Nictiz

Why Europe?

The importance of a joint European approach to information exchange in healthcare

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How relevant is a joint European approach to information exchange in healthcare? This paper describes why the Netherlands is working together with other countries in Europe, and how we are contributing to speeding up developments in the area of healthcare information exchange.

Looking at other countries around us, we see that the healthcare sectors in all these countries are faced with similar challenges, and are also thinking along the same lines for possible solutions. There is a growing realisation that international collaboration with regard to interoperability will benefit us all. By jointly identifying processes and reusable healthcare data, organising work internationally and sharing tasks, matters can be scaled up more quickly. Closer collaboration in the areas of standardisation and exchangeability of healthcare information offers new opportunities for interoperable systems, networked care and healthcare innovation. Based on mutual agreements, we can develop an ecosystem that will be to everyone's advantage.

This collaboration has been going on for years already, and is becoming increasingly important. Following the EU interoperability model (ReEIF), this paper outlines this international collaboration, providing examples per level. On the Legal and regulatory level, European legislation protects every EU country in terms of civil rights and privacy. On the Policy level, the EU is subsidising initiatives to enhance the exchangeability of healthcare information. As a result, healthcare information can be safely exchanged internationally, allowing EU citizens to also obtain proper care across borders. There are various EU projects and initiatives which aim for international standardisation of healthcare information and processes and the concept of clinical information models (CIMs, or zibs in Dutch) is receiving a lot of international interest. Additionally, EU countries are working together on the Application and Infrastructure levels to realise a secure and reliable environment for the international exchange of healthcare information.

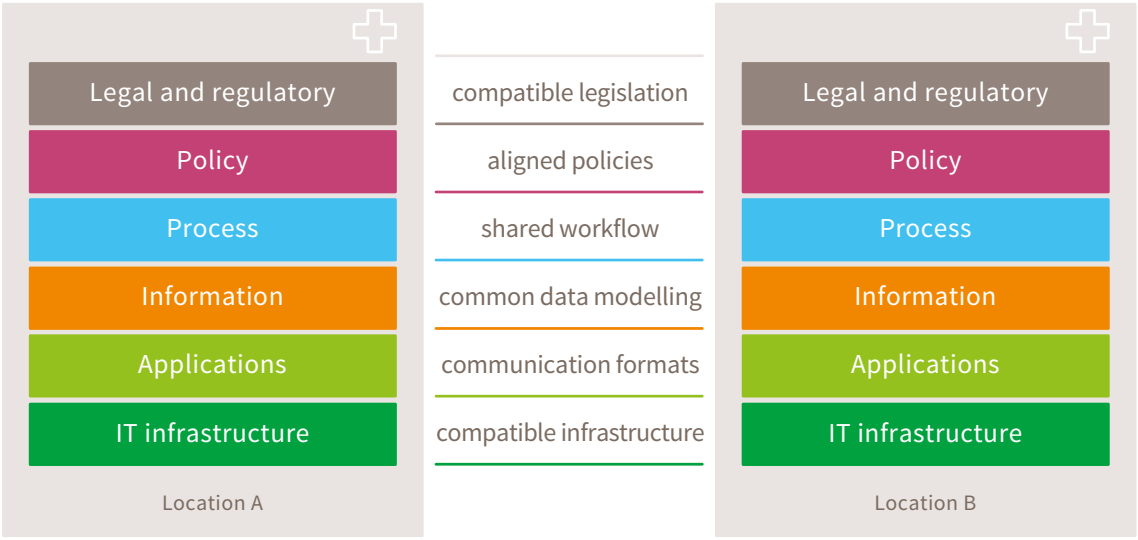
Summary

Introduction

"Why Europe when we aren't even able to exchange health data with everyone in the Netherlands yet?" "Things are going so slowly here in the Netherlands – should we really be waiting for other countries, as well?"
At a first glance these questions are understandable, but there are actually many reasons why the Netherlands is collaborating with the rest of Europe on information exchange in healthcare.

Interoperability is based on a system of agreements, on several levels, to ensure secure and reliable data exchange and process alignment.

Europe is more than Brussels alone: all countries in Europe are grappling with similar problems in healthcare. Think of population ageing, costs spiralling out of control, staff shortages, increasing administrative burden, and problematic sharing of information. In this paper we describe the importance of having a joint European approach to information exchange in healthcare. We do this based on a description for each level of the Refined eHealth European Interoperability Framework [1] (see figure 1).



(figure 1) ReEIF model

The Netherlands and Europe

When it comes to healthcare and IT, the Netherlands is on the right track. Over the past few years, information standards have been created for a variety of healthcare domains such as emergency care, medication, child healthcare, personal health environments, nursing transfer of care, and clinical information models (CIMs) [2]. And since the Dutch Ministry of Health, Welfare and Sport (VWS) has started incentive programmes, interoperability has gained momentum. Having a common language is the basis for interoperability, and the CIMs are a good starting point for this.

1| The Nictiz Layer Framework was adopted by the eHealth Network in 2015 and turned into a European framework (Refined eHealth European Interoperability Framework); see https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20151123_co03_en.pdf

2| See also: ISO 13972

At the same time it is clear that more must be done than just defining a set of information elements. When we look at the countries around us, at Europe, it is obvious that the healthcare sectors in all countries are faced with the same challenges, and are also thinking along the same lines for possible solutions.

Joint approach

The people, the diseases and the problems are the same – so why aren't we working together on the challenge of improving healthcare and actually realising interoperability? After all, this is an urgent matter: the costs of healthcare are still increasing, despite the many measures that have already been taken. There is a shortage of staff and at the same time a lot of time and money is wasted on slow and inadequate communication, excessive administrative burdens and avoidable errors, due to a lack of proper information. To improve the quality and efficiency of healthcare, the current status quo must be challenged. There is a growing realisation that if we join forces internationally in the area of healthcare interoperability, this will speed up developments and stimulate healthcare innovation. And people are starting to realise that Europe is an excellent breeding ground if we want to play a major role in this sector: thanks to the diversity of culture, languages and working methods, and the necessity of communicating with one another, interoperability is already familiar territory. By jointly identifying the processes and structuring healthcare data, organising the work internationally and sharing tasks, we can scale up more quickly and robustly. Based on mutual agreements on all levels of interoperability, factors that already play a key role in other sectors, such as big data, artificial intelligence, decision support, and deep learning, can also be applied in healthcare. When the EU member states take on this challenge together, we can develop an ecosystem that will be to everyone's advantage.

