Widespread Deployment
of Telemedicine Services in Europe

Report of the eHealth Stakeholder Group on implementing the Digital Agenda for Europe
Key Action 13/2 'Telemedicine'

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0 Executive Summary and Recommendations

This report assesses the user and stakeholder dimension of telemedicine services in Europe. Led by Key Action 13/2 (aka Action 75) of the Digital Agenda for Europe, the paper provides first hand stakeholder insight on how to make real that telemedicine services are made available to all European citizens/patients - latest by 2020.

This report provides an overview of the drivers (the why), the definitions (the what) and the established practice of telemedicine services (the how), as well as lessons learned. Last but not least, the report articulates recommendations on the measures needed to achieve widespread deployment of telemedicine services.

Issued by the EU eHealth Stakeholder Group (eHSG) coordinated by DG CNECT, the report reflects the knowledge provided by a broad spectrum of healthcare actors/stakeholders who are also geographically spread across Europe. Written by experts in the field, the report does not provide a comprehensive summary of European Projects.

The objective of the report is to describe the state of play today, and provide guidance achieving the Digital Agenda Key Action 13/2, namely 'widespread deployment of telemedicine services by 2020'. The report addresses also cross-border services in light of Directive 2011/24/EU on the application of patients’ rights in cross-border healthcare. Given this framework, it aims to maintain a fair balance of local versus cross-border services.

The main lesson learned is the need to differentiate two types of telemedicine services. They need to be clearly differentiated since e.g. their legal and organisational contexts are quite diverse.

1) Medical Act type telemedicine services: These services imply that registered medical doctors performs an existing medical practice over a distance (using digital technologies), like remote reading of x-ray images, remote microscopy or remote assessment of skin images, and many more. These services are already widespread and few pending issues remain, mostly related to cross-border use cases.

2) Telemonitoring type services: These services provide multi-professional care teams with physiological parameters of the patient, with the support of remote monitoring technologies. Telemonitoring supports patients at home as well as mobile citizens/patients on the move, and facilitates self-management and patient empowerment. Telemonitoring is a disruptive innovation: it challenges health care organisation, professional roles and reimbursement rules. Hence, a well-coordinated process for managing innovations jointly with all healthcare actors is needed.
Taking into account the advanced deployment of many telemedicine services in Europe, the EU eHealth Stakeholder Group issues eleven recommendations to achieve the goal “telemedicine for all by 2020” in a meaningful way:

1. Patients should have equal access to telemedicine services as part of standard health and social care schemes - and not just case by case - if services are beneficial and cost-efficient.

2. Digital literacy and training in using eHealth tools should become part of the educational curricula of all Health Professionals while no extra qualifications for telemedicine needed.

3. Transparency on the identity of a health professional providing a service must be maintained also for remote medical services, allowing e.g. patient's look-up for licensing and certification.

4. Benefit and added value of telemedicine services should be systematically monitored and evaluated to allow for justified inclusion into guideline supported clinical practice.

5. All telemedicine services - and in particular those involving cross-border transfer of patient data - must safeguard valid data protection including a declaration of informed consent.

6. Health and social care services shall maintain a helping hand to their clients, i.e. telemedicine services shall not replace feasible/useful patient–health professional encounters.

7. Usability and acceptance for citizen/patient/health professional users of telemonitoring type services should be maintained by a user driven approach to design and deployment.

8. For quality and safety and to avoid duplication of efforts, telemedicine services should be connected/integrated into interoperable and secure Electronic Health Record systems.

9. Complex document workflows e.g. for telemonitoring type services should be designed with ongoing standardisation in mind, e.g. the IHE Cross-Enterprise Document Workflow profile.

10. To balance liability issues, particularly in the cross-border use case, providers of professional liability insurance should extend their incident definition and offer sufficient coverage.

11. Contracting between healthcare providers for telemedicine services should be supported by contract templates and checklists maintained e.g. by European Provider Associations.
1 Introduction

Telemedicine comprises a multitude of healthcare services targeted to diseases and conditions as well as personal health services in support of well-being and prevention. Furthermore, telemedicine is - like wider eHealth - a timely reflection of the ubiquitous digitalisation of all sectors of society.

Telestroke services can be used as a meaningful example of telemedicine services. By using methods of teleneurology and teleradiology, a patient suffering from acute vascular blockage (with the risk of an imminent full vascular stroke) may receive local treatment under remote supervision that prevents most or all of the stroke symptoms. Therefore, this telemedicine service contributes to making medical treatment faster and more efficient.

The rise of telemedicine services is a reflection of the ubiquitous digitalisation of all sectors of society as recognised by the Digital Agenda for Europe\(^1\). At the same time, telemedicine services respond to the growing health needs resulting from an epidemic rise of chronic conditions - also in younger age groups. It challenges the sparse work force resources available currently to health and social care. Moreover, telemedicine can also contribute to counter-balance the problems caused by inner-state migration towards metropolitan areas that decreases the population and causes demographic imbalances in rural areas, even being a part of overall densely populated and highly industrialised European Member States.

Objective of the report: The eHealth Stakeholder Group report on telemedicine contributes to fulfilling Key Action 13/2 of the Digital Agenda for Europe, i.e. the 'widespread deployment of telemedicine services'. This means making telemedicine services available for all European citizens by 2020 as part of an overarching agenda for the transformation towards digital healthcare. The digitalisation of healthcare and the provision of services from a distance are also key elements of cross-border care as addressed by the European Directive 2011/24/EU on the application of patients’ rights in cross-border healthcare\(^2\) that serves as the second framework of reference to this report.

