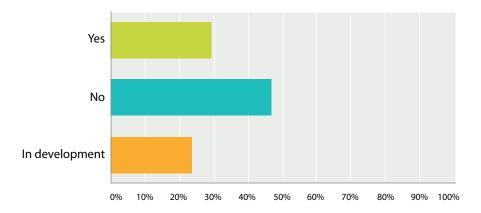


FIGURE 9: PATIENT INVOLVEMENT IN THE DESIGN/DEVELOPMENT/DELIVERY OF RESEARCH PROGRAMMES

The inclusion of patients in the design, development, and delivery of research programmes across the ENJECT member countries is reasonably varied. Nearly half of the respondants stated that there is no patient involvement in any of these processes, although such involvement does exist in nearly 30% of the ENJECT countries, including the UK<sup>133</sup>, Spain<sup>134</sup>, Portugal, Norway, and Ireland<sup>135</sup>. An additional c.20%, including Lithuania and Croatia, noted that this is an area currently under development. Difficulties in communication between the public and healthcare professionals has meant that developing a social partnership to include patients in the improvement of health system performance is challenging.

## DIGITAL LITERACY/ICT LITERACY STANDARDS TO GUIDE PATIENT INVOLVEMENT

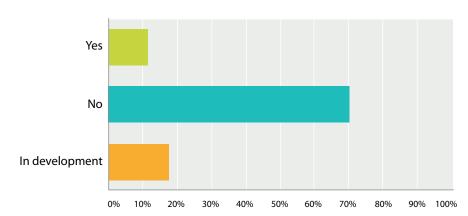


FIGURE 10: ARE THERE DIGITAL LITERACY/ICT LITERACY STANDARDS TO HELP GUIDE PATIENT INVOLVEMENT?

<sup>133</sup> http://www.nets.nihr.ac.uk/ppi

<sup>134</sup> http://www.slideshare.net/CalidadAppSalud/medicine-20-london

<sup>135</sup> http://www.hrb.ie/research-strategy-funding/grants-and-fellowships/hrb-grants-and-fellowships/grant/111/

The overwhelming majority of respondents stated that there are no digital literacy standards to help guide patient involvement in healthcare design. Those countries who already have these standards in place include the UK and Portugal. Others, such as Malta, Lithuania, and Croatia, are in the process of developing such standards, though it is generally a challenging process.

For example, in Lithuania, the 'National Concept for the Development of an Information Society' found that computer literacy is generally low, especially in rural areas. In 2001, only 8% of the population used the internet. While there has since been a drive to improve computer literacy in the country, there are still no education programmes available at a national or local level to promote the acquisition of either general, or eHealth specific, ICT skills. An additional effort has been made by Kaunas University of Technology in association with the Lithuanian University of Health Sciences through the development of an undergraduate degree programme with a specialisation in medical informatics (Health Informatics).

In Croatia, it has been noted that corruption within the healthcare sector is a major issue which could be combatted using ICT. Additionally, the provision of electronic access to information on patient rights and the introduction of eHealth tools, such as e-waiting lists, are areas being focused upon in both the Croatian and Maltese healthcare systems.

# SECTION 6: CONCLUSION

The conduct of this survey and the analysis of the data received has foregrounded a concern that has often been expressed at a micro state or project level but bears repeating at this aggregated level. Confusion abounds in the area of Connected Health. Indeed, our own research in this area required the use of words such as "eHealth" rather than Connected Health in order to make it easier for respondents to understand what we were examining. It should be emphasised, however, that eHealth and Connected Health are not the same thing. While eHealth refers to an infrastructural response to a health challenge, Connected Health speaks to a new model at the system or process level. It is this complexity, inherent in the concept of Connected Health, that causes confusion. It involves a complete transformation of the healthcare system in a long-term play that requires dedicated resources and political will. Many of these elements are difficult to capture with data points being largely qualitative and non-comparable. One example of this confusion can be seen in this report. While just under 58% of respondents said that their country had electronic health records in place, when asked this in the context of the policy environment and with regard to an interoperability question, over 80% of respondents replied that there was technical integration of healthcare records at a regional or national level within their country. These apparently conflicting results are likely because of differing definitions of "healthcare record" depending on the context in which the question is asked, as well as varying views on the concept of "interoperability". An ability to exchange records at the primary care level may constitute interoperability in one view, whereas another respondent may require access across primary, secondary, and tertiary care to term their healthcare system "interoperable". This limited example highlights both the difficulty in gathering data in this area, as well as the confusion that is apparent across the EU in terms of formulating a coherent Connected Health agenda - for policy, research, healthcare, or industry purposes.