The Netherlands, Europe and the world

We live in a *global* economy. Nearly all industries around the world are based on information, fast connections and collaborating systems that use and combine the information in smart ways. This globalisation increasingly leads to parties monopolising the market in various industries – after all, you need scale to be able to have an impact. Europe has relatively few digital champions with high economic value. Big tech companies from the US, like Apple, Google and Amazon, and Chinese players like Tencent and Alibaba dominate the market. And with the rapid changes in the industry, Europe is not always able to withstand this competition[3]. The same applies in healthcare. IT plays a decisive role in all economic sectors, but the healthcare sector is still completely stuck in the 20th century as far as IT is concerned. Europe is now looking to change this and is working on the realisation of a single digital market where the protection of online security and privacy is the number one priority. In addition, Europe is protecting the internal market by imposing fines on organisations that abuse their dominant position.

In this document we will highlight a number of examples from the many European programmes and projects that are relevant to the primary care process in the Netherlands[4]. At the same time, we are receiving many questions from our European counterparts about our approach to interoperability and standardisation in healthcare. For this reason, we also indicate per chapter what the Netherlands has to offer to other European countries and where we see opportunities for international collaboration.

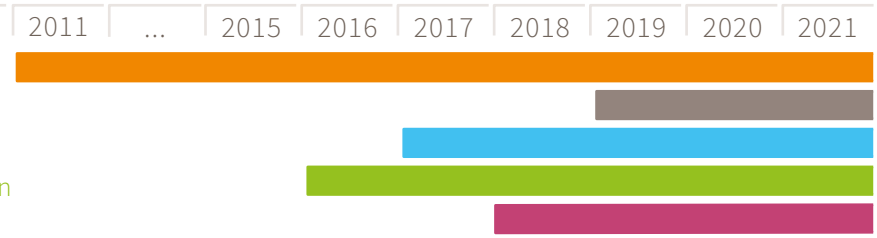
3| Information obtained via: https://dutchitchannel.nl/612528/dutch-transformation-platform-economy-paper-kpmg.pdf

4| Secondary use of data is important, as has also become evident from the corona pandemic. Where relevant, this has also been included in the scope of the present report.

ReEIF: Legal and regulatory

1

Europe does not determine how countries organise their healthcare. This is a national matter. Yet Europe does offer citizens the protection that enables them to receive good healthcare within the European Union (EU)[5]. The EU does this by drafting, coordinating and facilitating legislation. There are various examples of European laws and regulations that affect our national digitisation in healthcare. We have selected the most relevant ones and these are discussed in the present chapter (see figure 2).



(figure 2) Timeline of selected EU legal acts

Legal acts

The EU is working on improving its competitive strength in several areas. In the area of digitisation, the 'Digital Single Market Strategy' has been one of the EU's priorities since 2015. The EU wants to create a single digital market where differences in national legislation, for instance with regard to privacy, are to be ironed out. The vision is that "if a single rule or law applies in the whole of Europe, cross-border digital operations will become more efficient as well as cheaper"[6].

This strategy affects every European country and all sectors, including healthcare. To be able to exchange healthcare data securely and reliably, also internationally, measures must be taken to guarantee the security and privacy of that information, and those measures must apply to all EU countries. Information and people are not bound by country borders, so the protection does not stop at the border either. To make this possible, the EU adopts a variety of legal acts, such as regulations, directives, decisions, recommendations and opinions. These apply – to varying degrees – to every European country (see table 1).

"You will never again get lost in another country because you don't have access to Google Maps. You will never again have to drive around in circles while looking desperately for your hotel. You will never again have to go to McDonald's because they have Wi-Fi there. But also: you will never again experience the romance of watching Spanish soap operas without subtitling out of necessity in your hotel room, and you will never again be rid of Facebook. There's no escaping **the digital world** anymore." (Source: *de Volkskrant* newspaper, 15 June 2017)

Since 2017, no roaming costs apply when EU citizens go to a different country in the EU. Every European can use mobile internet, SMS and telephony in any other European country just like at home (hence the slogan **'Roam like at home')**.

5| Treaty of Lisbon (2007), Article 168.7

6| Information obtained via: https://ec.europa.eu/digital-single-market/en/policies/shaping-digital-single-market

Type (EN)	Brief description
Regulation	Binding legal act that is applicable throughout the EU.
Directive	Legal act that lays down a certain objective which all EU countries must achieve. Countries themselves can adopt the legislation needed to achieve that objective.
Decision	Legal act that is binding on the party to which it is addressed (an EU country or a business), and that applies directly.
Recommendation	Non-binding legal act that encompasses an appeal or proposal. Recommendations allow the EU institutions to make their views known and to suggest a line of action without imposing any legal obligation on those to whom it is addressed.
Opinion	Non-binding statement expressing a point of view.

(Table 1) Types of legal acts

Cross-border healthcare – Directive 2011/24/EU

Sometimes citizens need medical care in a different EU country than their country of origin. The preconditions for receiving this medical care and its reimbursement are set out in 'Directive 2011/24/EU' on the application of patients' rights in cross-border healthcare. Key points of this Directive are, among other things, that every country must make sufficient information for the continuity of care available to patients, must guarantee their privacy and must offer them access to their medical data within the European Union. One development resulting from the Directive is the eHealth Network, a voluntary European network consisting of the ministries of health of all EU countries. The Dutch Ministry of Health, Welfare and Sport is currently co-chair of the eHealth Network. Together, the European countries are working on the realisation of secure data exchange; see the 'Information' chapter in this regard as well.

Data exchange within the EU – Recommendation EEHRxF

Citizens have the right of access to their health data, but unfortunately their health data are generally not accessible yet in other countries. Various initiatives have been taken to allow the exchange of health information between countries, because it is in the interest of both citizens and healthcare providers that information is exchanged more rapidly and to a greater extent. In 2019, the 'Recommendation on a European Electronic Health Record exchange Format' appeared, with the objective of drawing up a European framework for the exchange of structured electronic healthcare information. This will allow health data to be safely exchanged and used across the border. All European countries are encouraged to offer secure access, create a digital network that supports exchange, and, in cooperation with the European Commission, accelerate innovation. This Recommendation also applies to the Netherlands. The Netherlands has taken

strategic steps for the realisation of the use cases and the further elaboration of the Recommendation, with the aim of bringing national priorities in line with EU priorities (also see the 'Information' chapter in this regard).

