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# Mapping out the obstacles of free movement of electronic health records in the EU in the light of single digital market

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KPMG Baltics OÜ

The study was commissioned by the Strategy Unit of the Government Office of Estonia. It is funded in accordance with the investment priority to improve the quality of policy making that is mentioned in section 2.12 Administrative capacity of "Operational Programme for Cohesion Policy Funds 2014-2020". The study was initiated and conducted in cooperation with the Estonian Ministry of Social Affairs.



# 1 Executive summary

The Government Office of Estonia commissioned a study on “Mapping out the obstacles of free movement of electronic health records in the EU in the light of single digital market”. The study was initiated and conducted in cooperation with the Estonian Ministry of Social Affairs.

This report is a summary of a study conducted in Estonian that analyses various obstacles of free movement of data across the EU and in the Member States to suggest recommendations to overcome the obstacles. Five Member States are chosen to have a better understanding of the diversity of eHealth systems being used in the EU. The chosen Member States were Finland, Germany, Poland, Sweden and the United Kingdom (England) (with Estonian eHealth system being used as a point of comparison). Although the systems were differently organised, it is impossible to say whether one was superior to the other. Therefore, the report does not favour a certain systems; instead it tries to give an overview of the different opportunities countries have when implementing a eHealth system.

In this report, the obstacles found have been stated as aspects surrounding eHealth that should be taken into consideration for eHealth systems. Some aspects are critical for eHealth systems (such as patients’ safety). Categorising this aspect as an obstacle could bring confusion. This is done to have a wider understanding of the eHealth landscape. The aspects should be considered when discussing eHealth strategy both at the Member State level and across the EU. Additionally, Maslow’s hierarchy of needs can be applied to the aspects surrounding eHealth. Some aspects are essential for the system to work successfully, hence can be seen as the fundamental needs. These aspects are data protection and trust. The other aspects will build on the fundamental needs by increasing the success rate. <sup>1</sup>

In conclusion, recommendations have been designed to lessen the potential negative effects of the found aspects surrounding eHealth. The recommendations can be implemented at both Member State level and across the EU.

## 2 Introduction

Healthcare is facing considerable changes that are brought on by the ageing population and rising healthcare costs. The traditional healthcare systems are not able to accommodate the needs of the society. Integrating technology by creating eHealth systems can ensure that healthcare systems evolve together with the society.<sup>2</sup> This idea has been acknowledged in the European Union where eHealth has been discussed since 2004.<sup>3</sup> It is an interdisciplinary topic that is covered in various EU strategies and regulations. The key legal documents that regulate health data in the EU are:

- The Charter of Fundamental Rights – regulating the fundamental rights including data and privacy protection
- Data Protection Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data
- Patients' Rights Directive 2011/24/EU on the application of patients' rights in cross-border healthcare
- General Data Protection Regulation 2016/679/EU on the protection of natural persons with regard to the processing of personal data and on the free movement of such data

These key legal documents regulate creation and movement of health data. They make it possible for patients to move their health data freely whilst ensuring that appropriate safety measures are used. This is regulated by the General Data Protection Regulation that states:

*Article 1 (3). The free movement of personal data within the Union shall be neither restricted nor prohibited for reasons connected with the protection of natural persons with regard to the processing of personal data.*

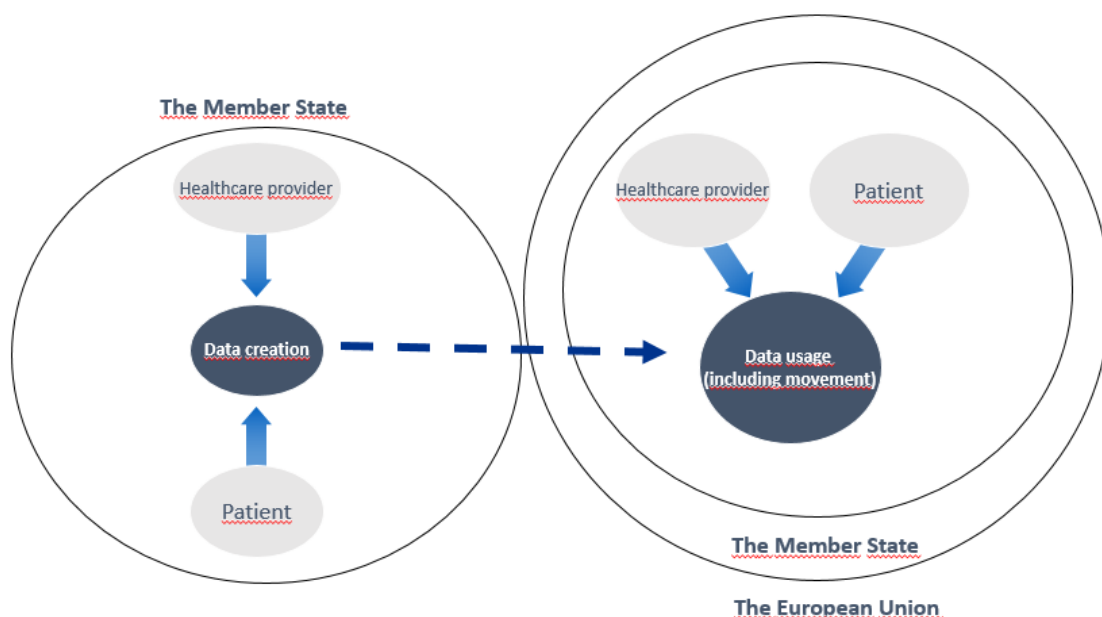
The same conclusion has been further developed by the European Commission in *Building a European Data Economy*.<sup>4</sup>

*„Privacy concerns are legitimate concerns but should not be used by public authorities as a reason to restrict the free flow of data in an unjustified way. As indicated above, the GDPR provides a single set of rules with a high level of protection of personal data for the entire EU. It reinforces consumer confidence in online services, and ensures a uniformed application of the rules in all Member States through stronger national data protection authorities. The GDPR fosters the necessary trust for data processing and is the foundation for the free flow of personal data in the EU. The GDPR bans restrictions on the free movement of personal data within the Union where these are based on reasons connected with the protection of personal data.“*

These ideas should be the cornerstone of every discussion on the movement of health data. It is necessary to keep in mind that protection of personal data is ensured by the regulations in all Member States. Plus, patients are free to use and move their health data throughout the EU with no restrictions. These were the key considerations on which the analysis in this report was based on.