### When we examine the output of this report, we can ask ourselves three questions:

- 1. How much are countries doing now in terms of pursuing a Connected Health agenda? What is the state of readiness for Connected Health at both a state and a European level?
- 2. How are individual countries approaching the challenge of evaluating Connected Health systems and offerings? How does Europe distinguish good from bad in the context of Connected Health?
- 3. How interoperable are our health systems across Europe? How connect-able is healthcare at both national and international levels?

## 1. STATE OF READINESS

It is clear from this report that different countries are at different stages of readiness in terms of Connected Health – both in terms of its research and its implementation. This reflects a suite of factors that vary from state to state and region to region, including financial investment in Connected Health infrastructures, legislation, and regulation to support the introduction of Connected Health, priority accorded to Connected Health implementations within the healthcare delivery system, and the political will at a government level to sponsor and champion the Connected Health agenda.

#### 2. EVALUATION CRITERIA

The evaluation criteria employed in different circumstances and different geographies across Europe are neither clear nor standardised. The value proposition of Connected Health has not been resolved into one coherent message that would allow a standardised approach to its evaluation. Different stakeholders in different regions perceive it to contribute in different ways. We can see this, in particular, when we look at the ways in which respondents interpreted Connected Health's contribution to the business and healthcare models within their regions or states. This ranged from the majority of respondents associating Connected Health with relatively superficial value propositions such as improved doctor/patient communication or improved patient satisfaction to a much lower embrace of the substantive contribution of improved healthcare provision.

#### 3. INTEROPERABILITY

No matter which Connected Health lane a region is in – whether fast or slow – it is nevertheless possible to address interoperability. It seems from the responses to our survey, however, that the majority of states and regions are so engaged in the process of ensuring interoperability at a regional or national level that they have little time or attention left to focus on the thorny issue of international interoperability. Exceptions are seen in some limited situations, such as the Republic of Ireland's design of their unique health identifier number so that it can engage with the UK health system, or the recently signed Joint Declaration on an Initial Roadmap for Cross-Border Data Exchange and Digital Services between the Republic of Estonia and the Republic of Finland.

## AN AGENDA FOR FUTURE RESEARCH IN CONNECTED HEALTH FOR EUROPE

### PROPER BASELINE DATA

A shared language around health records and a database that would facilitate the development of a Connected Health or eHealth scorecard would provide an "index" that weights various readiness factors for Connected Health, allowing countries to be rated and ranked in terms of their ability and readiness in respect of Connected Health solutions and services. It is hoped that this type of intervention would stimulate policy responses as countries seek to move themselves further up the Connected Health index – similar to the European Innovation Scoreboard.

### **EVALUATION FRAMEWORK**

Until we agree a common evaluation framework for Connected Health implementations, it will be extremely difficult to define and defend the value proposition that justifies investment in connected healthcare models. Such a framework must be multi-faceted, ranging from technology robustness to regulatory compliance and from economic sustainability to user acceptance. Both qualitative and quantitative measures will be required bringing in skillsets as varied as ethnography, engineering, marketing, economics, health science, policy-making, and more. A framework that does not encompass all of the above elements will most certainly be justifiably undermined and rejected by those that are excluded. This will render it useless to the cause of Connected Health.

### DATA PROTECTION GUIDANCE AND INTERPRETATION

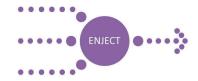
Although new rights are unlikely to be created in terms of data protection, there is evident confusion as to the application of existing rights in the context of Connected Health. With the added complication of the new EU General Data Protection Regulation (GDPR) coming into effect across the European Union from 25 May 2018, states that have found ways to give effect to the existing EU Data Protection Directive 95/45/EC will need to redesign and rethink their approach. We recommend an approach, specific to eHealth, that helps citizens, researchers, companies, and healthcare providers to understand how to live safely and privately in an era of healthcare data. Six countries within the ENJECT survey have already accomplished this translation of generic data legislation and regulation into the eHealth context. We suggest that studying how they have done this and distilling learnings and best practice from their experience could help to better design future guidelines and interpretations. This, in turn, could extend the reach of Connected Health by avoiding unnecessary shying away from data issues and encouraging research and evidence-based policymaking in the area.