Medical Devices Regulation

This Regulation lays down rules for medical devices in Europe. These include implants, medical instruments, but also many medical apps and software applications. The Regulation imposes stringent requirements on quality and safety, but at the same time takes account of small and medium sized businesses that are active in this sector[7]. This has consequences for manufacturers, importers and distributors of medical devices, because they are subject to all kinds of checks and reporting requirements. It also affects healthcare institutions, healthcare providers and patients. For instance, implants placed must be recorded in a national implants register[8]. At the European level, healthcare providers and patients will have access to a database (EUDAMED) containing information on medical devices on the European market[9]. This will make it easier for healthcare providers to choose the right devices, and for patients to receive information about the manufacturer after placement of an implant. Every EU country will enforce these rules on a national level. In the Netherlands these have been incorporated in the Medical Devices Act *[Wet medische hulpmiddelen]* which will enter into force in May 2021[10].

Regulation (EU) 2016/679 (GDPR)

An important requirement for the promotion of a European digital market and the exchange of information in the EU is the protection of citizens' personal data. The 'General Data Protection Regulation' (GDPR)[11] has been adopted for this purpose. On the one hand the GDPR offers protection for individuals throughout Europe and on the other hand it acts as an incentive for the economic market by promoting secure data transfer, for example. The main principles of the GDPR are as follows:

- *Integrity:* securing personal data using appropriate techniques and measures;
- *Lawfulness:* creating a legal basis for personal data processing;
- *Portability:* transferring personal data to other storage systems in a structured format;
- *Accuracy:* updating personal data correctly;
- *Purpose limitation:* only collecting personal data for specific, explicit and legitimate purposes;
- *Data minimisation:* limiting the collection of data to what is relevant and necessary for the purposes for which they are processed;
- *Storage limitation:* only storing data to the extent that this is necessary and reasonable.

7| Initially the rules were to apply as of 26 May 2020. However, due to the corona pandemic, the date of entry into force has been postponed for a year.

8| See https://www.igj.nl/onderwerpen/landelijk-implantaten-register (only available in Dutch).

9| https://eur-lex.europa.eu/legal-content/NL/TXT/HTML/?uri=CELEX:12016ME/TXT&from=NL#d1e4516-47-1

10| https://www.rijksoverheid.nl/onderwerpen/medische-hulpmiddelen/nieuwe-wetgeving-medische-hulpmiddelen (only available in Dutch).

11| When the GDPR was created, various opinions appeared to clarify certain points of view of the Regulation.

The above principles also apply to patient data which are available in the healthcare sector in the Netherlands. These data must be handled with utmost care. For instance, attention must be given to proper use of the correct information by the right people, but citizens also have the right to request data in a digital and (where possible) structured format and transfer the data to another party. The protection of the data of our Dutch patients does not stop at the border; the GDPR ensures that sensitive information is handled based on the same principles in all countries in the EU.

Electronic identification – eIDAS

To make electronic transactions between citizens, businesses and public bodies in the EU safer and easier, the eIDAS Regulation has been in force since September 2018 [12]. The main point of this Regulation is that electronic identification assigned in one EU country must also be recognised in all other EU countries. The Regulation applies to all systems for electronic identification, including the health system. For the healthcare sector in the Netherlands it has been agreed that the university medical centres must set up their eID service so that they can process the electronic identification of EU citizens [13]. As more healthcare institutions in the European Union set up this service, EU citizens will be able to identify themselves electronically throughout the EU as soon as a tool is available to them [14].

What is the relevance for the Netherlands?

In a general sense, we are already contributing to European laws and regulations, since these are drafted by the participating countries, and in that sense the Netherlands has an important say as well. In addition, European laws and regulations are important for the Netherlands because they give our citizens the following rights:

- The right to receive medical care across the border and to have it reimbursed;
- The right to have their personal data protected (though the GDPR), across the border but on a national level as well;
- The right of access to health data, meaning the right to inspect these data and transfer them to other healthcare organisations;
- The right to receive information, for instance on medical devices via EUDAMED;
- The right to the availability of services that enable the safe exchange of information, like the recognition of electronic identification in Europe.

12| It is only mandatory if the public body uses the levels 'substantial' or 'high' to gain access to the online services.

13| The UMCs were to meet this requirement by the autumn of 2019. The other hospitals are to follow.

14| At the moment, DigiD cannot be used as a recognised eID tool yet; see: https://www.government.nl/topics/online-access-to-public-services-in-the-european-union-eidas/everything-you-need-to-know-about-eidas

In addition, developments are taking place in the Netherlands that may be interesting for Europe. Examples of opportunities for collaboration between the Netherlands and other countries on the Legal and regulatory level are:

- NEN 7522 – NEN (the Royal Netherlands Standardization Institute), in close in collaboration with Nictiz, has drawn up a standard governance and methodology model regarding the development and maintenance of coding systems. This standard is a candidate for scaling up internationally into a European (CEN) or global (ISO) standard.
- The EGiZ code (Code of Conduct Electronic Data Exchange in Health care) [15] consists of a set of ethical rules drawn up by the main umbrella organisations in Dutch healthcare. It may be possible to incorporate this code of conduct into a framework that not only focuses on data protection, interoperability and architecture, but on all levels of interoperability.

15| See https://www.nictiz.nl/overig/gedragscode-elektronische-gegevensuitwisseling-in-de-zorg-egiz/ (only available in Dutch).

Organisation policy

2

Besides European laws and regulations, certain policy priorities apply in the EU for the protection and improvement of public health. These priorities and the resulting projects are described in this chapter, because they give focus to our Dutch activities, while we can also exert an influence on the European policy.

Focus in Europe

The Digital Single Market Strategy mentioned previously outlines how we can achieve a single European digital market with three main aims, i.e. the realisation of:

- Better access to goods and services;
- The right conditions and a level playing field for networks and services;
- Maximum growth potential for the digital economy and society.

In February 2020, the European digital strategy for the next five years was announced[16]. This strategy is based on a single digital data market which allows the EU to gain a better competitive position in the global market. It all revolves around data, which will be safely and purposefully accessed, shared and integrated by and between all EU countries in accordance with the applicable rules. The EU invests in infrastructures for the exchange of data, in instruments for data storage and compilation, and in regulations to guarantee data protection. The EU has the potential to become a successful digital marketplace. The major global powers, like China and the US, are innovating quickly and have enormous target markets. Europe is looking for ways to counterbalance their dominant positions, and this includes the EU coordinating and facilitating the efforts of its Member States. To realise this counterbalance we need a joint approach in order to safely and efficiently exchange information between EU countries, including in healthcare. And for this exchange we need to reach agreements and align initiatives.
At a first glance, on a national level, there are big differences, with each country having its own healthcare system, with central or regional control, and different combinations of public and private parties involved.
But on the level of the patient, the care provided and the information recorded in the process, the similarities are greater than the differences, and countries can work together to make those vital data exchangeable.

The corona pandemic

has highlighted the importance of data collection once again.

Which group is most at risk? Can you become ill again? How much time do patients spend in intensive care?

