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Industry Report on Telemedicine Legal and Regulatory Framework
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Abstract

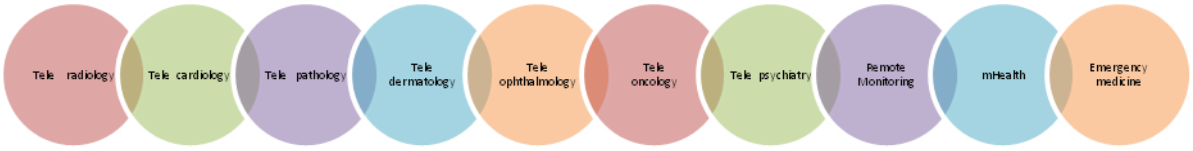
This report: analyses the legal and regulatory environments relevant for telemedicine implementations in which the pilot regions operate, as well as in other select Member States; identifies legal and regulatory barriers to telemedicine and to interoperable, multi-vendor integrated device connected systems; recommends appropriate action to address these barriers; and provides feedback towards an improved legal and regulatory environment.

Executive Summary

The use of telemedicine as a tool to help support better-integrated care is on the rise. One of the ways to support this in Europe is to capitalise on the potential of technological advances in ICT, and accelerate the adoption by (1) establishing an appropriate legal and regulatory framework for telemedicine consistently applied by Member States and by (2) ensuring telemedicine is integrated into, and interoperable with, existing care delivery structures.

Telemedicine applications (generally referred to as 'teleologies') are defined as the delivery of healthcare services through the use of Information and Communication Technologies (ICT) in a situation where the actors are not at the same location. The actors can either be two healthcare professionals, or a healthcare professional and a patient[1].

Teleology examples



Telemedicine is at the crossroad of ICT, health policy and data protection. Under European law, it is both a health service and an information society service. As a health service, citizens have the freedom to seek and receive healthcare services from another Member State regardless of how that service is delivered. As an information society service, that service is normally provided by remuneration. Legal and regulatory challenges at the European and Member State levels need to be overcome to help deliver on the promise of telemedicine.

Legal and regulatory challenges

A legal and regulatory framework needs to be established that is not only clear and simple, but also flexible and nimble, and that, as technological advances, allows for an ever-evolving variety of methods for patients, physicians, payers and regulators to interact.

Key Recommendations for an effective legal and regulatory framework:

1. Integrate telemedicine into care delivery structures.
2. Enable citizens' access to their data.
3. Develop appropriate reimbursement strategies.
4. Establish a harmonised data protection regime that allows innovation.
6. Provide clear regulatory guidance.
7. Foster use of widely recognised standards and support mobile broadband policies.

[1] COCIR Telemedicine Toolkit For a Better Deployment and Use of Telehealth and Mobile Health, COCIR, May 2011 http://www.cocir.org/fileadmin/Publications_2011/telemedicine_toolkit_link2.pdf

Change History

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0.1	14th January 2015	Initial Version
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Version Changes

0.1 Initial version
1.0 Minor updates prior to issue

Outstanding Issues

None.

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1. Introduction

1.1 Purpose of this document

The European Union (EU) has taken steps to expand the use of telemedicine by removing and revisiting regulations. Guidance has also been issued through the European Commission (EC) on how best to comply with these regulations. One such guidance is the "Commission Staff Working Document"[2] on how to comply with EU law related to telemedicine. The purpose of this document is not to replace the information provided in the Commission guidance, rather to supplement it with a review of the legal and regulatory framework at EU and Member State level, together with recommendations on the establishment of an effective framework to support the integration and adoption of telemedicine in Europe and beyond (Appendix A.)

Telemedicine is not a new medical act; rather, it represents an innovative way of providing health and care services, and as such should be integrated into existing care delivery structures. Cross-border activities in healthcare are on the rise. Patients might like be treated in a different Member State rather than their own because of long waiting lists in some Member States and / or better care in others. Doctors are increasingly engaging in the exchange of information with colleagues in remote locations. Healthcare professionals, hospitals and laboratories are using more and more ICT applications to communicate health data for treatment, diagnosis, consultation and other purposes. Many of these developments relate to telemedicine.

As telemedicine technologies continue to evolve, this document does not attempt to cover all possible current or future scenarios related to telemedicine activities and services, but simply the most likely legal and regulatory scenarios.

Objectives of the document:

1. Analyse the legal and regulatory environments relevant for telemedicine implementations in which the pilot regions operate, as well as in other select Member States.
2. Identify legal and regulatory barriers to telemedicine and to interoperable, multi-vendor integrated device connected systems.
3. Recommend appropriate action to address these barriers.
4. Provide feedback towards an improved legal and regulatory environment.

1.2 The Legal Definition of Telemedicine in Europe

The Commission Staff Working Document defines telemedicine as: “Telemedicine is the provision of healthcare services, through use of ICT, in situations where the health professional and the patient, or two health professionals, are not in the same

[2] Commission Staff Working Document on the applicability of the existing EU legal framework to telemedicine services, June 2012. http://ec.europa.eu/digital-agenda/en/news/commission-staff-working-document-applicability-existing-eu-legal-framework-telemedicine

location." The Commission refers to services such as teleradiology, telepathology, teledermatology, teleconsultation, telemonitoring, telesurgery and teleophthalmology (commonly referred to as 'teleologies'), but it also includes in the definition call centres, online information centres for patients, remote consultation / e-visits or videoconferences between health professionals. The definition does not however include for example, health information portals, electronic health record systems and electronic transmission of prescriptions or referrals (e-prescription, e-referrals). As a result, the definition is restricted to situations where electronic communications are used to provide services to an individual patient.

Examples of telemedicine according the Commission Staff Working Document:

- A physician, who communicates with a patient via e-mail to follow up a prior visit with the results of a treatment, would be considered "telemedicine" as a patient is involved.
- Personalised medical advice by a professional to a patient by means of e-mail or telephone would be considered "telemedicine".

Examples that are not telemedicine according the Commission Staff Working Document:

- An online videoconference to brief medical teams about the current status of the seasonal flu or other epidemic would not be considered "telemedicine" as no patients are involved.
- A discussion of an individual's specific medical case amongst professional colleagues would not be considered "telemedicine" if the identity of the patient is not transmitted or revealed.
- General health information provided on a website would not be considered "telemedicine".

The distinction in the definition in which the actors in a telemedicine activity can either be two healthcare professionals or a healthcare professional and a patient creates confusion in some Member States, where the application of the definition in some cases focuses only on the latter type of telemedicine or sometimes even only on a subset of this type.

The Belgium example

In a draft law proposed by the Belgian federal Minister for Public Health[3], the term "telemedicine" was defined as "transmission of personal health data between a patient and a healthcare professional, aiming at a total or partial provision of diagnosis, treatment or intervention with regard to the patient's health". The draft law also introducing two other concepts:

- Teleconsultation: "consultation of one or more healthcare professionals by one healthcare professional who is locally present, about the case of a patient, the diagnosis and the treatment, by means of telecommunications".
- Telemonitoring: "registering, transmitting, receiving and processing parameters concerning a patient, with or without the patient's intervention, in order to permit one or more healthcare professionals at a distant location to

[3] Projet de loi relative au traitement et à l'informatisation des données de santé ainsi qu'aux applications de télémédecine (10-10-2005): this draft law has never been discussed and adopted by the Belgian Parliament and finally became obsolete.

follow up and evaluate the health status of the patient, and to decide about a treatment within the boundaries of the transmitted parameters".

The France example

Article 32 of the French Health Insurance Act defines telemedicine as "including amongst others the practice of medical acts at a distance, under the control and responsibility of a physician, in direct contact with the patient, through communication means appropriate to the performance of the act."[4] This definition leads to two uncertainties, namely what should be understood by "in direct contact with the patient", and whether this article refers to a clinical and physical relation between the physician and the patient or a virtual relation with no clinical examination[5].

Any legal discussion related to telemedicine should start by determining which concepts should be included in the definition of telemedicine[6]. Furthermore, even if consensus on the definition is reached, it may well include a range of situations that may be too trivial for regulatory measures, e.g. physicians discussing individual cases via phone, instant messaging or e-mail.

1.3 Document Methodology

This document was compiled using results extracted from literature reviews, both peer-reviewed articles and articles focusing on different aspects of telemedicine policy and issues, as well as rules, regulations, working documents and other published or not officially published documents by the EU and / or Member States.

[4] "La télémédecine permet, entre autres, d'effectuer des actes médicaux dans le strict respect des règles de déontologie mais à distance, sous le contrôle et la responsabilité d'un médecin en contact avec le patient par des moyens de communication appropriés à la réalisation de l'acte médical. »

[5] LOI n° 2004-810 du 13 août 2004 relative à l'assurance maladie http://www.has-sante.fr/portail/upload/docs/application/pdf/loi_2004_810_du_13_aout2004.pdf

[6] Berger, S. & Cepelewicz, B., Medical-legal issues in teleradiology. AJR Am J Roentgenol 1996, Nr. 166, p. 505-510; Laske C. Legal aspects of digital image management and communication. Med Inf 1994;19:189-196; Granade PF., Malpractice issues in the practice of telemedicine, Telemedicine Journal 1995, nr.1, p. 87-89; Schiffer M. Legal aspects of telepathology, Zentralbl Pathol 1992;138:393-394

2. Telemedicine legal and regulatory environment

2.1 Telemedicine legal and regulatory framework at the European level

Healthcare is largely under the competence of Member States, but European level legal instruments in this field are not completely missing. The Community did not have legal authority in the field of public health until 1999, when the public health article was amended and renumbered by the Treaty of Amsterdam as the current Article 152. Treaty Article 152 presently defines the role of the EU as complementing national policies, setting out procedures by which the EU institutions may act in the health field, and delineating the types of measures that may be enacted.

As such, the EU does not define health policies, nor the organisation and provision of health services and medical care. Instead, its action serves to complement national policies, and to support cooperation between member countries in the field of public health.

Citizens in the EU are, in principle, free to seek any healthcare, wherever they want, and from whatever provider, with the only limitation being their ability to pay for it or the conditions set out by the public and private funding systems for healthcare.

The legal instruments affecting telemedicine in Europe include:

1. The Data Protection Directive.
2. The e-Commerce Directive.
3. Medical Device Directives.
4. Directive on Distance Contracting.
5. Directive on Electronic Signatures.
6. Competition law.
7. Directive on Professional Qualifications.
8. Reimbursement.

2.2 The Data Protection Directive[7]

The Directive contains several important principles that require compliance from telemedicine actors that process personal data concerning health. If national healthcare systems or other e-health actors create health grids, electronic national records, or information systems that may be used for treatment, quality review or research purposes, they have to comply with the principles of the Data Protection Directive.

[7] The 'Data Protection' Directive, Council Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data, OJ 1995 No. L281/31.

General principles:

- Protects individuals with regard to the processing and free movement of personal data.
- Applies to the automatic processing of personal data, in whole or in part.
- Prohibits processing of personal data concerning health unless that data is required for purposes of preventive medicine, medical diagnosis, the provision of care or treatment, or the management of health care services, or where that information is processed under national law or rule related to a professional or patient subject to professional confidentiality.

