European Commission Consumers, Health, Agriculture and Food Executive Agency

Provision of a market study on telemedicine

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Final Report

List of abbreviations

AAL	Ambient Assisted Living
ADI	Integrated Home Care
AI	Artificial Intelligence
AIT	Austrian Institute of Technology
AMA	American Medical Association
ARS	Regional Health Agencies
ATA	American Telemedicine Association
B2B	Business-to-Business
B2C	Business-to-Consumer
BCE	Before the Common Era
BLE	Bluetooth Low Energy
C2B	Consumer-to-Business
CAGR	Compound Annual Growth Rate
CBT	Cognitive Behavioural Therapy
CEA	Cost Effectiveness Analysis
CEF	Connecting Europe Facility
CEMA	Central and Eastern Europe, the Middle East, and Africa
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
COPD	Chronic Obstructive Pulmonary Disease
CT	Computed Tomography
CVD	Cardiovascular Disease
DARE	Database of Abstracts of Reviews of Effectiveness
DG CONNECT	Directorate-General for Communications Networks, Content and Technology
DK	Denmark
DSM	Digital Single Market
EC	European Commission
ECG	Electrocardiogram
ECHI	European Core Health Indicators
ECHIM	European Community Health Indicator Monitoring
EEA	European Economic Area
eHDSI	eHealth Digital Service Infrastructure
eHealth	Electronic Health
EHR	Electronic Health Record
ERN	European Reference Network
ETSI	European Telecommunications Standards Institute
EU	European Union
FDA	Food and Drug Administration
FIR	Fonds d'Intervention Régional
GDP	Gross Domestic Product
GDPR	General Data Protection Regulation
GHTF	Global Harmonisation Task Force
GP	General Practitioner
GSMA	GSM Association

HIMSS	Healthcare Information and Management Systems Society
HIT	Health Information Technology
HL7	Health Level Seven International
HR	Human Resources
HTA	Health Technology Assessments
ICER	Incremental Cost-Effectiveness Ratio
ICT	Information and Communication Technology
IHE	Integrating the Health(care) Enterprise
IMDRF	International Medical Device Regulators Forum
IPHS	Integrated Personal Health/care Services
ISO	International Organization for Standardization
IT	Information Technology
ITU-T	ITU Telecommunication Standardization Sector
JA	Joint Action
KPI	Key Performance Indicator
M2M	Machine-to-Machine
MCT	Mobile Cardiac Telemetry
MD	Doctor of Medicine
mHealth	Mobile Health
MHLW	Japanese Ministry of Health, Labour and Welfare
MRI	Magnetic Resonance Imaging
NASA	National Aeronautics and Space Administration
NFC	Near-Field Communication
NHS	National Health Service
NST	University Hospital of North Norway
OAD	Home Hospitalisation
P4P	Pay-for-Performance
PCHAlliance	Personal Connected Health Alliance
PDA	Personal Digital Assistant
QALY	Quality Adjusted Life Year
R&D	Research and Development
SDO	Standards Developing Organisation
SIM	Subscriber Identification Module
SIMPHS	Strategic Intelligence Monitor on Personal Health Systems Phase
SIRM	Società Italiana di Radiologia Medica
SME	Small and Medium-sized Enterprises
SWOT	A method to evaluate Strengths, Weaknesses, Opportunities and Threats
TSB	Technology Strategy Board
UK	United Kingdom
US	United States
WHO	World Health Organization

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Abstract

The aim of the study is to examine the telemedicine market in Europe and to understand the factors that determine its development. The analysis maps telemedicine applications and solutions, and applicable technical standards and guidelines; it also describes market dynamics and potential barriers limiting wider deployment and uptake of telemedicine solutions. Finally, the study assesses the cost-effectiveness of larger-scale deployment of telemedicine under current and future market conditions, to provide policy makers with advice and considerations for wider deployment of telemedicine.

To achieve the study aim, both qualitative and quantitative methods of analysis have been applied to primary and secondary data. The former includes a survey and interviews with key stakeholders in the telemedicine market ecosystem. The latter refers to scientific journals and research reports as well as statistical data.

The study recognises that EU policy makers have undertaken a number of successful initiatives to facilitate telemedicine adoption. Additional interventions that would support wider deployment and uptake of telemedicine include: raising public awareness about the benefits of telemedicine, supporting large-scale projects where telemedicine can be tested and its benefits assessed, as well as legislative interventions by the EC or MSs to address some of the barriers for telemedicine adoption in the EU.

Executive summary

This market study maps European telemedicine solutions and standards, assesses the current telemedicine market conditions, including barriers, and tests scenarios of the cost-effectiveness of wider deployment of telemedicine. The data collected, the analysis performed and the conclusions made can serve to inform policies on telemedicine as a key area of the Digital Single Market.

First, an **analysis of the existing telemedicine solutions and standards/guidelines** in Europe is provided on the basis of a systematic literature review, and in comparison with the telemedicine market in North America (United States, Canada) and Asia (Japan).

The **solutions mapping** reveals that **telemonitoring and prevention** are the predominant types of intervention for telemedicine solutions, along with **teleconsultation**. In terms of longevity, the majority of solutions analysed have been in use for **over five years**, which suggests stable demand, potential, and commitment to invest in this area.

The mapping also shows a concentration of solutions as part of **primary care**, with **cardiovascular diseases (CVDs)**, **chronic obstructive pulmonary diseases (COPDs)** and **diabetes** being the most common conditions targeted. It is evident from the research that a great number of solutions, especially mobile health applications, target **well-being and self-care** (non-medical conditions). In terms of solution types, **medical devices and software** dominate the market.

Most telemedicine solutions are deployed at the **national or regional level**, while only few are in use in multiple MS or outside the EU. This is due to the significant differences in national regulations and social security schemes, which also incentivised EU policy makers to take initiatives to promote **interoperability between solutions** and facilitate cross-border use. Such initiatives at EU level should remain a priority in the coming years, to stimulate the development of a vibrant telemedicine market in the EU.

Telemedicine **standards and guidelines** are found to address mainly **technical requirements**. In addition to international bodies, Member States also set their own **national standards**, especially to provide precise requirements for telemedicine solutions related to a given medical specialty. Regarding other types of guideline/rule, there seems to **be good coverage of all relevant domains** at present: data protection, organisational, human resources, ethical and EHR. What may deserve attention in the future is **compatibility** between standards, as an enabler for **interoperability**, when preparing the **deployment of telemedicine services on a large scale**.

Second, the study zooms into **telemedicine market fundamentals** and describes at length the **market environment**, culminating with a **market SWOT analysis**.

It emerges from this part of the market analysis that the **uptake of information technologies** in Europe is the main accelerator for telemedicine. The market potential of telemedicine is demonstrated to be strong and expected to grow at a compound **annual growth rate of 14%** in the coming years. The **well-being market** especially, enabled by digital technologies, mainly wearables and mobile applications, is also rapidly growing.

Although it appears that **demand for telemedicine solution outpaces supply**, this observation should be considered with care, as there are many telemedicine initiatives and solutions available in the market but hospitals and clinics do not always have the financial resources to adopt the state-of-the-art technology that will allow deployment of telemedicine services.

Telecommunication companies, ICT tools and electronics manufacturers, device manufacturers, pharmaceutical industry companies, and start-ups have been identified as **key players** in the value chain of the telemedicine market along with patients and health professionals.

Third, **barriers to telemedicine uptake** are identified in one of seven categories: cultural; regulatory and policy; social security; industrial and technical; knowledge; financial; and market-related. Based on a review of literature, **barriers are found to exist in all European countries** but do not affect them to the same degree. Thus, it is difficult to quantify how the impact of barriers varies across counties. Furthermore, since telemedicine is a multi-stakeholder market, barriers also affect the players differently within each country.

Decision-makers should be attentive towards the barriers and pursue actions to overcome them, in particular: **conservatism** or resistance to adopting new medical processes, **limited integration** between technology and medical practitioner's procedures, (**data protection**) regulations, **limited funding/financial incentives and interoperability**.

Importantly, uptake of telemedicine solutions across national health systems will also only be successful if key institutions in the medical community, such as recognised clinics and hospitals, establish new **partnerships**. These institutions will only be incentivised to do so if national decision-makers allow health systems to properly pay the utilisation of the technology, meaning developing **reimbursement schemes** for telemedicine utilisation. Further to this point, it is important to highlight that today, only direct consumer models have some degree of success, because institutional players cannot pay for or are not always reimbursed for telemedicine tools and services.

Despite the above barriers, it should be noted that there are a number of areas where EU and national initiatives have had significant **positive impact** on telemedicine uptake, for instance ePrescriptions and the Patient Summary.

Finally, the study offers an **economic assessment** with the objective of evaluating the potential benefits of future deployment of telemedicine tools and services across the EU. This assessment relies on scenario-based analysis using an economic decision model. The parameters used in the model are based on insight drawn from scientific research complemented by disease statistics.

In a first step, **research databases** are examined for evidence of **telemedicine cost effectiveness in medical trials**. The main findings of this analysis suggest that telemedicine is reported to be cost-effective in 73.3% of the cases covered by the literature, while negative effects account for 5.6% of the selected studies. The remaining 21.3% of the studies analysed present a neutral effect of the use of telemedicine as a means to save costs. **Parameters that have strong impact on the cost-effectiveness** of telemedicine solutions reported by the studies include: distance between patient and nearest healthcare professional; time required per consultation; cost of a doctor visit; QALYs; and mortality rate.

In a second step, these cost parameters are used as to assess **cost-effectiveness resulting from wide-scale deployment of telemedicine in Europe,** based on different levels of projected adoption. In this final part, the study examines two scenarios. Under the first scenario, it is assumed that 18% of health provision, mainly consultation and treatment, take place with the use of telemedicine. The second scenario examines the impact of an increase in the adoption level by an extra 5% to 23%. In both scenarios, the costs and benefits of telemedicine are compared to the traditional face-to-face patient journey to estimate the effect of a wider deployment of telemedicine. It becomes apparent that **the higher the share of telemedicine – the more cost-effective wide-scale deployment becomes**. An increasing share of telemedicine decreases the total cost of the patient journey, the total consultation time, the total distance travelled and the rates of mortality, while it increases QALYs gained.

However, this is only a first EE-wide assessment. Policy-makers need to invest in obtaining more scientific evidence for the efficiency of telemedicine by financing and monitoring large-scale experiments to assess the impact of a wider deployment. Raising-awareness (patients, doctors), stimulating integration between stakeholders and facilitating reimbursement are additional considerations for speeding up adoption and the realisation of benefits resulting from telemedicine use.

Résumé

L'objectif de cette étude est d'examiner le marché de la télémédecine en Europe et de comprendre les facteurs qui déterminent son développement. Cette analyse cartographie les applications et solutions utilisés par la télémédecine, ainsi que les directives et les standards techniques en vigueur ; elle décrit également les dynamiques de ce marché et les obstacles potentiels qui pourraient limiter l'adoption de solutions de télémédecine. Enfin, cette étude mesure le rapport coût-efficacité d'un déploiement à grande échelle de la télémédecine dans les conditions de marché actuelles et futures et ainsi mettre à disposition des décideurs politiques les éléments à considérer pour un plus grand déploiement de la télémédecine.

Afin d'atteindre les objectifs de cette étude, des méthodes d'analyse qualitative et quantitative ont été appliquées à des données primaires et secondaires. Les données primaires sont constituées d' une enquête, ainsi que des entretiens avec les parties prenantes clés de l'écosystème du marché de la télémédecine. Les données secondaires font référence à des publicationsscientifiques et à des rapports de recherche, mais aussi à des données statistiques.

Les résultats de l'étude indiquent que les décideurs politiques de l'Union Européenne (UE) ont entrepris un nombre d'initiatives réussies, afin de faciliter l'adoption de la télémédecine. D'autres interventions pourraientencourager une adoption et un déploiement plus grands de la télémédecine comme : la sensibilisation du public aux avantages de la télémédecine, le soutien à des projets d'envergure dans lesquels le déploiement de latélémédecine peut être testé et ses bénéfices évalués, mais aussi des interventions législatives par la Commission Européenne ou par les États Membres pour éliminer certains des obstacles à l'adoption de la télémédecine dans l'UE.

Synthèse

Cette étude de marché cartographie les solutions de télémédecine et les standards européens, évalue les conditions actuelles du marché de la télémédecine, en identifiant les obstacles et barrières à son déploiement, et modélise des scénarios de type coût-efficacité d'un déploiement de plus grande ampleur de la télémédecine. Les données collectées, l'analyse réalisée et les conclusions établies peuvent serviront les décideurs publics pour établir leur politique d'intervention dans le cadre dudu Marché Unique Numérique.

Dans un premier temps, une **analyse des solutions de télémédecine et des standards/principeses** en Europe a été réalisée sur la base d'une revue littéraire systématique, en comparaison du marché nord-américain (États-Unis, Canada) et asiatique (Japon).

Le **recensement des différentes solutions** révèle que **le télémonitoring et la prévention** sont les types d'intervention prédominants pour les solutions de télémédecine, de même que **la téléconsultation**. En termes de pérennité, la majorité des solutions analysées sont utilisées depuis **plus de cinq ans**, ce qui démontre la stabilité de la demande, le potentiel et la détermination à investir dans ce domaine.

Le recensement montre également une concentration des solutions en matière de **soins primaires** et plus particulièrement des **maladies cardio-vasculaires**, des **affections pulmonaires obstructives primaires** et du **diabète** qui sont des couramment ciblés. L'analyse met en lumière qu'un grand nombre de solutions, les applications de santé mobiles particulièrement, ciblent **le bien-être et l'auto-traitement** (conditions non-médicales). En termes de types de solutions, **les équipements médicaux et les logiciels** dominent le marché.

La plupart des solutions de télémédecine sont déployées **au niveau national ou régional**, tandis que très peu sont utilisées dans les États Membres ou en dehors de l'UE. Ceci est dû aux différences significatives entre les régulations nationales et aux modalités de prise en charges de la sécurité sociale, ce qui a notamment encouragé les décideurs politiques de l'UE à prendre des initiatives au niveau de l'UE pour promouvoir **l'interopérabilité entre les solutions** et pour faciliter leur utilisation transfrontalière. Ces initiatives au niveau de l'UE devraient rester une priorité dans les années à venir, pour stimuler le développement d'un marché de la télémédecine dynamique.

Les **standards et directives** en matière de télémédecine sont là pour répondre aux **exigences techniques** principalement. Au-delà des instances internationales, les États Membres définissent également leurs propres **standards nationaux**, particulièrement lorsqu'il s'agit de fournir des exigences précises pour des solutions de télémédecine spécifiques à une spécialité médicale. En ce qui concerne les autres types de directives/règles, il semble qu'il y ait aujourd'hui une **bonne couverture de tous les domaines clés** : protection des données, process et ressources humaines, éthique et dossier électronique du patient. Dans le futur, une attention particulière doit être portée surla **compatibilité** entre les standards, en tant que facilitateur de l'**interopérabilité**, quand il s'agira de préparer le **déploiement des services de télémédecine à grande échelle.**

Dans un deuxième temps, l'étude se focalise sur les **fondamentaux du marché de la télémédecine** et décrit en détail **l'environnement du marché**, aboutissant à une **analyse de marché « FFOM »** (Forces, Faiblesses, Opportunités, Menaces).

De cette partie de l'analyse de marché il apparait que **l'adoption des technologies de l'information** en Europe est le principal accélérateur pour le déploiement de solutions de télémédecine. Le potentiel du marché pour la télémédecine est très important et devrait croître à un **taux de croissance annuel composé de 14%** dans les années à venir. Le **marché du « well-being »** en particulier, grâce aux technologies digitales (dispositifs portables et applications mobiles principalement), croît particulièrement rapidement.

Bien qu'il apparaisse que **la demande pour des solutions de télémédecine dépasse l'offre**, cette observation est à considérer avec précaution, car de nombreuses initiatives et solutions sont disponibles sur le marché, mais les hôpitaux et les cliniques n'ont pas toujours les ressources financières pour adopter les technologies de pointe qui permettent le déploiement des services de télémédecine.

Les entreprises de télécommunication, les fabricants d'électronique et d'outils TIC (Technologies de l'Information et de la Communication), les fabricants de dispositifs, les entreprises de l'industrie pharmaceutique et les « start-ups » ont été identifiés comme les **acteurs clés** de la chaîne de valeur du marché de la télémédecine.

Dans un troisième temps, les **obstacles à l'adoption de la télémédecine** sont identifiés dans l'une des sept catégories suivantes : culturel ; réglementaire et politique ; sécurité sociale ; industriel et technique ; connaissances ; financier ; et lié au marché. Sur la base de la revue documentaire, **des obstacles ont été identifiés dans tous les pays européens,** mais sans les affecter de la même manière. C'est pourquoi il est difficile de quantifier comment l'impact des obstacles varie selon le pays. De plus, la télémédecine étant un marché avec de multiples parties prenantes, les obstacles impactent les acteurs en présence différemment dans chaque pays considéré.

Les décideurs devraient être attentifs à ces obstacles et mettre en place des actions pour les dépasser, notamment concernant : le **conservatisme** ou la résistance à l'adoption de nouveaux processus médicaux, le **manque d'interoperabilité** entre la technologie et les procédures des professionnels de santé, la législation (**protection des données**), le **manque de soutien financiers/d'incitations financières**.

Il est important de noter que l'adoption de solutions de télémédecine à travers les systèmes de santé nationaux ne sera fructueuse que si les institutions clés de la communauté médicale, telles que les cliniques et les hôpitaux emblématiques, mettent en place de nouveaux **partenariats**. Ces institutions ne seront encouragées à le faire que si des décideurs nationaux permettent aux systèmes de santé de prendre en charge correctement l'utilisation de cette technologie, ce qui signifie développer des **programmes de remboursement** pour l'utilisation de la télémédecine. Au-delà de ce point, il est important de souligner qu'aujourd'hui seuls les modèles en direct avec les consommateurs ont du succès, car les acteurs institutionnels ne peuvent asurer une prise en charge financière ou ne sont pas toujours remboursés pour les produits et services de télémédecine.

Malgré les obstacles décrits ci-dessus, il convient de noter que dans de nombreux domaines les initiatives nationales et de l'UE ont eu un **impact très positif** sur l'adoption de la télémédecine, comme avec les « e-prescriptions » (prescriptions électroniques) par exemple, ou le dossier du patient.

Enfin, cette étude présente une évaluation économique avec l'objectif de mesurer les bénéfices potentiels du futur déploiement d'outils et de services de télémédecine à travers l'UE. Cette évaluation repose sur une analyse elle-même basée sur des scénarios, qui utilise un modèle de décision économique. Les paramètres utilisés dans ce modèle sont tirés de recherches scientifiques complétées par des données statistiques sur les pathologies.

La première étape consiste à examiner des **bases de données de recherche** afin de mettre en évidence des preuves du **rapport coût-efficacité de la télémédecine dans les essais cliniques**. Les principales conclusions de cette analyse suggèrent que la télémédecine serait efficace en termes de coût dans 73,3% des cas couverts par la revue documentaire, tandis que les effets négatifs comptent pour 5,6% des études sélectionnées. Les 21,3% restants des études analysées présentent un effet neutre sur l'utilisation de la télémédecine comme moyen pour réduire les coûts. **Les paramètres qui ont un impact fort sur le rapport coût-efficacité** des solutions de télémédecine rapportées par les études incluent : distance entre le patient et le professionnel de santé le plus proche ; temps requis par consultation ; coût de la visite d'un docteur ; année(s) de vie pondérée(s) par la qualité ; et taux de mortalité.

Dans une deuxième étape, ces paramètres de coût sont utilisés pour mesurer **le rapport coût-efficacité qui résulte d'un déploiement à grande échelle de la télémédecine en Europe**, en se basant sur différents niveaux d'adoption projetée. Dans cette dernière partie, l'étude se penche sur deux scénarios. Dans le premier scénario, il est supposé que 18% des soins de santé, la consultation et le traitement principalement, ont lieu avec l'utilisation de la télémédecine. Le second scénario examine l'impact d'une hausse du niveau d'adoption de 5% à 23%. Dans les deux scénarios, les coûts et bénéfices de la télémédecine sont comparés au parcours traditionnel du patient en face-à-face pour estimer l'effet d'un déploiement plus grand de la télémédecine. Il apparait alors que **plus la part de télémédecine est importante, plus le déploiement à grande échelle devient efficace en termes de rapport coût-efficacité**. Une part croissante de la télémédecine réduit le coût total du parcours du patient, le temps de consultation total, la distance totale parcourue et les taux de mortalité, et augmente le nombre d'années de vie pondérées par la qualité.

Cependant, il s'agit seulement d'une première évaluation à l'échelle de l'Europe. Les décideurs politiques doivent investir pour obtenir plus de preuves scientifiques de l'efficacité de la télémédecine en finançant et en pilotant des expériences à grande échelle pour mesurer l'impact d'un déploiement de grande ampleur. Sensibiliser (patients, docteurs), soutenir l'intégration entre les différentes parties prenantes et faciliter le remboursement sont autant de considérations supplémentaires pour accélérer l'adoption et l'obtention des bénéfices résultant de l'utilisation de la télémédecine.

Introduction

Background

Telemedicine has a long history, as indicated in the Figure below. It started in ancient times, but evolved in the 19th century with the invention of electricity and radio, and in the 20th century with the development of television and the Internet.

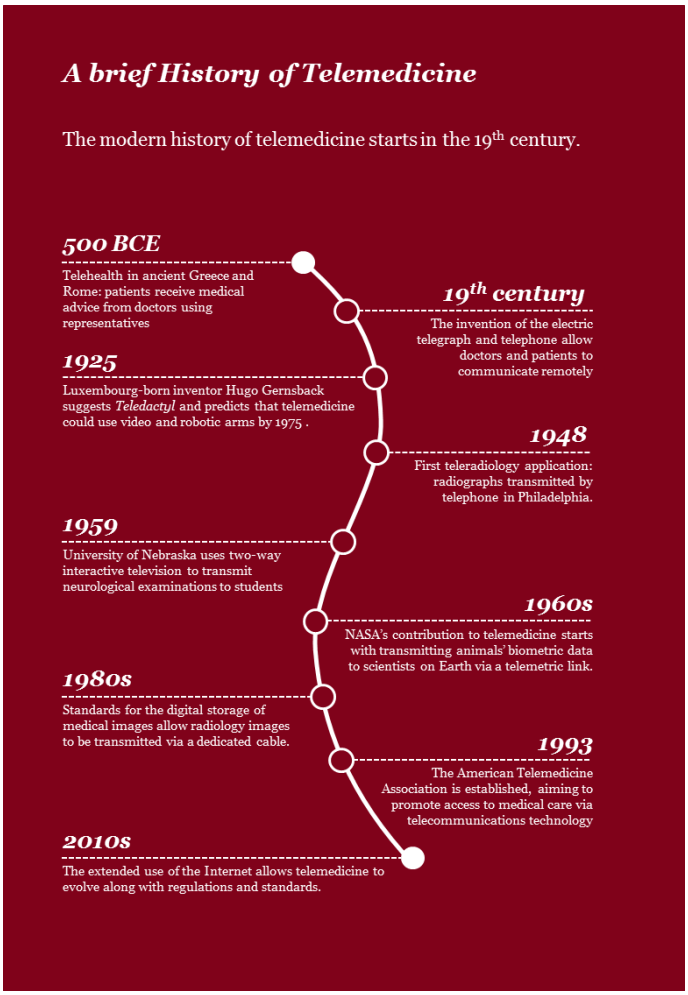


Figure 1: A short history of telemedicine

In recent years, technological development enabling data analytics, artificial intelligence and the healthcare Internet of things has disrupted traditional medical operations and transformed healthcare provision. The increase in connected wearables and health-related applications makes it possible to deploy telemedicine solutions on a wide scale. In 2016, 79% of EU residents between 16 and 74 years old accessed the Internet using a mobile phone or smartphone.[1] In the near future, robots will be able to perform surgery autonomously or driven by surgeons remotely.

[1] http://ec.europa.eu/eurostat/documents/2995521/7771139/9-20122016-BP-EN.pdf

The use of telemedicine is driven both by consumers, who seek to take advantage of technologies that can improve their health and quality of life, and by healthcare systems, which are interested in providing quality services with a reduced budget. The need for services is increasing due to a) the economic development that enables counties and individuals to buy better healthcare services, and b) the increase in the number of patients with chronic diseases as the post-war baby boom generation ages.

In addition, the physical geography of Europe, with many islands and remote areas, motivates the wide deployment of telemedicine. Several pilot projects have taken place in the last few decades and have recorded positive results in terms of both improvements in health and cost-efficiency. In 2014, five main use cases were reported in EU Member States:[2]

- Teleradiology – the remote assessment of X-ray images, including peer review;
- Teledermatology services, providing advice and second opinions both to physicians and directly to citizens/patients (based on images of their skin problems);
- Telestroke services (teleneurology), enabling early stroke treatment (thrombolysis);
- Telemonitoring for diabetes (with coaching support), improving lifestyle and conditions;
- Telemonitoring for chronic heart failure as a prototype for intensified patient care.

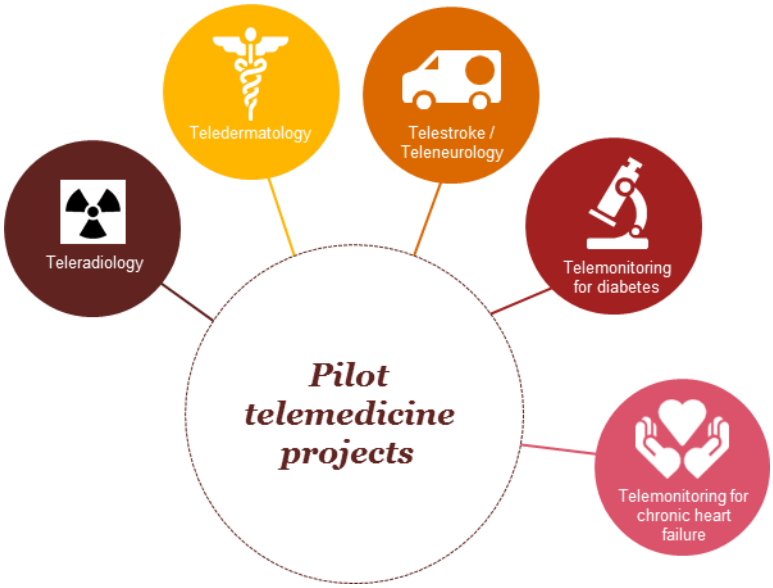


Figure 2: Pilot telemedicine projects

Recent technological advances have occurred to the extent that Healthcare 4.0 may be possible in the near future by using big health data analytics and artificial intelligence.[3] Today, fast Internet connections are widespread, through both fibre-optic and mobile networks (4G/5G), allowing for synchronous, uninterrupted video streaming (which is necessary in many telemedicine applications). All smartphones sold by major market players are equipped with a free application that can monitor the user's physical activity. At the same time, people may have already purchased smartwatches and smartphones with applications that can monitor and feed data to a medical professional. Connected wearables are the infrastructure that can deploy telemedicine for common chronic diseases such as

[2] 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'), version 1.0 final (12 March 2014)
[3] http://www.kmgus.com/blogs/healthit/index.php/2016/12/healthcare-4-0-the-future-of-healthcare

high blood pressure. Of course, telemedicine can be practised today in many ways, using specific hardware and applications for C2B (patient to doctor) and B2B solutions (health professional to doctor/clinic/hospital). One innovative example is the use of drones for emergencies such as heart attacks, which could dramatically increase survival rates as patients can be reached more quickly than by ambulance.