Although regulations ensure high level of protection of health data, there are still privacy concerns across EU.<sup>5</sup> Therefore, to fully understand the eHealth landscape, besides to the legal framework, the public preferences can be evaluated. Public opposition or mistrust can become fatal to any strategy a government would like to implement. Therefore, studying the public preference can be a key to a successful eHealth system. This report considers the attitudes to storing and sharing electronic health records across the EU that are captured in a pan-European survey.<sup>6</sup>

Nevertheless, for there to be movement of data, it needs to be generated first. The data creation takes place in the Member State by the healthcare providers and by the patient's own contributions (such as heart rate monitor watches). Whereas to gain from the benefits that arise from using or moving the data across the EU, both member State and the EU have to contribute.



*Figure 1: Data creation and usage*

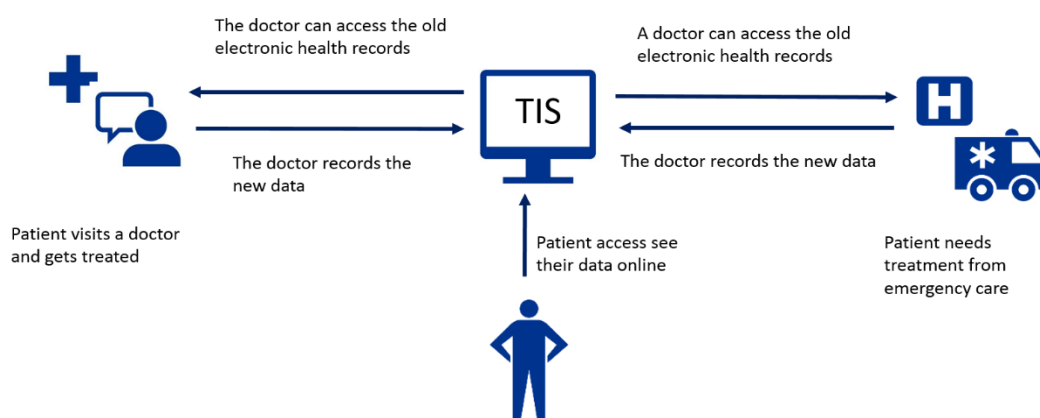
The key outcome of the report is to provide recommendations to facilitate the movement of electronic health records in the EU. In order to arrive at this outcome, a brief analysis of the eHealth systems of five Member States are discussed. The five chosen countries are Finland, Germany, Poland, Sweden and the United Kingdom (England) (with Estonian eHealth systems being used as a point of comparison). In other words, the report generalises the 5 different systems where the data is recorded. In the same section, the public preference are further evaluated. The third section analyses the obstacles of movement of health data. Following with recommendations that could help to relive the potential negative effects of the aspects. The methodology used for the research consisted of secondary research (official documents and academic literature), interviews, online surveys and expert groups; covering various stakeholders in healthcare.

### 3 Overview of the eHealth systems in the selected Member States

This section gives a short overview of the eHealth systems in five Member States with Estonia acting as the point of comparison. This allows the reader to have a better understanding of the vast variety of possible solutions across the EU. The knowledge gained from the selected Member States is then used to analyse the factors affecting the free movement of health data in the EU. The countries discussed in the section are Estonia, Finland, Germany, Poland, Sweden and the United Kingdom (England). All of the discussed countries have already or are in the process of deploying a secure telematics infrastructure in which data can be recorded and moved.

#### 3.1 Estonia

Estonia has a centralised health data repository called TIS that grants access to both patient and certified medical professional. Patient's explicit consent is not needed for recording nor sharing the data. However, as sharing of the data is based on implicit consent, patients have the right to hide the data they wish.<sup>7</sup>



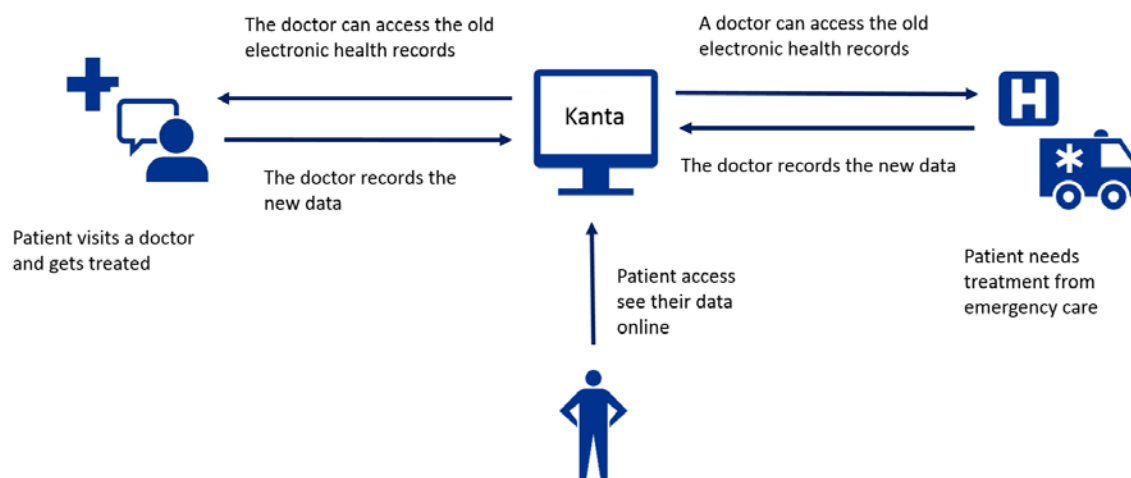
*Figure 2: The flow of electronic health data from patient's viewpoint*

#### 3.2 Finland

According to a survey conducted by OECD in 2013, all of the primary care physicians and hospitals use electronic health records.<sup>8</sup> Therefore, it can be seen as a natural course of action to develop an action plan. The eHealth Action Plan was supposed to come into effect in 2016.<sup>9</sup> The full incorporation of the strategy has been postponed to 2020 as the desired scope of health data has not been covered by the system.<sup>10</sup>

Kanta is a national repository for electronic health records. For a medical professional to get access to health records, the patient needs to give explicit consent. Once the consent is given, it will apply to all of the data in the system. However, patient has the right to limit the data that can be shared.<sup>11</sup>

Secondary use of electronic health data is an important part of national strategy for eHealth. In Finland national plan includes secondary uses such as monitoring public health and healthcare system, facilitating clinical trials, and supporting care.<sup>12</sup> Additionally, health data is used for scientific research, statistics and epidemiology.<sup>13</sup>