Principles relevant to telemedicine:

- Personal data used in telemedicine must be processed fairly and lawfully.
- Data must be collected for specified, explicit and legitimate purposes, and not undergo further processing that is not compatible with these purposes.
- Data must be adequate, relevant and not excessive in relation to the purposes for which they are collected.
- Data should be identifiable for no longer than is necessary or for as long is required for further processing.
- Data subjects should be informed regarding the processing of their personal data.

In 2012, the Commission proposed a major reform of the EU legal framework on the protection of personal data by adopting a draft General Data Protection Regulation which should in principle be adopted by the end of 2015.

2.3 The e-Commerce Directive[8]

The Directive does not apply to non-economic services of general interest or to healthcare services. However, healthcare actors that utilise telemedicine may be considered to be providing information society services.

General principles:

- Applies to information society services defined as any service normally provided for remuneration, at a distance, by electronic means, for the processing (including digital compression) and storage of data, and at the individual request of a recipient of a service.
- 'At a distance' means that the parties are not simultaneously present.

Principles relevant to telemedicine:

- May apply to the transmission of information via a communication network or access to a communication network.
- Depending on the legal definition of telemedicine, may apply to the use of fee-based electronic research registers by physicians.
- May apply to physicians who promote their activities via the web.

[8] The Directive on Electronic Commerce, European Parliament and Council Directive 2000/31/EC

- May apply to the sending of medical information among physicians for remuneration.

2.4 Medical Device Directives[9]

The Directive harmonises the rules for the circulation of medical devices in the EU. Products that fall within the scope of the Directive must meet all applicable essential safety and administrative requirements, and must bear an EC-conformity mark to show that they comply with the Directive.

The legal and regulatory framework related to medical devices continues to evolve. EC guidance document on software used in healthcare was published in January 2012, and in September 2012 the EC proposed new regulations on medical devices, though these have not yet been approved.

General principles:

- A medical device is any instrument, apparatus, appliance, software, material or other article, used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for, among other things, the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or handicap and the control of conception.

Principles relevant to telemedicine:

- Software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, is a medical device (2007/47/EC).

2.5 Directive on Distance Contracting[10]

The Directive involves the conclusion of contracts containing the description of the various parties' obligations, and any special clauses.

General principles:

- Applies to any contract concerning goods or services concluded between a supplier and a consumer under an organised distance sale or service by a supplier, who, for the purpose of the contract, makes exclusive use of one or more means of distance communication.
- Sufficient information on the identity of the supplier, the main characteristics of the services, the price of the services, the arrangements for payment, delivery

[9] European Parliament and Council Directive 2007/47/EC amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EEC concerning the placing of biocidal products on the market, OJ 2007 No. L247/21.

[10] European Parliament and Council Directive 97/7/EC on the protection of consumers in respect of distance contracts, OJ 1997 No. L144/19.

and performance, and the existence of a right of withdrawal, must be provided to the consumer.

- This information must be provided to the consumer in writing or via another durable medium available and accessible to them.

Principles relevant to telemedicine:

- A telemedicine contract between a professional and a consumer (patient) may be subject to rules related to contracts at a distance.

2.6 Directive on Electronic Signatures[11]

An electronic signature is a generic technology-neutral term covering the methods by which electronic records can be signed and created.

General principles:

- Member States may make use of electronic signatures in the public sector.
- Additional requirements by the Member States must be objective, transparent, proportionate and non-discriminatory, and should relate only to the specific characteristics of the application.

Principles relevant to telemedicine:

- Member State requirements may not become an obstacle to cross-border services for citizens.

2.7 Competition law

In order to create a single internal open competition market, a system of competition law has been developed to prevent the disruption of free competition or to neutralise any such disruption.

General principles:

- Prohibits undertakings from participating in anti-competitive activities such as agreements to set prices or abuse of dominant position.

Principles relevant to telemedicine:

- Operators of services of general economic interest are subject to the rules in so far as the application of the rules does not obstruct the performance, in law or in fact, of the particular tasks assigned to them.
- May apply to the use of electronic networks where healthcare practitioners may have a common computer servicer to exchange patient information.
  - May not be used for the exchange of competitively sensitive information (e.g., prices, turnover, etc.).
  - Cannot lead actors to no longer compete with one another.
  - Information network has to be open.

[11] European Parliament and Council Directive 1999/93 on a Community framework for electronic signatures, OJ 2000 No. L13/12

2.8 Directive on Professional Qualifications[12]

The establishment of the Single European Market encompasses the fundamental freedom of movement of persons, capital, services and goods throughout the Community. EU legislation on the free movement of professionals, including health professionals, has evolved through a series of directives leading to the current Directive on the recognition of professional qualifications.

General principles:

- Stipulates that Member States enact uniform, transparent, and non-discriminatory rules recognising professional qualifications and experience to allow professionals to work temporarily or permanently throughout the Union.

Principles relevant to telemedicine:

- Health professionals licensed in one Member State may practice medicine via telemedicine in other Member States without the need to obtain a medical licence in other Member States (Directive 2011/24/EU).
- Cross-border healthcare is to be provided in accordance with the legislation of the Member State of treatment (Article 4(1) of the Directive).
- Physician is free to provide services in other Member States so long as the physician complies with his or her Member State of establishment's legislation regarding holding a valid medical licence (Directive 2000/31/EC).

2.9 Reimbursement

The E-Commerce Directive does not regulate the reimbursement of telemedicine services, which falls under the jurisdiction of Member States.

Patients receiving healthcare in another Member State have to be reimbursed up to the level of reimbursement applicable for the same treatment in their Member State.

2.9.1 Cross-border telemedicine as a health care service

In 1998, the European Court of Justice ruled that Community nationals have the right to obtain medical treatment in any Member State without prior authorisation, and also to be reimbursed consistent with the tariffs of the state in which they are insured. In June 2008, the Commission published a proposal for a directive on patients' rights in cross-border healthcare[13].

Freedom to provide services

Telemedicine is a service, and as such falls under the provisions of the Treaty on the Functioning of the European Union (TFEU). The European Court of Justice has, on several occasions, stated that health services fall within the scope of the freedom to provide services (Article 56 TFEU)[14] and neither the special nature of health

[12] Directive 2011/24/EU

[13] European Commission, Proposal for a Directive of the European Parliament and the Council on the application of patients' rights in cross-border healthcare, COM(2008)414 final, http://ec.europa.eu/health/ph_overview/co_operation/healthcare/docs/COM_en.pdf

[14] ECJ judgment of 31 January 1984 in joined cases 286/82 and 26/83 Luisi and Carbone

services nor the way in which they are organised or financed removes them from the ambit of this fundamental freedom[15].

This includes the freedom for citizens to seek and receive health services from another Member State, regardless of how the service is delivered, i.e. including through telemedicine. Finally, the Court understood that the freedom to provide services applies to services which a provider supplies without moving from the Member State in which he is established, to recipients in other Member States[16].

Member States are, however, allowed to maintain or introduce restrictions to the free movement of services, provided that these are justified by imperative reasons of public interest (e.g. public health), do not exceed what is objectively necessary for that purpose, and that the same result cannot be achieved by less restrictive rules[17].

Patients' rights in cross-border healthcare

Telemedicine services fall within the scope of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare when they are health services provided by health professionals as defined in that Directive.

The Directive covers cross-border telemedicine services with two specific references to telemedicine: Article 3(d) and Article 7(7) allowing for "the provision of healthcare to patients, regardless of how it is organised, delivered or financed" (Article 1(2) of the Directive).

Although it does not solve all legal issues related to the provision of cross-border health services in the EU, the Directive does clarify patients' rights to be reimbursed for the provision of cross-border health services, including cross-border telemedicine services[18].

2.10 Telemedicine legal and regulatory framework at national level

Currently, the role of the involved stakeholders such as healthcare professional organisations, health insurance funds or public authorities in the deployment of telemedicine varies between Member States:

- Roles between the private and the public sector vary.
- Rules affecting how telemedicine is embedded in the larger national e-government policy vary.
- Rules on financing and reimbursement vary.

[15] See in particular ECJ judgment of 28 April 1998, in case C-158/96 Kohll; ECJ judgment of 12 July 2001 in case C-368/98, Vanbraekel; ECJ judgment of 13 May 2003 in case C-385/99, Müller-Fauré and Van Riet; ECJ judgment of 12 July 2001 in case C-157/99, Smits and Peerbooms; ECJ judgment of 16 May 2006 in case C-372/04, Watts.

[16] ECJ judgment of 10 May 1995 in case C-384/93 Alpine Investments

[17] ECJ judgment of 02 March 2011 in case C-108/91 Ker-Optika, 58 until 76. ECJ judgement of 4 December 1986 in case 205/84, Commission v Germany, paragraphs 27 and 29; ECJ judgment of 26 February 1991 in case C-180/89, Commission v Italy, paragraphs 17 and 18; and ECJ judgement of 20 May 1992 in case C-106/91, Ramrath, paragraphs 30 and 31.

[18] It is based on the European Court of Justice rulings issued over a decade confirming the right for patients to be reimbursed for care received in another Member State under certain conditions – see recent Case ECJ ruling of 27 October 2011, C-255-09, Commission v. Portugal

- Levels of ICT penetration vary.
- Regulatory framework for the healthcare profession and what constitutes medical acts vary.

Of particular interest to the scope of this document is how the regulatory framework for the healthcare profession and what constitutes a medical act currently differ amongst Member States, and the lack of clarity this poses for the adoption of cross-border telemedicine activities.

Most healthcare professions are regulated professions[19] and can only be exercised under strict legal conditions. These conditions can differ considerably from one Member State to another. For example, with regard to the rules applicable to physicians, Member States differ in their interpretation of what constitutes the "practice of medicine" and which activities only qualified physicians may perform. Each Member State also has its own licensing system; in most cases, a physician who wishes to exercise his/her profession in a Member State needs to apply for a licence in that Member State. Until recently (Directive 2011/24/EU), a physician or healthcare profession would have needed to register in every Member States where the telemedicine service was accessible.

In addition to the complexity related to the registration and licensing requirements of professionals, the coordination of supervision of healthcare professionals and the different rules of confidentiality which professionals in different Member States must operate according to, may also create barriers towards the adoption of cross-border telemedicine:

- Generally, every Member State has its own supervisory bodies for the various healthcare professions, with little or no exchange of information between these bodies across Member States.
- Because this information is not shared, a possible scenario may include a healthcare professional who is banned from exercising medical practice by a disciplinary sanction in one Member State, e-starting his activities in another Member State.
- The rights of the patient related to privacy and security of data might not always be protected according to the patient's Member State rights, as the application of the duty of confidentiality owed by healthcare professionals towards their patients differs amongst Member States.

Most Member States do not have legal instruments specifically dealing with telemedicine, and only a few have adopted national regulations or professional and ethical guidelines concerning the provision of telemedicine services. Legal rules dealing specifically with this field are uncommon because the range of services that can be considered as "telemedicine" is wide and diverse, and it is therefore difficult to formulate general rules applicable to all forms of telemedicine.

[19] Art. 2 (g) of the e-Commerce Directive 2000/31/EC defines "regulated profession" as follows: "any profession within the meaning of either Article 1(d) of Council Directive 89/48/EEC of 21 December 1988 on a general system for the recognition of higher-education diplomas awarded on completion of professional education and training of at least three-years or of Article 1(f) of Council Directive 92/51/EEC of 18 June 1992 on a second general system for the recognition of professional education and training to supplement Directive 89/48/EEC".