An emerging trend that could also form a significant part of the telemedicine market is electronic visits to doctors. In 2015 in the US, 800,000 out of 930 million doctors' visits were e-visits.[4] This is less than 1% of all doctors' visits that year in the US, while the American Medical Association states that 75% of all doctors' visits are either unnecessary or could be handled via telemedicine. In Europe, some telemedicine services, such as teleconsultation, are supported by start-up companies that allow patients to see a doctor online.[5]

However, the deployment of telemedicine to the whole population of a country depends on the country's level of digitalisation, including the digital skills of patients and health professionals, as well as the legislation governing the sharing and processing of health data. While teleconsultation can be easily deployed with a small investment (for example in France each doctor will get an up to 525 Euros support for the necessary software solutions), other telemedicine service require a significant initial investment. Thus, the cost-effectiveness and the return on investment need to be assessed in the longer term based on the current state financial and market conditions. Finally, risks related to healthcare data privacy breaches when exposing more data in networks and online platforms need to be taken into account and telemedicine application should be equipped or supported by strong encryption solutions. Such challenges are already being faced by countries inside and outside Europe[6].

Objectives of the study

The purpose of this study is to provide a full analysis of the market for telemedicine applications and solutions based on the current conditions. The data collected, the analysis and the conclusions will serve to inform and shape the Commission's policy on telemedicine. In detail, the study is divided into four main tasks with the corresponding number of work packages:

1. Mapping of existing solutions and relevant technical standards and/or guidelines;
2. Analysis of the market for such solutions, both in general and with regard to specific sub-areas;
3. Mapping exercise of barriers to the wider implementation of telemedicine, as well as potential EU-wide approaches or solutions;
4. Cost-effectiveness analysis of existing solutions and of potential wide-scale deployment.

[4] https://medium.com/@guidohegener/telemedicine-in-europe-battle-mode-on-b6ff4076ba5c
[5] For an example, see this UK-based solution: https://www.pushdoctor.co.uk/
[6] http://www.dsih.fr/article/3025/rendez-vous-medicaux-en-ligne-et-donnees-personnelles-le-scandale-australien.html http://www.dsih.fr/article/3037/singapour-l-infection-d-un-ordinateur-permet-le-vol-des-donnees-d-1-5-million-de-patients.html

Key terms and concepts

eHealth and mHealth

The World Health Organisation (WHO) defines eHealth[7] as *the use of information and communication technologies (ICT) for health*. The terms 'eHealth' (electronic health) and 'mHealth' (mobile health) have been used in recent years to describe the provision of health services using the Internet and mobile devices, respectively.

Telemedicine

Telemedicine is the provision of healthcare services where traditional face-to-face patient - doctor interaction (or doctor - doctor) is replaced by over-distance interaction through use of ICT. Several other definitions of telemedicine exist. Shaw[8] defines it as *the use of telecommunications technology for medical diagnostic, monitoring, and therapeutic purposes when distance separates the users*. The WHO has adopted the following description:[9] *the delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities*.

Telehealth

According to the WHO[10], *telehealth involves the use of telecommunications and virtual technology to deliver health care outside of traditional health-care facilities, [for example] a virtual home health care, where patients such as the chronically ill or the elderly may receive guidance in certain procedures while remaining at home. Telehealth has also made it easier for health care workers in remote field settings to obtain guidance from professionals elsewhere in diagnosis, care and referral of patients*. Similarly, Shaw[7] defines telehealth as *the use of electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health, and health administration*. Miller[11] suggests that ***telehealth*** *refers to* ***both clinical and non-clinical applications*** *in the way of education, administration, and research while* ***telemedicine*** *is often reserved for* ***clinical, patient care applications***.

There is a vast amount of literature with many definitions of the terms discusses above. We can conclude that telehealth is a more generic term that refers to health-related procedures, while telemedicine refers more specifically to treating people from distance. eHealth and mHealth are terms that are as generic as telehealth in terms of health services, but specific to the technologies used in delivering these services from distance: the Internet and mobile devices respectively. To make the latter explanation clearer, in the case of telehealth, we may have patient-doctor interactions without Internet or mobile devices.

[7] http://www.who.int/ehealth/about/en/
[8] Shaw, D. K. (2009). Overview of Telehealth and Its Application to Cardiopulmonary Physical Therapy. Cardiopulmonary Physical Therapy Journal, 20(2), 13-18
[9] http://www.who.int/goe/publications/goe_telemedicine_2010.pdf
[10] http://www.who.int/sustainable-development/health-sector/strategies/telehealth/en/
[11] Miller, E.A. (2007). Solving the disjuncture between research and practice: Telehealth trends in the 21st century. Health Policy 82,133-141

1. Mapping and categorisation

Key takeaways

- Telemonitoring and prevention are the main types of intervention for telemedicine solutions.
- Telemedicine's focus is on primary care, cardiovascular diseases (CVDs), chronic obstructive pulmonary diseases (COPDs) and diabetes.
- A great number of solutions target well-being and self-care, especially mobile health applications.
- Standards and guidelines mostly address technical requirements.

The aim of this chapter is to provide an analysis of the existing telemedicine solutions and standards/guidelines through a systematic literature review (publications and reports). The latter enabled us to highlight the main trends and characteristics of the telemedicine solutions and standards. Another aim of this chapter is to put the EU/EEA status of telemedicine into an international perspective, comparing it to the United States, Canada and Japan.

1.1. Analysis of telemedicine solutions

Telemedicine solutions can be described as products and services designed to utilise technology to improve and coordinate patient care, address growing health costs and confront the long-term burden of disease. This sector is revolutionising the healthcare industry through numerous applications in the fields of healthcare prevention and patient management and monitoring. The tools and solutions that have emerged in recent years are at the core of improved healthcare services provided by public and private organisations. These digital tools increase healthcare delivery efficiency, enable patients to be monitored remotely, improve access to electronic health information, enhance the quality of healthcare services, and reduce costs.

The uptake of telemedicine solutions has enabled healthcare service providers to improve patient-management processes through remote monitoring and follow-up, ensure the continuity of access to day-to-day care, and create a wider information base for clinical decision-making. Therefore, the uptake and wider implementation of these solutions across healthcare providers has the potential to bring positive effects in key healthcare fields such as chronic disease management.

These solutions comprise applications and tools that enhance the provision of healthcare services on a remote and distant basis. This characteristic addresses the need to ensure access to healthcare services for patients located at a distance from hospitals and clinics, and eases the process of prevention, patient management, follow-up and monitoring. This translates into concrete clinical health services that include teleconsultation, telemonitoring, tele-education, telecare and telesurgery, amongst others. These systems enable one or more patient disorders to be managed properly. For instance, patients suffering from heart and blood pressure ailments can be monitored on a daily basis, making treatment easier and more effective.

1.1.1. Technical considerations

This section refers to the discussion of the technical features of telemedicine solutions. Regarding the types of solutions, it appears from the analysis that products and platforms were prevailing. Regarding the technical type, most of the solutions are medical devices or include telemedicine support software. A specific section is dedicated to mobile applications.

1.1.1.1. Types of solutions

The trend that emerges from our research is that most telemedicine solutions are *products* and/or *platforms*. A telemedicine product is rarely marketed alone. Usually, companies provide a platform (or an application) on which the data is shared. Then, the data is stored in a database ready to be analysed and interpreted by a doctor, by another healthcare professional or by software. This **product-platform (-database) combination** is widespread in telemonitoring solutions. The Figure below provides an illustration of data collection and sharing by the IT element of the telemedicine solution.

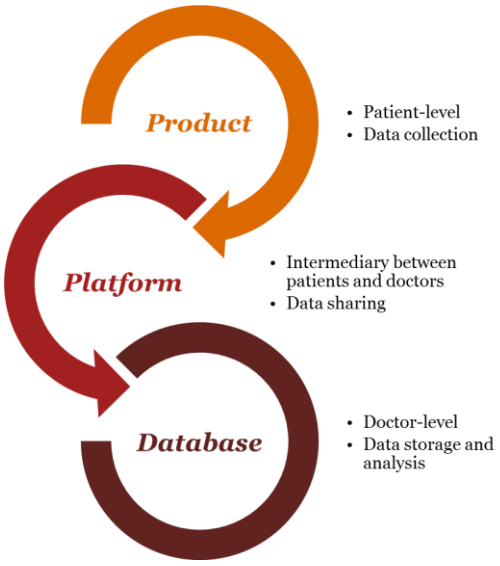


Figure 3: Data storage and sharing in tele monitoring software

For instance, the LifeWatch MCT 3 Lead is a mobile cardiac telemetry (MCT) product that detects, records and wirelessly transmits asymptomatic and symptomatic arrhythmia to clinicians for analysis. The four wearable cardiac electrodes are connected to a smartphone via Bluetooth. If arrhythmia is detected, the smartphone automatically sends the data to a monitoring centre for review and notifies a doctor if required.

Telemedicine services are often related to teleconsultations, telediagnoses or 24/7 call centres. For example, the Swedish company Kry provides online video consultation with a general practitioner holding a Swedish doctor's license. The patient books an appointment through the app, and then the doctor will call him/her, give him/her a 15 min consultation and send him/her a prescription, if needed. TeleRadiology Solutions provides radiology interpretation through teleradiology services (e.g. CT, MRI, X-ray, ultrasound, nuclear medicine, echocardiograms) to over 150 hospitals in 20 countries.

Databases are closely linked to platforms as well. They are useful tools for **storing medical information**, especially electronic health records (EHRs). The Andalusian eHealth Strategy & System DIRAYA in Spain, is a unified EHR system. It integrates patients' health information and intervention details in primary care, emergency services, mental health services and specialist outpatient care.

Other ICT tools are quite marginal and correspond to solutions that either include other technology or cannot fit into the given categories. For example, KineQuantum is a French start-up that aims at projecting users/patients (undergoing physiotherapy) in 3D and virtual-reality games. The idea is to have them perform exercises and specific movements to measure and visualise their progress.

Applications, especially those designed for mobile devices, are much more numerous than it appears in the mapping. Given the existence of hundreds of thousands of mHealth applications, these are further discussed below.

1.1.1.2. Technical type

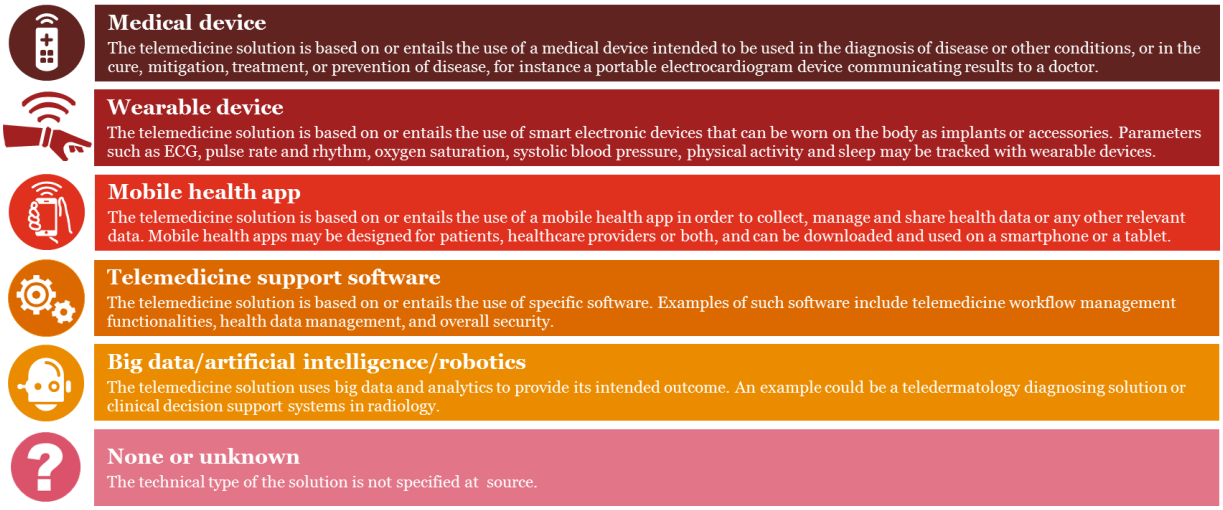


Figure 4: Technical type - data architecture in telemedicine solutions

The selections proposed in "*Technical type*" represent subsets of the selections proposed in "*Type of solution*". For instance, a "*medical device*" or "*wearable device*" corresponds to a "*product*", while a "*mobile health app*" refers to an "*application*". Therefore, conclusions can be drawn for the "*Technical type*" that are similar to those drawn for "*Type of solution*" in the previous section.

A *product-platform* solution corresponds to a piece of *telemedicine support software* integrated in a *medical or wearable device*. However, a *telemedicine support software* has a wider scope, since it also encompasses services and databases. Behind almost every telemedicine solution, there is a **specific piece of software running** because the latter is the fundamental technology that connects patients to healthcare professionals. This is why these solutions account for most of the solutions in the mapping.

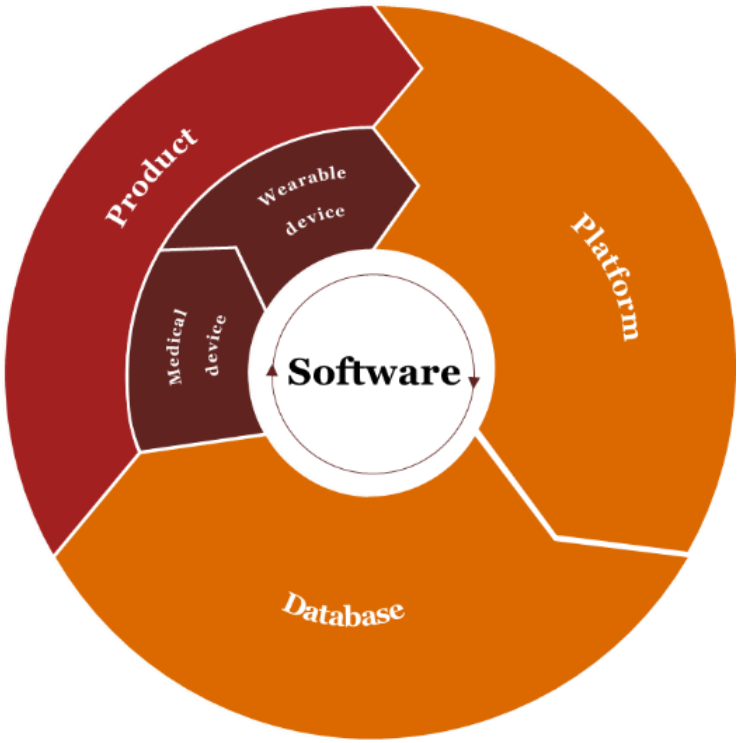


Figure 5: Telemedicine support software at the core of the solutions

Telemedicine products can be classified into two types: *medical* and *wearable devices*. These two types often overlap because medical devices can be wearable devices and vice versa. The WHO's definition[12] for a medical device is broad.

Yet, a distinction has been made between wearable devices used mostly for personal purposes (well-being, sport, fitness, etc.) and medical devices used in a medical framework (i.e. in relations with a healthcare professional). For instance, the Polar Pro strap developed by Polar Electro (Finland) is a soft textile strap with improved electrodes, which measures the patient's heart rate accurately. We considered this product wearable but not a medical device. On the contrary, Biotronik Arrhythmia Monitoring (Biotronik, Germany) is considered a wearable medical device for the purpose of this study, since it allows healthcare professionals to review and monitor patients' heart-rate data.

Big data/AI/Robotics are less common technical types of telemedicine solutions. The combination of Artificial Inteligence (AI) and robotics might lead to new approaches in surgery for instance. Up to now, Da Vinci's EndoWrist® is in fact only an improved surgical procedure. The instrument bends and rotates far more than by conventional laparoscopy but it's still the surgeon who performs the medical

[12] Medical device means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:
• diagnosis, prevention, monitoring, treatment or alleviation of disease,
• diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
• investigation, replacement, modification, or support of the anatomy or of a physiological process,
• supporting or sustaining life,
• control of conception,
• disinfection of medical devices
• providing information by means of in vitro examination of specimens derived from the human body;
and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

act. Zebra Medical Vision has created AI algorithms to read medical scans and detect anything untoward before humans can.

1.1.1.3. Mobile heath applications – mHealth

The WHO's definition of mHealth is also very broad: *"medical and public health practice supported by mobile devices such as mobile phones, patient monitoring devices, personal digital assistants (PDAs) and other wireless devices"*.

Worldwide – market size and growth[13]

According to a study by *Research 2 Guidance*, in 2017 there were 325,000 mobile health apps and 84,000 mHealth app publishers[14] in the five major app stores (Google Play, Apple, Microsoft Windows Phone, Amazon, and Blackberry). Healthcare mobile app development is one of the fastest-growing areas with a tremendous 32.5% CAGR[15] (41% expected for 2015-2020), and reached €17.64bn in market revenues at the end of 2017. **Europe accounts for 30% of the market**[16] (28% for the US). The global market is predicted to reach €38.64bn by 2020[17].

Europe is the fastest-growing segment in this market, with a CAGR of 61.6%.[18]

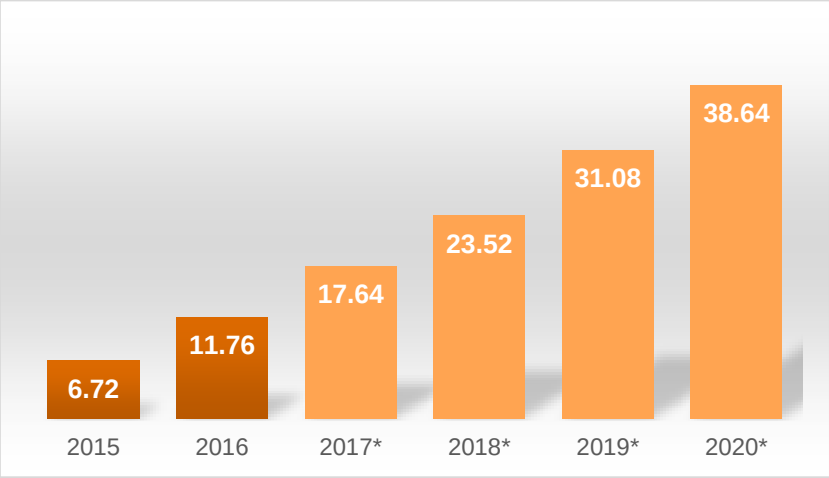


Figure 6: Mobile health market value (in billion Euros)
Source: Statista (2018)

The number of mHealth app downloads has also dramatically risen for the past four years, from 1.7 billion in 2013 to 3.7 billion in 2017 (+2bn in absolute terms, or +118%).

[13] N.B: the data available on mobile health apps includes both pure medical applications (used in medical treatment) and applications related to self-care, well-being or lifestyle
[14] Source: https://research2guidance.com/84000-health-app-publishers-in-2017/
[15] Compound Annual Growth Rate (CAGR) = (Ending Value/Beginning Value)$^{(1/\#\ of\ years)}$ - 1
[16] GSMA and PwC, "Touching lives through mobile health - Assessment of the global market opportunity", February 2012
[17] Source: https://www.statista.com/statistics/387867/value-of-worldwide-digital-health-market-forecast-by-segment. Statistics published in US$ converted to Euros with an exchange rate of 0.84 Euros per US$
[18] Dr Cheryl Lee Barton, BCC Research, Mobile Health (mHealth) Technologies and Global Markets (HLC162A), March 2014

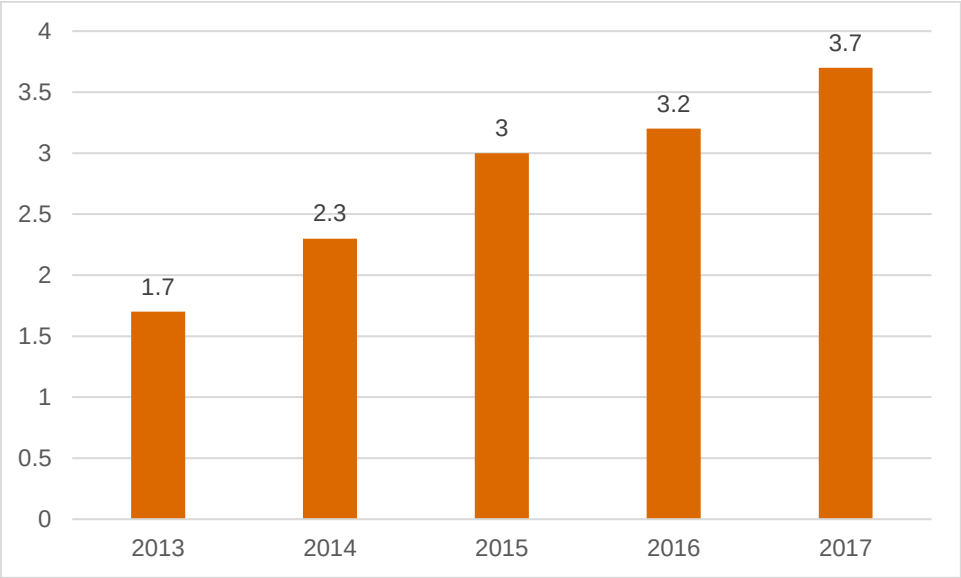


Figure 7: Number of mHealth downloads worldwide (billions)
Source: Statista – Research2Guidance

Leading European countries for mHealth apps

In a survey conducted by Research2Guidance in 2015, 4,471 mHealth app publishers and decision makers were asked to rank the top three countries in Europe in terms of favourable market conditions for mHealth business. The UK and Germany are the leading countries, with 55% and 41% (respectively) of the mHealth app publishers and decision makers mentioning them in the top three. We notice a strong attractiveness towards Scandinavian countries as well (Sweden 23%, Denmark 16% and Finland 15%).

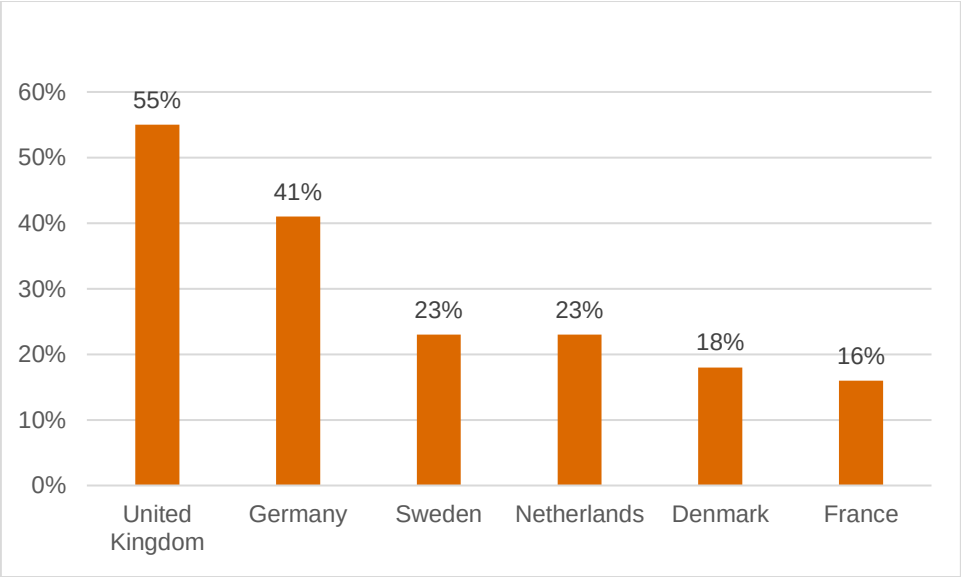


Figure 8: Share of mHealth publishers by country
Source: Statista – Research2Guidance

Disease specifics

Almost 1 in 3 mobile health apps are dedicated to mental health. Mental health relates to mental and psychological well-being (WHO). The available solutions are very diverse. Example include breathing exercises for stress management (Breathe2Relax); alert notifications to specific contacts for teenagers struggling with depression or bullying (Code Blue); and cognitive behavioural therapy (CBT) techniques with advice from real experts (Lantern).

In the 2013 study conducted by IMS Health,[19] the categorisation of endocrine included diabetes and metabolic syndrome, but in the 2015 study, these were categorised separately. Diabetes and heart/circulatory diseases are the next most treated diseases by mobile health applications: in 2015, 15% and 10% of disease-specific apps focused on these two diseases respectively.

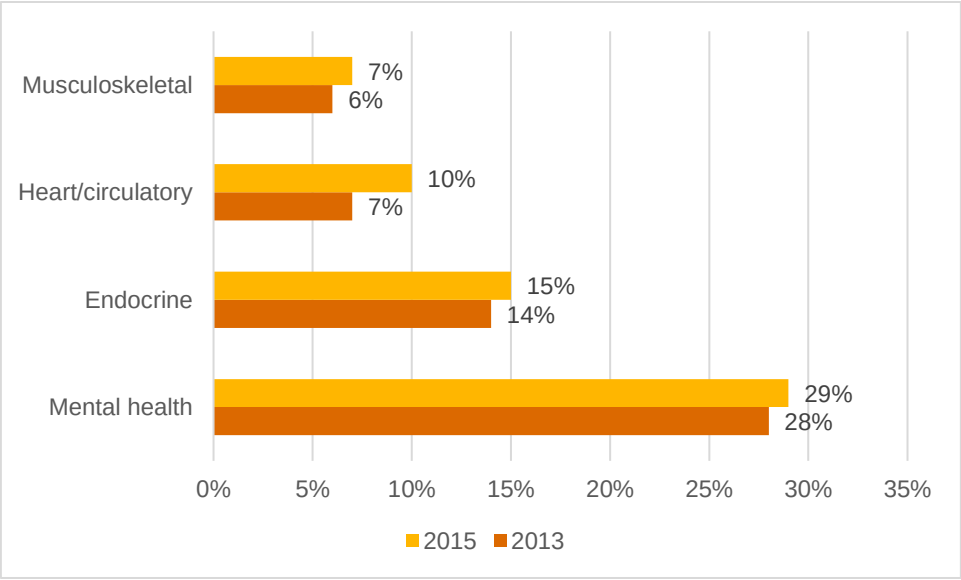


Figure 9: Distribution of disease-specific apps available worldwide in 2013 and 2015
Source: IMS Health

Health-context considerations

All the categories of mobile health apps (see Figure 10 below) are considered very promising by app publishers in terms of market potential. Remote monitoring devices increasingly use smartphone applications to store and monitor the data. Products are regularly being developed that synchronise with smartphones, enabling patients to monitor their conditions anywhere, anytime[20, 21]. Over 70% of mHealth app market players choose to publish their apps on both iOS and Android platforms.