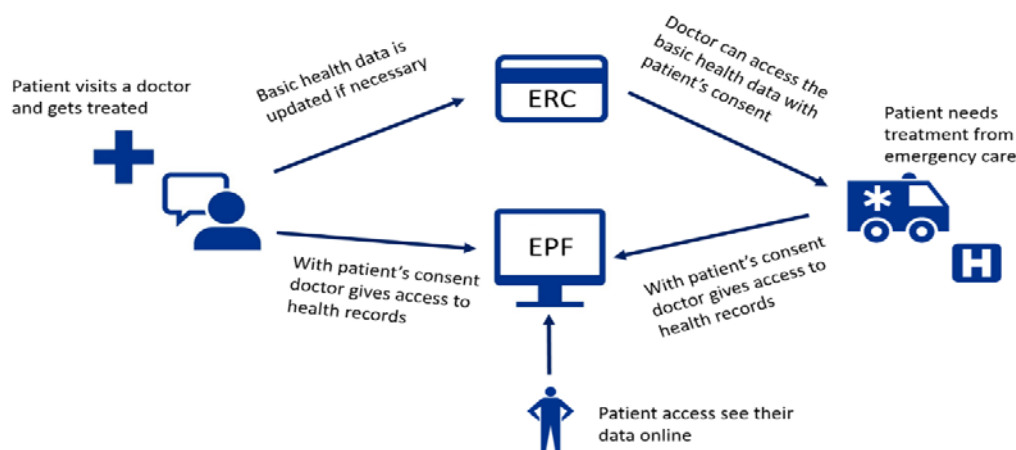
*Figure 3: The flow of electronic health data from patient's viewpoint*

### 3.3 Germany

Germany has introduced an E-Health Act end of 2015.<sup>14</sup> The law facilitates the launch of nation-wide telematics infrastructure in connection with the Electronic Health Card. Telematics infrastructure allows to share data securely between healthcare providers whilst the card enables the patients to move freely with their health data. The card holds administrative data and basic health data (such as emergency data and medication). However, every patient is free to decide, whether he or she wants to store health data on the card. If he wants to do so, health data is recorded on the card only if the patient has given an explicit consent. The patient can also decide which health professionals are entitled to access these data. Additionally, patient's consent is required every time a health professional wants to access the data on the card (except of Emergency data if prior consent was given). The health professional need to use his or her Electronic Health Professional Card as well (2-Card-Identification).

As of 2019, patients should be able to access their health data also online and mobile through Electronic Patient Folder. The Folder can be a filled up with personally collected data and/or with a copy of the Electronic Patient Records, which are for professional usage only and only accessible with the mentioned two Cards. Patient can request access to their health data from different medical facilities though their data will not be stored centrally. Due to historical and cultural context, secondary use of health data without the patient's explicit consent is seen as a potential interference to individual freedom.<sup>15</sup> Therefore, a patient's medical data on the EHR can only be used for his medical care. This is regulated by law.<sup>16</sup>





**Figure 4:** The flow of electronic health data from patient's viewpoint

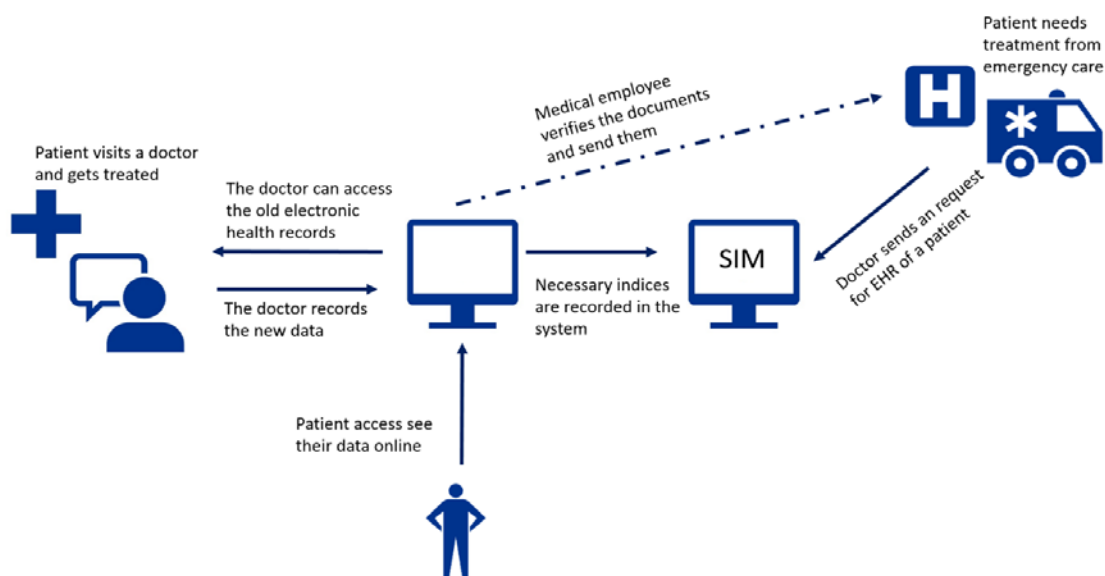
Note: The diagram represents the eHealth system after the eHealth Law comes into effect.

### 3.4 Poland

Poland is implementing an eHealth strategy that was presented in the Act of Information System in Healthcare. Starting from 2018, the act obligates the medical facilities to record patients health records electronically and grant patients' direct online access to their records.<sup>17</sup> Online access is granted by the healthcare provider through their information system. Nevertheless, the adoption of the electronic health records has been slow, mainly being used by medium and large private healthcare providers.<sup>18</sup>

In order to share health data a national platform, SIM, is created. Instead of recording health records, SIM has indices that allow the identification of the patient and the hospital with the health records. Therefore, if an emergency care or another healthcare provider wants to access patient's health records, it needs to send a request to SIM. This will then set off a chain of events that will lead to the health records to be sent to them. Patient consent is not required for this.<sup>19</sup>

Poland has a list of secondary users to whom health records are available.<sup>20</sup> Additionally, the data can be used for scientific research and statistics.



**Figure 5:** The flow of electronic health data from patient's viewpoint

Note: The diagram represents the eHealth system after the Act of Information System in Healthcare comes into effect.