These data are collected and exchanged, between EU countries as well, so that we can learn lessons and take measures, for example to be better able to help patients.

16| https://ec.europa.eu/commission/presscorner/detail/en/fs_20_283

Collaboration in Europe

As regards digitisation in healthcare in Europe, Member States are joining forces in the eHealth Network (as described in the Legal and Regulatory chapter). The eHealth Network is a voluntary collaboration of Member States with the aim of guaranteeing interoperability of health systems and their use in Europe. The European Commission's Directorate-General Santé is involved with the eHealth Network and is focusing on laws and regulations, European policy and EU subsidies. To support the network, several advisory subgroups – among which a semantic subgroup and a legal subgroup – have been set up. These groups draw up policy proposals and collaborate on new developments. The most recent development is the corona pandemic and the question of how data exchange can be accelerated in this context whilst still safeguarding privacy and security. The Netherlands is represented in these working groups so that we can safeguard our national policy by exerting an influence on what is agreed internationally in this area.

Until 2020, a EU Health Programme has been in place as a funding instrument to encourage EU countries to work together on healthcare. With a budget of nearly 450 million euro, the European Commission and the EU Member States have addressed 23 priorities in healthcare. This also included the *joint action* [17] referred to as eHAction, where EU countries collaborated and supported the eHealth Network in a variety of focus areas, i.e. empowering people, innovative use of health data, enhancing continuity of care, and overcoming implementation challenges. Together with Estonia, the Netherlands took the lead in the focus area of 'empowering people'. The Netherlands opted for this particular focus area, because it is in line with our national policy where citizens are to take centre stage. It enabled us to safeguard the patient-focused approach in Europe and exert an influence on European decision-making.

European funding

In addition to the drafting of EU policy, the EU is investing billions of euros in projects, research and innovation to implement the digitisation strategy. Horizon 2020 and Connecting Europe Facility (CEF) are examples of funding instruments where European countries are currently working together in consortiums. This offers Dutch organisations the possibility to receive subsidies, join consortiums, share knowledge and influence European initiatives. Examples of such initiatives vary from the actual realisation of cross-border data exchange to the creation of access to genetic data including legal and ethical safeguarding [18]. In 2021 we will see the start of the multi-annual financial framework of the EU through which 1074 billion euro will become available for research, projects and initiatives [19]. Healthcare will be a major topic here, partly due to COVID-19. Via various subsidy programmes, like Horizon Europe, Digital Europe, and EU4Health, opportunities will arise for Dutch organisations to participate in projects covered by these subsidies.

17| Joint actions have clear added value for the EU and are co-funded by the authorities of the European Commission and the responsible Member States.

18| 1 million genomes initiative, see https://ec.europa.eu/digital-single-market/en/european-1-million-genomes-initiative

19| On 21 July 2020, the EU heads of state reached an agreement on this multi-annual budget. See: https://www.europa-nu.nl/id/vkf4n0xn1wzp/europees_financieel_kader_2021_2027 (only available in Dutch).

What is the relevance for the Netherlands?

By linking up with Europe, the Netherlands ensures that the national developments around data exchange in healthcare are in line with European developments. In this way we can learn from each other, we do not have to reinvent the wheel, and Dutch activities can be accelerated. Coordination, management and collaboration in Europe offer opportunities for the Netherlands, i.e.:

- Improvement of the availability of data in European countries for citizens and businesses;
- Acceleration of Dutch data interoperability projects thanks to European developments;
- Increasing our innovative ability by having other countries join our efforts;
- Promotion of Dutch ideas beyond the Netherlands, for which Europe offers opportunities.
- Development of a European target market for entrepreneurs.

A number of developments are receiving interest from the rest of Europe, such as:

- The Healthcare Information Council *[Informatieberaad Zorg]* – by involving the 'whole system in the room', the Ministry of Health, Welfare and Sport aligns the entire healthcare sector (interest groups, policy-makers and experts) on focus points, urgent topics, innovation and progress, thereby stimulating and guiding developments in healthcare;
- Trust frameworks, such as the MedMij Trust Framework, are being used for a variety of domains and purposes. Laying down the preconditions that suppliers and organisations must meet as a basis for a level playing field has already widely received international attention;
- The Guide to Interoperability between Healthcare Institutions *[Handreiking Interoperabiliteit tussen zorginstellingen]*[20] contains principles, guidelines, advice, implementation examples and a normative framework for agreements on all levels of interoperability to safeguard data exchange and collaboration between healthcare organisations.

20| See https://www.nictiz.nl/standaarden/handreiking-interoperabiliteit-tussen-zorginstellingen/ (only available in Dutch).

Care processes

3

In the exchange of medical information, the importance of providing and receiving the right care is the number one priority. We want to be able to receive this care in the Netherlands, but also abroad. Within the EU, borders have become less important, and tourism has gone up tremendously over the past decade; in 2019, 335 million Europeans went on holiday in another European country[21], and 16 million European tourists visited the Netherlands[22]. A large share of EU citizens visiting the Netherlands come from our neighbouring countries. In the border regions shared with Belgium and Germany, citizens also cross the border for work or brief visits to relatives or shops. Dutch people regularly visit other EU countries as well. The present chapter addresses a number of examples of concrete data exchange in healthcare.

Receiving care in the Netherlands and abroad

If we have an accident in another European country, it helps if our data are available across the border. And it works the other way around as well: if an EU citizen needs urgent care in the Netherlands, it will be very useful for our doctors to have access to the relevant patient data, such as an overview of the patient's current medication. This applies, for example, to the many tourists visiting our country. Five A&E departments in the Netherlands have indicated that in 2018 they treated a total of around 3300 patients from other EU countries[23]. But it also applies to the over 50 Dutch COVID-19 patients who have ended up in intensive care departments in Germany.
To enable data exchange, the following priority care processes[24] have been singled out in the Netherlands and in Europe:

	Netherlands	Europe
1	Basic Healthcare Data Set (BgZ)	Patient Summary
2	Electronic prescriptions	ePrescription / eDispensing
3	Medical images	Medical imaging and reports
4	Emergency care	Laboratory request and reports
5	Nursing handover	Hospital discharge reports
6		Rare diseases

(Table 2) Priority use cases in the Netherlands and Europe

There are considerable similarities in the first three priority care processes, partly helped by propositions from the Netherlands. In this way harmonisation is taking place between the Netherlands and the rest of Europe with regard to these use cases. An example is the common ground between the Dutch Basic Healthcare Data Set (BgZ) and the European patient summary (PS).