[19] Statista, *mHealth*, November 2016
[20] Research2Guidance, "mHealth App Developer Economics 2016", October 2016
[21] European Commission, "COM(2014) 219 final GREEN PAPER on mobile Health (mHealth)", April 2014

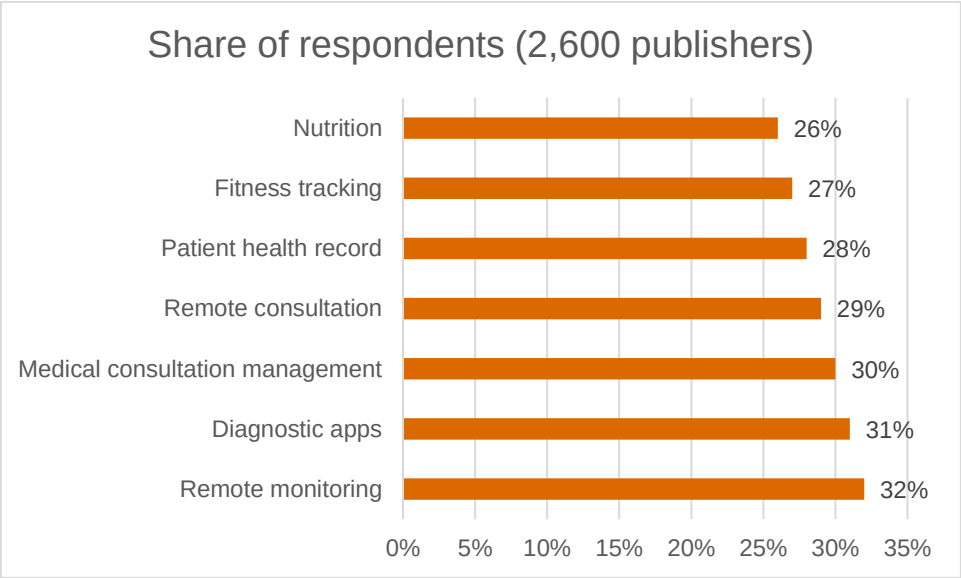


Figure 10: Mobile health app categories that will offer the highest global market potential in the next five years, as of 2016
Source: Research2Guidance

1.1.2. Geographical distribution

1.1.2.1. The EU leading countries

Three indicators have been selected in order to apprehend the geographical distribution of telemedicine solutions, as indicated in the illustration below:

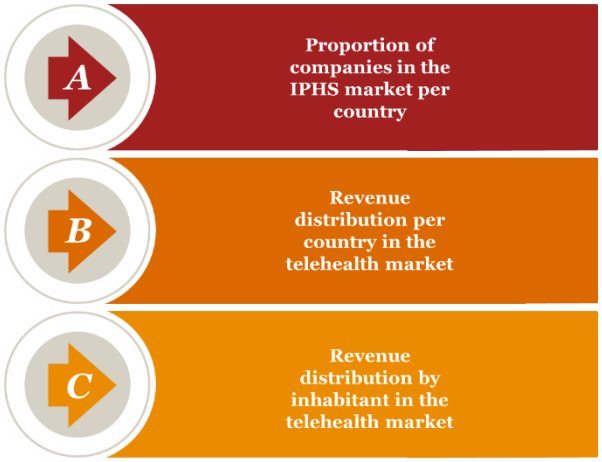


Figure 11: Indicators of the telemedicine market in Europe

Proportion of companies on the Integrated Personal Health/Care Services (IPHS) market per country

The number of companies on the IPHS market in Europe provides an overview of how the telemedicine solutions are distributed geographically. IPHS is a subcategory of telemedicine with a similar scope. According to the EU-funded project SIMPHS 2) Technical Annex:[22] "*Integrated Personal Health/Care Services address the health and/or social care needs of individuals outside of care institutions and support the work of care providers in an integrated fashion. IPHSs:*

a) *Can integrate assistance, remote monitoring of chronic diseases, wellness and fitness;*

b) *Are produced as a result of integration of different institutional and information systems. They are personal and possibly personalised in the way they gather, process, and communicate data (for feed-back/action) and in terms of technological components they can include".*

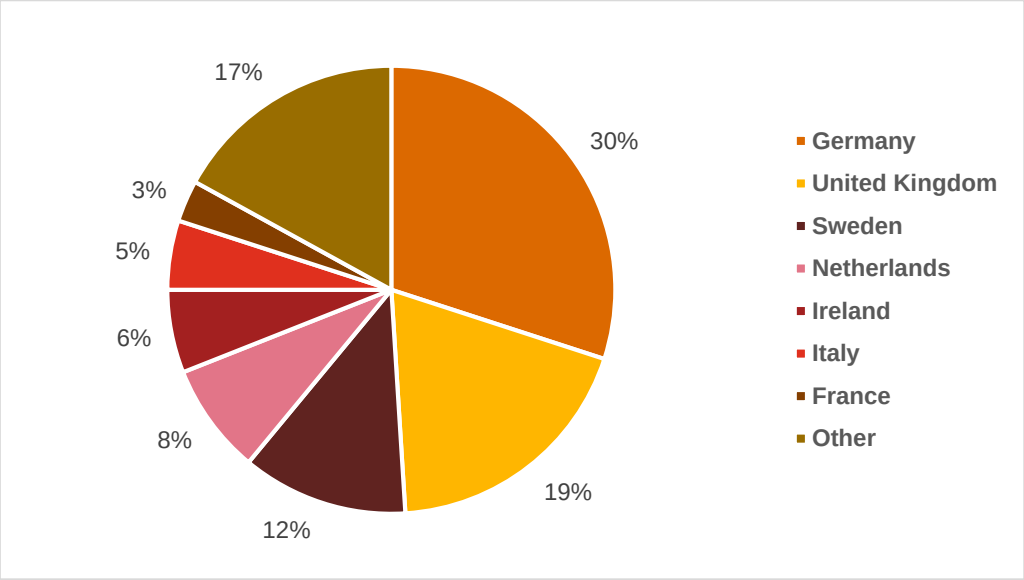


Figure 12: Proportion of IPHS companies per EU country
Source: SIMPHS 2 (2013)

The data referring to the IPHS companies on the market dates back to 2013 and takes into account 64 European IPHS companies identified by the Joint Research Centre. The proportional distribution of IPHS companies shows that Germany and the United Kingdom are the two European leaders in providing telemedicine solutions (see Figure 12 above). The same results emerge from our mapping: Germany and the United Kingdom are the two European countries in which telemedicine solutions are mostly used. The latter finding is expected give the population sizes of these countries.

Revenue distribution per country in the telehealth market

While – not surprisingly – Germany, France, the UK and Italy have a large proportion of telehealth market revenue given that they are among the largest EU countries, it is also interesting to note that if we aggregate the telehealth market revenues of Denmark, Sweden, Norway and Finland, Scandinavia appears to be a dynamic region in the market with revenues of over 129m euros. This is nearly 9% of total telehealth market revenues.

[22] Baum P., Abadie F., "Market Developments – Remote Patient Monitoring and Treatment, Telecare, Fitness/Wellness and mHealth", *JRC Scientific and Policy Reports*, 2013.

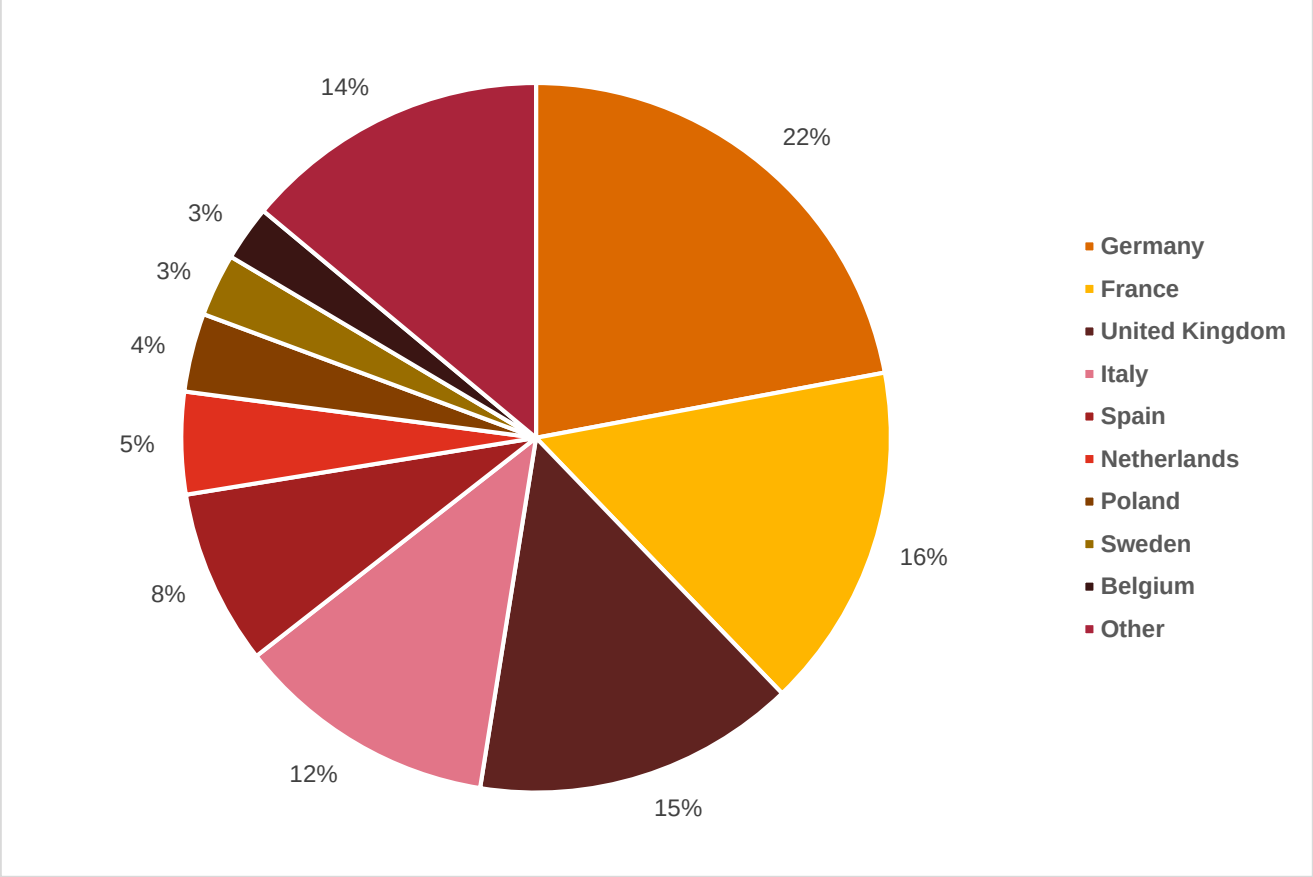


Figure 13: Telehealth revenue distribution in European countries (2016)
Source: Statista (2016)

Revenue distribution per inhabitant in the telehealth market

Indeed, when the telehealth market revenues are divided by each country's population, then the Scandinavian countries become EU leaders. Their telehealth market revenues per capita, especially in Denmark, exceed those of the United Kingdom and France. Of course, the living and medical costs in these countries are much higher to eastern and southern European countries.

Table 1: Telehealth market revenue per inhabitant in euros

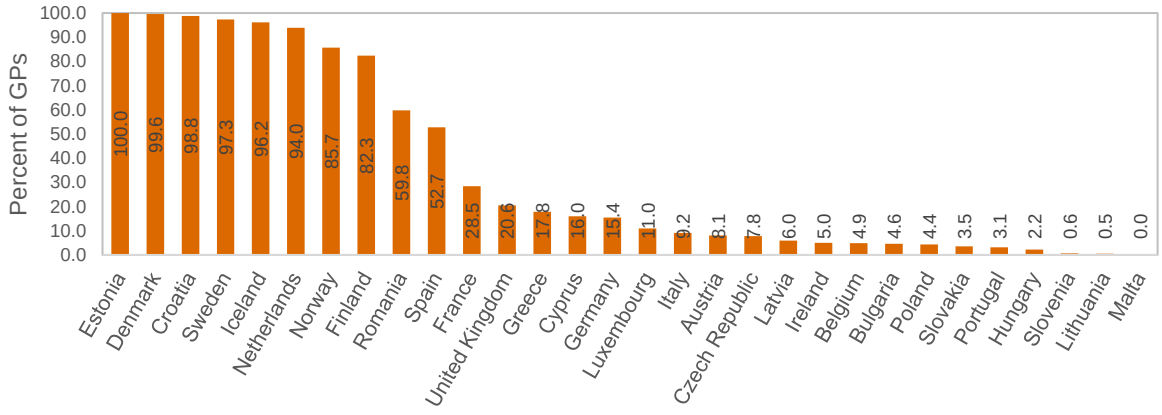
Country	eHealth market revenue per inhabitant (€)
Denmark	6.22
Sweden	5.05
Netherlands	4.75
Germany	4.69
Austria	4.66
Finland	4.46
France	4.09
United Kingdom	3.92
Belgium	3.87
Italy	3.38
Ireland	3.21
EU-24 average	3.05
Spain	2.97
Slovenia	2.68
Portugal	2.42
Czech Republic	2.26
Slovakia	2.14
Lithuania	1.98
Latvia	1.89
Croatia	1.80
Estonia	1.69
Poland	1.62
Hungary	1.25
Bulgaria	1.11
Romania	1.04

Further to the magnitude of the revenue per individual, which provides insight on the base of added value in the telemedicine sector per country and population, it is important to observe the **efforts and advancement of different countries from a different angle**. One way to illustrate such level of advancement of EU countries is to look at **other factors of development such** as the level of acceptance by the population and the speed of uptake of telemedicine solutions.

One indicator that can provide insight on the level of advancement of a country concerning the uptake of telemedicine tools and services is the **use of electronic networks and infrastructure by general practitioners in order to transfer prescriptions to pharmacists**, enabling a telemedicine solution that can improve patient management and follow-up.

In this specific domain, studies have shown that up to 2013, the top five EEA countries in terms of e-prescriptions were Estonia, Denmark, Croatia, Sweden and Iceland with nearly the full population of general practitioners using remote technologies for the transfer of prescription to pharmacists in digital format.

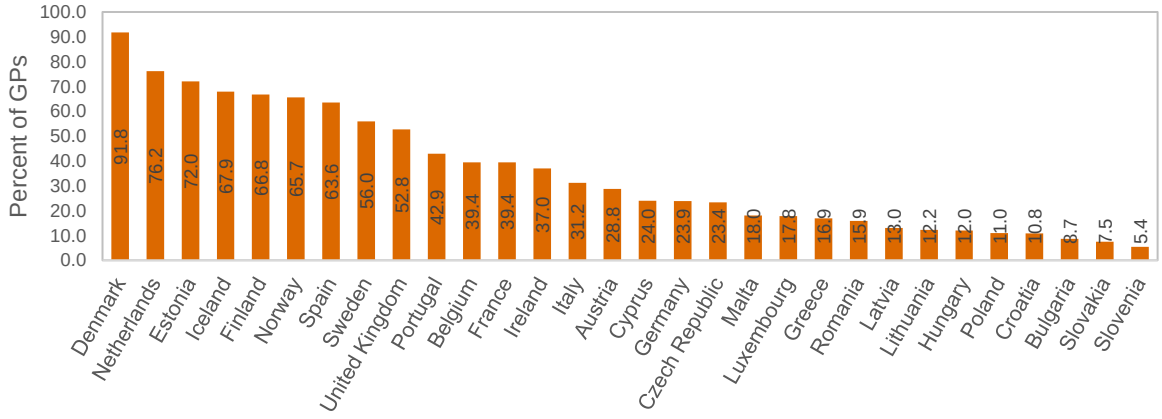
Figure 14 : Use of electronic networks for ePrescription (% of GPs)



Source: European Commission (2013). Benchmarking deployment of eHealth Among General Practitioners II.

The Commission study on the deployment of eHealth also indicates that the top five countries where **patient data exchange was the most accepted and diffused amongst general practitioners** were Denmark, the Netherlands, Estonia, Iceland and Finland.

Figure 15 : Patient data exchange with healthcare providers (% of GPs)



Source: European Commission (2013). Benchmarking deployment of eHealth Among General Practitioners II.

The observations made above show that even though wide revenues per capita in the sector of telemedicine can be made in northern and western European countries, it is in northern and eastern European countries where the adoption of telemedicine services and tools amongst health professionals and hence users is the fastest.

The outlook of the wide deployment of such tools and services across Europe depends not only on the size of national markets, but also on the speed of adoption by health professionals and by end users.

1.1.2.2. Scope of solutions by EU-based companies

Most solutions developed by EU companies have a **national or regional market**. Indeed, European market players first try to conquer national (or at least, regional) markets before taking the leap internationally.

Difficulties in entering markets in other EU countries or countries outside the EU are linked to **regulatory fragmentation** (different rules applicable to telemedicine in different countries) as well as **restrictions of the Social Security schemes** when it comes to their proposition to the patient. Overall, the interoperability of a telemedicine product/solution will be a crucial challenge in the next few years so that this product/solution can enter the global markets.

The European Commission, through its eHealth Action Plan 2012-2020, Digital Single Market policy and related initiatives[23] is endeavouring to **strengthen the interoperability of telehealth systems** between Member States and thereby cross-border use of telemedicine solutions.

1.1.3. Healthcare-context characteristics

Another result of our mapping is the identification of recurrent health-context characteristics. The major findings are:

- Prevention and telemonitoring are the more common usages for telemedicine solutions.
- Telemedicine solutions aim mostly at providing primary and home-based care.
- The main market segments are solutions for patient-doctor interaction, solutions for healthcare professionals' collaboration, and self-care solutions.

Figure 16: The main types of health context

[23] For instance the recent communication on enabling the digital transformation of health and care in the Digital Single Market, ttps://ec.europa.eu/health/sites/health/files/ehealth/docs/com2018_233_en.pdf

1.1.3.1. Health-context considerations

The study SIMPHS 3 (2015), conducted by the Joint Research Centre, exhibits the distribution of telemedicine solutions by type of intervention provided (from a sample of 86 solutions). The different types of intervention highlighted **do not include telemonitoring**. The graph below displays the distribution of telemedicine solutions among these types.

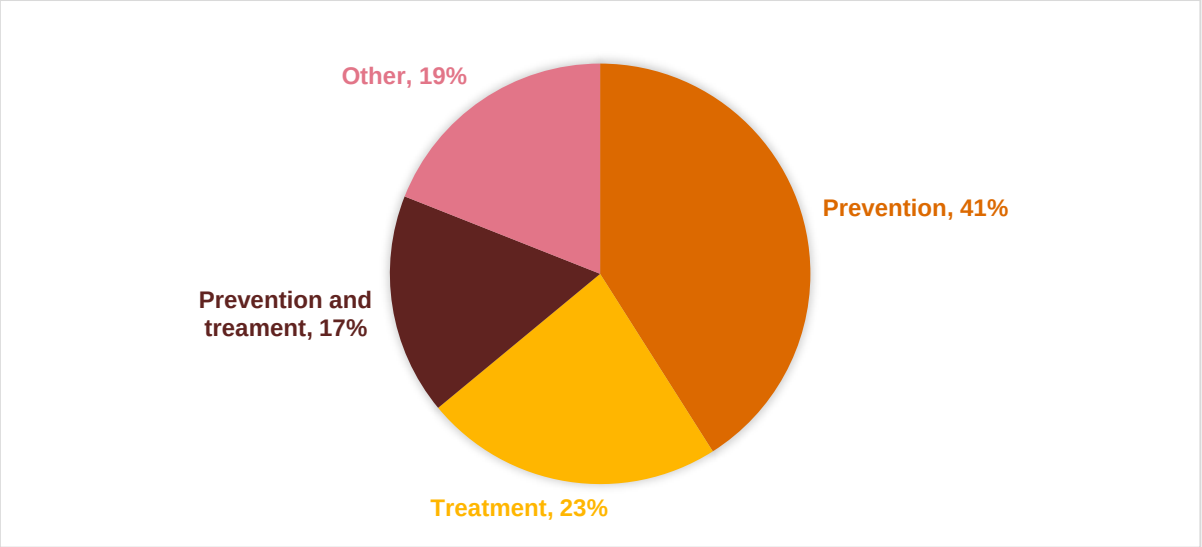


Figure 17: Type of intervention for telemedicine solutions
Source: SIMPHS 3 (2015)

Treatment for a disease is a type of intervention provided by 40% (23+17) of the telemedicine solutions. From our mapping, there are slightly fewer solutions that administer treatment. We understand medical treatment as the management and care of a patient to combat disease or disorder. Technologies able to cure or treat a disease directly seem less prevalent than they appear.

However, prevention is the dominant type of intervention covered by telemedicine, present in 58% of the solutions. We assume that telemonitoring has been included under prevention in this study, since telemonitoring contains reviews and follow-ups by professionals to reduce the occurrence of complications. Remote patient monitoring seems to be the most widespread telemedicine solution, as the existing technologies enable this medical practice to be implemented effectively.[24]

Voluntary (or unspecified) usage largely outweighs mandatory usage in our mapping. This is due to our methodology approach, which consists of considering a solution mandatory only when it is clearly specified. Another hypothesis is that conditions for mandatorily adopting telemedicine solutions in a healthcare programme have not yet been considered. These barriers from adoption are treated in Work Package 3.

[24] "Strategic Intelligence Monitor on Personal Health Systems, Phase 3", 2015

1.1.3.2. Level of care usage

Remote patient-monitoring devices are meant to increase *residential and home based care*. Hospitals use these solutions to substantially **lower costs and risks related to hospitalisation**. Indeed, by implementing suitable follow-up care and care management of patients at home, hospitals can prevent unnecessary readmissions.

Many of the solutions also aim at providing *primary care* to patients. Primary care providers such as general practitioners (GPs) can take a lot of time following up with patients coming into their office. Telemedicine offers appropriate means to **save time for both practitioners and patients without compromising on care efficiency**. Using the Telea Digital Home Platform developed by Sergas (Spain), a single healthcare professional can monitor up to 50 patients through videoconferencing, electronic health records, custom notifications, etc.

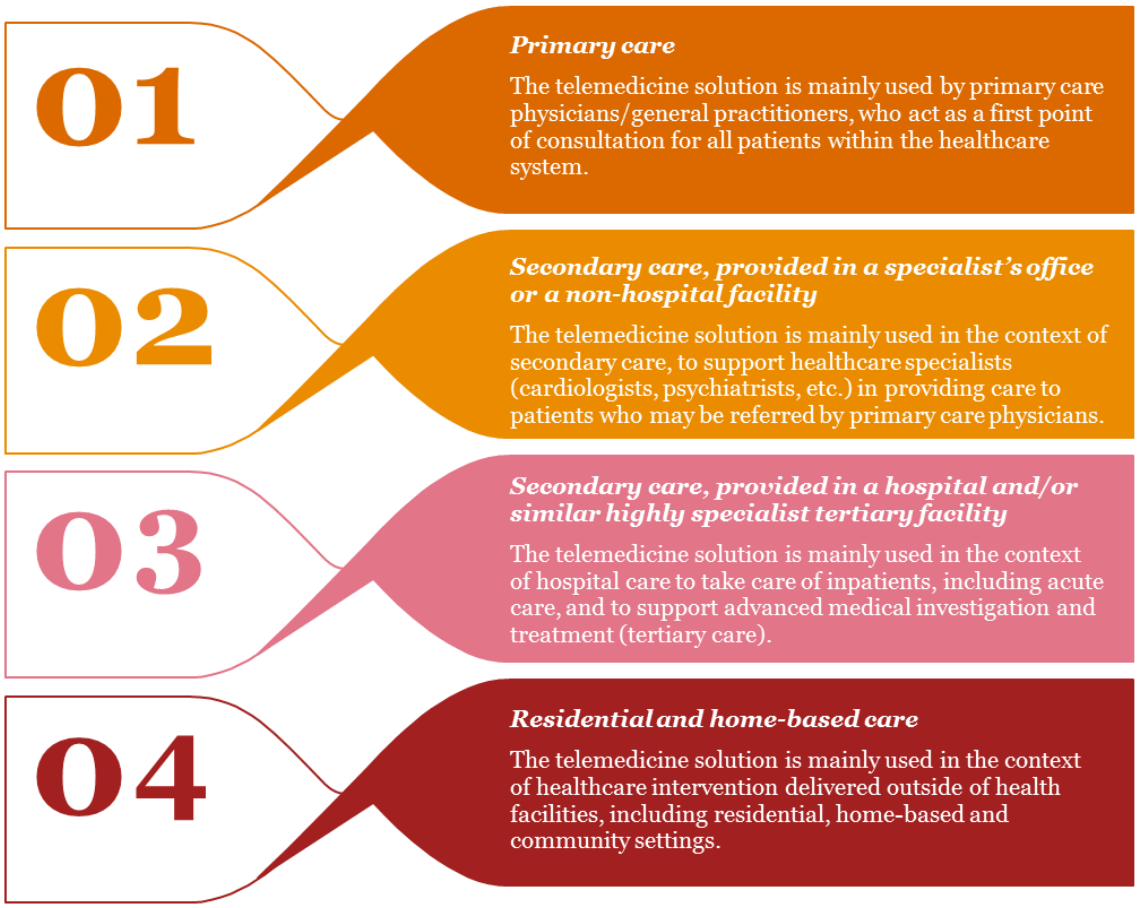


Figure 18: Different levels of care usage

Telemedicine solutions for *specialist care providers* are also becoming an integral part of healthcare delivery. They allow for patients with chronic conditions to be better managed, thanks partly to the remote monitoring devices. This also affects the patients' care pathway, as primary care doctors have easy access to specialists. This way, the specialist can make an immediate diagnosis and the primary care provider can start a treatment plan rather than sending the patient to the specialist.

For instance, Dermtest (Estonia) is a software platform connecting general practitioners with dermatologists, to provide an early skin-cancer detection service to patients at their local general practitioner's office.

1.1.3.3. Stakeholders

Our analysis shows that the market is mainly divided into two segments: a) solutions between healthcare professionals and patients (B2C), and b) devices for self-care. An illustration of the interaction between doctors, patients and health professionals is present in Figure 19 below.

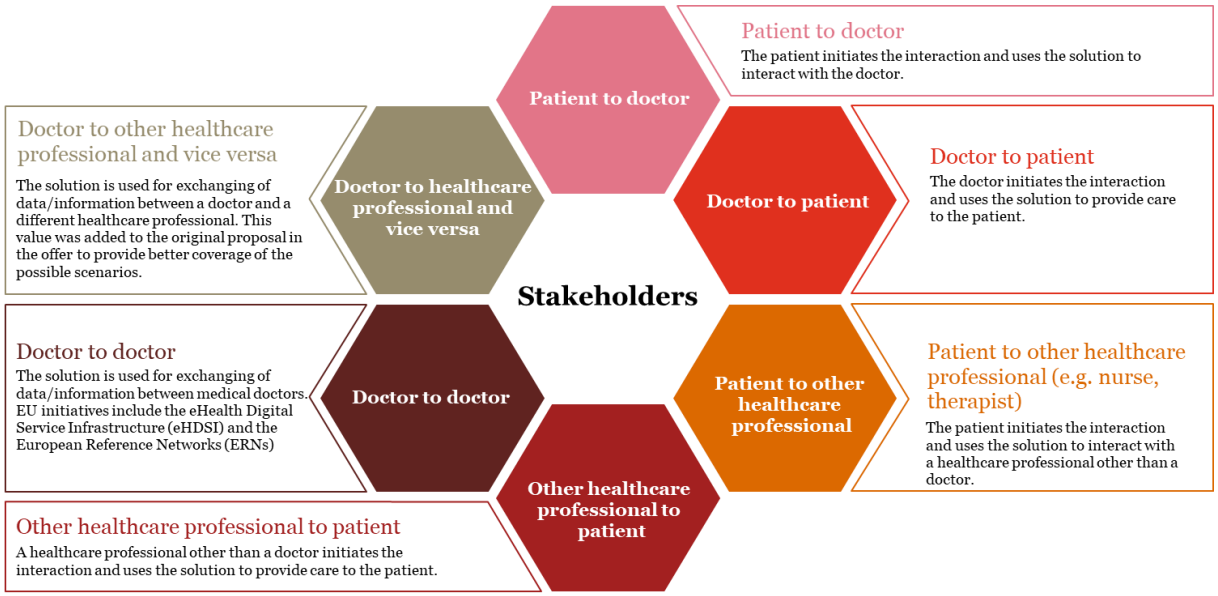


Figure 19: Interactions between stakeholders

Currently, one out of every two telemedicine solution targets self-care. In comparison, solutions for professionals are lagging behind. These findings are in line with our market research for 2017. There are only a few solutions involving doctor-to-doctor or doctor-to-healthcare-professional interactions. It seems that the health market is characterised by **slow adoption rates for solutions targeting collaboration among professionals (B2B)**. It merits note that the EU supports cross-border collaboration between health professionals. One such initiative by the EU is the **eHealth Digital Service Infrastructure**[25] (**eHDSI** or eHealth DSI), which is the initial deployment and operation of services for cross-border health data exchange under the Connecting Europe Facility (CEF). Another is the European Reference Networks (ERNs) – virtual networks involving healthcare providers across Europe. Indeed, ERNs aim to tackle complex or rare diseases and conditions that require highly specialised treatment and a concentration of knowledge and resources. There are 24 ERNS involving 25 European countries included Norway, over 300 hospitals with over 900 healthcare units and covering all major disease groups.[26]

Solutions for the interaction between patients and health care professionals utilise technology that provides more efficient care delivery. Such technology operates as a support mechanism and does not completely disturb the traditional doctor-patient relationship. However, devices for self-care do challenge this long-established relationship. Patients equipped with such devices may be able to take care of themselves, regardless of any doctor's intervention. Solutions for self-care might run counter to

[25] https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/eHDSI+Mission
[26] https://webgate.ec.europa.eu/ern/

telemedicine, which is defined as 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. Yet, all solutions relating to self-care ended up in the "Patient to doctor" category, as we consider that doctors can supervise self-care treatments.

