research

Observatoire social européen

paper

Cross-border telemedicine: practices and challenges

Sherihane Bensemmane
and Rita Baeten

Cross-border telemedicine: practices and challenges

Sherihane Bensemmane and Rita Baeten
European Social Observatory

The OSE Working Paper Series takes the form of three different publications available in English or French. The 'Research Papers' are intended to disseminate results of objective research and analysis. The 'Briefing Papers' contain readily accessible and regular information on a variety of topics. The 'Opinion Papers' consist of concise policy-oriented opinions and recommendations for policymakers.

Table of contents

Executive summary

Telemedicine is the provision of healthcare services through the use of information and communication technology (ICT) in situations where the health professional and the patient — or two health professionals — are not in the same location. Through telemedicine healthcare is provided at a distance, and this thus opens the door for the provision of healthcare by a health professional residing in a country other than that of the patient.

Little is known about the cross-border provision of telemedicine, and in particular about the involvement of Belgian providers and patients alike in this relatively new phenomenon. The present report addresses this gap in our understanding by mapping a) the different forms of cross-border telemedicine practices involving Belgian health professionals and patients; and b) the kinds of obstacles the actors involved encounter and the ways in which these are addressed. We collected our data in two ways: first through desk research and second through semi-structured interviews with key stakeholders.

We distinguish between telemedicine within national systems and in cross-border practices. Our findings suggest that currently, the implementation of telemedicine as a common practice within national contexts is limited, in Belgium as well as in other European countries. Most existing initiatives are pilot projects. And yet, some EU countries have recently incorporated some forms of telemedicine into their health systems. The main aim of such policies is to address the lack of healthcare services in remote areas and the shortage of health professionals in some regions. The emergence of mobile health applications and the potential thereof are drivers for the deployment of telemedicine services in public systems. It remains unclear, however, how successful these policy developments will be in practice and to what extent patients and professionals will really use them.

Cross-border telemedicine practices are even rarer, both in Belgium and other European countries, and almost exclusively take the form of tele-expertise. Tele-expertise happens between two or more professionals, without the patient's presence. It includes tele-diagnostic acts and second opinions. Belgian health professionals are involved in initiatives providing tele-expertise to patients abroad. These services are provided on a commercial basis, in an academic setting or with a 'humanitarian' perspective (e.g. between Belgium and developing countries). Tele-expertise mostly happens informally: physicians call on their personal and professional networks. More formal and therefore traceable practices are only now beginning to emerge, within recently-established networks. Cross-border telemedicine is also often used to address a lack of adequately qualified professionals, in particular in rural areas. This may explain why we only found a few practices importing telemedicine services into Belgium, mainly providing tele-expertise for highly specialized care. Generally speaking, there are no shortages

in healthcare supply in Belgium, in particular not for the usual services provided through telemedicine, such as medical-technical acts. For specific highly specialized medical care and care for rare diseases, however, the most suitable expertise may be available abroad.

While lack of trust is the main obstacle to the use of telemedicine, this is even more so in a cross-border setting. Guarantees as to the qualifications and quality of the health professionals providing the telemedicine, the safety and reliability of the devices used, and the protection of the data are often considered insufficient. This also explains why much tele-expertise occurs informally, between professionals who know and trust each other. Many issues exist with regard to data protection. Patient data may be sent over non-secured networks, it is not common practice to request the patient's consent to share the data, and the consultation of the tele-expert is usually not documented in the patient's medical file. Most obstacles to the use of telemedicine apply to both the national and cross-border contexts, although the latter adds further challenges, in particular because it implies interaction between different jurisdictions and health systems.

Several players, such as medical devices companies and ICT developers, have an interest in the deployment of telemedicine. The dominant businesses overlook data protection and ownership rules. Financial drivers may encourage health professionals to engage in these practices. However, most of the practices we found happened on a voluntary basis, in academic settings, and the health professionals involved were more interested in enhancing their knowledge, expertise and reputation.

In our assessment, cross-border telemedicine for Belgian patients will most likely remain a rather limited phenomenon. Telemedicine may, nevertheless, have an added value in some specific circumstances. In particular, it is useful where specific, highly specialised expertise is not available domestically, or for the treatment of complex cases and rare diseases, which require a pooling of human resources and multidisciplinary consultation. With a view to protecting patients' rights, robust guarantees are needed on the safety, quality and reliability of the tools used, the protection of data and the quality of the care provided. The report provides a number of policy recommendations to this effect.

1. Introduction [1]

Telemedicine is the provision of healthcare services through the use of information and communication technology (ICT), in situations where the health professional and the patient (or two health professionals) are not in the same location (European Commission 2008a). While the provision of telemedicine has been part of the EU level discussion on 'digital health and care' (eHealth) for more than a decade now, the potential of healthcare services provided at a distance has become clearer since the rapid expansion of mobile health applications. The term 'mobile health' (mHealth) covers medical and public health practice supported by mobile devices. According to the European Commission, over 100,000 mHealth apps are currently available on the market [2]. Many or even most of these apps have not been developed with a view to using them in the therapeutic relationship between a health professional and a patient, but they provide a broad range of possibilities for self-monitoring of physical and mental parameters and giving automated personalised information and advice. Many can, therefore, potentially also be used in a therapeutic relationship.

In Belgium, also, the debate on the use of ICT in the provision of healthcare has been boosted through the expansion of the mHealth apps market. While the initial Belgian action plan on eHealth, adopted in 2013, did not refer to telemedicine, it was updated in 2015 to include an Action Point on mHealth.

The discussion on the cross-border provision of telemedicine services was even more abstract. It was part of European Union (EU) discussions on the application of the free movement provisions to healthcare. However, this debate was not related to the actual provision of cross-border telemedicine. The much-debated EU Directive on patients' rights in cross-border healthcare (hereafter: the cross-border care Directive) [3], which became applicable in 2013, clarified the conditions under which a patient may travel to another EU country to receive medical care and the reimbursement of the care received. The inclusion of the reimbursement of cross-border telemedicine in the scope of application of this Directive barely, however, provoked any discussion. This is all the more surprising since this Directive applied the controversial country-of-origin principle to the provision of telemedicine. Thus, while, as a

---

2. European Commission website: http://europa.eu/rapid/press-release_IP-14-394_en.htm [last visited 15/10/2018].
3. Directive 2011/24/EU of 9 March 2011 on the application of patients' rights in cross-border healthcare, OJ L 88, 04/04/2011, p. 45–65.

general rule, the legal framework of the Member State where the care is provided to the patient applies to cross-border care, in the case of telemedicine, the applicable legislation is that of the Member State where the healthcare provider is established.

Little is known about the involvement of Belgian providers and patients alike in cross-border telemedicine. Do Belgian providers provide care for patients in other countries? Do Belgian patients receive care from providers established abroad through telemedicine? With our research, which we carried out at the request of the Belgian National Institute for Health and Disability Insurance (NIHDI ([4])), we intend to explore this phenomenon. We want to find out whether Belgian actors are involved in the provision of cross-border telemedicine and, if so, in what ways. We also want to explore the funding and quality arrangements that apply to this type of care, and to list the main problems encountered in relation to the provision of cross-border telemedicine.

In this Research paper we first describe our research questions and methodology (Section 2). Then we define the different forms of telemedicine (Section 3). Next, we discuss the policy initiatives related to e-health relevant for (cross-border) telemedicine, at both EU and national level (Section 4). Section 5 gives an overview of the different legal frameworks applicable to (cross-border) telemedicine. Section 6 reviews the implementation of telemedicine practices in European countries and beyond. Section 7 provides an overview of the (cross-border) telemedicine practices involving Belgian actors, while Section 8 provides a transversal analysis of these initiatives. Finally, Section 9 discusses the key findings and provides policy recommendations.

2.   Research questions and methodology

Our research aims to map the current practices with regard to cross-border telemedicine in Belgium. In particular, we aim to answer the following research questions:

- Are telemedicine services **exported**? In other words, we aim to find out whether Belgian health professionals, hospitals or other healthcare providers provide healthcare services at a distance for patients abroad; and if so, in which sectors this occurs, in which countries the healthcare is provided and how this healthcare is funded;

---

4.   *Rijksinstituut voor Ziekte- en Invaliditeitsverzekering (RIZIV)/ Institut national d'assurance maladie-invalidité (INAMI).*

- Are telemedicine services are **imported?** In other words, whether foreign telemedicine providers provide care to patients in Belgium. If so, we want to find out which sectors are involved, how these practices happen in practice and how the services are funded;

- Which kinds of problems do the actors involved encounter, how are those resolved and which **factors hinder or facilitate cross-border telemedicine practices**?

- What **are the expected future developments** in this field?

To answer these research questions, we first need to understand the different legal and policy frameworks applicable to (cross-border) telemedicine services in Belgium and second, to map which forms of telemedicine exist, how common they are and in which fields of healthcare and in which disciplines telemedicine practices are currently implemented.

We collected our data in two ways: first through desk research, second through interviews with key stakeholders.

In our desk research we looked at both academic and 'grey' literature, to give us an idea of existing (cross-border) telemedicine practices. In terms of scientific publications, we searched PubMed (a free web-based interface for searching MEDLINE, created by the US National Library of Medicine). We used search terms such as: 'telemedicine', 'telemed*', 'cross-border', 'remote care', 'teleconsultation', 'remote consultation', 'telemonitoring', 'tele-expertise', 'telehealth' and 'digital health'. Furthermore, we examined policy and legal documents at EU and national level to provide us with an overview of the different policy and legal frameworks. This includes the websites of the World Health Organisation (WHO), the European Commission and national authorities.

Furthermore, we carried out desk research to identify telemedicine practices involving Belgian healthcare providers or patients. We used Google Navigator for a broad search for telemedicine providers. In order to investigate telemedicine clinical trials involving Belgian institutions, we searched in two international clinical trial registry websites: www.clinicaltrialregister.eu and www.clinicaltrial.gov. We used as keywords for the search: 'telemedicine' OR 'teleconsultation' OR 'telemonitoring' OR 'tele-expertise' OR 'telecardiology' OR 'telesurgery' OR 'mHealth'.

The desk research allowed us:
- to understand the **context** of telemedicine;
- to develop an **overview** of the several forms of telemedicine and practices both in Belgium and at international level;
- to identify the **main players**;

- to **collect data** about telemedicine practices and legal frameworks.

To better understand how (cross-border) telemedicine practices are implemented in practice in Belgium, we conducted six semi-structured face-to-face interviews with twelve key stakeholders, involved in policies on telemedicine or in telemedicine practices (see Annex 1 for interview details). Interviewees were selected with a view to covering a wide range of perspectives, and included public authorities and healthcare providers involved in both commercial and not-for-profit cross-border telemedicine practices. We produced a specific interview grid for each interview. We also tried to obtain an interview with a health professional working in a commercial company involved in cross-border telemedicine, but this was unsuccessful. We recorded and fully transcribed each of the interviews. Interviewees also provided additional background documents and data. To process our data, we coded the interviews manually. Based on this, we carried out a qualitative analysis.

Additionally, we participated, as observers, in an evaluation session on pilot projects testing mobile health applications in the context of the Belgian national eHealth action plan (AP19 projects, see Section 4), held in February 2018. We drafted a summary of the key findings, with a focus on the opportunities and challenges emerging from pilot projects. We refer to these findings as 'evaluation AP19'.

3.   Definitions of different forms of telemedicine

Telemedicine is defined by the European Commission (2008a) as 'the provision of health care services, through the use of ICT, in situations where the health professional and the patient (or two health professionals) are not in the same location. It involves secure transmission of medical data and information, through text, sound, images or other forms needed for the prevention, diagnosis, treatment and follow-up of patients'.

Telemedicine is part of **eHealth**. The European Commission refers to 'eHealth' as 'digital health and care', and defines it as 'tools and services that use information and communication technologies (ICTs) to improve prevention, diagnosis, treatment, monitoring and management of health and lifestyle' ([5]). Besides telemedicine, the term includes, for instance, eHealth platforms, digital prescriptions, information systems and electronic health records (EHR).

---

5.   European Commission, eHealth: Digital health and care.
     https://ec.europa.eu/health/ehealth/overview_en [last visited 06/03/2019].

These tools and services are not regarded as telemedicine and are therefore not discussed in this paper.

Telemedicine can include a broad range of services, and it is therefore important to develop a terminology enabling us to describe the different existing telemedicine practices (World Health Organization 2016b; World Health Organization 2010; Venot *et al.* 2014). For our analysis, we distinguish between four forms of telemedicine services: teleconsultation, tele-expertise, telemonitoring and tele-assistance.

1. **Teleconsultation** ([6]) occurs between a health professional and a patient. It is a therapeutic or medical act carried out remotely, with or without the presence of another health professional next to the patient.

2. **Tele-expertise** ([7]) happens between two or more professionals, without the patient's presence. It includes diagnostic acts and second opinions. In both practices (teleconsultation and tele-expertise), the output can be a diagnosis, in which case we talk about *telediagnostics* (World Health Organization 2016b). A (tele-) diagnosis happens when a physician identifies the causes of a patient's symptoms and the nature of his disease or health problem.

3. To enable follow-up or integrated care, **telemonitoring** can be used. This happens when health professionals remotely check and monitor the data of a patient. In this case, data are collected outside a hospital setting, by the patient himself/herself, by another health professional, or automatically through a monitoring device.

4. **Tele-assistance** ([8]) is a practice occurring when a physician remotely guides (or performs) a medical act, for instance a medical procedure such as imaging or surgery. It can occur between two or more professionals or between a health professional and a third person not identified as a health professional. This can happen when a health professional remotely provides assistance to a third person present with the patient in emergency cases. For instance, a physician can allow a third person to perform a cardiopulmonary resuscitation act with his/her remote assistance.

Telemedicine can involve what is called a **requesting physician** or healthcare provider. This is a health professional at the bedside or in a therapeutic relationship with a patient, who contacts a peer professional in the context of telemedicine. It has to be distinguished from a

---

6. Own elaboration, based on the definition of teleconsultation in: Décret n° 2010-1229 du 19 octobre 2010 relatif à la télémédecine (France) and (World Health Organization 2010). JORF n°0245, 21/10/2010.
7. Own elaboration, based on the definition of tele-expertise in: Décret n° 2010-1229, op. cit.
8. Own elaboration, based on Ministère de la Santé et des Sports, France (Simon and Acker 2008).

referring physician, who redirects his/her patient to another specialist health professional for a consultation or teleconsultation. A health professional performing a teleconsultation is called a **teleconsulting health professional** for the purpose of this paper. In the case of tele-expertise, a requesting physician will ask for expertise from another physician, called the **tele-expert**.

In the literature, we find abundant terminology surrounding telemedicine, including teleradiology, telepsychiatry, teledermatology and tele-physiopathology. These terms refer to medical specialties where telemedicine can occur. For instance, in psychiatry, both teleconsultation and tele-expertise can be used, and these practices may be included in the term telepsychiatry.

Mobile health (**mHealth**) is closely linked to telemedicine. According to the European Commission, this term covers medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices. It furthermore includes applications (hereafter 'apps') such as lifestyle and wellbeing apps that may connect to medical devices or sensors (e.g. bracelets or watches), as well as personal guidance systems, health information and medication reminders provided by text and telemedicine provided wirelessly (European Commission 2014b). mHealth can be considered as telemedicine if it involves the provision of health services by health professionals at a distance. In practice, telemedicine practices through mHealth mostly relate to tele-monitoring, teleconsultation or tele-assistance.

As shown in Figure 1, all forms of telemedicine as well as mHealth are part of eHealth. Telemonitoring, tele-assistance, teleconsultation and tele-expertise are mutually exclusive.

