



A Personalised Integrated Care Platform

A Market Analysis for the Future Exploitation of PICASO

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Table of Contents

Executive Summary	4
1 Introduction	5
2 European Healthcare Landscape and Trends	6
2.1 The European Care Landscape.....	6
2.1.1 Structures of the European Secondary and Social Care Sectors	6
2.1.2 Economics of the European Healthcare Sectors	9
2.1.3 Readiness of e-health in European Countries	9
2.2 The European Social Care Landscape.....	11
2.3 Market Segmentation and Analysis Methodology	11
3 Analysis of Selected Member States	13
3.1 Denmark	13
3.1.1 Structure of the Care Sector	13
3.1.2 History of Electronic Care Systems	14
3.1.3 Legal Framework	14
3.1.4 Current Situation	15
3.2 Germany	17
3.2.1 Structure of the Care Sector	17
3.2.2 History of Electronic Care Systems	18
3.2.3 Legal Framework	18
3.2.4 Current Situation	19
3.3 Italy	19
3.3.1 Structure of the Care Sector	19
3.3.2 History of Electronic Care Systems	20
3.3.3 Legal Framework	21
3.3.4 Current Situation	21
3.4 Sweden	22
3.4.1 Structure of the Care Sector	22
3.4.2 Overview of the Swedish Healthcare Market.....	22
3.4.3 History of Electronic Care Systems	25
3.4.4 Legal Framework	25
3.4.5 Current Situation	26
4 Profiling Selected Member States	28
4.1 Slovakia	28
4.2 UK.....	28
4.3 Belgium	28
4.4 France.....	29
4.5 Spain.....	29
5 General Conclusions	30
References	31
Appendix A – Acronyms and Abbreviations	32

Executive Summary

This paper presents an analysis of the European healthcare landscape with a detailed analysis of four member states' healthcare markets: Denmark, Germany, Italy and Sweden. The market analysis was carried out in connection with the EU project PICASO - A Personalised Integrated Care Platform. It was thus carried out based on confidential knowledge of the PICASO results and potential exploitation avenues for project partners.

The domain of healthcare is a policy area strongly in the hands of the individual EU Member States, and as the European population is growing older, healthcare services face massive challenges. The political realm forces us to treat the European healthcare landscape in terms of each country's individual structure, opportunities and market attractiveness.

In order to focus the market analysis on the PICASO project's visions and results, the three most relevant segmentation variables were first identified: i) e-readiness level (acceptance of the use of ICT solutions in healthcare), ii) fragmentation (the number and nature of care players in a given geographical area), and iii) the relevance to PICASO partners (focusing on partner countries).

The four partner countries: Denmark, Germany, Italy and Sweden, stand as representative examples of the European healthcare landscape including countries of both Beveridge and Bismarck healthcare payment models, and universal versus insurance-based approaches. When looking at the statistical data on e-health for these four countries, Denmark and Sweden are quite advanced and they use multiple electronic health record (EHR) systems in their social care sectors. By way of contrast, Germany and Italy are placed significantly lower on the e-health indicators and rely more on private social care. In addition to the four in-depth analyses, an overall description of five additional countries (Belgium, France, Slovakia, Spain, and UK) is provided.

The analysis identified countries with similar structural challenges, such as the strongly regional based healthcare systems in Spain and Italy, yet very different outcomes in regard to current state of e-health implementation. The situation thus points towards the potential of using nationally orchestrated policies to support the deployment of regional e-health solutions in fields with diverse actors and organisations.

In regard to healthcare structures, countries dominated by smaller providers, such as private primary care providers or secondary care providers owned by various groups, typically show a higher number of active ICT suppliers because these aspects reduce barriers to market entry and allow for niche markets to develop. The predominantly private and small-scale primary and social care domains are the strongest example of such rather open markets, while secondary care competitors are less numerous and diverse.

1 Introduction

The market analysis presented in this paper has been carried out in the specific context of the PICASO project. The PICASO integration platform is the final, overall product of the PICASO project. It is built on a federation of multiple external and internal, individual cloud solutions in order to match the needs of future care provision, while still respecting the legacy structure of today's healthcare systems.

The paper provides an analysis of the European healthcare landscape and analyses specific partner countries' healthcare markets. While the level of e-health readiness and implementation differs significantly across Europe, e-health is currently the focus of development in all healthcare sectors. This leads to major healthcare reforms observed in many European countries and considerations of (digital) data protection, privacy and eGovernance is therefore increasingly becoming intertwined with the health sector.

In-depth analysis of the four partner countries (Denmark, Germany, Italy, and Sweden) which includes the analysis of the primary, secondary, and social care sectors of these countries. In addition, five member states (Slovakia, UK, Belgium, France, and Spain) are profiled giving insight into the basic nature of these healthcare markets.

2 European Healthcare Landscape and Trends

The domain of healthcare is a policy area strongly in the hands of European Union Member States individually. While certain EU policies affect decisions within the policy domain of healthcare, the recent GDPR as a good example hereof, most policies concerning healthcare are considered under the EU principle of subsidiarity to be sole national concerns.

Within EU Member States Healthcare is divided into three areas: primary, secondary and tertiary care. Primary care can be defined as the basic or general healthcare focused on the point at which a patient ideally first seeks assistance from the medical care system.

Primary healthcare is usually provided in the community by general practitioners (GPs), local health clinics/centres, district nurses and primary care specialists (e.g., physiotherapists). In Europe, primary care generally falls within the administrative responsibility of regions/districts, while local municipalities are often responsible for long-term care and home care.

Secondary care covers ambulatory medical services and hospital care (inpatient and outpatient services), thus offering specialised care generally provided through referral from primary care providers.

Tertiary care is the highly specialised care offered in specialist (or university) hospitals with sophisticated technological facilities and support. Hospitals offering secondary and tertiary care are generally administered at regional/district level or privately, although some EU Member States have a more centralised administration of hospitals.

National health legislation and healthcare policies are the responsibilities of the governments of the EU Member States. National governments also set the overall financial framework for the healthcare sector, albeit with varying degrees of control of the management of the allocated financial resources for healthcare services.

2.1 The European Care Landscape

Healthcare services across Europe face massive challenges in the future as the European population is growing older, more and more people have chronic diseases, and the general needs and expectations for efficient and effective healthcare services increase. These challenges concern both the quality of healthcare and the availability of resources – human as well as economic resources – to deliver healthcare services. Most European Member States are likely to face a severe shortage of healthcare staff to care for the growing number of patients.

From the economic perspective, a smaller working population means less tax revenue to finance the public healthcare system, thus placing additional strain on the resources within public healthcare delivery. This is expressed by the old-age dependency ratio, the number of pensioners aged 65+ per 100 working age citizens (age 20 to 64), which is expected by 2050 to reach values between 60 to 70 pensioners per 100 working age citizens in some European countries (Spain, Portugal, Italy, Greece, Germany, Slovenia). The other European countries report future old-age dependency ratios from 42.1 (Norway) to 55.4 (Poland)¹.

Public healthcare systems face serious challenges in controlling and managing healthcare costs while at the same time meeting healthcare needs. At the same time, the general public is likely to have higher demands requiring an efficient healthcare system. Public demands of high-quality care, easy access and fast and reliable treatment are most likely to become even more firm and influential in the future.

2.1.1 Structures of the European Secondary and Social Care Sectors

While there is lack of comparative data for primary care data between the European countries, secondary and social care are comparable based on European Commission and OECD data.

For secondary care the data reveals strong variations for both ownership type structures and sizes of secondary care facilities.

¹ https://www.oecd-ilibrary.org/social-issues-migration-health/pensions-at-a-glance-2015/old-age-dependency-ratio_pension_glance-2015-23-en

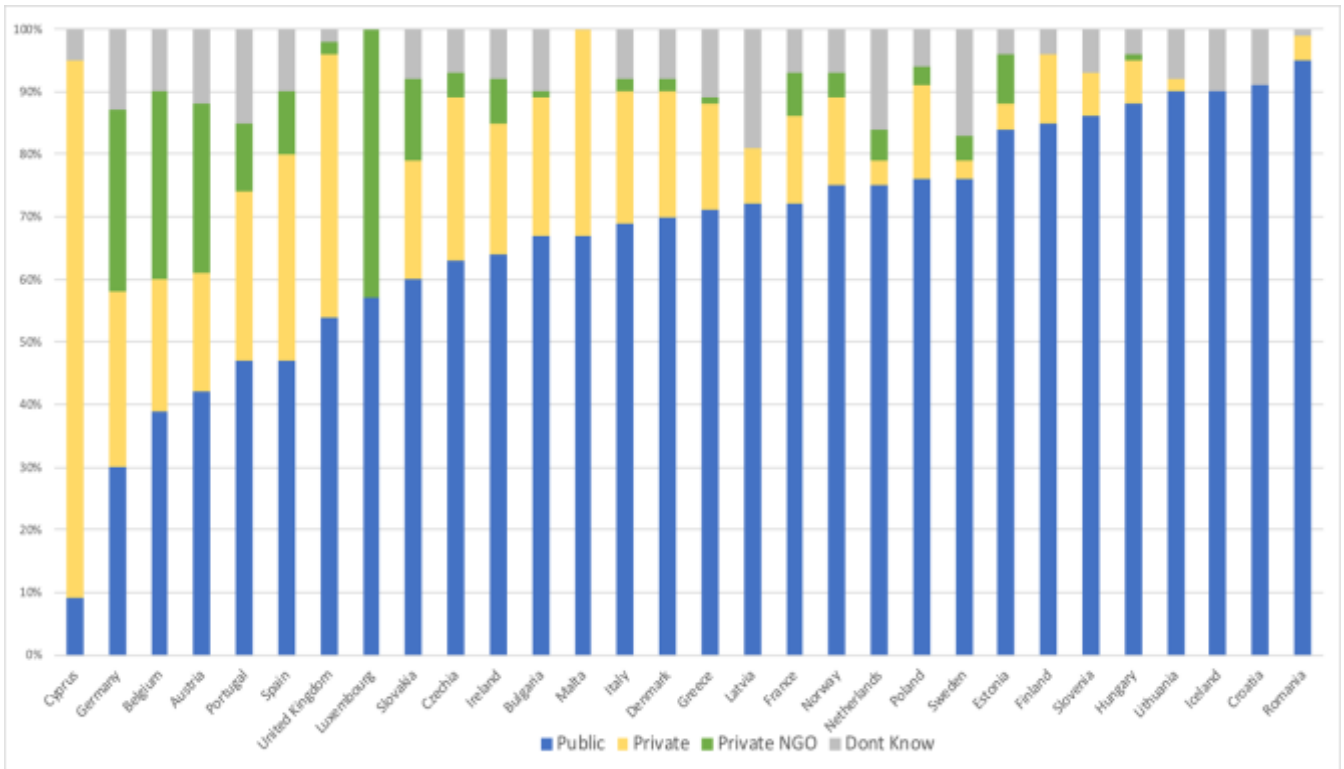


Figure 1 - Secondary Care ownership by types - Own visualisation with data from EC (2013)²

According to the data represented in Figure 1, public ownership of secondary care hospitals varies between 9% (Cyprus) and 95% (Romania) but in general constitutes the biggest share of ownership types in most European countries. Further, Germany, Belgium, Austria and Luxembourg have significant shares (over 25%) ownership type by Private NGO type operators, typically religious groups. Also, Portugal, Spain, Slovakia, Ireland and Estonia show sizable shares (above 10%) owned by Private NGO type organisations. Private ownership is generally low relative to shares of public ownership in most countries, except in Cyprus (86%).

However, a mere analysis of ownership structures may be misleading due to some countries potentially reporting many hospitals of a certain kind, yet all of them very small in size (measured by number of beds). Therefore Figure 2 analyses national hospital structure based on size. This reveals for example that while Cyprus has many privately-owned hospitals, a significant share of these appear to be very small in actual size, making them less interesting.