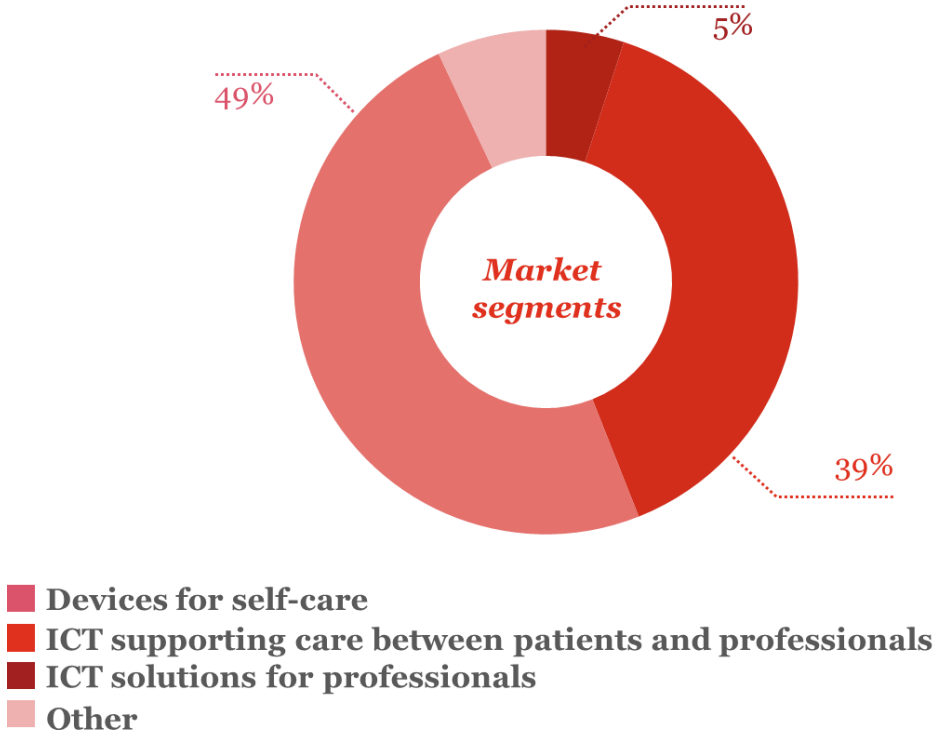


Figure 20: Solutions by market segment
Source: SIMPHS 3 (2015)

1.1.3.4. Specific medical aspects

The majority of telemedicine solutions mainly target primary care highlighting its importance. There are also solutions for specific medical specialties but these are more limited in scope. Most solutions with a medical specialty concern heart failure, diabetes and COPD, which concern a significant part of patients with chronic diseases.

Medical specialties

From our research, **telecardiology, telepulmomology and teleendocrinology** are the three medical specialties that account for most of the telemedicine solutions. The underlying hypothesis is that these specialties are particularly well suited to a technological and virtual-care environment. They are fully exploiting the currently available technologies to design devices and software tailored to patients' needs.

The above three solutions are followed by teledermatology, teleoncology, teleneurology and telemental health. Solutions in these specialties exist but are less widespread because they usually require more advanced technologies. For instance, many watches can measure heart rate and blood pressure, but no common devices exist to measure neurological activity.

Besides, a large number of telemedicine solutions reported in our mapping do not refer to any specific medical specialty. In particular, this observation concerns platforms that aim at connecting patients to specialist doctors.

Disease specifics

Unsurprisingly, the results for disease specifics corroborate those observed for medical specialists.

The chart below displays how many European companies on the IPHS market address the main diseases. In summary, cardiac conditions are addressed by 68% of the companies, diabetes and COPD by about 50%.

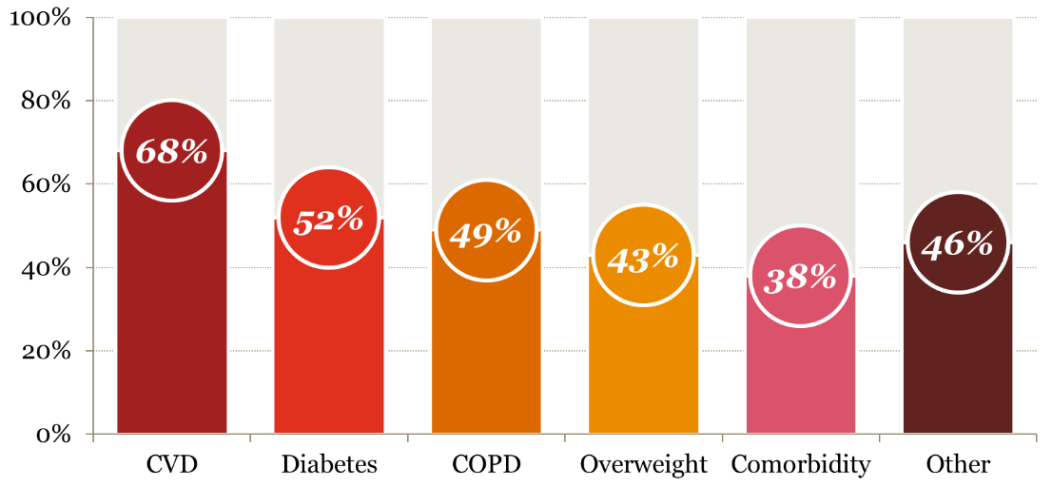


Figure 21: Companies on the IPHS market – medical focus
Source: IPTS – SIMPHS 1 (2011)

Cardiovascular diseases, diabetes and chronic obstructive pulmonary disease are the most treated by companies. This is consistent with the results for medical specialties, where telecardiology, telepulmonology and teleendocrinology accounted for the most of the telemedicine solutions.

1.1.4. Analysis of the status of telemedicine solutions

In this section, we focus on the timing of development of the telemedicine solutions. These solutions are in various stages of maturity, from pilot phase to operational for more than five years. Our analysis reveals that among the solutions studied as part of the mapping exercise **solutions operational for more than five years are slightly more common**.

Figure 22: Levels of development of telemedicine solutions

Indeed, the situation as of 2013 shows that companies existing for more than five years are dominating the market. Again, as IPHS is very close to telemedicine, the chart in Figure 23 provides significant conclusions as regards as the status of telemedicine solutions in 2013.

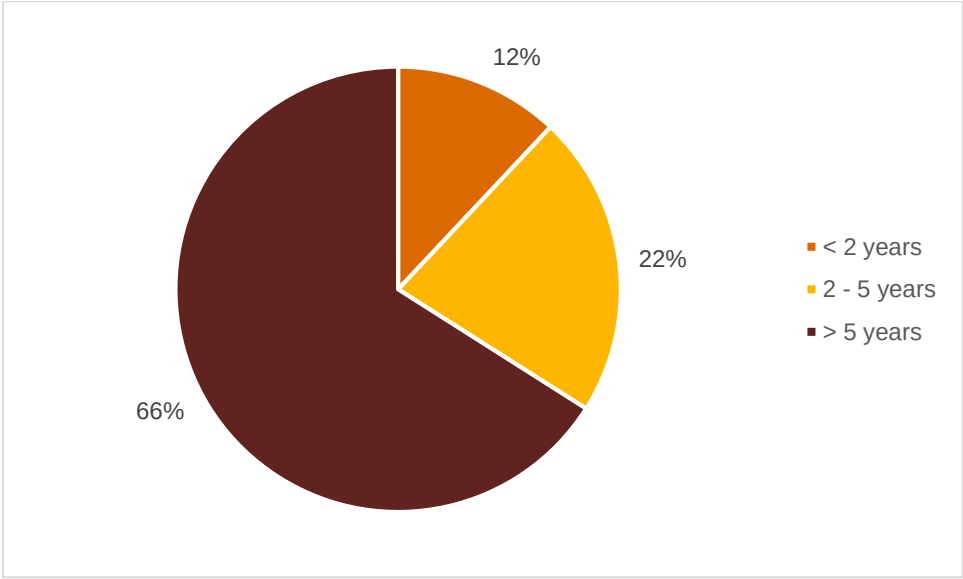


Figure 23: IPHS company distribution – years in business
Source: SIMPHS 1 (2011), SIMPHS 2 (2013)

It is apparent from our research that most solutions have been operational for more than five years. This means that the first versions of these solutions should have been launched before 2013, although they are likely to have evolved since then. On the contrary, telemedicine companies keep upgrading their products, platforms and software so that **they can incorporate new attractive options and the latest technology available**. They also offer the same product at different quality levels (and thus, prices), in order to target different segments of patients with various income levels.

Yet, new innovative solutions are increasingly gathering momentum in telemedicine thanks to the multiplication of start-ups and the initiatives of hospitals, research centres and universities. For instance, the University Hospital of North Norway (NST) and the Austrian Institute of Technology (AIT) are developing their own blood glucose measurement and management systems, which are currently in the pilot phase.

1.2. Analysis of standards and guidelines

Before presenting the results of the desk research on standards and guideless it is necessary to distinguish these terms and provide definitions that will allow for a better reading of this section. The definitions for the terms "standard" and "guideline" are provided in Figure 24 below:

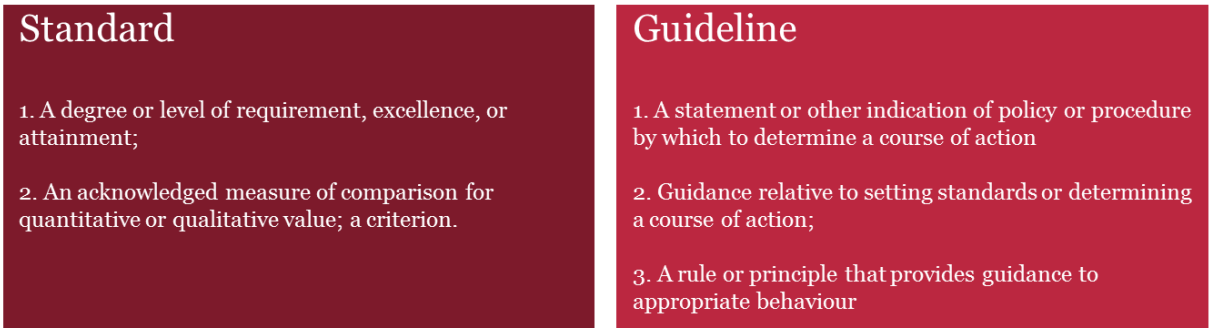


Figure 24: Definitions of standard and guideline

The current standards and guidelines identified have been classified in three ways: by typology of issuing bodies (e.g. EU standardisation, medical association, national standardisation), by geographical area (Europe, North America, international), and by category (data-protection rules, human resources guidelines, technology and equipment guidelines/standards, clinical guidelines, ethical guidelines, organisational guidelines, and EHR guidelines).

1.2.1. Typology of issuing bodies

The supranational standardisation bodies account for most of the existing standards and guidelines. Bodies such as the International Organization for Standardization (ISO) and the ITU Telecommunication Standardization Sector (ITU-T) have published hundreds of guidelines for providing telemedicine services. In the European Union, CEN is the supranational body that issues the most standards and guidelines.

As already stated, few telemedicine standards and guidelines spring from national standardisation bodies' publications, since they work in close coordination with CEN. However, *national medical associations* **supplement these national bodies with some additional standards and guidelines**. They usually have a medical focus and provide precise requirements for medical specialties (e.g. the *Società Italiana di Radiologia Medica* (SIRM) for teleradiology). In North America especially, the American Telemedicine Association (ATA, in the US) and more specific associations, such as the Canadian Association of Radiologists, also issue numerous documents and guides providing best practices and requirements for various telemedicine specialties.

1.2.2. Geographical spread

Most of the existing telemedicine standards and guidelines are **international in scope**. This is due to the sustained activity of supranational independent bodies that release numerous reports and documents each year. Their publications are usually **free to access** so that best practices spread all over the world. The International Organization for Standardization (ISO) is responsible for most publications of international standards.

Organisations from the US and the EU also play a key role in the publication of telemedicine standards. The primary goal is to standardise the best practices between their states and Member States respectively.

For the EU, the principal standardisation body is the European Committee for Standardization (CEN), which brings together the national standardisation bodies of 34 European countries. CEN is committed to developing and delivering European standards in close cooperation with ISO. Other European bodies are the European Committee for Electrotechnical Standardization (CENELEC) and the European Telecommunications Standards Institute (ETSI), which are very involved in telemedicine.

At national level, action on standards and guidelines relies on national standardisation bodies and medical associations. In the EU, national standardisation bodies aim at **coordinating standardisation in the country**, in collaboration with CEN, to which they belong. From our research, it appears that these national bodies are not as prolific as international or supranational bodies. For each country, we found a few standards and guidelines issued by national standardisation bodies. Our mapping shows that the UK's and France's bodies seem to publish the most national telemedicine standards in the EU.

1.2.3. Guideline/standard category

Technology and equipment guidelines/standards are the most widespread telemedicine standards. This result was quite predictable, since technology is at the core of telemedicine practice. Some examples of technology standards and guidelines include: the format and quality necessary for medical images in teleradiology; the performance requirements for software and medical products; the broadcast capability; video coding and decoding methods for moving pictures; and the clarification of the vocabulary specific to the security of information systems. Other standards/guidelines specify general and functional requirements for the use of the product/service.

Figure 25: Typology of standards and guidelines

Data-protection rules are also quite common. They **aim to control how personal data can be used and ensure the patient's rights regarding his/her information**. For instance, ISO/TS 17975 defines the set of frameworks of consent for the collection, use and/or disclosure of personal health information by healthcare practitioners or organisations. Another illustration is the Code of Conduct on privacy for mHealth apps issued by the European Commission in 2016, which is currently under review after the comments provided by the WP29[27]. It targets app developers and provides specific and accessible guidance on how European data-protection legislation (the General Data Protection Regulation - GDPR[28]) should be applied in relation to mHealth apps. At this stage, mHealth apps need to comply with the GDPR.

Organisational guidelines **outline the way in which business is to be conducted and govern what is deemed acceptable workplace behaviour**. The ISO 9001 standard is based on a number of quality management principles, including a strong customer focus, motivation and involvement from top management, process approach and continual improvement. It is supposed to help ensure that customers get consistent, high-quality products and services, which in turn brings many business benefits.

Clinical guidelines **recommend how healthcare professionals should care for people with specific conditions**. They can cover any aspect of a condition and may include recommendations about providing information and advice, prevention, diagnosis, treatment and longer-term management. *A Concise Guide for Telemedicine Practitioners Human Factors: Quick Guide Eye*

[27] http://www.osborneclarke.com/insights/mhealth-apps-the-code-of-conduct-on-privacy-explained/
[28] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN

Contact, issued by the American Telemedicine Association (ATA), is summarises eye contact and its importance for telemedicine practitioners delivering remote healthcare services. The guide covers the importance of eye contact, eye-contact etiquette, tips for camera positions and viewing screens, clinician positions, and other key tips for optimising healthcare provider-patient interactions and relationships.

Human resources guidelines **intend to inspire, educate and support board members, managers and employees with regard to the fundamental role that HR management policies and practices have in creating effective organisations**. Standards such as the International Code of Practice for Telehealth Services 2017 (Telehealth Quality Group) cover aspects including staff management, building a prepared and competent team, and the qualifications and responsibilities of personnel in a telemedicine environment. Nonetheless, human resources standards are rarer.

Ethical guidelines embrace a broad array of concepts. The American Medical Association (AMA) provides recommendations regarding:

- Managing conflicts of interest: physicians should provide objective and accurate information;
- Privacy and security: services must have appropriate protocols to protect the security of patient information and prevent unauthorised access to such information;
- Patient consent; and
- Standards of care: physicians should uphold the standards of professionalism expected for in-person interactions and adhere to applicable law governing the practice of telemedicine.

EHR guidelines **are intended to aid healthcare providers and healthcare IT implementers with in implementing an EHR system**. The overall goal of ISO 13606 is to define a rigorous and stable information architecture for communicating part or all of the electronic health record (EHR) of a single subject of care (patient). In addition to this standard, ISO 18308 defines the set of requirements formulated to ensure that these EHRs are faithful to the needs of healthcare delivery, are clinically valid and reliable, are ethically sound, meet prevailing legal requirements, support good clinical practice, and facilitate data analysis for a multitude of purposes.

Standards and guidelines aim to spread good practices and guarantee a certain level of requirement in the use of telemedicine solutions. They also aim to **ensure interoperability between different devices, systems, organisations and countries**. To increase the adoption of telemedicine in healthcare, it is fundamental to create conditions whereby solutions are compatible with other systems.

Thus, some institutions work to make sure that established standards are well coordinated. For instance, Integrating the Healthcare Enterprise (IHE) promotes the coordinated use of established standards such as DICOM and HL7 to address specific clinical needs in support of optimal patient care.[29] IHE also tests the interoperability of health information technology (HIT) systems. PCHAlliance, a non-profit organisation formed by HIMSS, encourages the global adoption of the Continua Design Guidelines, an open framework for user-friendly, interoperable health-data exchange in personal connected health.[30]

It is relevant to mention here the work of the *eHealth Network* as well, which is composed of members coming from the 28 EU Member States and Norway (as an observer) and holds biannual meetings[31] to discuss issues regarding patient access to electronic health record information, interoperability and standardisation. The Network has developed guidelines in relation to ePrescription and the Patient Summary:

[29] https://www.ihe.net/About_IHE/
[30] http://www.pchalliance.org/personal-connected-health-alliance
[31] https://ec.europa.eu/health/ehealth/events_en#anchor0

- The *Guidelines on ePrescriptions dataset for electronic exchange under Cross-Border directive 2011/24/EU: Release 1*[32] and the *Guidelines on the electronic exchange of health data under Cross-Border directive 2011/24/EU: Release 2 ePrescriptions and eDispen*sations[33] have been prepared and validated by the eHealth Network in 2014 and 2016, respectively;
- Similarly, the eHealth Network first adopted the *Guidelines on minimum/nonexhaustive patient summary dataset for electronic exchange in accordance with the Cross-Border Directive 2011/24/EU*[34] in 2013. Three years later (in 2016), after a revision, the eHealth Network adopted the *Guideline on the electronic exchange of health data under Cross-Border Directive 2011/24/EU: Release 2 Patient Summary for unscheduled care*[35].

1.2.4. Medical specialties

From our research, the vast majority of standards and guidelines **do not pertain to any medical specialty**. Recommendations formulated by bodies often lay down principles and good practices about telemedicine in general, without focusing on any specific discipline.

Telecare, telecardiology, teleradiology and teleendocrinology are the specialties most targeted by standardisation bodies. Obviously, this relates to their level of development and use: the more solutions, the more standards and guidelines.

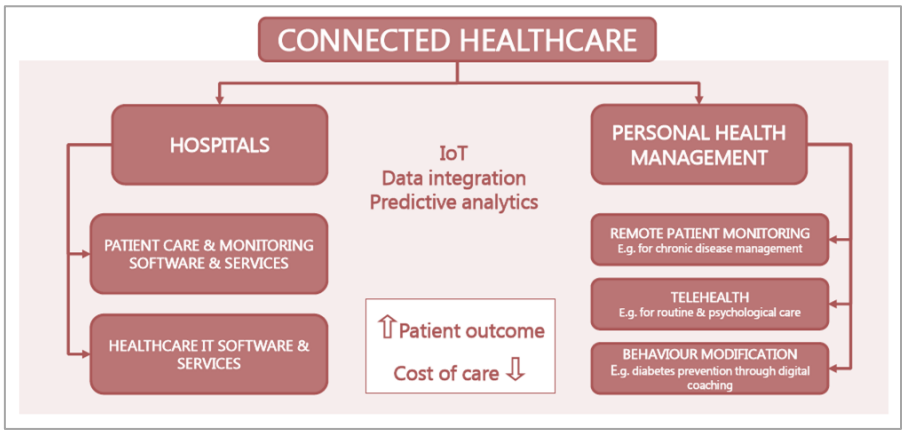
[32] https://ec.europa.eu/health/sites/health/files/ehealth/docs/eprescription_guidelines_en.pdf
[33] https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20161121_co091_en.pdf
[34] https://ec.europa.eu/health/sites/health/files/ehealth/docs/guidelines_patient_summary_en.pdf
[35] https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20161121_co10_en.pdf

2. Market analysis

Key takeaways

- The uptake of information technologies in Europe is the main accelerator for telemedicine.
- The market potential of telemedicine is strong. It is expected to grow at a compound annual growth rate of 14% in the coming years.
- The well-being market enabled by digital technologies (mobile applications, devices) is rapidly growing as well.
- Demand outpaces supply, but this should be read with care, as there are many telemedicine initiatives but hospitals and clinics do no have the means to pay for the technology.
- Market players include: telecommunication companies, ICT tools and electronics manufacturers, device manufacturers, pharmaceutical industry companies, and start-ups.
- US and Canada have outperformed the EU, whilst Japan has a lower number of users of telemedicine.

Key objectives addressed by the uptake of the telemedicine market are the improvement in patient management, treatment and care, coupled with a reduction in costs at both individual and societal levels. Telemedicine itself is part of a larger framework of connected healthcare, which takes the perspective of both institutional and individual users of health services provided in a remote manner through data transmission and new digital technologies.



Source: XERFI, 2017

Figure 26: Telemedicine in context, the connected healthcare framework

2.1. Market fundamentals

Telemedicine covers a very wide area of products, services, procedures and techniques. In essence, it designates all aspects relating to the progressive transformation of the health sector due to the introduction of ICT, and relies on continuous investment in digital infrastructure and digital skills in the healthcare industry. As part of a set of health information technologies, telemedicine has gained more visibility amongst governments and market players in recent years; these technologies play a key

role in the European Union's digital strategy and have become one of the lead initiatives to create an innovative Europe in a dynamic, knowledge-based economy.[36] Therefore, telemedicine technologies require not only the use of information technology (including hardware, software, telecoms and IT services), but also the leveraging of skilled human resources to enable healthcare services to be delivered from distance or a remote location.

The principal telemedicine market drivers and trends during recent years have therefore been an uptake and democratisation of information technologies, which have enabled the remote transmission of information at ease, speed and marginal cost. These information technologies have progressively defined a commercial ecosystem of health information technologies, which is currently experiencing rapid growth globally.[37] According to market figures provided by Statista, the global telemedicine market was valued at €16.3 billion in 2015, and is expected to reach more than €37 billion by 2021, with a CAGR of 14% during that period. This dynamic sector therefore has the potential to drastically influence the delivery of efficient patient care at a lower cost for healthcare markets worldwide.

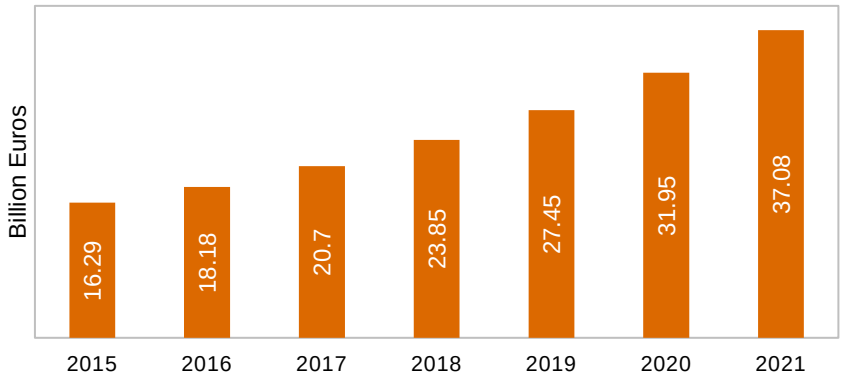


Figure 27 : Global telemedicine market size from 2015 to 2021 (in billion Euros)

2.1.1 Description of the solutions/products that make up the telemedicine market

As described in Chapter 1 of this report, telemedicine solutions include products and/or platforms that **collect and store patient information and data that can be treated remotely** by a doctor, healthcare professional or analyst to interpret it and enhance patient management, treatment and care.

These solutions often have multiple components, including hardware and software in embedded systems sold as one product.[38] The most prominent systems in telemedicine embed mobile technologies to ensure continuous functionalities related to the **storage and transfer of administrative and medical patient data** to health personnel and administrations. Furthermore, telemedicine solutions are increasing in complexity every day. The trend in newer generations of solutions is advancing the types of functionalities, which now include real-time communication,

[36] European Commission & Directorate General Information Society. (2009). Study on the Legal Framework for Interoperable eHealth in Europe. *European Commission*, 1–128.
[37] https://www.trade.gov/topmarkets/health-it.asp
[38] Global Intelligence Alliance. (n.d.). Embedded Systems for Telemedicine in Germany. Retrieved from https://www.cbi.eu/sites/default/files/study/product-factsheet-embedded-systems-telemedicine-sweden-finland-denmark-electronics-electrical-engineering-2014.pdf

adaptive scheduling, resource management, multitasking, artificial intelligence and the transfer of data from sensor to destination.

The use of these systems over recent years has intensified the development of remote patient management and monitoring. According to market estimation figures provided by Statista, the market revenue from wearable devices and services has constantly grown over the last five years from €13 billion to €23.1 billion and is expected to increase by an additional €9 billion by 2020.

2.1.2 Geographical distribution of the market

Telemedicine – and to a wider extent information health technology – encompass a sector that, as we described earlier, has experienced continuous incremental global growth in the last few years. Further analysis of available market data indicates a similar pattern of continuous growth, albeit at different pace, across several economies.

In Section 1.1.2, the geographical distribution of telemedicine solutions in the EU was estimated by studying the distribution of integrated personal healthcare services across EU Member States for which data is available. Based on this estimate, we have observed a concentration of companies in countries with relatively high healthcare expenditure per inhabitant. In economies beyond the EU28, this analysis indicates that the size of the telemedicine market, in estimated users per inhabitant, is growing across countries leading in digital technologies.