Figure 1:   the various forms of telemedicine within eHealth
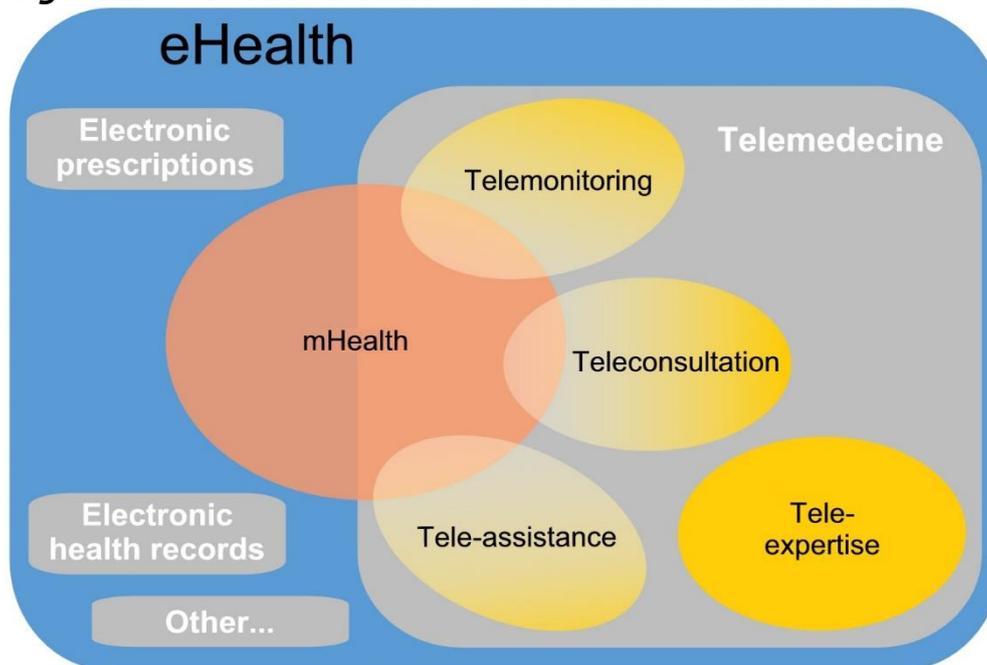
Source: authors' own elaboration.

4.   Policy frameworks on eHealth and telemedicine

In this Section we describe the aspects of European and Belgian eHealth policies that are relevant to telemedicine.

4.1 EU-level eHealth and telemedicine policies

For almost 15 years now, eHealth has been high on the EU policy agenda. It is part of the Digital Agenda for Europe, one of the seven Flagships of the Europe 2020 Strategy, which set objectives for the growth of the European Union by 2020. The Digital Agenda is designed to better exploit the potential of ICTs in order to foster innovation, economic growth and progress. eHealth was subsequently included in the 2015 Digital Single Market (DSM), aiming to enhance the use of digital technology ([9]).

Two action plans and several other Commission documents provided roadmaps for policy action at national and EU level. The Council of the EU provided the Commission with the necessary mandates to take action in this field (Council of the European Union 2004; Council

---

9.   eHealth: Digital health and care https://ec.europa.eu/health/eHealth/overview_en [last visited 18/09/2018].

of the European Union 2009; Council of the European Union 2017). Commission action mainly focused on supporting Member States, ensuring interoperability of eHealth solutions and disseminating and reinforcing eHealth practices (European Commission 2004; European Commission 2012a). The cross-border care Directive provided further tools to promote eHealth. Telemedicine is part of most of these policy initiatives on eHealth. In the following sections, we will discuss the relevant aspects of these policy initiatives.

The first eHealth action plan, adopted in 2004, urged Member States to develop a roadmap for eHealth, to set targets for the interoperability and the use of electronic health records, and to address issues such as the reimbursement of eHealth services. According to the action plan, the majority of European health organisations and health regions should be able to provide online services such as teleconsultation, e-prescription, e-referral, telemonitoring and telecare by the end of 2008 (European Commission 2004).

In 2008, the Commission issued a Communication stressing the role that telemedicine — and in particular telemonitoring and teleradiology — can play in the management of chronic diseases and care for the elderly. The document outlined a roadmap for implementation, between 2008 and 2011, of a series of initiatives aiming to build confidence in telemedicine, to clarify the legal framework, to solve technical issues and facilitate market development. It requested Member States to investigate their needs for telemedicine and to assess their regulations impacting the practice, in order to create suitable legislation at national level. The EU would support Member States' initiatives and foster collaboration between them (European Commission 2008a). In a follow-up, the Commission published a document on the applicability of the existing EU legal framework to telemedicine services (European Commission 2012b).

In the meantime, the cross-border care Directive (2011/24/EU) clarified the legal framework for patients to be reimbursed for cross-border healthcare, including for healthcare provided from a distance, i.e. telemedicine (See Section 5). The Directive also established an eHealth network to boost the interoperability of eHealth solutions. It is a voluntary network made up of representatives from national health authorities. A Joint Action was set up to support the eHealth network ([10]). The eHealth Network has adopted guidelines on minimum patient summary datasets for electronic exchange, and on e-prescriptions (eHealth Network 2014; European Commission 2013).

---

10. Joint Action to support the eHealth Network http://jasehn.eu/index.php/participants/ [last visited 16/10/2018].

Furthermore, the Directive provided the legal basis for the establishment of European Reference Networks (ERNs) of centres of excellence dealing with rare or complex diseases. In 2016, the Commission announced its intention to support Member States in the development of cross-border eHealth services, in particular telemedicine and tele-monitoring solutions, in connection with treatments provided by European Reference Networks (European Commission 2016).

Interoperability of eHealth solutions has been on the EU policy agenda since the 2004 eHealth action Plan. In 2008 the Commission published a Recommendation on cross-border interoperability of electronic health record systems (European Commission 2008b). A refined eHealth European Interoperability Framework (ReEIF), adopted by the eHealth Network in 2015, provides a common framework of terms and methodologies (eHealth Network 2015). In early 2018 the Commission published a recommendation on a European electronic health record exchange format. The framework includes (a) a set of principles that should govern access to and exchange of electronic health records across borders in the Union; (b) a set of common technical specifications for the cross-border exchange of data in certain health information domains; (c) a process to take forward the further elaboration of a European electronic health record exchange format. The recommendation proposes that Member States extend the electronic health records to laboratory tests, medical discharge reports and images and imaging reports (European Commission 2019).

Targeted funding to support research and innovation in digital health and care has been provided under the EU Research programmes (7th European Framework Programme (FP7) and Horizon 2020). Horizon 2020 funding included telemonitoring initiatives ([11]). The Connecting Europe Facility, a key EU funding instrument, is financing an EU digital infrastructure for eHealth and supports the building of infrastructure for cross-border exchange of patient summaries and electronic prescriptions.

Given the fast-growing uptake of tablets and smartphones, increasing attention has been paid to mobile health applications (mHealth). mHealth may include telemedicine services. The 2012-2020 European Commission Action Plan on eHealth had a special focus on mHealth (European Commission 2012a). In a follow-up, a broad stakeholder consultation on existing barriers and issues related to mHealth was launched in 2014, with the aim of identifying the future policy agenda in this domain (European Commission 2014b). The Commission published a Staff Working Document providing a non-exhaustive description of EU legislation, applicable

---

11. For instance, the RITMOCORE consortium, a group that works together to hire ICT services and solutions for comprehensive and integrated care management of patients using pacemakers http://www.ritmocore-ppi.eu/ [last visited 20/09/2018].

to lifestyle and wellbeing apps, with the aim of providing legal guidance to app developers, medical device manufacturers, digital distribution platforms, etc. (European Commission 2014a).

In a Communication in April 2018, the Commission highlights the disparity among Member States regarding the use of eHealth and the struggle to develop practices from pilot project to routine practices. The Commission announced that it will support local authorities, increase funding to support implementation of eHealth practices and foster collaboration and the sharing of knowledge (European Commission 2018). Three pillars were identified:
- Secure data access and sharing;
- Connecting and sharing health data for research, faster diagnosis and improved health;
- Strengthening citizen empowerment and individual care through digital services.

4.2 Belgian eHealth policies

Belgium has had an eHealth national strategy since 2013, but eHealth was already on the policy agenda prior to this. In 2008, a federal eHealth platform was set up as a public institution ([12]). The platform aims to promote and support exchange of data between all actors in healthcare by providing mutual electronic services to organise secure exchange of health data, determining standards of ICT use in healthcare settings and improving interoperability ([13]). The platform is used as a meta-hub. It connects the different regional exchange networks, where general practitioners (GPs) and specialists can share health data electronically and in a secure way, both in a hospital and in private practice: hubs are used by the hospitals, and 'health vaults' by the general practitioners. The following regional networks currently exist: the Hub Brussels Health Network (ABRUMET) and the health vault BruSafe in the Brussels region; the Réseau Santé Wallon (RSW), which acts both as a hub and a health vault in the Walloon Region; and the HUBs Collaborative Care Platform (CoZo) and Flemish Hospital Network KU Leuven (VZN KUL), as well as the health vault Vitalink in the Flemish Region.

Caregivers can thus consult the available documents about a patient, no matter where they are stored. Patients can also consult their own data. A physician only needs to consult one hub to receive the information from all hubs. The patient has to give informed consent for the exchange of his patient file and medical data between the health professionals with whom he has a therapeutic relationship. The physician needs to have a therapeutic relationship with the

---

12. Law of 21 August 2008, Loi relative à l'institution et à l'organisation de la plate-forme eHealth, Moniteur Belge 13/10/2008.
13. EHealth platform website https://www.eHealth.fgov.be/eHealthplatform/fr/taches [last visited 15/10/2018].

patient and to be able to justify consultation of the data. The use of the platform is voluntary and the platform does not require any specific hospital information system; the exchange of data only needs to be possible (interview 4).

The path towards implementation of the eHealth platform was not straightforward. It was preceded by BeHealth (Sénat de Belgique 2005), which was incorporated into law in 2006, but never implemented ([14]). The main difference between the BeHealth platform and the eHealth platform is that the current eHealth platform manages the exchange of data, rather than storing the data themselves. The eHealth platform is thus less centralized (Chambre des représentants de Belgique 2008).

A national eHealth action plan (2013-2018), which included eighteen action points on the implementation of ICT solutions in healthcare, was adopted and agreed between the different governance levels in 2013 and, given the speed of technological developments, was updated with two additional action points in 2015 (eHealth action plan/*e-Santé plan d'actions 2015-2018*) ([15]) ([16]). While the initial action plan did not cover telemedicine, the 2015-updated plan included an Action Point 19 (AP19) on mobile health (mHealth). mHealth covers medical and public health practices supported by mobile devices. This Action Point aimed to create and coordinate a framework to integrate mHealth applications legally, financially and organisationally into the health system. A call for proposals was addressed to Belgian stakeholders interested in using mobile health applications in healthcare provision. Out of 98 applications, 24 pilot projects were selected, proposed by various actors in the healthcare sector, including sickness funds, hospitals, home care services and doctors' associations. They received funding for a six-month period during 2017, based on a convention with the NIHDI. The aim of the pilots was to help to create a framework to implement mHealth in routine practice, to highlight areas where challenges exist and improvements are possible. Projects focused majorly on mental health, stroke, cardiovascular diseases, diabetes and chronic pain. The selection and evaluation of these pilot projects was carried out by experts from the NIHDI, the Federal Agency for Medicines and Health Products (FAMHP) ([17]), the Belgian Public Federal

---

14. Art. 4, Law of 27 December 2006, Loi portant des dispositions diverses (I), Moniteur Belge 28/12/2006.
15. Esanté website: http://www.plan-esante.be/ [last visited 12/12/2018].
16. In January 2019, the Interministerial Conference on Public Health approved a new eHealth Action Plan 2019-2021, which does not specifically cover telemedicine or mHealth: https://www.ehealth.fgov.be/fr/esante/roadmap-30/roadmap-30 [last visited 02/10/2019].
17. *Federaal agentschap voor geneesmiddelen en gezondheidsproducten (FAGG)/ Agence fédérale des médicaments et des produits de santé (AFMPS).*

Service (SPF) Health ([18]), and the eHealth platform ([19]). The projects were evaluated in February 2018 and received detailed feedback.

Based on this evaluation, an assessment and validation system for mHealth apps was set up. The assessment process consists of three stages, and is carried out by an entity which includes representatives of public authorities, health providers and industry ([20]). In a first stage, the quality of the app itself is checked in terms of technology, measurements and data protection. All apps must comply with the EU medical devices regulations and bear CE marking (i.e. the app has to be in conformity with EU health, safety, and environmental protection standards). In a second stage the interoperability of the app, the links to basic eHealth platform services and the implementation of sufficient security measures are checked. The last stage of approval concerns the cost-effectiveness of the app and its demonstrated clinical and health-economic advantages. For the apps that have completed this third stage, the NIHDI is currently developing a financing procedure. The applications satisfying the requirements are published on the national platform, mHealthBELGIUM ([21]).

---

18. Federal Public Service Health, Food Chain Safety and Environment/*SPF Santé Publique, Sécurité de la chaine alimentaire et Environnement/FOD Volksgezondheid, Veiligheid van de voedselketen en Leefmilieu.*
19. NIHDI website: http://www.riziv.fgov.be/fr/themes/qualite-soins/esante/Pages/mobileHealth.aspx#.Wn3KRCXOXIU [last visited 28/08/2018].
20. The MHealth Belgium platform is supported by the NIHDI, the SPF Health, AFMPS, the eHealth platform, as well as the industry federations Agoria and beMedTech.
21. MHhealth Belgium http://mhealthbelgium.be/en/home-3/ [last visited 02/10/2019].

5.   The EU and Belgian legal frameworks applicable to telemedicine

The provision of telemedicine implies three aspects: (a) the provision of healthcare; (b) the transmission of medical data and information and (c) the use of ICT. It thus requires compliance with legal frameworks on each of these aspects. This section first discusses the EU and Belgian legal frameworks applicable to the telemedicine act as a (healthcare and information society) service. Second, it considers the legislation applicable to the data collected and transferred for telemedicine and the protection of the data subjects. Third, it explores the legislation on the devices used for the provision of telemedicine. Fourth, it discusses the legal frameworks on health professional liability and finally, patients' rights.

5.1 The Provision of telemedicine services

Since telemedicine is the provision of healthcare services at a distance, including in another jurisdiction, in another EU Member State or beyond, it falls within the scope of the **EU provisions** on freedom to provide services of the Treaty on the Functioning of the European Union (TFEU) (Art. 56). As a consequence, citizens have the freedom to seek and receive telemedicine services in another EU Member State. Any obstacle to the freedom to provide telemedicine services across borders is prohibited, unless it is justified by an imperative reason to protect a public interest objective, for example to protect public health. Such justified hurdles may not exceed what is objectively necessary to protect the public interest objective, and it must not be possible to achieve the same result by a less restrictive measure. Administrative hurdles and those involving reimbursement may be obstacles in this regard (European Commission 2012b).

The cross-border care Directive (Directive 2011/24/EU) aimed to provide legal clarity on the application of the Treaty provisions on the free movement of services to patients wishing to receive reimbursement for care obtained in an EU Member State other than the Member State where they are covered for healthcare costs. The rules on reimbursement for cross-border care defined in this Directive also apply to telemedicine services. The Directive states that, in principle, the Member State where a patient is covered for healthcare has to reimburse the costs of cross-border healthcare if the healthcare in question is among the benefits to which the insured person is entitled in his Member State of affiliation. The Member State of affiliation may impose on an insured person seeking reimbursement of the costs of cross-border healthcare the same conditions, eligibility criteria and regulatory and administrative formalities as it would impose if this healthcare were provided in its territory (Art. 7).

It should nevertheless be noted that the way in which the cross-border care Directive should apply to telemedicine services remains unclear. In its report on the operation of Directive 2011/24/EU in 2015 (European Commission, 2015), the European Commission provides the example of consultations with general practitioners at a distance, which are reimbursed in some Member States, whilst not in others. If a patient from a Member State where such consultations are not provided or funded has a consultation via telemedicine with a GP in a Member State where such consultations are provided in this way, it is not clear whether the Member State of affiliation may, in such a case, refuse reimbursement. The Commission suggested 'to consider whether and how the applicable rules (e.g. on applicable legislation; access to, and reimbursement for, treatment) need to be developed and clarified'.

Telemedicine is not only a healthcare service, it is also an information society service, since it is provided by electronic means. The eCommerce Directive ([22]) therefore also applies to telemedicine services if they are 'normally provided for remuneration, at a distance, by electronic means, at the individual request of a recipient of service' (Preamble 17). This Directive creates a legal framework to ensure the free movement of information society services. It sets information requirements for the service providers, rules on commercial communications, on contracts concluded by electronic means and on the liability of intermediary service providers. The eCommerce Directive was transposed into Belgian legislation in 2003 ([23]).

