



REPORT

on

EU state of play on telemedicine services and uptake recommendations

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TABLE OF CHANGE HISTORY

LIST OF ABBREVIATIONS

| ACRONYM | DEFINITION |
|-----------|---|
| COPD | CHRONIC OBSTRUCTIVE PULMONARY DISEASES |
| EC | EUROPEAN COMMISSION |
| ECG | ELECTROCARDIOGRAM |
| eHSG | EHEALTH STAKEHOLDER GROUP |
| EU | EUROPEAN UNION |
| GDPR | GENERAL DATA PROTECTION REGULATION |
| GP | GENERAL PRACTITIONER |
| ICT | INFORMATION AND COMMUNICATION TECHNOLOGIES |
| ICU | INTENSIVE CARE UNIT |
| JAseHN | JOINT ACTION TO SUPPORT EHEALTH NETWORK |
| MAST | MODEL FOR ASSESSMENT OF TELEMEDICINE |
| MS | MEMBER STATES |
| РСР | PRE-COMMERCIAL PROCUREMENT |
| RENEWING | REGIONS OF EUROPE WORKING TOGETHER FOR HEALTH |
| HeALTH | |
| TeleSCoPE | TELEHEALTH SERVICES CODE OF PRACTICE FOR EUROPE |
| TFEU | TREATY ON THE FUNCTIONING OF THE EUROPEAN UNION |
| WHO | WORLD HEALTH ORGANIZATION |

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1. Executive summary

• Purpose and scope

This document intends to report on the state of play of European Union (EU) countries regarding telemedicine and telecare¹ services and provide uptake recommendations towards a solid and sustainable development of telehealth in Europe.

Despite the report's original focus on telemedicine services, it was decided to broaden the scope of the analysis and also report on telecare services, covering both preventive and curative healthcare.

It should be noted that, to be sustainable, telemedicine and telehealth should not be considered as separate from, but as an integral part of eHealth. Nevertheless, since this report concerns the narrow scope of telemedicine and telecare, different components of the eHealth ecosystem were analysed specifically for telemedicine and telecare.

• Methodology

After desk research, a framework for the analysis of telemedicine and telecare implementations was defined, comprising the state of play of the services themselves through a maturity scale, and also of the ecosystem that drives (or hinders).

Information was collected from a questionnaire distributed to national representatives of twenty-nine European countries who, with the help of several health experts, provided their feedback. A total of 18 countries answered the questionnaire, providing data and insights on national telemedicine and telecare ecosystem, the progress and evaluation of telemedicine and telecare services implementation, and barriers to their adoption.

• Main findings

- Implementation status. Countries are using telemedicine, mainly with local or regional scope, comprising interactions provider-to-patient and provider-to-provider and linking the different levels of care, although mainly between primary and hospital care. Several pairs of type of service and specialty are being provided, but the wider activity is in radiology telediagnosis, radiology teleconsultation, cardiology telemonitoring, cardiology teleconsultation, followed by dermatology teleconsultation and telediagnosis and pathology telediagnosis and teleconsultation. For the majority of countries telemedicine services are below 10% of total healthcare services. This coverage of the telemedicine services is not uniform throughout healthcare institutions, within each country neither throughout MS when comparing with each other. Furthermore, the percentage of patients involved in telemedicine services is still very low. Conversely, where MS embrace telemedicine as strategic priorities, the number of patients especially with chronic conditions is destined to rise.
- **Maturity level**: half or more of the respondents considered that telescreening, telediagnosis, teleconsultation, teletriage and telemonitoring are in maturity level of 'defined' large scale pilots implemented, or 'managed' services officially implemented.

¹ Given the limited scope of telemedicine services, and the opportunity to collect valuable inputs from Member States with the elaboration of an online survey, it was decided to broaden the scope of analysis and also report on *telecare* services.

However, when analyzing implementation at national level, the majority of the countries considered it being in an 'ad-hoc' phase – not fully integrated into a national strategy.

- Evaluation practices: the vast majority of existing telemedicine services did not undergo proper evaluation of final outcomes and it lacks complete consolidated registers of telemedicine activity. Although several works exist on telemedicine evaluation methods, they seem not being widely known among stakeholders. Work on this matter is being developed under JASEHN Task 7.4;
- **Expected value**: among several potential impacts of telemedicine and telecare services, top 10 expected impacts are: i. improve continuity of care; ii. improve quality care; iii. contribute to communication between healthcare providers; iv. help to reduce patient's and caregivers time; v. promote access for health services for patients in remote areas; vi. complement face-to-face consultations; vii. improve patient's empowerment and autonomy; viii. improve patient's adherence to treatments; ix. help to reduce patient's and caregiver's costs; x. help to reduce costs with prevention actions.
- Ecosystem of telemedicine and telecare: Concerning strategy and governance, it was concluded that several countries don't have a national telemedicine strategy (neither stand-alone nor included on wider-scope eHealth strategy) nor a national structure responsible for telemedicine development. In regard with financial and economic aspects, it was found that several countries don't have funding mechanisms to finance telemedicine development. It was also noticed that, although reimbursement mechanisms exist to pay for telemedicine services, they are considered below the expectative. In the technical domains, it was found that it still lacks adequate equipment in healthcare organizations and the existence of adequate national interoperability frameworks and standards. Concerning legal and security aspects, desk research and survey results confirmed that there are still some legal gaps and discrepancies from country to country which obstructs the development of cross-border telemedicine services and that there lacks regulation about reimbursement and liability. Finally, in respect to cultural and change management aspects, countries considered there is a medium awareness of telemedicine service among professionals and patients and that both of them are moderate to very high willing of use it. It was also noticed that not all the professionals have access to telemedicine training and that available training may not cover all the skills required.
- Main barriers for telemedicine and telecare development: aggregating the contributions of respondents a barrier top 10 was derived: *i. lack of funding mechanisms to develop telemedicine; ii. lack of reimbursement procedures for telemedicine services; iii. absence of telemedicine services sustainability;* iv. *lack of specific legislation/regulation on reimbursement procedure / guidelines;* v. *absence of a national strategy towards telemedicine development;* vi. lack of technical standards that ensure interoperability; vii. inability to evaluate and monitor the quality of telemedicine services; viii. little government support to prioritize telemedicine in health services delivery; ix. lake of user friendly systems and tools; x. little demand/acceptance of healthcare providers towards telemedicine services.

• Recommendations

Based on the state of implementation of telemedicine services and on the feedback provided by MS representatives responding the survey concerning telemedicine ecosystem,

telemedicine evaluation, barriers to the development of telemedicine and other suggestions, a set of 10 Recommendations were digested:

- 1. EU and MS should consider the establishment of a EU Telemedicine strategy (either stand-alone or integrated on e-Health strategy), included or strongly linked with EU Health strategy, with clear priorities and goals, established by healthcare outcomes indicators and aligned with other activities of EU eHealth Network Multi-Annual Plan;
- 2. MS should consider creating a national structure aiming to lead the adoption of telemedicine and telecare at national scale, ensuring a common vision of priorities, promoting the equity of access to telemedicine services and the adoption of interoperable processes and technologies and enabling the development of cross-border telemedicine and telecare services; This structure should also
 - i. Promote and validate tools, methods and techniques to help healthcare organisations to manage their digital transformation;
 - ii. Facilitate collaboration between existing testing environments, labs and large-scale implementations to promote transferability of lessons learned and to support the scaling-up of digital innovation.
- 3. EU and MS should consider strengthening funding of telemedicine capacity building initiatives and large pilots, especially in those countries lagging;
- 4. MS should consider reviewing reimbursement mechanisms of telemedicine and telecare as its effectiveness is considered bellow expectative;
- 5. EC and MS should consider promoting mechanisms of knowledge sharing regarding economic evaluation methods and cases of telemedicine and telecare services and boost their use throughout the adoption life cycle. These mechanisms should include several topics, namely:
 - i. how to assess the potential economic impact of telemedicine and telecare;
 - ii. how to incentivise successful adoption and the scaling-up of telemedicine and telecare;
 - iii. how to develop and implement models of risk-sharing as a tool to encourage cross-organizational and cross-sectoral working and transformational change underpinned by technologies.
- 6. EC and MS should consider defining a European interoperability framework for telehealth telemedicine and telecare based on open, international standards to allow interoperability between the diverse existing systems (including those acquiring patient generated data and those supporting healthcare providers, namely Disease Management Programs) and to facilitate wide geographic and cross-border telemedicine services;
- 7. EC and MS should consider creating a harmonized legal framework for telemedicine services, namely regarding liability and ensuring GDPR compliance.
- 8. EC and MS should consider engaging with relevant stakeholders to enlarge the availability of telemedicine training initiatives, as well its contents, in order to developed all necessary skills to develop, manage and provide telemedicine and telecare services;
- 9. EC and MS should enforce or at least maintain communication mechanisms both to healthcare providers and to patients to improve awareness and maintain their willingness to use;

EC and MS should gather efforts in registering telemedicine acts and define appropriate indicators to monitor its evolution. Also, since there is such a diversity of services and stakeholders, should promote means for sharing good practices mapped into the type of service, the specialty and the level of care interacting.

2. Introduction

One of the four specific priority areas in which the Joint Action to support eHealth Network (JAseHN) is committed with is the *exchange of knowledge* between Member States (MS). This subject is of the utmost importance because 1) countries have gathered significant information regarding their national eHealth experience, lessons learned, or effectiveness studies that could be shared with other MS, and because 2) there is a lack of standardization of guidelines and procedures on eHealth implementation across countries.

Therefore, the sharing of national knowledge and experiences may create synergies among countries, boost a transversal adoption of common practices, or even provide valuable insights to MS on a later stage of eHealth development.

Telemedicine and telecare are inside the broad concept of eHealth. In the last years, Europe has been committed with the development of telemedicine and telecare services, working on legal requirements for the adoption of this type of services. However, the maturity stage of telemedicine and telecare implementation has been unequal among MS, and there is a lack of global studies reporting on the current state of national telemedicine and telecare services at a European level.

2.1. Purpose

The overall purpose of this document relies on the:

- Analysis of the current state of telemedicine and telecare services in EU countries; and
- Definition of uptake recommendations for telemedicine and telecare adoption and development at a national level.

For the analysis of national telemedicine and telecare state of play, an online survey was conducted among twenty-nine European countries to collect valuable insights and to better understand the national ecosystem, the progress and evaluation of telemedicine and telecare services implementation, and barriers to their adoption in each country.

The results collected in the questionnaire contributed to provide a set of recommendations to guide telemedicine and telehealth services adoption, based on the lessons learned by the MS that have already started to deploy these type of services.

However, this report presents several limitations that are stated below:

- To simplify the information gathering process, the online survey was targeted to national representatives (who were strongly recommended to involve health experts to guarantee the quality of the answers provided), and not to patients and healthcare providers, which conditioned the type and detail level of the questions raised.
- Only 18 countries replied to the questionnaire, so a generalization at European level may not be valid.

Besides the questionnaire, no other methodology was used for the reading of situation and recommendations, although it might have been useful to carry out a focus group or another interactive methodology. In order to mitigate this limitation, it is presented a brief analysis of two large scale telemedicine deployments.

2.2. Scope

Despite the report's original focus on *telemedicine* services, given its limited scope, and the opportunity to collect valuable inputs from MS with the elaboration of an online survey, it was decided to broaden the scope of the analysis and also report on *telecare* services.

In order to clarify some related definitions and concepts usually misunderstood or confused, chapter 3 will provide a general overview of telemedicine and telecare, focusing also on an overall analysis of its main services and applications areas.

Afterwards, following a top-down approach, chapter 4 will contextualize telemedicine and telecare in the European scope, briefly describing previous projects and initiatives deployed in the scope of telemedicine and telecare, and the legal framework for telemedicine and telecare adoption.

Chapter 5 characterizes the current state of telemedicine and telecare development in European countries based on the results of the questionnaire. A conceptual framework for telemedicine and telecare implementation is briefly described to contextualize the online survey structure and questions presented. The questionnaire is divided into five different sections to appropriately address the current state of play of telemedicine and telecare development, and produce meaningful insights. Survey results and discussion are preceded by several details on the research methodology.

Chapter 6 synthetizes the main recommendations resulting from the data collected and the feedback received from MS.

3. Overview of telemedicine and telecare

3.1. Main concepts and terminology

Telemedicine and telecare are frequently confused with other terms included in the broad concept of eHealth, being even sometimes considered synonyms and most often used interchangeably [1, 2]. However, despite their similarity, each one refers to a different way of using information and communication technologies (ICT) to deliver healthcare services. Figure 1 describes a commonly agreed framework that illustrates the relationships between these terms [3], although there are no precise, unique, or definitive definitions for them.

Joint Action to support the eHealth Network

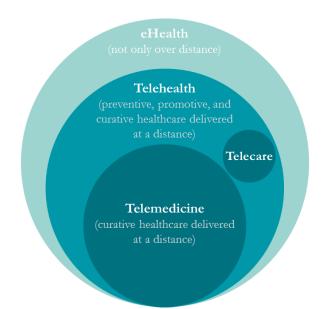


Figure 1 - Conceptual framework of the relations between eHealth, Telehealth, Telecare and Telemedicine

eHealth is considered the most comprehensive concept, encompassing multiple domains. However, there is a lack of consensus in a clear uniform definition - in a qualitative and systematic review conducted in 2005 by Oh *et al.* [4], they found 51 unique definitions for eHealth.