Some national legal systems require the physical presence of the patient and health professional at the same time and in the same place, for a medical act to be legally valid[20].

As a general rule, Member States should refrain from adopting any national law which would prevent service providers from using their freedom to provide telemedicine services. Any obstacle to the freedom to provide services across borders is prohibited, unless justified by imperative reasons of public interest, for example on the grounds of public health. Hurdles of an administrative and reimbursement nature might represent obstacles in this regard, and Member States should prove that they are justified.

Telemedicine is not a new medical act, and does not intend to replace traditional methods of care delivery such as face-to-face consultations. Instead it represents an innovative way of providing healthcare services, which can complement and potentially increase the quality and efficiency of traditional healthcare delivery. Providers of telemedicine are no less subject to the restrictions of licensure as those who practise medicine in the traditional setting.

2.10.1 Telemedicine legal and regulatory framework in United4Health pilot regions

The following table summarises which pilot regions have specific legal provisions related to telemedicine, and whether any practical problems exist within current legislation that create a barrier to the adoption of telemedicine in that region.

Table 1: Regulatory framework for United4Health pilot regions

Pilot Region	Telemedicine legal and regulatory specific provisions	Practical problems with telemedicine legal and regulatory framework
Czech Republic	**No**	**No**
Denmark	**Yes** The Danish National Board of Health issued legal guidelines regarding liability and other legal matters in connection with physicians' use of telemedicine in November 2005[21]. The guidelines refer to rules and principles in the existing legislation which also apply to the use of telemedicine.	**No** The guidelines conclude that the use of telemedicine does not change the traditional legal liability and other legal obligations of physicians. There is no jurisprudence with regard to the liability using telemedicine.
Finland	**Yes** The Executive Board of the Medical Association in Finland approved ethical guidelines on telemedicine in 1997. The guidelines define: medical competence, patient-doctor relationship, physician's responsible, quality, security and safety in telemedicine, handling of patient documents, and rules and practices for medical ethics,	**Mixed** There are no limitations related to physical presence of the physician as long as professional accreditation, authorisations and patient consent can be obtained as required by the law. Rules related to the liability of physicians who provided medical advice to patients by telephone are consistent with rules for

[20] In Poland, the Polish Act on the Profession of Physician and Dentist requires that a diagnosis is made only after personally examining the patient. Polish Act on the Professions of Physicians and DentistDentrist of 5 December 1996.

[21] Vejledning nr. 9719 af 9. November 2005 om ansvarsforholdene m.v. ved lægers brug af telemedicine" https://www.retsinformation.dk/Forms/R0710.aspx?id=10132 (only in Danish)

Pilot Region	Telemedicine legal and regulatory specific provisions	Practical problems with telemedicine legal and regulatory framework
	patient consent and confidentiality.	traditional liability for negligence. Generally, jurisprudence related to telemedicine concerns liability for negligence for not providing healthcare service in a timely manner.
France	**Yes** The concept of telemedicine was formalised in France in the 2009 "Hospital, patients, health territories" (loi hôpital, patients, santé, territoire) law and the 2010 decree through which it was applied. The decree published in October 2010 defined the main telemedicine fields (teleconsultation, teleexpertise, telemonitoring, teleassistance and telesurveillance), the implementation of telemedicine (in particular authentication of health professionals involved in the telemedicine act, identification of the patient, access by professionals to patient's data) and telemedicine organisation (by programs, contracts or agreements). This decree has been inserted in the public health code, which is a way to consider telemedicine as a standard medical act (which adds to and does not replace current medical acts) from a legal point of view.	**Yes** Guidelines on the use of telemedicine: • Specific circumstances. Only the health condition of the patient justifies the use of telemedicine in specific circumstances (emergency, insufficient number of physicians in a defined area, etc.). • Quality Requirements. The technical and communication means, and the competence and qualification of "tele-experts" should meet quality requirements. • Consent. The patient should freely consent to the use of telemedicine in writing. The information should be simple, concise and accurate. Consent should be obtained in writing. By the same token, inadequate telemedicine tools cannot be imposed to the physician. • Professional secrecy. The anonymity of the patient, the confidentiality of the personal medical records and the related communication, the staff's professional secrecy, and the tracking of the medical acts performed, should be ensured. The means to ensure professional secrecy should be clearly described in the contract governing the provision of telemedicine tools. • Liability. Patients are responsible for the information provided. The physician is liable for the use he makes of this information. The telemedicine contract should clearly identify the identity of the patient, the "tele-experts" and the physician in contact with the patient. • Contract. The physician practising telemedicine should be bound by contract that is compliant with the aforementioned criteria. The contract should include: o The mode of telemedicine, o Any material used, o Modalities of information to the patient; o Identity the physician consulted, o Identify the physician carrying out the act, o Outline means implemented to ensure professional secrecy, and o The contract should be submitted to the Provincial Council of the Order of Physicians for opinion.

Pilot Region	Telemedicine legal and regulatory specific provisions	Practical problems with telemedicine legal and regulatory framework
Germany	**No**	**Yes** A legal obstacle to practicing telemedicine in Germany relates to the professional code of conduct which requires physicians to restrain from diagnosis and starting therapy until they have personally examined a patient. Violation of the code may be cause for liability. Another obstacle is that data protection rules expressly refer to access and process health related data as they are supposed to be accessible by means of the electronic health card. Only the patient himself has access to his data, without needing a second person or card. All other persons who want to have access must be authorised by the patient (either in general, if technically registered within the IT-system, e.g. by means of an electronically recorded ticket which documents permissions for access, or case by case by using his PIN) and must authenticate themselves by their Health Professional Cards.
Greece	**No** The draft law for the establishment and operation of primary healthcare includes telemedicine in primary healthcare. More specifically, it describes the provision of medical consultancy and services from a distance and via the use of advanced technologies and infrastructures, especially via a special telemedicine system and an open communication line.	**Yes** The provision providing for medical consultancy and services from a distance is heavily criticised by doctors because it is not clear whether the offering of the services may be done by all medical doctors of the system or whether there will be a specific entity for this purpose, equipped with the necessary technical facilities.
Italy	**No** In Italy telemedicine is not currently regulated through specific legislation, so general rules on data protection and medical liability and ethics apply.	**Yes** Italian legislation puts emphasis on the privacy notice that must be given in the case of telemedicine, requiring that such notice details the specific risks of processing health-related data in telemedicine. Any processing of health-related data via an electronic communication needs to also be notified to the Italian Authority for data protection, before starting.
Norway	**No** The Norwegian Board of Health states that health advice based on health information from individuals is to be considered as healthcare, whether advice is given via internet or in a face-to-face consultation.	**No**
Poland	**No**	**Yes** The Professions of Physician and Dentist[22] Act of 1996 explicitly states that a doctor should announce the state of health of a given person after examining him/her personally, unless separate legislation provides otherwise. Other than the stipulation related physical examination, it is presumed that the practice of

[22] Ustawa z dnia 5 grudnia 1996 r. o zawodach lekarza i lekarza dentysty, Journal of Laws Year 2005, No. 226, item 1943, with further amendments.

Pilot Region	Telemedicine legal and regulatory specific provisions	Practical problems with telemedicine legal and regulatory framework
		telemedicine complies with the professional standards of the practice of medicine by a physician.
Scotland (part of UK NHS)	**No**	**Yes** Though there is no general legal principle requiring a doctor to physically attend a patient, discussion of this issue has been raised in the context of telemedicine.
Slovenia	**No**	**No**
Spain	**No**	**No** Generally, telemedicine is an undisputed and legally approved service in Spain; it is not perceived as an inferior service or "second-class medicine". It is seen as a complement to traditional healthcare and not as posing a threat.
Wales (part of UK NHS)	**No**	**Yes** See England (next section)

2.10.2 Telemedicine legal and regulatory framework in selected other Member States

Most Member States introduced general legal provisions on the delivery of healthcare before the concept of “telemedicine” was known. Though not exhaustive, the following table summarizes key issues of certain Member States where these provisions contain requirements that may or may not create barriers to providing remote care, i.e., by means of electronic communications, to patients,

Table 2: Regulatory Framework for Other Member States

Pilot Region	Telemedicine legal and regulatory specific provisions	Practical problems with telemedicine legal and regulatory framework
Austria	**No** The Health Telematics Act of Austria contains only provisions on exchange of health data, data security provisions, and publication of health information on the Internet. Telemedicine is also not explicitly mentioned in the list of compensations covered by the Austrian Social Security.	**Yes** Obstacles to practising telemedicine in Austria are found in the general provisions related to practising healthcare. According to section 49 of the Physician Act 1998, a physician's services must be carried out personally and directly. Treatment can be given if required in cooperation with other physicians, however the physician may not assign the treatment to another physician without the consent of the patient. Thus, in general, the current interpretation of the law as it relates to the physical presence of the physician being necessary has resulted in telemedicine being prohibited; exceptions may be allowed in the case of an emergency. Alternative interpretations of the law are currently being evaluated as it relates to telemedicine: • Some argue that certain types of telemedicine fulfil the requirement of personal and direct treatment; • Others argue that telemedicine is personal and therefore provision for direct treatment is not

Pilot Region	Telemedicine legal and regulatory specific provisions	Practical problems with telemedicine legal and regulatory framework
		required. For coverage by health insurance, treatments have to be necessary, adequate and appropriate.
Belgium	**No**	**Yes** The scarce legal literature about telemedicine in Belgium refers mainly to the application of personal data protection law and shared medical secret and to the regulatory framework for information society services (transposition of the e-commerce directive). In order to have a treatment reimbursed by the health insurance funds, the physical presence of the physician seems to be required, but there is no practical evidence that this prevents physicians, after a face-to-face consultation, to send, for instance, laboratory results to patients by e-mail and/or discuss these results by phone.
Bulgaria	**No**	**Yes** The compulsory health insurance does not currently cover telemedicine services. However, pursuant to the Bulgarian Health Insurance Act the provision of health services or products that are not covered by the compulsory health insurance may be covered by voluntary health insurance. No jurisprudence with regard to the provision of medical advice to patients by telephone has been found in Bulgaria.
England	**No** Telemedicine does not feature prominently as a specific concept in NHS reforms, but rather exists implicitly in many NHS developments which provide patients with access to a library of medical advice and also to telephone assistance service.	**Yes** Though not specifically raised in the context of telemedicine, and without any general explicit legal principle requiring it, the issue of whether a doctor is obliged to physically attend a patient is under discussion, though currently the NHS makes heavy use of the telephone and nurse advisers for consulting and advising patients. In legal terms, however, the fact that advice was dispensed by telephone rather than in face to face consultation would not per se give rise to potential liability unless in all the circumstances of that particular case, the giving of telephone advice alone was unreasonable and not supported by a reasonable body of medical opinion.
Hungary	**No**	**No** If the rigorous data protection rules in place in Hungary are not violated, there doesn't seem to be major legal obstacles to the practice of telemedicine.
Ireland	**No**	**No**
Lithuania	**Yes** In 2004 the Minister of Health of the Republic of Lithuania issued a decision on telephone consultation by healthcare providers that regulates the procedure and payment for telephone consultation services provided by physicians.	**Yes** Telephone consultations are not popular as they are not covered by the State Patients' Fund and patients are charged for them directly.