Scope of the report: The report aims to maintain a fair balance between the domains of local healthcare versus cross-border care. Given the current state of telemedicine deployment, significant emphasis is placed on the national roll-out of telemedicine services towards the target of widespread availability of telemedicine services everywhere in Europe by 2020. This seems to be an adequate reflection of the fact that the vast majority of health care encounters happen in a local environment, without crossing national borders.

On the other hand, digitalisation of healthcare and provision of services from a distance are key enablers for cross-border care as addressed by the European Directive 2011/24/EU on the application of patients’ rights in cross-border healthcare. While the cross-border healthcare directive is also part of the eHealth Stakeholder group's mandate, the cross-border dimension is highlighted for some of the use cases for telemedicine services within the "observations and recommendations" section (5).

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2 Why: Drivers for telemedicine in European societies and their healthcare systems

The eHealth Stakeholder Group acknowledges that telemedicine key drivers have already been widely identified. They include:

- Relative rise in patients with (multiple) chronic conditions - also in younger age groups.
- Increasing size of the elderly population, combined with a relative decrease in resources paid by fewer taxpayers (healthcare expenditures growing faster than economies)
- Decreasing work force of health care professionals in European Member States.

Additional drivers are identified as:

- **Safeguarding basic healthcare provision** vis-à-vis scarceness of resources in industrialised societies. Response to megatrends like migration to metropoli- tan areas and demographics;
- **Quality** of healthcare provision, prevention and rehabilitation: Get in touch with competencies one would not have had a chance to get in touch with.
- **Increasing cost-efficiency** of medical service provision: Diagnosing from remote: saving travelling both by the physician and the patient; replacing emergency care by routine care;
- **Open possibilities** to better involve patients in their own care and monitoring of their condition, in particular chronic diseases
- **Diagnosis and therapy for rare diseases**: Telemedicine has extra benefits particularly for rare diseases - often also known as orphan disease. The quality of care can only be maintained by involving centres of excellence that provide not only second opinion, but are needed to establish the diagnosis and treatment.
- **Tele-Education / Outreach**, tele-universities, raising the quality of medical training; all health professions
- **Peer review between health professionals**, e.g. in radiology. It is quite common that nowadays two reports by two radiologists are requested even for standard radiological reports. In almost every Member state screening mammography requires two reports and in case of disagreement a third report. An example outside Europe are the United States with the programme "Rad-Peer" by the American college of Radiology.
- **Travelling patients**; mobile health; medical support for a mobile population

3 What (Definitions): Providing routine healthcare over a distance via ICT

The eHSG adopts the definition provided by the European Commission\(^2\), i.e. **Telemedicine** is defined as "the provision of healthcare services, through the use of ICT, ...

in situations where the health professional⁴ and the patient (or two health professionals) are not in the same location. It involves secure transmission of medical data and information, through text, sound, images or other forms needed for the prevention, diagnosis, treatment and follow-up of patients⁵. While Telemedicine encompasses a wide variety of services such as teleradiology, teleconsultation, telemonitoring, telesurgery and teledermatology, which can therefore be regarded as different forms or ways of delivering telemedicine" it is not a synonym of eHealth services per se⁶.

Within the domain of telemedicine services, two types of services need to be differentiated since the legal and organisational context surrounding them is quite different:

### 3.1 Medical Act type telemedicine services

Medical Acts are performed by a "registered medical doctor/physician or under his or her direct supervision and/or prescription"⁶. Medical Act type telemedicine services imply that what is normally performed by registered medical doctors/physicians is practiced over a distance with the support of information and communication technologies (e.g. teleradiology - remote assessment of x-ray images, telepathology - remote microscopy/assessment of specimen, teledermatology - remote assessment of skin images sent by patients or doctors, etc).

Medical act type telemedicine services are today an well established - bringing medical expertise to remote locations where care infrastructures and/or expertise are missing. Pending issues remain with regard to cross-border use cases, yet fewer issues - particularly for reimbursement and professional regulations - remain in the regional or national use cases. Medical act type telemedicine services are sometimes also described as B2B (Physician to Physician, medical hospital to medical hospital, etc.) services.

Another example of providing medical expertise remotely is the treatment of patients with rare diseases that send information to a single physician or a specialised multi-professional and multidisciplinary centre who/which will provide care.

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⁴ The health care professional is here defined as in Article 3f) of Directive 2011/24/EU on the application of patients’ rights in cross-border healthcare: "means a doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist within the meaning of Directive 2005/36/EC, or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC, or a person considered to be a health professional according to the legislation of the Member State of treatment".

⁵ Health information portals, online pharmacy, electronic health record systems, electronic transmission of prescriptions or referrals (e-prescription, e-referrals) are not regarded as telemedicine services for the purpose of this Staff Working Paper. E-prescription is excluded as it is an ancillary and independent act, which can also be delivered in a face-to-face meeting with a doctor". cf. Commission Staff Working Document on the applicability of the existing EU legal framework to telemedicine services - SWD (2012) 414 final.

⁶ "The medical act encompasses all the professional actions, e.g. scientific, teaching, training and educational, organisational, clinical and medico-technical steps, performed to promote health and functioning, prevent diseases, provide diagnostic or therapeutic and rehabilitative care to patients, individuals, groups or communities in the framework of the respect of ethical and deontological values. It is the responsibility of, and must always be performed by a registered medical doctor/physician or under his or her direct supervision and/or prescription." (Definition adopted and updated by the UEMS Council, this latest version as of 25 April 2009, cf. http://www.uems-ophtalmologie.org/uems_documentation_doc_9i_definition_medical_act.php).