21| Statistics Netherlands (2019), page 38. Trend Report on Tourism, Recreation and Leisure Time *[Trendrapport toerisme, recreatie en vrije tijd]* 2019. See https://www.cbs.nl/nl-nl/publicatie/2019/48/trendrapport-toerisme-recreatie-en-vrije-tijd-2019 (only available in Dutch)
22| NBTC Holland marketing. See https://www.nbtc.nl/en/home/knowledge-data/figures-trends.htm
23| PIEZO, programme plan. Request for information from five participating hospitals.
24| Letters from the Dutch House of Representatives on data exchange in healthcare; https://www.rijksoverheid.nl/documenten/kamerstukken/2019/07/12/kamerbrief-over-derde-brief-elektronische-gegevensuitwisseling-in-de-zorg (only available in Dutch).

Paloma Perez from Spain has had an accident in Amsterdam. She is taken to the nearest hospital.

The doctor in A&E asks for her identification and for permission to retrieve her data from Spain. The doctor goes through the authentication process and retrieves Paloma's data. This allows him to treat her more carefully according to her.

When the BgZ was devised, the European patient summary was taken as a starting point, which means that the BgZ and PS overlap to a large extent and use a common language. The Netherlands is working with the PIEZO programme for implementation of European care services on establishing a Dutch national contact point for eHealth to be able to receive patient summaries for European patients. By the end of 2021, this will give our Dutch care providers access to the most important data for European patients, enabling better, safer and more rapid care. In the future this might be extended to sending patient summaries, and receiving and sending ePrescriptions. There are synergies here with the Dutch work in relation to the medication process as well. In addition, in the EU project X-eHealth the designs for the other European use cases are being developed as of September 2020 (images, lab, discharge letters and rare diseases). The project seeks to align with developments in the Netherlands as much as possible, so that both the Netherlands and the rest of the EU can learn from each other and so increase mutual understanding.

In addition to the use cases for unplanned care, the exchangeability in planned care will be addressed internationally as well. The European reference networks (ERN) are virtual networks of healthcare professionals from all over Europe for the treatment of rare diseases and conditions. The objective of these networks is to offer high-quality care to patients with a rare disease or condition through knowledge sharing, joint discussions and advice.

Data exchange in border regions

The Netherlands is also seeking collaboration with our neighbouring countries Belgium and Germany. In these border regions we already work together on various healthcare processes. For instance, Maastricht UMC+ sends Dutch patients in need of a liver transplant to the German city of Aachen, as this is closer to Maastricht than the nearest liver transplant centre in the Netherlands, Erasmus MC of Rotterdam [25]. The set of information that is exchanged currently accompanies the care provider or the patient from one hospital to the next. To enable digital data exchange here and in other existing cross-border collaborations, Nictiz has become involved in the Border Regions project. With this project, the Netherlands has taken the initiative of using border regions as practical cases for possible broader application in the future.

25| See https://www.leverpatientenvereniging.nl/ (only available in Dutch).

What is the relevance for the Netherlands?

By working together on healthcare processes, the Netherlands can be of service to its citizens, but also to its healthcare professionals, for instance by means of the following:

- Alignment of the work processes, for instance in the border regions, so that care is also available to Dutch citizens across the border, and Dutch healthcare professionals can (better) help European patients;
- Ensuring alignment of European and Dutch care processes, so that Dutch citizens have access to their health data across the border, and Dutch healthcare professionals have access to the health data of European patients.

The ‘export’ of Dutch ideas has turned out to be a success. Some examples:

- There is a great deal of interest in involving citizens in healthcare and in the deployment of personal health environments (PHEs) in the healthcare sector. By aligning the systems, new care processes can be deployed. Interest has also been shown in the MedMij approach with a trust framework and standardised information.
- In the Netherlands, multidisciplinary consultation is widely used with the aim of achieving optimum alignment for discussions about patients, particularly in the field of oncology. The outcome of this method includes not only an IHE profile that supports the process of multidisciplinary consultation, but also standardisation of test reports and a radiotherapy treatment plan.

Information

4

Information is of crucial importance for high quality healthcare, which is increasingly multi-disciplinary in nature. This chapter explores the possibilities of collaborating with other European countries in the standardisation of health information. All countries are faced with the same challenges as the Netherlands and are looking along the same lines for solutions as a result of the collaboration that has taken place over the past years.

Collaboration with Europe

Thanks to participation in the various projects and programmes in Europe, an international knowledge network has developed, in which insights, experiences and information regarding interoperability are being shared. In Europe as well as beyond, the Netherlands is currently regarded as one of the front runners when it comes to interoperability. Over ten countries[26] have shown an interest in the CIMs, for example, partly due to the fact that these already have an international focus, including links to international terminology systems such as SNOMED-CT[27]. These countries are eager to participate in adopting, managing and extending the CIMs internationally. A contributing factor for this being the fact that when the CIMs were defined, the specifications of the European patient summary drawn up jointly over the past years were expressly taken into consideration. In addition, the methodology around the development of CIMs will become an ISO standard in 2021 (ISO 13972, Clinical Information Models)[28].

The clinical information models ('CIMs') are a result of the programme called Facilitating Clinical Documentation at the Point of Care. They describe reusable clinical concepts, as separate from the technical elaboration. The CIMs can be used in various combinations and for multiple purposes, and so form the basic elements of information exchange for the entire healthcare sector.

Clinical information models (CIMs)

The clinical information models are generic and can be used as standard building blocks for several use cases. They form the basis for information transfer in the MedMij Trust Framework, but now also for emergency care, child healthcare, perinatology, laboratories, medication and nursing handover. This is an extra reason for countries to adopt the Dutch approach; thanks to their generic nature, CIMs can be deployed for multiple purposes. But we are not there yet: beyond the basic information elements, a large share of the data documented in healthcare is related to a specific healthcare demand, requiring more specialised information elements. For the data which are recorded during medical history-taking, physical examination, additional diagnostics and treatment, and which are often highly specific, it must be assessed to what extent these data can be documented using the existing CIMs and to what extent extensions are required. Very few reports of diagnostic studies or discharge letters have yet been standardised, meaning that they are not yet interoperable. Standardisation of all those data is a complex and time-

26| Austria, Belgium, the Czech Republic, Estonia, Finland, Germany, Portugal, Sweden and Switzerland want to play an active part. Denmark, Norway and Poland as well as Japan have shown an interest as well.

27| See https://www.nictiz.nl/standaardisatie/terminologiecentrum/ (only available in Dutch).

28| See https://www.iso.org/standard/79498.html

consuming process, and will result in growing management constraints as the number of information elements increases. To enhance the quality and efficiency of healthcare, we need to scale up internationally. All European countries are facing the same challenges in healthcare and are having to deal with similar problems. At the same time, international standards are already being used by all parties, so what is there to prevent further collaboration on a European level to accelerate and extend the available processes, concepts, reports and applications? Already this collaboration is taking shape in the European projects that focus on interoperability, patient focus, safety/security and innovation. A joint approach may reduce the time for development and the management constraints, increase the quality and reusability, and offer important strategic benefits for European countries.