² <https://ec.europa.eu/digital-single-market/en/news/european-hospital-survey-benchmarking-deployment-e-health-services-2012-2013>

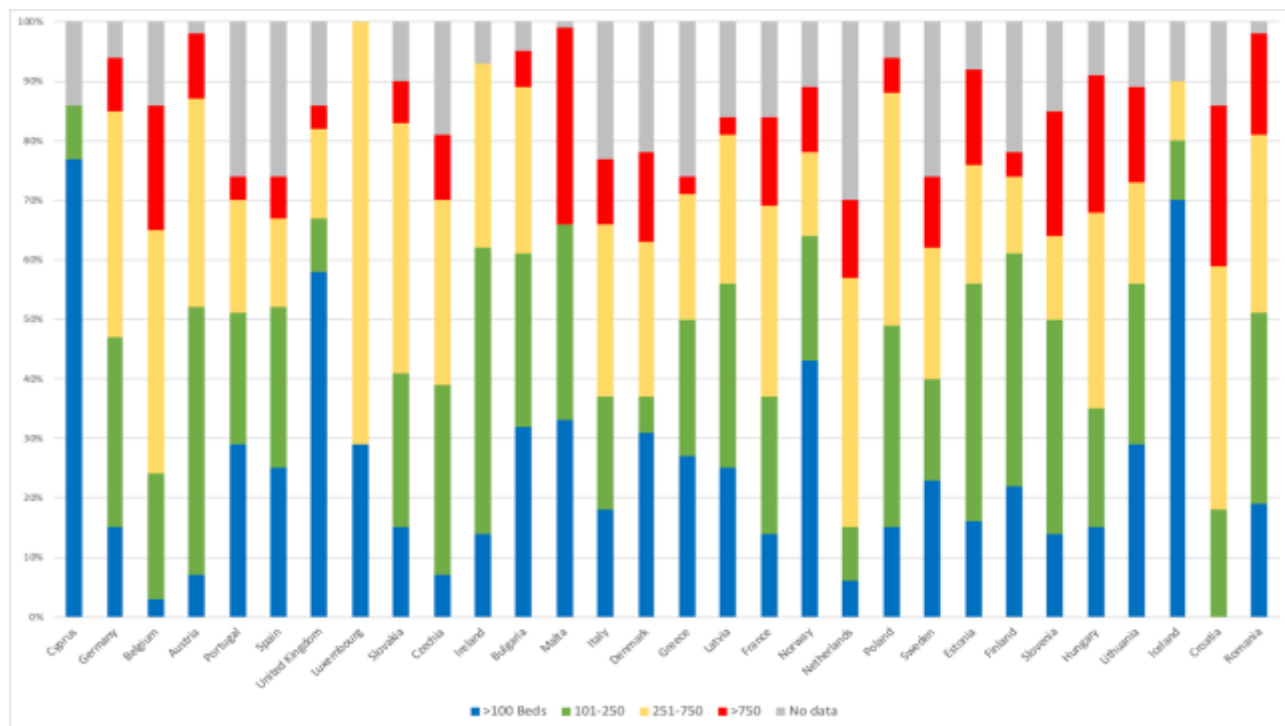


Figure 2 - Secondary Care hospitals by size (# of beds) – Own visualisation with data from EC (2013)³

In Figure 2, we can see that actual hospital sizes within countries are very diverse. Most countries do have mega hospitals (>750 beds) yet smaller and medium sized (from >100 up to 750 beds) hospitals still dominate in all European countries.

Combining insights from Figure 1 and Figure 2 allows certain insights such as privately held hospitals tend to be smaller in size, nicely illustrated in Cyprus and the United Kingdom.

³ <https://ec.europa.eu/digital-single-market/en/news/european-hospital-survey-benchmarking-deployment-e-health-services-2012-2013>

2.1.2 Economics of the European Healthcare Sectors

Economically all European countries spend significant shares of their annual GDP on healthcare. Figure 3 illustrates expenditures as national shares of GDP.

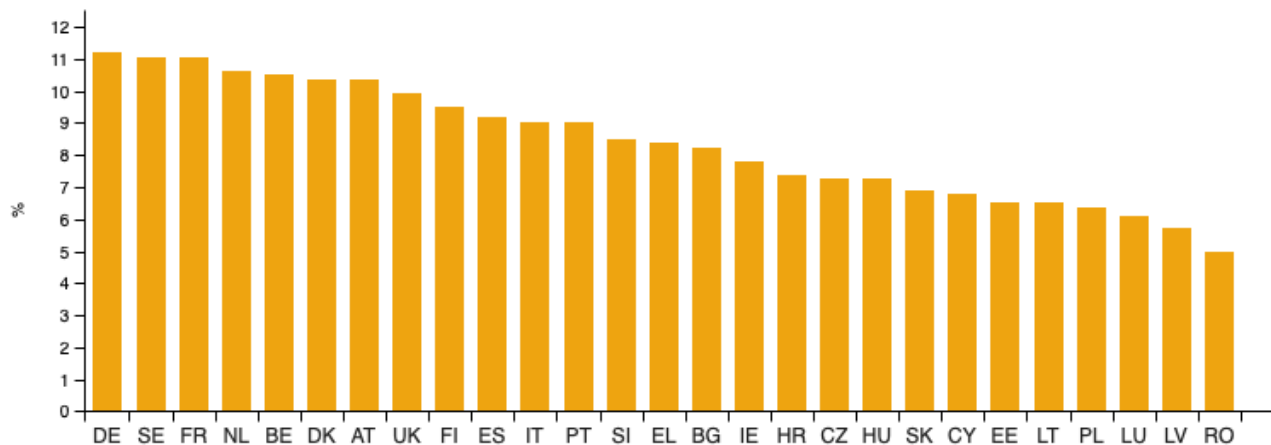


Figure 3 - Share of GDP spent on healthcare – Eurostat (2015)⁴

These expenditures clearly show how significant healthcare expenditures are in general. Countries spent between 11.15% (Germany) to 4.95% (Romania) while rather clearly indicating a tendency of western European countries spending higher shares than eastern European ones.

Healthcare services in Europe are mainly provided by the public sector. It is possible to distinguish between a) tax-based systems (based on the so-called Beveridge Model) where healthcare services are funded through general national tax revenue and provided by the public sector free of charge, and b) statutory health insurance systems (based on the so-called Bismarck model) where healthcare services are funded through non-risk related insurance contributions and provided by a greater mixture of public and private providers. The UK, Italy, Spain, Denmark and Sweden have tax-based healthcare systems, whereas e.g., Germany and France have social health insurance-based healthcare systems. Greece falls in-between the two systems as healthcare services are financed both by general taxes and statutory insurance contributions.

Statutory insurance contribution-based healthcare systems in Europe have a greater mixture of public and private providers of both primary and secondary healthcare services. The statutory health insurance schemes mainly act as purchasers of healthcare services from both public and private providers, albeit they may provide some healthcare services as well. The statutory health insurance schemes are responsible for providing public healthcare services and are the major source of financing healthcare.

2.1.3 Readiness of e-health in European Countries

The field of e-health is a rather new and broad field within healthcare. It is commonly regarded as a promising solution to modern challenges faced by established healthcare systems. These challenges were partly discussed in 2.1 in regard to aging populations and increased requirements of services covered. Though some of these challenges vary, especially the degree of old-age dependency ratio development, all European Member States recognise the importance of providing sustainable and adequate healthcare coverage in the future. Accordingly, all EU Members States are discussing the possibility of e-health to support these targets.

The area of e-health is currently the focus of development in all healthcare sectors. This leads to major healthcare reforms observed in many European countries and leading to a widening of the healthcare domain in general, with considerations of (digital) data protection, privacy and eGovernance becoming intertwined with the health sector. Further, e-health poses challenges to established models and structures of healthcare provision, especially in countries with a strong approach of regional devolution in the health sector, such as for example Spain and Italy. Compatibility and interoperability are major concerns especially in areas where diverse platforms and solutions are present, especially within same levels of healthcare service provision such as communication between professionals.

⁴ https://ec.europa.eu/eurostat/statistics-explained/index.php/Healthcare_expenditure_statistics

However, Figure 4 reveals that the reality in national healthcare systems in regard to e-health implementation levels varies significantly. Some countries appear to be in rather advanced stages of implementation, with doctors reporting regular use of typical e-health domains. The domain of online health information (blue) is the e-health domain most evenly established within all countries. On the other hand, the further three e-health domains considered reveal strong variations.

The integration of patients' mobile devices (sometimes referred to as mHealth) is currently also a major topic appearing in the discussions of most countries. However, some countries (for example Germany and Italy) have only recently invested heavily into the development of advanced electronic healthcare cards which are now at odds with implementation possibilities for mHealth solutions.

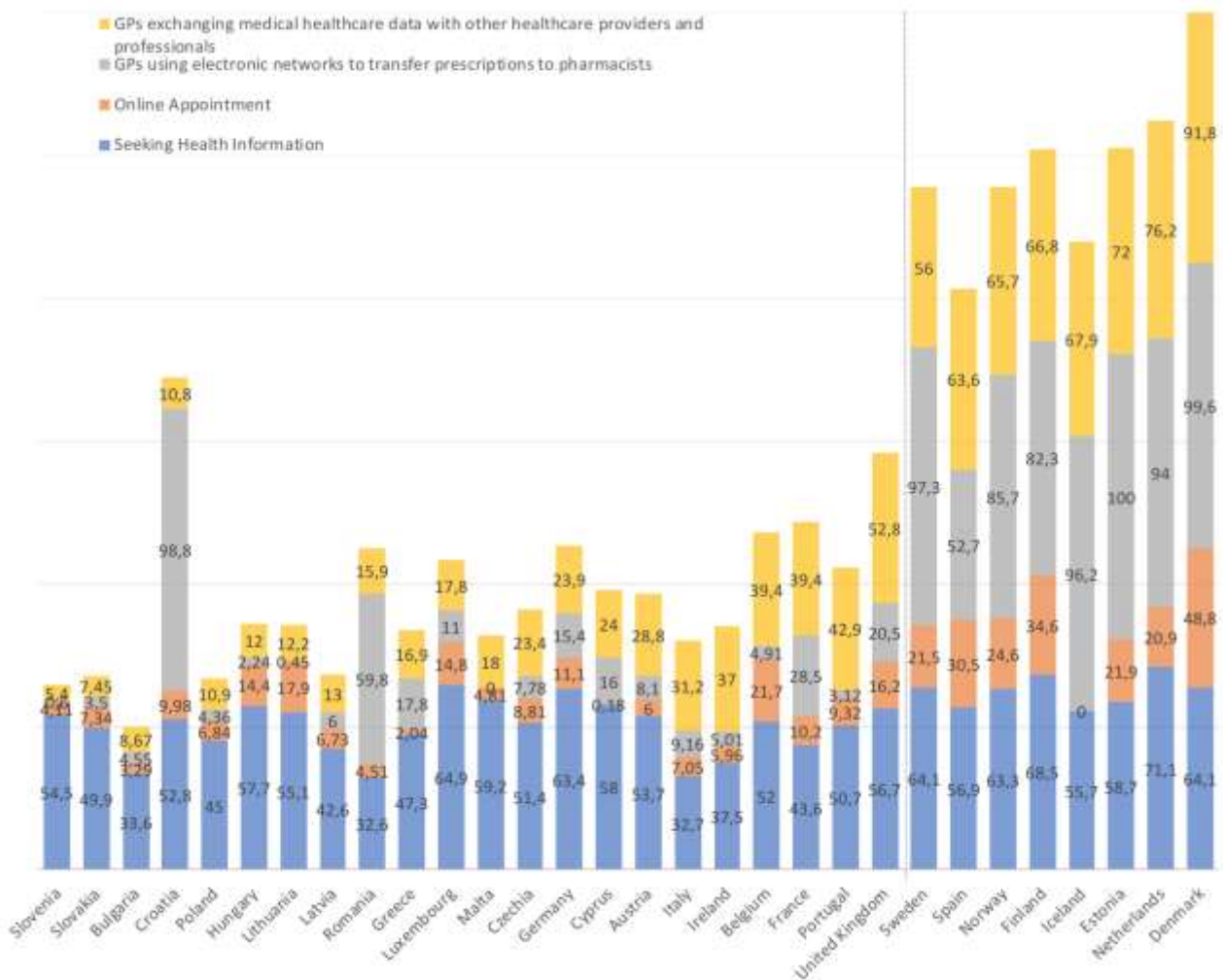


Figure 4 - e-health readiness indicators from the 2018 DESI, 5b e-health Sub-dimension, EC⁵

Figure 4 is a composite indicator of four different surveys done by the European Union between 2013 and 2018, each represented by one colour and topic. The graph reports, based on representative samples of doctors in each EU Member State, the percentage share of respondents reporting to (rather) regularly use the digital aspect concerned. For example, the yellow bar for the United Kingdom reports 52.8% of surveyed British doctors (rather) regularly “exchange medical healthcare data with other healthcare providers and professionals”, while for Denmark 91.8% of doctors report to do so (rather) regularly. Despite being included

⁵ <https://digital-agenda-data.eu/datasets/desi/visualizations>

in the European Commission 2018 DESI the yellow bar is based on an EU Commission survey conducted in 2013⁶.