3.2 Telemonitoring services

Telemonitoring type services are utilised in the context of the provision of medical care\(^7\) and provide health professionals\(^8\) with physiological parameters of the patient / citizen through the use of information and communication technologies (ICTs). Telemonitoring presents various benefits: it can improve the quality of life of chronically ill patients through self-management solutions; reducing hospitalisation costs; and saving on unnecessary emergency visits\(^9\).

Telemonitoring represents an innovative type of healthcare or personal service. It implies the involvement of multi-professional care teams, where the citizen/patient should also be seen as a member of the team. Telemonitoring raises the frequency of communication and interactions between a patient/citizen and his/her treating health professionals and as such enhances the continuity of care (as well as prevention and rehabilitation) for people with chronic conditions. Telemonitoring type services therefore represent a disruptive innovation in health care.

Telemonitoring services – as opposed to medical act type services – usually do not involve physicians in the first line of the services provision. Rather, many telemonitoring services are primarily managed by the nursing profession (cf. telemonitoring for COPD patients provided at the Odense University Hospital, Region of South-Denmark). Physicians are involved when vital signs indicate a deterioration of the patient’s condition. In this case it becomes a Medical Act.

Telemonitoring services are enabled by both fixed or mobile technologies in combination with sensor devices. In the case of mobile solutions, smartphones are increasingly used as local service platforms. The technology has emerged over the recent years and significantly contributes to the disruptive innovation of the provision of healthcare.

Furthermore, telemonitoring services involve the management of alarms and comprise rules-based surveillance schemes.Automated filtering of the primary data by computational algorithms may avoid false alarms and sensory overload of the health professionals in charge.

Telemonitoring improves the quality of medical care provided to chronically ill patients and reduces the frequency and the duration of hospital stays.

Telehealth is a further ‘extension’ of telemedicine. In addition to the remote monitoring of vital signs, it includes an educational component to empower the patient and encourages behavioural change.

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\(^7\) cf. Commission Staff Working Document on the applicability of the existing EU legal framework to telemedicine services - SWD (2012) 414 final

\(^8\) The health care professional is here defined as in Article 3f) of Directive 2011/24/EU on the application of patients’ rights in cross-border healthcare: “means a doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist within the meaning of Directive 2005/36/EC, or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC, or a person considered to be a health professional according to the legislation of the Member State of treatment” (adopted from SWD (2012) 414 final).

\(^9\) cf. Commission Staff Working Document on the applicability of the existing EU legal framework to telemedicine services - SWD (2012) 414 final
4 How do exemplary telemedicine services support remote healthcare in practice

- Medical Act type telemedicine services like teleradiology and telepathology extend Medical Acts over a distance. They can be understood as a straightforward adoption of the digital transformation of society as applied to the working methods of physicians for the 21st century.
- B2C Telemedicine services like telemonitoring support citizens' and patients' health and well being in the home and on the move. They provide some type of surveillance, advice and health coaching supported by ICT-mediated feedback on physiological parameters. The telemonitoring type of services extend the choices for citizens and patients, provides better services at home and enable a virtual healthcare continuum.

4.1 Extending Medical Acts over a distance: physicians' workflows spanning across institutional and national/regional boundaries

These services are characterised by asynchronous work flows spanning across organisations, such as

- Radiology: Image assessment by external experts
- Pathology: Specimen assessment by external experts
- Dermatology: Photo assessment by external experts

The service coordination between care providers must be established:

- Multidisciplinary Team Sessions
- e.g. Joint Telestroke assessments

They offer particular opportunities for quality assurance and peer review

- 'Distributed four eyes’ principle e.g. for mammography
- Second Opinion & consultation services for Rare diseases

The medical act type of practices have a straightforward cross-border dimension, particularly when they are based on imaging data which can be analysed when sufficient information on the patient history is provided to allow meaningful assessments.

- The intra-national (or regional) use cases currently mainly rely on national/regional legislation and reimbursement rules for the services of physicians or medical institutions. European wide regulations may apply both for patient safety and the need for technical and semantic interoperability.
- The medical act type of telemedicine services (teleradiology, telepathology, teledermatology etc.) are established in most or all Member States. Variation exists how these physician activities are authorised by governmental and professional regulations and whether they are reimbursed as element of the standard reimbursement procedures or as a separate service).
- An extra qualification for telemedicine practice is legally not needed. For cross-border use cases the health professionals must of course be equally qualified as they have to be in their home country.
4.2 Support for health and well being in the home and on the move: the Tele-monitoring family of services

Telemonitoring services extend choices for citizens and patients and enable a care continuum as well as better services at home. They are driven by health professionals and also contribute to empower citizen and patients to take an active role in managing their condition. In particular they allow patients to stay out of institutions, i.e. to prevent and reduce length of hospital stays; to establish nurses and other health professions as coach of the patient and to provide a new role for physicians as second line support in multiprofessional service environments - often coordinated by nursing professionals.

Telemonitoring can support enabling life-long Citizen involvement in their health

- Information platforms provide healthy life style information
- Health-Apps provide support for healthy life style – e.g. healthy food or physical activity
- Health-Games promote health behaviour in an entertaining manner

Empowering citizens and patients for prevention of risks and early assessment and treatment of medical conditions means that citizens at (health) risk get better information and support with the aim to stay healthy and independent as long as possible (education component). This implies raising the health literacy of the patient - a significant enabler for patient empowerment - and also targeted encouragement for preventive behavioural changes. In addition, patients are empowered to keep responsibility and control when a (chronic) condition has become manifest and needs medical treatment, as it is implied by the concept of a Digital Health Continuum.