### 3.5 Sweden

Sweden has a national platform to share data between medical professionals, NPÖ. It is an opt-out system, meaning that if patient do not wish to join they will need to notify the appropriate authorities. However, if a patient joins NPÖ, with their consent some of their medical data can be recorded on the platform. Patient's consent is also required when a medical professional wants to access NPÖ.<sup>21</sup>

By 2012, all of the healthcare providers in Sweden had implemented electronic health care records.<sup>22</sup> Nonetheless, patients did not always have the opportunity to access their health records online. According to the latest information this has changed, with 17 county councils already allowing patients to access their data online and four in the midst of planning to do the same.<sup>23</sup> Patient's will be able to access their electronic health records through a national portal, My Healthcare contact. Patient's consent is required to record the data on the portal.<sup>24</sup>

In Sweden, secondary use of data is not included in the national strategy. Still, electronic health records are regularly analysed for wide range of uses, such as monitoring public health and healthcare performance.<sup>25</sup>

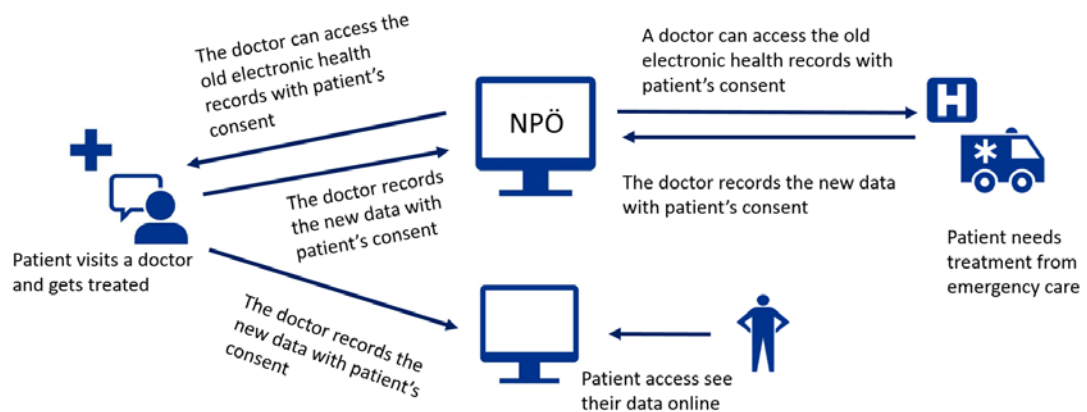


Figure 6: The flow of electronic health data from patient's viewpoint

### 3.6 The United Kingdom

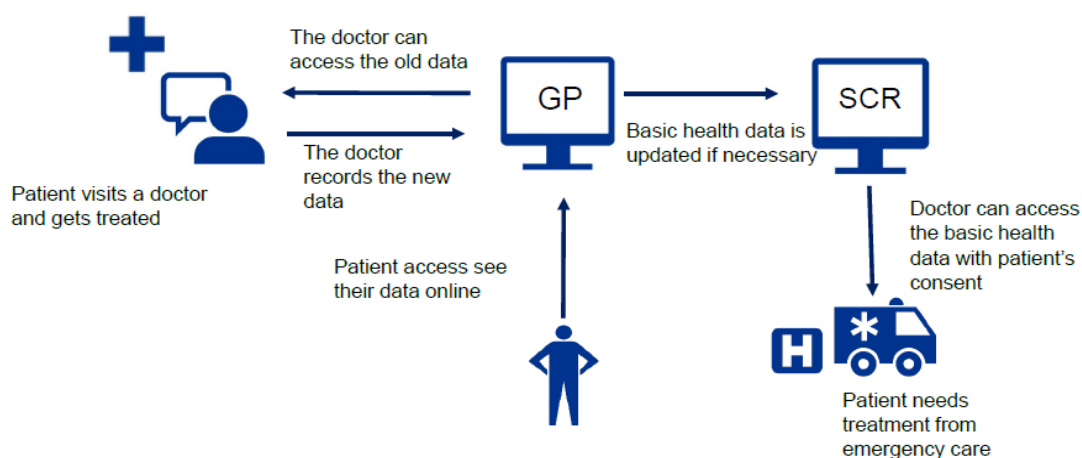
The United Kingdom consist of four countries: England, Scotland, Wales and Northern Ireland. All of the countries have separate national healthcare organisations (NHS) that governs the respective area.<sup>26</sup> The report concentrates on the biggest one, which is NHS (England). When it comes to national IT strategies, NHS has experienced some failures.<sup>27</sup> Learning form these projects, they have taken a new goal of paperless NHS by 2020.<sup>28</sup>

In England, patients are granted online access through the IT system of their general practitioner (GP). By 2015, over 97% of patients in England had the opportunity to access their electronic health records online.<sup>29</sup> However, during research and interviews, it became evident that people were not aware of this opportunity. One of the reasons could be that patient need to request it from their GP to gain access. Patient's explicit consent is not required for recording the data in the system.<sup>30</sup>

Additionally, GPs need to update the basic health data for the national Summary Care Records (SCR), either automatically or manually.<sup>31</sup> The system is created to facilitate sharing of basic data in the case of emergency or out-of-hour care. Patients have the opportunity to opt-out from the creation by filling in an appropriate form. Still, patient's consent is necessary every time a medical professional would like to access the health data.<sup>32</sup>



All of the secondary use of data is governed by NHS Digital that has the right to decide what health data would be necessary to collect and use. There are wide range of secondary uses that the data could be analysed for including scientific research, policy making, and healthcare performance monitoring.

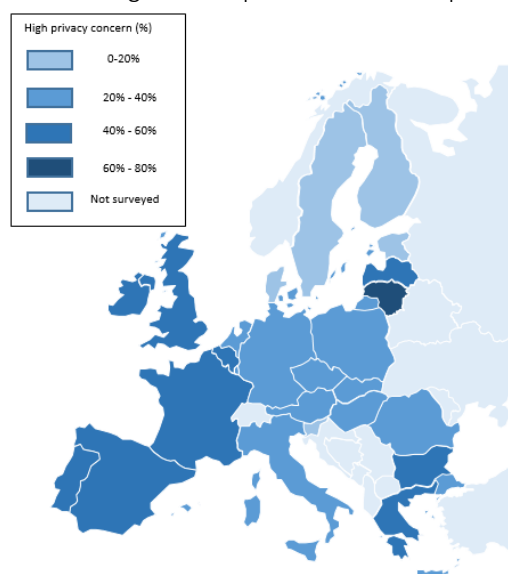


*Figure 7: The flow of electronic health data from patient's viewpoint*

### 3.7 Public preference

Public preference can be an important aspect when looking at the adoption of electronic health records in Member States. A pan-European survey captures the attitudes to storing and sharing electronic health records.<sup>33</sup> For the government to have a better understanding of all aspects of eHealth public preference should be looked at.