2.2 The European Social Care Landscape

Common for the member states covered here is that they are facing the challenge of an aging population who, on the average, lives longer than the previous generation combined with a declining birth-rate (see also Section 2.1). This calls for innovative solutions, such as e-health solutions, to lower the cost of long-term care for the older generation. From Section 2.1.3, the e-health readiness indicators, show that the member states are at different levels of implementing digital solutions. This is the also the case from the analyses of Sweden, Denmark, Germany and Italy. Sweden and Denmark use multiple electronic health record (EHR) systems in their social care sectors. Both Germany and Italy rely more on private social-care institution differentiating from the public push in Sweden and Denmark towards e-health solutions.

Figure 5 below shows that cost of long-term healthcare is considerable higher than long-term social care cost as represented by long-term care costs as per centage of national GDP.

The cost of long-term care in the nine member states covered by our analysis varies, with Sweden, Denmark, and Belgium in one end and Spain and Italy in the other. A likely explanation is found in who carries the responsibility of elderly care: In Sweden, Denmark and Belgium, elderly care (except opt-in private care) is the responsibility of public institutions. In Spain and Italy, the responsibility of elderly care is mainly placed with families. This is a characteristic of Southern European countries, which also cluster together in the low expenditure end in Figure 5. The graph also shows grouping of Nordic and Benelux countries in the high expenditure end. Central European countries such as France, UK, and Germany are positioned near the OECD15 average. Eastern European countries have the lowest expenditure for long-term care.

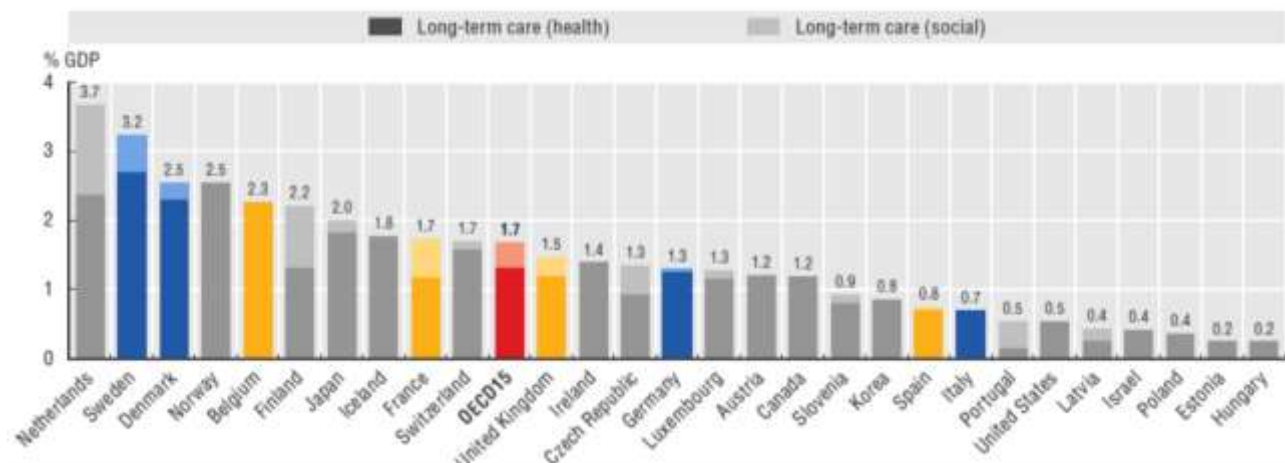


Figure 5 - Long-term care public expenditure (health and social components), by government and compulsory insurance schemes, as share of GDP, 2015 Source: OECD Health at a Glance 2017⁷

In Figure 5, red indicates the OECD15 countries’ average, blue is countries which are analysed in this paper, while yellow denotes countries that have been profiled. The data does not necessarily represent the actual national divide since the categorisation method of long-term healthcare and long-term social care can differ between member states.

2.3 Market Segmentation and Analysis Methodology

Different methods to segment and group the relevant European national healthcare markets were considered. However, comparative analysis such as those conducted in The European Care Landscape Section 2.1 only allow for rather broad and general views, while more detailed approaches to segmentation, such as based on technical requirements or organisation, proved too complicated due to lack of information.

⁶ <https://ec.europa.eu/digital-single-market/news/benchmarking-deployment-e-health-among-general-practitioners-2013-smart-20110033>

⁷ <https://www.oecd.org/els/health-systems/Health-at-a-Glance-2017-Chartset.pdf>

Attempting to analyse groupings of healthcare markets according to funding regimes, such as Beveridge vs. Bismarck payment model markets, is also too misleading, since these approaches often ignore significant differences within the established segments. Additionally, macro indicators for healthcare items are often not comparable between countries, further complicating any efforts toward broad and general market segmentations.

Due to these constraints efforts to analyse specific market segments were focused on four specific member states: Denmark, Germany, Italy, and Sweden. A summarising overview of the main characteristics of additional five European countries (Slovakia, UK, Belgium, France and Spain) is presented.

3 Analysis of Selected Member States

3.1 Denmark

The main feature of the Danish healthcare system is a decentralised responsibility for primary and secondary healthcare. Today, there are three administrative levels: The state, the regions and the municipalities, each with clearly defined responsibilities. All residents enjoy free access to health services.

3.1.1 Structure of the Care Sector

In 2007, Denmark was divided into five administrative regions with the main purpose of administrating healthcare. Denmark is further divided into 98 municipalities which administrate and fund most welfare tasks: infrastructure, libraries, social care, schools, integration, emergency services, etc.

The Danish care sector can be divided into primary healthcare, secondary healthcare, and social care:

Primary healthcare denotes the healthcare sector’s primary contact with the citizen: General Practitioners (GP) practising specialists, and pharmacies.

The GP and practising specialists run their own practice where they receive a fee for each consultation from the region. It is free to attend a GP, and the practising specialists are free with referral (some specialities are only partially covered, e.g., dental and chiropractic).

The pharmacies are run privately according to the guidelines of the Ministry of Health, which, depending on the type of medicine, covers some to most part of the medicine’s cost, the citizen pays the rest. The citizen can opt in for a private health insurance to cover medical costs.

Secondary healthcare assumes or resumes the treatment after referral from the primary care sector. In each region there are one or few university hospitals where all specialities are represented in one location. The hospitals are funded and politically managed by the respective regional council and administration. The regional council consists of politicians elected in regional election every fourth year.

The secondary healthcare sector also includes private hospitals, which are typically small, specialised hospitals, e.g., in plastic surgery. Ownership distribution is shown in Figure 6. Attending a private hospital is not free unless referred from a public hospital, in which case the private hospital treatment is performed on behalf of the public hospital.

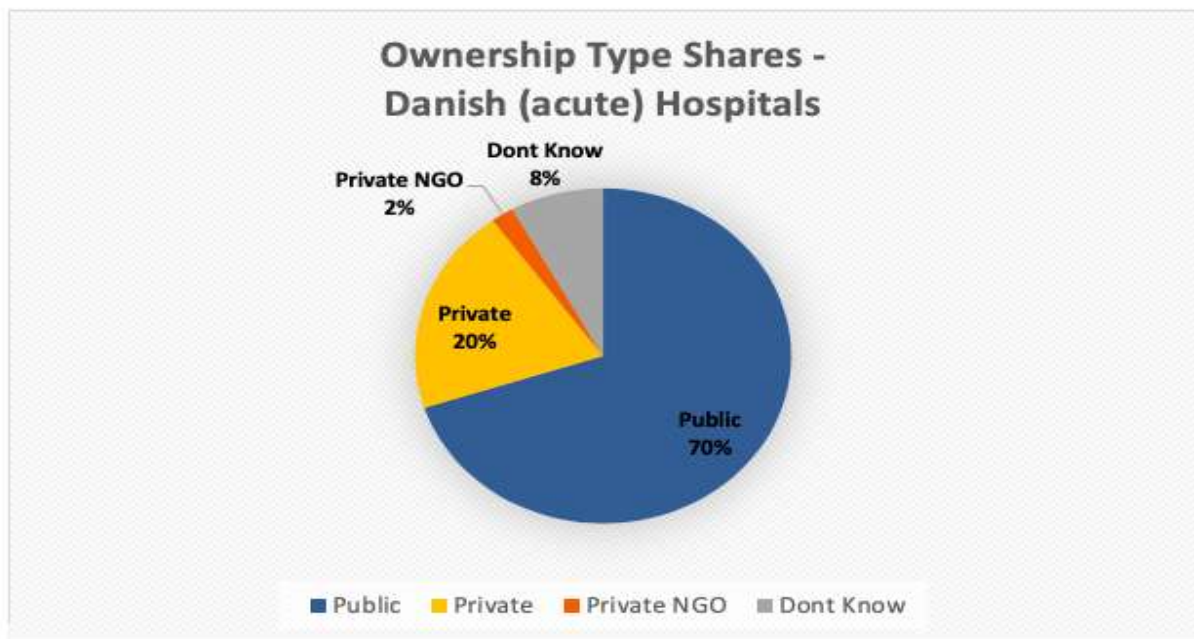


Figure 6 - Owner Type Shares, Danish (acute) Hospitals

Social care includes home care, long-term nursing homes, and a variety of social care offers (e.g., psychiatric offers for drug users). Social care is mainly administrated and funded on a municipal level; some institutions for people with social and special needs within education administrated and funded on a regional level.

Figure 7 showcases the access structure when the patient accesses the Danish healthcare system. The first column (specialist, GP, dentist) is the primary healthcare; the second column (private hospitals, hospitals, emergency ward) is the secondary healthcare.