In an attempt to provide a consensual definition, according to the definitions of World Health Organization (WHO) [5], European Commission (EC) [6], and Mitchell [7], eHealth refers to the combined use of electronic communication and information technology in the health sector to share, store and retrieve electronic health data for prevention, diagnosis, treatment, monitoring, educational and administrative purposes, both at the local site or at distance.

Telehealth is a subset of eHealth and refers to the delivery of healthcare *at a distance* – according to Greek language, prefix "tele" means "far" or "at distance", as explained by Varnosafaderani [8].

It comprehends the delivery of healthcare services by all healthcare professionals², where *distance* is a critical factor, through the use of ICT to provide clinical and non-clinical services - *preventative, promotive and curative healthcare* services, research and evaluation, health administration services and continuing education of healthcare providers [4, 9, 10]. Telehealth is a newer and broader term referring to remote healthcare, including services provided using telemedicine, as well as interaction with automated systems or information resources.

Telemedicine is a subset of telehealth, as concluded by Sood *et al.* in a 2007 study after analyzing 104 peer-reviewed definitions of telemedicine [11]. Although some authors inadequately use it to describe the delivery of healthcare services at a distance only by physicians, telemedicine is distinguished from telehealth in the sense that the former focuses

² Article 3/f of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare defines healthcare professionals as "a doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist within the meaning of Directive 2005/36/EC, or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC, or a person considered to be an health professional according to the legislation of the Member State of treatment."

on the *curative scope* of the healthcare services by all healthcare professionals, excluding therefore the preventive and promotive aspects of healthcare as remote training, administrative and educational services [3]. According to Bashshur, Telemedicine involves the use of modern information technology, especially two-way interactive audio/video communications, computers and telemetry to deliver health services to remote patients and to facilitate information exchange between primary care physicians and specialists at some distance from each other (Bashshur, et al., 1997).

Telecare consists on the use of ICT, like alerts and sensing technologies, for the remote monitoring of care needs, emergencies and lifestyle changes of elderly or vulnerable individuals with physical or mental disabilities for the provision of personalized care services at a distance, supporting patients' self-management and helping them to remain independent in their home environment [4, 7, 12, 13]. Given that telecare is strongly related with the preventive scope of healthcare and to ICT-enabled social services, it should be included as a subset of telehealth, outside the telemedicine sphere.

As explained previously, the scope of this report will focus on telemedicine and telecare. Therefore, it will address the services that use ICT for *curative* healthcare delivery at a distance, and for *preventive* healthcare delivery namely through remote monitoring and management of chronic conditions, excluding all the remaining preventive and promotive services as education, training and health management at a distance. As explained previously, the scope of this report will focus on telemedicine and telecare. Therefore, it will address the services that use ICT for curative healthcare delivery at a distance, and for preventive healthcare delivery at a distance, and for preventive healthcare delivery through remote monitoring, excluding all the remaining preventive and promotive services as education, training and health management at a distance.

3.2. Telemedicine and telecare services and application areas

The delivery of healthcare at a distance encompasses a broad range of services that can be used in several application areas/specialties, and deliver health data in different formats, through the use of different devices, methods and mechanisms.

Telemedicine services can be performed and approached using two different methods: storeand-forward (or asynchronous), real-time (or synchronous).

Store-and-forward (or asynchronous) telemedicine comprises the exchange of pre-recorded healthcare data between two or more individuals at different times, meaning that it does not require the presence of both parties at the same time [2, 14]. In this situation, the referring health professional or patient obtains and stores the necessary health and clinical data at a remote facility and then transfers it to other health professional or specialist for later analysis, who afterwards sends back to the submitter an opinion regarding diagnosis or treatment [2]. The transmission of information can be done in the form of data, digital images, audio, video clips, recordings, or web-applications, being e-mail the most commonly used device to exchange this information in an asynchronous way [15]. Store-and-forward telemedicine services are widely used as they are relatively inexpensive and easy to set up and practice [16].

Real-time (or synchronous) telemedicine requires the immediate transmission of information through a communication device to allow real-time interaction between patient/ healthcare professional and other healthcare provider/ specialist, who are simultaneously present, but remotely [2, 14, 15]. The transmission of information in real-time is commonly done using video-conference equipment, but a phone call or an online chat forum are also interactive forms of synchronous communication [14, 15]. Real-time telemedicine allows interactive

examinations that, with the help of peripheral devices connected to a computer, PDA, smartphone or video-conferencing equipment, can provide valuable information to remote healthcare providers/ specialists [14].

• Services

These two delivery methods are applied not only to a wide array of telemedicine services, including teletriage, teleconsultation, telediagnosis, telesurgery and telescreening, but also to telecare services – telemonitoring.

Teletriage refers to the process of identifying a patient's problem, accessing the level of urgency, and recommend advice via phone [17, 18] by trained professionals, in order to guarantee a safe, timely and appropriate disposition of patient symptoms [19]. Although nurses and physicians are considered the most common groups of teletriage practitioners, there are also non-clinicians involved in this process, like emergency medical dispatchers, clerical staff, and answering service staff [18]. The main task of these professionals is the ability to estimate urgent symptoms, rather than diagnose symptoms [20], and make safe decisions regarding patients, recommending on-site or home treatment. In this regard, professionals are trained to follow a list of predefined questions in order to determine whether symptoms are life threatening, emergent, urgent, acute or non-acute [21]. Teletriage is beneficial to patients as a powerful tool to use under conditions of urgency or uncertainty. From the health institutions' perspective, teletriage contributes to reduce healthcare system costs with inappropriate emergency visits.

Teleconsultation is the most frequent example of medical services provided at a distance [22]. It is defined as synchronous or asynchronous consultation between two or more geographically separated healthcare providers or between healthcare providers and patients using ICT to communicate at a distance, for the purpose of diagnosis or treatment of a patient at a remote site, to obtain a specialist's second opinion [23, 24] or to develop innovative care pathways. In case the patient has a healthcare professional physically present during a teleconsultation with other healthcare professional or specialist, the former can perform an interactive physical examination and report the results to the latter. Teleconsultation allows an easy and convenient access to medical services [25] and assumes a critical relevance for those who live in rural and remote areas, where sometimes there is a lack of healthcare professionals, and for people with physical disabilities, who have increased difficulties to attend physical consultations. Therefore, teleconsultations help save patients' time and transportation costs, as they can remotely access to a consultation directly from a local community healthcare center or home.

Telediagnosis is the determination of the nature of a patient's disease, at a remote location [26], based on the clinical data and information (i.e. data, images, and video records) transmitted through ICT. Telediagnosis made by medical experts helps healthcare professionals in remote areas to assess patient's health and provide the adequate treatment, bringing advantages for both patients and healthcare providers. Telediagnosis should not be confused with teletriage, as the former focuses on the detection and *diagnose* of the symptoms described by the patient, and the latter provide only an estimate of the *urgency* of the symptoms. Although one of the teleconsultation purposes is the diagnosis of a patient in a remote location, telediagnosis is not circumscribed to the teleconsultation scope, as it can be made during telescreening or telemonitoring.

Telesurgery refers to the use of telemedicine equipment and ICT to support and monitor surgical procedures at a distance, or to perform remote surgery [27]. This means that telesurgery can be performed using two methods: telementoring or telepresence surgery/ teleintervention. The former consists on the remote interactive assistance given by a specialist to a surgeon during a surgical procedure, through the use of video and audio connections [22]. The latter uses robotized and computerized technologies to actively perform remote surgeries, by linking surgeon's movements to a scale-down and very precise movement produced by a small robot machine [22, 28].

Telescreening consists on the use of ICT between patients and healthcare providers to remotely identify a possible disease that was not previously recognized in individuals without any signs or symptoms, or with pre-symptomatic or unrecognized symptomatic disease, through the use of medical tests that can also be provided remotely [29]. Telediagnosis should not confused with telescreening in the sense that the former intends to diagnose a certain disease, and the latter is more focused on the identification and subsequent follow-up of a pathology that can be suspicious. The application of telemedicine tools to screening allow healthcare providers to remotely access one or multiple sites to identify potential diseases in individuals or communities, which optimizes healthcare professionals' time and resources, while delivering quality screenings [30].

Telemonitoring, as explained previously in chapter 3.1., is not included in the curative scope of telemedicine, but in the telecare scope, focusing on the preventive aspect of healthcare. According to Nangalia [31], telemonitoring chain is composed of five stages: 1) data acquisition using an appropriate sensor; 2) transmission of these data from patient to clinician; 3) integration of the data with other data describing the state of the patient; 4) synthesis of an appropriate action, or response or escalation in the care of the patient, and associated decision support; and 5) data storage. Sensors used to remotely collect patients' condition data can do it continuous or intermittently, being even possible to determine the time of the next measurement based on the last value gathered [31]. The process of health data measurement and gathering may be automatic, or manual, in which case the patient records the data and transmits them by telephone or a networked system to a healthcare provider [22, 31]. Health data can be continuously transmitted to the clinician (through store-and-forward or real-time mode), or only in exceptional and urgent cases, when a potential dangerous occurrence in patient's health condition is detected [31, 32]. The integration of the data received is usually done by a computer or a health professional. Telemonitoring services (as well as teletriage) usually are not primarily performed by physicians, being only involved when patients present signs of health deterioration [33]. Concluding, telemonitoring services empower patients to actively manage their diseases, at the same time that enhance continuity of care and prevention of future occurrences in the context of chronic disease management [27, 33].

• Specialties and application areas

Telemedicine and telecare services are used in a broad range of specialties, being radiology, pathology, dermatology, psychiatry, cardiology and ophthalmology some of the most common ones.

In **Radiology**, ICT are used to transmit and exchange medical images (i.e. x-ray, MRIs, ultrasounds) for remote viewing, interpretation, assessment and diagnosis of a radiologist who is not present at the site where the images were taken. Teleradiology is generally considered the most advanced and commonly used specialty in telemedicine services [33], as the transmission

of a high-quality image is usually sufficient to provide a diagnosis, with no need for additional examinations [34].

Silva [35] explains that teleradiology is mainly sought by hospitals, radiology groups, referring physicians and patients:

- Hospitals are the main end-users of teleradiology, as they contract teleradiology service professionals to provide afterhours' coverage as a supplement to the on-site radiologists' hours, or to reinforce subspecialty coverage, at a more affordable cost to the hospital (pay-per-exam method);
- Radiology groups are usually required to provide off-site coverage in remote regional hospitals or imaging centers, where there is a lack of resources;
- Referring physicians use teleradiology to obtain specialists' opinion and provide local healthcare services to patients;
- Patients also search for teleradiology services to have a direct remote access to a radiologist or to obtain a second opinion on their medical images.

Pathology is another medical specialty where telemedicine services are applied. It refers to the use of ICT by pathologists or other laboratory personnel to remotely collect, interpret and transmit pathologic data and results for the purpose of diagnosis, consultation or second opinion [36, 37]. Unlike the majority of telemedicine specialties, telepathology does not require the patient to be present to make a diagnosis, being therefore a more dematerialized medical specialty [38].

There are three telepathology systems to perform a remote diagnosis on a pathology slide: static-image, dynamic or real-time, and whole slide image or virtual slides:

- Static-image telepathology is the simplest and most mature modality of telepathology [39], and involves the process of collecting and digitalizing high-quality images by the referring pathologist or non-expert to transmit, by electronic means, to a remote pathologist [34, 40];
- Dynamic or real-time telepathology consists on the implementation of a motorized microscope which can be operated remotely. In this case, the on-site pathologist or laboratory personnel use a video camera to provide real-time images from the microscope to the remote specialist, who can control the microscope to analyze a slide location or magnification [34];
- The whole slide image system is the most recent development on telepathology systems and involves "the use of an automated microscopic glass slide scanner that captures serial images from the entire specimen located on a microscope glass slide" [39]. These images are automatically stitched together, compressed in a single file, resulting in a virtual image of the entire specimen on a microscope slide, being therefore transmitted in digital form [39].

Dermatology is a medical specialty that frequently uses communication technologies to transmit medical information concerning skin conditions for the purpose of diagnosis or consultation. The diagnostic process is very focused on the *visual* appearance of the skin, facilitating the general acceptance and usage of telemedicine services for dermatology. Usually, store-and-forward is the most used method to delivery teledermatology services, in the form

of high-quality digital images [41, 42, 43]. Nevertheless, synchronous telemedicine is also applied through the use of videoconferencing equipment during a teledermatology consultation.

Tensen [41] states that teledermatology involves different actors, being therefore classified as it follows:

- Primary teledermatology intends to provide a first diagnosis or referral to a dermatologist and occurs between the patient and the general practitioner (GP);
- Secondary teledermatology is the most common one, and is performed between the GP and a dermatologist to exchange medical information, before referring the patient;
- o Tertiary teledermatology occurs between dermatologists;
- Patient-assisted teledermatology consists on the direct interaction of the patient with a healthcare professional, usually nurses, for follow-up care.

Psychiatry also uses information and communication technologies to provide remote psychiatric-mental health services, like psychiatric assessments, individual/ group/ family therapy, or patient medication management [44]. In opposition to other telemedicine specialties, telepsychiatry generally uses synchronous methods of communication between healthcare providers and patients, because psychiatrics need to evaluate patient's conditions related with mental status or verbal communications, rather than physical examinations [45]. Telepsychiatry is currently used not only for private practice, but also to provide psychiatric services to hospitals, schools, correctional facilities, or military treatment facilities [44].

Cardiology uses ICT to provide remote assessment, diagnosis, consultation and treatment of heart diseases through the interpretation of electrocardiographic (ECG) data.