Overall, the respondents agreed that storing electronic health data is beneficial for enhancing quality of the treatment, preventing health epidemics, and reducing delays, with 75.5%, 63.9%, and 58.9% respectively.<sup>34</sup> However, there were still concerns over appropriate methods taken into place to protect the data, with 38.4% of respondents thinking that healthcare providers provide effective data security successfully. The survey also measured the levels of privacy concerns in Member States (Figure 8<sup>35</sup>). From the chosen Member States, Estonia, Sweden and Finland had low levels of high concern response. The high concern responses from Germany and Poland were in the range of 20% - 40%. Lastly, UK had the highest level of high concern responses within the chosen Member State, falling in the range of 40% – 60%.<sup>36</sup>



**Figure 8 High privacy concern**

Additionally, there was a higher preference of storing the data, specifically with granting access to all health professionals. This suggests that respondents recognise the individual level benefits that can be achieved from using electronic health records. Nevertheless, there is less preference to share the health data with wider audience such as fire personnel and academic researchers even if the data is anonymised. This clearly shows that there is lower preference for gaining population level benefits.<sup>37</sup>

## 4 Free movement of health data

It is evident that some health data movement can be detected across the EU, although the amount is still minimal. The EU Patients' Rights Directive states that patients have the right to move across borders for healthcare. As patients cross borders to receive treatment, the health data moves with them. Understanding the current situation is essential for the analysis of the aspects.

From the interviews conducted, it was evident that there are many formats in which the data moves; from fax to email and dropbox, with paper being the most common one. One of the interviewees pointed out that many healthcare facilities do not accept health data electronically (on CDs, through email or on memory stick). The reason for this was that they are not able to open the files due to the strict security settings on their in-house systems.

Additionally, it was mentioned during the interviews that it is mostly the patient's duty to collect and translate the data, as well as ensuring the data is in the format acceptable to the healthcare provider. Although, patients receive support from patient associations and specialised organisations, it is still a time-consuming task.

From the previous section, it is evident that some data is or will be generated through the eHealth systems in the Member States. Nevertheless, health data is like a natural resource. In order to gain from it, it should be used. According to interviews, at the moment, most of the patient movement is to use it for planned medical treatment, where:

- Patient moves from one healthcare provider to another in the respective country
- Patient moves from one healthcare provider to another that resides in a different country
- Doctors consult each other or ask for second opinion in the respective country and across the border

It was seen common to involve specialist from other countries, either using a foreign lab for testing or exploiting foreign experts. It was usually done with patient's explicit consent.

An important factor that should be considered with sharing the data across borders is the guarantee that the data is valid. Can the health data from another country be trusted? During interviews many different opinions arose. However, mostly people trusted the government to ensure that the doctors are certified. Also, there is always an chance to redo the tests if there are any doubts in the validity.

### 4.1 The aspects surrounding eHealth

The aspects have not been portrayed as obstacles, but instead potential concerns when implementing an eHealth strategy. The aspects have been categorised into seven different features that should be included to create a successful eHealth system which will also allow the movement of health data. The features are interoperability, safe and trustworthy system, user-friendly and patient-centric system, inclusive system, cooperation and the business case. This section gives the reader a brief overview of the potential aspects; the full list can be found in Appendix 1.

Firstly, interoperability was looked at the widest angle; considering both: the ability for machines to understand each other and humans. It consists of aspects, such as differences in clinical practices, that

could make it hard for healthcare provider to understand the health record that has been generated somewhere else. Interoperable systems can lower the need to duplicate analysis if they are able to understand and trust the data coming from a different healthcare provider.

Safe and trustworthy system is one of the basic needs as described by the Maslow Hierarchy of needs.<sup>38</sup> In this report, safe system is considered to be a system that is able to protect patients' data (hence their privacy), and is considered to be safe by the public. If the eHealth systems is protected and the safeguards are effective, patients will trust the system more. Therefore, they are more inclined to use it. However, if the trust is broken, for example by a breach, it could cause a wide public opposition.

Patient-centric system can be seen as one the main goal for deploying an eHealth system. This would make the patients owners of their own health data; giving them more individual freedom. As patients have more opportunities to learn about their conditions and treatment, the relationship between the doctor and patient are changing. Traditional healthcare is evolving; but much like any change, it has certain aspects that need to be considered such as opposition to change. Additionally, patient-centric systems is further enhanced with ensuring user-friendliness. With user-friendly system, it is important to acknowledge all the different stakeholders for eHealth, from doctor and a patient to a policy maker and scientists. All of them have different expectations for the system. People might be hesitant to use the system if they do not see the fit between their expectations and what the system offers.

Inclusive system is necessary to increase the possibility of developing a successful eHealth system. Stakeholders should be informed about the system and potential benefits. Also, for them to accept the system fully, they need to have extensive knowledge on how it works. Otherwise they are unable to use it.

Cooperation between different stakeholders and Member States is important to improve the adoption and growth of eHealth systems across the EU. Healthcare has a large number of stakeholders that all have different interests. Therefore, it is difficult to find a solutions that would please everyone. This is evident from the research and interviews; with the most used example being standards.

The business case brings the value-added. During the interviews, it was found that just having an eHealth system should not be goal on its own. This could lead to inefficient and irrelevant system that is not used. There should be some kind of purpose that, if fulfilled, would benefit the stakeholders.

## 5 Recommendations

Technology is a tool to create a successful eHealth system that solves the issues of today's and future's society. Integrating information technology into healthcare can be seen as an essential element to ensure sustainable healthcare. With a goal to offer high quality healthcare to all EU citizens whilst optimising the cost.<sup>39</sup> Nevertheless, it is not enough to solely implement an eHealth system. Simply storing electronic health records does not guarantee success. In order to increase the rate of success, eHealth systems should serve a specific purpose or solve a particular issue. Limiting the system with one or few purposes means that the design of the system is more focused. This could be the key to solving the issues today's society is facing.

The following recommendations are designed based on the aspects mentioned in the last section. The intended goal of the recommendations is to increase the possibility of free movement of health data on both levels. As it was discussed in the introduction (Figure 1), both Member State and the EU have the potential to facilitate movement of health data across the EU. Therefore, the recommendations have been categorised according to the level the recommendations could be accomplished: at a national level, at the EU level or both.

### 5.1 National level

Healthcare falls under the jurisdiction of the Member States, meaning that they have the responsibility of implementing the eHealth systems and the respective laws. The following recommendations are designed to improve eHealth systems at the national level.