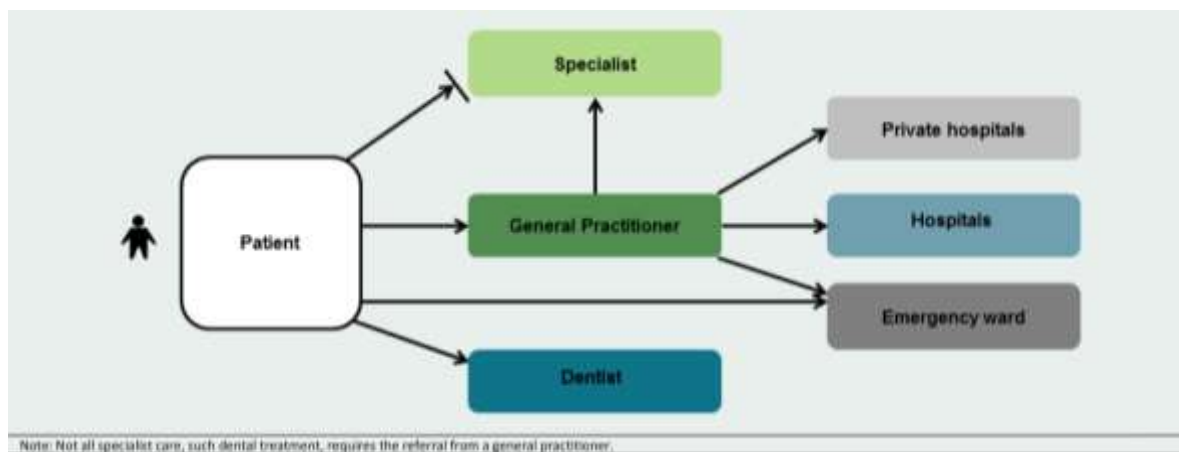


Figure 7 - Access structure of the Danish healthcare system – Source: Danish Ministry of Health⁸

3.1.2 History of Electronic Care Systems

The digitalisation of the Danish primary care sector started in the 1980s⁹. Systems began to be introduced at some GP offices. These systems are known as a Medical Practice System (LPS). Electronic Patient Journal (EPJ) systems started to be used in different departments at the hospitals in Denmark in the 1980s¹⁰. In the 90s and 00s the use and administration of EPJ systems remained fragmented. Since the introduction of the five administrative regions in Denmark in 2007 the EPJ systems have been run region-wide, standardising the electronic journal system used in each respective region.

Up until 2006, Denmark was developing a Fundamental Structure of Electronic Patient Record (GEPJ) which provided demands regarding clinical terminology, clinical structure, and data structure for EHR. The GEPJ was terminated in 2006 and since then Denmark has not had guidelines for or demands about the terminology and structure of an EHR system. Instead EHR systems are to follow the Danish legislation on use and management of medical data, which is fragmented into different laws.

In 2007, Denmark was partitioned into five administrative regions. Prior to this date, the selection and administration of EHR systems were fragmented and guided on a national level. After 2007, the task of selecting and administrating an EHR system for the secondary healthcare sector (i.e., hospitals) fell upon the regions. The decision is made by the regional council.

The Danish Ministry of Health reported in 2016¹¹ that all GPs use an EHR system: 98% exchange health records electronically, all GPs receive laboratory test results from hospitals electronically, 99% of all prescriptions are sent electronically to the pharmacies (via Common Medicine Card (FMK)), 97% of all referrals to hospitals are made electronically, all referrals to specialists are made electronically.

3.1.3 Legal Framework

EHR systems are to follow the Danish legislation on use and management of medical data, which is fragmented into different laws.

- The Health Law (Sundhedsloven) is the primary law in the Danish care sector. It sets rules about reporting, passing and using of patient data

⁸ https://www.sum.dk/~media/Filer%20-%20Publikationer_i_pdf/2016/Healthcare-in-dk-16-dec/Healthcare-english-V16-dec.ashx, p. 14

⁹ https://www.medcom.dk/media/8570/digital-almen-praksis_rapport_v1-0_2017_02_10.pdf

¹⁰ https://projekter.aau.dk/projekter/files/63241361/EPJ_i_Danmark_f_r_2007_2012_.pdf

¹¹ https://www.sum.dk/~media/Filer%20-%20Publikationer_i_pdf/2016/Healthcare-in-dk-16-dec/Healthcare-english-V16-dec.ashx, p. 36.

- The Personal Data Law (Persondataloven) describes the general rules for usage of personal data based on the EU regulation on data protection and usage of personal data (GDPR)
- The Authorisation Law (Autorisationsloven) describes the health personnel's obligations, e.g., medical record-keeping
- The Law of Due Process (Retssikkerhedsloven) includes the rules of consent in social care. It also includes rules about the exchange of patient data with admission and discharge from hospitals
- The Service Law (Serviceloven) includes rules about exchange of personal information in the preventive work with children and youths
- The Medicine and Pharmacy Law (Lægemiddeloven og Apotekerloven) describes the rules for collection and usage about medicine information
- Administration Law (Forvaltningsloven) dictates public employees' duty of confidentiality.

The Danish legislation does not include technical requirements for an EHR system but does include rules about usage of personal and medical data. The above laws which dictates use and management of medical data can be summarised as:

The patient must give consent before public personnel can access their medical data, unless it is necessary for the patient's treatment.¹² Consent can be verbal, written, and digital, e.g., a meeting at a GPs office for an appointment with your public health insurance card is taken as consent for the GP to access your medical data. With referral from GP to, e.g., hospital or another specialist consent is passed on as it is a part of the same treatment where the law describes that with the original consent all health and social personnel relevant to the treatment receives access to the patient's medical data. Written consent is signing a document. Digital consent is signed via the Danish nation-wide digital signature system "digital signature". The law requires the data responsible to be able to prove that the patient has given consent. If access to medical data is necessary, e.g., with acute hospitalisation, the relevant health and social workers gets access to the patient's medical data.¹³ The system is required to log when and who accesses the patient's medical data, as well as limiting access to only relevant personnel.

3.1.4 Current Situation

Electronic Patient Record (EPJ) is the electronic journal system used in the Danish secondary healthcare sector. The regions individually choose and run a regionwide EPJ system.

Currently, four different EPJ systems are used in Denmark. Figure 8 visualises where the different EPJ systems are used in Denmark today. It also indicates the change which will follow in the next few years where the EPJ, Columna, developed by the Danish company, Systematic, will be the EPJ system used in the three western regions of Denmark. Region of Southern Denmark has decided in 2018 to switch to Columna by 1st of January 2020. North Denmark Region has decided in 2018 to follow Central Denmark Region and Region of Southern Denmark in switching to Columna.¹⁴ The final decision of how and when will take place in 2019.

¹² <https://www.datatilsynet.dk/media/6562/samtykke.pdf>

¹³ <https://www.sundhed.dk/borger/service/om-sundheddk/om-portalen/datasikkerhed/andres-dataadgang/adgang-til-sundhedsdata/>

¹⁴ <https://dagensmedicin.dk/nordjylland-vaelger-samme-epj-system-som-midtjylland-og-syddanmark/>

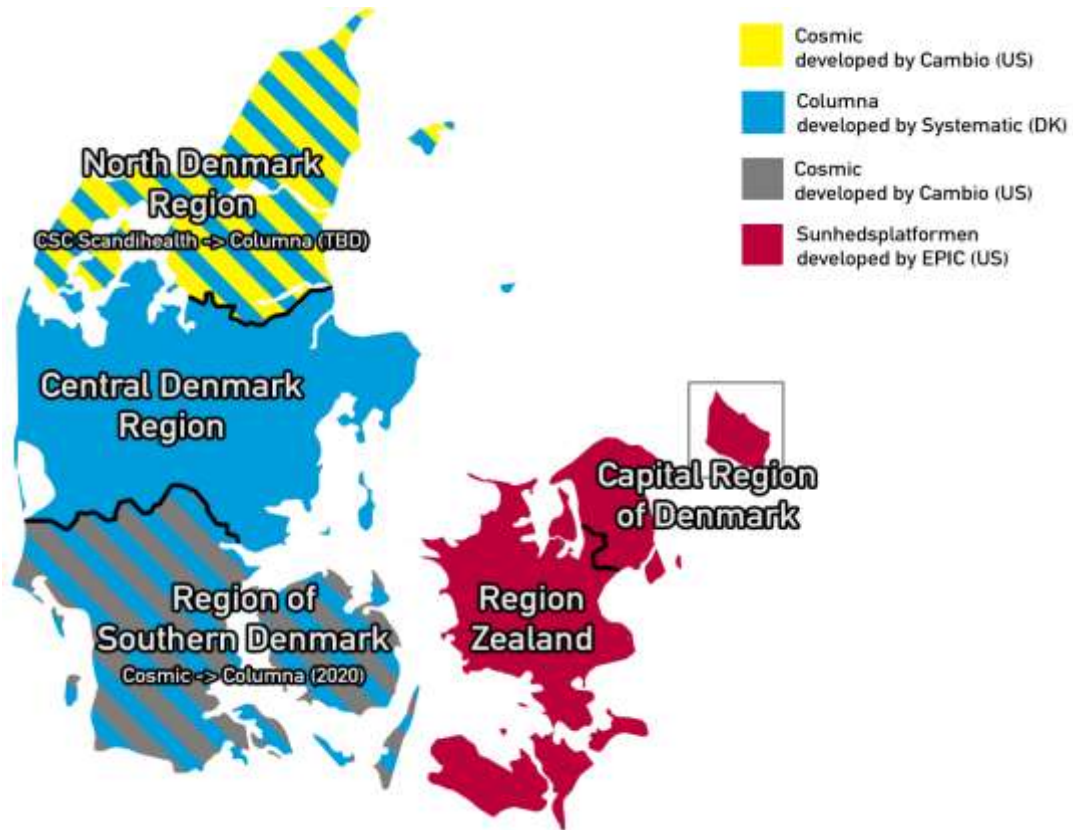


Figure 8 - Current and future division of EPJ systems in Denmark per region - Source: PICASO Project

In the social care sector, the Danish municipalities use an Electronic Care Record (EOJ). The largest EOJ system provider in Denmark is the Danish based company, KMD, a subsidiary of Japanese NEC (owned until the end of 2018 by Advent International [US] and Sampension [DK]).

Systematic’s Columna Cura system (i.e., EPJ) also works as an EOJ, recording social care in municipalities. In the end of 2018 around a third of the Danish municipalities had chosen Columna Cura as their EOJ system, around a fourth was running the system¹⁵.

The diagram in Figure 9 visualises where the four different electronic systems are used:

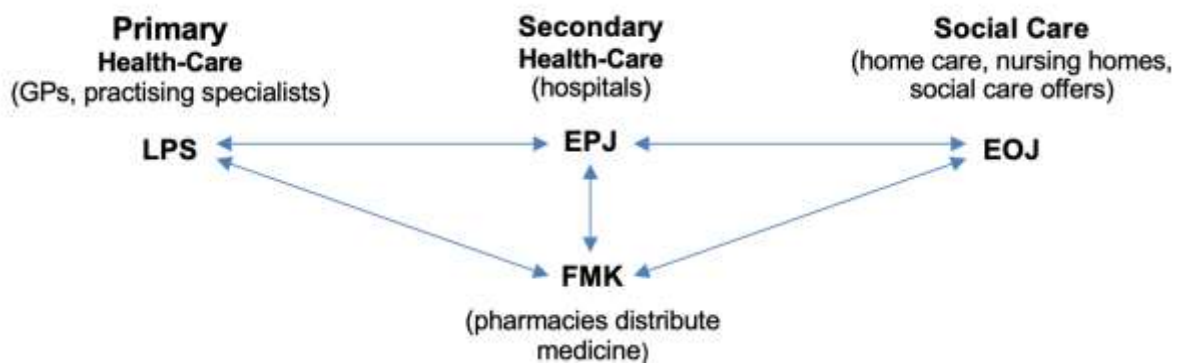


Figure 9 - Overview of Danish Electronic Care Systems Source: PICASO Project

The Medical Practice System (LPS) is an IT system used in the primary healthcare sector, i.e., in a General Practitioner’s (GP) office or, e.g., at a dentist’s office. The system handles, e.g., patient journals and time schedules. The GP uses the FMK on top of their LPS system to prescribe medicine for the patient. If a patient is referred to a hospital by the GP, the information on the patient that the GP has in his/her LPS is sent to the hospital to be entered into their EPJ system.

¹⁵ <https://da.systematic.com/healthcare/news/2018/slagelse-municipality-selects-electronic-citizen-record-from-systematic/>

The Common Medicine Card (FMK) is a separate IT system that handles prescription medicine and records the medication the patient receives. The system is used by (almost) all care professionals in Denmark: GPs, hospitals, social care workers, pharmacies etc.

3.1.4.1 Healthcare Reform Announced

The 16th of January 2019 the Danish government announced its healthcare reform plans¹⁶ which will dissolve the five administrative regions and instead create five healthcare coordination centres and 21 healthcare “communities” consisting of in average five municipalities.