Some pending issues on the telemonitoring type of services:

- **Evidence for telemonitoring services:** There is still a need to provide conclusive evidence on the clinical and socio-economic benefits of telemedicine services. In particular on what has proved to work in practice; on services that have been proven to be efficient for a particular group of citizens or patients. Good sources of results and evidence are the "Whole System Demonstrators" in the UK and the largest coordinated clinical trial in the world, the EU cofunded RENEWING HeALTH project which has included more than 7000 patients. Yet, one should not expect too simple answers to the complex demands of modern healthcare. Benefits demonstrated include reduction of hospital admissions, reduced length of stay for those who require admission and also reduction mortality. But depending from the condition under observation and the study design, other published clinical results were discouraging.

- **Assess better organisational dimension and Healthcare Management Perspective:** Successful telemedicine pilot projects and lessons learned from existing large scale deployments indicate that telemonitoring services can lead to better, safer and more efficient care. However integrating telemedicine in routine clinical care remains an issue and requires a re-organisation of health care systems.

- **Involvement of Hospitals in telemonitoring services:** Many hospitals in Europe are already involved in telemonitoring services as part of their role in integrated care. A survey ran by the Institute for Prospective technological Studies (IPTS) issued in 2011 reveals that only 8% of hospitals offer telemonitoring services to discharged patients. Developing this offer would require
would require reviewing the business model, including pricing, reimbursement and contractual arrangements between care providers and payers.

5 eHSG Stakeholders' observations and recommendations for telemedicine services

This section provides an overview on issues for enabling the deployment of telemedicine services to all European citizens/patients - latest by 2020. To avoid duplication, the eleven key recommendations are listed as part of the Executive Summary.

5.1 Observations and recommendations for data protection, patients rights and universal access

- **Data Protection:** The planned European Regulation foresees e.g. a right to be forgotten for the patients and most particularly a right on data portability at the patients' request. Currently, the data protection is implemented differently in the Member States.

- The current legal framework for the protection of personal data in Europe\(^\text{10}\) limits the possibilities for data sharing across borders and organisations, which might be a barrier to the provision of cross-border telemedicine services. In addition the current legal framework for the protection of personal data in Europe limits access to health data to health professionals who are bound by a professional obligation to secrecy. This limits access to health data by technical staff who may e.g. intervene for maintenance purposes. Hence it is recommended that:
  - The collection, storage, processing and sharing of health data should be allowed and supported by the data protection legal framework, with a simple and workable patient consent procedure.
  - Limited access to patient data by non-health professionals should be allowed for the delivery of telemedicine services, provided these professionals have signed a commitment to confidentiality by contract, and have been trained to the sensitivity of health data.

- **Informed consent** The basis for telemedicine services should be a valid declaration of informed consent by the patient; particularly on the cross border transfer of patient data if this applicable for the service; in addition clear rules and transparent processes are needed to define who has access to what data under what circumstances.

- **Universal and equal access:** Since most citizens/patients can only afford healthcare that is provided as part of the respective tax financed or Statutory Health insurance based system, the "ad hoc" situation on the reimbursement contract hampers universal access to telemedicine services. Access to telemedicine may be dependent on private out of pocket payments or a change of health care providing organisation if this is feasible at all. Therefore Telemedicine services should be integrated into routine care delivery structures, in order to benefit the whole population.

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\(^{10}\) 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

5.2 Observations and recommendations on the acceptance of telemedicine services

As summarised by the "Chain of Trust" project (co-ordinator EPF), many elements shape the user acceptance of telemedicine. To safeguard acceptance, these elements should be addressed:

- To accept telehealth, patients and health professionals want it to be user-centric as opposed to technology-driven;
- Telehealth should not negatively affect the patient–health professional relationship, but rather aim to increase mutual trust;
- Telehealth needs to deliver real benefits and add value to users in relation to solely conventional healthcare;
- Health professionals and patients will accept telehealth services only as long as they have at least the same safety and reliability standard as conventional health services;
- Self-confidence and competence in using telehealth services and mutual confidence between users are crucial and should not be underestimated;
- More conclusive evidence is needed to transform care over a distance into a standard component of guideline supported clinical practice, endorsed by the acceptance of all health professionals;
- Also health politicians and health care organisations are in need of more and adequate evidence: Emphasis should be on research that results in evidence for the guidance of routine care. Such research should be performed preferably in real life care settings (incl. the shortcomings of standard ambulatory care). Research should not be limited to academic clinical settings where diagnosis and therapy for both the control and the intervention group may be so comprehensive that the impact of telemedicine may be too small to be measureable.

5.3 Observations and recommendations on liability, professional registration and quality: focus on cross-border use cases

Legal grounds for cross-border telemedicine services are notably the Cross-Border Healthcare Directive (2011/24/EU) and the eCommerce Directive (2000/31/EC).

- Liability issues remain complex particularly in the cross-border use case while a multitude of rules and regulations is applicable\(^\text{11}\). E.g. different rules apply for services that are provided physician to consumer as compared to services provided physician to physician; again the liability implications differ when the telemedicine service is part of the publically provided healthcare. Since some issues for cross-border scenarios remain up to now unsolved, health care providers face a higher risk for mitigation than in the standard (intra-national) use case.

As a consequence, professional liability insurance needs to extend their incident definition. Yet contracting (cf. 5.4) can address the majority of liability issues.

\(^{11}\) For more details, see European Commission Staff Working Document on the applicability of the existing EU legal framework to telemedicine services
Health Professionals do legally not need an extra qualification for telemedicine practice. Accordingly, digital literacy and technical training in order to ensure that eHealth tools, especially telemedicine can be used, should become part of the standard educational curricula for health professionals. For cross-border use cases the health professionals must of course be equally qualified as they have to be in their home country.