According to Backman [46], telecardiology has rapidly evolved and offers, nowadays, advanced methods to perform accurate ECG interpretations remotely:

- 12-lead ECG device: hand-held device that encodes the ECG into sound, which is then sent to the telecardiology center to be decoded and displayed as a full image, being therefore analyzed by cardiologists or specialist nurses, who will act in accordance with the urgency of the occurrence, and the ECG is subsequently stored;
- Single-lead ECG device: wearable device, usually in the form of a watch that the patient can activate to records, store, and transmit vital signs to the telecardiology center.

Concluding, cardiology is one of the specialties that uses not only telemedicine, but also telecare services to prevent events, as telemonitoring.

Ophthalmology is also becoming a medical specialty that uses digital medical equipment and communication technologies to provide eye care health services remotely for the purpose of diagnosis, monitoring, screening, or consultation [47]. Store-and-forward is the mostly adopted method in teleophthalmology [48]: firstly, a GP takes ocular images of the patient's eyes with digital instruments to send to an ophthalmology, who will review the data collected and will provide a diagnosis and send back a report [49].

In addition to these medical specialties, telemedicine is also present in other areas as nursing and pharmacy.

Nursing uses information and communication technologies to deliver nursing care and conduct nursing practice remotely [50]. Nurses work closely with physicians and other healthcare professionals in the provision of telemedicine services.

Some of the most common services of telenursing are teletriage, telemonitoring and tele-home care for case management [51]:

- Teletriage performed by nurses ensures that patient's problems are identified and that they are recommended on how to proceed, based on the urgency of their symptoms;
- Telemonitoring not only help to collect patients' data, such as blood pressure, blood glucose, or respiratory peak flow, and transmit them to nurses, but also to offer social care services, helping individuals to become more independent;
- Tele-home care allows patients to contact on-call nurses anytime a problem or doubt arises and receive counseling and appropriate care.

Pharmacies can also provide telemedicine services. Telepharmacy enables the delivery of pharmaceutical services such as medication review, dispensing and compounding, patients counseling, prescription verification, and therapeutic drug monitoring by a pharmacist to remote patients [52, 53]. Similar to what has been presented in teleradiology, telepharmacy services are demanded by healthcare institutions in remote areas, where there is a lack of 24-hours pharmacy services, or where the pharmacy coverage is insufficient [54].

4. European background on telemedicine and telecare development

European healthcare systems are facing several challenges in their path to provide sustainable and equitable healthcare to all citizens. Healthcare costs have been increasing exponentially because, on the demand side, there is an increasing size of the elderly population, a growing incidence of chronic diseases, and increased demands from patients for more quality in provision of healthcare services; and, on the supply side, there are still shortages in healthcare workforce, which makes it difficult to accommodate this growing demand [55].

Aware of the key role of new technologies in responding to these growing demands of healthcare services, EC has been strongly committed with the maximization of ICT potential to deliver healthcare services at a distance. The first eHealth Action Plan was adopted in 2004 and invited MS to adopt pilot actions in order to [there seems a part of the sentence missing?] "by the end of 2008, the majority of European health organizations and health regions (communities, counties, districts) should be able to provide online services such as teleconsultation, [...] telemonitoring and telecare" [56]. Since then, the EC has been working to foster a widespread adoption of telemedicine services by developing some working document and policy initiatives, like the Communication of the Commission on telemedicine for the benefit of patients, healthcare systems and society [55], the Commission Recommendation on cross-border interoperability of electronic health record systems [57], or the 2014 report of the eHealth Stakeholder Group (eHSG)³ on the widespread deployment of telemedicine services in Europe [33]. More recently, the Digital Agenda for Europe, announced

³ The eHealth Stakeholder Group (eHSG) is an EC advisory group, composed of representatives from the most important European organizations active in the eHealth field, covering a wide range of stakeholders: from patients, consumers, healthcare professionals to the industry, and was created following a call for expression of interest end 2011.

in 2015, identifies seven priority areas and proposes several key actions, being one of them "achieve by 2020 widespread deployment of telemedicine services" [58].

4.1. Main European initiatives, projects and documents

As a result of these EC policy initiatives, and in order to support the development of telemedicine and telecare services, EC has been funding several initiatives, projects and pilots, being below highlighted the most relevant ones:

- MethoTelemed (2009 2010) [59] this project intended to provide a structured framework for assessing the effectiveness and contribution to quality of care of telemedicine applications, and to produce a basis for decision making on the use of telemedicine solutions in EU and the European countries. This framework entitled MAST (Model for Assessment of Telemedicine) is divided into seven domains, follows a stakeholder-oriented approach, and evaluates information about the medical, social, economic and ethical issues related to the use of telemedicine. MAST was tested in twenty pilot project of telemedicine applications in nine European countries in the EC project RENEWING HeALTH, as well as in a large number of national and international telemedicine studies in Europe. The overall impression is that MAST is a valuable framework for pilot evaluations [60].
- **RENEWING HeALTH** | REgioNs of Europea WorkINg together for HEALTH (2010-2013) [61] this project aimed to implement, validate and evaluate innovative telemedicine solutions for the management of chronic diseases diabetes, chronic obstructive pulmonary and cardiovascular diseases in nine European regions. This project involved about 7.000 patients, being the largest Randomized Controlled Trial study in telemedicine in Europe in2013. The project fostered patients' involvement and empowerment in the management of their own diseases, at the same time that helped to optimize the use of resources in healthcare provision [62, 63].
- **TeleSCoPE** | Telehealth Services Code of Practice for Europe (2010-2013) [64] this project arose from the EC Action Point on COM2008:689 to 'improve confidence in and acceptance of telemedicine', and developed a comprehensive Code of Practice for Telehealth Services, more focused on telecare [65]. The Code sets service standards and a quality benchmark around topics like data privacy, access to information, and moral and ethical issues [65]. The use of the Code will help to increase the trust between patients and healthcare professionals, and overcome some of the current barriers [66].
- Chain of Trust (2011-2013) [9] despite the focus on the broad scope on telehealth, this project "assessed the views, needs, benefits and barriers related to telehealth from the perspective of the main end users across the EU (patients, doctors, nurses and pharmacists) to see whether and how they have evolved since the initial deployment of telehealth and what barriers there still are to building confidence in and acceptance of this innovative type of services [that also includes telemedicine and telecare]. Ultimately the project aimed at strengthening significantly the levels of awareness and trust for all key stakeholders" [67].
- **MOMENTUM** (2012 2015) [68] this thematic network produced a blueprint for telemedicine deployment that provides a holistic European reference for developing a telemedicine service framework, and a toolkit for capacity-building among telemedicine

doers, in order to move telemedicine from an idea or a pilot to daily practice. Eighteen critical success factors to telemedicine development were defined, as well as a set of relevant performance indicators to test the degree of readiness of a telemedicine solution for a large-scale deployment.

- United4Health (2013 2016) [69] the core ambition of this project was to exploit and scale up telemedicine solutions implemented and trialed under the RENEWING HeALTH project. Through fourteen large-scale telemedicine pilots in Europe involving approximately 12.000 patients, this project has sought to deliver telemedicine and telecare to the many people suffering from Chronic Obstructive Pulmonary Diseases (COPD), diabetes and cardiovascular diseases.
- Thalea (2013 2019) [70] through this on-going project, "five hospitals from Germany, Netherlands, Spain, Belgium and Finland will initiate a joint Pre-Commercial Procurement (PCP) focusing on getting a highly interoperable telemedicine and telemonitoring platform (a central 'monitoring cockpit') for improving the care of acutely live-threatened patients at intensive care units (ICUs). THALEA intends to launch a European wide published PCP call for tender for the value of around €1,55M" [71].
- ELECTOR (2015 2018) [72] this on-going project intends to "develop, test, implement, and evaluate an eHealth platform for home-based monitoring of patients with arthritis. The proposed platform will encompass state-of the art technology a web-based software for communication and data transfer in combination with miniaturized biochemistry devices. The end result is an eHealth platform that will provide an integrated and direct collection of data into patient notes in the set-up of an eHealth outpatient clinic for citizens with rheumatoid arthritis. The adaptive and flexible nature of this solution will change the provision of healthcare and may be disseminated to monitor a variety of diseases" [72].

4.2. Brief overview on the European legal framework for telemedicine services

Despite the widespread awareness of the benefits of telemedicine, the lack of legal clarity remains as one of the biggest challenges to telemedicine adoption.

In order to raise awareness on how telemedicine is affected by current EU legislation, the EC announced, in 2008, the elaboration of an extensive analysis on the European legal framework regarding telemedicine services, which was published in 2012, as an accompanying document of the eHealth Action Plan 2012-2020 [73].

The first legal issue regarding telemedicine is the fact that it can be considered both a *healthcare service* and an *information and telecommunication service*. In the former, telemedicine as a healthcare service is included in the scope of Article 56 and 57 of the Treaty on the Functioning of the European Union (TFEU), and to that extend is subject to the general freedom regarding free movement of services [74], meaning that it can be argued that "neither the special nature of health services nor the way in which they are organized, [delivered] or financed removes healthcare services from the ambit of this fundamental freedom" [73]. Additionally, telemedicine as a healthcare service also falls within the scope of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare [75], being referenced in Article

3(d) and 7(7). In the latter, telemedicine as an information and telecommunication service falls within the scope of the Directive 2000/31/EC on Electronic Commerce [76] in the sense that it defines information society service as a "service normally provided for remuneration, at a distance, by electronic means, at the individual request of a recipient of service"⁴.

In addition to the fact that there is a lack of consensus at an European level towards telemedicine services scope, the majority of regulatory competences still rests with the MS, and the differences between countries are still massive: that some countries regulate telemedicine from an IT perspective, and others approach it as a healthcare service, or even a social security issue [74].

Cross-border telemedicine within the European territory is also addressed in the scope of several EU legal instruments, being the most relevant one the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, due to be transposed by 25 October 2013. Some of the most important legal issues regarding cross-border telemedicine concern: licensing/registration of health professionals performing cross-border telemedicine services; the conditions for legal processing of health data; the right of reimbursement of a cross-border telemedicine act; and finally the determination of potential liability, competent jurisdiction, and applicable law [73].

Figure 2 summarizes the main key findings on EU legislation applicable to cross-border telemedicine, and was adapted from the accompanying document of the eHealth Action Plan 2012-2020 [73] and updated with information on the new General Data Protection Regulation (GDPR) published by Law 360 [77]:

MAIN KEY FINDINGS

Patients' rights

"The rights of patients when receiving cross-border healthcare, including telemedicine, are enshrined in Directive 2011/24/EU on the application of patients' rights in cross-border healthcare. They include the right to:

- receive treatment in another MS and be reimbursed under certain conditions;
- have access to a written or electronic copy of their health records." [73]

Licensing/registration of healthcare professionals

"Directive 2011/24/EU on the application of patients' rights in cross-border healthcare requires that cross-border healthcare is to be provided in accordance with the legislation of the MS of treatment. In the case of telemedicine, it expressly defines the MS of treatment as that of the service provider's MS of establishment."

"Indeed, to provide cross-border telemedicine services, the professional does not need to move. Logically, the professional do not have to have an authorization of the MS of residence of the patient. This is only in the case where he wants to exercise in another MS that the one of its habitual residence that he/she may need to request an authorization" [73].

⁴ Article 2(a) of the e-Commerce Directive and Article 1(2) of the "Transparency Directive". Other relevant documents concerning telemedicine as information and telecommunication service are: Directive 98/34/EC on Services of the Information Society; and Directive 2002/58/EC on Privacy and Electronic Communications or e-Privacy Directive.

Processing of health data

The procession of personal health data related to health is regulated by the new General Data Protection Regulation (GDPR) (EU 2016/679), published in May 2016, replacing Directive 1995/45, and will be directly applicable to all MS by May 2018, without the need for implementing national legislation. Some of the most relevant topics regarding processing of personal health data are presented below:

• Special Categories of Personal Data

The GDPR prohibits the processing of certain special categories of personal data, including genetic data, data concerning health or other types of sensitive personal data. However, it is subject to certain exceptional circumstances when:

- "the individual has given his/her explicit consent to the processing for one or more specified and lawful purposes (unless such consent is prohibited by applicable EU or MS law)" [77];
- "the processing is necessary to protect the "vital interests" of the individual (generally, this exception can only be relied on in "life or death" type situations)" [77];
- o "the processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services on the basis of EU or MS law or pursuant to contract with a health professional and subject to certain conditions and safeguards"; [77] and
- o "the processing is necessary for public interest reasons" [77].

• Consent

"If processing [of data] is based on consent, organizations must be able to show that individuals have agreed [with that]. Furthermore, if consent is given in a written declaration that also relates to matters other than the consent, the consent request must be presented in a way that is clearly distinguishable from the other matters". Additionally, "individuals have the right to withdraw their consent to the processing of their personal information at any time" [77].

• Anonymization and Pseudonymization

GDPR states that "data protection principles should apply to any information concerning an identified or identifiable individual" [77]. This includes "personal data that has undergone pseudonymization that could be attributed to an individual by the use of additional information" [77].

• Data Protection Design and Default and Privacy Impact Assessments

"Data controllers must adopt appropriate technical and organizational measures to ensure that, by default, only personal data that is necessary for each specific purpose of the processing is processed and that, by default, personal data is not made accessible without the individual's intervention to an indefinite number of people.

The GDPR also formally requires data controllers to carry out privacy impact assessments in relation to any personal data processing that is likely to result in high risks to individuals' rights and freedoms, particularly where the processing uses new technologies" [77].