The plans consist of a range of different steps, but most relevant to this analysis is that included in the plans is moving the decision about digital healthcare solutions and systems are moved to the parliament and the planned institution Healthcare Denmark (Sundhedsvæsen Danmark). The plans describe this as how “nation-wide” digital solutions are approved. It is not known at the time of writing if this means that the plans include a national EHR strategy instead of the region-wide strategy that Denmark has today.

Denmark is facing a general election in the first half of 2019, which means the scope and the timeframe of the healthcare reform are quite uncertain.

3.2 Germany

Germany is a federal republic consisting of 16 states (Länder). The Federal Government provides the regulatory framework for healthcare, but the states are responsible for providing healthcare and planning capacities, including financing investments in hospitals, nursing homes and institutions for social care.

3.2.1 Structure of the Care Sector

Representing Europe’s most populous country, Germany offers the largest market for healthcare and Life Sciences products. With 300 BEUR spent yearly, Germany is the 3rd largest market for healthcare in the world and there is high density of med-tech companies and innovative clusters. Germany has a universal healthcare system and contains a mix of public law-enforced healthcare insurance and private healthcare insurances. The healthcare budget reaches 11% of GDP, which makes Germany one of the most expensive public healthcare systems in the world (see Section 2.1.2). One reason for the high costs is the high density of hospitals and practices. The secondary-care hospital scene is split into three equal shares of ownership groups of public, private and Private NGO ownerships, as shown in Figure 10. A similar division can be observed in the social care domain. High fragmentation in both ownership and size results in an also highly fragmented current market for medical practise systems found between and within organisations and health regions.



Figure 10 - Ownership Type Shares, German (acute) Hospitals

¹⁶ <https://www.altinget.dk/artikel/ny-naerhedsfond-flere-sygeplejerske-og-farvel-til-regionsraad-her-er-regeringens-sundhedsreform>

3.2.2 History of Electronic Care Systems

At the German national level, the Federal Ministry of Health (Bundesministerium für Gesundheit (BMG)) is responsible for legislation regarding the health and care sector. At the beginning of the 2000's, the ministry initiated a process towards the digitisation of the German healthcare sector, leading to the establishment of gematik (Gesellschaft für Telematikanwendungen der Gesundheitskarte/company for telematics applications for the electronic health card) in 2005. Founded by interest organisations of doctors, dentists and German statutory health insurances among others, gematik's main task was the establishment of the electronic health card (elektronische Gesundheitskarte (eGK)) which was completed around 2014 and is since being rolled out. The gematik sets the conceptual framework for the telematics infrastructure as a comprehensive and secure network, coordinates its reliable operation and the market-driven structure. The gematik ensures the functionality and interoperability, i.e. the smooth interaction between the various components, services and applications in the telematics infrastructure, and sets standards in the digital German health care system.¹⁷

The most recent standard published by gematik at the end of 2018 refers to specifications and technical requirements of an electronic patient record (elektronische Patientenakte (ePA)) eligible to run within the German telematics infrastructure. The specifications include the prerequisites for patient data (such as discharge letters, emergency data, medication plan) to be made available to the patients in an electronic patient record and required authorization procedures. This will enable the patients to share key health data with their care providers.¹⁸ All companies developing an ePA must adhere to the defined specifications and apply for certification of their product at gematik before they can enter the market.

3.2.3 Legal Framework

Announced in September 2017 the E-Health Law II (E-Health-Gesetz II) is expected as the next cornerstone to German legislation on the field. As for the content of the E-Health Law II a variety of pressing issues are expected to be addressed also in regard to the government's digitization strategy for the healthcare sector. Since the E-Health Law II is still under negotiation and not all developments aimed for in E-Health Law I could be achieved yet, important issues such as providing the legal requirements for development of an electronic patient record (ePA) became part of acts for the healthcare sector issued meanwhile. For ePA this was the German Appointment Service and Supply Act (Terminservice- und Versorgungsgesetz (TSVG)) that requires all statutory health insurances to provide a gematik approved ePA to their customers by 2021. The act came into force in May 2019 and among others lists key subjects to be included in ePA such as results of functional diagnostics, referral and discharge letters and a medication plan.

Legal requirements for (electronic) medication plans

Since the end of 2016, all patients in Germany have the right to a medication plan. However, this right is limited to the medication plan being in paper format and conditional on the patient having been prescribed at least three or more medications. The E-Health Law I also required patient medication plans to be saved on the electronic health card (eGK) by the beginning of 2018. However, the nationwide implementation of the eGK turned out to be problematic, so the deadline was extended and the rollout is still ongoing.

Legal requirements for electronic patient records (ePA)

By the beginning of 2021 electronic patient records need to be available to patients in Germany. Required features are results of functional diagnostics, diagnoses, treatment plans, referral and discharge letters, vaccination, medication plan and emergency data. Health insurances are free to add further information subjects. Ownership of the gathered patient record is to lie with the patient himself while every individual institution involved only stores the data, they themselves have created and are responsible for. For the patient to grant access to personal health data stored, the German Appointment Service and Supply Act foresees that the patient or another person appointed by the patient can preconfigure access rights, e.g. access for the personal GP, and/or provide ad-hoc access when being physically present at, e.g. a doctor's practice, by providing his/her electronic health card (eGK) and a 4 digit pin code. The health professional is also logged into the system by his/her personal health card (Heilberufsausweis (HBA)) (see Fig. 11). This system is already implemented in the Austrian ePA called "ELGA".¹⁹ Alternatively, the German Appointment Service and Supply Act requires that patients shall be able to provide access without eGK, i.e. a mobile device.

¹⁷ <https://www.gematik.de/ueber-uns/>

¹⁸ <https://www.gemalto.com/govt/customer-cases/germany-second-generation>

¹⁹ <https://www.elga.gv.at/faq/datenschutz-und-datensicherheit/index.html>

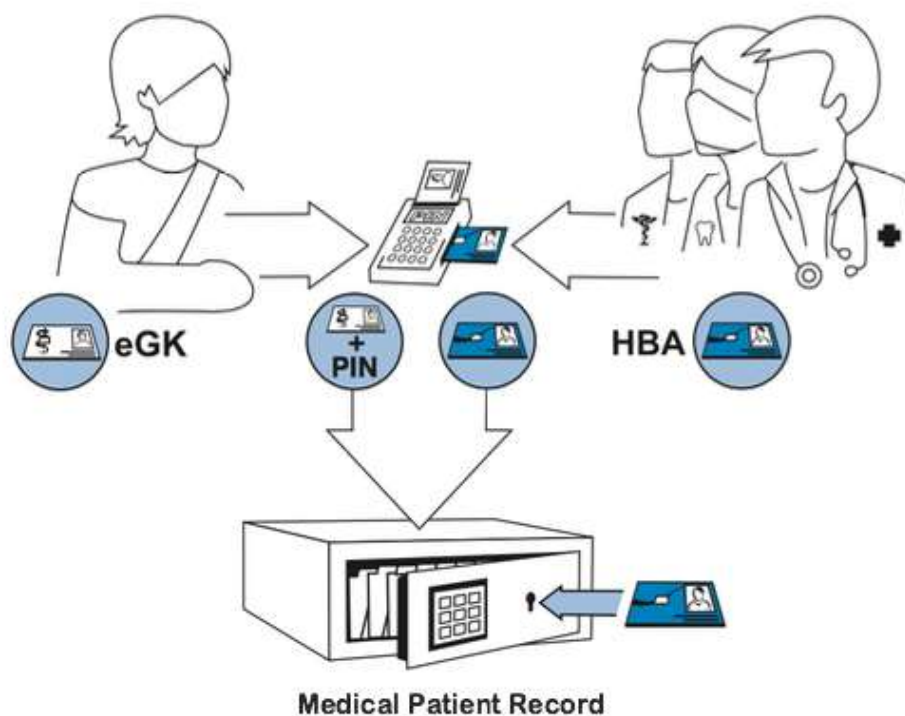


Figure 11 – Ad-hoc authorization with the “Four-Eye Principal” as imagined in the gematik Whitepaper (2016)²⁰

3.2.4 Current Situation

The ePA is currently under development in Germany. To support this, gematik has given workshops to industry in regard to technical requirements and specifications. The ePA must be capable of storing, processing and using data concerning, e.g., medical findings, diagnoses and treatment measures. Furthermore, patients will gain the option to upload own data (e.g. from wearables) and transfer it to physicians.

Compared with other countries in Europe, Germany still has some catching up to do but the digital health market seem to have all the potential to really accelerate now. Germany’s growing digital economy offers unusual conditions for new products in the healthcare industry. The exponential increase in internet usage, the lucrative software market and the influx of mobile devices have incentivized digital healthcare in the country. mHealth is also a key factor in the healthcare aspect with nutrition and workout being the most popular mHealth apps. The biggest hurdle for the implementation is that one needs interoperable systems throughout Germany and for all health facilities. Until now, proprietary systems following own standards are in use for data storage by health insurance companies, doctors, hospitals and the social care sector.²¹

3.3 Italy

Italy is located in southern Europe and is bordered by France, Switzerland, Austria and Slovenia. It has a population of 60.6 million (2017) divided over 20 federal regions. Italy has one of Europe’s highest life expectancy at birth, averaging around 83.3 years currently. However, in almost all indicators a significant difference between northern and southern regions prevails and demographic challenges of an aging society, similar to the ones of Germany, are expected to put pressure on the Italian healthcare system.

3.3.1 Structure of the Care Sector

Italy’s healthcare system is a regionally based health service (Servizio Sanitario Nazionale [SSN]) that provides universal coverage free of charge at the point of service. The national level is responsible for ensuring the general objectives and fundamental principles of the national healthcare system. Regional governments, through the regional health departments, are responsible for ensuring the delivery of a benefits package

²⁰ https://www.gematik.de/fileadmin/user_upload/gematik/files/Publikationen/gematik_whitepaper_web_Stand_270916.pdf

²¹ <https://www.gemalto.com/govt/customer-cases/germany-second-generation>

through a network of population-based health management organisations (azienda sanitaria locale [ASL]) and public and private accredited hospitals. There is considerable variation between the north and the south in the quality of healthcare facilities and services provided to the population, with significant cross-regional patient flows, particularly to receive high-level care in tertiary hospitals.

The catalogue of SSN benefits, the *livelli essenziali di assistenza (LEA)*, is defined in terms of a positive and negative list. The positive list contains the services that the SSN is required to provide uniformly in all regions. Regions are free to provide non-LEA services to their residents but must finance these with own source revenues.

Healthcare in general is mainly financed by earmarked central and regional taxes – a corporation tax that is levied on the value added tax of companies and on the salaries of public sector employees, and an additional regional income tax. The former tax is collected nationally, but 90% of its revenue is allocated back to the region in which it is levied, thus favouring those regions with a stronger industrial base, typically found in the northern parts of the country.