Professional Registration: Some open issues remain about the requirements for Professional Registration in the case of a cross-border service: The Commission Staff Working Document on the applicability of the existing EU legal framework to telemedicine services\(^\text{12}\) clarifies that - as defined by the eCommerce Directive (2000/31/EC) and the Cross-Border Healthcare Directive (2011/24/EU) - a healthcare professional offering telemedicine needs only to be registered in the country where he/she is physically established. Yet it is currently not clear whether e.g. a physician must be registered first for traditional i.e. "brick and mortar" healthcare practice to be then allowed to practice telemedicine. This is implicitly recommended in France, for instance, because - according to the telemedicine decree of 19 October 2010 - a foregoing face to face contact between the physician and the patient is recommended for all telemedicine use cases. Since this is not mandatory, flexible practice may evolve over time.

Quality assurance: The full flexibility for sending digital data around the globe makes it necessary to have complete transparency as to whom has provided e.g. an X-ray report, so that a company registered in a Member State does e.g. not in its turn have doctors, or other personnel stationed even outside EU, that would prepare the reports that would then be signed by a physician registered in a Member State).

5.4 Observations and recommendations for the organisation and financing of telemedicine services:

- Contracts in support of telemedicine services: There should be guidance on what has to be regulated in contracts between healthcare providers, e.g. between hospitals. Regulation are needed on the documentation duties (where are reports to be sent to, in what language, who has prepared and finally taken responsibility for the quality etc.), on the approach to data protection and informed consent etc.)
  - Standard form contracts and checklists would be a useful asset;
  - Insurance issues for the cross-border use cases should be part of the contracts.
  - Contracting in the cross-border use case should include language issues; e.g. in which language a physicians report has to be provided (at the same time one could imagine that professional registration may include the subject of language testing in the future).

- Reimbursement: As also outlined in the Commission Staff Working Document on the applicability of the existing EU legal framework to telemedicine services\(^\text{12}\)

\(^\text{12}\) Commission Staff Working Document on the applicability of the existing EU legal framework to telemedicine services - SWD (2012) 414 final - Accompanying the document "Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Region-eHealth Action Plan 2012-2020 – innovative healthcare for the 21st century"
the reimbursement of a telemedicine act is up to the Member States. In a cross-border situation the telemedicine act will be reimbursed up to the level of reimbursement applicable for the same treatment in their country so long as this telemedicine act is reimbursable in the country of the patient.

- Within Member States, reimbursement is currently often decided on a case by case basis. Hence whether a patient receives telemedicine services as part of standard healthcare regimes (i.e. not privately paid) may be subject to where he lives, how the healthcare is organised and what is the health care payer involved.

**In order to improve access to telemedicine services, these should be funded by social security systems, as conventional consultations or medical acts.**

5.5 Observations and recommendations on workflows, integrated care pathways, process organisation and quality assurance

IHE (Integrating the Healthcare Enterprise - an international standards profiling organisation) has already worked on standard workflows and on cross-enterprise data exchange in the field of telemedicine:

- Telemedicine related work is being done in the framework of the Cross-Enterprise Document Workflow (XDW) profile. The XDW profile enables participants in a multi-organisational environment to manage and track the steps related to patient-centric workflows as they coordinate their activities.

- One example relevant to this subgroup is the Cross Enterprise TeleHomeMonitoring Workflow Definition Profile (XTHM-WD), developed by a team from Veneto Region.

5.6 Observations and recommendations for eHealth infrastructure integration, semantic and technical interoperability and certification

- **Integration to Electronic Health Record systems** is often not achieved - telemedicine is provided via systems not connected to an interoperable eHealth infrastructure.

- **Standards and interoperability for telemedicine:** Telemedicine applications should be able to use existing infrastructures for messaging and electronic health records to safeguard seamless information flows, security and privacy protection.

Enablers for the B2B services i.e. medical acts are e.g.

- A national infrastructure with electronic health care records is seen as an enabler.

- Standardisation and interoperability, both on device communication and EHR level.
6 Annex 1 - Use Cases in European Member States

To demonstrate the current use of telemedicine, five exemplar services have been chosen that are already established beyond pilot stage at least in some of the Member States and represent different types of interaction modes (physician to physician or physician to patient/consumer).

- Teleradiology, i.e. remote assessment of x-ray images including peer review.
- Teledermatology services providing advice and second opinion both to physicians and directly to citizens/patients provide (based on images of their skin problems.
- Telestroke services (Teleneurology) that enable early treatment of stroke (thrombolysis)
- Telemonitoring for Diabetes (with coaching support) improving life style and conditions.
- Telemonitoring for Chronic Heart Failure as a prototype for intensified care for patients

6.1 Teleradiology

_Teleradiology is a medical act, i.e. established as a practice of medical doctors with a focus on the remote assessment of x-ray images. Teleradiology also includes peer review between health professionals, e.g. as a precondition for radiology reports in most Scandinavian countries or for screening mammography in many countries._

Teleradiology has reached the status of routine use already well ahead of other fields of telemedicine. Recent figures are provided by the European Society for Radiology (ESR) in a study published recently in Insight Imaging with the objectives to maintain an overview of teleradiology usage within Europe, to evaluate the current opinion and future vision about this technique and using a web-based survey targeted at active radiologists throughout Europe.

_Results:_ A total of 368 radiology professionals participated in the survey: radiologists (71 %), residents (14 %) and radiology managers (6 %). The participants represented 35 European countries, the largest groups were from Austria (22 %) and Belgium (22 %) followed by the UK (7 %), Netherlands (6 %), Germany (5 %), Italy (4 %), Estonia (4 %), Spain (4 %), France (3 %), Greece (3 %) and Sweden (3 %). The locations of the main professional activities of the respondents are: public or private hospitals (55 %), university hospitals (36 %), or a private practice or private medical centre (24 %). All the respondents work within a group of radiologists: the majority in a small groups of 2–10 (41 %); others in larger groups between 10 and 20 (22 %) or over 20 (30 %).