Recommendations at national level	
<b>Recommendation 1</b>	<b>Allow the patient to move their data to research facilities and to receive results from the studies conducted</b>
	<p>Secondary use of health data by research facilities can have a wide range of benefits, from increased quality to healthcare services to new clinical practises. As it was said in section 3.7, patients prefer to use the health data for their personal good, such as treatment. They are not inclined to share their data to research facilities. Nevertheless, there should be an opportunity for people who wish to actively contribute to research with their health data. An opportunity should be created that allows patients to move their data to the research facilities and receive data about the studies.</p> <p>Additionally, people prefer to have individual gain from the research over population level benefits.<sup>40</sup> Thus, in order to promote secondary use of health data for research, patients should be able to receive some individual benefit from the conducted studies. An example of this is Estonian Genome Centre (The Estonian Biobank), where participants took active part in recording large amount of their personal data, medical history and current health status for the research. For joining the Estonian Biobank, participants receive their gene map.<sup>41</sup></p>

<b>Recommendation 2</b>	<b>Create an opportunity that allows patients to move their own health data from/to healthcare services</b>
	<p>A large amount of health data is being recorded and used outside of healthcare services. Health data that could be relevant to health professionals is gained through health diary apps, heart rate monitor watches or exercise stress test done outside of direct healthcare service (for example in gyms). Yet patients do not have the capability to directly move the data from/to facilities outside of healthcare (including apps or exercise stress tests). With patients consent, the data should be able to move securely between the various sources of data outside of healthcare and the eHealth systems. This will allow patients to become managers of their own health data.</p>
<b>Recommendation 3</b>	<b>Create patient-centric systems that respects different perceptions on eHealth</b> <p>As it is mentioned in the eHealth Action Plan 2012-2020<sup>42</sup>, the eHealth systems should be focused on integrating emerging patient-centric technologies. This idea should be further expanded by integrating technologies and solutions that allow individual approach. For example, a healthcare application that allows pharmacist access to health data, improving the pharmacy services.<sup>43</sup> People who want to share their health data with the pharmacists can use the service, whilst people who do not wish to share their data are not obliged to use the service (meaning their data will not be shared with the pharmacists). This will offer patients more individual freedom in healthcare.</p>
<b>Recommendation 4</b>	<b>Disclose synopsis of the security guards in place to protect the health data</b> <p>As it is seen in section 3.7, across the EU there are privacy concerns when it comes to the health data. These concerns can be alleviated through disclosing the methods used to ensure patients privacy. To further lessen the concerns, the Data Protection Audit should be disclosed as well. Nevertheless, it is important to ensure that the disclosure does not danger the high level of privacy that is required by the General Data Protection Regulation 2016/679/EU.</p>
<b>Recommendation 5</b>	<b>Include stakeholders in the whole life cycle of the systems</b> <p>In order to create a patient-centric system that is representative, various stakeholder should be involved into the developing stage with the concertation being on the end-users of the system.</p> <p>Formal structure for the involvement could be considered to ensure that all of the relevant stakeholders (such as patients, doctors, the government) are included throughout the life cycle; from deciding on the standards to designing new services. Additionally, to ensure that the system is user-friendly, relevant and necessary; the stakeholders must be involved from the stage of idea generation. The actual needs of the stakeholders should be considered when developing the systems. The common needs should be identified and solved; specifically concentrating on solutions that can have a large impact, but are easy to implement. Specific focus should be on the end-users to create a system that is user-friendly (discussed more in Recommendation 9), but also can increase the adoption rate.</p>

	Furthermore, Member States have defined differently the healthcare specialist that are allowed access to eHealth systems. However, all specialists (in accordance to the responsibility) involved in providing healthcare services need some amount of health data.
<b>Recommendation 6</b>	<p><b>Improve digital literacy through incorporating technology even further into education</b></p> <p>Low levels of digital literacy have a negative effect on the adoption of eHealth system. If people do not know how to use a new eHealth solution, they won't use it. One of the ways to improve digital literacy is to incorporate IT into education. These skills should be learnt starting from the basic education. This would ensure that the skills match the latest technology, and that people are aware of the IT solutions used in their specific area of work. This will not only increase digital literacy, but also could decrease the opposition to new technology. People might be wary of technology or information system, they are not aware of. Whenever a new eHealth solution is implemented, the staff should be trained accordingly. So they could feel more confident when moving forwards with the changes IT solutions bring.</p>
<b>Recommendation 7</b>	<p><b>Comply with the eHealth European Interoperability Framework for deployment of eHealth systems.</b></p> <p>eHealth European Interoperability Framework is an operational tool that can be used as a reference guide for the deployment of eHealth systems by the Member States. The framework promotes cross-border interoperability of eHealth systems through contributing to the convergence of the standards and technical specifications used across the EU. In order to facilitate the free movement of health data, Member States should leverage the eHealth European Interoperability Framework whilst designing and implementing their eHealth systems.</p>
<b>Recommendation 8</b>	<p><b>Reconsider health insurance policies and legal acts to also include telemedicine</b></p> <p>Electronic health records enable the growth of telemedicine that can decrease the inequality of healthcare through allowing physicians to expand their reach beyond their local office. Yet, telemedicine is not always covered by the health insurance. This can hinder the growth of telemedicine.</p> <p>In addition, the current payment systems could favour face-to-face consultation. It can be an obstacle to implementing technology in healthcare. For example, although the doctor is able to give the same quality help via communication software (such as Skype or email), patients need to consult their doctor face-to-face. This could be because the doctor is not being paid for consulting the patients via these kinds of software, therefore they will be more willing to have the consultation. This obstacle can be overcome by revising the legal system surrounding telemedicine to include the technological solutions that are being used.</p>



<b>Recommendation 9</b>	<b>Create eHealth system with one of the main focus being on user-friendliness</b>  User-friendliness should be one of the priorities whilst designing the system, if the aim is to develop a successful eHealth solution. If a system is difficult to use, it is harder to see the benefit of it. Confusing and challenging system might also negatively affect the public opinion of eHealth, as people are not able to use it to its full capacity. Additionally, in order to create a truly user-friendly system, people with special needs, such as visual impairment, should also have the opportunity to easily access to the system. The eHealth systems should be audited regarding their user-friendliness, to ensure that all the stakeholders have appropriate level of access to the system.
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## 5.2 The EU level

The EU unites all of the Member States under a common roof. Therefore, the following recommendations have a broader impact that could promote eHealth systems and improve cross-border movement of health data.