Making all the data recorded in the primary care process exchangeable offers an enormous added value. Not only can the data be re-used in the information exchange between patients and healthcare providers (as referrals, requests, patient reports and discharge letters), but also in scientific research, epidemiology, quality registrations, production figures, decision support, process optimisation and financial accountability. Provided this is done in a user-friendly manner, building this exchangeability into the various systems can result in a significant improvement in quality and efficiency.

EU programmes and projects

Within the EU there are various projects and programmes that organise international standardisation of healthcare information and care processes. Examples of projects that the Netherlands is currently participating in are:

X-eHealth

In September 2020, a major European project in the field of interoperability started, called X-eHealth ('Cross-eHealth'). This project is the result of the European EHR Exchange Format Recommendation (EEHRxF) of the European Commission, and its goal is to enhance the cross-border exchangeability of electronic medical information in the EU. Besides the existing use cases that are being exchanged between countries for unplanned care, i.e. the Patient Summary [29] and the ePrescription, data specifications will be defined for four new domains: laboratory requests and reports, exchange of images and imaging reports, hospital discharge letters, and the possibility to exchange information on rare diseases, resulting in a European standardisation of data elements for more specific care domains. In this context the Netherlands is the leader of the project group elaborating the functional specifications for these new use cases. In addition, the Netherlands is participating in the preparation of a roadmap for the addition of further new use cases.

UNICOM

Over the past ten years the set of ISO standards IDMP (IDentification of Medicinal Products) has been published [30], which enables uniform, structured documentation of medication in Europe. Z-index and NEN (the Royal Netherlands Standardization Institute) have contributed to this as well.

29| A patient summary consists of a general set of standardised health data. It largely corresponds with the Dutch Basic Healthcare Data Set *(Basis gegevensset zorg* or BgZ).

30| The IDMP has been built around a number of ISO standards: ISO 11238, ISO 11239, ISO 11240, ISO 11616 and ISO 11615.

The UNICOM project has been set up to implement this standard in European countries over the coming years. This is an enormous task, but the advantage is that this international standard will make it possible to improve medication monitoring, decision support, scientific research and support for citizens. In addition, it also offers opportunities for software suppliers, the pharmaceutical industry and app builders to organise better products and better services.

What is the relevance for the Netherlands?

- The Dutch information standards are based on international standards like HL7, IHE, SNOMED and LOINC. By participating in these organisations, the Netherlands can play a role in the development of these standards.
- Internationalisation of clinical information models makes it possible to work together on the management and extension of these CIMs. This will result in improved interoperability and it allows sharing of the maintenance burden. Over ten countries[31] are eager to help think about and realise the internationalisation of the Dutch clinical information models.
- Common standards allow Dutch suppliers to extend their operations internationally, and Dutch healthcare institutions can also make use of solutions offered by international suppliers.
- The Dutch translation of SNOMED terms (over 200,000 terms so far) has provided us with considerable experience regarding both methodology and efficiency.

31| Austria, Belgium, the Czech Republic, Estonia, Portugal, Sweden and Switzerland have already indicated that they want to play an active part. Denmark, Finland, Germany, Norway and Poland, plus Japan and the United States, have shown an interest.

Applications

5

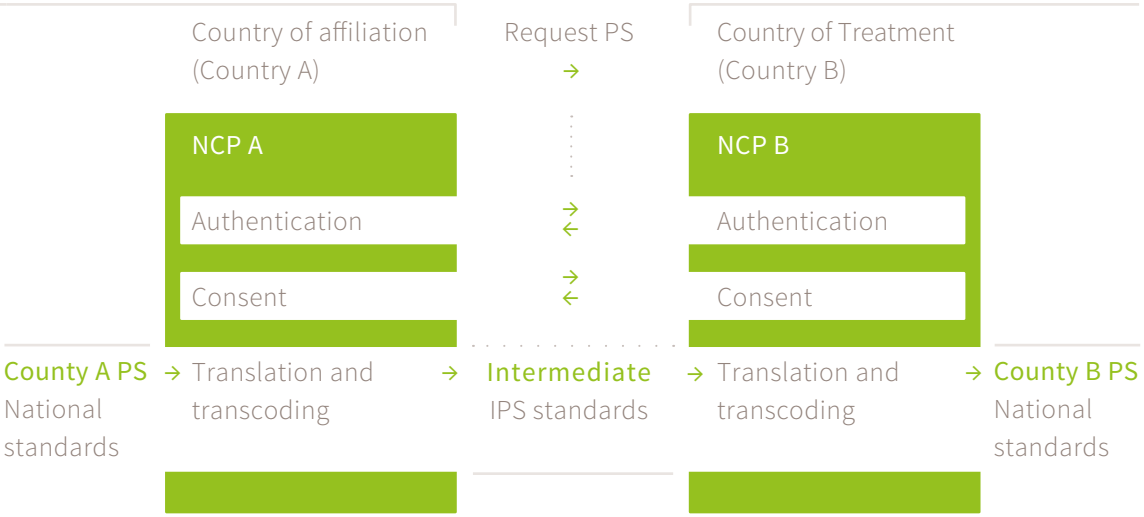
Once the information has been standardised and implemented, exchange will become possible within the organisation itself, between healthcare institutions, within regions and even between countries. With standardised information, applications will also be better able to communicate with one another. In this chapter we look into what is already happening on the Application level in Europe and into the possibilities for realising more interoperability at this level.

Interoperable applications

Most information systems in healthcare are geared towards an organisation's own operations. However, in order to obtain the required information, these systems need to communicate with peripheral equipment, integrate information from other hospital departments (e.g. radiology, laboratory) and exchange information with external systems. Currently, these elements all require separate links, to each system, of each supplier. Using standard interfaces (APIs) considerably reduces the number of customized connections and also makes it possible to set up modular healthcare information systems and make them fundamentally interoperable ('interoperability by default'). The standardised interfaces of MedMij applications are a good example of this, but a lot more is possible in this area: standardised interfaces allow the development of applications that can be used internationally.