Both the cross-border care Directive and the eCommerce Directive apply the so-called 'country of origin principle', which means that the health professional providing telemedicine services has to comply with his/her country legislation and not the legislation of the country of the recipient, who may be another health professional or a patient. Indeed, the cross-border care Directive stipulates (Art. 3 (d)) that healthcare is considered to be provided, in the case of cross-border telemedicine, in the Member State where the healthcare provider is established, and the Member State where the service provider is established must ensure that the healthcare in question is provided in accordance with its legislation (Art. 4 (1)). Similarly, pursuant to the eCommerce Directive, the telemedicine provider has to comply with the legal requirements of the country of establishment. The Member State where telemedicine services are imported thus cannot impose its legislation on a health professional (Art. 3), nor can the doctor be required to obtain any authorization or license there (Raposo 2016). The telemedicine service provider has to render some information easily accessible to the recipients

22. Directive 200/31/EC of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the internal market, OJ L 178, 17/07/2000, p. 1.
23. Law of 11 March 2003, Loi sur certains aspects juridiques des services de la société de l'information, Moniteur Belge 17/03/2003.

of the service and to the public authorities. This includes his contact and identification details and, for regulated professions (which includes most of the health professions), information on the professional body with which he is registered, his professional title and a reference to the applicable professional rules in his Member State of establishment (Art. 5). Telemedicine providers may use commercial communications online, provided that they comply with the professional rules governing the independence, honour and dignity of the profession (Art. 8 (1)).

It should be noted that, in contrast to the two above-mentioned Directives, the Directive on the recognition of professional qualifications for regulated professions (Directive 2005/36/EC) ([24]), applies the so-called *'host Member State principle'*. According to this Directive, a healthcare provider who temporarily provides services in another Member State is subject to the professional rules - such as those concerning the definition of the profession, the use of titles and serious professional malpractice, as well as disciplinary provisions — which are applicable in the host Member State to professionals who pursue the same profession in that Member State. Strikingly, however, these provisions only apply where the health professional moves to the territory of the host Member State to pursue his professional activity, and as a consequence, this Directive does not apply to cross-border telemedicine services.

In **Belgium**, according to the National Medical Council (*Ordre des médecins – Orde der artsen*), services that do not involve a diagnosis, such as the remote monitoring of a patient's medical parameters (telemonitoring) or consultation between physicians on a specific patient (tele-expertise) may be authorised, subject to certain conditions (*Conseil national de l'Ordre des médecins 2015*). These conditions include: guarantees concerning the privacy of the patient, the possibility of checking the identity and the qualifications of the physician providing the tele-expertise, and guarantees on the safety and the reliability of the devices used for telemonitoring or mHealth.

Nevertheless, up until very recently, the Medical Council did not allow a doctor to make a diagnosis remotely, i.e. without a physical examination of the patient. In a revised advice issued on 21 September 2019, the Council opens the door to teleconsultation with a view to making a diagnosis and proposing a treatment, and to inclusion of such practices in the telemedicine act for the healthcare system. The advice establishes technical and functional quality and safety requirements. Teleconsultation can be considered if the doctor: (a) knows the patient; (b) has access to the medical information concerning her/him (medical file); and

---

24. Art. 5 (2) Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications, OJ L 255, 30/09/2005, p. 22–142.

(c) can guarantee the continuity of care. The medical condition must also allow care to be provided via teleconsultation (e.g. chronic illness) (Conseil national de l'Ordre des médecins 2019).

Teleconsultation is currently not reimbursable in Belgium, since the NIHDI nomenclature of health services ([25]) requires the physical presence of the physician with the patient ([26]), but the recently revised position of the National Medical Council may enable amendments to the legislation in this respect. The physical presence of a radiologist is also required when radiological examinations are performed. However, the radiologist can document the examination and draft the report remotely. Tele-radiology services can therefore be reimbursed by the health insurance system. The only difference with the standard provision of such acts is that the report is drafted remotely.

5.2 The transfer of data and data protection

Telemedicine requires the transfer, storage and processing of a patient's health data by electronic means. Health data are transferred between healthcare providers, information technology (IT) providers and patients. Given the sensitivity of personal health data, and in order to protect the patient and the confidentiality of the relationship between the patient and the health professionals treating him, it is important to guarantee confidentiality when health data are transferred, stored and processed. In particular, when data move across international borders, between different jurisdictions, the necessary guarantees should be provided at international level.

5.2.1 EU law on data protection

The current framework on protection of personal data is Regulation (EU) 2016/679, known as the General Data Protection Regulation (hereafter GDPR). It was adopted in 2016 and has been in force since 25 May 2018 ([27]). The Regulation deals with the protection of natural persons with regard to the processing of personal data and the free movement of such data.

---

25. The NIHDI nomenclature of health services classifies and encodes medical acts and defines the rates of reimbursement from the health insurance system.
26. Art. 1 § 4 et 4 bis, Arrêté royal du 25 juillet 1994, annexed to: Arrêté royal du 14 septembre 1984 établissant la nomenclature des prestations de santé en matière d'assurance obligatoire soins de santé et indemnités,
https://www.riziv.fgov.be/SiteCollectionDocuments/nomenclatureart01_20181201_01.pdf
[last visited 11/12/2018].
27. 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, OJ L 119/1 of 04/05/2016, p. 1–88.

The regulation aims at reducing the collection of data from consumers without their knowledge and without transparency.

The GDPR applies to the EU and European Free Trade Association (EFTA) countries (Iceland, Liechtenstein, Norway and Switzerland). It includes, furthermore, a process to determine if a third country provides sufficient data protection safeguards to allow data exchange with the EU ([28]).

Data have to be collected and processed for a specific, explicit and legitimate purpose. The integrity of the data (i.e. the data are not altered and are consistent and reliable), data confidentiality and protection have to be ensured by implementing 'appropriate technical and organisational measures' (Art. 5, recitals 39, 49 and 78, GDPR).

In general terms, the GDPR prohibits the processing of sensitive data such as health data, and allows this only if justified (Art. 9, GDPR). Health data can be processed for health-related and scientific purposes. However, as argued by den Exter (2017), there seems to be no comprehensive definition of 'health data'. In particular, it remains unclear whether and to what extent lifestyle and well-being information collected by health apps constitutes health data. Processing is justified where there is explicit consent by the data subject, or in the context of the doctor-patient treatment relationship (Ibid). In the latter case, no explicit consent is required, since a physician is bound by professional secrecy and data processing is considered a legitimate purpose as defined in Article 9. Still according to den Exter (2017), the deployment of health information to third persons (e.g. technical staff) does not fall under the treatment exemption and, therefore, requires explicit consent.

Member States may maintain or introduce further conditions and limitations with regard to the processing of genetic data, biometric data or data concerning health (Art. 9(4), GDPR). This may create differences between Member States and could be a challenge for cross-border telemedicine.

The GDPR regulates the reliability of the processor and controller of personal data (Art. 4). The *controller* is the person or entity which determines the purposes and means of the use and storage of the personal data, and which should specify the various usages and objectives of data processing. A hospital, a European Reference Network, the physician or mHealth platform could, for instance, be considered a controller. A *processor* is defined as a body which processes personal data on behalf of the controller. It is important to note that a Cloud or a

---

28. Art. 45, GDPR. Only a few countries have so far been recognized by the EU under this provision.

subcontractor can be considered as a processor. Usually, health data collected through mobile apps or a platform will be stored in a Cloud. A processor established in the EU has to be compliant with the GDPR, irrespective of the territory where the data are processed. If the processor is established in the United States (US), it has to be compliant with the EU-US privacy shield decision ([29]).

The controller has to keep a record of the compliance of all his processors with the Regulation. An internal or external Data Protection Officer (DPO), in charge of the compliance assessment, has to be appointed. When using personal data, the controller should be able to provide answers to the following questions to the data subject, and potentially to the public authorities:

- *Which data will be used*?
- *For which purpose will the data be used and/or stored*?
- *Where will the data be stored and in which format: anonymised, pseudo-anonymised or raw data* ([30])?
- *How long will the data be stored?*

Patients have to provide informed consent to process their personal data. They should receive enough information, explaining the purposes of the use of their data and allowing them to make their decision. Consent has to be explicitly asked for and signed and the consent has to be obtained without coercion. For example, if a data subject uses a website platform for teleconsultation, it cannot be assumed that, by using the website or using a particular product, the data subject agreed to any data processing. Furthermore, the consent is active. This means that if the purpose of the data collection changes, patients' consent has to be asked for again, and the data subject can restrict consent to only partial use.

Rights provided to patients or data subjects by the GDPR include ([31]):

- *Ownership* : the right to receive the personal data concerning them;
- *Portability* : the right to transmit those data to another controller without hindrance from the controller;

---

29. The EU-US privacy shield aims to protect EU citizens' data that are used by companies and transferred to the USA https://ec.europa.eu/info/law/law-topic/data-protection/data-transfers-outside-eu/eu-us-privacy-shield_en [last visited 28/09/2018].
30. Anonymisation is a process through which it becomes impossible to identify data; the data will be encoded in such a way that it will be impossible to identify the data subject to whom a set of data belongs. Pseudo-anonymisation makes the direct identification of the data subject impossible, but the data subject could be identified by linking the data through a secured identification key to the data set. The data are thus not identifiable, but neither are they anonymous. Art. 4, GDPR.
31. Art. 12 to 23, GDPR.

- *Transparency* : any action on the data, apart from those discussed and consented to beforehand, has to be shared with the data subject and new consent has to be obtained. Any third party involved has to be mentioned;
- *Access* : the right to access their data at any moment and to request their personal file from the controller;
- *Erasure* : the right to be forgotten. At any moment, an entity can be asked to delete the patient's file or specific data which the patient no longer wishes to share.

While it is compulsory for the controller to carry out a data protection impact assessment in specific cases involving a high risk to the rights of natural persons (Art. 35), this is not an obligation for personal data processed by health professionals (Recital 91).

Since telemedicine is usually internet-based, it is important to also comply with Directive 2002/58/EC ([32]) on the protection of privacy in electronic communications. The e-Privacy Directive focuses specifically on the processing of personal data for electronic communication services, and deals with aspects such as spam and cookies.

5.2.2 Belgian legislation on data protection

Since the GDPR is a regulation and not a directive, it is directly applicable, without transposition into national law. Nevertheless, to implement the GDPR a Data Protection Authority had to be set up. Such an Authority ([33]) (*Autorité de protection des données/ Gegevensbeschermingsautoriteit*) was recently set up as the guardian of the GDPR in Belgium ([34]). It is an independent federal legal entity that ensures that the basic principles of the protection of personal data are properly complied with. It replaced the Commission for the protection of Privacy ([35]), which previously ensured that personal data were used and processed in conformity with the law.

---

32. Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector. OJ L 201, 31/07/2002 p. 0037 – 0047, amended by Directive 2009/136/EC of the European Parliament and of the Council of 25 November 2009. OJ L 337, 18/12/2009, p. 11–36.
33. Data protection Authority website: https://www.autoriteprotectiondonnees.be/ [last visited 11/12/2018].
34. Law of 3 December 2017, Loi portant création de l'Autorité de protection des données. Moniteur Belge 10/01/2018 p. 989.
35. *Commission de la Protection de la Vie Privée/ Commissie voor de bescherming van de persoonlijke levenssfeer*.

A Law on the protection of natural persons with regard to the processing of personal data, adopted on 30 July 2018 ([36]), addresses the national specificities of the GDPR within the Belgian territory. This Framework Act, applicable since 5 September 2018, states that if a processor based in Belgium acts on behalf of a controller based in another EU Member State or EFTA country, the processor's duties and the laws applicable are those of the controller's country. This Act also specifies that personal data usage for scientific purposes is subject to fewer constraints, and may be subject to some exemptions (in accordance with Art. 89 GDPR) ([37]).

5.3 The use of devices: reliability and product safety

Telemedicine implies the use of various devices to collect data and communicate at a distance. This includes, for instance, patient monitoring devices measuring vital signals such as heart rate or breathing, devices transmitting data between patients and doctors or between health professionals, and software used to programme the monitoring. It is important that these devices are reliable and safe.

Most of the devices used in telemedicine fall within the scope of the EU legislation on medical devices ([38]). These directives lay down requirements on safety and performance of the device, with the aim of ensuring the protection of the health and safety of patients. Depending on the risk category of the device, requirements may be different. A CE mark denotes a formal statement by the manufacturer of compliance with the directives' essential requirements regarding safety and specified administrative requirements. This legislation, however, does not provide sufficient guarantees with regard to safety and reliability of the devices (Hantson 2019). Furthermore, the technical CE label does not provide evidence of clinical effectiveness, nor of the clinical safety and potential long-term adverse events in the patient populations concerned (Vinck *et al.* 2010). This seriously undermines any guarantee of reliability of the applications.

---

36. Law of 30 July 2018, Loi relative à la protection des personnes physiques à l'égard des traitements de données à caractère personnel. Moniteur Belge 05/09/2018, p. 68616.
37. Linklaters (law firm) website https://www.linklaters.com/en/insights/data-protected/data-protected---belgium published on November 2018 [last visited 15/11/2018].
38. Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, OJ L 189, 20/07/1990 p. 0017 – 0036; Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, OJ L 169, 12/07/1993 p. 0001 – 0043, Directive 98/79/EC of 27 October 1998 on in vitro diagnostic medical devices, OJ L 331, 07/12/1998 p. 0001 – 0037.

Art. 1 of Directive 93/42/EEC defines medical devices as:

> 'any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:
>
> - diagnosis, prevention, monitoring, treatment or alleviation of disease,
>
> - diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
>
> - investigation, replacement or modification of the anatomy or of a physiological process,
>
> - control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;'

Devices such as smart phones, software, or webcams, can be considered as a medical device if they are specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, for the benefit of individual patients. Health apps used as tools to support diagnosis or treatment (e.g. to monitor blood pressure), or to calculate the dosage of medication (e.g. insulin), will also have to comply with the regulations on medical devices. In practice, however, only a limited number of health apps bear a CE mark. Furthermore, as argued by den Exter (2017), the difference between wellness and medical apps becomes blurred when preventive and self-monitoring activities (fitness apps) are part of a treatment regime, and ambiguity in the classification may expose patients to unsafe products. In case of harm, the physician may face liability for using such an 'unregistered app'.

The European legislation on medical devices was transposed into Belgian law in 1999 ([39]). The existing Directives will be replaced by two new Regulations, adopted in 2017, which will be applicable respectively from May 2020 and May 2022 onwards ([40]). The new rules will impose tighter controls on high-risk devices such as implants. Controls will also be tightened on clinical trials as well as on the bodies that can approve the marketing of medical devices.

---

39. Royal Decree of 18 March 1999, relatif aux dispositifs médicaux. Moniteur Belge 14/04/1999.
40. 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, OJ L 117, 05/05/2017, p. 1–175, applicable from May 2020 onwards; Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, OJ L 117, 05/05/2017, p. 176–332, which will be applicable from May 2022 onwards.

Liability for defective products is regulated at EU level by Directive 85/374/EEC ([41]). Under this Directive, the producer will be held liable and has to pay compensation for damage resulting from a defect caused to persons or properties. If more than one person is liable for the same damage, joint liability is applicable. This means that the injured patient can claim full compensation for the damage from any one of the liable persons (European Commission 2012b).

5.4 Health Professional liability

Medical liability is regulated at national level. There are no European norms dealing with the substantive regime of medical/professional liability for damage caused by healthcare services, nor with the quality of care (Vinck *et al.* 2010; Raposo 2016). Directive 2011/24 on cross-border healthcare requires Member States to ensure that a system of professional liability insurance, or a similar guarantee, is in place (Art. 4, 2 (d)).

In case problems occur with the provision of telemedicine services, it is important to know in which Member State patients or requesting physicians can sue. According to the European Commission (European Commission 2012b), the patient always has the option of suing the professional in the Member State where the professional is domiciled. In many cases, (s)he may also be able to sue in the Member State of his own domicile if he so chooses. The relevant legislation is Regulation (EC) No 44/2001 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters ([42]), and the so-called 'Rome II' Regulation ([43]) (European Commission 2012b). For more details on this complex matter, we refer to the Commission Staff Working Document (European Commission 2012b). Box 1, taken from this Staff Working Document, presents an example of how these different legal frameworks may apply to cross-border telemedicine services.