# **APPENDICES**

Appendix I: ENJECT Connected Health Regional Survey

Appendix II: University-Based Programmes to Develop Future Healthcare Professionals that are Connected Health/E-Health Aware: A Sample from 15 European Countries





## **ENJECT Connected Health Regional Survey**

12th May 2015

Dear ENJECT Management Committee member,

The survey below aims to develop an understanding of Europe's readiness to adopt Connected Health/eHealth solutions at both a regional and a European level. The survey asks the two MC members for each country to come together to complete one response per country. The ideal scenario is that the questions should be answered at a national level, but it is understood that in some countries there may be regional differences that must be reported.

It is hoped that the majority of questions can be answered by the MC members without too much additional effort but we do understand that you may need to refer to reports or get input on individual questions and so we will allow time for such investigations.

We greatly appreciate the input and hope that the final results will deliver valuable insights and form the basis for future research. We will work together to ensure maximum dissemination of the output.

I would very much appreciate it if you could return the completed survey for your country to Nicola (Nicola.mountford@ucd.ie) by 3rd July 2015

With best wishes,

Prof Brian Caulfield Chair, ENJECT

P	OLICY				
1.	What is the national/regional policy for evaluating quality of care/health services?				
2.	Is there a local, personalised e-health and/or Connected Health (CH) strategy?  ☐ Yes ☐ No ☐ In Development  If yes, please include link to soft copy (electronic copy).				
3.	Do the following Connected Health activities exist in your region/country? Underline relevant status.				
	☐ E-prescribing	Planned	Active		
	☐ E-referral between practitioners	Planned	Active		
	☐ Electronic Health Records	Planned	Active		
	☐ Personal Health Records	Planned	Active		
	If yes to HER/PHR, then please specify format (e.g. on identity card) and locus of control (central v patient).				
	☐ E-scheduling	Planned	Active		
	☐ Personalised Medicine	Planned	Active		
	☐ Citizen Services (please specify)	Planned	Active		
	☐ Other (please specify)	Planned	Active		
4.	What governs privacy and security at the	e national/regiona	l level in regards to the development and		

# **EDUCATION**

implementation of policy?

1. Are there university based educational Connected Health/eHealth programmes in place for future Healthcare Professionals?

5. Is there publication of any political instruments/statements (election manifestos or public statements) to guide

the direction of Connected Health policy-making? If so, please include links to soft copy.

Programme	Category	Provider	Link to website	Does it include:		
				Reg.	DA	Dev.

Categories: Healthcare Informatics, Biomedical and Health Informatics, Connected Health, E-health Reg.: Data regulation; DA: Data Analytics; Dev.: Devices

2. Are there programmes to help create eHealth/Connected Health-informed care-givers and/or patients? Case Studies here. Please include partner organisations; managing organisation; technology used; funding model; size of cohort; clinical area/disease focus; and any outcomes/evidence.

3. Do programmes exist that improve the health literacy index?
Case Studies here. Please include partner organisations; managing organisation; technology used; funding
model; size of cohort; clinical area/disease focus; and any outcomes/evidence.
Business/Health Models
Please take the relevant section from a WHO observatory study to describe your national/regional healthcare
system paying particular attention to flow and reimbursement models. Please then give one or two case studies
to illustrate:
Case Studies here. Please include partner organisations; managing organisation; technology used; funding model; size of cohort; clinical area/disease focus; and any outcomes/evidence.
Types of case studies:
Patient pathways
System organisation
Public and private framework
<ul> <li>The relationship between care models and patients</li> <li>Social interventions/care schemes</li> </ul>
Social interventions/care schemes
Interoperability
1. What level of healthcare technical integration is in place nationally/regionally?
☐ Health records ☐ Measurement devices ☐ Prescriptions
Please give details including:
How easily an application can be produced that communicates with both healthcare professional and
<ul><li>personal caregiver/patient populations?</li><li>Whether separate organisations are facilitated to work together?</li></ul>
<ul> <li>Whether open data initiatives regarding health exist?</li> </ul>
Whether open data initiatives regulating health exist.
Consider using case studies here. Please include partner organisations; managing organisation;
technology used; funding model; size of cohort; clinical area/disease focus; and any outcomes/evidence.
Person
1. Are there requirements/guidelines requiring patient involvement in the design/development/delivery
of research programmes?
□Yes □ No □In Development
If yes, please include link to soft copy.
<del></del>
2. Are there digital literacy/ICT literacy standards to help guide patient involvement?
□Yes □ No □In Development
If yes, please include link to soft copy.