Reimbursement

"Directive 2011/24/EU on the application of patients' rights in cross-border healthcare provides that the costs incurred by the patient for cross-border healthcare, such as telemedicine, should be reimbursed if the healthcare in question is among the benefits to which the insured person (i.e. patient) is entitled in his/her MS of affiliation" [73].

<u>Liability</u>

EU has still not issued specific rules on medical liability of healthcare professionals, and it varies from one MS to another. The liability regime for defective products is the only one that is regulated at a European level to the provision of telemedicine.

Competent jurisdiction

"The patient always has the possibility of suing the professional in the MS where the professional is domiciled. The alternative optional jurisdictions are likely in very many cases to allow him/her to sue in the MS of his/her own domicile if he/she so chooses." [73]

Figure 2 - Main key findings on EU legislation regarding cross-border telemedicine

Concluding, although all the efforts to guarantee a uniform and common legal framework to telemedicine, the truth is that there are still some legal gaps in what concerns European norms, like on medical liability or standard of care [74]. With several legal discrepancies from country to country, the EC will have the challenge to create a legal framework concerning a broader range of telemedicine domains, beyond technology or privacy. Although the responsibility of creating and delivering telemedicine services falls on MS, the EC has the important role of support and coordinate policy initiatives to support convergence towards common solutions.

5. Current state of telemedicine and telecare in EU countries

5.1. Conceptual framework for telemedicine and telecare services implementation

In order to characterize the current state of telemedicine and telecare in EU countries in the most comprehensive and complete way, it is important not only to address the state of play of the services themselves, but also to analyze all the ecosystem that drives (or hinders) the development of telemedicine and telecare services in a country.

In an attempt to schematize a conceptual framework that illustrates the stages and components required for a telemedicine service implementation, below it is presented a framework to address this issue. This framework served also as the basis for the survey structure.

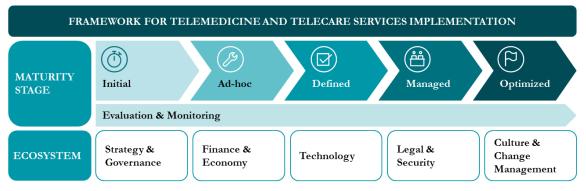


Figure 3 - Framework for telemedicine and telecare services implementation

Independently of the type of service, until the full implementation of a telemedicine or telecare service, there is a path towards continuous improvement based on a scale of maturity stages defined as it follows:

• Initial stage

There are no formal telemedicine services defined. Pilot projects/ initiatives are conceptualized and planned in a decentralized way to implement telemedicine services.

• Ad-hoc stage

Small-scale, short-term and independent pilot experiments are developed, implemented and used by few health stakeholders, to help to check the conditions and operational details of how a large-scale project might work in practice.

• Defined stage

Large-scale, transversal and integrated pilot initiatives are developed, implemented and used by several health stakeholders across the country to test the final feasibility of the implementation of telemedicine services.

Managed stage

Telemedicine services are officially implemented across the country.

• Optimized stage

Telemedicine services are fully implemented and integrated within the healthcare ecosystem. They are delivering the expected results and healthcare stakeholders support telemedicine development.

Throughout all these stages, the evaluation and monitoring of the progresses of each service must be carried out in order to measure and assess final outcomes, and to provide valid scientific evidence of the benefits of the adoption of telemedicine and telecare services. In fact, one of the obstacles for wider development of telemedicine concerns the lack of high-quality studies to attest the outcomes of telemedicine services. Therefore, several evaluations models have been used to assess the efficacy of telemedicine services, being MAST model considered one of the most comprehensive and multidisciplinary frameworks. Furthermore, work is being done under JASEHN Task 7.4 to define a Health Technology Assessment framework to access the value of National eHealth projects.

The correct implementation of these services is influenced by different components of the telemedicine ecosystem: strategy & governance, finance & economy, technology, legal & security, and culture & change management. It should be noted that ideally this ecosystem is an integral part of the eHealth ecosystem. To be sustainable, telemedicine and telehealth should not be considered as separate from, but as an integral part of eHealth deployment and infrastructures, which should be able to deliver all digital services within healthcare. Nevertheless, since this report concerns the narrow scope of telemedicine and telecare, it was conducted the analysis of the different components of the ecosystem specifically for telemedicine and telecare.

Regarding the **strategic & governance** level, it is important to analyze what is the maturity stage of the national telemedicine strategy and what is the level of commitment of the Government and national bodies and authorities towards the adoption of telemedicine services in the country.

The **financial & economic** level is also extremely important in the sense that telemedicine services need substantial investment to allow healthcare delivery at a distance. Therefore, funding mechanisms reveal to be important drivers of telemedicine adoption, not only in the initial maturity stages to support pilot projects, but also afterwards to guarantee project sustainability. Additionally, one of the most relevant issues regarding telemedicine services is reimbursement that reveals to be a major obstacle to full adoption. Therefore, it is important to analyze if there are national reimbursement mechanisms, who is in charge of them, and what is the degree of satisfaction.

In what concerns **technological** level, and taking into account that one of the benefits of telemedicine is to provide healthcare services to patients in rural areas, it is important to analyze if there are technological infrastructures and equipment across the country, as well as national coverage and high-speed internet. Furthermore, telemedicine services deployment is dependent on the adoption of common data structure standards and terminologies to allow interoperability between the diverse systems.

Other relevant dimension of telemedicine ecosystem concerns **legal & security** issues. Beyond the efforts being made by the EC towards a common legal framework⁵, national legislation on telemedicine topics is also fundamental, with particular emphasis in legislation on reimbursement mechanisms, medical liability, security of data transfer and storage, and privacy and confidentiality of patients' data.

Last, but not the least, the **cultural & change management** dimension can strongly condition telemedicine adoption. Both healthcare professionals and patients have to be aware of telemedicine benefits and willing to use these services, with the support of several adoption mechanisms and the involvement of both educational institutions and healthcare organizations in the provision of specific training regarding telemedicine skills.

5.2. Survey results and discussion

5.2.1. Research methodology

• Data collection and sample

⁵ Further details on chapter 4.2.

The questionnaire was designed based on the key findings found in literature review regarding telemedicine and telecare, namely the MAST framework, and partially inspired in other surveys carried out worldwide to analyze this subject, namely "Third Global Survey on eHealth" of WHO [78], the survey conducted in the scope of the MOMENTUM Thematic Network – Advancing Telemedicine Adoption in Europe [79].

This questionnaire contains mainly closed questions, but has also some open questions to guarantee the content received is diversified and reflects national experiences and views.

The first part aimed to gather general information about the respondents – national representatives, but also national experts, who may be involved in the process, to guarantee the quality of the information, as recommended. The second part intended to explore the national telemedicine and telecare ecosystem based on 1) strategy and governance context; 2) financial and economic context; 3) technology context; 4) legal and security context; and 5) cultural context. The third part aimed to collect valuable insights regarding the current state of telemedicine and telecare services, and the main specialties/ application areas where they are used. The fourth part intended to understand if these services are being subject to evaluation studies, and what the most common final outcomes of these studies are. The fifth part aimed to collect insights on the main barriers to telemedicine and telecare adoption. The last part intended to collect feedback regarding lessons learned during telemedicine/ telecare implementation, as well as suggestions/ recommendations.

In order to guarantee the quality and completeness of the questionnaire, it was subject to a predistribution phase to the national representatives of JAseHN T7.1 MS, in order to collect their feedback on possible enhancements/ amendments to the questionnaire. Comments and suggestions were incorporated into the final version.

The questionnaire was hosted online using SurveyMonkey® platform and it was available in English from the 20th of April until the 15th July. **Annex A** shows the structure, questions and interface provided. Twenty-nine European countries were asked to participate in this online questionnaire⁶. Invites to participation were sent by email to each national representative, and individual contacts were made in order to receive the last-minute questionnaire entries.

At the end, a total of **18** questionnaires were completed⁷, representing a **62%** of response rate. **94%** of surveys were filled with experts' contribution, ranging from 1 to 5 contributing experts.

• Data reliability and validity

Reliability is the "extent to which results are consistent over time and an accurate representation of the total population under study".⁸ To ensure this property, one of the most used techniques is a test-retest method.⁹ However, since it was a rather extensive and demanding questionnaire, and given the difficulty of collecting a significant number of responses, it was not feasible to use a test-retest model. Therefore, the main method to guarantee reliability was to design an

⁶ Countries contacted: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

⁷ Countries that completed the survey: Austria, Croatia, Cyprus, Estonia, Finland, Greece, Hungary, Italy, Latvia, Lithuania, Malta, Netherlands, Norway, Portugal, Slovenia, Sweden, Switzerland and the United Kingdom

⁸ Joppe, Marion. 2000. The Research Process. Retrieved February 25, 1998, from: http://www.ryerson.ca/~mjoppe/rp.htm

⁹ Golafshani, Nahid. 2003. "Understanding reliability and validity in qualitative research." The Qualitative Report, 8(4), 597-606. http://www.nova.edu/ssss/QR/QR8-4/golafshani.pdf

intuitive questionnaire with clear questions. All the concepts employed during the survey were clarified not only in the introductory part, but also throughout the questionnaire, whenever needed, which helped to avoid uncertainty about the questions asked. Although some of the questions were not considered easy to answer due to its content, almost all the questions had an intuitive multiple-choice format, and it was strongly recommended the participation of a group of 3-5 national experts to help to answer the questions in an accurate and trusted way. Furthermore, the online questionnaire was previously tested not only by national representatives, but also by individuals outside the sample who tested the platform used, and their feedback about survey structure and clarity was taken into account.

Validity is the "extent to which observations accurately record the behavior in which the researcher is interested".¹⁰ To satisfy this condition, the questionnaire was constructed in partnership with several telemedicine experts and validated by several national representatives who provided feedback on whether the questions are essential, useful or irrelevant to measure the construct under study.

5.2.2. Data analysis and results

Processed compiled results for each question are shown in Annex B.

Annex C shows individual countries responses.

• Telemedicine ecosystem

Strategy and Governance Context

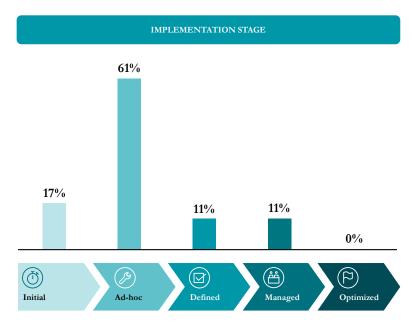


Figure 4 - Telemedicine and telecare national implementation maturity stage

In strategy and governance context, 61% of the eighteen answers considered that the implementation of telemedicine is in an ad hoc stage, meaning that several relevant telemedicine initiatives are developed, implemented and used by several stakeholders, but they are not fully integrated into a national strategy and planning (see **Erro! A origem da referência não foi encontrada.**).

¹⁰ Sapsford, Roger, and Victor Jupp. 2006. Data Collection and Analysis. London: SAGE Publications

Concerning governance structures, 61% of the countries don't have specific bodies/authorities responsible for telemedicine development (see Erro! A origem da referência não foi encontrada.).



Figure 5 - Question on the Specific bodies/ authorities responsible for telemedicine development

Regarding the national telemedicine strategy, 33% of the countries don't have one. Only 39% have specific guidelines for national and/or organizational development of telemedicine in their national strategy (see **Erro! A origem da referência não foi encontrada.**).



■ Yes ■ No ■ DK/ DA ■ My country does not have a telemedicine strategy

Figure 6 - Question on the Specific guidelines for national, regional and organization development of telemedicine services

Erro! A origem da referência não foi encontrada. shows that 82% of the countries that have a national strategies, these strategies devise the development of cross-border telemedicine services.



Figure 7 - Question on the development of cross-border telemedicine services in national strategies

Financial and Economic Context

In financial and economic context 61% of the answers indicate that the countries have funding mechanisms available for telemedicine development (Erro! A origem da referência não foi encontrada.). 91% of that countries have public funding, representing more the majority of funding for all but two countries. Other fund sources exist, mainly donor a public-private partnerships (see Erro! A origem da referência não foi encontrada.).



Figure 8 - Question on funding mechanisms available for telemedicine development

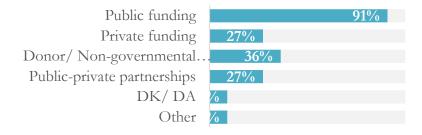


Figure 9 - Question on the type of funding available for telemedicine development

For 73% of the countries there are economic studies/business cases prepared to support funding. However, 18% answered that they didn't know or didn't answer (see Figure 10).



Figure 10 - Question on economic studies/ business cases prepared to support funding

55% of the countries indicate that their country has mechanisms of reimbursement (see Figure 11) and 80% of these are from public health insurance companies, followed by 50% from government (see 2).



Figure 11 - Question on reimbursement mechanisms to get paid for telemedicine services

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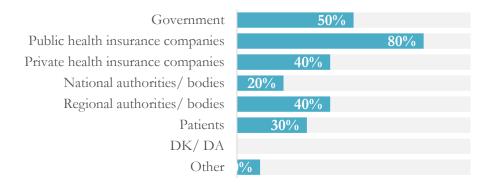


Figure 12 - Questions on the stakeholders in charge to reimburse telemedicine services

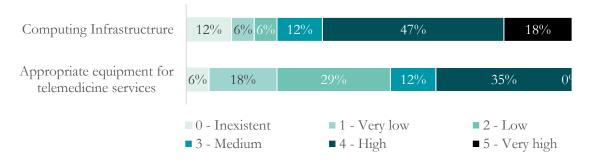
In Figure 13 70% of the countries consider that the effectiveness of the current reimbursement mechanisms available for telemedicine services are below to expectations and 20% affirmed that they didn't know or didn't answer.