Pilot Region	Telemedicine legal and regulatory specific provisions	Practical problems with telemedicine legal and regulatory framework
Netherlands	**Yes** A guideline issued by the Royal Dutch Medical Association[23] concerning online doctor-patient contact addresses the question of the conditions under which doctors may treat patients via the Internet[24].	**Yes** The guideline is applicable to all contact between doctor and patient that take place over the Internet, and in which an agreement for treatment is initiated or continued. The guideline is however restricted to three types of contact and not applicable in other cases: • contact in which the doctor gives a patient advice for a specific situation; • contacts in which the doctor commences pharmacotherapy; • contacts in which the doctor gives repeat prescriptions. The basic principle is that care is required when the Internet is used, in the interests of the quality and continuity of the care provided for the patient. Medication may only be prescribed online if there is a pre-existing doctor-patient relationship, i.e. if the doctor knows the patient, has seen him and has the medication history available.
Portugal	**No** Though no explicit legal provisions, there are guidelines to for the delivery of telemedicine.	**Yes** The guidelines state the delivery of telemedicine must meet the following: (i) Observe the guidelines of the Permanent Committee of European Physicians; (ii) Patients must preferably be personally assisted, and telemedicine should be limited to the situations where the physicians is not able to be on site; (iii) When a patient opts for telemedicine, the assistance must be made by the patients' usual doctor; (iv) Secrecy and other registration data must be observed; (v) The practice of telemedicine is only allowed by registered physicians.
Slovakia	**No**	**Yes** The scarce legal literature about telemedicine primarily refers to the application of personal data protection law and shared medical secret and to the regulatory framework for information society services.

[23] The Royal Dutch Medical Association (KNMG) is the professional organization for physicians of The Netherlands. Since January 1st 1999 the KNMG has become a federation of medical practitioners' professional associations. The federation exists of the National Association of salaried Doctors (LAD), the National Association of General Practitioners (LHV), the Dutch Association for occupational Health (NVAB), the Dutch Association for Nursing Home Physicians (NVVA), the Dutch Association of Insurance Medicine (NVVG), the Dutch Order of Medical Specialists (Orde van Medisch Specialisten) and a group of individual KNMG members and students. http://knmg.artsennet.nl/Over-KNMG/about-knmg.htm

[24] In 2007 this guideline has been revised and in January 2008 the revised guideline came into force. The key change with respect to the old guideline is that prescribing medication over the Internet for patients who you do not know is no longer allowed, as a result of a change in the new Pharmaceuticals Act *http://www.bakermckenzie.com/files/Uploads/Documents/Global Pharmaceuticals/Netherlands.pdf*. *http://knmg.artsennet.nl/web/file?uuid=9f20288a-48d8-43f6-a004-dfb4273147a7&owner=fee3a874-12d9-4756-b7e1-55b6ae79a364*

Pilot Region	Telemedicine legal and regulatory specific provisions	Practical problems with telemedicine legal and regulatory framework
		Also, the physical presence of the physician appears to be required In order for treatment to be reimbursed by the health insurance funds.
Romania	**No** The Health Reform Law of Romania refers to telemedical systems used for the transfer of data in emergency situations but does not explicitly define the use of telemedicine.	**No** The Professional Ethics Code of the Physicians (the "Ethics Code") stipulates that a physician may not treat a patient without personally examining him/her first except in cases of emergency or force majeure. Generally however there does not seem to be major legal obstacles to practicing telemedicine.

2.11 Future regulatory trends

Telemedicine using live (synchronous) and store-and-forward (asynchronous) technologies have improved access to specialised healthcare services in almost all clinical subspecialties. This form of delivery of medicine has also been used to improve access to sources of knowledge for patients, healthcare providers, and the general population. Advances in Electronic Health Records (EHRs), Picture Archival and Communication Systems (PACS), and Health Management Information Systems (HMIS) now provide support to healthcare professionals and managers to aid in the treatment of patients. The use of the Internet and handheld devices has opened new avenues for telemedicine.

The use of telemedicine involves a number of factors that require proper planning. Many issues cannot be addressed without the support of well-defined policies, rules, standards, or guidelines at the institutional, jurisdictional, and European level.

2.11.1 Networked Care

Financial and legislative policies should be enacted to ensure that an environment of networked care enables a smooth adoption of telemedicine solutions.

- Funding of telemedicine programmes by institutions and governments is essential for other stakeholders to commit to telemedicine systems.
- Clear reimbursement policies for specialists, and remuneration for all healthcare staff for telemedicine activities and payment policies for patients, are essential for the buy-in of telemedicine activities.
- Policies related to the content and authorisation for sharing patient information between healthcare professionals, departments, and institutions are necessary to facilitate networked care. These include creating unique patient identifiers to ensure that patient information is comprehensive, comprehensible, and transferable.
- Policies on the type and processes for sharing of services between institutions and jurisdictions should be developed.
- Policy and adoption of standards related to interoperability to enable the transfer of information from one provider or institution to another in a smooth transition should be introduced. These include policies guiding the purchase or development of hardware and software between different partners, ensuring

that the information transferred between providers or organisations, e.g. with the use of EHR/PHR/EMR, is interpreted the same way as it was intended.

- Policy related to the transfer of information in a secure and integrated form should be adopted. This is important for proper coding of patient information and removal of identifiers that could affect patient privacy during the transfer of information from one source to the other. Policies for authorising that only the relevant people access patient information are also important.

Challenges to keep in mind include:

- Issues related to accountability and liability.
- Ensuring confidentiality and privacy of patient information through properly structured authorisation to patient information to avoid any conflicts and ethical issues.
- Appropriate ICT infrastructure and backup plans to ensure smooth connectivity between sites.
- Stringent policies to ensure that malpractice, such as access to patient information or breach in the privacy or quality of care, is controlled.

2.11.2 Interjurisdictional practice

Policies to address the transfer of information and provision of care between different jurisdictions should be defined. These policies should enable healthcare providers to provide care to patients or give advice to physicians in jurisdictions other than where they are currently licensed. Restrictions from licensing authorities to practice medicine and nursing in different jurisdictions need to be addressed, as well as the lack of recognition of some institutions in their own or other jurisdictions which may cause inability of providers to be part of any telemedicine activity.

Challenges include policy issues that can inhibit implementation of interjurisdictional telemedicine. It is important that telemedicine policies developed by any organisation or jurisdiction complement similar policies in other institutions and jurisdictions. Different healthcare regulations in different regions related to issues such as privacy, confidentiality, and reimbursement may hinder participation in coordinated care and transfer and storage of patient information.

2.11.3 Diffusion of telemedicine

Policy that enhances the diffusion of telemedicine among all populations is needed.

- Governments should develop policies to allow greater penetration of telecommunication companies, such as mobile companies, ISPs, ISDN service providers, and satellite vendors to reach the remotest regions of their countries. This may include policies to reduce the cost of telecommunication.
- Governments should develop policies to provide universal and unlimited access to the Internet to their populations; this may also include efforts to reduce costs and increase bandwidth of the Internet available for the social sector.

2.11.4 Integration into existing systems

Enacting policies facilitating the integration of telemedicine projects and programmes with regular services is critical towards quality of care goals.

- Institutions and governments should have targets to improve effectiveness of care by increasing interaction between different groups of providers and users. The use of telemedicine should not compromise quality of care.
- There should be a strong commitment to improve access of populations living in rural and remote areas to better care and services, as well as a strong focus on using telemedicine to reduce the cost of care.
- Simple and workable processes for payment should be implemented.
- Policies to enhance awareness and comfort levels among healthcare providers and clients towards acceptance of telemedicine among patients and providers are necessary for its sustained implementation.
- Explicit policies on various ethical issues, such as use among different gender and socio-cultural groups, transfer and storage of information, consent from the patients, confidentiality and privacy, etc. are critical for wider ethical acceptability of telemedicine services.
- Clear policy guidelines related to various delivery models of telemedicine, e.g. cloud services, software as a service, etc., are required to avoid interruption of services.

2.11.5 Ethical issues

Ethical issues should be addressed so that they do not hinder the adoption of telemedicine. Laws differ in many areas on obtaining consent for care before transferring patient information online, or before arranging video-conferencing sessions. Enacting clear policies guiding such consent would benefit healthcare institutions and providers. Policies clarifying liability are also important in cases of inter-jurisdictional care. Last but not least, enacting clear policies regarding a patient's right to access his or her own information is important.

Certain provisions of the proposed General Data Protection Regulation as put forward by the European Commission and European Parliament will restrict the sharing of health data, create legal uncertainty, and increase compliance costs if they remain unchanged, ultimately delaying the development and introduction of innovative healthcare solutions.

3. Interoperable telemedicine regulatory and legal framework in Europe

Telemedicine applications and infrastructure have been in use in Europe for at least a decade, though often in isolation from one another. Despite the early innovation, these systems suffer as they do not have the capability to exchange data with other systems, often driven by the lack of recognised IT standards for software and devices.

> Interoperability is sometimes considered simplistically as a technological notion associated with "connectivity" and "connectedness". However, interoperability implies not only that information can be communicated between many systems or services, but that the receiving system is able to use the information received to perform specific actions (which effectively extends the scope of the interoperability).
>
> *DG CONNECT eHealth EIF - D2 Study Plan*[25]

With the expansion of Member States joining the EU, there are places where the infrastructure is largely insufficient to fully utilise the most current Internet technologies. Often this is driven by the instability of electric power supplies and the unavailability of Internet connectivity, e.g. outside of large cities, unreliable connectivity, limited bandwidth, etc.

Unless remedied, the inability to use available data may prevent patients from receiving better healthcare.

- Internet congestion can lead to delayed imaging.
- Poor image resolution may limit the efficacy of remote diagnosis.
- Slow bandwidth can prohibit the use of real-time videoconferencing.

Promotion of telemedicine interoperability is a priority of the EC as outlined in various instruments such as the Digital Agenda, the eHealth Action Plan, and the ICT Standardisation Regulation. The Commission's objective is to reduce the fragmentation of the telemedicine market in Europe by promoting the use of existing EU standards and fostering the adoption of interoperable telemedicine solutions to enable the seamless exchange of information within and between countries.

Interoperability allows different technological solutions to communicate with each other, allowing patients and doctors to exchange medical information across healthcare settings, and across borders, even if using different devices (medical software, computer, phone, medical equipment, etc.) or ICT providers. EU policies related to telemedicine interoperability address the generally recognised four layers of interoperability, namely technical, organisational, legal and semantic interoperability.

Interoperability of telemedicine solutions is crucial as it:

- Supports the patient's safety and mobility;

[25] eHealth European Interoperability Framework European Commission - ISA Work Programme Version 1.2, 14/02/2013. ISBN 978-92-79-30348-7 DOI: 10.2759/14325

- Facilitates the work of healthcare professionals; and,
- Removes barriers (i.e. borders) for the deployment of telemedicine.

4. Regulatory barriers and obstacles

4.1 Telemedicine

Legal and regulatory considerations are a major obstacle to telemedicine uptake. These include a lack of policies that govern patient privacy and confidentiality vis-à-vis data transfer, storage, and sharing between health professionals and jurisdictions; health professional authentication, in particular in e-mail applications; and the risk of medical liability for the health professionals offering telemedicine services.