# **APPENDIX II:** UNIVERSITY-BASED PROGRAMMES TO DEVELOP FUTURE HEALTHCARE PROFESSIONALS THAT ARE CONNECTED HEALTH/E-HEALTH AWARE: A SAMPLE FROM 15 EUROPEAN COUNTRIES.

Country	Programme	Provider	Link to website
Lithuania	Bachelor of Health Informatics	Jointly: Kaunas University of Technology (Faculty of Informatics) and The Lithuanian University of Health Sciences	http://ktu.edu/en/programme/b/health-informatics
Lithuania	Bachelor of Biomedical Engineering	Kaunas University of Technology (Faculty of Electrical and Electronic Engineering)	http://ktu.edu/en/programme/b/biomedical-electronics
Lithuania	Master of Biomedical Engineering	Kaunas University of Technology (Faculty of Electrical and Electronic Engineering)	http://ktu.edu/en/programme/m/biomedical-engineering
Lithuania	Master of Public Sector Economics	Mykolas Romeris University	https://stdb.mruni.eu/ects_katalogas/programa_en-6724.html
Ireland	MSc in Health Informatics	University College Dublin	http://www.ucd.ie/medicine/studywithus/graduatestudies/ healthcaremgtinformaticsriskquality/mschealthcareinformatics/
Ireland	MSc in Health Informatics	Trinity College Dublin	https://www.scss.tcd.ie/postgraduate/health-informatics/
Ireland	MSc in Health Informatics	University of Limerick	http://www.ul.ie/graduateschool/course/health-informatics-msc
Turkey	Human care science and postmodern nursing course	Erciyes University	http://watsonibb.erciyes.edu.tr/
Turkey	Infection control programs	Erciyes University	http://hastaneler.erciyes.edu.tr/Content/files/pdf/enfeksiyonkontrolprogrami.pdf
Norway	Master of health informatics	University of Agder	http://www.uia.no/studier/helse-og-sosialinformatikk
Norway	Master of health informatics	University of Oslo	https://www.uio.no/english/studies/programmes/ #topic=helsefag-medisin&type=to-aarig-master
Norway	Master of health informatics	The Artic University (Tromsø)	https://en.uit.no/education/courses/course?semester= H&p_document_id=455747&ar=2016
Norway	Master of health informatics	Norwegian Technical University (NTNU)	http://www.ntnu.edu/studies/mhlsinf
Germany	Medical Bioinformatics	Various	http://www.gmds.de/weiterbildung/biomedinfo.php
Croatia	Graduate Professional Programme in IT (Information Systems – specialisation in e-Health)	Polytechnicum Zagrabiense	http://www2.tvz.hr/ishodi-specijalistickog-diplomskog-studija-informatike/?lang=en