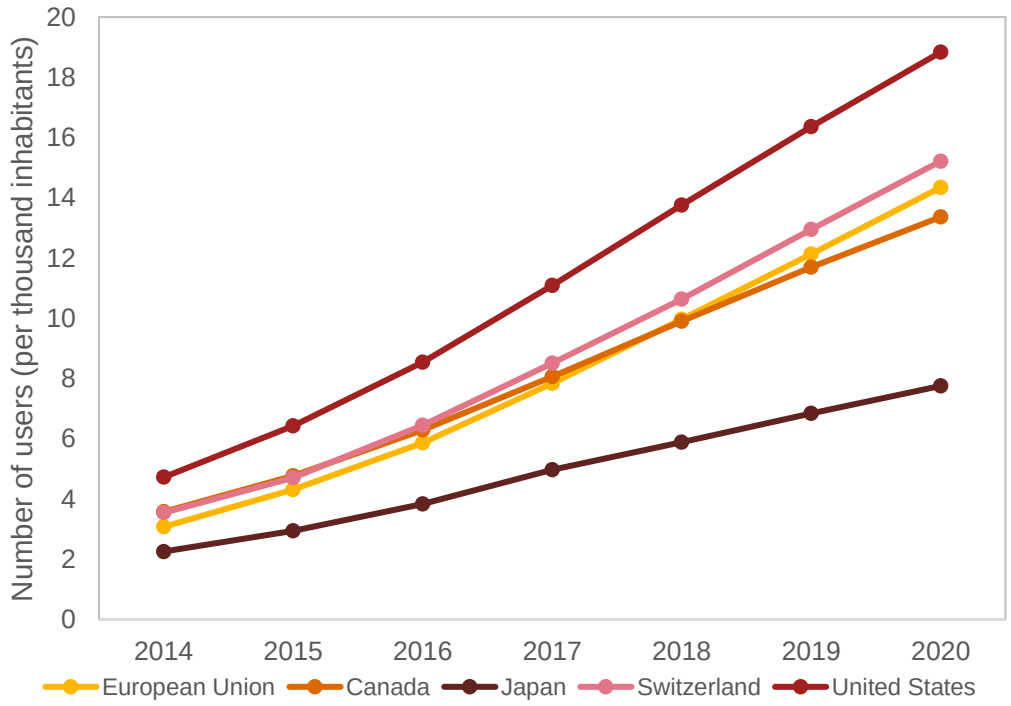


Figure 28: eHealth market outlook. Total number of users in the market (millions) by geographical region. Source: Statista estimates – trends include per population for three principal diseases (diabetes, hypertension and heart failure) and World Bank data on total population

According to Statista's "Digital Market Outlook"[39], the "number of users" covers users in three main telemedicine product categories:

- Connected medical devices ("smart devices"[40]);
- Digital tracking and monitoring applications for smartphones and/or tablets ("apps"); and
- Telemedical services for patients at risk ("telemedical services"). Hardware and software solutions for healthcare professionals (e.g. medical equipment for hospitals and doctors' surgeries) are not included.

Further to this trend, total market revenues associated with the number of users follows similar pattern. This analysis of the potential market size is estimated by calculating the number of users and the total revenue for three principal chronic diseases (diabetes, hypertension and heart failure), and is expressed in total users and total Euros per thousand inhabitants. It shows that although the use of telemedicine solutions and information health technologies is expected to follow a similar pattern across the main economies under review, the gap between generated revenues is currently increasing and diverging, indicating an increased ability of other economies to obtain larger shares of value creation.

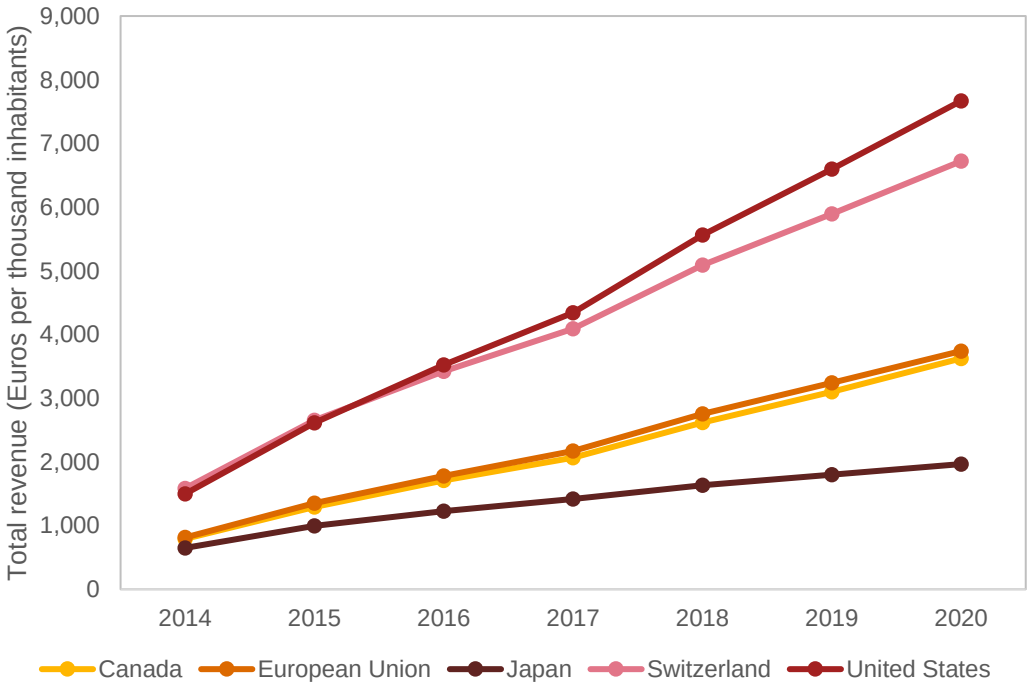


Figure 29: eHealth market outlook. Per capita market revenues (Euros/1000 population) by geographical region.
Source: Statista estimates. Trends include per population for three principal diseases (diabetes, hypertension and heart failure) and World Bank data on total population

[39] Statista (2015). Digital Market Outlook. Available at https://www.statista.com/outlook/digital-markets
[40] The "Smart Devices" segment covers medical devices (hardware) that are equipped with dedicated interfaces or SIM cards that serve to transmit measurement data across a wireless connection (e.g. via mobile networks, WiFi, Bluetooth, M2M technologies, NFC, BLE). The selection of suitable equipment is dependent on the individual health status of the patient and the severity and presence of other conditions (e.g. a combination of severe heart failure and cardiac arrhythmia).

In terms of total volumes of revenues and users, the US eHealth market is much larger Canada's and Japan's eHealth market.

However, it is important to notice that Japan presents total revenues of €448m in 2018 in the eHealth market that can be compared to the total revenues in the eHealth market in leading EU countries; indeed, these revenues are close to Germany's €554m and are higher than France's €400m and the UK's €366m[41]. On the contrary, the eHealth market in Canada represents half the size of the market in the above EU countries and for 2018 it is expected at the level of 165 million Euros.

2.1.3 Focus on three key global markets

We have dedicated this section to the development of telemedicine in the United States, Canada and Japan. Overall, our main observations indicate that:

- The United States is the pioneer country worldwide in telemedicine,
- Canada is a forerunner in binding market players to comply with national telemedicine standards and interoperability; it has established certification processes, and is considered an early adopter of data protection legislation for eHealth,
- Japan is lagging behind in relative terms.

USA

From a global comparison perspective, most eHealth revenue is generated in the United States (€3,210m in 2018). Furthermore, revenue is expected to grow at an annual rate (CAGR 2018-2020) of 14.2%, resulting in a market volume of EUR 4,187 million in 2020. The market's largest segment is heart failure, with a market volume of EUR 1,319 million in 2018. In addition, investment deals in the eHealth sector are mainly observed in the USA.

Among eHealth solutions for diabetes, hypertension and heart failure, products for heart-failure patients generated the highest revenue in 2016, at €854 million. Heart disease is the major cause of death in the United States, accounting for 23.4% of deaths in 2014. Like in the EU, prevention and treatment are the prevailing types of intervention for telemedicine solutions. Ambient assisted living (AAL) only includes devices to track the user's health data at home, and cannot therefore fall under the telemonitoring category. In the same way as the distribution of intervention types in the EU countries, we assume that other telemonitoring solutions are split between prevention and treatment.

[41] Source: https://www.statista.com/statistics/515701/global-comparison-ehealth-revenue-digital-market-outlook/

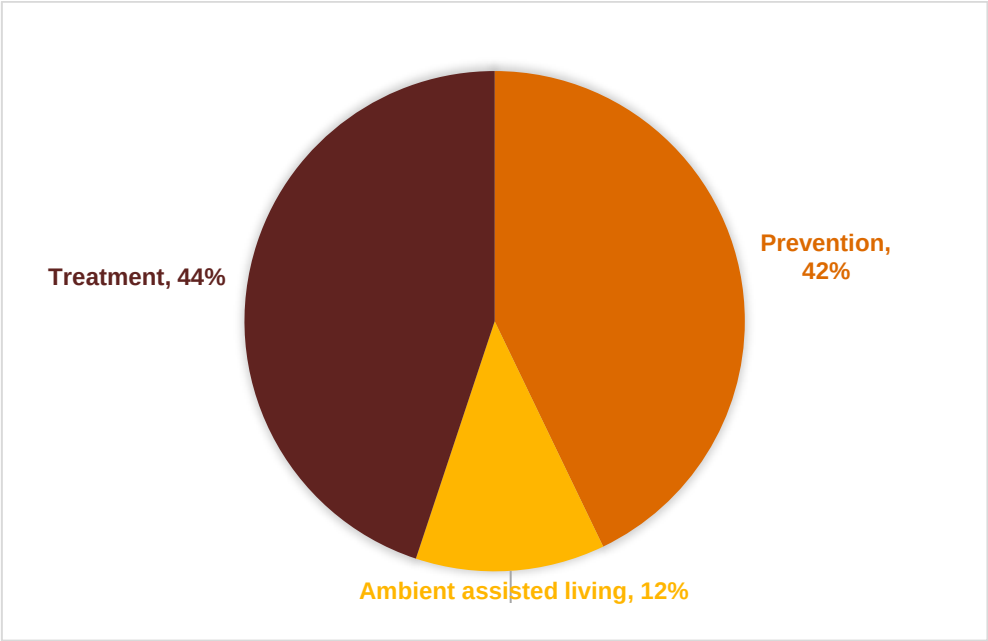


Figure 30: Distribution of eHealth revenue across three key categories of utilisation in the United States in 2016
Source: Statista (2017)

In summary, the United States can be considered a **pioneer and leading country in embracing telemedicine**. Furthermore, telemedicine in the US has conquered healthcare at all levels.[42] The following examples support this finding.

1. Hospitals use telemedicine to provide their patients with specialist care (chronic disease monitoring, follow-ups) to prevent unnecessary and costly readmissions.
2. Telemedicine is a way for employers to establish cheaper insurance plans for their own employees. Nine out of ten employees can use telemedicine services.
3. Telemedicine also concerns urgent and primary care, as it raises customer retention and saves costs in 24/7 services.
4. Doctors use telemedicine to avoid unnecessary, time-consuming visits to their offices.

Canada

The adoption of telemedicine in Canada has fallen in the last few years in comparison to other developed countries. However, the country endeavours to catch up with these countries, now that **conditions for countrywide implementation have been fulfilled**.

Across Canada, the delivery of care via telemedicine continues to expand. Telemedicine grew by 45.7% from 2012 to 2014. From 2010 to 2016, telemedicine delivery more than doubled. Besides, the delivery of telemedicine services through means such as remote monitoring or teleconsultation is a tremendous opportunity for Canada, since the country suffers from an unequal geographical distribution between trained medical professionals and the general population. The increasing popularity of telemedicine solutions might provide the large rural population with easier access to healthcare.[43]

Actually, according to Infoway, both the public and medical professionals are embracing telemedicine. In 2015, more than one in five hospitals made remote monitoring services available and more than

[42] Dr Andrew Lin, "2017: Telemedicine in the US and beyond", April 2017.
[43] International Trade Administration.

350,000 Canadians used medical devices that capture and transmit data electronically to their healthcare provider for monitoring and support.

Canada has been a forerunner in binding market players to comply with national telemedicine standards and interoperability, which can be considered a strength for the national market environment. Furthermore, in 2013, Canada was the only country to establish a certification process that targets market players' products and services. Amongst other things, the process included a number of usability requirements such as service levels, technical-support responsiveness and financial viability. Finally, Canada is an early adopter of data protection in the field of eHealth, imposing since 2013 a signed obligation, such as a data-sharing agreement or a contract for data recipients. These documents aim to legally bind market players to the rules protecting the privacy and confidentiality of the data to which they have been approved access.[44]

In addition, given the close proximity of the United States offers Canada the opportunity of benefits from strong relationships between Canadian and US companies that may include **learning effects** for market players.

Japan

We have already highlighted that the Japanese eHealth market is sizeable in volume but rather small in relative terms.

In Japan, the financial cost of providing ample healthcare services to the population is unsustainable, especially in a slow-growth, developed/mature market. In 2014, the Japanese Government spent €346bn on the provision of healthcare services; such an expenditure has triggered the search for new ideas to curb healthcare expenditure. As a result, private-sector healthcare providers in Japan (through improved home care and community-based care, enhanced by mobile health and telehealth solutions) are expected to acquire a bigger market share for treatment services, particularly for the elderly population. This development could also help expand knowledge of the health of the Japanese population by analysing big data collected for patients.

Given Japan's mature and considerable ICT market (worth nearly €370billion[45]), its substantial ageing population, its high concentration of people clustered in urban areas, and its tech-friendly society, the country currently gathers the set of **conditions for success and growth in developing telemedicine in the country**. Indeed, an increased focus on home care (including mobile health and telehealth) would alleviate the country's reliance on hospitals. Patients could receive proper care from home, and hospital bed utilisation would be optimised for emergencies.

A high-quality technological network exists and can deliver telemedicine in Japan, with 3G and 4G systems and high-speed broadband Internet widely available. The widespread prevalence of Internet connectivity may have some impact on mobile health and telehealth deployment in Japan. Mobile telemedicine solutions could be used for collecting and measuring vital health information more consistently.

According to a 2014 survey by the Japanese Ministry of Health, Labour and Welfare (MHLW), only 18 hospitals and 544 clinics nationwide offered telemedicine and telecare. However, with technological advances, experts in deregulation urged the Ministry to amend the legislation in force. The Ministry had prohibited telemedicine for a long time, only authorising face-to-face treatment and making telemedicine available only to patients with chronic diseases in remote areas (Medical Practitioners Act). A decision issued in 2015, strongly backed by medical associations, and effectively lifted the ban, allowing various start-ups to offer the service. This prompted many **medical start-ups to launch telemedicine services in metropolitan areas**.

[44] OECD, 2013.
[45] https://www.statista.com/statistics/820926/ict-industry-total-sales/

Finally, recommendations have been issued for implementation[46] regarding the revision of the article 20 of the Medical Law, in particular on the clarification of who can practise telemedicine, the enlargement of the scope of practitioners beyond medical doctors, and the definition of reimbursement schemes and number of telemedicine services eligible for reimbursement.

It is important to notice that most telemedicine studies in Japan are published in Japanese, and thus, they are practically inaccessible to the rest of the world.

2.2. Market environment

2.2.1 Market PlayersThe literature suggests five main categories of telemedicine solutions providers: telecommunications companies and mobile operators; big ICT and electronics groups; manufacturers of medical/monitoring devices/platforms; pharmaceutical industries; and start-ups. The Figure below shows these categories, along with example companies[47, 48, 49]. A more detailed presentation of each category follows.

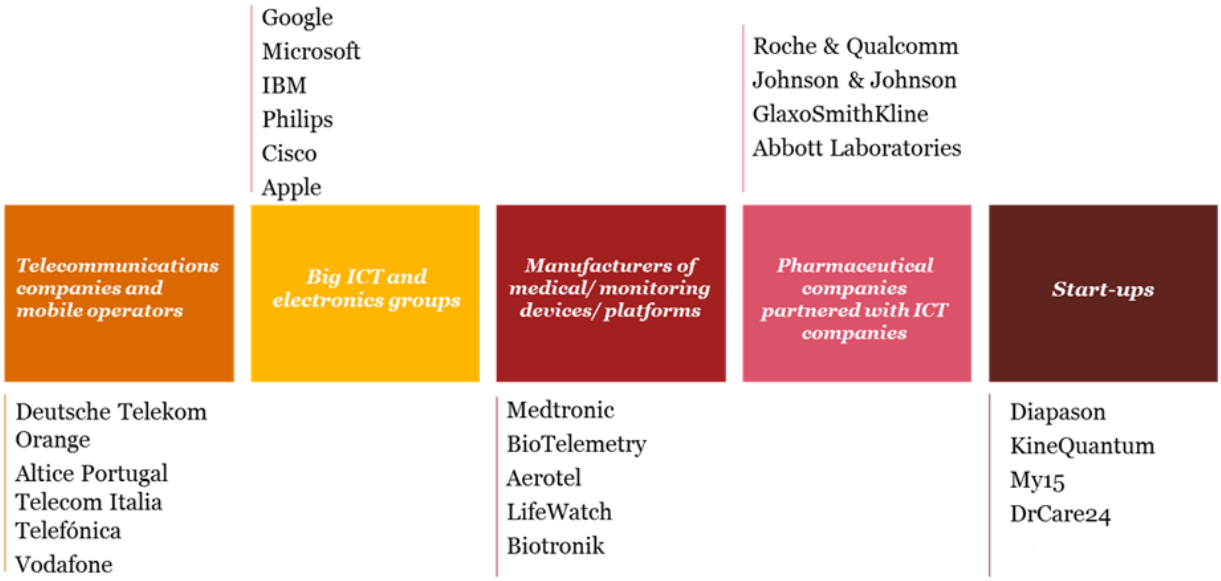


Figure 31: Telemedicine value chain key players

Telecommunications companies and mobile operators

They actively invest in telemedicine to make up for declining market shares and decreasing profit in their traditional activities. Medical products and services are seen as a premium segment in which security and quality requirements outweigh price considerations.

[46]The American Chamber of Commerce in Japan (ACCJ) (2014).

[47] Androuchko L. Wright D., "Telemedicine and developing countries", *Journal of Telemedicine and Telecare*, vol. 2, nº 2, 1996, RSM Press Ltd.)

[48] Baum P., Abadie F., "Market Developments – Remote Patient Monitoring and Treatment, Telecare, Fitness/Wellness and mHealth", *JRC Scientific and Policy Reports*, 2013.

[49] Commission Staff working document SWD(2012) 414 final on the applicability of the existing EU legal framework to telemedicine services.

In addition to providing data centres to store and manage health data, telco players make available networks with sufficient bandwidth and data upload capabilities, supporting high-quality image and video-based services. This is crucial for services such as teleconsultation and teleradiology, which demand high-resolution pictures. Therefore, telemedicine may **increase traffic on their networks**, thus boosting their revenues. Also, remote patient monitoring services – despite requiring lower bandwidth – ensure continuous cash flows.

Big ICT and electronics groups

Telemedicine market players like these rely on their core competences, such as managing data and structuring workflows. Their strategy is to capture sizeable shares in this fast-growing market.

More specifically, ICT market players use their expertise to create innovative products, software and platforms that provide patients and healthcare professionals with increasingly advanced functionalities. For instance, personal health record apps or platforms on which people can access their medical records, track their data from devices (smart activity, blood pressure monitors, blood glucose monitors) and share it with anyone they choose.

Manufacturers of medical/monitoring devices/platforms

They now have a wider market scope, since they target the remote patient monitoring market, home-based care, independent living and well-being. Consequently, they have adapted their value proposition so that it meets non-professionals' needs. Their products usually incorporate advanced technology and include sensors, software and/or connectivity to EHR so that consumers can consult the data collected.

The market seems highly **fragmented, with numerous competitors** (including sport equipment manufacturers entering the market) getting a small share of it[50]. Brand loyalty and improved technology are the main factors behind growing sales, even though the market is already well established.

Pharmaceutical industries

Pharmaceutical companies see telemedicine as a great opportunity for growing sales, especially in a context of toughening regulation and high R&D costs for developing new drugs. Furthermore, generic producers are an additional threat to pharmaceutical companies, as the latter need to justify the higher prices of their new drugs compared to generic medication.

By deploying telemedicine, they are able to build **new revenue streams**. Partnerships between pharmaceutical companies and ICT groups are multiplying. Their complementary expertise enables them to offer cutting-edge products and services.[51]

Start-ups

Telemedicine start-ups are proliferating. They provide **tailored solutions** and usually aim at making easy access to healthcare the status quo. Their innovative solutions have enabled them to easily raise funds; providing them with the financial means to deploy their products. Innovative delivery models

[50] Some of the products available are ePatch (BioTelemetry), Health@Home, DiabMemory, myAirCoach, Commander FLEX (Medtronic), Heartline ECG Monitoring (Aerotel), LifeWatch and Latitude NXT (Boston Scientific Group).
[51] The collaboration between Roche and Qualcomm Inc., which gave birth to Qualcomm Life, is one of the many illustrations of this. Qualcomm Life has developed the 2net Hub, a wearable medical device that transmits vital medical data to the 2net platform for telemonitoring purposes. Servier has followed to same approach to develop WeHealth.

are a distinct part of the start-up service officering, e.g. diagnosis through gaming or through the use of virtual reality.[52]

Other types of telemedicine market players include universities, research centres, and EU-funded projects, which also develop, test and deploy telemedicine solutions.

In recent years, the development of synergies between healthcare and technology has generated a telemedicine market environment, both globally and in the EU, defined by a set of key players, including the producers of products and services, their users, and the regulating authorities. Figure 32 below provides a few examples of synergies between the healthcare and technology industries, as illustrated by recently developed key partnerships.

This intersection between healthcare and technology has given rise to numerous business opportunities and benefits from the fast-paced diffusion of digital communication technologies. As healthcare providers have begun to use technology for patient management and care purposes, individuals around the globe have also started to adopt wearables, biosensors and digital applications for health management and care. The demand for technology-based treatment and care has allowed market players to deliver telemedicine solutions at scale and with constantly increasing cost-effectiveness.

Figure 32: Examples of recent partnerships between traditional healthcare and technology companies
Source: XERFI (2017)

At the same time, large ICT and electronics groups also **invest in attractive start-ups**[53] to gain a better market position and keep the pace of innovation in telemedicine.

[52] Two examples to illustrate this point are Diapason and KineQuantum. Diapason (Immersive Therapy) is a mobile application that performs accurate audiograms through games to locate the person's hearing loss, then offers therapy based on sending sound signals to readjust parts of the hearing. KineQuantum's virtual-reality headphones project users in 3D games, measure their movements rigorously and show their progress, as part of physiotherapy.

[53] For instance, IBM has recently acquired Cleveland-based Explorys, a healthcare intelligence cloud company that has built one of the largest clinical data sets in the world.

2.2.1.1. Key players and investments

A significant share of healthcare technology and innovation in connected health is increasingly driven by communication technologies focused on transmitting large data streams (precision imagery, video, etc.). The market environment depends on the dynamics of the digital health industry: market players in the areas of health analytics, telemedicine, connected health devices, etc., have developed and established within this market environment.

Numerous established firms, such as Medtronic, Roche, Johnson & Johnson, have been actively pursuing investments during recent years, constantly reshaping the telemedicine field.[54]

This "expansion-oriented" behaviour amongst main market players can be explained by the increasing investment trend in the field during recent years. The Figure below indicates the amount of investments in digital health worldwide from 2010 to 2017[55] suggesting a sharp increase from 2014 to date.

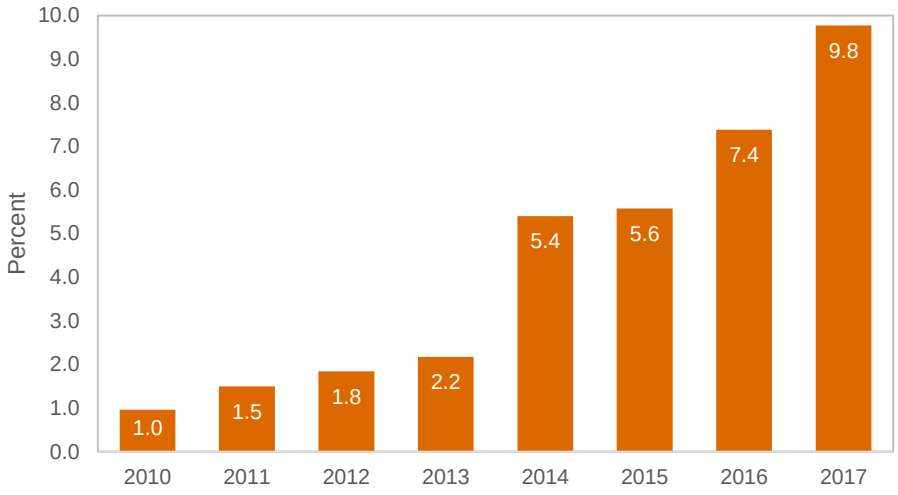


Figure 33: Total digital health industry funding worldwide (2010 – 2017)

2.2.1.2. Consumers

Population ageing is accelerating worldwide, particularly in developed economies, where fertility rates are down and life expectancy is rising. In 2015, people aged over 65 made up 17% of the developed markets' population. The increase in the average age of a population results in a higher incidence of chronic diseases, thus creating sustainable demand for health technologies[56]. According to the base scenario of the population projections by Eurostat for the period 2015 to 2050: *the share of people aged 65 and over is projected to increase from 18.9% in 2015 to 28.1% by 2050, with the share of people aged 85 and over more than doubling from 2.5% in 2015 to 6.0% by 2050*[57]. This poses specific challenges to the provision of medical services in a traditional set-up, also for healthcare providers.

[54] XERFI. (2017). The Global Medical Technology Industry.
[55] Source: https://www.statista.com/statistics/388858/investor-funding-in-digital-health-industry/
[56] XERFI. (2017). The Global Medical Technology Industry.
[57] http://ec.europa.eu/eurostat/statistics-explained/index.php/Statistics_on_regional_population_projections

A second important trend is the worldwide increase in **chronical diseases**. As discussed above, cardiovascular diseases, diabetes and chronic obstructive pulmonary disease are the most treated by companies. Healthcare systems intend to limit the burden linked to these conditions by prevention programs and better monitoring and long-term treatment.

2.2.1.3. Regulators

Governments in many countries worldwide are coming together to establish frameworks that promote the convergence of standards and regulations for telemedicine solutions. For instance, the Global Harmonization Task Force (GHTF) was initiated by a main group of countries (the US, Canada, Japan, the EU and Australia), with the objective of streamlining and harmonising all regulatory requirements regarding medical technologies. In addition, efforts have been made at global level to help developing economies such as India, China and Brazil converge in terms of regulation in the sector. These efforts led to the creation of the International Medical Device Regulators Forum (IMDRF) in 2011, a coalition of medical device bodies from various countries that seeks to accelerate global regulatory convergence across the medical technology industry.[58]

2.2.2. Supply and demand structure

Different forms of provision and use of telemedicine solutions and services can define the supply and demand structure in the telemedicine market. On the supply side, the current complexity and cost of providing telemedicine solutions and services is driving two business models: a managed service model operated by service providers, and a technology platform model operated by medical personnel. On the demand side, the current use of telemedicine solutions and services is driven by the needs of institutional and individual users to access different degrees of health services for expertise, consultation and monitoring.

Three of the many drivers influencing IT investment in healthcare are ubiquitous access to mobile technology, the criticality of IT security, and the rising need for chronic care following the demographic and epidemiological transformation[59]. Today, healthcare systems usually focus on hospital-centric care models and are often not well equipped to meet today's epidemiological challenges of preventing chronic diseases, diagnosing them early and managing them effectively. Healthcare stakeholders across the EU are urged to leverage innovative technologies to fundamentally redesign the way in which healthcare is administered and delivered.

Technology is developed rapidly, although the adoption is slow mainly due to barriers to the adjustment of societal behaviours. Society, especially the patient population, needs time to adapt to the technology being offered. There are big gaps between the two dynamics; this is mainly due to the lack of evidence on the efficiency and utility of telemedicine. It is difficult to adopt if the different parties involved do not understand each other. Indeed, the medical and paramedical professions do not often understand the IT development professions, or the business models. This issue of integration of different aspects of telemedicine makes it hard to for the offer to meet the demand. The complex use of solutions requires a professional to communicate and facilitate the discussion between technical people and health professionals.