Recommendations at the EU level	
<b>Recommendation 10</b>	<b>Focus on the cooperation between countries with similar digital maturity and the willingness to collaborate</b>  In order to find the best synergies, the cooperation between Member States should focus on countries with similar digital maturity. This could increase the success rate of implementing such innovations. Furthermore, the successful examples are inspiring to other countries. Thus, they could be scaled across the EU.
<b>Recommendation 11</b>	<b>Conduct research that analyses the sources of privacy concerns</b>  As it is mentioned in section 3.7, patients across the EU to different extent have privacy concerns when it comes to health data. However, people are posting personal data (including health data) on social media, which is not a secure platform. <sup>44</sup> A study should be conducted that analyses the differences in people's views when posting their personal data in social media compared to recording data in national systems. This study could help to understand the distrust patients might have against the national systems. Hence appropriate measures can be taken to alleviate the distrust.
<b>Recommendation 12</b>	<b>Credit and share best practices across the eHealth landscape</b>  Through the interviews conducted for this study, it was found that some patients did not feel the need for innovative eHealth solutions that were offered in other countries, as they were not aware of the solution nor the benefits. If people are not aware of the solutions, there is no demand. Promotional activities should be used to create a pull strategy where end users (patients, doctors) are actively seeking innovative solutions.  This is not true only for citizens, but also governments. There have been projects involving successful implementation of eHealth systems in the EU and

	<p>beyond. These examples should be shared not only for motivational purposes but also so that Member States could learn from them. An example of a network that shares best practise in the EU is European Innovation Partnership on Active and Healthy Ageing. The partnership has created an opportunity for reference sites to share positive examples.<sup>45</sup></p> <p>Moreover, providing cost-efficient and high quality social care and healthcare services is becoming more difficult. Using IT systems (for example integrating eSocial and eHealth) could help to tackle with these issues.<sup>46</sup> The systems that are designed based on the needs of the people that use social care and healthcare services create more patient-centric eHealth landscape. The successful systems should be credited and shared across the EU.</p>
<b>Recommendation 13</b>	<p><b>Incorporate the eHealth European Interoperability Framework as one of the eligibility criteria for projects financed by the EU</b></p> <p>In order to promote cross-border interoperability, when applicable, eHealth European Interoperability Framework should be one of the criteria that is considered when financing a new eHealth project. In the future the Semantic Interoperability Strategy should be added as one of the criteria. (Recommendation 14)</p>

### 5.3 Both (at the national and EU level)

Both Member States and the EU can play a big role in the successful adoption of eHealth systems. For the following recommendations both the Member States and the EU can play a role in facilitating the movement of health data across the EU.

Recommendations that can be applied at both (national and the EU level)	
<b>Recommendation 14</b>	<p><b>Further develop the eHealth European Interoperability Framework</b></p> <p>Although there is evidence that Member States (eg. Germany, Sweden) base their standards on the European standards<sup>47</sup>, they do not incorporate it fully.<sup>48</sup> Hence, there are differences between the Member States in the standards that they use. In order to facilitate interoperability, the aspects from the framework that are not incorporated should be recognised and discussed. Together with the Member States, the framework should be developed further to ensure common practices.</p> <p>Furthermore, semantic interoperability has been a subject to different projects. The examples of the projects include Assess CT that evaluating SNOMED CT for eHealth deployment in the EU.<sup>49</sup> Another example is the <i>SemanticHealthNet</i> project that generalise the best practises to facilitate semantic interoperability.<sup>50</sup> The knowledge from the projects and the EU Semantic Interoperability Catalogue could be used to develop Semantic Interoperability Strategy in the EU.<sup>51</sup> The strategy together with the European Interoperability Framework promote cross-border interoperability.</p>

<b>Recommendation 15</b>	<p><b>Raise awareness as a part of the process for implementing eHealth solutions</b></p> <p>Every time a new eHealth solution or service is introduced, there should be promotional activities that introduces the new solution and its benefits. This will help to lessen the opposition to change that could potentially restricts the usage. More importantly, it will increase the number of people that are aware of the eHealth systems that are offered in their country. If people do not know that they are able to access their health data online, they will not do so. Therefore, it is important to inform people of the opportunities they have.</p> <p>Promotional activities should also be used to familiarise people with secondary uses of health data, especially when it comes to science and data analytics. People can feel distant from these subjects. Additionally, as mentioned in the section 3.7, the public tends to be unaware of the opportunities scientific research and data analytics could offer to them personally (such as improving the quality of healthcare services). If people do not trust the technology or methods, they will be reluctant to be involved in this kind of research. Thus, it is important for people to understand the added value scientific studies can bring to them personally.</p>
<b>Recommendation 16</b>	<p><b>Create a summary of the legal framework that is easy to comprehend</b></p> <p>Patients are not always aware of their rights when it comes to their health data. This problem is not only limited to patients, also healthcare providers, entrepreneurs or policy makers may be misinformed about the patients' rights. This can lead to low usage of health data as people are concerned of mishandling the sensitive data. This is partly as there are a vast number of legal documents that can be vague and difficult to understand. Therefore, it is important to create summaries of the most important legal documents that could be understood by all of the stakeholders.</p>
<b>Recommendation 17</b>	<p><b>Use the data that has been generated</b></p> <p>Secondary use of data can be extremely valuable for the whole society. It can serve wide range of purposes from decision support for doctors to improving transparency of healthcare systems. The regions, where secondary use of health data has not been restricted by law, should realise the benefits it offers. These countries should also advocate their positive experiences. This in turn can act as a motivation for the other areas, to use their health data in innovative ways.</p>

# Appendix 1

## The aspects surrounding eHealth

This list is supposed to give the reader an extensive view of the potential factors that could affect health data movement.

### Interoperability

**Certified doctors.** There is no unified register of doctors that extend across the EU. Therefore, there may be issues to guarantee that the health data is validated by a certified doctor.

**Complex world of standards, code and terminology** can hinder interoperability across the EU. This can include medical terminology but also IT formats that are unable to communicate to each other.

**Digital maturity.** Healthcare professionals are more positive towards eHealth systems when they have had the experience of using information technology in their line of work before.<sup>52</sup>

**Differences in clinical practices** may mean that there are variety of ways across the EU of recording the data or treating a patient.

**Differences in electronic identification** will make it harder to identify patients travelling across the EU, thus being potential hindering factor for free movement of data.

**Differences in the definition of healthcare** may hinder interoperability due to the differences that it brings to the legal system.

**Interoperability** is a considerable factor that limits the free movement of data across the EU.<sup>53</sup>

**Lack of machine readable data** restricts the potential usage of health data, thus limiting potential value to be gained from them.

**Medical devices** have built in standards that may be difficult to incorporate into the information system.

**Probable diagnosis.** Whether probable diagnosis should be accessible to patients remained a debatable issue in the interviews.