---

41. Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, OJ L 210, 07/08/1985, p. 29–33 ('the defective products Directive').
42. Council Regulation (EC) No 44/2001 of 22 December 2000 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (Brussels I Regulation), OJ L 12, 16/01/2001, p. 1-23.
43. Regulation (EC) No 864/2007 of the European Parliament and of the Council of 11 July 2007 on the law applicable to non-contractual obligations (Rome II Regulation), OJ L 199, 31/07/2007, p. 40-49.

Box 1: Case study on health professional liability

Further to a persistent cough, patient X, who is affiliated to Country A's social security scheme, is asked by his general practitioner in his Member State to undergo chest x-ray tests. However, the hospital in Country A where the x-rays were taken has no lung radiologist ([44]) specialist on site to interpret the results. Using electronic means, images are thus sent to a teleradiologist established in a hospital in Country B, with whom the Country A hospital has a contractual relationship for the provision of such types of teleradiology services. The specialist in Country B is asked to deliver a medical opinion on the x-rays to support the medical doctor in Country A in his diagnosis of the patient's conditions.

The teleradiologist in Country B provides a consultation falling short of the expected medical standard, resulting in an incorrect diagnosis. This negatively impacts on the treatment decision prescribed by the treating doctor in Country A. Besides not addressing the patient's cough, the treatment provokes a worsening of the patient's conditions, raising an issue of medical negligence.

The telemedicine service is provided cross-border between two healthcare professionals located in two different EU Member States, which are bound by an established contractual relationship. The patient only has a contractual relationship with his healthcare provider in Country A. There is no contractual relationship between the patient and the teleradiologist in Country B.

Liability action against doctor in Country A introduced by patient X in Country A

As the patient and his doctor have their residence in Country A, there is no cross-border situation. Therefore, the Courts of Country A are competent and the law of this country will also apply.

Liability action introduced by patient X against Country B's teleradiologist

As there is no contract binding patient X and the radiologist from country B, the patient will have the option of suing in the MS of domicile of the teleradiologist ([45]), namely country B, or in the patient's Member State of residence, which is the one where the harmful event occurred ([46]). This means either where the negligence took place or where it caused harm, i.e. where it was acted on, namely country A. Whereas the law applicable will be the law of the country where the damage occurred ([47]).

Source: European Commission 2012b.

5.5 Patients' rights

Patients who have received cross-border telemedicine services are entitled to a written or electronic medical record of their treatment, and access to at least a copy of this record, in accordance with the EU Directive on cross-border healthcare (2011/24/EU) (Art. 4).

Also, under the Belgian patient's rights act ([48]) the patient has the right to direct access to his/her patient file and to a copy of it (Art. 9). It includes furthermore the right to information (Art. 7) and the right to free and informed consent (Art. 8). This implies that, in the case of

---

44. In the Commission document this was mistakenly formulated as a 'teleradiologist'.
45. Art. 2, the Brussels I Regulation.
46. Art. 5.3, Brussels I Regulation.
47. Art. 4.1, of Rome II Regulation.
48. Law of 22 August 2002, Loi relative aux droits du patient, Moniteur Belge 26/09/2002.

telemonitoring, the patient has to be clearly informed on the modalities and limitations of the system (Vinck *et al.* 2010).

6.   Telemedicine policies and practices: country examples

To understand the potential nature and scope of cross-border telemedicine, we first have to understand to what extent telemedicine practices are implemented in routine practice within countries. In this section we provide an overview of telemedicine policies and practices in European countries as well as in Asia, Africa, Canada and the US, based on examples provided in academic and grey literature. It shows that telemedicine in many countries is still at a pilot stage and often implemented to ensure access to care for patients in remote areas. The policies and practices in Belgium are discussed in respectively Section 4.1 and in Section 7.

In 2015 the WHO launched a survey on the status of eHealth in **125 countries worldwide**, questioning digital health experts and WHO staff in the various WHO regions. In this survey, telehealth was defined as the 'practice of medicine at a distance'. Respondents from 27 countries stated that they had a telehealth policy, and 43 reported that their eHealth policy covers telehealth even if no separate policies exist. Since 2006, there has been an increase in the number of telehealth-related policies established. 77% of the countries in the survey reported teleradiology programmes (tele-expertise or teleconsultation), teledermatology (46%) (tele-expertise or teleconsultation), telepathology (52%) (tele-expertise or teleconsultation) and telepsychiatry 34% (teleconsultation) and/or telemonitoring (47%). Teleradiology is the most developed field and telepsychiatry is one of the oldest. The majority of these programmes exist in a pilot phase at local or national level. Around 20% are set up at international level, half of which occur between countries within the same WHO-Region ([49]). The majority of respondents rated the lack of funding as a major impediment to the implementation of telemedicine (World Health Organization 2016b).

---

49. The WHO regions are: Africa, the Americas, South-East Asia, Europe, Eastern Mediterranean, Western Pacific http://www.who.int/about/regions/en/ [last visited 06/03/2019].

6.1 Telemedicine policies and practices in European Countries

A 2016 population survey carried out by Eurofound ([50]) revealed that 11% (13% in urban areas and 10% in rural areas) of the respondents had had a medical consultation over the phone or online over the last 12 months. Numbers were particularly high in some of the Nordic countries: Estonia (30%), Sweden (40%), Denmark (42%) and Finland (46%), but also in Croatia (26%). No distinction was made between phone consultations and teleconsultations (Ahrendt *et al.* 2017).

In **Denmark**, telemedicine is specifically targeted at patients with Chronic Obstructive Pulmonary Disease (COPD) who tend to have frequent visits to a clinic (Europe Economics 2019).

In **Estonia,** since March 2013, consultation of the family doctor with a specialist is reimbursed by the Estonian Health Insurance Fund (EHIF). The specialist provides his instructions for treatment (by e-mail or other means) and receives 68% of the normal rate for a face-to-face consultation (Kruus *et al.* 2015). Only limited use has been made of this practice (Lai *et al.* 2013; Kruus *et al.* 2015; Žmenja *et al.* 2017). Some national and cross-border projects exist (telepsychiatry and telemonitoring – pilot phase) but are not established as part of regular practice (Lai *et al.* 2013; World Health Organization 2016b).

Finland has had a telemedicine strategy since 1995. Teleradiology has become regular practice and is the main telemedicine act in Finland. Most district hospitals provide teleradiology and telelaboratory services and offer teleconsultation for primary healthcare centres. These activities are partially covered by the healthcare system and the budget of the healthcare centres. Other telemedicine services provided are telepsychiatry, tele-opthalmology, teledermatology and teledentistry. Most telemedicine projects, focusing on teleconsultation and telemonitoring, were funded by public funds and EU projects (Khatri *et al.* 2011).

In **Germany,** according to the professional codes, diagnoses and prescriptions have to be provided after a face-to-face meeting between the patient and the physician and after an examination. Teleconsultations are possible for follow-up purposes and have been eligible for financial compensation since 2017, as have tele-expertise services (Hantson, 2019). Since the ban on tele-therapy only applies if the practising physician is a member of the German medical

---

50. European Foundation for the Improvement of Living and Working Conditions, a tripartite EU agency.

association (*Bundesärztekammer*), it does not apply to telemedicine provided by health providers outside the territory (Europe Economics 2019). The government has provided considerable funding for large-scale randomised clinical trials to encourage telemedicine projects and to assess their effectiveness. In some regions, specific telemonitoring services are included in contracts for integrated care between health insurers and providers, or through funding by local authorities (Rojahn *et al.* 2016).

In **France**, teleconsultation has been reimbursed since 2018 at the same rate as a normal consultation, as long as there is a prior therapeutic relationship between the health professional and the patient. Tele-expertise has been funded since February 2019. Two levels of tele-expertise are defined, depending on the complexity of the telemedicine services provided. Reimbursement of level 1 (low difficulty) services is possible for a specialist providing his expertise up to four times per year per patient, at a tariff of €12 per act. Level 2 services, which can be provided up to two times a year at a tariff of €20, are applicable for patients with specific chronic conditions, for example patients with chronic pain or a chronic inflammatory disease. For tele-expertise, the tele-requesting physician will be paid €5 for level 1 tele-expertise and €10 for level 2, limited to €500 per year ([51]). Strikingly, only doctors who are allowed to provide services in France are authorized to perform telemedicine (Europe Economics 2019). The legislation aims at redressing regional inequalities in the availability of medical services. The deployment of telemonitoring projects for the improvement of health care pathways is encouraged and financially supported by the programme *Expérimentations de Télémédecine pour l'Amélioration des Parcours En Santé* (ETAPES) ([52]). In the region Franche-Comté, eight emergency departments used telemedicine services provided by the Centre Hospitalier Régional Universitaire de Besançon for cases involving neurological patients. Between 2002 and 2015, within this network, called the *Réseau Urgences Neurologiques de Franche-Comté*, 23 710 patients have been treated through teleconsultation and tele-expertise (Medeiros de Bustos *et al.* 2018).

In **Italy**, many telemedicine projects have been initiated but only a few were sustainable. Telemonitoring and teleradiology are considered established practices, while telepathology, teledermatology and telepsychiatry, in the form of teleconsultation and tele-expertise, exist as pilot projects or informal practices (World Health Organization 2016a). Telemonitoring pilot projects are being implemented at a regional level by the regional health authorities (*Azienda Sanitaria Locale, ASL*) (Rojahn *et al.* 2016).

---

52. ÉTAPES website : https://solidarites-sante.gouv.fr/soins-et-maladies/prises-en-charge-specialisees/telemedecine/article/etapes-experimentations-de-telemedecine-pour-l-amelioration-des-parcours-en [last visited 03/10/2019].

In the **Netherlands**, since 2019, it has been made easier for health care providers and health insurers to include digital consultations in funding agreements. For GPs it no longer matters how the doctor organizes the consultation with the patient: in the consultation room, by telephone, by e-mail or using other digital means. In specialist medical care it has become easier to fund remote monitoring of patients ([53]). Attempts have also been made to implement telemonitoring for heart failure and diabetes in Dutch hospitals (Kroneman *et al.* 2016; Faber *et al.* 2017).

In Norway most telemedicine services are available through projects. There is however a disparity between implementation by the Norwegian government and the actual use of telemedicine (Alami *et al.* 2018).

In **Portugal**, a national telehealth strategy and policy was implemented in 2013. One third of hospitals have offered telemedicine services since 2014 (Pina 2015; Dias 2017). Since 2013, the Health System administration has funded several telemonitoring projects. Local authorities have created a certification for teleconsultation. When a teleconsultation is required between a specialist and a patient, primary care units appoint a coordinator or the patient's own General Practitioner to assist during the consultation (Oliveira *et al.* 2014). More than half of hospitals use remote screening, particularly in the area of dermatology, and have carried out teleconsultations (The Portugal news 2019).

In the **United Kingdom**, telemonitoring is an established practice (World Health Organization 2016a). Remote diagnostics are also applied, whereby test results are sent to diagnostic labs in other jurisdictions (Europe Economics 2019). Since 2017, patients can consult with a general practitioner using an app that allows them to video-call the doctor. Through the app, the general practitioner can assess the symptoms, write a prescription and determine whether an in-person examination is necessary ([54]). In remote and rural areas in Scotland, a GP can advise a patient with the help of a local nurse at the patient's side, can prescribe medication, or send the patient to the hospital for further examination (World Health Organization 2016a; Border 2014).

Cross-border telemedicine practices, although limited, seem to exist mostly between adjacent countries. Most of the projects are EU-funded or Research and Development (R&D)

---

53. NZa verruimt mogelijkheden voor e-health : https://www.nza.nl/actueel/nieuws/2018/06/18/nza-verruimt-mogelijkheden-voor-e-health [last visited 03/10/2019].
54. GP online consultation systems fund https://www.england.nhs.uk/gp/gpfv/redesign/gpdp/online-consultations-systems-fund/ [last visited 18/02/2019].

oriented, to show the feasibility and cost-effectiveness of telemedicine practices or to suggest procedures (Belcher 2013).

6.2 Telemedicine practices outside the EU

In the **USA**, telemedicine services are widely used and are part of routine practice. Many commercial providers exist. Most common are teleconsultation practices. Policies are in place allowing telemedicine to be reimbursed through the Medicare program (Jahns 2017, Horton *et al.* 1014). Reimbursement is allowed when there is a proven shortage of health professionals in a rural setting or when the practice is part of a federal telemedicine project. Some insurance companies provide telemedicine, in particular teleconsultation, to their clients, whether or not the providers are based in the USA. Contrary to the EU, the US regulators require a remote doctor to be licensed or registered with the regulator in the patient's jurisdiction (Europe Economics 2019). Worth mentioning is also the virtual healthcare centre opened by the Mercy Hospital St. Louis (Missouri) in 2015 ([55]). The nurses and physicians involved use telemonitoring and teleconsultation to provide care to patients residing in various states. They also work with other hospitals as a back-up (Kahn *et al.* 2016; Allen 2017).

In **Canada** telemedicine practices are increasing and already common in some areas. For instance, telesurgery has been taking place since as early as 2003 between hospitals located at a distance of 400km from one another, thus linking urban and rural areas (Cazac and Radu 2014). Teleconsultation is also on the rise (Owens 2018).

In **India**, there are both public and private initiatives providing telemedicine, mostly teleconsultation and telemonitoring. Official standards have been created for telemedicine by the public authorities. Training on the use of telemedicine is organized for health professionals by the government and universities. Cross-border telemedicine services are provided to South Asia and Africa, mostly in the form of tele-expertise ([56]) (Mishra *et al.* 2009).

In **Iran**, some programmes exist, in pilot and starting phases, on telemonitoring and tele-expertise, mostly at national level (World Health Organization 2016b; Darvish and Far 2017).

---

55. Mercy virtual website http://www.mercyvirtual.net/how-mercy-is-using-technology-to-bring-health-care-to-the-patient/ [last visited 24/08/2018].
56. Ministry of Health and Family Welfare webpage on e-governance. https://mohfw.gov.in/about-us/departments/departments-health-and-family-welfare/e-health-telemedicine/e-governance [last visited 06/03/2019].

Since geographical access to healthcare services is often limited in **Africa**, telemedicine, and in particular mHealth applications, are often used to improve access to healthcare. mHealth applications are used in primary care, tele-ophthalmology, teleconsultation and tele-expertise (Wamala and Augustine 2013). Often, however, projects are privately funded and sustainability is a major issue (Kiberu *et al.* 2017). In South Africa, since 1998, there have been telemedicine programmes managed by the Ministry of Health. They mainly provide teleradiology, tele-ophthalmology, tele-ultrasound and telepathology services. At local level, mHealth applications are used for teleconsultation and tele-expertise (Wamala and Augustine 2013).

7. Overview of (cross-border) telemedicine practices in Belgium

In this section, we provide an overview of telemedicine initiatives involving Belgian healthcare providers and/or patients, with a focus on the (potential) cross-border provision of care. It is based on desk research and interviews with key stakeholders.

Most telemedicine projects in Belgium are at a pilot stage. We found 23 trials (see Annex 3 for further details) providing some form of telemedicine involving Belgian hospitals registered in the US registry on clinical trials ([57]) ([58]). Thirteen of them provide telemonitoring services, and four trials focus on telecardiology and involve at least one other European country, thus potentially providing some form of cross-border telemedicine (see Annex 3).

Pilot projects on mobile Health (mHealth) have been adopted under the national eHealth action plan and carried out over a 6-month period during 2017 (see Section 4 and Annex 2). Of the 24 selected projects, 21 involved telemedicine in the form of telemonitoring, sometimes combined with teleconsultation ([59]). None of these pilots involved cross-border provision of healthcare services, since the selection criteria required that the pilots were established in Belgium, involving Belgian healthcare professionals and addressing Belgian patients. It should nevertheless be noted that some of these projects used a platform established in another EU country or outside the EU - data were transferred through this platform, and sometimes data were stored in another country ([60]).