65 % currently use teleradiology. The main usages are in-house image distribution (71 %) and on-call readings from home (44 %). The major advantages are improved collaboration with other radiologists (46 %) and efficient distribution of workload (38 %). Outsourcing is performed by 35 % of the participants, among them 68 % use commercial services.

The major advantages of outsourcing are availability of second opinions (82 %) and additional capacity for on-call services (71 %). The major disadvantages are insufficient integration of patient history and priors (69 %), and limited communication with clinicians (68 %). The majority expressed a positive opinion regarding the future of teleradiology
(80%) predicting a growing importance (46%). Opportunities ought to be found in emergency reading services, flexible support of small practices and in collaborative platforms.

Several respondents are providers of teleradiology services, whether on a non-commercial (32%) or commercial (26%) basis. These services consist mostly of primary (77%) and subspecialty readings (51%). The examinations are sent from other hospitals within the same country (87%), most often associated hospitals or hospitals within the same region.

The authors conclude: A wide usage of teleradiology throughout Europe is perceived; however usage of commercial services is relatively limited. Regarding cross-border services, there is a great demand for a focused Pan-European legislation, an adapted price regulation and a quality assurance framework.

Main Messages

- A wide variety of teleradiology applications exist in Europe
- Implementation mainly occurs in countries with a high concentration of networked PACS
- Usage of commercial teleradiology services in Europe is relatively limited
- Language is an unsolved issue and limiting factor for further deployment of services
- There is a demand for a Pan-European legislation, price regulation and quality assurance framework

6.2 Teledermatology services

Teledermatology comprises a variety of services, some similar to teleradiology (medical acts for remotely assessing pictures or specimen provided by fellow colleagues), some as business to consumer services where citizens/patients provide images of their skin problems and get advice by a health professional.

Teledermatology services use case Scotland: Currently there is a mismatch of the number of referrals to secondary (skin) care with the capacities that the dermatologists in Scotland can offer. Teledermatology is already used – but not yet fully systematically to alleviate this bottleneck. The common principle is to provide images of the skin lesions to the specialists (secondary care). Those images are sometimes taken in the GP practice, by patients themselves or – in higher quality by sending patients to three hospital sites that provide the service to produce high quality photos which are then used for diagnosis or triage. Triage means that the specialists can prioritise those patients (e.g. with lesions suspicious for melanoma) for physical appointments that are most likely to benefit most of it. In NHS Lothian, an email service with image transfer saves 50% of referrals to secondary care.

Still, for the time being, Teledermatology in Scotland relies much on a limited number of enthusiasts and is not yet systematically organised on a National level. Thus the physicians involved in the service call for a more systematic and nationwide approach, based on practice standards for dermatology. Furthermore, a better dialogue and a learning process between GPs and secondary care could lead to a better overall quality of the assessments by the GPs thus reducing the need for the consultation of expert dermatologists. Currently the gatekeeping could be improved: Out of 100 suspected melanomas
only 2 % have been confirmed. Plus there are of course good and bad performers as in all businesses. Scotland also wants to share practices with colleagues in Europe. The discussion reveals that the role of GPs in the system may need further consideration: If GPs would make no contribution to the diagnostic quality one could even think of bypassing them completely. This is what often happens in other European countries without an effective gate keeping system: Most patients would consult a dermatologist directly.

Still another approach is reported from Switzerland where patients send in their pictures themselves. Lessons learned there indicate that 80 % of the patients and the lesions the pictures taken by the patients themselves are good enough.

6.3 Telestroke (Teleneurology)

Telestroke networks enable early treatment of stroke and even reverting the symptoms in the larger group of patients that suffers from obstructed blood vessels as cause of the stroke symptoms. Early thrombolysis can partially or fully revert the obstruction and thus improve the symptoms and prognosis of stroke patients. The remote consultation comprises assessment of x-ray images, e.g. from Computed tomography (CT) and a remote neurological consultation with the patient. This allows to perform early thrombolysis also outside of highly specialised hospitals. Teleneurology is also a (complex) medical act.

6.3.1 Telestroke use case in Catalonia (Telectus)

The telestroke network is a Catalan national wide programme and a telemedicine service with the goal of facilitating a specialised / tertiary attention to stroke patients, during the first hours of the acute phase. Stroke is the second cause of death worldwide and the main cause of disability in industrialized countries. For patient’s survival, one of the most determining factors is response time. By deploying the TELESTROKE Network (since 2006) the goal is to reduce response time in stroke diagnoses in Catalonia, and therefore also the consequences of these strokes.

The key element is to enable an expert neurologists specialised in Stroke on duty located in a Reference Hospital to diagnose a stroke right when it arrives at the emergency room of a Local or Regional Hospital. Specialists via videoconference provide support to all professionals in the emergency service of the hospitals.

The Telestroke Network is organised around 10 health regions with 8 hospitals. There is a STROKE lead at each hospital and a Stroke Committee in each region.

The local hospitals involved in the service must be reachable in less than 40km, reachable in less than 1 hour and having more than ten thrombolysis treatments per year.

The average cases served per telemedicine per year are 100 cases.

During 2013 the Telestroke services have been extended with mobile neurologists accessible by GSM so that specialist will be reachable in larger extent and the potential will cover 1000 stroke cases.