[58] XERFI. (2017). The Global Medical Technology Industry.
[59] Giguashvili, N., Alexa, J. IDC Health Insights (2016). CEMA Healthcare Outlook 2016: Transformation Under Way.

2.2.2.1 Characteristics of the supply side

In recent years, the main players in the digital and health industries have greatly increased their focus on healthcare technologies designed to provide remote access to health services and improve patient management and monitoring. Nowadays, digital and health industry players mainly provide telemedicine solutions and services through two principal business models:

1. ***Managed services***, through which a remote healthcare activity is outsourced by an institutional user to a service provider. In this model, the service provider, which is specialised in the technology embedded in telemedicine solutions, enables functional telehealth care provision at a lower cost, based on the optimal transmission and exchange of clinical data and the evaluation of results.

2. ***Technology platform services***, through which a manufacturer or provider puts in place the infrastructure to support the remote delivery of medical services. Large medical institutions that offer remote medical services to individual patients and other smaller institutions operate this infrastructure.

These two main business models encompass all different types of solutions and technical types of telemedicine products and services described in Chapter 1. Indeed, either through outsourcing or internalisation, healthcare providers rely on digital industry players to set up and manage/support products, platforms or databases to ensure the provision of remote health services.

Nevertheless, the current dynamics of the telemedicine market indicates that variations in the provision of telemedicine solutions and services will converge into medical services operated from technology platforms, where a group of technology providers will manage/support remote care medical services. This convergence towards outsourced telemedicine services from healthcare providers to digital industry players is explained by the degree of specialisation required from the service provider, and the transaction costs associated with either business model or the other.

Based on the interviews with key stakeholders in the value chain of telemedicine, it can be concluded that the most predominant types of telemedicine solutions and services are:

- Teleconsultation: in this case the doctor communicates remotely with the patient, using for example video conference (with dedicated software that ensures privacy), to hear the symptoms and make the diagnosis. Teleconsultation could also work well in cases of regular prescription of drugs or medical tests (e.g. blood test) or just medical advice on specific issues. However, lack of direct human interaction can be problematic for some examinations or treatments (e.g. if the doctor need to inspect the ear). In these cases, a face-to-face meeting with the doctor is a necessity. There are other occasions where an initial physical meeting is important followed by teleconsultations for monitoring the development of the illness. In essence, for diagnostic/consultative context telemedicine can be widely adopted. However, treatment may still require a physical visit the doctor in many occasions.

- Telemonitoring: this type refers to digital therapeutics that can be used anywhere (with the appropriate device and application). For example, a patient in a comma can live at home and constantly monitored remotely by a hospital clinic. Telemonitoring can also be important to lonely people with dementia or cognitive decline. Mobile devises, wearables, smart homes, connected vehicles and advanced telemonitoring devices including life support devices combined with technology such as the Internet of Things, AI and Data analytics can enable remote healthcare and early preventative intervention (already very advanced in the US) at a large scale.

The development of technology provides numerous telemonitoring options. Biomarkers or sensors of activity enable doctors to do a constant monitoring of the patient, look for risk factors, and identify health conditions earlier. Sensors are providing adequate data and input for clinicians to carry out assessments; these can provide early warnings about any factor that goes wrong.

Currently, there are many options to monitor physical activity when doing sports or at a patient's home. Sensors mount on the walls can track in-house movement, which then can be analysed in order to provide behavioural patterns that can be monitored. Such a telemedicine application is useful for elderly people whose health may radically deteriorate if they fall and get injured.

Today, solutions can provide telemonitoring for weak heart conditions of a patient on a constant basis. As soon as there is an alert, the clinician is notified and can take a decision that will help prevent the person from going into a cardiac arrest. These types of solutions are currently being used in the US in order to reduce the risk of stroke with an early preventive intervention.

It is also apparent from the interviews that while market players are growing very fast, even though there is an unmet demand, the level of adoption is rather low. Thus, it is important for the industry to better understand the client needs and meet the actual demand from clinics and hospitals who ask for specific solutions. For a higher adoption of telemedicine solutions, the clients (individuals, clinics, hospitals) need to be convinced that that the solutions are suitable for them. If the clients have to pay for a solution, which is not going to be reimbursed by the health care system, the decision to buy the solution becomes harder. Thus, either the market players need to provide good value for money solutions that will be easier to sell, or the national governments and the EU has to cover some all the expenses to assist the further deployment of telemedicine.

One key barrier identified during the interviews is the apparent conservatism in the adoption of new technologies in established practices. For example, many clinicians in many countries are very conservative about adopting new tools and methods to do therapy, even though they are aware of the benefits of telemedicine. This is a big barrier in the clinical healthcare provider area. This may be due to lack of awareness of lack of trust at the abilities of telemedicine to replace traditional approaches. Thus, interventions are necessary to both raise awareness among health professionals and managers about the benefits of the adoption of telemedicine the potential return of investment as well as to ensure that telemedicine products and solutions available in the market are credible.

Furthermore, there are apparent difference among EU member states in terms of medical care attitudes that also affect (promote or restrict) the digital transformation of health care. The business model behind each system is different. In Sweden, the consumer makes the choices, thus it seems to work better than other countries. In the Netherlands, arguing to "keep patients away from the hospital" is counterintuitive as that means killing the business. The more patients, the more procedures, the more money. The same could be argued for other EU medical systems, where income is generated by having patients in the hospitals and there is uncertainty for the sustainability of the turnover when a significant part of treatment happens remotely. This is a key barrier also related to the reimbursement model for telemedicine versus traditional medicine.

Changing the model is a long process. For example, it took 5 years for the DK authorities to be convinced to change the model. The regulator must understand how the financials work in a new model in order to be able to support the uptake of telemedicine.

Another interesting area of this market relates to services that can offered to a big scale. In this submarket, the biggest players are in diabetes prevention in the US. Omada[60], "a digital behaviour change program that can help the patient lose weight, reduce his/her risk for chronic disease, and feel better than he/she have in years" is the biggest one. Omada transformed diabetes prevention programmes to a digital therapy solution to prevent diabetes. Using behaviour science the can help

[60] https://www.omadahealth.com

people change their living habits (eating, exercising, sleeping), improve their health and reduce their risk of chronic disease. They have been working to get a reimbursement status in the US and according to their website this is the case for some health plans.

It is also apparent from the interviews that if the therapy from a telemedicine solution is well documented, recognized and well established, it is possible for the State or the health insurance to pay for it, but for that to happen it needs to have a strong clinical evidence that the therapy actually works. Indeed, it is critical for any provider of digital therapy to have clinical evidence that the solution actually works in order to get a reimbursement model. In the meantime, what these market players can do is to get clinics and hospitals to finance the solution from their internal budget. Many market players and institutions who are willing to pay for it when they are convinced that the solution actually works also apply this business model. Since healthcare systems are often both care givers and service providers (take care of patients and get paid by patients), they have a strong incentive to implement good solutions.

The issues around telemedicine based on the interviews conducted match the description of services and solutions identified during the mapping exercise.

2.3.2.2. Characteristics of the demand side

The demand for telemedicine solutions in the market is mainly determined by two types of users: individuals and healthcare providers. National States and their health care systems are currently facing challenges due to demographic and epidemiological trends that add pressure to meet the needs of ageing populations with an increasing incidence and prevalence of chronic diseases. Regarding this particular aspect, the demand is – and will continue to be – affected by the dynamics of chronic disease amongst the EU population. According to the World Health Organization (WHO), over 85% of deaths in the EU are due to five major chronic diseases (diabetes, cardiovascular diseases, cancer, chronic respiratory diseases, and mental disorders).[61]

Therefore, the potential demand for telemedicine applications can be analysed under a market study approach that allows us to estimate the needs of individual and healthcare providers under the aforementioned ageing and disease constraints. This study approach must also integrate the potential willingness to pay for telemedicine solutions across EU Member States and EEA countries, based on historical sectorial health data. This approach relies on information available from Eurostat, most of which is included in the set of European Core Health Indicators (ECHI) defined by the EU-funded Joint Action (JA) on European Community Health Indicator Monitoring (ECHIM) in support of the EU Health Strategy[62].

The set of indicators used for the study of the potential demand is structured under the three main pillars of the ECHI indicators: i) demography, ii) health status, and iii) health interventions/services.

Demand estimate approach

- ***Step 1:*** The first step in our approach to study the potential demand is to link information on the European population (total demography) with information on the population presenting health conditions that require the provision of healthcare services. Using information available from Eurostat on the self-reported prevalence of specific diseases in the population across countries, we estimate the number of individuals suffering from critical health conditions to define the population at risk as a base for our demand analysis. The outcome of this first step is

[61] Giguashvili, N., Alexa, J. IDC Health Insights (2016). CEMA Healthcare Outlook 2016: Transformation Under Way.
[62] See https://ec.europa.eu/health/indicators/echi/list_en

an estimate of the potential market size, expressed by the number of individuals affected by the diseases that require the provision of health services.

- ***Step 2:*** The second step of the approach involves reconciling the total population of individuals at risk (step 1 analysis) with information on Member States' total health expenditure across different types of healthcare providers. This stage allowed us to initially segment the potential demand for telemedicine solutions by distinguishing between health expenditure by hospitals, outpatient healthcare, residential long-term healthcare and other preventive healthcare providers.

  During this step, we estimate the potential market value for telemedicine solutions, taking into account the population at risk and the associated share of health expenditure. The outcome of the analysis is an estimate of the potential expenditure that can be associated with serving the total population affected.

- ***Step 3:*** The last step in our approach uses the output from the previous analysis, combined with the parameter on the willingness to see a doctor over video, which was obtained in the American Well survey (2016). This provides an indication of a patient's desire to be treated with the help of telemedicine solutions, and is used as a proxy to indicate the extent to which the total population is likely to shift towards telemedicine (along with the associated expenditure), and hence reflects the potential future expenditure in telemedicine solutions.

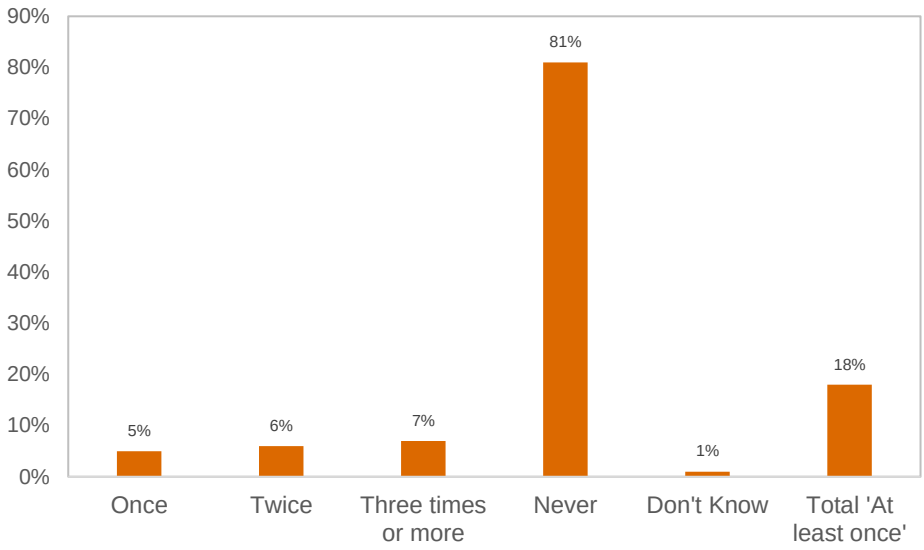


Figure 34 : Online health utilisation – "In the last 12 months, how often have you used, if ever, health and care services provided online without having to go to the hospital or doctor's surgery (for example, by getting a prescription or a consultation online)?"

Source: Eurobarometer 460 "Attitudes towards the impact of digitisation and automation on daily life"(2017)[63]

[63] European Commission (2017).
http://ec.europa.eu/commfrontoffice/publicopinion/index.cfm/ResultDoc/download/DocumentKy/78998

It is important to note that the three-step approach can be expanded to take into account specific chronic diseases by introducing an intermediary step between steps 1 and 2. In this particular case, we would estimate the potential volume of patients affected by a specific set of chronic diseases; the intermediary step of the approach would involve estimating the proportion of inpatients treated by hospitals, and by chronic disease, amongst all inpatients treated.

As part of this intermediary step, we would obtain a set of parameters, one for each chronic disease, enabling us to estimate the share of healthcare expenditure that can be associated with each of these chronic diseases. These shares could therefore be applied as parameters under step 3 of the approach in order to obtain an estimate of the potential market value for telemedicine solutions that takes into account the population of individuals affected by the chronic diseases in question.[64]

Demand estimate results

Under the first step of the demand estimation, we used the share of individuals suffering from a long-standing illness or health problem drawn from the SIMPHS 2 survey. This share was calculated using the survey data by country for 13 EU countries[65], the remaining countries in were assigned the average share.

The share of individuals suffering from a long-standing illness was applied to the total population by country in order to obtain the volume of inhabitants possibly suffering from a chronic disease. Results from this estimation indicates that in average, nearly 40% of the EU population is suffering from a chronic disease. The Figure below provides an illustration of the potential market distribution, expressed in volume (total inhabitants suffering from a chronic condition), which could be addressed by the wide deployment of telemedicine solutions.

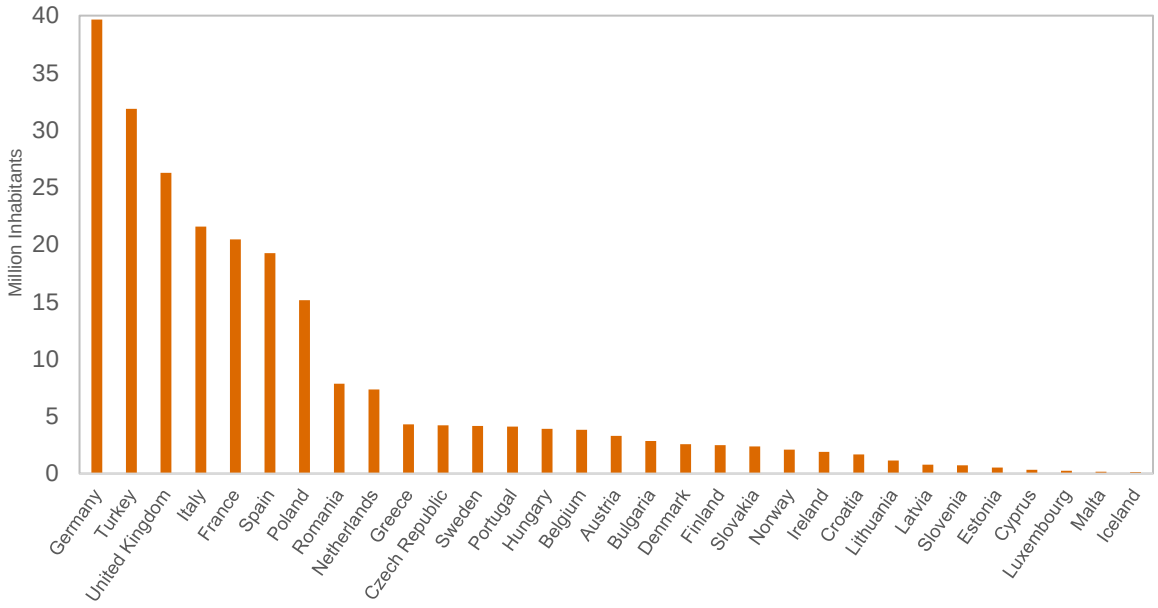


Figure 35 : Estimated total population suffering from a chronic disease (in volume)

Source: PwC Analysis (based on Eurostat data on total population and SIMPHS 2 survey data on long-standing illness)

[64] It is important to highlight that in the absence of such information for all types of healthcare providers, this analysis relies on a hypothesis of the proportions being distributed equally across providers and uses the estimates drawn from hospital inpatients.
[65] Member States participating in the SIMPHS 2 survey: Austria, Belgium, Germany, Denmark, Estonia, Finland, France, Italy, Netherlands, Sweden, Slovakia, Slovenia, Spain.

Under the second step of the analysis, this distribution of the estimated population suffering from a chronic disease (in volume) was multiplied by the estimated health expenditure on chronic diseases. For this purpose, we used Eurostat information on hospital discharges (records of at least one hospitalization day) by type of health issue, focusing on any chronic disease. In average, hospital discharges associated to the treatment of chronic diseases across the EU represent 11.6% of all hospital discharges. This share was then applied to the total amount of health expenditure expressed in euros per capita for each of the following types of healthcare providers:

- Hospitals;
- Residential long-term care facilities;
- Providers of ambulatory healthcare;
- Providers of preventive care.

Multiplying the estimated number of individuals addressed by the market with the estimated amount of health expenditure per individual associated with the treatment of a chronic disease provided the potential market value addressed by the EU wide deployment of telemedicine solutions. The Figure below illustrates the distribution of the potential market value by country.

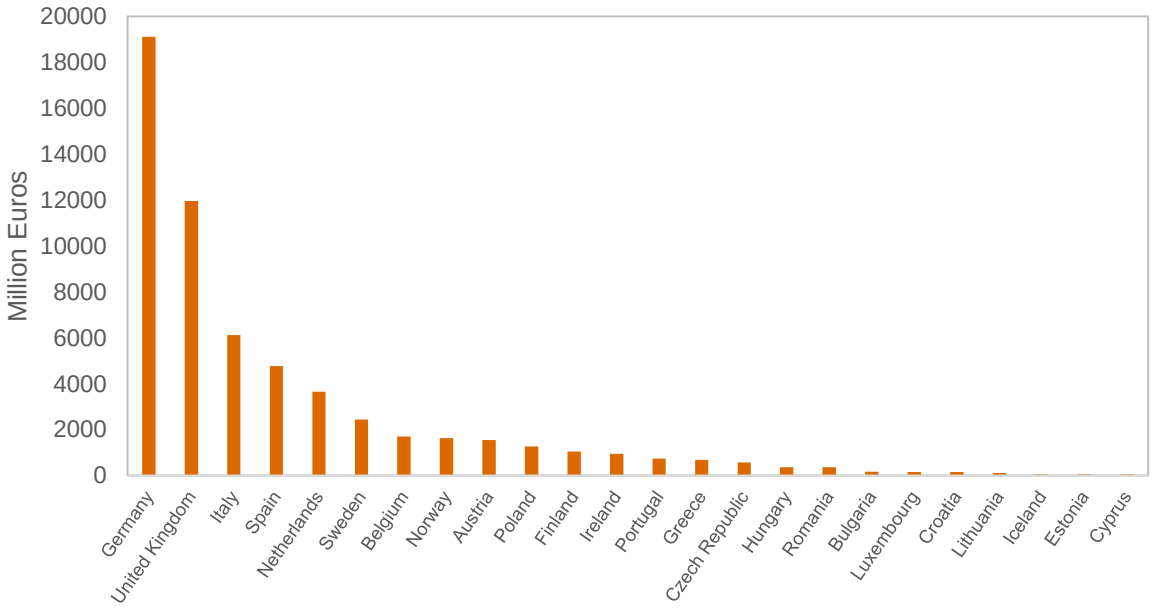


Figure 36 : Estimated health expenditure associated with the treatment of a chronic disease (in value)

Source: PwC Analysis (based on Eurostat data on health expenditure and SIMPHS 2 survey data on long-standing illness)

Under the final step of the estimation, we applied to each estimated market volume and value the likelihood of consulting a doctor or a nurse online drawn from the SIMPHS 2 survey; the total share of individuals who declared that they are likely or very likely to consult online amounts to 17,9% of the surveyed sample.

This result indicates that the potential market volume for the EU concerns about 36.6 million people and amount to over 10 billion euros for the sole EU territory. The Figures overleaf illustrate the distribution of potential market volume and value for the EU under current condition, estimated using the likelihood of consulting a doctor or a nurse online across the EU.

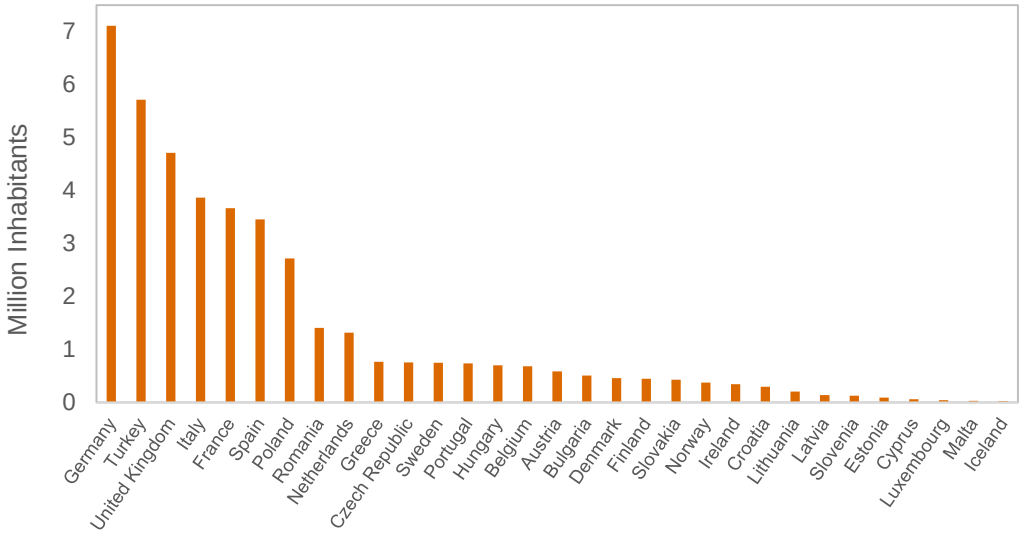


Figure 37 : Estimated market demand for telemedicine solutions (in volume)

Source: PwC Analysis (based on Eurostat data on total population and SIMPHS 2 survey data on long-standing illness and likelihood of consulting online)

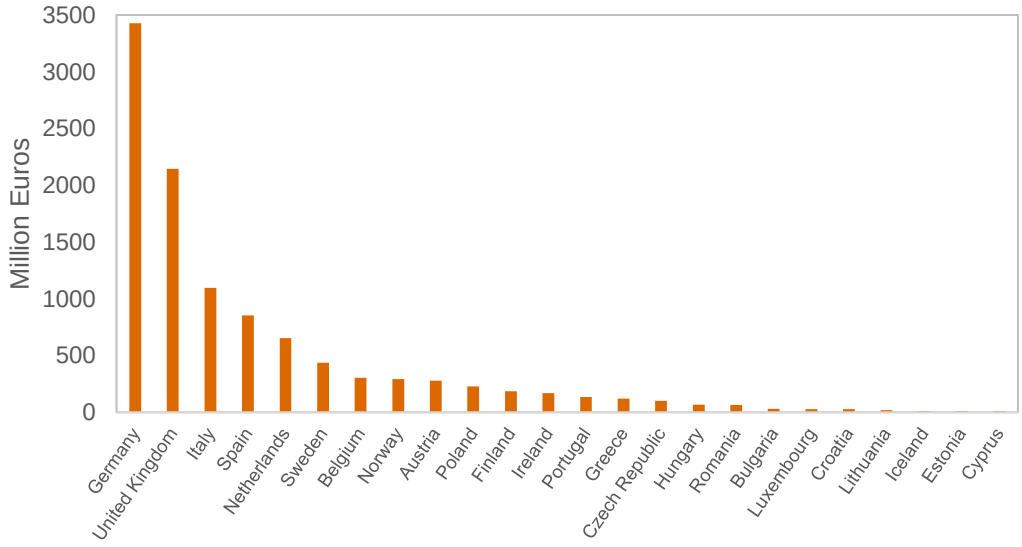


Figure 38 : Estimated market demand for telemedicine solutions (in value)

Source: PwC Analysis (based on Eurostat data on health expenditure and SIMPHS 2 survey data on long-standing illness and likelihood of consulting online)

2.2.3. Industry structure and market conditions

2.2.3.1 Availability and access to telemedicine solutions

Telemedicine solutions have recently started to take up across EU Member States. The pace at which they are deployed depends on several factors, including the availability of funding for investment in medical technology and infrastructure, the availability of digital skills amongst medical personnel, and the ability of the market environment to match the supply and demand for telemedicine solutions and services.

The rising costs of disease treatment within national health systems and the demographics in the EU are increasingly putting pressure on public expenditure budgets; consequently, cost containment and efficiency is becoming a great concern, both for EU Member States and worldwide.

Relevant authorities are now closely scrutinising healthcare spending, with the objective of reducing and optimising expenditure in the provision of health services. With constantly increasing demand for health services driven by demographics and epidemiology, and lower relative funding for health systems, diffusion and access to telemedicine services will increasingly become a major strategic concern in the short term.

To address this issue, key players in the technology and medical sectors are designing and providing holistic solutions, comprising both devices and solutions (e.g. software and consulting), to improve patient outcomes while maximising care-setting efficiency.[66] The wide-scale availability of these healthcare services will mainly depend on the ability of EU and national authorities to adapt and adjust to convenient models that match the supply and demand of telemedicine solutions. For instance, of the way in which telemedicine costs are reimbursed needs to be thought out. Either fee-based or value-based reimbursements will need to be studied, taking into account the different ways of providing and consuming telemedicine solutions, whilst considering the objective of improving the quality of health services at a lower relative cost for society.

Finally, a lack of willingness to adopt new solutions is a barrier to innovation. Resistance to change is a complex issue related to various factors, including the problems of an ageing workforce, salary levels, workloads, and often the lack of digital skills. In particular, the shortage of necessary digital skills among clinical personnel is viewed as one of the main factors hindering the uptake of telemedicine solutions and services across the EU, as well as being a key barrier to the uptake of e-health innovation.

2.2.3.2 Financial sustainability of health systems across Member States

Several factors need to be considered regarding the reimbursement models associated with the future deployment of telemedicine solutions and services across the EU, most notably the escalating costs associated with healthcare provision (infrastructure and operational expenditure) and the dynamics of the workforce in the medical field.

The availability of financial resources for healthcare is extremely problematic in some CEMA countries. According to the latest available data from the World Bank, the average amount spent on healthcare in 2013 was €689 in Central Europe and the Baltic States and €2,595 in the EU overall. However, healthcare systems continue to struggle with unsustainable conditions due to demographic dynamics in the EU, the decreasing share of the active population, and the increasing need for treatment for chronic diseases.

[66] XERFI. (2017). The Global Medical Technology Industry.

These conditions continue to put pressure on healthcare costs. For instance, long-term projections show that the fiscal impact will be high in most EU Member States. According to the 2015 Ageing Report,[67] economic and budgetary projections for the 28 EU Member States (2013-2060) indicate that the projected change in strictly age-related public expenditure will amount to 2 percentage points of the GDP between 2013 and 2060, with an increase driven mostly by healthcare and long-term care spending.

Healthcare financing systems will thus be challenged by the fact that complementing healthcare funds with private expenditure (e.g. out-of-pocket payments and patient co-payments for doctors' visits) has proven to be extremely difficult, as these systems have traditionally been funded primarily by public sources.

An additional factor to consider is that the human resources deficit in the medical sector remains critical in certain Member States and healthcare systems, hindering healthcare reach, quality and outcomes. The deficit of medical professionals is severe: on average, there are currently only 3.5 physicians available per 1,000 inhabitants in the EU, despite considerable government efforts and investment in training and educating healthcare professionals.

This lack of healthcare workers needs to be considered with particular attention in central and eastern European countries, which have a lower number of physicians per capita than those in Western Europe. For example, in 2015 Romania has 2.77 physicians per 1,000 inhabitants, and Poland has only 2.33, compared to 4.14 in Germany and 5.1 in Austria[68]. Beyond the issue of human-capital availability, other considerations need to be taken into account. The mix of an ageing population and an ageing healthcare workforce indicates that while demand for medical services will grow, the supply of available skilled labour will decline.