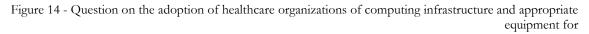


Figure 13 - Question on the level of effectiveness of the current reimbursement mechanisms available for telemedicine services

Technology Context

In the technology context, 65% of countries considered healthcare organizations having a high or very high degree of development in adoption of computing infrastructures, Concerning the existence and appropriateness of equipment for telemedicine services, only 35% classified it as high and 53% considered it below medium (inexistent, very low or low) (see **Erro! A origem da referência não foi encontrada.4**).





In the wider dimension of availability of ICT services and technologies, 28% of the countries reported that their penetration rate of high-speed internet bandwidth is still lower than 50%. The vast majority of countries reported high or very high penetration rate of households with internet access (73% of countries with penetration rate above 81% and 67% of the countries with penetration rate of smartphones above 71%) (see **Erro! A origem da referência não foi encontrada.**5 and 16).

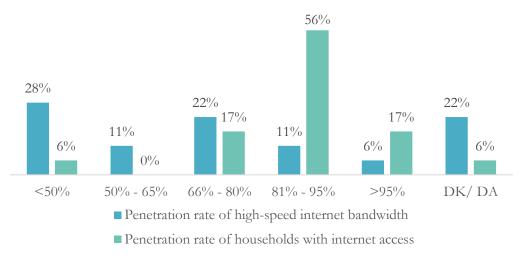


Figure 15 - Question on the penetration rate of high-speed internet bandwidth and households with internet access

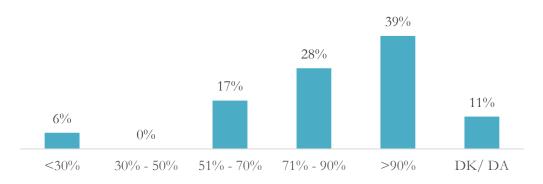


Figure 16 - Question on the penetration rate of smartphones nationwide

Figure 17 shows that 50% of the countries answered that they do not have interoperability requirements or standards for telemedicine services nationwide and 6% didn't know or didn't answer.



Figure 17 - Question on commonly agreed interoperability requirements or standards for telemedicine services

In **Erro! A origem da referência não foi encontrada.**8, 61% of the countries do not have any accreditation standards for telemedicine services which focus on ensuring interoperability with other services and 6% didn't know or didn't answer.



Figure 18 - Question on accreditation standards for telemedicine services which focus on ensuring interoperability with other

In

9, there are 50% of the countries with national registers/health information repositories of telemedicine services.



Figure 19 - Question on national registers/ health information repositories of telemedicine services

Legal and Security Context

In the legal and security context for telemedicine practice, half of the countries stated that telemedicine practice is covered by general or specific legislation, however only 44% affirmed having legislation defining medical liability and 39% having regulation covering reimbursement definition. Concerning security issues, 83% of countries have legislation on privacy and confidentiality related to data sharing, transfer and storage between healthcare providers and 72% have legislation governing these issues in the context of telemedicine services. Only 17% of countries declared their national legislation to be already aligned with GDPR (see Erro! A origem da referência não foi encontrada.20).

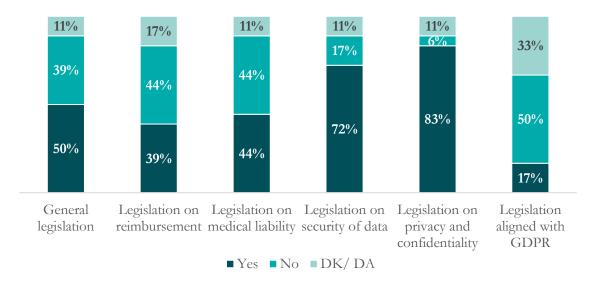


Figure 20 - Questions about the legal and security context

Cultural Context

In the cultural context, even though a quarter of the countries considered that healthcare professionals do not have awareness to telemedicine services or is very low, or low, half of the countries answered that healthcare professionals have a medium awareness of that services and other quarter considered high or very high awareness (see **Erro! A origem da referência não foi encontrada.**1), which means that 75% of the healthcare professionals have awareness of telemedicine services.

Related to patients, the answers are quite similar to the perspective of the healthcare professionals, 25% do not have awareness to telemedicine services or is very low, or low, 50% have medium and 25% have high, but distributed differently in the lower scale (12,5% of them are not aware of the telemedicine services), as well as, in the higher scale (any patient have a very high awareness).

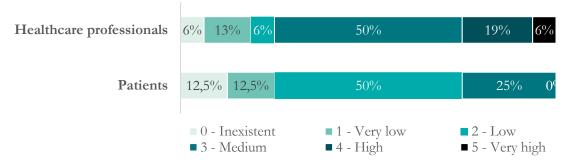


Figure 21 - Question on the awareness of telemedicine services by healthcare professionals and patients

In which concerns with adoption mechanisms to promote telemedicine, several countries informed they are currently doing nothing (28%) and planning nothing (17%). The type of initiatives that registered more answers were stakeholders engagements forums and training programs/sessions (28% each), followed by awareness campaigns (22%). Some countries also have in place financial incentives programs to boost telemedicine adoption. A growth trend can be noticed in all kind of initiatives (see Erro! A origem da referência não foi encontrada.2).

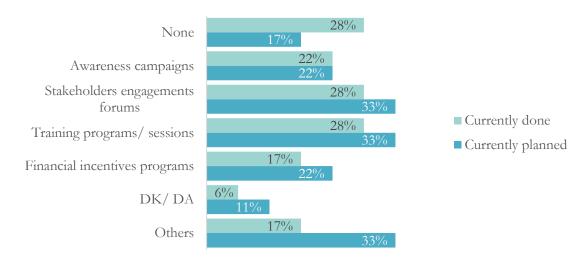


Figure 22 - Questions on the kind of adoption mechanisms to promote telemedicine

In the context of providing telemedicine training in tertiary institutions (universities or technical schools), 56% of the countries answered they provide training to health sciences' students to deliver telemedicine services. Only 22% of the counties answered that this kind of training is not provided (see 3). When asked about the proportion of tertiary institutions offering these

courses, 80% of the countries answered that this kind of training is only available in less than half of the tertiary institutions (see **Erro! A origem da referência não foi encontrada.**4).



Figure 23 - Question on the provision of telemedicine training to health sciences studies in tertiary institutions

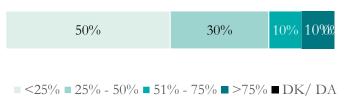


Figure 24 - Question on the proportion of tertiary institutions that offer telemedicine-related courses

Concerning the recipients of the available training on telemedicine, *Figure 26* shows that 90% of courses are directed to medicine professional group, 50% to nursing/midwifery, healthcare technicians or medical informatics.

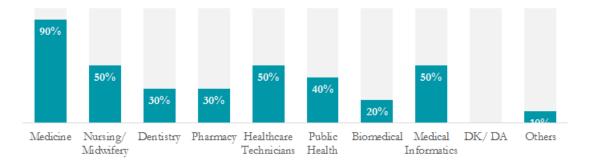


Figure 25 - Question on professional groups that receive telemedicine-related training on tertiary institutions

Figure 26 shows the major skills developed on telemedicine-related courses on tertiary institutions, where 60% are technological skills or clinical skills, 40% are legal skills on telemedicine, and with classification of 30% are communication/relational skills and financial and economic skills.

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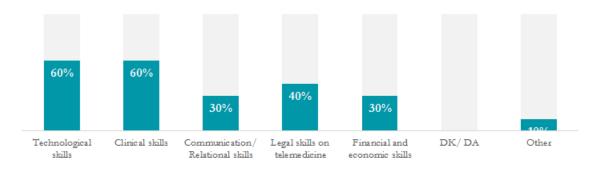


Figure 26 - Question on the type of skills developed on telemedicine-related courses on tertiary institutions

Regarding the provision of in-service training to healthcare professionals by institutions/ organizations as part of the continuous education, 28% of the counties replied that none institution provides that kind of training while 39% answered that there is at least one institution that does offer it (see Figure 27), although in less than 50% of institutions (see Figure 28).



Figure 27 - Question on the provision of telemedicine in-service training to healthcare professionals by institutions/ organizations

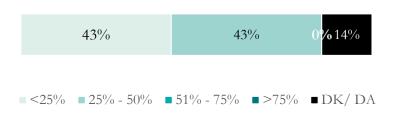


Figure 28 - Question on the proportion of institutions/ organizations that offer telemedicine-related courses

Figure 29 shows the answers for professional groups receiving telemedicine-related training on healthcare institutions/ organizations, and 71% are for medicine, 57% are for medical informatics and 43% are for nursing/midwifery and healthcare technicians.

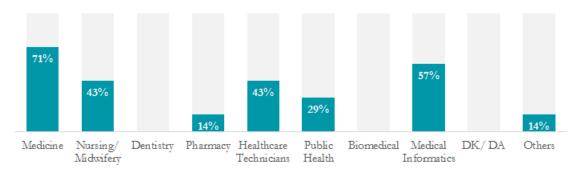


Figure 29 - Question on professional groups receiving telemedicine-related training on healthcare institutions/ organizations

In Figure 30 is presented the major skills that professionals developed on telemedicine-related courses on healthcare institutions/organizations, and 86% are legal skills on telemedicine, 71% in communications/relational, 57% are clinical skills or technological skills.

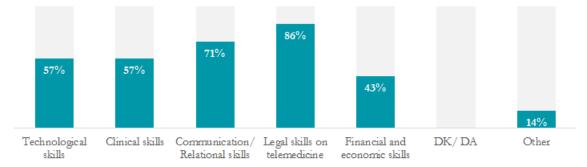


Figure 30 - Question on the type of skills developed on telemedicine-related courses on healthcare institutions/ organizations

For questions related to patient's training/education prior to the use of telemedicine services, 44% of respondents said there was none. Only 11% of countries guaranteed patients always receive some kind of training or education (see Figure 31).



Figure 31 - Question on patients training/ education prior to the use of telemedicine services

Figure 32 shows on a scale from 0 (No awareness) to 5 (very high awareness) with 56% of healthcare professional having a medium willingness to use telemedicine services, 25% of them have a high willingness or very high willingness, and 18% have low, or very low, or no willingness.

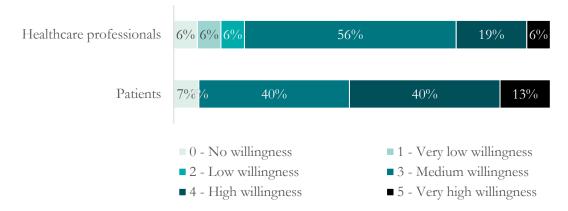


Figure 32 - Question on the willingness to use telemedicine services by healthcare professionals and patients

• Current state of telemedicine services

For 83% of countries have telemedicine services planned or implemented, only one of the responding countries informed that still there are not telemedicine services (see Figure 33).



Figure 33 - Question on the existence of telemedicine services

Based on the previous question, the main service being planned or implemented is teleconsultation, with 73%, followed by telediagnosis and telemonitoring / telecare with 67% of responses. Telesurgery has no answers (see Figure 34).

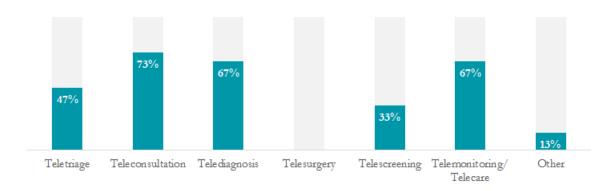


Figure 34 - Question on the telemedicine services planned/implemented

Related to type of specialties/applications areas offer (or are working to offer) in telemedicine services per country, the major offer is radiology with 87%, followed by cardiology with 80%. The lower offers percentages are nutrition (7%), ophthalmology (20%) and psychiatry (27%) (see Figure 35).

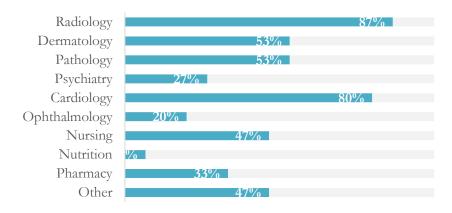


Figure 35 - Question on the specialties/ application areas with telemedicine services

Table 1 presents the results on the available telemedicine services by specialty/application area. The services with higher distribution among the specialties/applications areas mentioned previously are radiology telediagnosis and teleconsultation, and cardiology telemonitoring and teleconsultation. Follows teleconsultation and telediagnosis in dermatology and pathology.

| | Radiology | Dermatology | Pathology | Psychiatry | Cardiology | Ophthalmology | Nursing | Nutrition | Pharmacy | Other |
|-----------------------------|-----------|-------------|-----------|------------|------------|---------------|---------|-----------|----------|-------|
| Teletriage | 17% | 28% | 11% | 17% | 22% | 11% | 17% | 0% | 11% | 50% |
| Teleconsultation | 50% | 39% | 33% | 17% | 44% | 22% | 17% | 6% | 6% | 50% |
| Telediagnosis | 61% | 33% | 39% | 11% | 28% | 17% | 0% | 0% | 0% | 33% |
| Telesurgery | 0% | 0% | 0% | 0% | 6% | 0% | 0% | 6% | 0% | 0% |
| Telescreening | 11% | 6% | 6% | 6% | 6% | 11% | 0% | 0% | 0% | 6% |
| Telemonitoring/ Telecare | 0% | 6% | 0% | 6% | 50% | 6% | 22% | 6% | 0% | 39% |
| Others | 6% | 0% | 0% | 6% | 0% | 6% | 17% | 11% | 0% | 0% |

Table 1 - Question on the available telemedicine services by specialty/application area

With concern to the purpose of the telemedicine services available in the countries, diagnosis with 67% of the responses is the main purpose, followed by emergency care and vital sign monitoring with 53%. The answer with lower percentage is palliative care with 13% (see Figure 36).