6.3.2 Telestroke in Scotland

Stroke is the third most common cause of death in Scotland and the most common cause of severe physical disability amongst adults. Every day in Scotland it is estimated 35 people have a stroke, totalling 12,657 people every year. Hospital care for people who
have had a stroke accounts for 7% of all NHS beds and 5% of the entire NHS budget. Against this background the Scottish Government has identified stroke as an NHS clinical priority.

The rationale for early treatment of stroke is the fact that the larger group of patients suffers from obstructed blood vessels as cause of the stroke symptoms. Early thrombolysis can partially or fully revert the obstruction and thus the symptoms and the prognosis of stroke patients are improved. For Scotland there is a potential to save 140 patients per 1000 strokes from death and physical dependency or 12 patients from death per 1000 strokes. The Scottish Government recommended that a **National Telestroke Service**, providing access to acute stroke thrombolysis (clot busting) for the areas unable to provide 24/7 stroke thrombolysis, was delivered by 2012. By May 2012 it is expected that all relevant sites will be fully operational.

Computed tomography (CT) modalities were already linked across all Scotland. CTs for stroke patients are judged by neurologists and not by radiologists. Liability of remote diagnoses has not the same importance than in some other European countries since all responsibility is shared across the NHS, there are no individual responsibilities like elsewhere.

There are now five acute telestroke networks across Scotland. The five networks cover 11 health boards; the telestroke update page provides the latest information on these. Most are now routine services. The stroke managed clinical network is strong in Scotland. Working with the network allows identification of other areas where telehealth can improve service or enable services to be provided. The network also provides access to a spectrum of relevant stakeholders. This is particularly relevant in stroke rehabilitation and there are now several services and feasibility trials ongoing throughout Scotland, these can be found on the Telestroke Rehabilitation page.

Thrombolysis rates were quite low before the telestroke network started. Lysis was only performed in 3 to 4 highly specialised centres. Nowadays the thrombolysis rate is the third highest in Europe.

Audit Scotland has summarised the benefits of telehealth for patients, staff and NHS boards:

- **Before telehealth:** In NHS Borders, Fife, Forth Valley and Dumfries and Galloway, patients who suffered a stroke were only offered thrombolysis if they could reach a hospital with the appropriate scanning equipment, be seen by a stroke consultant on-site, and receive thrombolysis within 4.5 hours, in line with best practice guidance.

- **Using telehealth:** Patients suffering a stroke are taken to the nearest hospital with scanning equipment. An on-call stroke consultant based in NHS Lothian assesses the brain scan image electronically from their office or home, consults with the patient via video-conferencing, and then decides whether thrombolysis should be offered. Thrombolysis is then given to the patient by staff locally within 4.5 hours.

- **Potential benefits of telehealth**
  - Thrombolysis may reduce a patient’s length of stay in hospital and reduce the need for stroke rehabilitation services, improving the outcome for the patient and potentially reducing costs for the NHS board.
• Patients receive a treatment they may not have previously been offered

Another crucial element of the early therapy for stroke patients is the overall response time, i.e. the time from symptom onset to qualified diagnoses and therapy. Analyses of earlier processes within NHS and NHS 24 have demonstrated room for improvement concerning this span. As a consequence all patients with suspected severe stroke are immediately referred to the "999" Scottish Ambulance Service (SAS) and transported to the nearest qualified hospital. The direct referral to SAS instead of the usual consultation process saves an average of 3 quarters of an hour, i.e. the CT scan starts already 1.75 hrs after symptom onset compared two 2.5 hrs. Given that evidence exists that thrombolysis - allowed up to 4.5 hrs after the onset - has a much better prognosis in the first than in the second half of this time window, that improves dramatically the prognosis.

6.4 Telemonitoring for Diabetes (with coaching support)

Telemonitoring for Diabetes represents a new service type that is directly (remotely) offered to patients.

6.4.1 [Finland] Personal eHealth service offered in the region of South Karelia

The personal eHealth service offered in the region of South Karelia, Finland aims for the improvement of the health situation of chronically ill patients that suffer either from diabetes or heart failure. The personal role of the patient for the improvement of his own health status is encouraged and supported by a dedicated health coach. The South Karelian District of Social and Health Services (Eksote) merged primary healthcare, specialist healthcare and social care for a fully integrated health and social care provider.

Patients suffering from Diabetes mellitus Type 2 or Cardiovascular Disease (CVD) receive support for managing their diseases and risks through personal or group rehabilitation and coaching. The process is extensively supported by telemonitoring, including measurements of various health parameters such as blood pressure, blood glucose and body weight. The aim is the improvement of self-management and care for chronically ill patients within two diagnosis groups, namely Diabetes mellitus Type II and heart failure caused by cardiovascular disease (CVD). Patients suffering from these conditions receive support for managing their diseases and risks through personal or group rehabilitation and coaching.

The measurement results and other personal health data will be shared between the professional and the individual through a Personal Health Record (PHR).

The overall health objective is patient-oriented healthcare. Patients are planned to get as much as possible of the care they need at their homes. The introduction of large-scale personalised and technology supported self-management, telemonitoring and health coaching interventions is expected to improve diabetes self-management through increased disease control, and should result also in improvement in terms of health related quality of life. Likewise, for CVD, the introduction of large-scale personalised and technology supported self-management together with health coaching interventions produces benefits in terms of clinical outcome, health related quality of life (HRQOL), and health status for patients with ischemic heart diseases.
The Health Coaching is based on the Chronic Care Model developed by Wagner\textsuperscript{13} which is designed to promote effective change and effective treatment for patients with chronic conditions. The measurement results and other personal health data are shared between the professional and the individual through a PHR. To enable the service provision, all participating patients receive the appropriate equipment and guidance needed for carrying out health parameter measurements at home.