---

57. In the EU register (https://www.clinicaltrialsregister.eu/ [last visited 06/03/2019]), no telemedicine trials involving Belgian hospitals were mentioned.
58. US Database of clinical trials www.clinicaltrials.gov [last visited 06/03/2019]
59. Mobile Health dans le cadre du Plan d'actions e-santé : Projets pilotes. [last visited 6/03/2019]. https://www.riziv.fgov.be/fr/themes/qualite-soins/e-sante/Pages/mobile-health.aspx
60. The data from the Project 'Télé-assistance des patients BPCO sévères ' were stored in a Cloud in France (AirView system) and for the project 'e-Mental-Health: *zelf aan de slag*', the platform and data storage were in the Netherlands (Cf. Annex 2). Self-user in line used a device provided by Abbott and data were stored in a Cloud in the USA (interview 4, Annex 2).

Several other initiatives are being implemented. Table 1 provides a summary of established initiatives providing telemedicine services, involving Belgian healthcare providers and/or Belgian patients, whose services include or at least aim to include cross-border telemedicine. Although most of these initiatives have started, their activity level is often unclear and their functioning is sometimes unstable, with partners, funding schemes, their website, etc. changing frequently.

Table 1: *Overview of telemedicine providers involving Belgian actors, potentially providing cross-border care*

	Initiators	Objectives and activities	Payment for the care service	Type of arrangement	Funding of the platform and investment costs	Providers	Users/clients
ANDRAL - France	*Groupe Francophone d'Hématologie Cellulaire*	Provide support to medical biologists through tele-expertise	No	Charter signed by users and reviewers through the platform	Project grant from regional public authorities, a sickness fund and an NGO in France	Experts, medical biologist, from France and one from Belgium	Medical biologists from France, Belgium, North Africa, Congo, etc.
SODIRAY – Belgium ([61])	Belgian independent radiologists	Provide teleradiology support to hospitals with a shortage of radiologists, through tele-expertise	Service fee paid by the user	Contract between the radiologist from SODIRAY and the hospital of the requesting healthcare professional	No	Belgian certified hospital radiologists	Healthcare professionals through their hospital (Belgium, France, Africa)
Institut Jules Bordet, partner in ERN-EURACAN	Organisation of European Cancer Institutes (OECI),	Support and exchange on rare cancers through tele-expertise	No	European Reference Network (ERN)	EU funding	Expert physicians from the European centres involved in the Network	Physicians from the European centres involved in the Network
Radiomatix ([62]) **- Belgium**	Belgian radiologists and industry leaders	-Enable partners without medical domain expertise to own and operate top-level diagnostic centres or radiology departments -Provide teleradiology support worldwide through tele-expertise	Service fee paid by the user	Contract between the provider and the user	Private investors Users have to become franchise partners, investing in the company	Belgian and European radiologists	Insurance companies, governments, NGOs, hospital groups and investors from Europe, the Middle East and Africa

61. SODIRAY website https://www.sodiray.be/ [last visited 18/06/2018].
62. Radiomatix website https://www.radiomatix.com/ [last visited 26/06/2018].

Vividoctor – Belgium (63)	Start-up founded by two engineers and a doctor (also the medical director)	-Teleconsultation through videocontact: diagnosis, prescriptions and evaluation -provide a video and text-based platform for teleconsultation to hospitals and other healthcare organisations	Service fee paid by the patient	Contract with patients, physicians and hospitals	-Investors from ICT and other businesses -Payment by the partner healthcare institutions	-Belgian certified physicians and psychologists -One French speaking psychologist established in Spain	-Patients in Europe. Services are provided in EN, FR and NL -Hospitals and healthcare providers
Diagnose.me (64) **– the Netherlands**	Two entrepreneurs in collaboration with a physician	-Teleconsultation, in particular second opinions, based on the medical file provided by the patient -Diagnostic app	Service fee paid by the patient	Contract with the patient	Investors from ICT and healthcare industries	Medical specialists, worldwide, including two Belgian radiologists.	-Patients, worldwide, with a focus on US patients -Employers, insurance companies
eSCART – Belgium (65)	The Institute of Tropical Medicine, Antwerp	Support for HIV/AIDS care in low- and middle-income countries (LMICs) through tele-expertise and tele-education	No service fees	Agreement upon registration and acceptance through the platform	Belgian Directorate General for Development Cooperation (DGD)	Expert medical doctors from the Netherlands and Belgium	Healthcare professionals from the LMICs
TSF (Teleradiology Without borders) – Luxembourg (66)	Radiologists	Cooperation, support for radiologists from LMICs through tele-expertise and second opinion	No service fees	Experts sign the TSF Charter	Industrial sponsorship (by a PACS (67) provider)	Volunteering radiologists from Belgium, France, Luxembourg, USA, Venezuela and Portugal	Healthcare professionals from LMICs

Source: authors' own elaboration, dedicated sources provided in footnotes.

63. Vivi Doctor website https://app.vividoctor.com/doctor/find [last visited 18/06/2018].
https://www.vividoctor.com/fr/visites-virtuelles-de-vrais-medecins-en-ligne/#how-it-works [last visited 18/06/2018].
64. Diagnose.me website https://www.diagnose.me/en/ [last visited 26/06/2018].
65. eSCART website http://escart.itg.be/?lang=fr [last visited 26/06/2018].
66. Téléradiologie sans frontières (TSF) website http://www.teleradiologie-sans-frontieres.org [last visited 26/06/2018].
67. Picture Archiving and Communication System.

We briefly describe three of the initiatives mentioned above. They were selected as an illustration of different types of cross-border telemedicine practice.

1. **ANDRAL**

ANDRAL was a network providing tele-expertise in haematology-cytology, created by and for medical biologists to offer them support in their practice. ANDRAL stopped its activities in early 2019. The main reasons given to us were the incompatibility of the concept of the ANDRAL network with the regionalised health system in France and the consequent lack of financial support.

It was initiated by *Groupe Francophone d'Hématologie Cellulaire* (GFHC), an academic society representing French and francophone physicians and biologists working on cytology and haematology. The group of experts was part of GFHC. All experts were approved in the light of their experience and expertise. They work mostly in university hospitals and proofread the biological examinations on a voluntary basis. There was only one Belgian expert involved in the network.

The request for feedback was sent to the reviewers on duty; each file was analysed by two or three reviewers and feedback was to be given within 24 hours. Users, requesting medical biologists, were predominantly from private practices, mainly from France. Only 12% of users were located outside France (mainland and overseas territories), and a few were Belgian biologists using the platform for their patients (Leymarie *et al.* 2017). Expert reviewers and requesting physicians had to register and sign up to the charter stating the role of each party and their responsibilities. Both users and experts used the platform voluntarily. Reviewers had to ensure follow-up until the file review is completed. The requesting physicians were generally satisfied; 94% found the platform useful and relevant (Leymarie *et al.* 2017).

Regarding data protection, the platform was approved by the French data protection regulator, the *Commission Nationale de l'Informatique et des Libertés de France* (CNIL). Since the requirements imposed by CNIL initially did not take into account the specificity of the work to be carried out, requirements were relaxed after discussion with GFHC. For instance, in the work of a medical biologist, the patient's consent is rarely asked for before processing and analysing the patient's samples, while the CNIL asked to have the patient's consent to allow the use of the platform. The CNIL was also concerned about the duration of data storage and asked that patients' data be deleted after a few days. However, extra examinations may be required, and thus the patient file should remain in the programme longer. In the end the CNIL removed both requirements. Early 2018 none of the pseudo-anonymised data encoded and stored in the platform had been deleted.

The project was funded in October 2012 by the French *Agence Régionale de la Santé* (ARS)-Limousin, *Mutualité française* and *Ligue contre le cancer* (Leymarie *et al.* 2017), and by ARS-Nouvelle Aquitaine (of which Limousin became part in 2014) until the end of 2018. It was supported as a pilot

project and re-approved in 2017 as part of the ETAPES programme mentioned above (see Section 6.1). The funding was used to support the platform and technical arrangements, such as cloud storage. It was also endorsed by the French telecommunication company Orange and private actors in the field of telemedicine ([68]). The reviewers received no financial compensation.

The network was not used at its full capacity; it had 403 subscribers in early 2018 (mainly from France, Belgium, North Africa, and Congo).

2. **SODIRAY**

Solution Diagnostique Radiologique (SODIRAY) is a radiology tele-expertise provider created in 2008 in Liège. The Society is registered as a limited liability company according to Belgian law ([69]). Initially, the company's aim was to provide a service to French hospitals with a shortage of radiologists and to act as a support network for this profession. When it was created, no legal framework existed in Belgium nor in France. The developers consulted French and Belgian lawyers and followed the codes of conduct published by the European Society of Radiology and the French Council of Radiology (*Conseil Professionnel Français de la Radiologie*).

Fifteen Belgian certified hospital radiologists provide teleradiology services. They have different sub-specialties, providing a wide range of expertise. The clients are hospitals or radiology departments of hospitals, including the Belgian centres CHU Mont-Godinne and Cliniques Universitaires Saint-Luc in Brussels, and the African hospitals Clinique Santé & Vie in Lubumbashi and the Centre Médical de Kinshasa (C.M.K), both in the Democratic Republic of the Congo (DRC) ([70]). An arrangement with the French hospital CH Argentan ended and has not been renewed.

Each radiologist is appointed to specific hospitals; (s)he works part-time in teleradiology with a status of external consultants (approximately 20% of their overall practice as radiologists). In Belgium, hospitals using SODIRAY services pay fees equivalent to the usual fee for in-house radiology services. Hospitals also contribute to any additional technical costs. Data are stored in Belgium on a local SODIRAY server for a maximum of one year. The server is secured and allows for monitoring as well as data tracking. To access data from a Belgian hospital, the secured hospital exchange network is used.

The company has two types of cross-border experience: in Europe and in Africa. In Europe, the arrangement with the only foreign client, the French hospital CH Argentan, ended. With regard to

---

68. Orange- Solutions et services. Andral, un réseau d'expertise libre et gratuit (Orange- Solutions and services. Andral, a network of free and free expertise), http://dialogues.orange.com/solutions-et-services/andral-un-reseau-dexpertise-libre-et-gratuit/ [last visited 05/08/2018].
69. *Société Coopérative Société Privée à Responsabilité Limitée* (SC SPRL).
70. SODIRAY website: https://www.sodiray.be/ [last visited 06/03/2019].

cooperation with African hospitals, there is a contract between the Belgian radiologists and the hospitals in the DR Congo. The services provided include diagnosis, expertise, and prior, on-site training for the technical staff to ensure the quality of the examinations. Sometimes, the Belgian radiologists assist the African technicians by advising them on procedures such as injections of contrast agents for specific scans.

3. **Institut Jules Bordet, a partner in ERN-EURACAN**

The Brussels-based Institut Jules Bordet, a hospital entirely devoted to cancer patients, is a partner in ERN-EURACAN, a European Reference Network (ERN) for rare adult solid cancers, which brings together several cancer centres in the EU working on rare tumours. It aims to provide support and an interface to discuss rare cases between healthcare providers. The Organisation of European Cancer Institutes (OECI) initiated the project and it was launched in 2017, coordinated by the Léon Bérard centre in Lyon.

European Reference Networks (ERNs) are networks of specialist centres within Europe focusing on rare diseases. The legal framework for the establishment of ERN was created by the EU, pursuant to the cross-border healthcare Directive 2011/24/EU (see Section 5). The national centres involved in a European Network have to be recognized by their national ministry of health. In addition, the partner institutions in ERN-EURACAN had to be labelled as complying with specific predefined criteria (e.g. the number of cases treated by year) by an OECI committee and the coordinator of ERN-EURACAN (interview 3). The purpose of an ERN is to share knowledge, to create guidelines and provide support between experts as well as to discuss difficult cases among centres. In some cases, to enable better medical care, patients can be transferred to another ERN centre.

The network relies on volunteering physicians belonging to the partner hospitals. Around €200,000 is allocated for the network of the 80 centres involved in the EURACAN network. The majority of this budget is used for coordination. So far, only healthcare providers within the network can ask for a second opinion.

Early 2018, exchanges usually occurred informally between experts within or outside the ERN. For informal exchanges within the Network, experts use their own procedure. In the J. Bordet Institute, all exchanges — whether happening through ERN-EURACAN or not — with anonymised or pseudo-anonymised data are encrypted in a server to be shared. The end user, generally a physician, is granted access and receives a personal access key through another channel. The system's respect of data protection rules is guaranteed.

Since mid-2018, a platform called Clinical Patient Management System (CPMS) is operational, allowing the sharing of data and transfer of expert opinions within and between the European

Reference Networks ([71]). It is managed by the EU. Through the platform, patient summaries, images and other examination results are shared for discussion and follow up of the patient through his care pathway. In line with the GDPR, the patient has to provide a 'consent for Care' before a healthcare professional submits a patient case to the CPMS. Patients have a right to access data held about them. Patient data are anonymised when discussing them with healthcare professionals who do not have a therapeutic relationship with the patient.

According to our interviewees, this Network could provide advantages in terms of shared expertise, building a European expert community for rare tumours, and could potentially lead to more harmonized practice. Given the limited funding, keeping the Network financially viable is considered to be a major challenge. According to our respondents, substantial harmonization issues remain in various areas: patient consent requirements, medical encoding, and patient summaries.

8.   Analysis of the (cross-border) telemedicine practices in Belgium

This Section, provides a cross-cutting analysis of the initiatives, with a focus on the potential cross-border provision of care. We discuss the different forms of telemedicine practice existing in Belgium (8.1); provide an overview of the types of telemedicine providers (8.2); assess whether care is mainly exported from or imported to Belgium (8.3); discuss the arrangements and funding (8.4); discuss the most burning problems and possible solutions (8.5) as well as the opportunities and risks of cross-border telemedicine (8.6).

8.1 Forms of (cross-border) telemedicine practised in Belgium

Tele-expertise

According to our interviewees, tele-expertise is a routine practice and is usually provided in cross-border settings. Often, it happens off the record. Tele-expertise platforms exist in many forms: North-South cooperation, healthcare professionals' community support systems, commercial services and academic projects. The most common form is neither structured nor homogenized. At an individual level, it is generally based on the physicians' own network or occurs through scientific societies, as an academic exchange. Other voluntary forms exist: experts offering services to a larger community. ERN-EURACAN and ANDRAL provide tele-expertise through organized networks.

Generally, the experts contacted are located outside the country of work of the requesting physician (interviews 1, 3, 6). If expertise is available domestically, the patient is usually referred to the

---

71. European Reference Network website, webpage on Clinical Patient Management System (CPMS): https://ern-euro-nmd.eu/clinical-patient-management-system/ [last visited 05/03/2019].

colleague-specialist. Experts are chosen according to their level of expertise, often linked to their academic reputation or personal network. Commercial platforms, such as Radiomatix or diagnose.me, often export tele-expertise provided by European physicians (or worldwide) to healthcare providers abroad, for instance by providing second opinions.

Teleconsultation

Teleconsultation as such is limited in Europe. Start-up commercial services are flourishing on the internet, but their impact and their economic value are hard to assess. It is difficult to know if and to what extent Belgian patients use these platforms. Belgian physicians, however, are present as telemedicine service providers.

This is, for instance, the case for the platform *Vividoctor*. According to its website, this start-up offers virtual doctors' consultations, including prescriptions, to registered private consumers who pay on a fee-for-service basis. Moreover, it provides, against a monthly fee, a video and text-based teleconsultation platform for hospitals and other healthcare organisations, to facilitate the follow-up between patients and the hospital ([72]). Vividoctor works in partnership with the Belgian hospitals CHU Saint-Luc in Brussels and CHU de Liège ([73]). It has the potential and the ambition to provide cross-border healthcare services. One of its teleconsulting healthcare providers is established in Spain, and it provides services in English, French and Dutch.

It could also be argued that diagnostic teleconsultation is happening when a neurologist interprets a patient's situation before arriving at the patient's hospital unit, or when an on-call radiologist interprets patients' scans remotely (interviews 2, 5).