National Contact Points for eHealth

Citizens in Europe have the right to receive proper healthcare, regardless of the country where they are currently located. For this we also need to make proper care information available. To make this possible, 22 countries are already working on the realisation of National Contact Points for eHealth (NCPeHs), which will allow the secure exchange of medical data of EU citizens. The NCPeHs form a secure and reliable network for the exchange of medical information and subsequently convert the structured care information from the patient's country of origin into the language of the country of treatment with the aid of algorithms and translation tables. As a result, a patient summary recorded in Estonia can be used immediately in the Netherlands for emergency care, for example. The national contact points are connected through a European infrastructure, the eHealth Digital Services Infrastructure (eHDSI) (see figure 3 and the 'Infrastructure' chapter). This eHDSI is based on a concept of a 'circle of trust', where Member States are entrusted with the authentication, delivery and processing of the information. The management of the generic facilities is the responsibility of the European Commission, while the Member States each manage their own NCPeH. At the moment, patient summaries and prescriptions can be exchanged via eHDSI. As described in the 'Information' chapter, the X-eHealth programme will also make it possible to share laboratory data, images, discharge letters and rare disease information internationally in a couple of years' time.



(figure 3) The connection between national contact points and the core services

Reusable European services

To help the aforementioned digital single market succeed, the programme Connecting Europe Facility (CEF) is funding a series of generic and reusable digital services, also referred to as CEF building blocks. The CEF functional building blocks can be reused in every European project to facilitate the provision of digital public services, across borders. There are already multiple CEF building blocks[32] that can be used, including Big Data Test Infrastructure (a test environment for large data collections), Context Broker (which merges information from different sources for research purposes), eArchiving (secure storage) and eID (authentication).

27 European reference standards

IHE profiles are implementation specifications for standardised application modules, which can mutually exchange information and perform specific tasks. In 2015, the eHealth Network designated a number of IHE profiles that can be required by clients for public tenders, the so-called IHE profiles for public procurement. One of these profiles has been used for the software for the National Contact Points for eHealth, for example. By standardising only the interfaces of the software, applications that make use of IHE profiles can communicate with one another, while suppliers can show their added value in areas like functionality, user-friendliness and costs.

32| See https://ec.europa.eu/cefdigital/wiki/display/CEFDIGITAL/. The website also gives examples of how these building blocks have been used in the context of COVID-19.

Standardisation bodies

Because the Netherlands is actively involved in the main international standardisation bodies, like HL7, IHE, SNOMED, LOINC, NEN, DICOM and GS1, we are keeping abreast of developments and are so able to exert influence. For instance, the rapid development of FHIR can be largely considered a Dutch success.

What is the relevance for the Netherlands?

- Thanks to the national contact points, Dutch doctors can provide better care to foreign patients because they have access to the main medical data, in Dutch. In the future, Dutch citizens that need healthcare abroad can also receive better care because their data will be available there in the language of the country they are staying in.
- Adoption of European common services will reduce the costs of development and make the exchange between countries easier.
- The Netherlands is currently considered one of the forerunners in Europe when it comes to interoperability. Internationally there is a lot of interest in our sector-wide approach and the MedMij Trust Framework, because of the standardisation and this system itself.
- Together with the United States the Netherlands is a world leader in the FHIR profiles being developed as a standard for communication between healthcare providers and with patients, no longer just for apps, but for the entire care spectrum as well.
- ART-DECOR is an open-source tool for defining and specifying structured healthcare information, to which Nictiz is making an important contribution. Internationally this tool is already being used by several countries and standardisation organisations. Further international/ European scaling-up of ART-DECOR is already being worked on.

Infra-structure

6

Every country in Europe has its own type of solution for healthcare infrastructure. Countries like Finland and Estonia use a single central database, while other countries have fully decentralised storage or do not even have any infrastructure for national exchange at all. History often plays an important role in this; at some point a country made a certain decision and it is not easy to quickly change an infrastructure. In this chapter we briefly address a number of relevant European initiatives which can be used as inspiration for the discussion concerning a nationwide network in our own country.

International data exchange

Europe cannot influence how national infrastructures are organised. It does, however, offer a solid architecture for secure exchange of medical data between countries, the eHealth Digital Services Infrastructure (eHDSI). eHDSI is a programme to set up a standardised infrastructure which countries in Europe can use to exchange health information in a safe, efficient and interoperable manner. It concerns a secure network between the National Contact Points for eHealth, which have already been described above. The information is exchanged by means of a protected European network, the secure Trans European Services for Telematics between Administrations (sTESTA). Other European networks include European Reference Networks (ERN) – secure virtual networks of healthcare providers in which healthcare professionals can interconnect in relation to patients with rare diseases.

Inspiration from other countries

In the Netherlands, the Twiin [33] programme is being used to come up with architecture solutions for national information exchange. This programme has also looked at the various solutions that have been developed in other European countries. For the exchange of images, particular attention is being given to the international IHE implementation standards and to solutions where use is made of FHIR resources. The advantage of these two solutions is that they are based on international standards, and individual countries can benefit from the development of those standards.

What is the relevance for the Netherlands?

- The Netherlands can learn from the various infrastructural solutions and architectures in other countries.
- In the future, our national infrastructure can link up with the European infrastructure, allowing the exchange of information throughout Europe. Collaboration in border regions will become easier, and personal health information will become available across the border as well.
- International adoption of the National XDS metadata set offers Dutch suppliers the possibility to create applications that do not need to be set up differently in every country.
- The results of the Twiin programme are also interesting for countries that are working on their own national infrastructure solutions. This offers export opportunities as well.

33| See: https://www.twiin.nl/

Conclusion

7

This report has set out the importance of having a joint European approach to information exchange in healthcare. The main findings on the levels of the Refined eHealth European Interoperability Framework are:

- **Legal and regulatory:** There are European laws and regulations that protect the rights of our citizens. These laws and regulations affect the Netherlands to varying degrees, but the Netherlands can influence them as well.

- **Organisation policy:** The EU has the potential to become a single, successful digital marketplace. The major global powers, like China and the US, are innovating quickly and have enormous target markets. In the area of interoperability, Europe may be able to counterbalance the dominant players by promoting the realisation of joint European policy.

- **Care process:** Dutch people increasingly go on holiday abroad, work outside the Netherlands or make use of healthcare in other European countries. Dutch citizens should be able to rely on proper healthcare, also abroad. Particularly in the case of emergency care, it is essential for healthcare providers to have correct information that is understandable to them.

- **Information:** Thanks to joint efforts, the development of specifications for structured documentation and exchange is gaining momentum, not only in the fields of laboratory testing and imaging, but also for planned care in the form of discharge letters. The COVID-19 crisis makes it clear once again how necessary it is for this process to accelerate. In addition, exchangeability of data is also a precondition for secondary use for, among other things, scientific research, decision support and epidemiological research.

- **Application:** The National Contact Points for eHealth enable the exchange of healthcare information between countries in the EU, with the structured data being translated into the language of the healthcare provider. Particularly in emergency situations, this information can be of crucial importance.