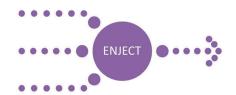
Country	Programme	Provider	Link to website	
Croatia	MSc in ICT (Information Processing) elective courses: Biomedical informatics, Biomedical signals and systems, Multisensor systems and locomotion, Sensor technology,	Engineering and Computing	http://www.fer.unizg.hr/en/education/msc_study/ict/oi	
Finland	eHealth	Multiple universities provide individual courses		
Finland	Medical Informatics	Multiple universities provide individual courses		
Finland	Health Informatics	University of Oulu	http://www.oulu.fi/koulutustarjonta/education- programmes/hyvinvointitekniikan-koulutusohjelma# content-top	
		Tampere University of Technology	http://www.tut.fi/en/personal-health-informatics/	
Finland	Health Literacy	Multiple universities provide individual courses		
Portugal	Master in Biomedical Engineering	Faculdade de Engenharia da Universidade do Porto	https://sigarra.up.pt/feup/en/cur_geral.cur_view?pv_ curso_id=617	
Portugal	Doctoral Program in Biomedical Engineering	Faculdade de Engenharia da Universidade do Porto	https://sigarra.up.pt/feup/en/cur_geral.cur_view? pv_curso_id=681	
Portugal	Master in Healthcare Information Systems Management	Polytechnic Institute of Leiria	http://mestradosportugal.ipleiria.pt/en/master/healthcare-information-systems-management-mgsim/	
Portugal	Integrated Master in Biomedical Engineering	University of Lisbon	https://fenix.tecnico.ulisboa.pt/cursos/mebiom	
Portugal	Competitiveness in medicine and biomedical engineering	Portuguese Universities and Harvard Medical School, MIT and CMU	https://hms.harvard.edu/departments/portugal-clinical- scholars-research-training-program http://www.cmuportugal.org/ http://www.mitportugal.org/	
Malta	Health Information - PHL5108	University of Malta	http://www.um.edu.mt/ms/studyunit/PHL5108	
Malta	Management, Leadership, Quality and Medical Informatics	University of Malta	http://www.um.edu.mt/ms/studyunit/FME5020	
Malta	Information Management in Healthcare	University of Malta	http://www.um.edu.mt/healthsciences/studyunit/NUR3522	
Poland	No such programmes			
Greece	Medical Informatics Msc Programme	Aristotle University (interdepartmental)	http://promesip.med.auth.gr/	
Greece	Modern Medicine: regulations and bioethics	Aristotle University (interdepar	rtmental)	

Country	Programme	Provider	Link to website
Serbia	Biomedical Engineering, undergraduate and Master level	Faculty of Technical Sciences, University of Novi Sad	http://www.ftn.uns.ac.rs/1797176794/ biomedical-engineering
Serbia	Biomedical and Ecological Engineering, Master level	School of Electrical Engineering, University of Belgrade	http://bmit.etf.rs/index.php?id=12
Serbia	Medical Physics, undergraduate and Master level	Faculty of Sciences, University of Novi Sad	https://www.pmf.uns.ac.rs/en/studies/study_programmes/physics/bachelor_academic_studies_in_physics
Serbia	Health Institution Management, specialist studies	Graduate School of Business studies, Megatrend University	http://en.fps.naisbitt.edu.rs/specialist-studies/
Macedonia	General medicine	University Sts Cyril and Methodius in Skopje, University Goce Delcev in Shtip	https://www.ukim.edu.mk/en_index.php  https://www.ugd.edu.mk/index.php/en/faculties/faculty -of-medical-sciences
France	Master mention Vieillissement, sociétés, technologie - spécialité gérontechnologie	UJF	http://www.sfr-sante-societe.net/fr/les-missions-structure-recherche-sante-societe/formation-master-vieillissement-societe-technologies/item/download/54_1aefe88d58ec 9d0735c08a606946af76
France	University Degree in Telemedicine	Medicine Faculty of Bordeaux	http://du.med.univ-montp1.fr/fmc/ du-telemedecine-179.html
France	University Degree in Telemedicine	Medicine Faculty of Montpellier-Nimes	http://du.med.univ-montp1.fr/fmc/ du-telemedecine-179.html
Spain	Master de Telemedicina	Open University of Catalunya	http://studyincatalonia.gencat.cat/en/estudis/ estudis-universitaris/UOC-Telemedicina-00001
Spain	Bioengineering Programmes	Various	http://seib.org.es/formacion/educacion/#

Copyright 2016 The Authors.

This report is based upon work from COST Action (ENJECT TD1405), supported by COST (European Cooperation in Science and Technology).

University College Dublin, July 2016 ISBN: 978-1-910963-05-0







This report is based upon work from COST Action (ENJECT TD1405), supported by COST (European Cooperation in Science and Technology)