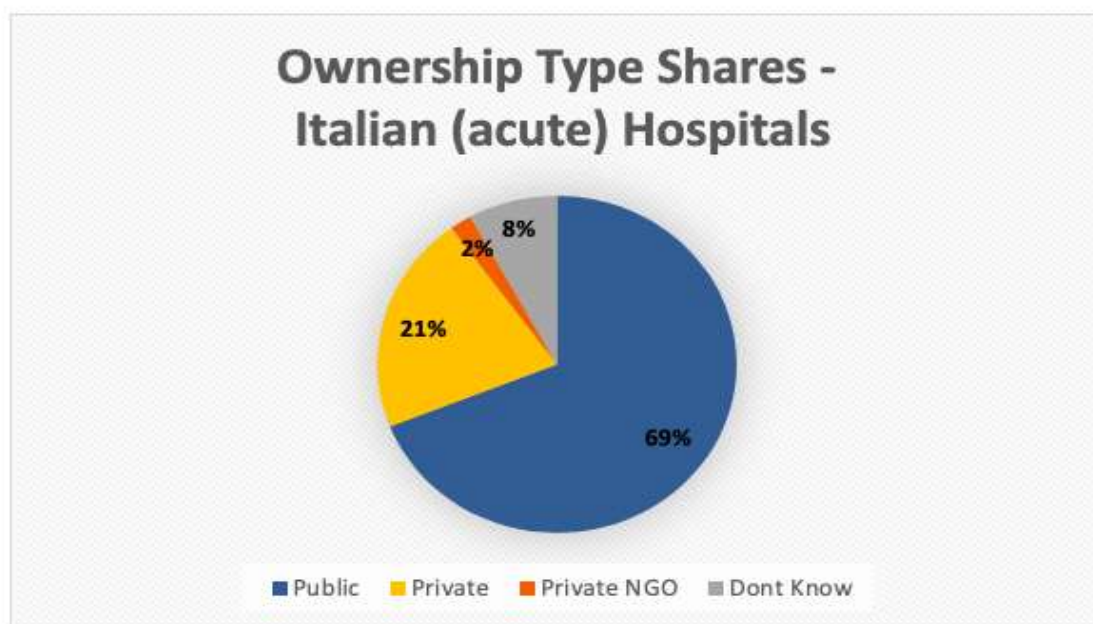


Figure 12 - Ownership Type Shares, Italian (acute) Hospitals

3.3.2 History of Electronic Care Systems

In the last few decades, Italy has made impressive efforts to improve its information technology and, consequently, healthcare service delivery, as well as to monitor the accountability of health professionals and institutions. In 2001 the New Health Information System (Nuovo Sistema Informativo Sanitario (NSIS)), has been established by the Ministry of Health, making possible the creation of a huge database on all healthcare services. Moreover, in 2003, the Ministry of Health, in collaboration with the Ministry of Finance, initiated a project to introduce a citizens' electronic health card (e-card). The e-card was disseminated across Italy, starting with distribution in some pilot regions, and gradually rolling out delivery to all citizens, who received their e-card with a letter explaining its main functions. The e-card contains demographic information on individuals (fiscal code, date of birth and place of birth) and a magnetic code that will make it possible, in the future, to trace their entire patient pathway. Moreover, information on the e-card will be used to monitor pharmaceutical expenditure all over Italy; in some regions, this system has already been implemented, while in some others the quality of information is not very reliable. Since January 2008, the e-card has been used in pharmacies to validate out-of-pocket purchases of drugs for the purpose of tax deductibility.

In spite of these improvements, some problems still persist. Firstly, regulation and governance of third-party payers/service providers do not promote full accountability in final purchasing decisions, a problem that is also due to the fact that, in some cases, population health needs do not represent the main priority and healthcare delivery is often planned on the basis of political strategies and existing facilities and staffing. Secondly, while the devolution process has given greater autonomy to the regions, at the same time it has also created some problems regarding relationships and communication between the central and regional levels of government,

creating concrete difficulties in the division of responsibilities, and often causing cost shifting and duplication of services.

Additionally, many Italian regions launched programmes to create electronic patient records using the Internet to connect patients, GPs, other healthcare professionals and hospitals. Among the regions, the CRS–SISS (CRS, Regional Services Card; SISS, Healthcare Information System) project in Lombardy can be considered, at the moment, to be the most advanced experiment in the creation of an integrated e-health strategy. The 'Healthcare Extranet' represents the core of the project, which links professionals, social services, organisations and citizens, tracking all the events that occur in the patient treatment pathway and providing value-added services. It is based on smart card technologies, granting access to the network to both citizens and healthcare professionals through their CRS. A CRS allows every citizen to access all public administration services and enables them to access private services. On the other hand, the SISS is the regional network connecting all health and social care players in Lombardy and provides e-health services to ensure continuous care.

3.3.3 Legal Framework

The legal framework for the Italian e-Government strategy is the Code of Digital Administration (CAD, in Italian), which establishes a framework for the digitisation of public administrations, thus enabling the efficiency and effectiveness of the e-health domain. The CAD regulates the creation, management, preservation and transmission of electronic documents used by the Public Administration and promotes the reutilisation of public information systems. The Code also introduces the Public Connectivity System (SPC), i.e., the connectivity infrastructure for Italian PAs, and the Public Connection and Cooperation System (SPCoop), the infrastructure for the interoperability and cooperation between Public Administrations. The Public Connection and Cooperation System is a complex system including technical communications infrastructures, services, registries, rules and guidelines (about 30 documents) for the entity connection. SPC is fully mandated by the Law on Digital Administration (CAD).

The aims of the SPC can be summarised as follows:

- Provide a set of common, shared connectivity services for administrations
- Ensure interaction of central and local administrations with anyone connected to the Internet, promoting the provision of quality services for citizens and business
- Provide a central communications infrastructure
- Provide services to administrations who wish to connect to the infrastructure
- Drive a multi-vendor delivery model for the infrastructure implementation
- Ensure data security, confidentiality and privacy on SPC systems
- Respect the autonomy of information assets of the administrations.
- The governance of SPC employs a multi-layer model.

The Italian National Agency for the Digitalisation of Italian Public Administration (DigitPA) governs the implementation of SPC guidelines and standards in multiple ways:

- by overseeing the implementation of the national SPC communications infrastructure (including public tendering) and associated services (such as identity management)
- by evaluating IT projects in governments beforehand and afterwards, including a certification program to validate eServices that connect to SPC.

The SPC and the Applied Cooperation Services are governed according to a federal model in which a Coordination Commission (presided over by DigitPA), is responsible for strategic governance while all the entities (Regions and DigitPA) are responsible for the management of the shared resources, for their quality and security, and for the planning, implementation and development of SPC.

3.3.4 Current Situation

The strong autonomy of Italian regions in regard to healthcare provision has resulted in each region autonomously starting to develop and implement self-developed HER, thus providing some EHR services to citizens, or at least laying the foundations for their provision.

In 2008, the Italian Ministry of Health conducted a study to determine the status of adoption of the EHRs. The study showed that 43% of the local health authorities, 62% of the hospitals and 19% of local clinics use the electronic health records.

As far as health workers using electronic health records, a coverage of 71% was estimated for general practitioners and paediatricians, 67% for other doctors in the National health service while 29% of nurses and 5% of pharmacist adopted it.

The heterogeneity of such regionally developed EHR systems has resulted in an interoperability issue. Thus, in the last few years, a lot of work has been done by governmental institutions, regional administrations, and public research centres aiming at creating a cooperative network to define regulations for health data management, acquiring both International Standard Board guidelines and EU recommendations. Among these efforts, the InFSE project aimed at proposing a technological infrastructure for making heterogeneous health information systems mutually cooperate among each other.

3.4 Sweden

Sweden has an integrated public healthcare system in which the majority of financing and almost all the delivery is provided by the public sector. The healthcare system is mainly financed by regional taxes. The Swedish National health service (NHS) provides coverage for all residents irrespective of nationality.

3.4.1 Structure of the Care Sector

The public part of healthcare in Sweden is provided by the county councils (hospital care and primary healthcare) and the municipalities (care of the elderly, home care). These two levels have their own political powers to set priorities, run healthcare and, consequently, launch e-health initiatives. However, the government sets the overall framework for healthcare by holding national legislative power. There are e-health initiatives in all of the 21 county councils (regions) and in many of the approximately 300 municipalities in Sweden.

3.4.2 Overview of the Swedish Healthcare Market

Swedish Healthcare's share of GDP was 10.9 percent in 2017. The public authorities funded 84% of total costs while households through patient and other fees accounted for 15%.

Somatic specialist care is the heaviest entry for county councils and regions. It amounted to approximately SEK 142 billion, just over half of the total cost close to SEK 274 billion for 2017. Not unexpectedly, diseases in the circulatory system, such as myocardial infarction and stroke, cost the most.

The responsibility for health and medical care in Sweden is shared by the central government, county councils (landsting) and municipalities (kommuner). The Health and Medical Service Act regulates the responsibilities of county councils and municipalities and gives local governments more freedom in this area.

The role of the central government is to establish principles and guidelines, and to set the political agenda for health and medical care. It does this through laws and ordinances or by reaching agreements with the Swedish Association of Local Authorities and Regions (SALAR), which represents the county councils and municipalities.

Healthcare in Sweden is largely tax-funded. Responsibility for providing healthcare is devolved to the county councils and, in some cases, municipal governments. County councils are political bodies whose representatives are elected by county residents every four years on the same day as national general elections.

Swedish policy states that every county council must provide residents with good-quality health and medical care, and work to promote good health for the entire population. County councils are also responsible for dental care for local residents up to the age of 21.

Sweden is divided into 290 municipalities and 21 county councils. Three of the county councils: Halland, Skåne and Västra Götaland – as well as Gotland municipality – are called regional councils and have assumed responsibility for regional development from the state.

There is no hierarchical relation between municipalities, county councils and regions. Around 90 per cent of the work of Swedish county councils concerns healthcare, but they also deal with other areas such as culture and infrastructure.

Sweden's municipalities are responsible for care for the elderly in the home or in special accommodation. Their duties also include care for people with physical disabilities or psychological disorders and providing support and services for people released from hospital care as well as for school healthcare. Chronic diseases that require monitoring and treatment, and often life-long medication, place significant demands on the system.

3.4.2.1 Hospitals and Primary Care Centres

Hospital facilities primarily care for inpatients as well as specialised outpatient care for patients undergoing finite courses of treatment. The hospitals are thus responsible for patients with diseases or injuries that cannot be investigated or treated in primary care (primärvård). As a rule, outpatient care is available at the clinics or at specialist clinics that are represented at the hospital.

There are 100 hospitals in Sweden, of which 85 are run by county councils and the remaining are privately run. Seven of these 85 are regional university hospitals.

Primary care provides the care that most patients need. Patients who do not require the hospitals' technical and medical resources are taken care of by the health centres for medical treatment, rehabilitation, nursing and preventive work. Patients with chronic diseases, such as diabetes, go to the healthcare centre for regular checks.

The doctor on the nursing home usually places the first diagnosis in case of serious illnesses. The patient receives a referral to specialist reception if the healthcare centre cannot provide treatment or diagnosis.

Several occupational categories work in primary care: doctors, psychologists, nurses, medical secretaries, midwives, physiotherapists, occupational therapists, curators and speech-language pathologists. The doctors are trained in general medicine and nurses often have specialist training for district nurses. Primary care also includes home care, based on doctors, district nurses and nurses.

Most of the primary care is provided by primary care centres (vårdcentraler). The primary care centres may also be called a doctor clinic (e.g., in Stockholm County) or family doctor clinic (Västmanland County).

The primary care centres act as a first level of care for patients who have non-acute and non-acute diseases. Physicians at the primary care centres also often have overall and coordinating responsibility for their patients and may, if necessary, refer to other specialists for investigation and care. The primary care centres also handle laboratory tests, recurring blood pressure checks and other more or less routine care and investigation efforts.

The number of primary care centres (vårdcentraler) was 1,144 in 2016, a decrease of 6 from 2015. Of these, 486 were run privately, i.e., 42 percent.

In Figure 13 below the ownership of Swedish (acute) hospitals are shown in percent.