Telemonitoring

Telemonitoring has potential for patients with chronic diseases, cardiovascular diseases or for care-dependent patients. Pilot projects testing this form of technology are currently being carried out in Belgium (evaluation AP19). Telemonitoring systems are used in Belgium for defibrillators implanted in patients without acute cardiac conditions. It was estimated in 2010 that several dozen Belgian hospitals used cardiac remote monitoring systems for patients with implanted defibrillators (Vinck *et al.* 2010). We did not come across practices of telemonitoring in cross-border contexts. Nevertheless, data may be stored abroad, or the telemedicine platform helpdesk may be abroad. Practices were mentioned where the telemedicine is provided domestically, but data are stored in a cloud based in France or the USA (interview 5/evaluation AP19). Similar practices were mentioned in the above-

---

72. Vividoctor website, webpage on hospital partnership: https://www.vividoctor.com/why-hospitals-should-implement-online-consultations/ [last visited 06/03/2019].
73. Vividoctor website https://www.vividoctor.com/nl/ [last visited 06/03/2019].

mentioned report on remote cardiac monitoring systems (Vinck *et al.* 2010). This can be a problem when data are stored outside the EU, where the GDPR does not apply. In particular, if a company that owns the storage does not disclose the data processing details, the privacy and security of data are at risk (interview 5, evaluation AP19).

Tele-assistance

Tele-assistance, defined as a medical act carried out with remote assistance, seems to be the least frequent form of telemedicine. It mostly happens in contexts where resources are scarce, such as military settings, prisons, or in emergency situations (Ferrer-Roca and Sosa- Iudicissa 1999; Ajami and Lamoochi 2014). It was mentioned, in the interviews, as a potentially useful tool in specific settings where there is a lack of expertise, for instance in low and middle-income countries (LMICs) (interview 2) or when guidance from a distance is needed for certain medical examinations, for instance in a military context (interview 1). We did not find evidence of cross-border tele-assistance practices.

8.2 Types of telemedicine providers

Various types of telemedicine providers exist: commercial, voluntary and academic. The most common telemedicine practices in Belgium seem to be provided in the context of research projects or initiated by a group of professionals through professional networks or scientific societies (e.g. ANDRAL, ERN-EURACAN, eSCART telemedicine). They are often pilot projects or initiatives set up as a way to support health professionals. Telemedicine can be provided commercially, with various legal statuses (e.g. Diagnose.me, SODIRAY, Radiomatix). Other providers are registered as not-for-profit associations (for instance TSF).

8.3 Import versus export of telemedicine services

Overall, the initiatives we encountered tend to be *exporting* telemedicine services, providing services to patients or health professionals in another country, rather than foreign telemedicine providers providing services to Belgian users. Services are often provided to professionals outside the European Union. Belgian physicians export their expertise voluntarily to support practices elsewhere under the eSCART project or Teleradiology Without borders (*Téléradiologie Sans Frontières* - TSF) (see Table 1). These providers are usually set up by research groups or scientific societies and funded by grants. Commercial platforms such as Radiomatix or diagnose.me often export tele-expertise to health providers in the USA or Gulf countries.

Telemedicine services provided by foreign health professionals to Belgian patients are hard to quantify but seem sporadic.

8.4 Arrangements and funding

A wide variety of arrangements exist to define the relationship between the providers and users of telemedicine: contracts, agreements or simply a code of conduct set by the organization providing the service. In voluntary-based initiatives between healthcare providers, an agreement or a charter is usually signed by the two parties involved, although these are not legally binding. In commercial initiatives, contracts are drawn up between the users and the telemedicine service providers defining the responsibilities of both parties and the fees. In the case of cross-border provision of services, the contracts are adapted to the requirements of the country of the user.

Tele-radiology services, such as those provided by SODIRAY, can be reimbursed by the health insurance system, both in Belgium and France: the radiologists provide their services to the hospital as external consultants in the same way as any independent radiologist. The only difference is that their reports are drafted remotely. Nevertheless, at least one in-house radiologist must be present in the radiology department of the hospital (interview 2). In this way, French patients treated in CH Argentan and benefiting from the services of Belgian radiologists from SODIRAY did not spend extra money, since the radiologists were paid directly through their contract with the hospital and the procedure was part of regular practice (interview 2). The example of the provision of teleradiology services in France, is the only one we found of cross-border telemedicine reimbursed by the health system abroad.

Beyond the cost of the medical act provided by a health professional, telemedicine services involve considerable technology costs. In research and project-based initiatives, the available funding is mainly used to create a secure and reliable platform and to maintain the technological aspects. In commercial initiatives, these costs may be calculated into the fee paid by the patients, and in several companies (Vividoctor, diagnose.me) the platform is made available to healthcare organisations against payment, or upon the condition that they become investors in the business.

8.5 Challenges

Our interviewees mentioned several challenges for providing (cross-border) telemedicine services, and clarified the way in which some of these challenges were addressed, often in a creative way.

Many interviewees stressed that, without a proper and operational platform, **data sharing can occur in unsafe settings** and can be dependent on the deontology or awareness of the physician. Programmes and platforms created by the industry, initiated first by an IT department or engineers, often do not sufficiently take into account data security and patient privacy issues (interview 5).

To secure data transfer, all teleradiology initiatives used a RIS-PACS (Radiology Information Systems — Picture Archiving and Communication System), combined with a system for access and authentication (interviews 2, 6). Other solutions driven by health professionals are secured in a similar way (interviews 2, 3, 4). However, data transfer is not always done in a secure way, with regard to both data and privacy protection. According to our interviewees, practitioners already aware of or involved in telemedicine practices may be more inclined to take data protection issues seriously, while those who lack knowledge or awareness mostly focus on medical choices, deontology and patient pathways. Issues with security could occur when data exchange, especially in tele-expertise, happens outside a structured network, i.e. off the record.

Cross-border exchange of data can give rise to legal issues. Although it is expected that, with the implementation of the GDPR, approaches will become more harmonised within the EU/EFTA, differences in interpretation could lead to legal issues or challenges in the setting up of telemedicine (interview 6). The GDPR aims to protect patients' data, but respondents warned that the use of anonymised healthcare data is not monitored, and anonymisation is relative when considering, for instance, genomic data.

Interoperability is an important issue, nationally but in particular at international level. Often a health provider will use at least two different systems to process health data, because different data may be available through different platforms, for instance through the official Belgian eHealth platform (see Section 4) and the hospital's own platform. Also, some platforms may be inefficient for specific kinds of formats such as MRI (interview 6).

Informed consent for data storage and transfer is, under the GDPR, not mandatory between a patient and his treating physician(s), although national authorities can impose additional requirements. If data are shared with third parties who do not have a therapeutic relationship with the patient, including technical staff but also a tele-expert, consent should in principle be requested. Consent requirements are not harmonized between EU Member States. However, in the case of tele-expertise, patients' consent is rarely asked for when data are shared with an expert who has no therapeutic relationship with the patient. Respondents flagged that this is not always easy and not compatible with all medical settings. Patients are not always aware that their data are shared. Requesting physicians rarely specify the use of the platform in the Electronic Health Record (EHR), nor do they officially report the experts' reviews. According to our interviewees, it may become standard practice to warn the patient that his data may be discussed with an external expert (interviews 1, 3).

Respondents highlighted that a **lack of trust** among health professionals may be an obstacle to the use of a tele-expertise platform. **Verification of the qualifications** of the professionals providing telemedicine services may be an issue, in particular in cross-border settings. The professional title

given to the Belgian SODIRAY radiologists is determined with reference to the legislation of the country of the user. To be able to provide teleradiology services in France and to comply with the French legislation and be recognized, the radiologists first registered with the French national registry of health professionals (ADELI). The Radiomatix radiologists are certified in the country where they are established and accredited by the French '*Conseil d'accréditation pour la formation médicale continue*'.

Liability for the services provided has been raised as an issue by the physicians involved in cross-border tele-expertise. Professional liability provisions vary between medical specialties and between countries. It is unclear to both the tele-experts and to the requesting physicians, who is liable for the services provided (interviews 1, 6). Some telemedicine providers define, in their charters or contracts, the responsibilities of each party. However, these charters and contracts do not always correspond to the legal requirements in all the countries involved (interviews 1, 2). In the ANDRAL network and SODIRAY, the tele-expert is responsible for the opinion given. They can refuse a case if the quality and the quantity of the data provided in the patient record are not sufficient to give a complete and accurate medical opinion or if the quality of the images is insufficient. However, they are responsible if they agree to analyse the data even though the technical and quality requirements are not met. Nevertheless, if the reviewer makes a medical error, the requesting physician will be called out and will have to justify the medical choices made. In ERN-EURACAN, the issue of medical liability has not been settled, especially when the decision is taken jointly by several health professionals.

Communication may be a challenge in cross-border settings. Language can form a barrier to exchange and communication between health professionals, and medical terminology may differ (interviews 2, 3 and 5).

When the cross-border provision meets the local practitioners' need for specialist expertise, tele-expertise or telediagnostics are welcomed. Cross-border telemedicine can, however, also face **resistance from domestic players** who view the foreign providers as competitors. SODIRAY, for instance, experienced resistance from the French Board of Radiologists (*Conseil professionnel de la radiologie française*), before jurisprudence was issued in support of the SODIRAY radiologists. Furthermore, the French Professional Radiology Council (G4) rejected teleradiology as well as the idea of outsourcing to another country (ARS de Normandie 2017) (interview 2). However, SODIRAY met with no resistance to the radiology services provided in Africa, since its services responded to the need for specialist expertise in the countries.

Setting up a telemedicine service implies an investment in human and financial resources (interviews 1, 2, 3 and 5). This includes the cost of the implementation of the technology, of maintaining the platforms or other systems in place, data storage as well as human resources, such as a case

manager, IT specialists and a Data Protection Officer (DPO) (interview 4 and evaluation AP19). Technologies require continuous development and upgrading in order to guarantee the quality and safety of the service provided. **Funding of tele-expertise platforms** has been highlighted as an issue, in particular to ensure long-term viability of non-commercial initiatives. Grants and subsidies are usually limited in amount and time. For ERN-EURACAN, the allocated funding does not allow implementation of telemedicine in all centres, especially if they have no pre-existing system.

In the non-commercial initiatives, many activities happen through the networks and beyond, and are neither recorded nor invoiced. Often, the practice relies on the motivation of volunteering physicians. A key problem identified by many respondents, is that it is not possible for the **fee for medical examinations to be shared** between the tele-expert and the requesting physician since in the Belgian nomenclature, interpretation and diagnosis are not always dealt with separately.

To offer a proper teleconsultation or diagnosis, the physician providing telemedicine services needs **access to the patient's medical history**, for instance the patient's Electronic Health Record (EHR). However, the EHR is not routinely used in all medical specialties nor in all countries, and there is, so far, no harmonization across countries (nor within countries) in Europe despite several attempts (interview 3).

8.6 Opportunities and risks

A series of drivers, encouraging healthcare professionals to engage in (cross-border) telemedicine practices, were mentioned by our respondents. Physicians providing tele-expertise confirm or establish their reputation, obtain recognition from their peers and help the physicians' community to solve complicated cases. Furthermore, working on complicated or unusual cases triggers their academic curiosity and encourages them to launch novel practices (See also: Saigí-Rubió *et al.* 2014). Expertise can be shared among different specialties and between experts, which is considered as a valuable academic exchange. Tele-expertise in cooperation with providers in less well-equipped healthcare systems can be seen as altruistic and offers the opportunity to work on unusual cases. For professionals providing teleradiology, the practice allows them a more flexible time schedule and workflow than in routine settings. The requesting physician is provided with expertise difficult to access domestically and can learn through this process. In this way, the experts and the requesting physicians find mutual benefit in the academic exchange of tele-expertise. Tele-expertise provides opportunities for training, educating fellows and supporting the physicians' community as a whole in order to improve the practices and patient care.

Financial incentives may be an important driver for some healthcare professionals providing cross-border telemedicine services. Telemedicine can indeed provide an additional income for physicians, or more freedom in tariff setting, in particular when providing cross-border services. For a provider

such as SODIRAY, telemedicine allows the pooling and rational use of human resources, thus enabling the provision of a 24/24 teleradiology service.

Respondents also warned of potential risks associated with telemedicine, in particular in cross-border settings. Concerns have been voiced about quality of care. Teleconsultation through commercial platforms can be risky for patients, since they are unable to check the qualifications of the people behind the screen giving advice. The opinion, moreover, is in principle not followed up with actual examinations and therefore important health issues may be missed. When providing diagnostic services there is in many cases a need to meet the patient or to discuss the case with the referring physician. There may also be a difference in quality of care between domestic health professionals and professionals providing cross-border telemedicine services. Standards of practice and medical resources differ between countries, and physicians' education is not harmonized across countries (interview 6). Physicians could be inclined to leave regular practice and switch to telemedicine to increase their income or have more flexible working hours. However, working fulltime in telemedicine decreases social interaction with patients and colleagues, and some interviewees argued that this could lead to a reduced quality of the care provided (interviews 2, 6).

Some respondents warned of a drift in practice towards telediagnostic services. Hospitals could install a low-cost model by outsourcing diagnosis, with no guarantees as to the qualifications of the providers, nor as to the protocols used. In this way, they could conclude contracts with cheaper physicians abroad and reduce in-house staff accordingly (interviews 4, 6). One of our respondents mentioned an initiative by a Belgian hospital and a Belgian sickness fund aimed at using an Indian platform providing teleradiology services. Given the legal problems and, in particular, issues with regard to the recognition of the professional qualifications of the Asian radiologists, the initiative did not go ahead. Our interviewee feared that if telemedicine were to be used routinely, this could lead to abuse and risks for patients if not well regulated (interview 6).

9. Discussion, policy recommendations and general conclusion

9.1 Discussion

This Research paper explores to what extent and in what ways Belgian actors are currently involved in cross-border telemedicine practices, and examines the issues faced by health professionals, patients, and health systems.

Our findings suggest that currently, the implementation of telemedicine as a common practice is limited, in Belgium as well as in other European countries. Most initiatives are pilot projects. Some EU countries have recently incorporated some forms of telemedicine into their health systems. The main aim of such policies is to address the lack of healthcare services in remote areas and the shortage of health professionals in some regions. The emergence of mobile health applications and the potential thereof are drivers for the deployment of telemedicine services in the public systems. It remains unclear, however, how successful these policy developments will be in practice, and to what extent patients and professionals will really use them.

Cross-border telemedicine practices are even rarer, both in Belgium and other European countries, and almost exclusively concern tele-expertise and tele-diagnostics. They occur almost exclusively between health professionals. Belgian health professionals are involved in initiatives providing tele-expertise to patients abroad. These services are provided on a commercial basis, in an academic setting or with a 'humanitarian' perspective. Tele-expertise mostly happens informally; physicians call on their personal and professional networks. More formal and traceable practices are now beginning, within recently-established networks, but this is an exception. As for telemedicine practice within a country, cross-border telemedicine is also often used to address a lack of adequately qualified professionals, in particular in rural areas. This may explain why we only found a few practices importing telemedicine services into Belgium, mainly providing tele-expertise for highly specialized care. Generally speaking, there are no shortages in healthcare supply in Belgium, in particular not for the usual services provided through telemedicine, such as medical-technical acts. For specific highly specialized medical care and care for rare diseases, however, the most suitable expertise may be available abroad. Cross-border telemonitoring for specific rare diseases could also become an option in the future.

Most obstacles to the use of telemedicine affect both the national and international contexts, although cross-border telemedicine adds further challenges, in particular because it implies interaction between different jurisdictions and health systems. While lack of trust is the main obstacle to the use of telemedicine, this is even more so in a cross-border setting. Guarantees as to the qualifications and quality of the health professionals providing the telemedicine, the safety and reliability of the devices used, and the protection of the data are often considered insufficient. This

also explains why much tele-expertise occurs informally, between professionals who know and trust each other. Since the health professional providing telemedicine has to comply, based on the EU internal market rules, with his/her country legislation and not the legislation of the country of the user or the patient, the latter do not know which legislation the telemedicine provider has to comply with, and are unable to assess her/his qualifications. This leads to the paradoxical situation that while these internal market rules, applying the *'country of origin principle'*, are intended to remove obstacles to cross-border trade in health services, they create de facto obstacles to the free movement of telemedicine services.

Reliability and usability of the devices, medical liability, funding of the platform and care services and, obviously, language are other important barriers.

Many data protection issues were voiced by the interviewees. Patient data may be sent over non-secured networks, it is not common practice to request the patient's consent to share the data, and the consultation of the tele-expert is usually not documented in the patient's medical file. Physicians do not always pay sufficient attention to issues of data protection and do not invest in suitable tools if these are not easily usable or already in place.