The factors affecting the production and uptake of telemedicine solutions must be investigated to develop optimal pricing strategies across the EU and to allow supply and demand in the industry to be matched.

2.3. SWOT analysis of the market

An increasing number of healthcare providers are starting to adopt connected telemedicine technologies, as the sector has the potential to deliver significant cost savings for healthcare provision across EU national health systems. Large medical technology players such as Medtronic and GE Healthcare are seeking to build up capabilities in the area by acquiring digital start-ups or teaming up with technology giants such as IBM or Philips, which are currently adapting fast to tap the potential benefits of digital health growth.[69]

[67] European Commission (2015). The 2015 ageing report.
[68] http://ec.europa.eu/eurostat/tgm/table.do?tab=table&init=1&language=en&pcode=tps00044&plugin=1
[69] XERFI. (2017). The Global Medical Technology Industry. The Market, (April, 2017).

CONNECTED HEALTH AREA	DISEASE	TOTAL SAVINGS OPPORTUNITY
Remote patient monitoring	Heart disease, asthma, diabetes	$200+ billion
Telehealth	Routine & psychological care	$100+ billion
Behaviour modification	Obesity, smoking cessation, overall lifestyle improvement	Unbounded

Figure 39: Potential economic impact of connected healthcare in the US
Source: XERFI, 2017

Business development in the sector rests on several factors, which we have considered below as part of a SWOT analysis:

Strengths

- Heavy political focus on healthcare as a core state responsibility.
- Government support for global convergence of standards and regulations on medical technologies, hence telemedicine.
- Continued economic development in emerging markets outside the EU and converging economies within the EU.
- Intellectual property protection.

Weaknesses

Amongst the weaknesses of the EU in terms of telemedicine adoption, one may highlight the need for more support and quantity of applied research projects to provide evidence and properly reflect the actual benefits of the telemedicine. There is a need to increase the base of evidence through implementation exercises as today we focus mostly on theoretical studies, but lack actual large-scale implementation. Indeed, there is a mismatch driven by the development of innovations that do not take into account the actual needs of the patients. This mismatch reflects the different perspective from different parties involved in the process of telemedicine adoption highlighting problems of communication, collaboration, and lack of understanding between them. For instance, nurses and doctors may have a different understanding of a patient's need; as an example, in the case of Parkinson's disease, nurses are prone to focus on the quality of life, while doctors are prone to focus on medication to be able to walk. In addition, technicians and developers of telemedicine solutions will focus on the technical development rather than the integration of technology across several professions. This issue points out to the fact that today, telemedicine development and uptake is dealt with from different angles depending on each party. When the come together they have a better understanding of each other. To solve this weaknesses of integration all actors involved need to come together to clearly understand the medical professions, the patient's needs, and the technical development limitations.

- Indebted healthcare systems increase pressure for cutbacks in healthcare spending.
- Reduction in individual disposable income.
- Increasingly stringent regulations, which can slow down technology diffusion and adoption by wide pools of users.
- Global inconsistencies in regulations.
- Stricter and lengthier regulations increase time-to-market and development costs.

- Lack of interoperability due to fragmentation.

Opportunities

- Ageing and wealthier populations.
- Limited access to healthcare in rural areas
- Rising urbanisation is accompanied by a growing prevalence of lifestyle diseases that.
- Opportunities in healthcare technology spurred by new digital technologies (5G, big data and artificial intelligence, cybersecurity).
- The market has high potential for growth with a significant likelihood of start-ups and large firms entering the telemedicine market.

Threats

There are several threats or delaying factors in the EU concerning the uptake of telemedicine. One of the key threats is the Global Data Protection Regulation, which is generally positive, as it has streamlined the rules on the use of individual data, but has a clear downside in terms of delaying the creation of evidence and the adoption of digital health solutions. Indeed, the burden on small telemedicine start-ups is pushing these companies leave the EU and settle in the US since the regulation there is more flexible and allows them to work directly with large health systems. The uptake of telemedicine depends on the handling and treatment of medical data, which requires permissions and flexibility to carry out advanced analysis in order to generate evidence for the market a convenient pace.

Other important threats for the uptake of telemedicine in the EU concerns regulatory approval (by CE Mark) which is necessary, but is unaffordable for small companies. Indeed, today, approval for a class 2 or 3 device the process becomes so expensive that the process crowds start-ups out, limiting innovation as only big players can go through the process. The only way to succeed is to have very strong support from big partners (VC capital). Those pathways can work efficiently, although they will definitely hinder disruptive innovation.

In addition, further threats include:

- Cybersecurity risks posed by mobile and digital-related health.
- Shrinking working population.
- There may be significant rivalries due to the many major players in the sector concentrating the market; new entrants are competing to gain a market share.
- Bargaining power:[70]
  - ***Bargaining power of suppliers:*** Several suppliers are active in the telemedicine market, but they are not price-makers. End-product suppliers and institutional users can reduce the suppliers' bargaining power.
  - ***Bargaining power of buyers:*** There are several successful and established market players in the market as well as institutional consumers. This allows for significant consumer market power.

[70] Technavio report, 2015

2.4. Company profiles

This section is dedicated to the key players operating in the global telemedicine market[71]. It shows the positioning of some of these actors in Europe, complements the analysis on distribution of services, and gives insight into solution portfolios. It further presents a business overview of each player.

PHILIPS
Healthcare

General overview	Royal Philips is a leading health technology company focused on improving people's health and enabling better outcomes across the health continuum from healthy living and prevention, to diagnosis, treatment and home care. It is the leader in diagnostic imaging, image-guided therapy, **patient monitoring and health informatics**. Philips telemedicine solutions target both patients and doctors, and have demonstrated the following **results**: • Reduction in overall costs of care • Reduction of hospitalisations • Reduction of the number of days in hospital • Reduction of readmission rates
Solution portfolio	• Remote patient monitoring solutions • Remote chronic disease management solutions • Readmission management solutions, via home devices • Sleep therapy solutions
Geographical reach	Global
Business strategy	Philips's strategy focuses on a more **connected, predictive and personalised care** delivery. It prioritises **partnerships**; at present, the company has 40 long-term relationships with healthcare providers from medical universities to hospitals.
Recent developments	• January 2018: Strategic partnership with American Well™, the leading U.S. telehealth provider • Deployment of Philips Avent uGrow, a parenting app to monitor baby development and 24/7 access to professional medical consultations • HealthSuite Digital Platform: consumers and patients can secure and select which data to share with health professionals • Philips will join the American Well Exchange™ clinical services marketplace, which enables healthcare partners to exchange telehealth services with one another and redistribute them to new patient populations

[71] As referenced in the Tender Specifications for the study, and in the market study "Telemedicine Market - Global Industry Analysis, Size, Share, Growth, Trends and Forecast, 2014 - 2020" by Transparency Market Research.

General overview	Polycom (now a part of Plantronics) is a provider of communications and collaboration technology. More than 400,000 companies and institutions worldwide defy distance with video, voice and content solutions from Polycom. In healthcare, Polycom provides **video collaboration solutions** that connect healthcare professionals with each other and/or with patients. The company also provides medical education, healthcare administration.
Solution portfolio	• Video collaboration solutions • Medical education and healthcare administration videos
Geographical reach	Global
Business strategy	Polycom solutions are **flexible**, i.e. designed to be applicable in any environment, feature **multi-vendor interoperability** and have a high degree of **security**. Similar to other key players, the company relies on **strategic partnerships** for its success, including with: Huawei, Alcatel, Cisco, Avaya, and Microsoft.
Recent developments	• January 2018: Merger with Obihai Technology, Inc., an innovator in VoIP audio solutions • Cloud services launched focusing on audio devices and solutions today, anticipating support to video communication by end of 2018 • Polycom has unveiled new, high-end video capabilities, such as facial tracking, dual monitor support, superior audio coverage, and easier content sharing

General overview	OBS Medical is the global leader in the development and provision of **predictive algorithms** for identifying critical instability in patients that is not picked up by traditional methods. As such, the company's main customers are healthcare professionals.
Solution portfolio	Medical software
Geographical reach	Global

Business strategy	OBS Medical's strategy relies on direct collaboration with **healthcare providers**, **hospital data service providers** and **medical device manufacturers** (e.g. ExcelMedical, Connexall, Caretaker Medical). **Innovation** is an essential part of the company's DNA – indeed, it pioneers artificial intelligence to provide healthcare professionals with patient risk stratification and alerts.
Recent developments	OBS Medical aims at expanding in the US

General overview	InTouch Health provides cloud-based network and virtual care solutions that ensure **connectivity for health systems, providers, and patients at all times**. Over 130 health systems are supported by the company at present. It boasts 8,600 registered network users and 1,000,000 telehealth virtual care sessions over its platform.
Solution portfolio	• Virtual medical care platform • Telehealth devices
Geographical reach	Global
Business strategy	In addition to a portfolio of solutions, InTouch also offers **support services** for telehealth implementation and **consulting services**. Its goal is to expand its market share as a preferred **partner for hospitals and health schemes**. **Strategic partnerships** include those with: Bon Secours, hospitals, Dignity Health, Ohio State University, Mission Health, the Hospital Consortium of America, Standford Medicine, Kaiser Premanente, and PinnacleHealth.
Recent developments	• April 2018: InTouch Health acquired REACH Health, a telemedicine software company based in Georgia • January 2018: InTouch Health acquired Truclinic, a web design telemedicine provider based in Utah specializing in direct to consumer virtual care solutions

Honeywell | Life Care Solutions

General overview	Honeywell Life Care Solutions (formerly Honeywell HomMed) offers **remote patient monitoring services**, **remote patient management applications,** as well as decision support and evidence-based disease management. Honeywell telemedicine solutions target healthcare providers, and have demonstrated the following **results**: • Multimillion cost savings • Reduction of readmission rates
Solution portfolio	• Solutions integrating EHR and other medical records • Remote clinical monitoring software • Remote patient monitoring software and devices • Telehealth platforms
Geographical reach	North America
Business Strategy	Honeywell is one of the pioneers in telehealth for over 18 years. Its success is based on **quality** but also **lower product costs**. **Key partnerships** that have facilitated its market rise include those with: MobileHelp, Samsung and Fuwe.
Recent development	• June 2017: Launch of latest version of the monitoring software, including a more efficient navigation, a mobile platform, an improved patient dashboard, advanced scheduling and reporting • Updates to the company's telehealth platform featuring fully-integrated video communication enabling individuals with chronic conditions to meet with their doctors and nurses face to face without having to leave their home • Honeywell Select Services introduced to streamline the telehealth delivery process between healthcare providers and patients, by monitoring patients from Honeywell's nurse call center headquarters

CISCO Healthcare

General overview	Cisco delivers **'care at a distance'** solutions, connected imaging solutions, **telehealth and collaboration** solutions. The company has been in healthcare for more than 20 years, spanning 17,000 healthcare organisations and 118 countries around the world. In addition lower readmission rates, Cisco telemedicine solutions used by healthcare providers have **resulted** in a lower numbers of adverse drug events.

Solution portfolio	• Virtual health solutions (telemonitoring, teleconsultation, video care) • Patient engagement solutions (e.g. *Inpatient Bedside Technology*) • Converged clinical workflow solutions (e.g. location tracking) • Health data exchange platforms and real time analytics
Geographical reach	Global
Business strategy	What differentiates Cisco is the company's commitment to **data security**. Indeed, Cisco offer **secure access** to network resources and applications from any location in order to promote security best practices that meet regulatory compliance goals.
Recent developments	• Goal to create a complete digital strategy for healthcare providers around the world • Launch of HealthPresence Telemedicine Solution – an advanced video collaboration technology giving patients an immersive and highly-secure remote healthcare experience • Telemedicine pilot programmes in several countries to test willingness to use and satisfaction with remote patient care

Medtronic

CARDIOCOM

General overview	Medtronic is a medical device company that acquired Cardiocom in 2015. Cardiocom used to provide **telemedicine solutions for daily remote patient monitoring and disease management**. Used by healthcare professionals since 1998, Medtronic solutions have recorded over 5 million telehealth patient months of use, and currently service over 95,000 patients.
Solution portfolio	• Remote patient monitoring solutions, including advanced medical monitors • Wireless cardiac monitors and mapping solutions • Remote monitoring system for diabetes (including insulin pump systems, infusion sets, injection ports)
Geographical reach	Global
Business strategy	Medtronic targets **specific diseases**, in particular heart failure, Parkinson's disease, obesity, diabetes. In doing so, it establishes targeted partnerships, for instance with IBM Watson.
Recent developments	One of the company's priorities is reaching underserved populations and the Middle East where it actively works to expand clinic-based models

General overview	AMD Global Telemedicine is a pioneer in clinical telemedicine equipment and **technology that is used to connect a patient with a remote healthcare provider**. AMD solutions primarily target rural health clinics, school health centers and pharmacy clinics. To date, the company has over 8,300 patient end-point installations set up in 98 countries.
Solution portfolio	• Telemedicine carts and systems • Telemedicine encounter management software (for real-time remote patient exams) • Medical devices and equipment designed to deliver superior quality medical images and precise patient data, especially for difficult or remote application
Geographical reach	Global
Business strategy	AMD's niche is rural and **underdeveloped regions** around the world. Therefore, the company prioritises **partnerships** with local and national-level public organisations, e.g. schools (health) alliances, national telemedicine associations and national health associations.
Recent developments	• April 2018: Development of OnDemand Visit, a direct-to-consumer telehealth platform • 2017: 6th enhancement release of AGNES Interactive telemedicine software that aggregates medical device data and shares it in real-time with the remote physicians

General overview	Allscripts provides hospitals and other healthcare providers with practice management and **EHR technology**. At present, it reaches 45,000 physician practices; 180,000 physicians; 19,000 post-acute agencies; 2,500 hospitals; 100,000 electronic prescribing physicians; 40,000 in-home clinicians; and 7.2 million patients.
Solution portfolio	• Health management platforms • EHR platforms • Patient engagement platforms (notably FollowMyHealth)
Geographical reach	• North America • India • Australia

	• UK • Singapore • Israel
Business strategy	The strategy of Allscripts is based on two pillars: **IT management services** as part of the value proposition and **innovative technology**.
Recent developments	• Goal to create the healthcare IT architecture of tomorrow and keep being the industry leader enhancing excellence • Selected the Vidyo.io platform from Vidyo to power virtual consultations directly embedded into the Allscripts FollowMyHealth patient portal, thereby enabling patients to do video consultations with physicians either over the web or through a mobile app • Series of acquisitions (e.g. patient communication and engagement platform HealthGrid) in a shift to value-added care tools beyond its current EHR-centric solutions • Collaboration with Hale Health on a free telemedicine solution for sharing photos and videos, conducting live video visits and asynchronous messaging

GlobalMed®

General overview	GlobalMed is the worldwide leader in **telemedicine** enabling more than 3 million teleconsultations annually.
Solution portfolio	• Telemedicine stations • Examination cameras • Connected medical devices (conference cameras, stethoscopes, exam cameras) • Video conferencing and software that allow for connected care and dynamic collaboration of healthcare professionals at remote locations
Geographical reach	Global
Business strategy	GlobalMed relies on a number of **key partnerships** for its success, including with leading medical groups, healthcare enterprises and government agencies. HP, TeleMedGlobal, AT&T, and BT are also among its business partners.
Recent developments	GlobalMed recently acquired TreatMD, a telemedicine company that provides "on-demand healthcare platforms", via which patients can book phone and video consultations with physicians.

3. Barriers to access to telemedicine solutions

Key takeaways

- Telemedicine barriers exist in all countries but do not affect them to the same degree. It is difficult to quantify how their impact varies from one country to the next.
- Since telemedicine is a multi-stakeholder market, barriers also affect the players differently within the countries.
- The lack of a legal framework means there are other underlying obstacles (reimbursement, lack of interoperability, lack of acceptance).
- Funding and financial incentives are key drivers of telemedicine initiatives.
- From our mapping, the lack of acceptance of telemedicine solutions by stakeholders, the poor regulatory framework, the insufficient funding and the inadequate IT infrastructure are the most prevalent barriers to telemedicine widespread deployment.

The aim of the chapter is to:

- Identify and examine barriers to telemedicine in each country;
- Highlight the main barriers encountered in the EU countries;
- Analyse and interpret the areas where EU cooperation or action is needed, based on existing literature;
- Perform a SWOT analysis of the telemedicine framework; and
- Provide policy recommendations for each barrier/dimension of telemedicine.

3.1. Identification and analysis of telemedicine framework conditions

The illustration below presents seven different types of conditions that create barriers to telemedicine. A detailed presentation of each type follows.

Figure 40: Different types of conditions creating barriers to telemedicine

Figure 41 below brings out the most important barriers hampering the use of eHealth tools in programs within the framework of the ICARE4EU project. The study was conducted in 2016 providing an online questionnaire to the managers of the 58 care programs from 24 European countries. The results observed from the study are in line with our findings in the mapping. All the barriers mentioned by the respondents were confirmed by conclusions of publications and report (see Excel file that maps out the barriers to telemedicine country by country).

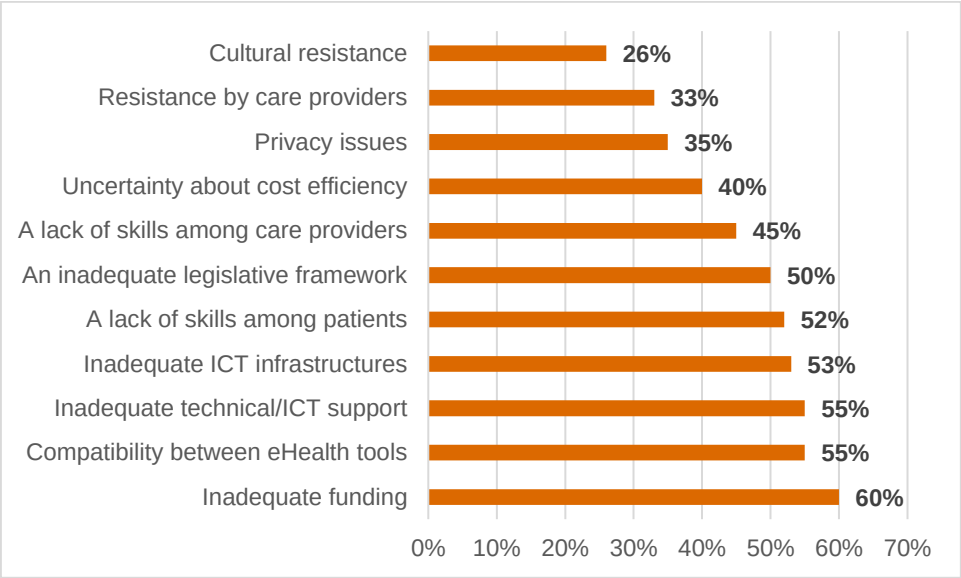


Figure 41: Barriers hampering the use of eHealth tools included in the programs (% agreeing)
Source: Melchiorre M.G., Papa R., Rijken M., van Ginneken E., Hujala A., Barbabella F., eHealth in integrated care programs for people with multimorbidity in Europe: Insights from the ICARE4EU project, 2016

3.1.1. Cultural conditions

- Healthcare professionals consider telemedicine as a threat to the patient-doctor relationship.
- Stakeholders in more advanced countries (in terms of adopting telemedicine solutions) need to communicate and raise awareness of the benefits of telemedicine. They are crucial to demystify and popularise telemedicine practices in other countries.[72]
- A high level of mistrust towards technology in healthcare has been observed across EU countries.

Lack of acceptance by doctors

A persistent cultural barrier impeding the wide adoption of telemedicine is the lack of acceptance of using telemedicine practices by doctors and healthcare professionals in general. A survey on the usability of telemedicine application among a few hundred adults in Austria in 2015 identified the "lack of acceptance by doctors" as the second top ranked overall barrier of the adoption of telemedicine.[73] It is somewhat related to the **reluctance to use innovative technologies** to treat patients. The doctors' attitude towards adoption of telemedicine will strongly influence its acceptance by their patients. Thus, it remains crucial to inform and train healthcare professionals about the advantages of telemedicine to encourage wider deployment of telemedicine.

Besides, surveys conducted by polling organisations[74] highlighted that **the doctor-patient relationship was the prime emotional factor for healthcare staff**. Regular physical contact with patient is what stimulates most doctors in the way they practice. Consequently, they might perceive telemedicine as a threat to a preferred way of delivering health.[75]

[72] SIMPHS 2 (2013), JRC
[73] Haluza D., Naszay M., Stockinger A., Jungwirth D. "Prevailing Opinions on Connected Health in Austria: Results from an Online Survey", *Int J Environ Res Public Health*, August 2016
[74] Ipsos-MORI, "What Matters to Staff in the NHS", 2008
[75] SIMPHS 2 (2013), JRC

In addition to the fear of patient loss, the resistance from medical personnel to adopting technology in healthcare can also be explained by conservatism in some countries. Healthcare professionals tend to protect the traditional models they have grown up with instead of embracing new ways of providing healthcare.

Lack of acceptance by patients

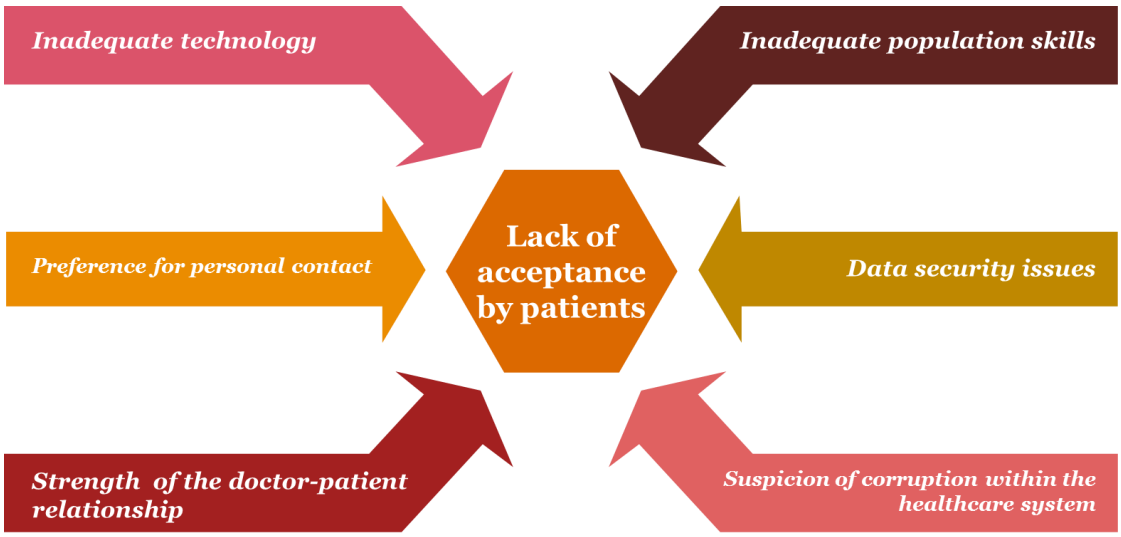


Figure 42: Factors explaining the lack of acceptance of telemedicine solutions by patients

Inadequate technology

Patients are sometimes reluctant to use telemedicine because they consider the existing technology inadequate for treatment; this is prevalent in countries with limited access to/penetration of advanced technology. In these cases the reason for the patient's reluctance to adopt or even demand the use of telemedicine solutions is lack of **awareness of the** existence of advanced solutions or low confidence in technology in general.

Inadequate digital skills

The lack of acceptance by patients is also linked to the **low level of digital literacy** in parts of the population in some countries. People who live well below the poverty line and older people aged over 65 or over 80 often have low ICT skills and are unfamiliar with/unaware of new technologies. In 2016, 17.3% of the population in the EU were at risk of poverty and 7.5% of the population in the EU were severely materially deprived[76]. In addition, 27 million people aged 80 and over lived in the EU in 2016. Finally, 169 million Europeans between 16 and 74 years, this is 44% of the population, do not have basic digital skills[77]. In all these cases, the lack of digital skills can be an important reason of weak end-user adoption of telemedicine solutions.

Preference for personal contact

Some EU nationals strongly believe that technology will never act as a substitute for physical contact in health. In some cases, a **deep-rooted emotional bond links patients and doctors**. General

[76] https://ec.europa.eu/eurostat/statistics-explained/index.php/People_at_risk_of_poverty_or_social_exclusion
[77] https://ec.europa.eu/digital-single-market/en/news/digital-skills-gap-europe

practitioners or other healthcare professionals have sometimes been family doctors for decades and patients want to keep this relationship the way it has always been. In health, old habits die-hard.

Data security

Another reason for the lack of acceptance by patients is the **general fear of data security breaches**. People are not eager to store and share their medical data online because they fear that their personal information might be disclosed to third parties. Because of hacking risks, patients are still reluctant to share their data in most countries.

Suspicion of corruption within the healthcare system

Finally, in a few countries it emerges that the suspicion of corruption within the healthcare system is a major barrier to telemedicine deployment.

All these factors are impeding the complete development of telemedicine. This resistance can even turn into fierce opposition. For instance, the European electronic health insurance card[78] was one of the regulatory actions in Lead Market Initiative[79] but the initiative was hindered due to national opposition from Member States.[80]

The unshakeable doctor-patient relationship

Opponents to telemedicine often blame ICT for **dehumanising healthcare** and fostering impersonal disease management. Technology should not interfere with the sacrosanct doctor-patient relationship.

Patients and doctors are really attached to their usually longstanding personal relationship as sometimes doctors provide also psychological support to their patients. Telemedicine, with technology acting as an intermediate, is perceived to potentially jeopardise that relationship. **Primary care is firmly rooted in face-to-face interaction**.

Based on the findings from the Ipsos MORI study[81], participants perceived that financial interests rather than humane considerations drove the introduction of ICT in healthcare. Yet, the latter constitutes the prime emotional motivator for healthcare professionals.

In summary, the feeling that telemedicine endangers the doctor-patient relationship is a barrier to these services being mainstreamed. Face-to-face interaction is still a pillar of healthcare today for both patients and healthcare professionals.

To overcome these cultural barriers, pressure from the demand side, communication and training are potential actions to pursue.

[78] http://ec.europa.eu/health/ph_information/implement/wp/systems/docs/ev_20071119_co01_en.pdf
[79] http://ec.europa.eu/growth/content/lead-market-initiative-%E2%80%93-speed-time-market-innovations-and-pilot-new-innovation-policy-0_en
[80] Final Evaluation of the Lead Market Initiative
[81] Ipsos MORI, *Attitudes to healthcare services in the UK*, 29 November 2013. Ipsos MORI interviewed a representative sample of 1,009 adults aged 18+ across Great Britain. Interviews were conducted by telephone between 12th – 14th October 2013

3.1.2. Regulatory and policy conditions

Figure 43: Regulatory and policy barriers

The absence of a national strategy

The absence of a national-level strategy for telemedicine is unusual but observed in a few countries. Some governments do not feel the urgency to develop telemedicine and do not consider it a high priority of health strategic direction.

Lack of a legal framework

Most EU countries have a national strategy. However, it emerges that almost all **lack a precise legal framework to regulate telemedicine practices**. Existing laws are usually no longer in line with recent telemedicine innovations.

Thus, it is important for decision-makers to undertake reforms of the current laws in order to promote telemedicine as this will also will encourage the local market. For instance, in Switzerland, the government enacted a law in April 2017 to adopt interoperable patients' electronic health records (EHRs) and thus paved the way to its broad adoption.