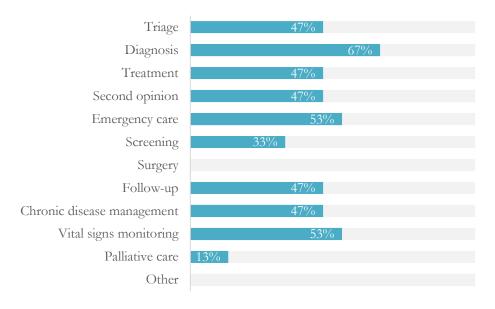


Figure 36 - Question on the purpose of telemedicine services available

In the context of the maturity stage of telemedicine services, Figure 37shows that the higher maturity level evaluation is telescreening, with 50% of the answers in the optimized stage, followed by telediagnosis with 45%. The telemedicine service with the lower maturity level evaluation is telesurgery with 100% of the responses in the initial stage.

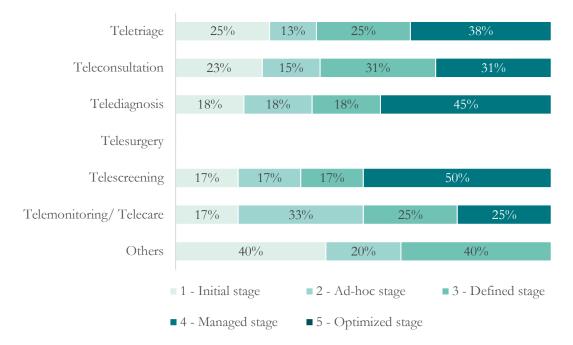


Figure 37 - Question on the maturity stage of telemedicine services

On the territorial scope of telemedicine services, Figure 38, the majority of the telemedicine services have a main regional distribution, except teleconsultation and telediagnosis with a predominant national scope. Telescreening have an identical, national and regional, scope.

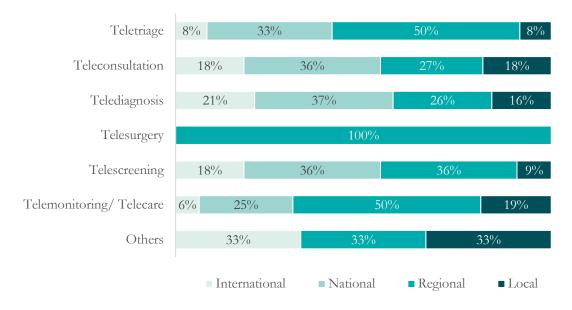


Figure 38 - Question on the territorial scope of telemedicine services

On the type of interactions between the individuals established in each one of the telemedicine services, several countries registered patients connecting directly with healthcare professionals in telemonitoring / telecare (71%) telescreening (50%), teletriage (38%), telediagnosis (25%) and teleconsultation (19%). (see Figure 39).

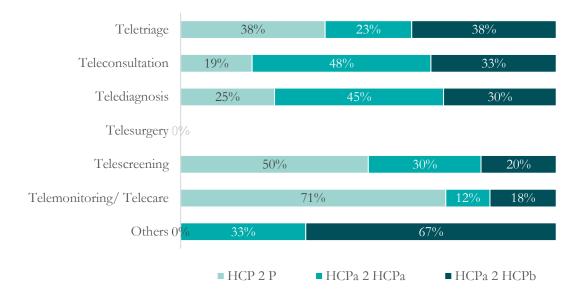


Figure 39 - Question on the type of interactions between the individuals established by telemedicine service Regarding the level of care interacting on each side, results have shown that telemedicine is still most used between primary care and hospital care (see Table 2).

| Level of care | P 2 PC | P 2 HC | P 2 CC | PC 2 HC | HC 2CC | PC 2 CC | DK/ DA |
|--------------------------|--------|--------|--------|---------|--------|---------|--------|
| Teletriage | 24% | 24% | 6% | 12% | 12% | 12% | 6% |
| Teleconsultation | 18% | 12% | 12% | 53% | 24% | 24% | 0% |
| Telediagnosis | 24% | 24% | 18% | 41% | 24% | 24% | 0% |
| Telesurgery | 6% | 0% | 0% | 0% | 0% | 0% | 6% |
| Telescreening | 12% | 6% | 6% | 12% | 6% | 6% | 6% |
| Telemonitoring/ Telecare | 41% | 29% | 18% | 24% | 12% | 18% | 6% |
| Others | 6% | 12% | 0% | 0% | 0% | 0% | 18% |

Table 2 - Question on the available telemedicine services by level of care interacting

Although respondents have reported difficulties to estimate the % of telemedicine services of total healthcare services, the majority considered it below 10% for all types of telemedicine services. Considering telemedicine in general, 38% of the responses considerate telemedicine services to be below 1% of total healthcare services and another 38% of countries to be below 10%. (see Figure 40).

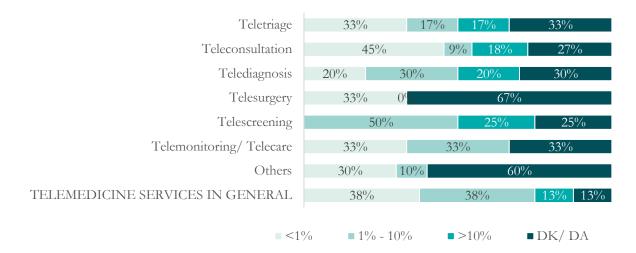
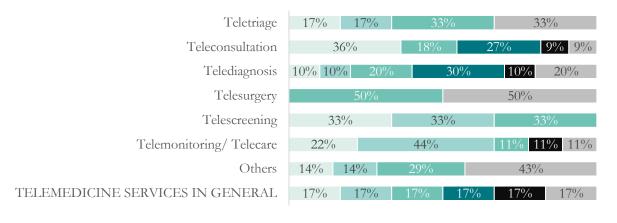


Figure 40 - Question on the % of telemedicine services in total healthcare services

Concerning the percentage of healthcare institutions providing telemedicine services, for telemedicine services in general, the responses are disperse, meaning that for some countries telemedicine is restricted to a few institutions and in others is generalized (Figure 41).



■ <1% ■ 1% - 10% ■ 11% - 25% ■ 26% - 50% ■ >50% ■ DK/ DA

Figure 41 - Question on the % of healthcare institutions with telemedicine services in total healthcare institutions For question related with the % of patients involved in telemedicine services in total patients, the majority of countries able to answer it, have estimate it below 1% for all types of services except telesreening and others. 25% of the countries reported to have more than 10% of patients engaged with telescreening. Considerate for telemedicine services in general, the responses have this distribution: more than 10% patients are involved in telemedicine services - 13% of the responses; between 1% and 10% of the patients are involved in telemedicine services - 13% of the responses; less than 1% of the patients - 50% of the responses and 25% answered that they didn't know or didn't answer (see Figure 42).

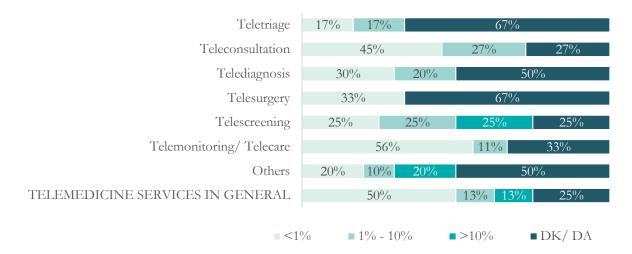


Figure 42 - Question on the % of patients involved in telemedicine services in total patients

• Evaluation of telemedicine services

In respect to evaluation procedures, although existing methodologies and studies, 57% of the countries reported that none of the existing telemedicine services did undergo proper evaluation of final outcomes. (see *Figure 43*). The majority of countries who did carry out evaluation studies, have done it for more than 5% and less than 20% of telemedicine initiatives/services (see *Figure 44*).



Figure 43 - Question on evaluation o measure and assess telemedicine initiatives/services final outcomes

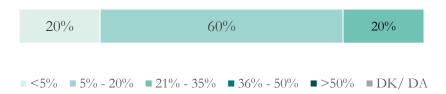


Figure 44 - Question on the % of telemedicine initiatives/ services subject to an evaluation study Regarding the criteria used in the evaluation of telemedicine initiatives/ services, the most frequently use criteria are program acceptance by patients and patient's satisfaction, both in 75% of responding countries. 50% of countries reported that impact on access, quality, technical safety, program acceptance by professionals and professionals' satisfaction are occasionally accessed. The majority of countries reported that clinical safety, cost-effectiveness for healthcare providers, cost-effectiveness for patients, health outcome and sustainability are rarely or very rarely assessed (see Figure 45).

| Program acceptance (healthcare.09 | 0 | 50% | | | | 50% | | 00 |
|--|--------------|------------------|-----|-----|-----|-----|-----|-----|
| Program acceptance (patients) 09 | 6 25% | | | | 75% | | | 00 |
| Access 09 | 0 | 50% | | | | 50% | | 00 |
| Quality 09 | 6 25% | | 25% | | | 50% | | 00 |
| Clinical safety | 25% | 0% | 25% | | 25% | | 25% | 00 |
| Technical safety | 25% | 0 <mark>%</mark> | 25% | | | 50% | | 00 |
| Cost-effectiveness (healthcare | 25% | 0% | | 50% | | 0% | 25% | 00 |
| Cost-effectiveness (patients) | 25% | 0% | 25% | | 25% | | 25% | 00 |
| Satisfaction (healthcare professionals) 09 | 0 | 50% | | | | 50% | | -04 |
| Satisfaction (patients) 09 | 6 25% | | | | 75% | | | 00 |
| Health outcome 09 | 0 | 50% | | | 25% | | 25% | 00 |
| Sustainability | 25% | 0% | 25% | | 25% | | 25% | 00 |
| | | | | | | | | |

■ 0 - Never ■ 1 - Very rarely ■ 2 - Rarely ■ 3 - Occasionally ■ 4 - Frequently ■ 5 - Very frequently

Figure 45 - Question on the use of evaluation criteria for telemedicine initiatives/ services

On the expectation for telemedicine services, all (100%) responding MS agreed or strongly agreed that the adoption of telemedicine services would *improve quality of care, improve continuity of care, contribute to communication between healthcare providers* and *complement face-to-face consultations*. Other frequent expected outcomes of telemedicine are: *improve patient's adherence to treatments, promote access for health services for patients in remote areas, improve patients empowerment and autonomy, help to reduce patient's and caregivers time and costs, help to reduce costs with prevention actions, bring operational efficiency* and *faster cross-border telemedicine services with other MS* (see Figure 46).

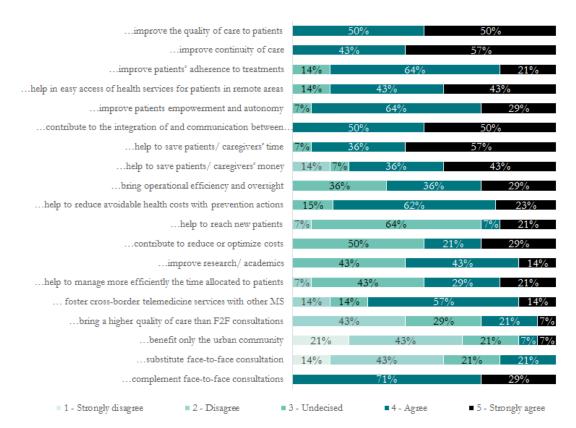


Figure 46 - Question on impact expectations from telemedicine services

Figure 47 shows the same results after being processed in order to make it clear what are the MS expectancies for telemedicine and telecare services.

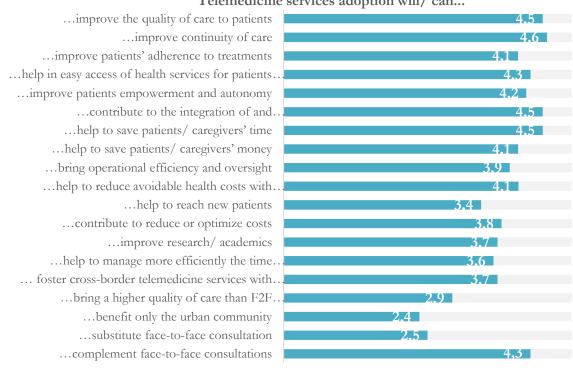




Figure 47 - Question on impact expectations from telemedicine services, proccessed

2 - Disagree

3 - Undecised

= 1 - Strongly disagree

• Barriers to telemedicine adoption

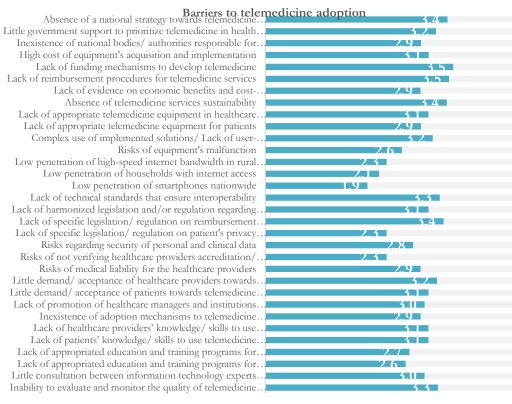
Figure 48 shows on a scale from 1 (Not important barrier) to 5 (Extremely important barrier) the countries' rate for the potential barriers to implement telemedicine. To simplify the reading of the results, a single composed indicator was derived (see Figure 49).