Several players have an interest in the deployment of telemedicine. Medical devices companies are clearly pushing for the expansion of telemedicine. Investors from ICT and other businesses are involved, sometimes as initiators, in the commercial initiatives active in Belgium. The dominant businesses overlook data protection and ownership rules. Financial drivers may encourage health professionals to engage in these practices. However, most of the practices we found happened on a voluntary basis, in academic settings, and the health professionals involved were more interested in enhancing their knowledge, expertise and reputation.

9.2 Policy recommendations

Based on the above analysis, combining desk research, semi-structured interviews and participant observation, we make the following policy recommendations:

1. The **quality and safety of the technology**, i.e. the medical devices and the platforms, needs to be ensured, and the technology must be safe, secure and user-friendly. The device provider should be able to ensure suitable responsiveness to the needs of the patients and healthcare professionals. From the outset of an initiative, or the development of a tool, cooperation between users, healthcare professionals and IT developers is needed, to ensure quality and security and to properly address both the medical needs and the ethical aspects.

2. The treating doctor and his/her patient should be granted **direct access to measurements** collected for medical purposes, and health professionals should not need to log into the medical device provider's platform to access the patient's data.

3. It is crucial that telemedicine users can **verify** the **competences of the health professionals** providing telemedicine services, in order to ensure quality and safety of the care provided. The country of the telemedicine user should be able to check practitioners' identity and qualifications, including through national registers. Organisations of health professionals could be involved in guaranteeing the quality of the experts providing the telemedicine.

4. Health professionals and other **professionals** involved in the telemedicine process should acquire the necessary information and communication technology (ICT) competencies and be made familiar with the use of the technologies, in a way that ensures safety, quality and protection of privacy. They should **be trained** in all aspects to be considered when using telemedicine services. They should be made aware of the applicable legislation and the risks involved, for the patient and for their professional liability, when using insecure networks or devices.

5. To facilitate exchange across borders, **medical terminology** and medical coding should be **harmonised**. Organisations of health professionals could play a role in this.

6. **Liability** issues should be discussed and settled before engaging in any telemedicine activity. Professional liability arrangements vary between medical specialties and between countries. Clarity should be provided as to the respective responsibilities of the tele-expert and the requesting physician. Rules should be established to harmonise responsibilities both at national and at European level, and could be required in the contracts with telemedicine providers. The possibility of shared liability should be investigated.

7. Telemedicine services should be documented; the **use of tele-expertise must be traceable** in the patient file and this should be monitored. If tele-expertise takes place through a hospital, the physician providing telemedicine needs the status of external consultant, to allow him/her access to the patient files and to ensure that the therapeutic relationship with the patient is traceable.

8. To ensure that health professionals continue to maintain their skills and have sufficient direct patient contact, telemedicine practice **should remain additional to conventional practice**. Telemedicine practice should therefore be limited.

9. **International practice standards** should be established, to avoid a drift in the quality of healthcare through the provision of low-cost cross-border telemedicine.

10. **The sharing of the medical fee between the requesting physician and the tele-expert(s)** should be made possible. The funding for the technical act (preparation, sampling, scanning/digitization) could be separated from the act of diagnosis (interpretation). The introduction of a multidisciplinary consultation fee for tele-expertise could be considered.

11. The **GDPR** is an important step forward but, as shown in this paper, **its application to the field of telemedicine and mHealth requires further clarification**. Issues remain with regard to informed consent; data sharing; defining which are the parties authorised to access and process data as well as issues related to the storage of health data.

12. Also, the revised EU legislation on medical devices includes improvements to the current situation. However, it does not provide the much-needed guarantees with regard to reliability, safety and certainly not effectiveness of the tools (see also Hantson, 2019). A **stronger legal framework on medical devices** is necessary

13. Last but not least, legislation could be better enforced, notably regarding the use of devices and transfer of data. **Monitoring** of telemedicine, in particular commercial initiatives, is vital to avoid malpractice.

9.3 Conclusion

In our assessment, cross-border telemedicine for Belgian patients will most likely remain a rather limited phenomenon. Telemedicine may, nevertheless, have an added value in some specific circumstances. In particular, it is useful where specific, highly specialised expertise is not available domestically, or for the treatment of complex cases and rare diseases, which require a pooling of human resources and multidisciplinary consultation. In such cases, these services should be rendered in circumstances that provide all the necessary guarantees **to ensure high quality care and protect patients' rights**. Robust guarantees are needed on the safety, quality and reliability of the tools used, the protection of data and the quality of the care provided. These guarantees are currently not always provided. We hope that this Research paper may contribute to raising awareness about the need to improve such safeguards in cross-border telemedicine.

Bibliography

ARS de Normandie (2017) Bilan du SROS de Basse-Normandie, Agence Régionale de Santé de Normandie, 2017, https://www.normandie.ars.sante.fr/sites/default/files/2017-02/Bilan%20SROS%20ex-BN.pdf [last visited 06/03/2019].

Ahrendt D. *et al.* (2017) European Quality of Life Survey 2016: Quality of life, quality of public services, and quality of society, Loughlinstown, Eurofound, 122p.

Ajami S. and Lamoochi P. (2014) Use of telemedicine in disaster and remote places, J Educ Health Promot., 3 (26), 3 May 2014, doi: 10.4103/2277-9531.131886.

Alami H. *et al.* (2018) Exploring factors associated with the uneven utilization of telemedicine in Norway: a mixed methods study, BMC Med Inform Decis Mak, 17(1) 180, 28 December 2018, doi: 10.1186/s12911-017-0576-4.

Allen A. (2017) A hospital without patients, Politico, 11 August 2017, https://www.politico.com/agenda/story/2017/11/08/virtual-hospital-mercy-st-louis-000573 [Last visited 25/08/2018].

Belcher P. (2013) EU Crossborder health care collaboration, Eurohealth, European Observatory on Health Systems and Policies, 19 (4), 56p.

Border P. (2014) Telehealth and Telecare, The Parliamentary Office of Science and Technology, POSTnote 456, London, 14 February 2014, https://researchbriefings.parliament.uk/ResearchBriefing/Summary/POST-PN-456/ [last visited 08/03/2019].

Cazac C. and Radu G. (2014) Telesurgery - an efficient interdisciplinary approach used to improve the health care system, J Med Life, 7 (3), 137-41.

Chambre des représentants de Belgique (2008) Rapport du Projet de Loi relatif à l'institution et à l'organisation de la plate-forme eHealth - rapport fait au nom de la commission de la santé publique, de l'environnement et du renouveau de la société par Mme Maya Detiège, Document 52, 1257/003, Bruxelles, Chambre des représentants de Belgique, 9 July 2008.

Conseil national de l'Ordre des médecins (2015) Médecins et médias numériques, Bulletin 148, doc a148006, 07 February 2015, https://www.ordomedic.be/fr/avis/conseil/respect-de-la-vie-prive-par-le-mdecin-lorsqu-il-utilise-les-diffrentes-applications-numriques [last visited 08/03/2019].

Conseil national de l'Ordre des médecins (2019) Téléconsultation en vue de poser un diagnostic et de proposer un traitement, Bulletin 166, doc a166007, 21 September 2019, https://www.ordomedic.be/fr/avis/conseil/teleconsultation-en-vue-de-poser-un-diagnostic-et-de-proposer-un-traitement [last visited 17/10/2019].

Council of the European Union (2004) Council conclusions on eHealth, 9628/04, Brussels, 27 May 2004.

Council of the European Union (2009) Council conclusions on Safe and efficient healthcare through eHealth, 2009/C 302/06, Brussels, 1 December 2009.

Council of the European Union (2017) Council conclusions on Health in the Digital Society — making progress in data-driven innovation in the field of health, 2017/C 440/05, Brussels, 1 December 2017.

Darvish A. and Far M. (2017) Review on Implementation of Electronic Health in Iran Literature, MOJ Womens' Health, 5 (5), 294-298.

den Exter A. (2017) e-Health challenges under EU law, den Exter A.P. (ed.), Cross-border health care and EU law, Rotterdam, Erasmus University press, 245p.

Dias A. (2017) Home Monitoring in Portugal an Overview on Current Experiences, HealthInf 2017 - 10th International Conference on Health Informatics proceeding, 66-76.

e-Health Network (2014) Guidelines on ePrescriptions dataset for electronic exchange under cross-border directive 2011/24/EU, Brussels, 18 November 2014, https://ec.europa.eu/health/sites/health/files/ehealth/docs/eprescription_guidelines_en.pdf [last visited 08/03/2019].

e-Health Network (2015) Refined e-Health European Interoperability Framework. Adopted by consensus by the eHealth Network, Brussels, 23 November 2015,

https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=2ahUKEwj qsszKzMrgAhXSGuwKHUw4Bn4QFjAAegQICRAC&url=https%3A%2F%2Fec.europa.eu%2Fhealth%2Fsites%2 Fhealth%2Ffiles%2Fehealth%2Fdocs%2Fev_20151123_co03_en.pdf&usg=AOvVaw1qG-jViBxwyEnUGyhW- RJ [last visited 20/02/2018].

Europe Economics (2019) Regulatory approaches to telemedicine, London, 12 August 2019, https://www.gmc- uk.org/-/media/documents/regulatory-approaches-to-telemedicine_docx-73978543.docx [last visited 12/08/2019].

European Commission (2004) e-Health - making healthcare better for European citizens: An action plan for a European e-Health Area, COM(2004) 356, Brussels, 30 April 2004.

European Commission (2008a) Telemedicine for the benefit of patients, healthcare systems and society, COM(2008) 689, Brussels, 4 November 2008.

European Commission (2008b) Cross-border interoperability of electronic health record systems, COM(2008) 3282, Brussels, 18 July 2008.

European Commission (2012a) e-Health Action Plan 2012-2020 - Innovative healthcare for the 21st century, COM(2012) 736, Brussels, 6 December 2012.

European Commission (2012b) Staff working document on the applicability of the existing EU legal framework to telemedicine services, SWD(212) 414, Brussels, 6 December 2012.

European Commission (2013a) Final summary minutes, 3rd eHealth Network meeting, 14 May 2013, Dublin. sanco.ddg1.d.3, 2031164, Brussels.

European Commission (2014a) Commission staff working document on the existing EU legal framework applicable to lifestyle and wellbeing apps, SWD(2014)135, Brussels, 10 April 2014.

European Commission (2014b) Green paper on mobile Health ('mHealth'), COM(2014) 219, Brussels, 10 April 2014.

European Commission (2015) Commission Report on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, COM(2015) 421, Brussels, 4 September 2015 .

European Commission (2016) EU eGovernment Action Plan 2016-2020, COM(2016) 179, Brussels, 19 April 2016.

European Commission (2018) Communication on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society, Brussels, COM(2018) 233, Brussels, 25 April 2018.

European Commission (2019) Recommendation on a European Electronic Health Record exchange format, C (2019)800, 6 February 2019, https://ec.europa.eu/newsroom/dae/document.cfm?doc_id=57253 [last visited 01/03/2019].

Faber S., Geenhuizen M. and de Reuver M. (2017) e-Health adoption factors in medical hospitals: A focus on the Netherlands, Journal of Medical Informatics, 100, 77-89.

Ferrer-Roca O. and Sosa-Iudicissa M. (1999) Handbook of Telemedicine, 54, Studies in Health Technology and Informatics, Amsterdam, IOS Press, , 300p.

Hantson (2019) De mobiele gezondheidszorg en de telegeneeskunde, finaal rapport dd 20 februari 2019, Hantson advocatenkantoor, Gent, 80 p. https://www.inami.fgov.be/SiteCollectionDocuments/telegeneeskunde_rapport_meester_hantson.pdf [last visited 03/10/2019].

Jahns R. (2017) European countries are behind the USA in regards to telemedicine maturity, but they`re beginning to catch up, Research2guidance, https://research2guidance.com/european-countries-are-behind- the-usa-in-regards-to-telemedicine-maturity-but-theyre-beginning-to-catch-up/# [last visited 06/03/2019].

Kahn E., La Marca F. and Mazzola C. (2016) Neurosurgery and Telemedicine in the United States: Assessment of the Risks and Opportunities, World Neurosurg, 89, 133-8.

Khatri V. *et al.* (2011) Review of Telemedicine Services in Finland, International Federation for Medical and Biological Engineering Proceedings, 34, 1-8.

Kiberu V., Mars M. and Scott R. (2017) Barriers and opportunities to implementation of sustainable e-Health programmes in Uganda: A literature review, Afr J Prim Health Care Fam Med., 9 (1), e1-e10, 29 May 2017, doi: 10.4102/phcfm.v9i1.1277.

Kroneman M. *et al.* (2016) The Netherlands: health system review, Health Systems in Transitions, 18 (2), 1-239.

Kruus P. *et al.* (2015) E-consultation service supporting Moldovan family doctors, Praxis - Center for Policy Studies, 56p.

Lai T. *et al.* (2013) Estonia: health system review, Health Systems in Transition, 15 (6), 1-196.

Leymarie V. *et al.* (2017) ANDRAL network: First tele-expertise solution in cytology haematology, Review of a European experience ongoing since November 2012, European Research in Telemedicine, 6, 34-35.

Medeiros de Bustos E. *et al.* (2018) Evaluation of a French Regional Telemedicine Network Dedicated to Neurological Emergencies: A 14-Year Study, Telemedicine and e-Health, 24 (2), 155-160.

Mishra S., Kapoor L. and Singh I. (2009) Telemedicine in India: Current Scenario and the Future, Telemedicine and e-Health, 15(6), 568-575.

Oliveira T. *et al.* (2014) Telemedicine in Alentejo, Telemedicine and e-health, 20 (1), 90-93.

Owens B. (2019) Telemedicine on the rise but lagging in Canada, CMAJ, 190 (38), 2018, E1149-E1150, 24 September 2019, doi: https://doi.org/10.1503/cmaj.109-5634

Pina A. (2015) Funding of telemedicine in the Portuguese National Health Service, Communications orales du 8e Congrès européen de la SFT-ANTEL, European Research in Telemedicine/La Recherche Européenne en Télémédecine, 4, 141-148.

Raposo V. (2016) Telemedicine: The legal framework (or the lack of it) in Europe, GMS Health Technol Assess, 12 (03), 16 August 2016, doi: 10.3205/hta000126.

Rojahn K. *et al.* (2016) Remote Monitoring of Chronic Diseases: A Landscape Assessment of Policies in Four European Countries, PLoS ONE, 11 (5): e0155738, 19 May 2016, doi: org/10.1371/journal.pone.0155738.

Saigí-Rubió F., Torrent-Sellens J. and Jiménez-Zarco A. (2014) Drivers of telemedicine use: comparative evidence from samples of Spanish, Colombian and Bolivian physicians, Implement Sci, 9 (128), 8 October 2014, doi: 10.1186/s13012-014-0128-6.

Sénat de Belgique (2005) Demande d'explications de M. Jan Stevelynck au ministre des Affaires sociales et de la Santé Publique sur ` le plan d'action relatif aux e-soins de santé ' n° 3-1060, Annales 3 (131), Brussels, 27 October 2005.

Simon P. and Acker D. (2008) Rapport: La place de la télémédecine dans l'organisation des soins, CGES, Rapport mission thématique 7/PS/DA, Ministère de la Santé et des Sports, 160p.

The Portugal news (2019) Telehealth used in 87% of hospitals, 6 may 2019, https://www.theportugalnews.com/news/telehealth-used-in-87-of-hospitals/49787 [last visited 10/10/2019].

Venot A., Burgun A. and Quantin C. (eds.) (2014) Medical Informatics, e-Health: Fundamentals and Applications, Health Informatics, Paris, Springer-Verlag, 494p.

Vinck I *et al.* (2010) Surveillance à distance des patients porteurs de défibrillateurs implantés, Evaluation de la technologie et cadre réglementaire général, KCE Reports 136B, Brussels, Centre fédéral d'expertise des soins de santé, 251p.

Wamala D. and Augustine K. (2013) A meta-analysis of telemedicine success in Africa, Journal of Pathology Informatics, 4 (6), 30 May 2013, doi: 10.4103/2153-3539.112686.

World Health Organization (2010) Telemedicine: opportunities and developments in Member States: report on the second global survey on eHealth 2009, Global Observatory for eHealth Series, World Health Organization, 96p.