The equipment includes

- a mobile phone with specific software needed for manual and/or automatic reporting of data
- measuring devices such as blood pressure meters (devices are individually allocated according to the condition of the patient).

While using the service, patients upload their monitoring reports to a PHR as specified in the self-management plan tailored for the patient. Depending on the condition of the patient, the measurements may include weight, blood pressure, blood glucose and physical activity.

In addition to measurements, heart disease patients typically have to respond to a set of questions concerning their experienced health status. All patients use a mobile PHR application for uploading data to the PHR and receiving related feedback. The mobile phones and applications are included into the service provision without extra costs for the patients. The service is also foreseen to improve the patients' self-management skills: a personal health coach is appointed to each patient. They are specifically trained to motivate and empower the patients to take better care of their chronic condition and change their life-style healthier. The health coaches are the primary contact for the patients in case of issues regarding remote patient monitoring equipments.

Based on the reported data the patients receive notifications generated by the self-management server. Feedback is generated based on the reported health parameters and their compliance with the self-management plan. Notifications are triggered for reminding the patient to carry out the agreed measurements. In parallel, the health personnel receive notifications when interventions are needed due to exceptional measurement data or other reasons.

When needed to contact health professionals, the patients may send a safe message via application. The patients also have the option to call the health coach when there is need.

6.4.2 [Norway] Diabetes care Use Case

In North Norway, Diabetic individuals use a mobile phone with a diabetes diary application ("Few Touch Application" - FTA), a self-help tool that allows e.g. food habits registration, blood glucose data management and physical activity registration. The users may monitor themselves at their discretion and at intervals that they feel beneficial and manageable. As opposed to many other telemedicine solutions, FTA as such is a self-help tool, the purpose is primarily to support the individual user in the management of his/her health.

\textsuperscript{13} Wagner EH. Chronic disease management: what will it take to improve care for chronic illness? Effective Clinical Practice: 1998. 1(1): p. 2-4

condition - thereby leaving it to the user to decide whether he shares his diary information with health professionals. Recently the service can be combined with supervision by health professionals (with or without additional health counselling).

The aims for the patient are: 1) Better metabolic control, self-monitoring and quality of life by using mobile monitoring tools and 2) Empowerment.

The five main elements of the mobile diabetes diary application are: food habits registration, blood glucose data management system, physical activity registration, personal goals setting and general information. While blood glucose data is automatically transferred to the phone from the blood glucose meter, activity data and food habits have to be entered manually by the user.

This software has been tried out for smaller groups and through several projects with the Norwegian Centre of Integrated Care and Telemedicine and is now implemented for new and larger groups, where new support mechanisms may be needed. Such mechanisms can be automated, like software for technical support and monitoring, or it may be follow-up activities and routines from health care personnel or organisations.

The introduction of personalised and technology supported self-management, telemonitoring and health coaching interventions is expected to improve diabetes self-management through increased disease control, and should result also in improvement in terms of health related quality of life. The additional health counselling intervention is based on principles from cognitive behavioural therapy, and the diabetes nurse is using Motivational Interviewing\textsuperscript{15}, and the Transtheoretical Model (Stages of Change model)\textsuperscript{16} when counselling the patients by telephone. In the practical development of this low-intensity treatment intervention, problem-solving models are used with, for example, identification of the patients’ problems, identifying possible solutions, analysing strengths and weaknesses, selecting a solution, planning implementation, implementing, and reviewing – all together with the patients.

6.4.3 [Denmark] A shared care solution for diabetic foot ulcers

A strategy for regional implementation of a shared solution for diabetic food ulcers is currently trialling new ways of cooperating between primary care and hospital specialists. Teams of doctors and nurses work together on the initiative. The quality of care and the implications for the financing of the service are also being explored.

In the Southern Denmark region, with its population of 1.2 million inhabitants, there are 57,000 people with diabetes. The Danish Diabetic Association assumes that the number may even be double (due to persons who have undiagnosed diabetes). The incidence of foot ulcers is about two per cent a year of this total, i.e., 1,130 diabetic foot ulcers per year. Of course, not all incidents lead to hospitalisation.

Southern Danish nurses make home visits to severe diabetic patients: among their responsibilities is to help with the cleansing of foot ulcers.

\textsuperscript{15} Miller WR & Rollnick S. Motivational interviewing: preparing people for change. 2002, New York, Guilford

The expectation of the pilot is that, if nurses doing home visits to patients they can take photos of sufficiently acceptable quality that are transmitted to the specialist clinicians, deterioration in foot ulcers may be spotted earlier. This is likely to result not only in fewer acute contacts, fewer and shorter hospital stays, and considerably lower transportation costs associated with outpatient visits but also improved collegiality and teamwork between the doctor and nurse, and a better understanding of their conditions by patients.

Overall, the expectation is that this experience pilot will result in:

- Quick recognition of any negative evolution in foot ulcers.
- Lowering of the threshold for contact so that more care can be undertaken in the patient’s home.
- Avoidance of acute hospital stays and surgery.
- Facilitation of early discharge from hospital.
- Testing how wound care can be supported by telemedicine in conjunction with appropriate re-organisation of the treatment system.
- Increased quality of care and increased cost effectiveness.

### 6.5 Telemonitoring for Chronic Heart Failure (Telecardiology)

*Telemonitoring for CHF represents a new service type that is directly (remotely) offered to patients.*

This service is extensively offered in e.g. the FONTANE framework in Berlin-Brandenburg, Germany. It is furthermore subject to special contracts between the Statutory Health Insurance and private service providers. Those contracts are present in the majority of German states - hence a nation-wide coverage for telemonitoring services for CHF patients seems to be nearly achieved.