Top 10 major barriers are:

- 1. Lack of funding mechanisms to develop telemedicine;
- 2. Lack of reimbursement procedures for telemedicine services;
- 3. Absence of telemedicine services sustainability;
- 4. Lack of specific legislation / regulation on reimbursement procedure / guidelines;
- 5. Absence of a national strategy towards telemedicine development;
- 6. Lack of technical standards that ensure interoperability;
- 7. Inability to evaluate and monitor the quality of telemedicine services;
- 8. Little government support to prioritize telemedicine in health services delivery;
- 9. Lake of user friendly systems and tools;
- 10. Little demand/acceptance of healthcare providers towards telemedicine services.

| Absence of a national strategy towards telemedicine development | 14% 7% | 29% 2 | 1% 29% |
|--|--------------------|----------------|-------------------------|
| Little government support to prioritize telemedicine in health services delivery | 14% 14% | 21% | 36% 14% |
| Inexistence of national bodies/ authorities responsible for telemedicine development | 14% 29 | 21% | 21% 14% |
| High cost of equipment's acquisition and implementation | 38% | 23% | 31% 8% |
| Lack of funding mechanisms to develop telemedicine | 23% | 31% 1 | 5% 31% |
| Lack of reimbursement procedures for telemedicine services | 8% 15% | 31% 1 | 5% 31% |
| Lack of evidence on economic benefits and cost-effectiveness of the programs | 15% 8% | 54% | 15% 8% |
| Absence of telemedicine services sustainability | 8% 8% | 33% | 33% 17% |
| Lack of appropriate telemedicine equipment in healthcare institutions | 14% 29 | 9% 14% | 21% 21% |
| Lack of appropriate telemedicine equipment for patients | 7% 43 | 3% 149 | 21% 14% |
| Complex use of implemented solutions/ Lack of user-friendly systems and tools | 31% | 31% | 31% 8% |
| Risks of equipment's malfunction | 7% | 57% | 14% 14% 7% |
| Low penetration of high-speed internet bandwidth in rural and remote areas | 36% | 36% | 7% 7% 14% |
| Low penetration of households with internet access | 29% | 57% | 0% 14% |
| Low penetration of smartphones nationwide | 46% | | 38% 8% 8% |
| Lack of technical standards that ensure interoperability | 36% | 21% | 21% 21% |
| Lack of harmonized legislation and/or regulation regarding telemedicine | 7% 29% | 29% | 21% 14% |
| Lack of specific legislation/ regulation on reimbursement procedures/ guidelines | 7% 7% | 43% | 29% 14% |
| Lack of specific legislation/ regulation on patient's privacy and confidentiality | 29% | 36% | 21% 7% 7% |
| Risks regarding security of personal and clinical data | 7% 36% | 3 | 5% 14% 7% |
| Risks of not verifying healthcare providers accreditation/ licensing | 29% | 36% | 21% 7% 7% |
| Risks of medical liability for the healthcare providers | 8% 8% | 77% | 8% |
| Little demand/ acceptance of healthcare providers towards telemedicine services | 8% 23% | 23% | 31% 15% |
| Little demand/ acceptance of patients towards telemedicine services | 7% 21% | 43% | 14% 14% |
| Lack of promotion of healthcare managers and institutions to telemedicine services | 9% 27% | 27% | 27% 9% |
| Inexistence of adoption mechanisms to telemedicine implementation | 8% 23% | 46% | 15% 8% |
| Lack of healthcare providers' knowledge/ skills to use telemedicine equipment/ systems | 29% | 50% | 7% 14% |
| Lack of patients' knowledge/ skills to use telemedicine equipment/ systems | 29% | 43% | 21% 7% |
| Lack of appropriated education and training programs for healthcare providers | 57 | 7% | 21% 14% 7% |
| Lack of appropriated education and training programs for patients | 57 | 7% | 29% 7% 7% |
| Little consultation between information technology experts and clinicians | 8% 31% | 38% | 6 23% |
| Inability to evaluate and monitor the quality of telemedicine services | 25% | 42% | 17% 17% |
| 1 - Not a barrier 2 - Slightly important barrier 3 - Important barrier | 4 - Very important | harrian 5 Ente | emely important barrier |

Figure 48 - Question on barriers to telemedicine adoption



Inexistence of national bodies/ authorities responsible for. High cost of equipment's acquisition and implementation Lack of funding mechanisms to develop telemedicine Lack of reimbursement procedures for telemedicine services Lack of evidence on economic benefits and cost-Absence of telemedicine services sustainability Lack of appropriate telemedicine equipment in healthcare. Lack of appropriate telemedicine equipment for patients Complex use of implemented solutions/ Lack of user-. Risks of equipment's malfunction Low penetration of high-speed internet bandwidth in rural. Low penetration of households with internet access Low penetration of smartphones nationwide Lack of technical standards that ensure interoperability Lack of harmonized legislation and/or regulation regarding. Lack of specific legislation/ regulation on reimbursement. Lack of specific legislation/ regulation on patient's privacy. Risks regarding security of personal and clinical data Risks of not verifying healthcare providers accreditation/ Risks of medical liability for the healthcare providers Little demand/ acceptance of healthcare providers towards. Little demand/ acceptance of patients towards telemedicine. Lack of promotion of healthcare managers and institutions. Inexistence of adoption mechanisms to telemedicine. Lack of healthcare providers' knowledge/ skills to use... Lack of patients' knowledge/ skills to use telemedicine. Lack of appropriated education and training programs for.. Lack of appropriated education and training programs for. Little consultation between information technology experts.

Figure 49 - Question on barriers to telemedicine adoption, processed

5.2.3. Selected case studies on large scale telemedicine deployments

We are supplementing the survey results with two case studies to illustrate specific challenges related to large-scale telemedicine deployments. There is considerable agreement among experts that, to reap benefits from telemedicine and telecare technologies, they need to be integrated into clinical workflows, and be part of a wider strategy of advancing and even transforming the delivery of healthcare towards integrated, patient-centered care.

This integration requires political leadership and commitment from the health authorities (in most cases this is a ministry of health) to effect the necessary changes in finances/reimbursement, legal and liability issues, and the integration of telemedicine technologies with the health IT system (such as an electronic health or patient medical record system).¹¹

In **Denmark**, the national telemedicine strategy has been embedded in wider EUR 6 billion investment to modernize the country's healthcare system, make hospitals more efficient, and move patient care from the hospital to the home.¹²

Until the national ministry recognized telemedicine as a strategic opportunity and priority, there was widespread experimentation (some would call it "pilotitis") with telemedicine. According to a December 2013 mapping exercise, there were more than 600 individual projects ranging in in purpose, scope and technology.¹³

The Danish Ministry of Health, in cooperation with the Danish regions and municipalities, developed the National Action Plan for the Deployment of Telemedicine in 2012, which outlined the major action items that were required to advance telemedicine in Denmark.¹⁴ A technical *Reference Architecture for Collecting Health Data From Citizens* (June 2013) was delivered in June 2013.¹⁵

One of the initiatives from the 2012 Action Plan became the Telecare North pilot for more than 1,000 patients with chronic obstructive pulmonary disease (COPD) in the Danish province of North Jutland.¹⁶ Following the successful completion of the Danish pilot, the Danish national, regional and local governments agreed that telemedicine should be provided nationwide to all relevant patients with COPD (Chronic Obstructive Pulmonary Disease) by the end of 2019. A tender is expected to be published before the end of 2017.¹⁷

Austria has been rolling out its national electronic health record ELGA ("ELektronische GesundheitsAkte") since early 2015, capping a more than ten-year planning and development

¹⁵ The "Reference architecture for collecting health data from citizens" (June 2013) is available in English at <u>http://sundhedsdatastyrelsen.dk/-/media/sds/filer/rammer-og-retningslinjer/referenceaktitektur-og-it-standarder/referencearkitektur/referencearchitecture-collecting-health-data-citizens.pdf?la=da (accessed October 2017).</u>

¹¹ See for example the United4Health policy recommendations,

https://ec.europa.eu/health//sites/health/files/ehealth/docs/ev_20160607_co10_en.pdf ¹² See for resoucres http://healthcaredenmark.dk/

¹³ The December 2013 report has been updated periodically and is referenced on the Medcom website at <u>http://medcom.dk/projekter/basisaktiviteter/telemedicinsk-kortlaegning</u>.

¹⁴ The Action Plan "National handlingsplan for udbredelse af telemedicin" (August 2012), in Danish, is available at http://www.sum.dk/Aktuelt/Nyheder/Digitalisering/2012/August/~/media/Filer%20-

^{%20}Publikationer_i_pdf/2012/Telemedicin/Telemedicinsk-handlingsplan.ashx (accessed March 2017).

¹⁶ The focus on COPD was motivated by the alarming incidence of COPD in the Danish population – the number of COPD patients is estimated at 430,000. For more infomration on the Telecare Nord project go to http://www.telecarenord.dk.

¹⁷ See National dissemination of telemedicine for patients with COPD by the end of 2019 in https://www.digst.dk/Servicemenu/English/Policy-and-Strategy/Strategy-for-Digital-Welfare/Telemedicine.

period. Full coverage, including resident doctors, is expected by the end of 2017.¹⁸ With a safe, secure and accessible place for storing patient information in sight, the Federal Ministry for Women and Health in 2013 convened an expert commission to explore the feasibility and potential for large scale telemedicne services. In 2015, the commission issued recommendations to implement telehealth services for patients with diabetes and chronic heart disease, as well as for patients with recent cardiac implants. The Ministry's framework directive ("Rahmenrichtlinie") containing crucial financial, regulatory and technical guidelines is expected before the end of 2017.¹⁹

There are additional early attempts at deploying telemedicine services at scale in Europe. In December 2017 the ministry of health in **Finland** will launch its MyKanta personal health record with the option for citizens to upload and share their health data with healthcare professionals.²⁰ In **Norway** the health ministry has been rolling out the *National Program for Personal Connected Health and Care* to deliver health and social services with an eye to serving the ageing population.²¹ In **Sweden**, the SALAR association of local governments and regions and the Swedish government published their *Vision for eHealth 2025 – common starting points for digitisation of social services and health care* that laid out a plan for the development of telehealth services.²² In **Switzerland**, various cantons are seeking to develop "mHealth services", and the national coordination office "eHealth Suissse" has issued recommendations to coordinate action.²³

5.2.4. Discussion

Compiled answers related with **implementation of telemedicine and telecare** the following assessment:

- Country adoption: In all but one country, providers and professionals are using telemedicine in some extent, mainly with local or regional scope, comprising interactions provider-to-patient and provider-to-provider and linking the different levels of care (patient, primary care, hospital care and continued care), although most of the activity still is between primary and hospital care. Estimates of relative production concluded that for the majority of countries telemedicine services are below 10% of total healthcare services, although; some countries, for some services estimate it above 10%. This coverage of the telemedicine services is not uniform throughout healthcare institutions, within each country neither throughout MS when comparing with each other. Furthermore, the percentage of patients involved in telemedicine services is very low. Conversely, where MS embrace telemedicine as strategic priorities, the number of patients especially with chronic conditions is destined to rise. MS should adopt policies to facilitate the implementation of this type of services that are able to promote equity of access to telemedicine services;
- **Type of services and specialties**: multiple type of telemedicine and telecare services exist and are applicable to various specialties. The most widely used telemedicine and

¹⁸ Detailed documents on the ELGA structure and specifications are available on the ELGA portal: <u>https://www.elga.gv.at/technischer-hintergrund/technischer-aufbau-im-ueberblick/index.html</u>.

¹⁹ For an overview of the Ministry's strategy on telemedicine (in German) go to

https://www.bmgf.gv.at/home/Gesundheit/E_Health_Elga/Telemedizin/

²⁰ Presentation by Konstantin Hypponen "Free flow of health data in Finland, the citizen's perspective" at eHealth Tallinn, 17 October 2017.

²¹ https://ehelse.no/nyheter/ny-rapport-om-arkitektur-for-velferdsteknologi

 $^{^{22}}$ Available on the website of the Swedish eHealth agency "eHälsomyndigheten", in English, at

https://www.ehalsomyndigheten.se/globalassets/dokument/vision/vision-for-ehealth-2025.pdf

²³ eHealth Suisse, mobile Health (mHealth) Empfehlungen I - Ausgangslage und erste Schritte, 16 March 2017, available for download at https://www.e-health-suisse.ch/fileadmin/user_upload/Dokumente/2017/D/170316_mHealth_Empfehlungen_I_d.pdf (accessed 26 April 2017)

telecare services are Radiology Telediagnosis, Radiology Teleconsultation, Cardiology Telemonitoring, Cardiology Teleconsultation, followed by Dermatology Teleconsultation and Telediagnosis and Pathology Telediagnosis and Telecondultation. No country reported to be using telesurgery;

• Maturity: half or more of the respondents considered that telescreening, telediagnosis, teleconsultation, teletriage and telemonitoring are in maturity level of 'defined' - large scale pilots implemented, or 'managed' – services officially implemented. However, when analysing implementation at national level, the majority of the countries considered it still in an ad-hoc phase – not fully integrated into a national strategy.