World Health Organization (2016a) Atlas of eHealth country profiles 2015: the use of eHealth in support of universal health coverage, based on the findings of the 2015 global survey on eHealth, Geneva, 392 p.

World Health Organization (2016b) Global diffusion of eHealth: making universal health coverage achievable. Report of the third global survey on eHealth, Global Observatory for eHealth Series, World Health Organization, 156p.

Žmenja M. (2017) Provision of Health-care Service over the Internet – the Legality of E-consultations in Estonia, Juridica international, 26, 47-55.

Annex 1:   List of interviews

Number	Date	Interviewees	Institution
Interview 1	19/03/2018	Two medical specialists working in a Belgian hospital and, through phone contact, one French physician participating in the same cross-border network	Belgian university hospital, participating in a cross-border telemedicine network
Interview 2	14/03/2018	Radiologist	Cross-border commercial telemedicine provider
Interview 3	27/03/2018	Three health professionals, an IT expert, and a Data Protection Officer	Belgian hospital, European reference network
Interview 4	19/02/2018	Two civil servants involved in eHealth policies	Belgian Federal Public Authority
Interview 5	14/02/2018	Programme manager, Project coordinator on eHealth	Development and Innovation Hub
Interview 6	04/04/2018	Belgian radiologist	Belgian university hospital

Annex 2:   Action Plan 19 pilot projects

* **Cardio@home** (AZ Groeninge), patients at high risk of heart failure were telemonitored at home and received teleconsultations through videoconferencing to coach them to improve their lifestyle and decrease the risk.

* *Télé-assistance de patients insuffisants cardiaques sévères* (CHU Liège, CHR Citadelle): telemonitoring project of patients with severe heart failure, involving a system of telemonitoring in their homes combined with an educative programme for the patients and their families.

* **TOC-m-health** (Wit-Gele Kruis Antwerpen, AZ Sint-Maarten): monitoring of medication intake for patients with cardiovascular diseases needing multiple treatments and with a risk of low treatment compliance.

* **Nefrocare** (UZ Leuven): telemonitoring of the vital organs of patients with kidney failure.

* **24/7 monitoring van vitale lichaamsfuncties in de thuiszorg** (Wit-Gele Kruis Antwerpen): continuous telemonitoring of patients at home.

* **mHartslag** (AZ Sint-Jan Brugge, Thuiszorg CM, UZ Antwerpen, Virga Jesse Hasselt, Ziekenhuis Oost-Limburg, cercles des médecins généralistes des régions impliqués): the use of wearables to telemonitor blood pressure and weight of patients with heart failure.

* **HartfalenCoach** (OLV Aalst, Wit-Gele Kruis Oost-Vlaanderen, AZ Glorieux): telemonitoring of vital parameters and guiding patients with heart failure through a mobile application.

* **moveUP** (AZ Maria Middelares, Jan Yperman Ziekenhuis, Medisch Centrum Latem, Universiteit Gent): tele-rehabilitation after an orthopaedic procedure. Data regarding sleep quality, pain, activity level recorded by the patient are used by the health professional to provide the patient with a personalized rehabilitation programme, using a platform.

* **Dolora@home** (AZ Groeninge,huisartsenkring Zuid-West-Vlaanderen, Wit-Gele Kruis West-Vlaanderen, Bond Moyson, Solidariteit voor het Gezin), the project used teleconsultation and telemonitoring of outcome measurements such as pain intensity, symptoms for chronic pain patients undergoing interventional pain treatment.

* **Diabetes On The Run** (Thuisverzorging In Solidariteit vzw, Sovervlag vzw, Bond Moyson/De Voorzorg, Union Nationale des Mutualités Libres): a programme to telemonitor diabetes 2 patients combined with telecoaching provided through a monthly phone call.

* **MyGlycMon** (Collaboratief Zorgplatform): telemonitoring of glycaemic data from patients with diabetes.

* **Interpret-Dia** (UZ Brussel): Telemonitoring glucose levels of Type 1 diabetic paediatric patients.

* **Blended Acceptance and Commitment Therapy** (Psychologenpraktijk De Braam), patients with mental problems use a mobile application to follow up their status and schedule a face-to-face consultation when needed. The application is used as a complementary tool, between consultations.

* **e-Mental Health: *zelf aan de slag*!** (Liberale Mutualiteit Oost-Vlaanderen): a self-help platform used by patients, with a referral to a psychologist if the programme is not sufficient.

* **Beeldbellen** (Netwerk GGZ Midden-West-Vlaanderen PRIT, Netwerk GGZ Zuid-West-Vlaanderen): a mobile psychiatric team follows patients with whom a prior therapeutic relationship exists through teleconsultation.

* **In-Ambulance Telestroke** (UZ Brussel, UZ Antwerpen, UCL Saint-Luc, ULB Erasme): the use of telemedicine in the ambulance for stroke patients, to make a quick diagnosis before arriving at the hospital and to ensure efficient triage of patients.

* **Beroertecoach.be** (Belgian Stroke Council): a platform used for patients post-stroke to improve recovery through coaching and teleconsultation.

* **Prenatal Remote Monitoring for High-Risk Pregnancies** (Ziekenhuis Oost-Limburg, Jessa Ziekenhuis, Sint-Franciskus Ziekenhuis, Heilig Hart Mol, Ziekenhuis Maas en Kempen, Sint-Trudo, AZ Vesalius): a telemonitoring project allowing the follow-up of pregnant women by a midwife in the hospital; patients can receive phone consultations and advice digitally.

* **Fibrichek (fusion of POTUS and MoTIVatie)** (AZ Delta, Jan Yperman Ziekenhuis, Ziekenhuis Oost-Limburg, Wit-Gele Kruis Antwerpen, AZ Sint-Maarten): monitoring of patients through a mobile application measuring heart rate to avoid cardiovascular incidents.

* **Self-user in line** (Hôpital Jolimont, Hôpital Tubize-Nivelles, CHR Mons-Hainaut): patients with diabetes are monitored through a mobile application recording insulin dosage shots and a device recording glycaemia.

* **3S Homecare** (Centrale de Service à Domicile de Namur, Fédération des CSD, CHR Namur): telemonitoring of patients in their home.

* Stay on track (AZ Maria Middelares, UZ Antwerpen): telemonitoring of cancer patients at home.

* **Sleep Cloud** (CHU Liège, CHR Namur): telemonitoring of patients with sleep disorders at home to allow measurement of parameters during sleep such as eye movements, brain activity and respiratory functions.

*_**Télé-assistance des patients BPCO sévères**_ (CHU Liège): telemonitoring of patients with Chronic obstructive pulmonary disease.

Annex 3: Clinical Trials on telemedicine, involving Belgian centres, registered in the US registry [74]

Title	Status	Medical conditions	Interventions	Institutions
Telemedicine for Optimized Collection of Clinical data on Patients with Suspicion of Acute Stroke	Unknown status	Stroke	Device: Telemedicine	Universitair Ziekenhuis Brussel, Brussels, Belgium
Prehospital Study at the Universitair Ziekenhuis Brussel II	Unknown status	Stroke	Other: Telemedicine	Universitair Ziekenhuis Brussel, Brussels, Belgium
Impact of Telemonitoring to Improve Adherence in Continuous Positive Airway Pressure (CPAP)-Treated Patients	Completed	Obstructive Sleep Apnoea	Device: T4PTelemonitoring| Device: CPAP	CHU St Pierre-sleep lab, Brussels, Belgium
Feasibility of Ambulance-based Telemedicine (FACT) Study	Completed	Acute Stroke	Telestroke	Universitair Ziekenhuis Brussel, Brussels, Belgium
Prehospital Stroke Study at the Universitair Ziekenhuis Brussel I (PreSSUB I)	Completed	Stroke	Telestroke - feasibility trial	Universitair Ziekenhuis Brussel, Brussels, Belgium
Telemonitoring During Phase 2-3 Cardiac Rehabilitation	Completed	Ischemic Heart Disease	Device: physical activity monitors| Other: No physical activity monitors	Jessa Ziekenhuis, Hasselt, Belgium
A Two-way Communication System to Coach Elderly Patients With Heart Failure	Active, not recruiting	Heart Failure	Device: Telemonitoring	Ziekenhuis Oost-Limburg, Genk, Belgium|Jessa Ziekenhuis, Hasselt, Belgium

---

74. US registry for clinical trials: https://ClinicalTrials.gov/ [last visited 29/08/2018]. Keywords used for the search were 'telemedicine' OR 'teleconsultation' OR 'telemonitoring' OR 'tele-expertise' OR 'telecardiology' OR 'telesurgery' OR 'mHealth'.

Telerehabilitation in Coronary Heart Disease	Unknown status	Coronary Artery Disease (CAD);|Myocardial Infarction (MI);|Percutaneous Coronary Intervention (PCI);|Coronary Artery Bypass Grafting (CABG)	Behavioural: Centre-based cardiac rehabilitation| Behavioural: Home-based training with telemonitoring guidance	KU Leuven, Leuven, Belgium
Implementing a Postoperative MIRP (Minimally Invasive Repair of Pectus) Programme Via Tele-monitoring	Recruiting	Postoperative Pain| Postoperative Nausea	Procedure: Pectus surgery	University hospital Antwerp, Edegem, Antwerp, Belgium
Identifying the Effect and Working Mechanisms of MyPlan 2.0 in Adults with Type 2 Diabetes	Recruiting	Chronic Disease	Behavioural: MyPlan 2.0	Department of Movement and Sports Sciences, Ghent, Belgium
Multidisciplinary Care for Patients with Chronic Kidney Disease to Increase Their Self-management	Recruiting	Chronic Kidney Diseases	Behavioural: Lifestyle counselling	University Hospitals Leuven, Leuven, Belgium
Web-based Education for Diabetes Patients on Adaptable Insulin Schedules	Completed	Diabetes	Device: web-based education (telemonitoring)	Ghent University Hospital, Ghent, Belgium| AZ Nikolaas: Department of Endocrinology, Sint-Niklaas, Belgium
Self-operated Endo-vaginal Telemonitoring (SOET), an Economic and Patient-empowered Method for Ovarian Stimulation for In-vitro Fertilization (IVF)	Unknown status	IVF Treatment	Device: Perform Echo at home	University Hospital VUB, Brussels, Belgium| Ziekenhuis Oost-Limburg, Genk, Belgium| Ghent University Hospital, Ghent, Belgium | Clinique Saint-Vincent, Rocourt, Belgium

Validation Study of mHealth Technology in HIV to Improve Empowerment and Healthcare Utilisation: Research and Innovation to Generate Evidence for Personalised Care (EmERGE)	Recruiting	HIV Infections	Other: mHealth platform	Prins Leopold Instituut Voor Tropische Geneeskunde, Antwerp, Belgium| Klinika za Infektivne Bolesti Dr. Fran Mihaljevic, Zagreb, Croatia|Centro Hospitalar de Lisboa Central, Lisboa, Portugal|Hospital Clínic i Provincial, Barcelona, Spain|University of Brighton, Brighton, United Kingdom
Telemonitoring of Hypertensive Patients	Not yet recruiting	Hypertension	Other: Telemonitoring of self-measured blood pressure	UZ Leuven, Leuven, Belgium
Integration of Follow-up by First- and Second Line Practitioners by Telemonitoring in Heart Failure	Terminated	Chronic Heart Failure	Device: integrated follow-up| Device: standard care	Middelheim Ziekenhuis, Antwerp, Belgium| UZ Brussel, Brussels, Belgium| Ziekenhuis Oost-Limburg, Genk, Belgium| AZ Maria Middelares, Gent, Belgium| Jessa ziekenhuis, Hasselt, Belgium| AZ Groeninge, Kortrijk, Belgium| CHR.Citadelle, Liege, Belgium
Effectiveness of the HeartHab Application on Exercise Capacity in Patients with Coronary Artery Disease	Completed	Coronary Artery Disease	Other: Use of HeartHab application followed by usual care| Other: Usual care followed by the use of HeartHab application	Jessa ziekenhuis, Hasselt, Belgium
Real-time Attended Home-polysomnography Through Telematic Data Transmission	Completed	Obstructive Sleep Apnoea	Device: polysomnograph Dream and Sleep Box	CHU St Pierre, Brussels, Belgium
Telemetric Arrhythmia and Syncope Diagnosis - Evaluation of Arrhythmia Treatment Efficacy	Unknown status	Atrial Fibrillation|Arrhythmias, Cardiac	Device: Prolonged telemetric Full Disclosure ECG recording	Universitair Ziekenhuis Brussel, Centre for Heart- and Vascular diseases, Brussels, Belgium| Klinika Kardiologii CMKP, Warsaw, Poland| Institute of Cardiology, Warsaw, Poland
Personal Decision Support System for Heart Failure Management	Recruiting	Heart Failure, Congestive	Device: HeartMan system	OLV Hospital Aalst, Aalst, Belgium| General Hospital Maria Middelares, Ghent, Belgium| University Hospital Ghent, Ghent, Belgium| Rieti General Hospital, Rieti, Italy

A Smartphone-based Intervention to Promote an Active Lifestyle in Low Educated Working Young Adults	Completed	Physical Activity	Behavioural: smartphone-based intervention with Active Coach app	Ghent University, Ghent, Belgium
European Health Economic Trial on Home Monitoring in ICD and CRT-D Patients (EuroEco)	Terminated	Ventricular Fibrillation|Tachycardia, Ventricular|Ventricular Flutter	Device: Home Monitoring provided by Biotronik ICD and CRT-D devices|Device: No Home Monitoring	Heart Rhythm Management Institute, Free University of Brussels, Brussels, Belgium| Ziekenhuis Oost Limburg, Campus St. Jan, Genk, Belgium| Jessa Ziekenhuis (Campus Virga Jesse), Hasselt, Belgium| UZ Gasthuisberg, Leuven, Belgium| University of Oulu, Oulu, Finland| Helios Klinikum Aue, Aue, Germany| Charité Berlin Campus Mitte, Berlin, Germany| Städt. Klinikum St. Georg gGmbH, Leipzig, Germany| Herzzentrum Leipzig, Abteilung Rhythmologie, Leipzig, Germany| Leiden Universitair Medisch Centrum, Leiden, Netherlands| Hospital Universitario La Paz, La Paz, Spain| Hospital Universitario Puerta de Hierro Majadahonda, Madrid, Spain| Hospital Ntra.Sra.de la Candelaria, Tenerife, Spain| Arrythmia Unit, Complejo Hospitalario de Vigo (Hospital Xeral), Vigo, Spain| Cardiology, Aberdeen Royal Infirmary, Aberdeen, United Kingdom| Cardiology, St. Peters Hospital/St. George's, Chertsey, United Kingdom| Cardiology; Raigmore Hospital, Inverness, United Kingdom
Clinical effect of Heart Failure Management Via Home Monitoring with a Focus on Atrial Fibrillation (effect)	Terminated	Heart Failure (HF)|Atrial Fibrillation	Device: Home Monitoring (Cardiac resynchronization therapy and atrial fibrillation therapy, with Home Monitoring feature)|Device: Home Monitoring (Cardiac resynchronization therapy and atrial fibrillation therapy, without Home Monitoring)	A.Z. Middelheim, Antwerp, Belgium| AZ St. Jan, Brugge, Belgium| Nemocnice Ceske Budejovice, Czech Republic| FN Olomouc, Olomouc, Czech Republic| Hôpital Gabriel Montpied, Clermont Ferrand, France| CHRU de Lille, Lille, France| CHRU Hôpital de Villeneuve, Montpellier, France| Hôpital Pasteur, Nice, France| Hôpital La Pitié Salpetrière, Paris, France| CHU Haut Lévêque, Pessac, France| CHU des Rennes, Hôpitalde Pontchaillou, Rennes, France| HôpitalNord, Saint Etienne, France| Centre Hospitalier de Rangueil, Toulouse, France| Charité¨ Berlin, Berlin, Germany| Städtische Klinikum Dresden-Friedrichstadt, Dresden, Germany| University Hospital, Ulm, Germany| Rijnstate Ziekenhuis, Arnhem, Netherlands| University Hospital, Groningen, Netherlands| University Medical Center, Leiden, Netherlands| Karolinska University Hospital Stockholm, Stockholm, Sweden| St. Peter's Hospital, Chertsey, United Kingdom

Source: authors' own elaboration.