- **Infrastructure:** In the area of infrastructural provisions, too, EU countries are working on various solutions based on international agreements. Standards on this level will increase the transparency, testability and interoperability, and support secure and reliable availability of the necessary information relating to healthcare.

Based on the present report the authors offer the following recommendations:

A joint approach is needed and offers benefits

Standardisation is a prerequisite for both the quality and the efficiency of healthcare. But it is also a complex and time-consuming process. More collaboration is desirable to enable secure exchange of health-related data, also across borders. Interoperability does not stop at the border – mutual acknowledgement of similar challenges in healthcare forms the basis for the joint development of a system of shared principles, goals, methodologies, standards and implementation profiles, on all levels of interoperability. Based on these agreements, a safe, modular and flexible ecosystem can be developed in which innovative and collaborative healthcare applications will optimally support both healthcare and citizens. A shared basis enables the introduction of *collaborative big tech* as a starting point for acceleration and innovation in the EU.

Participation in European and international projects, organizations and meetings have enforced the Dutch strategic role; we help shape an innovative climate in terms of interoperability, patient empowerment, and primary and secondary use of data. This has led to the Netherlands being co-chair of the eHealth Network for the next two years. In addition, 'bottom-up' cooperation with other countries is increasingly taking place, in particular with our neighbours. The collaboration in the area of exchangeability of healthcare information is appreciated and endorsed by all parties, and closer cooperation is advocated.

The EU is a perfect breeding ground for innovation in eHealth and interoperability

Europe has a combination of properties that can form the basis for an important role to be played in the area of interoperability: diversity, ethical principles, civil rights, a strong research field, and the need to work together and exchange information in multiple languages provide the ideal breeding ground for further development of this modular approach.

Dutch information standards are already based on international standards, so that the Netherlands is closely involved in the latest developments and can influence them as well. The Dutch innovative approach to, for example, the clinical information models and personal health environments is recognised internationally and has already resulted in more international approaches. Based on joint agreements on standardisation and interoperability, a fruitful basis is being developed, as well as the possibility to target new markets with our innovative solutions.

About the authors

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Elise Peters is International Team Lead at Nictiz.

She deals with cross-border topics relating to digital data exchange in healthcare. For example, she is working on the creation of European policy and the realisation of international data exchange. In addition, she likes to keep up to date with activities in the Netherlands and she is highly interested in positioning issues in healthcare, partly thanks to her degrees in Information Management and Business Communication.

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He is involved in international collaboration and the development of a vision with regard to interoperability, architecture, information standards and healthcare innovation. Among other things he is Chair of the eHealth Network Subgroup on Technical Interoperability and Work Package Lead of the X-eHealth programme. Over the past few years Vincent has also participated in a number of other EU projects (Antilope, eStandards).

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Annex – Sources for more information

CE marking
Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93
Link: https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1415011406506&uri=CELEX:32008R0765

Charter of Fundamental Rights of the European Union
Link: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A12012P%2FTXT

Digital Health Europe
Link: https://digitalhealtheurope.eu/

EU Cybersecurity Strategy
JOINT COMMUNICATION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS
Cybersecurity Strategy of the European Union: An Open, Safe and Secure Cyberspace
Link: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52013JC0001

eIDAS Regulation
Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC.
Link: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32014R0910

General Data Protection Regulation (GDPR, AVG)

Regulation (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)
Link: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.119.01.0001.01.ENG&toc=OJ:L:2016:119:TOC

IHE profiles for public procurement

Commission Decision (EU) 2015/1302 of 28 July 2015 on the identification of 'Integrating the Healthcare Enterprise' profiles for referencing in public procurement.
Link: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32015D1302

Medical Device Regulation

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
Link: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0745

NIS Directive

Directive (EU) 2016/1148 of the European Parliament and of the Council of 6 July 2016 concerning measures for a high common level of security of network and information systems across the Union Link: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.194.01.0001.01.ENG&toc=OJ:L:2016:194:TOC

Patients' rights in Cross-border Healthcare

Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare
Link: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32011L0024

Projects related to standardisation and interoperability

- epSOS (2008-2014, www.epsos.eu)
- Trillium Bridge (2013-2015, www.trilliumbridge.eu)
- ANTILOPE (2013-2015, www.antilope-project.eu)
- e-SENS (2013-2017, https://www.esens.eu/)
- EXPAND (2014-2015, www.expandproject.eu)
- eStandards (2015-2017, http://www.estandards-project.eu/)
- VALUeHEALTH (2015-2017, http://www.valuehealth.eu/)
- JAseHN (2015-2018, http://jasehn.eu/)
- EuroCAS (2016-2018, https://www.euro-cas.eu)
- ISA^2 programme (2016-2020, https://ec.europa.eu/isa2/isa2_en)
- eHAction (2018-, http://ehaction.eu/)

- Unicom (2020-, https://unicom-project.eu/)
- X-eHealth (start in September 2020)

Other links
Care across borders
http://ec.europa.eu/digital-agenda/en/care-across-borders

CEF programme
https://ec.europa.eu/inea/en/connecting-europe-facility

eHealth interoperability – A European perspective
Gerald Cultot, European Commission, IHE World Summit 2016
Link: https://na.eventscloud.com/file_uploads/6e9ef758308046e4710acaf0e2fc912d_Gerald-Cultot_eHealth-interoperability-A-European-perspective.pdf

eHealth Studies: an Overview
http://ec.europa.eu/digital-agenda/en/ehealth-studies-overview

eHealth Network
http://ec.europa.eu/health/ehealth/policy/network/index_en.htm

eHealth strategies
http://www.ehealth-strategies.eu/

EU policy for eHealth
http://ec.europa.eu/digital-agenda/en/eu-policy-ehealth

European '1+ Million Genomes' Initiative
https://ec.europa.eu/digital-single-market/en/european-1-million-genomes-initiative

Horizon 2020
https://ec.europa.eu/programmes/horizon2020/en

Introduction to eHealth Digital Service Infrastructure
Natalia Zylinska-Puta, Policy Officer, European Commission DG SANTE
https://na.eventscloud.com/file_uploads/4dfa305ce2e3933a49ae8653a43e922b_Natalia-Zylinska-Puta_Introduction-to-eHealth-Digital-Service-Infrastructure.pdf

mHealth
http://ec.europa.eu/digital-agenda/en/mhealth

Nictiz is the independent Dutch centre of expertise for electronic exchange of health care information. The activities of Nictiz include the targeted development and management of information standards at the request of and in partnership with the stakeholders in healthcare. Nictiz advises these parties on all aspects of information exchange and identifies (future) national and international developments.

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