Along with legal considerations come technological challenges. The systems being used are complex, and there is the potential for malfunction, which could trigger software or hardware failure. An increase in the mortality of patients and the liability of healthcare providers is a factor as well.

In order to overcome these challenges, telemedicine must be regulated by definitive and widely applied comprehensive guidelines. Concurrently, legislation governing confidentiality, privacy, access, and liability needs to be instituted. As public and private sectors engage in closer collaboration and become increasingly interdependent in eHealth applications, care must be taken to ensure that telemedicine will be deployed intelligently to maximise health services and optimise quality, and guarantee that for-profit endeavours do not deprive citizens of access to fundamental public health services.

In all countries, issues pertaining to confidentiality, dignity, and privacy are of ethical concern with respect to the use of ICTs in telemedicine. It is imperative that telemedicine be implemented equitably and to the highest ethical standards, to maintain the dignity of all individuals, and ensure that differences in education, language, geographic location, physical and mental ability, age, and sex will not lead to marginalisation of care.

4.1.1 Legal concept of telemedicine

Legally, telemedicine is a difficult concept as it covers a very broad range of activities and services. Telemedicine is not a specific technique or piece of equipment; it is a process of delivering healthcare services. Legal issues would be better tackled by addressing the various activities and services as opposed to a broad based legal definition of telemedicine. It would appear to be more appropriate to issue specific guidelines, for example, for e-mail communication between physicians and patients, instead of general guidelines attempting to cover every possible “telemedicine” use case.

Similarly, approaching “telemedicine” as a category of healthcare for reimbursement is too broad. Rather, the discussion related to telemedicine and funding or insurance would be best serviced by addressing it at a more specific level, e.g. at the level of particular telemedicine applications.

Many types of telemedicine applications are directly linked to the introduction of the shared electronic health record. Healthcare professionals will, in most situations,

combine the provision of a telemedicine service, either to another professional or to a patient, with accessing the patient's record.

Multiple legal obstacles hinder the provision of cross-border telemedicine services in Europe. These obstacles can be divided into two categories. A first category of obstacles is related to the national character of the regulatory framework governing healthcare in the Member States. The Barcelona Telemedicine Clinic, for instance, works with "national" radiologists. A radiologist working for Scandinavian countries must be fully registered with the "Swedish medical board or with another Scandinavian country." For the UK, candidates must be fully registered with the GMC, or eligible for inclusion on the GMC specialist register. It is evident that such requirements prevent flexibility in the service provision, and can lead to almost unsolvable complexity in case of European-wide roll-out of telemedicine services.

As a consequence of the divergences between the national legal frameworks for healthcare, it is crucial to determine which national law applies in case of a cross-border telemedicine relationship. In many cases, it requires a detailed analysis of the particular case and requires specialised legal expertise. What is the scope of the provisions of the eCommerce Directive with regard to telemedicine? In which cases can it be considered as an "information society service" and in which cases will the country-of origin principle apply? Unfortunately, most of these questions can only be answered on a case-by-case basis, and the answer will very much depend on which countries are involved in the cross-border situation.

A second category of legal obstacles relates to the fact that telemedicine, as it is currently conceived in the Member States, is based on the creation of a national online community including the stakeholders of the national healthcare sector: healthcare professionals, healthcare institutions, patients, health insurers, public health administrations. The rules that are created to govern this community are primarily, in most cases even exclusively, designed to be applied by and to the members of this community. This results in numerous practical difficulties in case of cross-border provision or use of online healthcare services. By way of example, the NHS Direct telephone service uses a UK 0800 (freephone) number. Such numbers cannot be called from abroad, except by subscribers of UK mobile phone operators when they are travelling outside the UK.

4.1.2 Electronic health records and eHealth platforms

Electronic health records are not a subset of telemedicine, but not including a brief discussion in the context of telemedicine would be remiss, as the use of electronic health records is pivotal to the exchange of information in telemedicine activities and services. Member States are largely adopting electronic health records or eHealth platforms in order to make available health data for medical treatment. Public authorities believe that electronic health records may improve quality of care and patient safety; they also can be used as an instrument to control the rising demand for (and cost of) health services. However, the use of electronic health records that contain data about an individual compiled from existing medical information from different sources may result in allowing easier and more widespread access to this sensitive information. More categories of people may gain access to data if hospitals, pharmacies, laboratories, sickness funds, etc., that process health data become members of (international) groups.

There is concern that relying only on the obligation to practise professional confidentiality does not provide sufficient protection; more specific safety measures should be taken, and patients should be asked for consent as to which categories of people may have access to their records.

In addition to patient rights related to EHR systems, legal rules regarding the processing of personal health data for purposes other than treatment purposes, such as research and quality review, should be evaluated. Better and more specific provisions in the Directive for the further use of health data are needed, as the use of such data takes place increasingly within a globalised context of healthcare stakeholders, and in several Member States where national rules regarding certain types of processing differ. Globalisation in healthcare has become a reality, since not only pharmaceutical companies but also sickness funds, patients groups, research institutes, hospitals and laboratories are becoming part of an increasing number of European-wide organisations or groups.

The globalisation of healthcare stakeholders requires more harmonised rules for health data processing, particularly as the exchange of data between European eHealth stakeholders will not be limited to the treatment of patients; the data also can be processed for evaluation, research or statistical purposes. Currently, harmonised rules in this area are lacking. Several Member States have formulated strict rules for the processing of medical data for research purposes, while other Member States have more flexible rules. The Directive leaves too much room for different legislation in the Member States, which is not good for the establishment of an EU internal market in which international quality review projects, epidemiological studies, clinical trials and post-marketing surveillance projects are emerging.

4.1.3 Health grids

A grid is a technology that aims to enhance the services already offered by the Internet. It offers rapid computation, large-scale data storage, and flexible collaboration by harnessing the power of a large number of commodity computers or clusters of other basic machines. Health grids have been used in some medical and healthcare applications; however, there is a tension between the spirit of the grid paradigm, and the requirements of medical or healthcare applications. On one hand, the grid stores data in the most convenient way according to performance criteria. On the other hand, a hospital or other healthcare institution is required to maintain control of the confidential patient data and to remain accountable for its use at all times.

Health grids provide doctors, researchers and health system planners with the opportunity to support areas of healthcare such as medical imaging and image processing, modelling the human body for therapy planning, pharmaceutical research and development, epidemiological studies and genomic research, and treatment development. However, in order to be truly effective, such grid applications must draw together huge amounts of data from disparately located computers, which implies data sharing across jurisdictions and the sharing of responsibilities by a range of different data controllers. Since not all Member States have adopted the European Data Protection Directive in the same way, and since the Directive itself allows Member States to adopt legislative measures to restrict the scope of some obligations and rights, there are differences in the level of protection granted to personal data between EU Member States, which might be a problem for

the implementation of the health grid technology throughout the whole territory of the European Union.

If health grids are to grow to their full potential and deliver on their promises, adjustments must be made to national and European legislation. This implies the development and adoption of robust guidelines developed specifically for the health grid context, which address the balancing of interests between an individual's privacy and medical advancement.

4.1.4 Guidelines on the reimbursement criteria for telemedicine

The lack of legal clarity with regard to reimbursement is a major challenge for the success of telemedicine in Europe, as the E-commerce Directive does not regulate the reimbursement of telemedicine services, which falls under the competence of Member States. European and international telemedicine projects have failed because they are too expensive for patients, and reimbursement by their health insurance funds has not been possible.

There is also the question as to whether or not the criterion of physical presence for the reimbursement of treatment remains an obstacle to the free movement of services.

4.1.5 European legal framework on liability and telemedicine

One of the important questions in cases of liability and telemedicine will be whether or not the telemedicine transaction is the most suitable approach for the treatment of patients. Telemedicine may alternatively pose an increased risk or greater benefit to a patient:

- A delay in an emergency situation may pose a greater risk to the patient than a prompt intervention with telemedicine.
- A physician may not always be able to effectively resolve a problem during a telemedicine transaction.
- Altering the course of a procedure to address complications, for example during surgery, may be difficult.
- Online telemedicine sessions may be disrupted, or connectivity may fail, leaving no direct access by the tele-expert to the patient.

Compared to traditional medical treatments, more and different parties may be held liable if something goes wrong during the telemedicine session. For example, the technical failure of a device used during a telemedicine session could potentially lead to liability claims against software producers or Internet providers.

The issue of liability becomes very important in the case of remote monitoring, where medical devices are implanted to monitor and follow the patient. Whether the device fails to send an alarm, or the physician fails to respond promptly, it is critical that patients have accurate information regarding the functionality of the device and the availability of the professional.

4.1.6 European JURISDICTION AND REGISTRATION

In order to practice within a particular jurisdiction, a doctor, nurse or dentist must be registered in that jurisdiction. Once registered, the professional is subject to the rules of that country or state whenever they practice within that jurisdiction.

In the EU, the medical qualifications awarded by one member state are valid in all the other member states. However, there is no automatic right to registration. Cross-border medical practice in the EU requires the recognition of the doctor's registration to practice in countries other than that in which they are living and working, and the completion of formal registration requirements in all those 'host' countries in which the doctor intends to treat / advise patients, even though they may never be physically present in that country.

Telecommunications-based services that cross legislative boundaries are almost free of regulation. In principle, legislation should be independent of the communication medium used: the same ethical principles and liabilities should apply to telemedicine as to conventional patient care.

4.2 Interoperable solutions

It is recommended that specific measures necessary for achieving the interoperability of ICT systems in healthcare be adopted. These measures should specify in particular the necessary standards and terminologies for interoperability of relevant ICT systems to ensure safe, high-quality and efficient provision of cross-border health services.

Although interoperable technology in itself is not always a critical limiting factor for the wider implementation and mainstreaming of telemedicine, there remains a continuing need for further technological innovation that encompasses advanced user interfaces for patients and carers, as well as better “ease of use”, i.e. users should be able to use these new technologies without the need to rely on support from information systems specialists; this is often facilitated when systems are interoperable or "plug-and-play".

Telemedicine adoption will be aided by consideration of the interoperability of ICT systems and devices across the care continuum. Only if technical as well as semantic (issues around the language used by different professionals as well as in ICT systems) interoperability of all the disparate ICT solutions that may be involved in supporting continuity of care is assured, can the full benefits of integrated telemedicine be attained. Such interoperable systems will not only allow all actors involved in the care of a person to communicate seamlessly in a commonly understood way, but also permit technical system components to exchange, aggregate and analyse all the uniquely structured and coded data generated by the care and monitoring process. This will drive improved service delivery, management support, transparency and control, knowledge generation and decision support at the point of care, for both patients and their family carers.

In addition to a clear legal and regulatory framework, ethical issues, organisational changes and relevant technological aspects, there is also a need for technical standardisation, security policy, and possibly certification of devices and systems, as well as issues of education and training, financing and procurement. All of these

elements together constitute a complex framework to enable ICT systems and care teams to work together and deliver to their full potential.

5. Recommendations

The current legal and regulatory framework, such as the Data Protection Directive, the e-Commerce Directive, the Medical Devices Directives and the Distance Contracting and Competition Rules Directive, plays an important role for telemedicine. However, despite these rules and policy attention, the existing legal and regulatory framework is not yet complete. The current European rules often remain too vague. The issues confronting healthcare players have to be addressed at the European level, as some important legal and regulatory issues, as well as technological developments, need a clear legal answer.