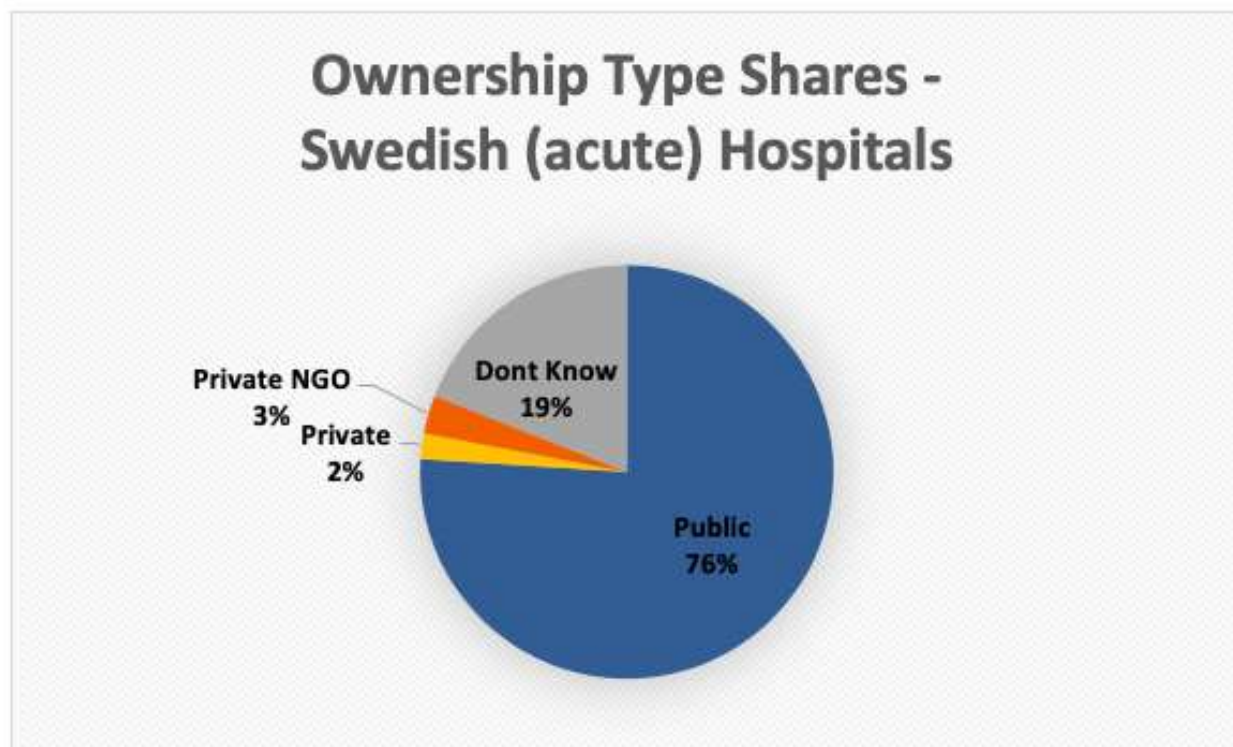


Figure 13 - Ownership Type Shares, Swedish (acute) Hospitals

3.4.2.2 Private healthcare providers

It is now more common for county councils to buy services from private healthcare providers. In 2013, 12 per cent of healthcare was financed by county councils but carried out by private care providers. An agreement guarantees that patients are covered by the same regulations and fees that apply to municipal care facilities.

The ten largest private healthcare providers together account for almost 40 percent of the market. (Praktikertjänst, Capio, Ambea, Previa, Förenade Care, Team Olivia, Frösunda, Humana, Aleris, Attendo).

During 2015, three of the top ten companies have been listed on the Stockholm Stock Exchange, and the AP funds are among the largest owners in two of these.

3.4.2.3 Swedish Occupational Health Market

According to the Swedish Work Environment Act, employers are required to give employees the occupational health service required in their profession. Occupational health primary task is to remove or reduce the risks in the work environment.

Approximately 4000 people are employed within the occupational health sector. Added to this there are a large number working as subcontractors and consultants. The largest occupational group is nurses who comprise nearly a third of the industry's all working. Next, behavioural scientists, doctors and ergonomists, work environment engineers, wellness consultants, group administrators and other specialists.

Occupational health sector is mostly private and operates on an open market. Over 80 percent of the more than 600 occupational health providers are run as individual companies, while the remaining percentage is "built in" and is included in the client company's operations. About half of the companies providing occupational health services are owned by counties and municipalities, and half owned by the private sector.

2014 was the industry's turnover about four billion SEK (compare over 11 billion SEK in Finland), equivalent to an investment by the employer on approximately 1300 SEK per employee in the form of services from occupational health services.

The three largest nationwide private occupational healthcare providers (turnover) are Previa AB (1.2 billion SEK), Avonova AB (1 billion SEK) and Feelgood (0.5 billion SEK).

The ability for employees to have access to occupational health services varies widely between different sectors and size of company. The state and local governments as well as large companies, most employees

have access to occupational health services. Of Sweden's approximately 4.7 million jobs offered about 3.1 million (about 65 percent) occupational health services through their employer.

The Swedish occupational health market has a yearly growth of approx. 5%, mostly within stress prevention and psychosocial rehabilitation.

3.4.3 History of Electronic Care Systems

In a number of projects, telemedicine boomed in Sweden during the 1990s, with applications that included ophthalmology, odontology, transplantation surgery (video-conferences), ENT, dermatology, psychiatry, geriatrics, home care and cross-border projects. The term telemedicine, referring to "medicine at a distance", has been used, and is still heavily in use in Sweden. It stands for a broad interpretation of remote services in healthcare. However, the extensive widening of applications which enter into the domain of public health and cover almost all parts of healthcare services, including fields such as empowerment, prevention, administration, screening, diagnosis, treatment, monitoring, follow-up and rehabilitation, opens possibilities for the use of a broad "umbrella" term. In this regard, "e-health" has come into recent use in Sweden²².

In 2004 a national system for electronic medicine prescriptions were introduced by the Swedish Pharmacy chain, Apoteket.

The electronic health record (EHR) landscape in Sweden is heavily fragmented county councils are responsible for choosing, implementing, and maintaining an EHR system. The 290 municipalities are responsible for EHR systems used in social care. A range of digital solutions have replaced analogue methods in Sweden.

3.4.4 Legal Framework

The National Board of Health and Welfare (Socialstyrelsen) plays a fundamental role as the central government's expert and supervisory authority.

The Swedish Association of Local Authorities and Regions (SALAR) represents the government, professional and employer-related interests of Sweden's 290 municipalities, 21 county councils and four regions.

The Swedish e-health Agency (eHälsomyndigheten) is a new authority responsible for coordinating government e-health initiatives with the main goal of better information-sharing within health and social care using digital tools and sharing information digitally to achieve and maintain a good level of health.

The Medical Responsibility Board (Hälso- och sjukvårdens ansvarsnämnd) is a government agency that investigates possible breaches of standards by healthcare professionals.

Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU – Statens beredning för medicinsk och social utvärdering) seeks to identify the best treatment methods for patients and most effective use of resources.

The Dental and Pharmaceutical Benefits Agency (Tandvårds- och läkemedelsförmånsverket) is a central government agency assigned to determine whether a pharmaceutical product or dental procedure should be subsidised by the state.

The Medical Products Agency (Läkemedelsverket) is the national authority responsible for regulating and monitoring the development, manufacture and marketing of drugs and other medical products. (lakemedelsverket.se). They are responsible for the CE-marking of medical devices.

Swedish Institute for Health Services (SPRI). SPRI was a government agency that provides health authorities in the Swedish county councils with recommendations for healthcare.

Symbiocare – Health by Sweden is a Swedish government and industry initiative founded in 2010. It is a communication platform run by Business Sweden and Swecare Foundation. The purpose is to promote Swedish healthcare and life science internationally and to spur collaboration.

3.4.4.1 National Patient Overview (NPÖ)

National Patient Overview (NPÖ) enables authorised healthcare professionals to obtain, with patient consent, journal information registered with other county councils, municipalities or private healthcare providers.

²² Olsson, S. and Jarlman, O. "A short overview of e-health in Sweden". *International Journal of Circumpolar Health* 63(4), 317-321. Retrieved January 16, 2019 from: <https://doi.org/10.3402/ijch.v63i4.17748>

Inera AB is a limited company, owned by Swedish Association of Local Authorities and Regions (SALAR). Inera coordinates the integration and development of national digital healthcare services that are used by healthcare employees, the general public and decision-makers. Inera is also responsible for the technical infrastructure and IT architecture that are required for the national digital health services.

Two of the most important services provided by Inera is 1177.se and NPÖ (National Patient Overview).

1177.se provides online advisory healthcare information and a new ability ("The Journal") for a citizen to access a consolidated view of their digital medical records.

3.4.4.2 SLL VAL Databases²³

All healthcare providers who have concluded an agreement with Stockholm County Council (SLL) are committed to providing electronic information to SLL. Depending on the activity, the healthcare provider reports care events to different source systems consolidated and exported to the VAL databases. The databases are mainly used by analysts/controllers in SLL's healthcare for analysis/follow-up of medical/financial information of produced care. Due to the level of detail and scope of the content of the data storage, the user should have a good business knowledge in the area to be followed up and a good knowledge of the recommended analytical tools used for the data storage, in order to make a reliable report/analysis. This limits the selection of users who are entitled to "directly" connect to VAL's data storage to about 50 within SLL.

The VAL databases are updated once a month with data from each source system:

When loading individual event care events, the personal identification number is encrypted for a unique ID number for each patient, which means that the patient's identity cannot be disclosed in the VAL. As of 1995, this ID number is unique to the patient over the years and in all CHOOSE databases. This makes it possible to follow an (unidentified) person's healthcare consumption over the years in the different databases. The databases are supplemented with a number of help variables from other systems, such as the code server, and create custom computation variables to facilitate statistical follow-up. The databases are stored as SAS data sets in GUPS (Joint Follow-Up Platform SLL). Access to VAL is done via SAS software or with any software that may constitute ODBC client, such as Access.

3.4.4.3 The National Quality Registries (NQR)

The very first Swedish national quality registry was created in the 1970s, based on a well-established tradition of systematically noting patient-individualised medical interventions and outcomes after treatment. Today there are about 100 registries that receive central funding in Sweden, in areas such as stroke, hip replacement, dementia, diabetes, various forms of cancer and palliative care.

A National Quality Registry contains individualised digital data concerning patient problems, medical interventions, and outcomes after treatment; within all healthcare production. It is annually monitored and approved for financial support by an Executive Committee.

Competence centres for the National Quality Registries have been established. In a competence centre, several registries share the costs for staff and systems that a single registry could not bear, e.g., in technical operations, analytical work, and use of registry data to support clinical quality improvement and helping to make registry data beneficial for different users. Hence, a continued development of the registries can be assured although the system follows a decentralised model, i.e., each registry is governed by a professional collaboration.

3.4.5 Current Situation

Public sector costs for health and medical care, excluding dental, were SEK 65 billion in 2015, one of the larger expenses for the government. Since the turn of the millennium, the cost of Swedish healthcare has increased by average 4.2 per cent per year - 0.9 percentage points more than GDP. 1.1 percentage of this cost increase is in line with annual population growth. The remaining increase, 3.1 percentage, is due to increasing unit costs. If this trend continues it means that a continuously increasing share of public funding will be invested in healthcare.

But it is unlikely that society will sustain long-term cost increases of this level, and already today, demands are made for more efficient healthcare. If nothing is done, there is a significant risk the healthcare system ends up in a negative spiral where outdated systems increase administrative burden on staff and where the working environment is deteriorating, while increasing numbers of older and severely ill Patients need care.

²³ <http://www.gups.sll.se/val/Valhandbok.pdf>

Therefore, prioritised areas should be the introduction of integrated medical records, systems for online consultation and the surveillance of elderly patients and individuals with chronic diseases. Moreover, digital technology for connectivity, automation and advanced data analysis can help to enable a long-term sustainable cost development so that future healthcare needs can be met with existing resources. Digitalisation can also make it possible to adapt healthcare to individual needs and to raise the general medical quality.

There is a number of challenges and opportunities:

- Finding and scheduling physician appointments is perceived as complex and hard
- Rapidly increasing costs for elderly care and home healthcare
- People with chronic diseases have low and intermittent access to specialists
- Limited patient access to and control of digital healthcare information
- Limited sharing of digital health information between new commercial health solutions, healthcare providers and with academic research
- Complex and time-consuming healthcare processes due to limited use of modern digital communication technology. Patients can not directly communicate with healthcare providers using digital tools and for example medical letters of referral, between healthcare providers, is done using regular mail or fax
- Rapidly increase of digital devices and mobile apps for self-measurement of vital values like ECG, blood pressure, pulse, pulmonary function, blood glucose, etc.
- Low use of clinical decisions support tools and untapped potential in automated analysis of large digital data sets.