**There cannot be free data movement unless the data is generated.** There are be numerous reasons why the data not being recorded electronically. Firstly, it could be that healthcare professionals do not enter the data because they are not motivated to do so or are unaware how to do it. Second reason could be opt-in systems that requires patient's consent.

**Validated and complete data.** There were concerns over the quality and the completeness of that data that is entered electronically. Interviews revealed instances of data going missing from the eHealth systems.

## Safe and trustworthy system

**Confidentiality** is usually build into the system with restrictions on the access to the electronical health records. Nevertheless, this may exclude medical professionals such as physiotherapists.

**Increase in cybercrime**, even if it is perceived, will hinder the facilitation of eHealth systems.<sup>54</sup>

**Over regulation** hinders innovation and the growth of the eHealth market.

**Patient's safety** can be improved through medical professionals (such as pharmacist) being able to access patient's complete health records.

**Patient's viewpoint on the use of data.** Patients agree it is beneficial to store health records for improving healthcare services. Whilst, they were more negatively geared towards using anonymous data for scientific research.<sup>55</sup>

**Privacy concerns.** Privacy concern is especially prevalent with secondary use of the health data. This can be linked with the rise of big data that makes it easier to identify a person from sets of anonymous data.<sup>56</sup>

**Safety of the information systems**, also perceived safety can hinder sharing of health data. If patients are worried about their information leaking into the public due to the poor design of the systems, they will oppose on sharing data.

**The ghost of Personal Data Protection Act.** Different stakeholders have concerns about high level of regulations that govern personal data protection, although they were mostly groundless. Many interviewees believed that EU regulations prohibit transfer of health data even when patient's consent is obtained.

## User-friendly and Patient-centric system

**Accessibility of electronic health records (for users with visual impairment).** If the interface does not accommodate to the people with visual impairment, it may exclude them from the system.

**Disruptions in the workflow of healthcare professionals** can occur with the integration of information systems.<sup>57</sup>

**Information asymmetry.** During interviews it was expressed that medical professionals may be against electronic health records as it facilitates googling amongst patient, which leads to reductions in information asymmetry. Nevertheless, there are healthcare professionals that see this more of an inconvenience rather than a benefit.

**One solution for all.** An interviewee suggested that eHealth system should consider the different attitudes towards electronic health records. This can be done by building a consent based system through which a patient can express their wishes.

**Patient as the owner of their data.** Although different sources agree on this statement, the actual ownership of data is expressed by the different rights patients are given. For example in many countries, patients are not allowed to enter nor delete any data. Thus, it raises a question on the extent of the ownership.

**Patient's right to delete data** is handled differently in Member States. In Finland a patient is able to hide data whilst in Germany patients have the right to delete the data.

**Patient's right to high quality healthcare,** which is facilitated by sharing electronic health records.

**User-friendliness.** It was apparent from the interviews that poorly designed interfaces will lead to slower adoption of such systems. Plus, interfaces that are difficult to use have been associated with medication errors.<sup>58</sup>

## Inclusive system

**Education.** Healthcare professionals do not know how to use the information systems as they are never trained to do so.

**Effective cooperation and communication with stakeholders** can lead to higher adoption rate. It is important to involve all the stakeholders in to the design of the eHealth information systems to ensure that the needs of all of the stakeholders have been taken into account.<sup>59</sup>

**Lack of digital literacy.** There are parts of the population that are being excluded from the possible benefits of electronic services due to the lack of digital literacy. The digital divide is further enhanced with the shortage of employees with required digital skills across the EU.<sup>60</sup>

**Patients, citizens and healthcare professionals are not aware of the eHealth systems in place.**

**Opposition to change.** Integrating eHealth does not just require adapting to new technology but also change in workflow and people's attitude towards healthcare.

## Cooperation

**Cooperation and decision making at the EU level.** The numerous differences between the Member States hinder creation of a system at the EU level.

**Complex legal systems surrounding health data** can make it difficult to integrate eHealth systems.

**Differences in the documentations and the reality** portrays a false image of the possibilities for interoperability.



**Diversity of digital markets across the EU.** It is difficult to have a single digital market with vast differences in the development of digital markets across EU.

**Historical and cultural context** are different in the Member States. This can lead to differences in legal and information systems due to the overarching attitudes towards the issues surrounding electronic health records.

**Lack of clarity in the legal system surrounding mHealth** hinders the adoption of these applications.

**Lack of investments made into telematics infrastructure** limits the adoption rate.

**Legacy systems.** Healthcare facilities use information systems and equipment that are outdated.

**Legal systems are unclear and fragmented (e.g. there are no reimbursements for using telemedicine).** This limits patient movement across the EU.

**Member States are responsible for their own healthcare policies.** EU does not have exclusive jurisdiction over Member States healthcare policies, thus there is only so much that can be done at the EU level.

**Organisational boundaries** are becoming blurred with the integration of information systems. Thus it can be unclear which organisation should be responsible for providing respective eHealth services.<sup>61</sup>

**Political priority** could be a hindering factor of implementation of eHealth strategies.

**The government/EU needs to provide the necessary infrastructure** to facilitate implementation of electronic health records.

**The lost opportunity for tackling societal problems** such as ageing population, increasing healthcare expenditure and healthcare inequality.

**Whose interest prevail?** There is a wide range of stakeholders whose interest may be in conflict with each other. The design of the legal system will probably prefer one stakeholder over another with setting certain jurisdictions and rights.<sup>62</sup> This is evident from different regulations surrounding secondary use. In Estonia, it can be said that public interest prevails with health data being used for statistics without patient's explicit consent. Whilst in Germany, secondary use without patient's consent is not allowed, thus it could be said that individual interest dominates.

## The business case

**High investment cost** can be demotivating.

**Lack of innovation and R&D.** There is unused potential of innovative firms as small and medium sized firms are not able to voice their new ideas in the complex legal systems.

**The business case of the eHealth systems.** From a cost-benefit viewpoint, it was seen unreasonable to share all health data across EU. Thus, it was deemed to be important to concentrate on certain areas that have higher potential value.

**The financial gains from implementing eHealth systems are unclear.**<sup>63</sup>

**(Un)clear opportunities for private companies** bring high uncertainty for private companies, which discourages them from investing in developing new services in the eHealth market. The interviews revealed that the uncertainty was caused by changes in regulations and the services that are provided by the government.

**Variety in the demand for eHealth applications/services** leads to different expectations of the services provided. This can be amplify various stages of implementation across the EU.

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