Specific attention should be given to the legal definition of telemedicine, the need to enact European criteria on the reimbursement of telemedicine, and to the (no-fault) liability issues. Before telemedicine can play an important role for healthcare players and healthcare systems, while respecting the interests of patients, healthcare providers and public authorities, the European Union has to provide a clear answer to the challenges caused by new technical developments such as eHealth platforms, electronic health records, and health grids.

In addition to the above general recommendations the following specific recommendations, though not exhaustive, would greatly benefit the healthcare sector, and specifically the adoption of telemedicine activities and services.

5.1 Integrate telemedicine into care delivery structures

1. Licensing, authorisation and registration of the telemedicine provider

Directive 2005/36EC on the recognition of professional qualifications does not apply to healthcare professionals providing cross border telemedicine, as it is only applicable to situations where the telemedicine provider moves to another host state. As a result, the telemedicine provider should be responsible to the professional registration authorities of the Member State where he/she performs the telemedicine service, and should not be required to register with the patient's Member State authorities.

2. Telemedicine as a medical act

It is important to underline that telemedicine is not a new medical act, and it is not intended to completely replace all traditional methods of care delivery, such as face-to-face consultations. Rather it represents an innovative way of providing healthcare services, which can complement and potentially increase the quality and efficiency of traditional healthcare delivers.

3. Patients' rights when receiving cross border telemedicine

Patients' rights when receiving cross border telemedicine are encompassed in the cross border healthcare directive (Art 4 and 6) and include:

- The possibility to receive treatment in another Member State and be reimbursed under certain conditions.

- Patients who have received treatment are entitled to a written or electronic medical record of such treatment (Art 4.2(f)).
- Upon request, relevant information on the standards and guidelines on quality and safety from the telemedicine providers' Member State should be available from the national contact point of that Member State of treatment.
- The Member State of treatment must ensure that the telemedicine provider provide relevant information, including on the availability, quality and safety of the service that is used, and that they also provide the interpretation and clinical advice relative to the telemedicine service as well as information on the telemedicine providers' authorisation or registration status (Art 4 2(b)).
- There are transparent complaints procedures and mechanisms for patients to seek remedies in accordance with the legislation of the Member State of treatment if they suffer harm from the treatment they receive (Art 4 2(c)).
- Systems of professional liability insurance or a guarantee of similar arrangement are in place (Art 4 2(d)).

5.2 Develop appropriate reimbursement strategies

4. Patients' rights when receiving cross border telemedicine

Patients' rights when receiving cross border telemedicine are encompassed in the cross border healthcare directive (Art 4 and 6) and include:

- The possibility to receive treatment in another Member State and be reimbursed under certain conditions.

5.3 Establish a harmonised data protection regime that allows innovation

5. Maintain clear and separate responsibilities between the healthcare provider and the medical technology provider (data processor) as per the current regime to secure legal certainty

The healthcare provider (data controller) should be responsible and liable towards the patient data subject. The medical technology provider (data processor) should be responsible and liable towards the healthcare provider (data controller) by contract. Medical technology providers process personal data based on instructions from the healthcare provider. They do not maintain a direct relationship with the patient, and should not be liable to them.

6. Simplify the condition for sub-contracting between the healthcare provider and the medical technology provider

The relationship between the healthcare provider and the medical technology provider should be established by contract, not by law. Requesting the 'prior permission' of the healthcare provider before sub-listing another processor creates additional burden and might create delays. In healthcare, delays in processing health data may be prejudicial to patient health and safety.

7. Avoid unnecessary administrative burden linked to impact assessment obligations

The Commission proposal provides prescriptive obligations for carrying out impact assessments. Healthcare organisations should be able to maintain their own assessment, based on their specific type of organisation, legal requirements, contractual obligations, and, where appropriate, internal policies.

8. Allow and support the sharing of health data for health and research purposes

Data collected and managed in Member States in compliance with harmonised legislation must be able to be securely transferred, within and across Member States, for the purposes of patient care and relevant medical and healthcare research. Telemedicine and the use of 'Big Data' promises to help empower better research and better patient care. It needs as much data as possible to do this, and international and global databases will be essential in some instances.

9. Enable the secondary use of data for health and research purposes by adopting a workable consent requirement

Ease the conditions for consent for health and research purposes. This will accommodate the secondary use of data in research. A 'broad consent' seems more workable than a 'specific' or 'purpose explicit' consent. Maintaining Article 83 as proposed by the Commission would suffice.

10. Clarify the exemption to the right to be forgotten for 'health purposes'

Clarify the exemption to the right for erasure / right to be forgotten for 'health purposes' rather than for 'reasons of public interest in the area of public health'. The concept 'reasons of public interest in the field of public health' lacks clarity, and may not include delivery of care. The use of 'for health purposes' is recommended as it will help clarify the ambiguity of the current proposal, and should provide greater legal clarity.

11. Ensure only data related to a data subject are subject to the regulation by adopting a proportionate definition of personal data

The definition of personal data should not be too broad. For instance, the serial number of a medical device may be regarded as personal data subject to the Regulation. This will increase the administrative burden for medical device manufacturers without bringing benefits for privacy.

12. Enable citizens' access to their health data

The collection and processing of health data plays a central role in facilitating citizens' interaction with, and access to, the healthcare system. Indeed, the prompt availability and integrated use of health data are not only necessary for the better internal functioning of healthcare systems, but ultimately serve the purpose of facilitating citizens' inclusion and empowerment. Citizens cannot be in control of their health if they do not have access to their medical data. This will increasingly involve more innovative technologies such as mobile devices and applications. Policymakers are urged to not lose sight of this when developing a data protection framework that effectively promotes citizens' engagement.

5.4 Provide clear regulatory guidance

13. Provide a harmonised regulatory framework for telemedicine across the European Union

Provide for a high level of harmonisation so that telemedicine stakeholders do not need to address different rules throughout the 28 Member States. This will provide legal clarity and simplification.

14. Adopt a regulatory framework that allows access to health data with proportionate safeguards

- Promote a pragmatic, flexible, future-proof legal framework.
- Allow the secondary use of data for health purposes, with patient consent.
- Allow transfer of data over national borders.

5.5 Foster use of widely recognised standards and support mobile broadband policies

15. Invest in robust networked IT infrastructures

Investments in robust IT infrastructure, technological upgrades, structural changes and technical interoperability are needed to provide a sound basis for collecting, processing, and analysing data from disparate sources. These investments are needed at all levels: care providers, health authorities, research and academics.

16. Continue efforts to promote open and standardised data

- Share results of clinical trials in a transparent and exploitable format.
- Promote the adoption of international consensus data standards.
- Invest in interoperability between health data and information and image databases.

17. Digitise patient records and drive interoperability to ease access to clinical data

Telemedicine requires access to and integration of clinical data. Care providers must continue to invest in deploying Electronic Patient Record systems, to capture and store clinical data in an efficient, standardised and cost-effective manner, whilst protecting individual privacy. Additionally, all care providers involved in taking care of a patient must team up to enable integration and access to all patient relevant data.

Appendix A: Global telemedicine legal and regulatory framework

There are no international treaties or global agreements that deal with telemedicine. The same choices of law and jurisdictional questions discussed in relation to Europe in this document also have to be addressed on an international basis.

A.1 Legal and regulatory telemedicine framework in the United States

A.1.1 Licensure

Similar to Europe, physician licensure and governance issues related to the delivery of telemedicine services have been a major area of concern in the United States. 1997 and 2001 Telemedicine Reports to Congress by the Office for the Advancement of Telehealth identified licensure as a major barrier to the development of telemedicine[26].

Traditionally, in order to practice medicine in a state in the U.S., a physician must be licensed in that state. However, in regards to telemedicine, it is unclear whether the practice of medicine occurs where the patient is located, where the physician is located, or both. Most states require physicians to be licensed to practice in the originating site's state, and some states require providers using telemedicine technology across state lines to have a valid state licence in the state where the patient is located. Generally, with limited exceptions, telemedicine consultations with a physician across state lines require licensing paperwork.

The development of a form of national or multi-state licence for telemedicine as a possible solution to licensure issues is gaining traction.

A.1.1 Reimbursement

Reimbursement for Medicaid covered services, including those with telemedicine applications, must satisfy federal requirements of efficiency, economy and quality of care. States are encouraged to use the flexibility allowed in the law to create innovative payment methodologies for telemedicine services. For example, states may reimburse the physician or other licensed practitioner at the distant site and reimburse a facility fee to the originating site. States can also reimburse any additional costs such as technical support, transmission charges, and equipment. These add-on costs can be incorporated into the fee-for-service rates or separately reimbursed as an administrative cost by the state.

States have the option / flexibility to determine whether (or not) to cover telemedicine; what types of telemedicine to cover; where in the state it can be covered; how it is provided / covered; what types of telemedicine practitioners /

[26] Telemedicine report to the Congress, GPO No: 0126-E-04 (MF), Washington, DC. U.S. *Department of Health and Human Services; and 2001 Telemedicine Report to Congress, GPO No: 619-261/65410, Washington, DC. U.S. Department of Health and Human Services*

providers may be covered, etc., as long as such payments do not exceed federally approved upper limits.

A.2 Legal and regulatory telemedicine framework in China

In August 2014, the National Health and Family Planning Commission of the People's Republic of China (NHFPC) published interpretations and associated guidelines related to telemedicine services in China. These documents, known as The Opinions, are the first official telemedicine guidance since the former Ministry of Health's 1999 "Notice on Strengthening the Administration of Telemedicine", and represent China's policy position and regulatory expectations for telemedicine providers.

The Opinions are divided into four major opinions, each with various subsections:

1. Enhance overall coordination and actively promote the development of telemedicine services.
    a. Authorities at local levels should include the construction of a telemedicine service system in their regional health plans.
    b. Local officials should actively coordinate with financial authorities to provide funding, support and safeguard the development of telemedicine services.
2. Clarify service items and ensure the quality and safety of telemedicine services.
    a. Telemedicine definition and content.
        i. Defines telemedicine services as medical activities whereby a “host” medical institution allows other “invited” medical institutions to use communications and information technologies to provide technical support in the diagnosis and treatment of patients in the “host” institutions.
        ii. Telemedicine services include: direct-to-patient telemedicine diagnostic and treatment services provided by “host” institutions, remote pathological diagnosis, remote medical imaging diagnosis (including imaging, ultrasound, nuclear medicine, electrocardiograms, electromyography and electroencephalograms), remote patient monitoring, remote outpatient services and remote case discussions and other items provided by administrative authorities above the provincial levels in charge of health and family planning.
    b. Regulatory compliance expectations.
        i. During the performance of telemedicine services, medical institutions must strictly comply with China’s laws, regulations, information standards and technical practices, ensuring the quality and safety of medical services and protecting the legal interest of patients.
        ii. Non-medical institutions are not authorized to provide telemedicine services.
        iii. Clarifies the applicability of the Opinions to foreign medical institutions providing telemedicine services in China: when telemedicine services are performed between medical institutions [in China] and medical institutions outside China, reference should be made to the guidelines.