There are three major trends currently developing in healthcare both in Sweden and globally:

- Techniques for connection over the Internet, to mobile platforms and using sensors can facilitate preventive health work and provide self-care tools, remote monitoring and proactive care of the elderly and chronically ill. They can also streamline healthcare chains through new digital channels for consultation with doctors and other healthcare professionals and by reducing the administrative burden if patients can, for example, take care of their bookings themselves over the internet.
- Automation techniques, such as integrated medical record system between different healthcare providers, can ensure that the right information is available to the correct care provider at the right time. This can help reduce the risk of malpractice and to optimise care processes so that care times are shortened and reloads are avoided, with great cost savings like sequence. Technology for automation can also help challenge and simplify existing ones Care processes and improve the working environment for healthcare professionals so that focus can be put on Patients rather than administration.
- Advanced data analysis with the help of supercomputers include areas such as artificial Intelligence, machine learning and analysis of very large and unstructured data sets. Already today, information about each individual healthcare contact, performer and outcome is documented in different ways in Sweden. At the same time, very large amounts of data are becoming in medicine Research, especially in genetics, available to healthcare practitioners worldwide. Advanced analysis of this information may make it possible to predict disease progression and figure out the best treatment methods for the individual patient. Using the computer capacity, it is possible to build tools for clinical decision support that rest on a huge amount Medical evidence - more than any single doctor could accumulate during a professional life.

New healthcare technology is creating a positive change that will transform healthcare organisations and society. Digital breakthroughs are enabling healthcare enterprises to improve labour productivity, clinical outcomes and human experiences.

This unprecedented era of technology innovation is allowing clinicians and service workers to broadly apply their knowledge, freeing up more face time to spend delivering a human touch. And, as technology gives greater opportunities for self-management, it's empowering people to consume healthcare on their own terms.

Digitisation has great potential to be a transformative force in the Swedish healthcare systems. But in order for it to work we must allow it to penetrate all the health-related parts of our lives. It requires major changes in both organisations, approaches and technology development.

4 Profiling Selected Member States

A summary of the basic nature of the healthcare markets in Slovakia, UK, Belgium, France, and Spain is presented in the following sections.

4.1 Slovakia

Slovakia is with 5.5 million people one of the smaller EU Member States. The country spent 6.9% of its annual GDP on healthcare and reports average life expectancy of its citizens around 76.7 years²⁴.

In the Slovak Republic all workers (45% of the population) are covered by mandatory health insurance financed through employer and employee contributions linked to revenues, while their families and other non-workers are covered via direct payments from the national government who pays premiums to health insurance companies on behalf of the beneficiaries.

A total of three not-for-profit insurers provide basic health coverage for the typical employed adult. The social security funds are the main funder, providing about 60% of total health spending. Insurer can be chosen freely and switched annually. Insurers cannot modulate premiums and are required to offer the same benefit package and the same level of coverage. They can select providers and negotiate contracts with specialists and individual hospitals about the prices, quantity and quality of healthcare services. A healthcare provider may contract with any or all health insurance companies and vice versa. Patients can choose primary care physicians, specialists and hospitals freely. Registration with a primary care physician is compulsory, as is referral to access secondary or specialised care. Private health insurance is practically non-existent.

In 2018 the Slovak government launched its national e-health system for which all GPs were mandated to participate. A main cornerstone of the Slovak e-health initiative is that access to medical records is granted via normal personal ID cards instead of specialised health insurance cards²⁵, similar to the approach taken in Nordic countries such as Sweden and Denmark.

4.2 UK

Healthcare in the United Kingdom (UK) is organised within its four constituent countries, England, Scotland, Wales and Northern Ireland. With a population of 55.6 million England is the major constituent while Scotland, Wales and Northern Ireland have a combined population of roughly 10.5 million people - making the United Kingdom the third largest country in the European Union. The country spent 9.7% of its GDP on healthcare expenditure while maintaining an average life expectancy of 81.0 years²⁶.

The devolved healthcare is organised in four organisations, NHS England, NHS Scotland, NHS Wales and HSC Northern Ireland each operating independently and being responsible to their respective government.

In January 2019 the NHS England revealed its “NHS Long Term Plan” or “NHS 10-Year Plan” outlining the agencies priorities for the upcoming decade. One of the document’s seven chapters is focusing on e-health “Chapter 5: Digitally-Enabled Care Will Go Mainstream Across The NHS”²⁷. The document sets specific milestones for healthcare digitalisation in England reaffirming the organisations commitment to the NHS App and the Longitudinal Health and Care Record Platform (LHCR) linking NHS and local authorities. While currently being rolled out gradually, the NHS App is still on track to fully release across England by 1 July 2019²⁸. It will allow for basic features such as checking symptoms and guides in case of emergency while also offering more advanced aspects such as GP appointments, ordering prescriptions and viewing of GP medical records. In order to allow for these advanced features, the NHS App promises to be fully integrated with the four IT systems currently used by English GPs (EMIS, TPP, Vision and Microtest).

4.3 Belgium

The Belgian healthcare system is mainly organised on two levels, i.e., federal and regional. Since 1980, part of the responsibility for healthcare policy has been devolved from the federal Government to the regional governments. Responsibility for healthcare policy is shared between the federal Government, and the Dutch, French and German speaking community Ministries of Health. Belgium spends around 10.4% of its annual

²⁴ <https://www.oecd.org/els/health-systems/Health-at-a-Glance-2017-Chartset.pdf>

²⁵ <https://spectator.sme.sk/c/20729936/slovakia-launches-online-healthcare.html>

²⁶ <https://www.oecd.org/els/health-systems/Health-at-a-Glance-2017-Chartset.pdf>

²⁷ <https://www.longtermplan.nhs.uk/wp-content/uploads/2019/01/nhs-long-term-plan.pdf>

²⁸ <https://digital.nhs.uk/services/nhs-app>

GDP on healthcare with spending on long-term care being very high, similar to the Scandinavian countries and the Netherlands. Average life expectancy is at 81.1 years while yearly alcohol consumption was recorded as the second highest in the OECD with only Lithuania reporting values above²⁹.

Primary care services are mainly provided by private solo practices, but also by private group practices. The same is the case for outpatient specialist services. Acute hospital care is provided by private not-for-profit hospitals and public hospitals; the ratio of number of beds is approximately 33/33/33% showing a similar fragmentation as Germany and Austria Figure 2.

The federal government is responsible for regulating and financing the compulsory health insurance, for determining accreditation criteria, for financing hospitals and so-called heavy medical care units, for legislation covering different professional qualifications and for registration of pharmaceuticals and their price control. Numerous public authorities are responsible for the funding of healthcare and for overseeing its organisation. The division of responsibilities is mirrored by the fragmented structure of the Belgian State.

In 2019 Belgium will allow for its medical professionals and citizens to share medical information and documents using a secured government platform called EPD (Elektronische Patienten Dossier).

4.4 France

France is the second most populous country in the European Union with a population of 67.2 million. Its citizens enjoy a high average life expectancy at 82.4 year on average³⁰. The country spends a significant share of its annual GDP on health, roughly 11.0%.

France's health system is based on a national social insurance system complemented by elements of tax-based financing (especially the General Social Tax) and complementary voluntary health insurance. The Government decides the methods of financing and sets tariffs. The Ministry of Finance and Ministry of Social Affairs and Employment holds authority over finances, including the financial administration of the French healthcare system.

Early 2016 the French Health Ministry unveiled the 2020 e-health National Strategy, with the intent to boost innovations through the use of big data in health. The initiative is prompted by the advances in the ability to collect massive amounts of health data through connected devices such as phones, watches and apps, which present the opportunity to improve health monitoring, prevention and research. In addition, according to past surveys, a vast majority of French people view e-health initiatives as a promising tool for modernizing their healthcare system, but consider France to be lagging behind in this sector.

The Ministry has announced a €2 billion investment, including €750 million for the development of digital tools. The Ministry will also soon create a new "Strategic Council" to monitor the plan.³¹

4.5 Spain

With a population of roughly 46.7 million (2018) Spain is the fifth largest country within the European Union, bordering Portugal, France and Italy. The country has a similarly high life-expectancy to Italy, which at 83.3 (OECD, 2017) is the second highest in the world behind Japan. Spanish healthcare provision is highly deregulated in the 17 autonomous regions. Only two autonomous cities (Ceuta and Melilla) are administrated at the national level.

In general, the national level Ministry of Health establishes laws that define minimum requirements for healthcare provision, while the inter-territorial council (Consejo Interterritorial Del Siistema Nacional de Salud) is responsible for guaranteeing cohesion between the health systems. Primary care in public health centres is free, but patients pay directly for visits to specialists in private practice. If they are covered by private insurance, they will receive part or full reimbursement, depending on the type of insurance.

A national database (BDPP-SNS) is the foundation of Spain's national e-health governance. Due to its interoperability the national database is accessible for healthcare personal from all Spanish regions and allows them to access information generated anywhere within the Spanish system.

²⁹ <https://www.oecd.org/els/health-systems/Health-at-a-Glance-2017-Chartset.pdf>

³⁰ <https://www.oecd.org/els/health-systems/Health-at-a-Glance-2017-Chartset.pdf>

³¹ <https://www.insidemedicaldevices.com/2016/10/france-boosts-its-e-health-initiatives/>

5 General Conclusions

Concluding from the in-depth and general country profiles we find a diverse European healthcare market as the previous European-level analysis in Section 2 already suggested. Also, for the state of e-health we find a diverse landscape, even between countries that earlier analysis in Section 2.1.3 suggested to be rather similar. All countries analysed share some overall general trends, albeit on different levels and to different extents, regarding system compatibility and interoperability. Also, a move towards centralisation, either of the healthcare sector in general (e.g. Denmark) or of the organisation of e-Health requirements (e.g. Spain, Sweden, and Italy) was found. This also applies to Germany where analysis showed that there is a promising potential of using nationally orchestrated policy to support the deployment of e-health solutions in fields with diverse actors and organisations. However, countries dominated by smaller care providers typically show a higher number of active ICT suppliers and nice markets are more prone to develop.

Moreover, the analysis has shown, that a large, unfilled potential exists in the countries that are moving towards integration of health and social care, since the two types of care are usually provided by a more fragmented landscape of actors than the primary healthcare provisioning. An analysis of the social care landscape illustrates that there exists three different social care categories: Institution, Mixed, and Family.



Figure 14 - Structure of social care providers in the nine countries analysed or profiled

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Appendix A – Acronyms and Abbreviations

Denmark

Acronym/Abbreviation	Original Term	English Translation
EOJ	Elektronisk OmsorgsJournal	Electronic Care Record
EPJ	Elektronisk PatientJournal	Electronic Patient Record
LPS	LægePraksisSystem	Medical Practice System
FMK	Fælles MedicinKort	Common Medicine Card

Germany

Acronym/Abbreviation	Original Term	English Translation
eGK	Elektronische Gesundheitskarte	Electronic healthcare
ePA	Elektronische Patientenakte	Electronic Patient Record
HBA	Heilberufsausweis	Medical Professional ID

Italy

Acronym/Abbreviation	Original Term	English Translation
SSN	Servizio Sanitario Nazionale	National Health Service
LEA	Livelli Essenziali di Assistenza	Catalogue of SSN benefits
NSIS	Nuovo Sistema Informativo Sanitario	New Health Information System

Sweden

Acronym/Abbreviation	Original Term	English Translation
SALAR	Sveriges Kommuner och Landsting	Swedish Association of Local Authorities and Regions
NPÖ	Nationell PatientÖversikt	National Patient Overview
SLL	Stockholms Läns Landsting	Stockholm County Council