Considering the way countries are **evaluating telemedicine services** results point to the following:

- **Methodologies availability**: several works exist on telemedicine evaluation methods but they are not widely known among stakeholders;
- Evaluation practices: the vast majority of existing telemedicine services did not undergo proper evaluation of final outcomes and it lacks complete registers of telemedicine activity. Conducted studies usually miss cost-effectiveness, sustainability and health outcomes evaluation. Work on this matter is being developed under JASEHN under Task 7.4;
- Expected value: among several potential impacts of telemedicine and telecare services, countries' representatives responding the survey ranked the following top 10: i. *improve continuity of care; ii. improve quality care;* iii. *contribute to communication between healthcare providers; iv. help to reduce patient's and caregivers time; v. promote access for health services for patients in remote areas; vi. complement face-to-face consultations; vii. improve patients and caregiver's costs; x. help to reduce patient's adherence to treatments; ix. help to reduce patient's and caregiver's costs; x. help to reduce costs with prevention actions*

Regarding the existence of facilitators of telemedicine adoption, results have shown:

- Strategy and governance: a third of the responding countries don't have a national telemedicine strategy (stand-alone or included on wider-scope eHealth strategy) nor a national structure responsible for telemedicine development. This fact may compromise the scale up of existent telemedicine services to wider geographic domains because of misaligned awareness, capacity, processes and technologies. One can also conclude that the inexistence of a common national vision for telemedicine and telecare raises huge barriers to the development of European scale telemedicine and telecare services. Only two countries consider the development of cross-border telemedicine services part of their national strategy;
- Financial and economic: a third of responding countries don't have funding mechanisms to finance telemedicine development. Those countries reported being at national implementation stage 1 or 2, therefore it is possible that this could be a major obstacle in that cases. In the majority of countries having funding mechanisms, public funding represents the main part of it, although a mix of funding sources exist. Economic studies supporting the adoption decision exist, although some countries are not aware of it. Reimbursement mechanisms exist to pay for telemedicine services although they are considered below the expectative;

- **Technical**: although there is a general favourable technologic context for the adoption of telemedicine and telecare, in both citizen and healthcare organizations sides, it still lacks adequate equipment in healthcare organizations and the existence of adequate national interoperability and accreditation standards and registries; Lack of interoperability is a common lament among practitioners of telemedicine since there is not a universally recognized and adhered-to set of standards and profiles, especially where patients and their devices interface with the regional or national electronic record systems. Most Member States that deploy telemedicine at scale provide such guidance, and in June 2016 several of them (including Austria, Denmark, Finland, Norway, Sweden, together with the regional government of Catalonia/Spain) signed a joint letter to the eHealth Network asking for a European approach towards an end-to-end interoperability framework for telehealth.²⁴ At the time being, the most relevant international initiative may be the research and report of relevant authorities in the Nordic countries (Denmark, Finland, Norway and Sweden) to map and align their telehealth standards, with a report issued in March 2017.²⁵
- Legal and security: results confirmed that there are still some legal gaps and discrepancies from country to country which obstructs the development of crossborder telemedicine services; Most of the countries do not have their legislation in compliance with the GDPR - European General Data Protection Regulation which will be in force May 2018;
- Cultural and change: countries considered there is a medium awareness of telemedicine service among professionals and patients and are developing initiatives to promote adoption. Training courses on telemedicine exist in less than a half of tertiary institutions (universities or technical schools), which means that not all the students get to acquire the required skills for telemedicine. Also, it seems that those training courses tend to focus on technical and clinical aspects, leaving outside the development of other crucial skills for telemedicine provision, namely communication and relational skills, and for telemedicine adoption as economic skills. On the other hand, in-service training is also scarce inexistent in some countries, provided by less than a half of institutions in others. When existing, these in-service telemedicine courses seem to cover a much wide range of skills than those offered by tertiary institutions. The results show that responders consider that both healthcare professionals and patients will not offer resistance to telemedicine, being in fact moderate to very high willing of use it;
- Main barriers for telemedicine and telecare development: aggregating the contributions of respondents a barrier top 10 was derived: *i. lack of funding mechanisms to develop telemedicine; ii. lack of reimbursement procedures for telemedicine services; iii. absence of telemedicine services sustainability;* iv. lack of specific legislation/regulation on reimbursement procedure / guidelines; v. absence of a national strategy towards telemedicine development; vi. lack of technical standards that ensure interoperability; vii. inability to evaluate and monitor the quality of telemedicine

²⁴ The eHealth Network Secretariat forwarded the 26 June 2016 letter from the six governments on 30 November 2016 to the members of the eHealth Network. The letter itself can also be accessed at

http://www.pchalliance.org/news/six-european-governments-request-support-interoperable-teleheath-joint-letterehealth-network.

²⁵ See *Towards a Nordic Reference Architecture for Personal Connected health and care Technology,* from the Norwegian Directorate of eHealth, Inera AB/Swedish Association of Local Authorities and Regions, Danish Health Data Authority, and the Finnish Ministry of Social Affairs and Health, March 2017, at http://www.hl7.fi/wp-content/uploads/Nordic-Reference-Architecture-for-Personal-Connected-Health-Technology-2017-03-19.pdf.

services; viii. little government support to prioritize telemedicine in health services delivery; ix. lake of user friendly systems and tools; x. little demand/acceptance of healthcare providers towards telemedicine services.

6. Recommendations

Based on the state of implementation of telemedicine services and on the feedback provided by MS representatives responding the survey concerning telemedicine ecosystem, telemedicine evaluation, barriers to the development of telemedicine and other suggestions, a set of 10 Recommendations are suggested:

- 1. EU and MS should consider the establishment of a EU Telemedicine strategy (either stand-alone or integrated on EU e-Health strategy), included or strongly linked with EU Health strategy, with clear priorities and goals, established by healthcare outcomes indicators and aligned with other activities of EU eHealth Network Multi-Annual Plan;
- 2. MS should consider creating a national structure aiming to lead the adoption of telemedicine and telecare at national scale, ensuring a common vision of priorities, the equity of access to telemedicine services, the adoption of interoperable processes and technologies and enabling the development of cross-border telemedicine and telecare services. This structure should also
 - i. Promote and validate tools, methods and techniques to help healthcare organisations to manage their digital transformation;
 - ii. Facilitate collaboration between existing testing environments, labs and large-scale implementations to promote transferability of lessons learned and to support the scaling-up of digital innovation.
- 3. EU and MS should consider strengthening funding of telemedicine capacity building initiatives and large pilots, especially in those countries lagging;
- 4. MS should consider reviewing reimbursement mechanisms of telemedicine and telecare as its effectiveness is considered bellow expectative;
- 5. EC and MS should consider promoting mechanisms of knowledge sharing regarding economic evaluation methods and cases of telemedicine and telecare services and boost their use throughout the adoption life cycle. These mechanisms should include several topics, namely:
 - a. how to assess the potential economic impact of telemedicine and telecare;
 - b. how to incentivise successful adoption and the scaling-up of digital services;
 - c. how to develop and implement models of risk-sharing as a tool to encourage cross-sectoral working and transformational change underpinned by technologies.
- 6. EC and MS should consider defining a European interoperability framework for telehealth, telemedicine and telecare based on open, international standards to allow interoperability between the diverse existing systems (including those acquiring patient generated data and those supporting healthcare providers, namely Disease Management Programs) and to facilitate wide geographic and cross-border telemedicine services;

- 7. EC and MS should consider creating a harmonized legal framework for telemedicine services, namely regarding liability and ensuring GDPR compliance.
- 8. EC and MS should consider engaging with relevant stakeholders to enlarge the availability of telemedicine training initiatives, as well its contents, in order to developed all necessary skills to develop, manage and provide telemedicine and telecare services;
- 9. EC and MS should enforce or at least maintain communication mechanisms both to healthcare providers and to patients to improve awareness and maintain their willingness to use;
- 10. EC and MS should gather efforts in registering telemedicine acts and define appropriate indicators to monitor its evolution. Also, since there is such a diversity of services and stakeholders, should promote means for sharing good practices mapped into the type of service, the specialty and the level of care interacting.

7. Appendices

| COPD | Chronic Obstructive Pulmonary Diseases |
|-----------|---|
| EC | European Commission |
| ECG | Electrocardiogram |
| eHSG | eHealth Stakeholder Group |
| EU | European Union |
| GDPR | General Data Protection Regulation |
| GP | General Practitioner |
| ICT | Information and Communication Technologies |
| ICU | Intensive Care Unit |
| JAseHN | Joint Action to support eHealth Network |
| MAST | Model for Assessment of Telemedicine |
| MS | Member States |
| РСР | Pre-Commercial Procurement |
| RENEWING | REgioNs of Europe WorkINg together for HEALTH |
| HeALTH | |
| TeleSCoPE | Telehealth Services Code of Practice for Europe |
| TFEU | Treaty on the Functioning of the European Union |
| WHO | World Health Organization |

7.1. Appendix A: Glossary

| CONCEPT | DEFINITION |
|-----------------------------------|---|
| | Please check "Store-and-forward telemedicine" definition |
| Asynchronous telemedicine | Please check Store-and-forward telemedicine definition |
| eHealth | Combined use of electronic communication and information technology in the health sector to share, store and retrieve electronic health data for prevention, diagnosis, treatment, monitoring, educational and administrative purposes, both at the local site or at distance |
| Real-time telemedicine | Immediate transmission of information through a communication device to allow real-time interaction between patient/ healthcare professional and other healthcare provider/ specialist, who are simultaneously present, but remotely |
| Store-and-forward telemedicine | Exchange of pre-recorded healthcare data between two or more individuals at different times, meaning that it does not require the presence of both parties at the same time |
| Synchronous telemedicine | Please check "Real-time telemedicine" definition |
| Telecardiology | Use of ICT to provide remote assessment, diagnosis, consultation and treatment of heart diseases through the interpretation of electrocardiographic data |
| Telecare | Use of ICTs like alerts and sensing technologies, for the continuous, automatic and remote monitoring of care needs, emergencies and lifestyle changes of elderly or vulnerable individuals with physical or mental disabilities for the provision of personalized care services at a distance, supporting patients' self-management and helping them to remain independent in their home environment. Usually related to ICT-enabled social services. |
| Teleconsultation | Synchronous or asynchronous consultation between two or more geographically separated healthcare providers or between healthcare providers and patients using ICT to communicate at a distance, for the purpose of diagnosis or treatment of a patient at a remote site, or to obtain a specialist's second opinion |
| Teledermatology | Use of communication technologies to transmit medical information concerning skin conditions for the purpose of diagnosis or consultation |
| Telediagnosis | Determination of the nature of a patient's disease, at a remote location, based on the clinical data and information (i.e. data, images, and video records) transmitted through ICT |
| Telehealth | Delivery of healthcare services by all healthcare professionals, where distance is a critical factor, through the use of ICTs to provide <i>preventative, promotive and curative</i> healthcare services, research and evaluation, health administration services and continuing education of healthcare providers. Telehealth is a newer and broader term, including telemedicine and telecare |
| Telemedicine | Delivery of healthcare services by all healthcare professionals, where distance is a critical factor, through the use of ICTs, especially two-way interactive audio/video communications and telemetry systems to deliverhealthcare services, mainly <i>curative</i> . Services, to remote patients, and to facilitate information exchange between primary care physicians and specialists at some distance from each other. |
| Telemonitoring | Telecare services focusing on the capture of clinically relevant data in the patients' homes or other locations outside of hospitals, clinics, etc and the subsequent transmission of the data to central locations for review. There is no new diagnosis process in telemonitoring, the diagnosis has already been done before (main difference with telemedicine). Also called Remote Monitoring |
| Telenursing | Use of information and communication technologies to deliver nursing care and conduct nursing practice remotely |

7.2. Appendix B: Definitions

| Telepathology | Use of ICT by pathologists or other laboratory personnel to remotely collect, interpret and transmit pathologic data and results for the purpose of diagnosis, consultation or second opinion |
|------------------|--|
| Telepharmacy | Delivery of pharmaceutical services such as medication review, dispensing and compounding, patients counseling, prescription verification, and therapeutic drug monitoring by a pharmacist to remote patients |
| Teleophthalmolog | Use of digital medical equipment and communication technologies to provide eye |
| у | care health services remotely for the purpose of diagnosis, monitoring, screening, or consultation |
| Telepsychiatry | Use of information and communication technologies to provide remote psychiatric-mental health services, like psychiatric assessments, individual/ group/ family therapy, or patient medication management |
| Teleradiology | Use of ICT to transmit and exchange medical images (i.e. x-ray, MRIs, ultrasounds) for remote viewing, interpretation, assessment and diagnosis of a radiologist who is not present at the site where the images were taken |
| Telescreening | Use of ICT between patients and healthcare providers to remotely identify a possible disease that was not previously recognized in individuals without any signs or symptoms, or with pre-symptomatic or unrecognized symptomatic disease, through the use of medical tests that can also be provided remotely |
| Telesurgery | Use of telemedicine equipment and ICT to support and monitor surgical procedures at a distance, or to perform remote surgery |
| Teletriage | Process of identifying a patient's problem, accessing the level of urgency, and recommend advice via phone by trained professionals, in order to guarantee a safe, timely and appropriate disposition of patient symptoms |

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