3. Perfect the service process and ensure the high quality and efficiency of telemedicine services.
    a. Expertise to perform telemedicine services.
        i. Medical institutions must possess the required diagnostic and treatment technology and expertise required to perform telemedicine services, including the appropriately qualified personnel, equipment and facilities.
        ii. This may include designating a dedicated department or personnel responsible for testing, registrations, maintenance, modifications and upgrades of the instruments, equipment, facilities and information systems used in telemedicine services.
        iii. Medical institutions must ensure their telemedicine service systems (hardware and software) are in standard operation and meet the relevant health information standards and privacy and security provisions related to telemedicine services.
    b. Telemedicine cooperation agreement.
        i. Agreement should include the purpose of the agreement, the conditions of cooperation, processes for telemedicine services, the rights and obligations of the parties and risk sharing regarding liabilities and responsibilities.
    c. Patient consent.
        i. The “host” medical institution should fully inform patients and obtain their written consent to telemedicine services.
        ii. When it is not appropriate to offer an explanation to the patient (e.g., in minor patient situations), the written consent of the guardian or a close relative of patients should be obtained.
    d. Patient privacy.
        i. When the “host” medical institution needs to discuss individual patient cases regarding telemedicine services, it must submit a request to the “invited” medical institution.
        ii. The guidance describes the elements required in that request, as well as the process the two medical institutions must follow.
        iii. The “host” medical institution has the right of medical disposal with respect to the patients and should, based on the clinical information on the patients and with reference to the diagnostic opinions of the “invited” medical institution, have ultimate authority for final diagnostic and treatment decisions.
    e. Patient records.
        i. The “host” and “invited” medical institutions should jointly complete medical record information in accordance with laws regarding completion and safekeeping of medical records.
        ii. The guidance describes specifics regarding storage and ownership of original copies, as well as expectations regarding electronic transmission of medical records and signature requirements.
    f. Partnership between medical institutions.
        i. The “host” and “invited” medical institutions should set up matching support or another kind of partnership relationship.

ii. The guidance discusses situations when telemedicine services and the process used must be reflected in the parties' telemedicine cooperation agreement.

g. Prior approval by medical institutions.
   i. In arrangements where healthcare professionals provide direct-to-patient telemedicine services outside their medical institution, they should first obtain the permission of the medical institution(s) where they are registered to practice.
   ii. When providing these services, the professionals should utilize the health information platforms established by the medical institutions when providing diagnostic and treatment services for patients.

4. Enhance supervision and management and guarantee the legitimate interests of both physicians and patients
   a. Unless previously approved by the NHFPC, no medical institution performing telemedicine services should include in their name "China," "Chinese" and "National" or other alternative names or names that imply a nationwide or interprovincial scope or imprimatur.
   b. Medical institutions offering telemedicine services must take steps to control safety risks, including planning for emergencies and serious adverse consequences directly related to the telemedicine services. If such occurs, telemedicine services should be stopped immediately and a report should be filed with the administrative authorities.
   c. When administrative authorities discover quality and safety concerns related to telemedicine, they will immediately commence an investigation into the practices of the related medical institutions. The guidance describes sanctions and corrective actions that may be applied to noncompliant medical institutions.
   d. In the event of any medical dispute regarding the telemedicine services, the "host" and "invited" medical institutions should handle the matter in accordance with the applicable laws and regulations and the telemedicine cooperation agreement. The guidance also describes sanctions for noncompliance with medical licensing and practice standards in China.

A.3 Legal and regulatory telemedicine framework in the developing world

A.3.1 ICT in the health sector

ICT is a cornerstone of efficient and effective services. Despite the significant spread of broadband networks and the development of new telemedicine applications, access to these development is not universal, and many countries do not benefit as they might from advances in ICT and telemedicine. Telemedicine policy makers need to work with ICT policy makers and participate in the national policy-making process to ensure that national ICT policy meets the interest of the health sector including the use of telemedicine.

A.3.2 Electronic Health Records

At the core of telemedicine is the electronic health record (EHR) which provides a consistent view of a patient's records. Many developing countries are taking the first step of implementing EHRs as a first step to eHealth, including telemedicine.

Appendix B: Glossary

B.1 Definitions

A number of key notions and terms are frequently referred to in this document. To avoid any ambiguity, the following definitions apply to these notions and terms and should also be used by the stakeholders engaged in telemedicine.

Anonymization	The process used to strip personal data from all elements likely to help identify directly or indirectly the data subject (e.g., name, age, address, social security number, etc.). These elements are deleted to ensure re-identification is impossible.
Authentication	Confirmation of the identity of a user requesting access to services and/or patient data.
Authorization	Refers to: • The permission of an authenticated (e.g., a person) to perform a defined action or to access a defined resource/service, or • The process of determining, by evaluation of applicable permissions, whether an authenticated entity is allowed to perform a defined action or has access to a defined resource.
Cloud Computing	Internet-based computing, where shared servers provide computing power, storage, development platforms or software to computers and other devices on demand. There are several possible deployment models for clouds, the most important being: • Public Cloud - a service provider makes resources, such as applications and storage, available to the general public over the Internet, for maximum cost-efficiency, resilience and elasticity. • Private Cloud - the infrastructure is operated solely for a single organization. The resources have all the key characteristics of the public cloud (see above) but are dedicated to a single organization, giving it more control over security and access, and the ability to tailor/customize characteristics offered by a public cloud. • Hybrid Cloud - the infrastructure combines the approaches of a Public Cloud with that of a Private Cloud. Generally, sensitive applications and data are in a Private Cloud and more generic systems and processes are in a Public Cloud.
Data Authentication	Information provided for verification, with more or lesser degrees of certainty, of the origin and the integrity of data.
Data Controller[27]	The natural or legal person, public authority, agency or any other body which alone or jointly with others determines the purposes and means of the processing of personal data; where the purposes and means of processing are determined by national or Community laws or regulations, the controller or the specific criteria for his nomination may be designated by national Community law.
Data Processor[28]	A natural or legal person, public authority, agency or any other body, which processes personal data on behalf of the Data Controller.

[27] http://ec.europa.eu/justice/data-protection/document/review 2012/com_2012_en.pdf
[28] http://ec.europa.eu/justice/data-protection/document/review 2012/com_2012_en.pdf

Data Security	The protection of personal data from unauthorized or unintentional loss, theft, access, use, modification, or disclosure.
Doctor	Refers to a medical doctor and is in particular to a tile attributed to a physician.
eDispensation (Electronic Dispensation)	The act of electronically retrieving a prescription and dispensing medicine to the patient as indicated in the corresponding ePrescription. Once the medicine has been dispensed, the dispenser sends an electronic report on the medication dispensed.
eHealth	All aspects relating to the transformation of the health sector as a consequence of introducing digital information and communication technologies.
Electronic Health Record	A comprehensive medical record or similar documentation of the past and present physical and mental state of the health of an individual in electronic form.
Electronic Identity	Identity data (of a person) usable in electronic format.
Electronic Patient Record	A record in digital format containing medical information about a patient. Such records may include a broad range of data in comprehensive or summary form, including demographics, medical history, medication and allergies, immunization status, laboratory test results, radiology images, vital signs, personal statistics (e.g., age and weight), and billing information. The purpose of the EPR is to capture a complete record of patient encounters that allow the automation and streamlining of workflow in health care settings with the objective of increasing safety through evidence-based decision support, quality management, and outcomes reporting. Electronic Patient Records may also be referred to as: • Electronic Medical Record (EMR) • Patient summary • Personal health record • Computerised Patient Record (CPR)
Electronic Signature	Data in electronic form which are attached or logically associated with other electronic data and which serve as a method of data authentication.
Encryption	Process of encoding message or information in such a way that only authorized parties can read it. Encryption does not prevent hacking but it reduces the likelihood that the hacker will be able to read the data that is encrypted.
ePrescription (Electronic Prescription)	Electronic format of a medical prescription, as defined by Article 9(19) of Directive 2001/83/EC47, i.e., a medical set of data that generally includes the drug ID, drug name, strength, form, dosage and/or indication(s), is issued by a healthcare professional and transmitted electronically.
Healthcare	The prevention, treatment, and management of illness and the preservation of mental and physical well-being through the services offered by the medical, nursing, and allied health professions. Healthcare embraces all the goods and services designed for people's health, including preventive, curative and palliative interventions, whether directed to individuals or to populations.

Health Data[29]	Information relating to the health of an identified or identifiable natural person. It can include demographics (age, sex, date of birth, etc.), clinical information (blood type, medical history, allergies, medical images, laboratory results, diet), genetic information (genotype, family disease history), disease information (cancer, HIV-AIDS, Alzheimer, etc.), medical interventions (delivery, abortion, surgery interventions, long-term care information), etc.
Health professional	A doctor of medicine or a nurse responsible for general care or a dental practitioner or a midwife or a pharmacist within the meaning of Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications 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.
Identification	Performance of tests to enable a data processing system to recognize entities and individuals.
Identifier	An attribute or set of attributes of an entity (e.g., a person), which uniquely identifies the entity in a given context.
Identity Management	The broad administrative area that deals with identifying entities in a system (such as a country, a network, or an enterprise) and controlling their access to resources within that system by associating user rights and restrictions with the established identity.
Imaging Network	An ecosystem of connected care providers, allowing the seamless exchange of medical imaging and documents and related clinical data.
Information Systems (IS)	Any combination of information technology and a person's activities using that technology to support operations, management and decision-making. The term information system is frequently used to refer to the interaction between people, algorithmic processes, data and technology. In this sense, the term is used to refer not only to the information and communication technology (ICT) an organization uses, but also to the way in which people interact with it.
Infostructure	Infostructure refers to the information applications and processes that are required for an information-dependent organization or function. eHealth Infostructure refers to the foundation layer containing the data structures, codifications, terminologies and ontologies, data interoperability and accessibility standards, stored information and data, as well as rules and agreements for the collection and management of these data and the tools for their exploitation.
Interoperability	The ability of two or more eHealth systems to use and exchange both computer interpretable data and human understandable information and knowledge. There are three levels of Interoperability: 1. Organisational interoperability - the broader environment of laws, policies, procedures and bilateral cooperation needed to allow the seamless exchange of information between different organisations, regions and countries. 2. Semantic interoperability - the ability to ensure that the precise meaning of exchanged information is interpretable by any other system or application not initially developed for this purpose. 3. Technical interoperability - the ability of two or more ICT applications, to accept data from each other and perform a given task in an appropriate and satisfactory manner without the need for extra operator intervention.

[29] http://ec.europa.eu/justice/data-protection/document/review2012/com_2012_11_en.pdf

mHealth - Mobile Health	Mobile Health, or mHealth, is the provision of eHealth services and information that relies on mobile and wireless technologies. Similarly to eHealth, of which it is a part, mHealth describes a broad set of technologies that can support a variety of health-related services, and is not a separate category of services in itself. Mobile technologies are utilised across the range of healthcare, social care, wellness and prevention and form an integral part of telemedicine, telehealth and telecare.
Patient	Patient refers to any natural person who receives or wishes to receive healthcare in a Member State.
Patient Centred Care	Patient Centred Care refers to health care that establishes a partnership among practitioners, patients, and their families (when appropriate) to ensure that decisions respect patients' wants, needs, and preferences and that patients have the education and support they need to make decisions and participate in their own care.
Patient Registry	Patient Registries are collections of secondary data related to patients with a specific diagnosis, condition, or procedure. In its most simple form, a disease registry could consist of a collection of paper cards kept inside a box by an individual doctor. Most frequently, registries vary in sophistication from simple spread sheets accessed by a small group of doctors to very complex databases with online access across multiple institutions. They can give healthcare providers (and / or patients) reminders, e.g., to check certain tests in order to reach certain quality goals. Patient registries are less complex and simpler to set up than Electronic Medical Records (EMR) / Electronic Patient Records (EPR). An EMR / EPR keeps track of all patients a doctor follows while a registry only keeps track of a small sub-population of patients with a specific condition.
Patient Self-Management	Patient Self-Management is the systematic provision of education and supportive interventions by healthcare staff to increase patients' skills and confidence in managing their health problems including regular assessment of progress and problems, goal setting, and problem-solving support. Self-management support programs may be able to help patients with condition such as asthma, cardiovascular disease, depression, diabetes, heart failure, migraine headaches, etc. (Pearson et al, 2007). Self-management programmes may also support patients' management of other health related activities that may not be specific to a given condition, such as medication management or prevention and wellness.
Patient Summary[30]	A subset of an electronic health record that contains information for a particular application and particular purpose of use, both for unexpected, as well as expected, healthcare contact.
Personal Data[31]	Information relating to an identified natural person ("Data subject"); an identifiable person is one who can be identified, directly or indirectly; in particular by reference to an identification number or to one or more factors specific to their physical, physiological, mental, economic, cultural or social identify.
Privacy[32]	The generic interest a patient has in being able to control who has access to his or her information, and keep his/her information away from public view.

[30] http://www.epsos.eu/faq-glossary/glossary.html?tx_a21glossary%5Buid%5D=542&tx_a21glossary%5Bback%5D=5&cHash=d5b49de1d6 http://www.epsos.eu/faq-glossary/glossary.html?tx_a21glossary%5Buid%5D=542&tx_a21glossary%5Bback%5D=5&cHash=d5b49de1d6

[31] http://ec.europa.eu/justice/data-protection/document/review2012/com_2012_11_en.pdf http://ec.europa.eu/justice/data-protection/document/review2012/com_2012_11_en.pd f

[32] WHO - Global Observatory for eHealth - Volume 5 - legal frameworks for eHealth – 2012

Personal Health Record	A health record that is initiated and maintained by an individual. Other health records such as Electronic Patient Record or Electronic Medical Record are generated and maintained within an institution, e.g., a hospital, clinic, or physician's office.
Personal Health Systems	Used to assist in the provision of continuous, quality controlled, and personalised health services, including diagnosis, treatment, rehabilitation, disease prevention and lifestyle management, to empowered individuals regardless of location. PHS consist of intelligent ambient and / or body devices (wearable, portable or implantable), intelligent processing of the acquired information and active feedback from health professionals or directly from the devices to the individuals.
Personalised Medicine	An evolution from today's medical model of standardised clinical pathways and drugs, towards an approach which recognises the differences between individuals in their health risks, and their responsiveness to treatments.
Physician	Refers to a healthcare professional authorised to perform medical acts.
Pseudonymisation	The process of disguising identities whose object is to be able to collect additional data relating to the same individual without having to know their identify. This is particularly relevant in the context of research and statistics. Disguising identities can also be done in a way that no re-identification is possible, e.g., by one-way cryptography, which creates anonymised data.
Profile	A selection of specifications and options from existing standards, combined to serve a specific use case. Profiling is conducted in order to achieve interoperability between different products and implementations.
Registration	A process in which a partial identity is assigned to an entity and the entity is granted a means by which it can be authenticated in the future.
Software As A Service (SAAS)	Software as a Service (SaaS), sometimes referred to as "software on demand" is software that is deployed over the internet and deployed to run behind a firewall on a local area network or personal computer. With SaaS, a provider licenses an application to customers either as a service on demand, through a subscription, in a "pay-as-you-go" model, or at no charge. This approach to application delivery is part of the utility computing model where all of the technology is in the "Cloud" accessed over the internet as a service.
Standard	An agreed, repeatable way of doing something. It is a published document that contains a technical specification or other precise criteria designed to be used consistently as a rule, guideline, or definition. Standards help to make life simpler and to increase the reliability and the effectiveness of many goods and services.
Structured Data	Data that is organised in such a way that the different attributes of the data, e.g., patient name, diagnosis and medication, are interpretable by an IT system.
Unstructured Data	Information that either does not have a pre-defined data model or is not organised in a pre-defined manner. Unstructured information is typically text-heavy, but may contain data such as dates, numbers, and facts as well. This results in irregularities and ambiguities that make it difficult to understand using traditional computer programmes as compared to data stored in fielded form in databases or annotated (semantically tagged) in documents.
Unique Identifier	In healthcare, a unique identifier is a unique number that has been assigned to a healthcare consumer (patient), to a healthcare provider and to an organisation that provides health services. The aim of unique identifiers is to ensure that individuals and providers can have confidence that the right health information is associated with the right individual.

Vital Sign Monitoring[33]	Vital signs are to be understood as a set of physiological indicators, which reflect the overall status of the body. With the help of technologies they can be checked regularly to assess body functions of an individual making it possible to remotely monitor the patient or user status, without the need of a caregiver to be present. The measurement and the resulting data are either collected discretely meaning at predetermined intervals called spot-checking or continuously. Originally automated vital signal monitoring was used in Intensive Care Units (ICUs), Cardiac Care Units (CCUs) and Operating Rooms (ORs). Today spot-checking certain parameters forms part of the procedures for most medical physical examinations. In addition, it can be used to determine training effects.

B.2 "Tele" Definitions

Tele-Assistance	Can be a medical act when a doctor remotely assists another doctor carrying out a medical or surgical act. The doctor can also assist another health professional who carries out an act of care or imaging, even within the framework of an emergency, to remotely assist a first aid worker or any person providing medical assistance to someone in danger while waiting for the arrival of a doctor.
Telecare	Term used to describe systems and services that are capable of social alert and social services. Often used to monitor the situation of people with a chronic illness and / or dependent on external help (i.e., elderly or disabled) in the home or assisted living settings.
Telecardiology	Remote collection of cardiology data, mostly ECG data, and their transmission to a service centre. In the centre, the data are evaluated by qualified staff who give advice to a patient or another healthcare provider. In emergencies, the service centre may also trigger rescue measures. Data transmission can either take place continuously or at clearly defined points of time. Data collection can take place either at the patient's home or remotely.
Teleconsultation	General term for any virtual consultation between clinicians or between clinicians and patients. (i.e., on a network or video link, e.g., Facetime, intranet, Internet, Skype, etc.).
Teledermatology	Teledermatology describes the transmission of visible light images (photos or videos) of disorders of the human skin for classification and diagnosis. It can take the form of primary as well as secondary diagnosis. Detection and classification of skin cancers is a typical example. Since dermatology is a high-specialized discipline and many patients will see a general practitioner first, the use of teledermatology my shorten the diagnostic process and speed up the start of appropriate treatment.
Tele-Expertise	A virtual consultation between at least two healthcare professionals without the presence of the patient.

[33] Institute for Prospective Technological Studies -- Strategic Intelligence Monitor on personal health systems

Telehealth (includes Remote Patient Management or "RPMT")	Systems and services linking patients with care providers to assist in diagnosing and monitoring, as well as the management and empowerment of patients with long-term conditions (chronic patients). Telehealth solutions use devices (interactive audio, visual and data communication) to remotely collect and send data to a monitoring station for interpretation and to support therapy management programmes and improve patients' knowledge and behaviour. Telehealth solutions comprise systems and components (patient interfaces in hardware and software, sensors/peripherals, operating software and applications intended for care provider usage, clinical content and intelligence; data transmission, storage and intelligent routing) as well as supporting services (system operation, logistics, financial services, etc.).
Tele-Intervention	A therapeutic medical act which is performed remotely by a physician on a patient, without or with the local presence of other healthcare professional(s), e.g., telesurgery.
Telemedicine	The provision of healthcare services, through use of ICT, in situations where the health professional and the patient or two health professionals, are not in the same location. It is an overarching definition covering Telehealth, Telecare and other 'teledisciplines'. Telemedicine includes all areas where medical or social data is being sent/exchanged between at least two remote locations, including both care provider to patient/citizen as well as doctor-to-doctor communication. Telemedicine may include the exchange of patient data, including transfer of relevant data, outside of the country of origin.
Telemonitoring	The use of ICT to monitor patients at a distance. Some of the more promising applications for telemonitoring include on-going remote assessment by sensors attached to the patient of chronic illnesses such as cardiopulmonary disease, asthma, and hear failure in the home. Foetal heart rate monitoring and infant cardiopulmonary functions are also being monitored at a distance, as well as coagulation, or the level of activity of the elderly.
Tele-Ophthalmology	The remote diagnosis of medical conditions of the human eye. Similar to teledermatology, patients may not have immediate access to an opthalmologist and typically use photos or videos to exchange information.
Telepathology	Enables remote staff pathologists, and thir-party providers, to securely share images of anatomical pathology specimens to complete primary and non-primary diagnostic evaluation, and to also seek expert second opinions, and primary interpretations of urgent cases, from operating rooms.
Telepsychiatry	Form of teleconsultation between a psychiatrist and a patient suffering from a mental disorder.
Teleradiology	Information Systems that enable secure remote evaluation of digital diagnostic studies (CT scans, MRIs and X-Rays). This technology enables both remote staff radiologists and third-party providers to complete primary and non-primary diagnostic studies from any location. It encompasses hospital-to-home teleradiology for out-of-hours healthcare coverage, i.e., remote working for radiologists being part of the hospital radiology department. It also covers outsourcing to other imaging centres or commercial teleradiology companies that provide outsourcing services for image interpretation (night and/or day reads).
Telescreening	The use of a first or second opinion through a remote connection in screening programmes. Either medical data is transferred to a remote specialist for primary evaluation, e.g., in the case that a specific medical qualification is required. Another scenario involves a second opinion in order to increase the quality of the screening process. An example in the form of teleradiology would be the use of screening centres in mammography screening. The data transmitted during telescreening can take any form from digital X-Ray images to video files or ECG or laboratory data.

Telesurgery	The remote controlling of surgical apparatus, e.g., a surgical robot, by an experienced surgeon or the remote advice provided by an experienced surgeon on duty in the operating theatre. In the latter case, a live video connection and an audio connection between the two surgeons is sufficient. In the former case, a data link between the surgical apparatus on site and the remote manipulation tool is required.

B.3 Acronyms

CPR	Computerised Patient Record
EHR	Electronic Health Record
eID	Electronic Identity
eIDM	Electronic Identity Management
EMR	Electronic Medical Record
EPR	Electronic Patient Record
GP	General Practitioner
ICT	Information Communication and Technology
NHS	National Health Service
NHIF	National Health Insurance Fund
PHR	Personal Health Record
PHS	Personal Health System
PS	Patient Summary
RPMT	Remote Patient Monitoring
SaaS	Software as a Service
SHI	Statutory Health Insurance
VHI	Voluntary Health Insurance
TTP	Trusted Third Party

Appendix C: References and Bibliography

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