Interoperability – Lack of standards and guidelines

The lack of widely accepted/adopted standards and procedures represents a further obstacle.[82] **It limits trust in the quality and reliability of telemedicine solutions**. Within and across countries, telemedicine practices are not necessarily standardised and thus not necessarily compatible. However, as mentioned above, there are initiatives in these directions (e.g. the guidelines adopted by the eHealth Network), which should be taken into consideration by the telemedicine market stakeholder even if these guidelines are optional.

Many specific topics need special attention. For instance, no European rules address the regime of medical liability or the standard of care for healthcare providers.

It brings about a **serious issue of interoperability between telemedicine solutions**. Interoperability is fundamental to avoid legal obstacles (various telemedicine laws), operational obstacles (various methods for data collection) or language obstacles (various terminology or translation issues). The **EU has taken measures to improve interoperability and standardisation in eHealth[83], but it still needs to develop a uniform set of norms** to

[82] Berti P., Verlicchi F., Fiorin F., Guaschino R. and Cangemi A., *The use of telemedicine in Italian Blood Banks: a nationwide survey*, 2014
[83] https://ec.europa.eu/digital-single-market/en/interoperability-standardisation-connecting-ehealth-services

regulate it. For now, Member States still have jurisdiction to regulate this area.[84] Despite repeated initiatives from the EU to initiate coordination, Member States have legal frameworks, approaches and levels of telemedicine development that are too heterogeneous to hope for effective standardisation of practices in the short term. Besides, countries sometimes adopt or adapt specific international standards according to their own needs, which represents an additional barrier to interoperability.

Through the *eHealth Action Plan 2012-2020*[85], the European Commission aims to support patients and healthcare workers, to connect devices and technologies, and to invest in making medicine more personalised. In particular, by capitalising on tablet and smartphone technology (mhealth) the Action Plan seeks to ensure the provision of smarter, safer and patient-centred health services in the future.. In addition, digital health is one sector of the Digital Single Market (DSM), which is one of the European Commission's main priorities. In this direction, the European Commission adopted an action plan in order to enable the digital transformation of health and care in the Digital Single Market on April 2018. The aim of this action plant is to put EU citizens at the centre of the healthcare system[86]. To allow EU wide deployment of developed solutions, interoperability is high priority of the EU strategy in DSM. *The eHealth European Interoperability Framework* references standards but Member States can choose to approve open international standards. Therefore, non-interoperable solutions persist and impede the scaling-up of telemedicine.

This lack of standards has mostly been felt in relation to **data ownership and data sharing**. Indeed, countries have been struggling to implement regulations or requirements related to cross-border sharing of patient data. Therefore, the need for EU-wide harmonised standards and guidelines to ensure interoperability in data access and processing has been explored in EU-funded projects (such as ESPOS and Antelope).

Data security

Because of the legal vacuum regarding data protection and security in most countries, many fear a **commercial or malicious use of patient data**. The recent example of the personal data misuse by Cambridge Analytica, which caught the public's attention, increased this fear. Determining the right of access to patient information is a difficult question to solve.[87] How much patient information should be made available to hospitals? Legal loopholes are persisting on these issues and responsibilities are not clearly defined[88]. Sharp rise in hacker attacks and in medical identity theft has been noticed. Yet, we underlined earlier that these concerns represent a major barrier to patients' acceptance of telemedicine.

While policies are too permissive or non-existent in some countries, **others have adopted very stringent data protection laws**, which impede any information sharing between healthcare professionals. EU countries definitely need to strike a balance between data security and data sharing. Addressing aspects of privacy, confidentiality, and data security is vital in order to give new impetus to telemedicine.

Liability issues

Legislations are not clear regarding liability and accountability of practitioners in telemedicine. Therefore, physicians are reluctant to embrace telemedicine since they are worried about being made **responsible for failing to act**.

[84] Vera Lúcia Raposo, *Telemedicine: The legal framework (or the lack of it) in Europe*, 2016
[85] https://ec.europa.eu/digital-single-market/en/news/ehealth-action-plan-2012-2020-innovative-healthcare-21st-century
[86] https://www.covingtondigitalhealth.com/2018/05/summary-of-the-european-commissions-ehealth-strategy/
[87] Professeur Hervé Dumez, Professeur Etienne Minvielle, Madame Laurie Marrauld, *État des lieux de l'innovation en santé numérique*, November 2015
[88] Topol E., *The Creative Destruction of Medicine: How the Digital Revolution Will Create Better Health Care, Basic Books, August 2013*, p. 336

For instance, a telemonitoring device such as LifeWatch transmits wirelessly and continuously asymptotic and symptomatic arrhythmia to clinicians. If the doctor is busy and does not have time to review the patient's daily activity, he/she might not notice the patient's condition worsening. If the patient passes away, would the doctor be made responsible for held liable?

The legal framework in EU countries **does not provide explicit rules about liability**. In the Netherlands, for instance, due to the lack of regulation, healthcare professionals are fearful of using telemedicine because they deem that the nature of remote or virtual care exposes them to the risk of malpractice.

Challenge of medical licensure or credentialing

Especially in the US, healthcare providers must have a **medical license available in the patient's state to deliver care**. This regulation acts a barrier to telemedicine expansion within the country.

Nonetheless, progress has been made. The Interstate Medical Licensure Compact, supported by the American Medical Association and enforced in 2015 by 17 states, allowed physicians to practice telemedicine in these states.

In the EU, each country has its own rules for delivering a medical license to practice healthcare in its territory. Although the procedure to get a license in a Member State is generally smoothed for doctors coming from EU countries, the heterogeneity of the models makes it difficult for professionals to understand which conditions they must meet to practice in a specific country.

3.1.3. Social security conditions

Telemedicine reimbursement rules within the country

In almost all countries, reimbursement schemes of teleconsultation or other telemedicine services to patients remain vague or non-existent. Health funds are often held responsible for **narrow restrictions on the coverage and reimbursement of telemedicine services**. The slow pace of legislation change is not helping solve this problem.

Sometimes, market players have reached agreements with insurance companies (Germany, the Netherlands) or public healthcare providers (the UK, Italy, Spain) but they are the results of **time- and resource-consuming negotiations**. While some telemedicine services are now eligible for reimbursement, patients still bear the cost of most of them. In addition, reimbursement from health funds often takes place if specific conditions are met (e.g. service provided in a doctor's office or patient living in a rural area). Thus, **non-transparent and complex reimbursement models** confuse patients who are not able to understand which services are reimbursable and to what extent.

For instance, in Italy, the outcome of the cooperation between the government and the regions was the integration of telemedicine into the definitions of home hospitalisation (OAD) and integrated home care (ADI). However, these efforts have been fruitless since the reimbursement schemes and financing structures have not kept pace with these changes. Misalignment between policy and execution accounted for the hardship of generalising telemedicine practice in the case of MyDoctor@home for example.

~~Without proper reimbursement rules, the telemedicine market will not grow as expected.~~

France recently decided to reimburse teleconsultation exactly as if it was a face-to-face consultation. This rule starts on Sept 2018. It will be interesting to monitor the impact on the development of teleconsultations in the short and long term.

Telemedicine reimbursement rules between EU countries

This reimbursement issue is even more blatant between EU countries. Since reimbursement schemes vary from state to state, patients struggle to be reimbursed for telemedicine services provided abroad.

Directive 2011/24/EU on patients' right in cross-border healthcare defines the conditions under which a patient may receive medical care and reimbursement from another EU country. Furthermore, Coordination *regulations (EC) Nos. 883/04 and 987/09* entitle insured individuals to receive healthcare elsewhere within the EU or EEA and in Switzerland. It covers healthcare costs, as well as the prescription and delivery of medications and medical devices as it would in their home country. Usually, patients pay upfront and get reimbursed afterwards by their home health fund on the same amount they would have received in their own country (article 7).

However, the rules on reimbursement are **valid only if the treatment is available and covered in the patient's home country**. These rules are obviously applicable to telemedicine but national legal frameworks and reimbursement schemes (especially for telemedicine) are **unclear and highly heterogeneous**. National health funds might not reimburse the same (tele)medical acts and if they do, not necessarily in the same amount or proportion. Besides, a health fund can refuse to reimburse a patient if it deems that the medical treatment could have been delivered in the home country.

3.1.4. Industrial and technical conditions

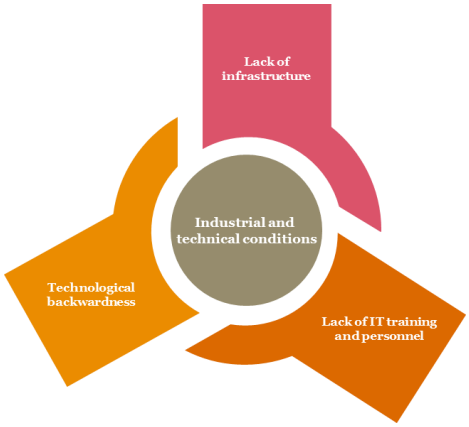


Figure 44: Industrial and technical barriers

Lack of infrastructure

EU countries are also facing a lack of IT infrastructure, which is generally **too basic or inadequate to integrate the telemedicine solutions currently available**. Insufficient funding and poor investment in modern equipment for hospitals do not permit to bridge the gap between the innovative and advanced telemedicine products/services and the existing infrastructure. Yet, setting up reliable and broadband systems is crucial to provide quality telemedicine practices. For instance, the lagging information and process management infrastructure in Ireland is hampering the widespread adoption of telemedicine in the country[89].

In addition, countries are struggling to implement interconnected networks across various levels of the health sector. A **uniform and standardised IT infrastructure would provide network synergies and bring significant improvements in information and resource flows**. Instead,

[89] Department of Health, *eHealth strategy for Ireland*, 2014

the heterogeneity of the systems adopted by the entities in the health sector results in time and resource being wasted.
In Slovenia, the government's failure to reach its ambitious telemedicine goals (defined in 2005 by the Ministry of Health) results in persistent bureaucratic procedures and non-functional IT infrastructure in the healthcare sector[90].

Lack of IT training/personnel

Another identified barrier to the uptake of telemedicine is the lack of IT training for healthcare providers. Physicians in general are not familiar with the new technologies and need some professional IT support to understand how to properly use them in a medical context. Telemedicine is constantly developing, market players are flooding the market with new solutions and thus, **doctors are struggling to keep pace with the latest developments**.

Telemedicine technologies often require highly specialised knowledge. Yet, there is an **inadequate pool of specialised medical personnel** capable of exploiting them since few physicians have the necessary skills to introduce technology in their patients' pathway.

A reason for this is that practical training in telemedicine **has not been firmly incorporated into continuing education**. Both at EU and national level, updated training programmes must be created to increase digital literacy and to expand the workforce's capabilities regarding the use of technology in telemedicine.

It is fundamental to recall that telemedicine means introducing ICT to help improve healthcare delivery and is not meant to replace healthcare providers. Therefore, authorities should not overlook investments in human capital, which are essential for effective implementation of the technology.

Less technologically advanced countries

Some EU countries are lagging behind regarding technological development. Limited **internet connectivity in medical establishments** combined with the population's **poor computer literacy** undermines the potential of telemedicine deployment in those countries.

In some countries such as Ireland, physicians also reported system crashes linked to power outages, computer viruses or hardware failures. Having an IT infrastructure in medical establishments is a first step but it needs to be **efficient and reliable to support leading-edge technologies**.

A number of less developed EU countries still rely on *"paper-based"* hospitals in which the telemedicine potential is very restricted. Not only would digital procedures mean **increased workload** for healthcare professionals because these procedures would coexist with the usual paperwork but they would increase the **risk of information and data misalignment**. Missing or outdated technology represents an additional barrier to telemedicine adoption.

3.1.5. Knowledge conditions

Lack of evidence, awareness, education

The lack of unambiguous evidence of the benefits holds up widespread adoption of telemedicine by all stakeholders. A stronger consensus on cost-effectiveness would enable patients, healthcare professionals, insurance companies and policymakers to understand the potential of telemedicine in healthcare. However, EU citizens are not fully aware of it.

[90] Stanimirović D., Mirko Vintar M., *Analysis Of E-Health Development In Slovenia*, 2013

Scientific-based evidence of telemedicine benefits is not abundant. Besides, scientific papers proving the cost-effectiveness of telemedicine solutions generally use a jargon inaccessible to non-experts. Consequently, policy-makers are unwilling to make hasty decisions on legislation, reimbursement and funding as long as there is little available and standardised evidence. This in turn feeds through to market players who cannot spread out their products and services and have to keep prices high due to missing market scales.

Higher education ability to deliver a skilled workforce

Medical schools have **not yet firmly incorporated telemedicine training into their academic standards**. Yet, it would be wise to teach students the difference between remote care and in-person care as well as the benefits, limitations and regulations of telemedicine. It would familiarise them with telemedicine practices and enable them to integrate them properly in care delivery.

Germany has started to address this issue and the University Medical Centre Mainz offers a teaching encompassing five modules, which aim at upgrading students' skills in telemedicine. This makes sense since today's medical students have **grown up using digital technology** and thus are much more comfortable with integrating it in the delivery of medical care. This high digital literacy must nevertheless be sustained by formal and structured training in order to ensure that they will provide high-quality telemedical care.

3.1.6. Financial conditions

Funding matters

Telemedicine uptake also relies on the financial resources made available, essentially to **cover for technology purchase upfront costs**. The question is who should be responsible for the funding.

The studies conducted by JRC showed that, regardless of the source, **funding is crucial to incentivise telemedicine initiatives**.

However, funding relying only on the industry is not viable. Funding must also come from national, regional or EC budgets to be sustainable. It constitutes a prominent driver for SME and start-up involvement since it enables them to benefit from subsidies or preferential loans from the government.

For instance, in France, since 2012, the *Fonds d'Intervention Régional (FIR)* has invested €40 million each year in actions and experiments validated by the regional health agencies (ARS) in order to stimulate telemedicine projects and foster innovation. Yet less than 50% of this annual budget has been effectively dedicated to telemedicine, the regional health agencies using the *"fungibility principle"* to allocate these resources to other projects. In this case, the initial objective of promoting telemedicine initiatives is partially compromised by the **poor management of resources**. Although it needs to further efforts, the UK government also provides funding through the *Technology Strategy Board (TSB)* or the *Department of Health*. The TSB has notably supported services and applications for the elderly such as the *ALIP platform*, *Year Zero* or *Living It Up*.

EU countries all have **different funding patterns**. For France and the UK, the government might be a key player but other countries just rely heavily on European Commission funding. This happens when national or regional sources are quite limited and when governments cannot afford to invest in telemedicine. The European Commission has implemented many EU-funded projects (*MOMENTUM*, *United4Health* and Renewing Health for instance): the subsidies granted, however, must supplement other funding since the EU will not fund 100% of a project. Therefore, EU countries need to **boost co-payment for telemedicine projects or solutions by strengthening industry commitment in telemedicine funding**. To drive companies to invest in telemedicine projects, governments must create research incentives and tax benefits to get the industry involved in this sector.

Nevertheless, some EU countries act as role models in terms of funding. In Denmark, the *PWT Foundation* is providing many pilot projects with substantial resources: it endeavours to narrow the gap between the R&D phase and the implementation and distribution phases. As of 2010, 54 local demonstration projects had received funding from *the PWT Foundation*. In Scotland, success stories in funding to overcome financial barriers also exist. The Scottish government's budget for eHealth was €112.5 million in 2012, of which the great majority goes to NHS National Services Scotland to fund national eHealth projects. For instance, *the TeleScot project*, a program of academic research investigating telemetric-supported telemonitoring of a number of long-term health conditions, received funding of around €2.375 million from different sources.

3.1.7. Market conditions

Fragmentation between primary and secondary care

The fragmentation between primary and secondary health care is also slowing down the adoption of telemedicine solutions.

Professionals in hospitals believe that the **initial impetus must come from GPs** because they are in a position to identify and convince the patients more suited to use telemedicine in their care pathway. This first approach from GPs could help hospitals to resort to these technologies when they face full bed occupancy and must discharge some of their patients early.

Nonetheless, there is a **lack of coordination between primary and secondary care professionals**, who shift the blame onto each other regarding the slow deployment of telemedicine. In addition, the lack of incentives and of e-readiness is preventing GPs from embracing telemedicine: **this results in a stalemate within the medical sector**.

Fragmentation of the solutions

The solutions developed by the various companies are usually **not interoperable in relation to how data is structured, stored, transmitted and accessed**. They are therefore deeply fragmented instead of being integrated. As a consequence, the telemedicine solutions implemented in a country's hospitals or regions might be completely ineffective elsewhere.

This problem underlines **how critical it is to adopt common standards** for telemedicine. Interoperability is key to efficiently integrating the new solutions into the established systems.

Multilevel policy intervention and the involvement from all stakeholders, including the industry, are required to improve this situation.

Buyers' fragmentation and constraints on market scale

The procurement process of telemedicine solutions differs from a country to another. German companies negotiate with health funds whereas in Spain, companies have talks with local healthcare providers. In Italy, they first need to approach regions and then municipalities.

These **heterogeneous models add confusion for companies** that would like to make their solutions available internationally since they do not necessarily know who they should approach to do so. Companies struggling to enter foreign markets do not benefit from economies of scale and thus keep a **strong "home base"**.

In conclusion, the fragmentation of solutions, of buyers and between primary and secondary care acts as a heavy barrier to telemedicine and seriously restricts the potential for its widespread adoption across EU countries.

3.2. SWOT analysis of the telemedicine framework

Based on the review of literature, we provide the following SWOT analysis[91, 92, 93, 94, 95]:

Table 2: SWOT analysis of the telemedicine framework

Strengths	Weaknesses
Cultural conditions - Overall high digital literacy of the population. **Regulatory and policy conditions** - National policy/strategy in telemedicine. - Policy focus on chronic disease management. **Industrial/technical conditions** - Multiplication of innovative and advanced solutions. **Financial conditions** - Dedicated budget from the EC to telemedicine projects. - National or regional funding mechanisms promoting sustainability of initiatives. **Market conditions** - Cost-effectiveness of telemedicine solutions.	**Cultural conditions** - Lack of patient/social awareness of telemedicine. - Fear of malpractice among healthcare providers. **Regulatory and policy conditions** - Legal loopholes regarding liability and data confidentiality and security. - Poor regulatory framework, lack of standards and guidelines. - Misalignment of national policies might jeopardise an EU-wide uniform approach to telemedicine. - Different data privacy policies. **Social security conditions** - No clear and efficient reimbursement models. **Industrial/technical conditions** - Insufficient interoperability. - Poor system reliability and response time. **Knowledge conditions** - Lack of scientific-based evidence of the benefits of telemedicine. - Shortage of trained staff in telemedicine. **Financial conditions** - Limited support from government. **Market conditions** - Complexity of relationship and interest management between the various players and stakeholders. - Interoperability challenges due to EU fragmentation.

[91] SIMPHS 2 (2012), JRC
[92] Hoerbst A, Schweitzer M. A systematic investigation on barriers and critical success factors for Clinical Information Systems in integrated care settings.
[93] Study on Big Data in Public Health, Telemedicine and Healthcare, Final Report, December 2016
[94] eHealth in Europe - Status and Challenges
[95] Report on the public consultation on eHealth Action Plan 2012-2020

Opportunities	Threats
Cultural conditions - Develop proper dissemination and communication strategies to overcome GPs' reluctance. - New generations more comfortable with using technologies in healthcare. - Use already interested public and private stakeholders as levers to increase acceptance. - Communication with the public can increase awareness of how important open data and data sharing are. **Regulatory and policy conditions** - New legislation can be the foundation of wider use of telemedicine. - Find common ground between Member States' legislations and national standards. - Define clear rules on liability when using telemedicine solutions. **Social security conditions** - Develop of new reimbursement frameworks. **Industrial/technical conditions** - Technology needs to be flexible to meet users' needs properly. It has to allow for personalisation (e.g. parametrisation). - Promote training of healthcare professionals and end-users. - Invest in IT infrastructure in hospitals or other specialist facilities. - Further cooperation with industry to ensure interoperability and alignment with clinical protocols. **Knowledge conditions** - Achieving a minimum level of cross-linked knowledge of all involved parties may facilitate wider use of telemedicine solutions. - Increased motivation for education and training in telemedicine. - Multiply health technology assessments (HTAs) to obtain a systematic evaluation of properties, effects and impacts of telemedicine. - Greater involvement of HTA bodies recently that are able to provide scientific-based evidence. **Financial conditions** - Diversify funding schemes and increase commitment from the industry. - Promote multi-source financing and public-private partnerships in funding. - Review existing incentives. **Market conditions** - Leverage demand from patients in “ICT-advanced” settings. - Gain the support of GPs so that they can influence their patients.	**Cultural conditions** - Loss of the doctor-patient relationship and of the social link. - The elderly's resistance of technology in the care process. - Lack of experts' commitment to telemedicine practices. **Regulatory and policy conditions** - Persisting lack of interoperability between solutions and difficulty in aligning national standards and protocols. - Different political priorities and interests hindering the wider use of telemedicine. - Restrictive (privacy) laws might hinder data sharing. **Social security conditions** - Lack of coordination between EU countries in establishing reimbursement rules. **Industrial/technical conditions** - Risk of technological flaws. - Risk of data leaks. - Data overload can create resistance. - Different technological levels and advancement of involved national bodies and stakeholders. **Knowledge conditions** - Dearth of impact assessments to balance the need for sound evidence of telemedicine benefits. Reports including qualitative and quantitative elements are crucial to facilitate decision-making. - The swift pace of technological change could cause educational programmes to be outdated by the time of their implementation. **Financial conditions** - Financial burden of initial investment in telemedicine. - Expensive solutions from some market players. **Market conditions** - Increased workload for healthcare professionals if data coexists with paper. - “Silo thinking” and lack of cooperation between primary and secondary care. - Enduring strong national focus from telemedicine market players. - Market players fear a potential loss of intellectual property.

3.3. Policy recommendations

3.3.1. Actions to overcome cultural barriers

Trigger pressure from the demand side

Patients from advanced countries in telemedicine **expect GPs to be up to date regarding ICT in healthcare**. For instance, Danes consider doctors who are not equipped with a PC during a consultation to be second-rate. Doctors are more likely to adopt telemedicine and technologies in general when they are urged to do so by patients.

Launch appropriate communication campaigns

Another way to overcome this barrier is to set up **suitable communication events to raise awareness of telemedicine benefits**. It is fundamental to emphasise that technology is a complement rather than a substitute to face-to-face interaction. Dialogue between all stakeholders (patients, healthcare professionals, market players, health insurance companies) might be the best way to remove initial doubts and reservations about telemedicine. In Italy, notable communication operations have been launched as well as seminars to sensitise interested parties to the benefits of telemedicine.

Train healthcare professionals

Integrating technologies in doctors' in-service training may release the full potential of telemedicine development. It would enable the **workforce to become more familiar with telemedicine** and thus to be more confident in using it in the care delivery.

In France, SF Telemed offers training in order to support all kinds of healthcare professionals in their learning process of telemedicine. Similar training courses are available in most EU countries but their prices are often prohibitive.

3.3.2. Actions to overcome regulatory barriers

Top-down approaches

Top-down approaches are useful levers to ensure interoperability and service quality standards. The EU has a key role to play in this field. An effective policy would allow for guidance, support and skills development likely to comply with central requirements, regulations and incentives.

Countries such as Estonia have already tackled this interoperability issue. X-Road is an e-solution that allows the nation's various public and private sector databases to link up and function in harmony[96].

Government could establish **funding eligibility criteria**: projects that show significant advances towards interoperability must receive assistance in priority.

Simplify and secure health data sharing

The Member States must allow effective collection, storage, processing and sharing of health data and **set up a clear data protection legal framework**, with a simple and workable patient consent procedure.

Decision makers need to implement these policies **without jeopardising patients' rights to privacy and confidentiality**. Member States should set up governance mechanisms to guarantee

[96] https://e-estonia.com/solutions/interoperability-services/x-road/

secure and fair use of data. The General Data Protection Regulation (Regulation 2016/679) could be used as a model, as one of its objectives is to protect the rights of natural persons.

Coordination

EU countries should **harmonise their legal frameworks** in order to make solutions compatible and to enable cross-border telemedicine practices.

They also need to **agree on terminology and definitions to share the same language** and align already existing standards before incorporating them into the national legislation. Besides, existing standards should be updated regularly for two main reasons: to keep pace with the ever-changing technological environment and to avoid overlaps between existing and new standards that might create confusion.

3.3.3. Actions to overcome social security barriers

Public authorities are starting to address these social security barriers. Although few telemedicine practices are currently eligible for reimbursement, all Member States are redoubling their efforts **to extend the scope of telemedicine by gradually adding new acts covered by social security**. Amplifying and simplifying reimbursement rules could bring down major barriers and speed up telemedicine adoption.

In France, thanks to an initiative from the Health Ministry, representative unions of private physicians and the health insurance fund have sat down together and opened negotiations to extend reimbursement schemes in telemedicine, in particular for teleconsultation. Articles 54 and 55 of the draft law on the financing of the health fund (PLFSS 2018) set up the conditions to facilitate the eligibility and the registration procedure for the reimbursement of telemedicine acts.

3.3.4. Actions to overcome industrial/technical barriers

Several avenues of thought to overcome industrial/technical barriers:

- **Increase public investment** to enhance the IT infrastructure and reinforce its capacity to process information flows.
- **Strengthen human capital** so that the medical workforce meets the current telemedicine requirements.
- **Integrate practical training in the curricula of medical schools** to ensure an acceptable degree of technological skills development.
- The European Commission could fund appropriate initiatives **aimed at facilitating knowledge sharing**.

3.3.5. Actions to overcome knowledge barriers

In order to tackle knowledge barriers, EU countries need **to promote scientific-based evidence of telemedicine benefits** in a language, which is accessible to any reader. A number of patients and doctors are still reluctant to use telemedicine solutions because they consider that there is still a lack of information as to their effectiveness. The main findings of telemedicine studies should be made available through the **right communication channels** to reach the entire population.

In a similar vein, telemedicine market players also need to learn **how to correctly market their service** to patients because too many patients are not aware of the existence of solutions that could suit their needs. Appropriate and targeted marketing campaigns could be a good means for companies to make themselves more visible.

Finally, governments could fund additional training courses in telemedicine for GPs who are the main contact points for patients and thus are able to convince the latter to use telemedicine solutions to treat their diseases. **Upskilling health professionals** (including medical doctors) **in digital technologies** is key for the digital transformation of health.

3.3.6. Actions to overcome financial barriers

To get healthcare professionals involved in the development of telemedicine, EU countries could implement pay-for-performance (P4P) schemes **to reward doctors** (bonuses, add-on payments) when they meet patient satisfaction benchmarks in telemedicine.

The **EC also has a role to play to remove financial barriers**. It should steer suitable investment to relevant initiatives in order to guarantee cost-effectiveness and sustainability. However, the EC cannot be the only one responsible for funding. Member States need to favour **multi-source financing and public-private partnerships to spread the initial financial burden** and the risk of investment associated with the development of new telemedicine solutions.

Another strategy to ensure interoperability is to make it a criterion in public procurement. By setting interoperability standards that solutions should meet in order to be selected during a public procurement process the EU and MS governments can stimulate interoperability.

3.3.7. Actions to overcome market barriers

Recommendations for market players[97]:

- Examine the policy context and identify **potential blockers and enablers**. Market players should develop their solutions around the enablers, and define workarounds to resolve blocking elements. This includes mapping existing resources in relation to the implementation context, financing, internet access, legislations, etc.

- Make sure that their telemedicine **solutions meet defined user needs**, focusing on care professionals, patients or other key stakeholders. In addition, design and plan awareness actions to make sure target users are informed about the benefits of the new system.

Recommendations for governments:

- **Appoint champions to advocate the initiative**, monitor change management and define new roles for care professionals whenever required, to implement the change and coordinate the new care processes. “Innovators” and “early adopters” can foster the use of innovative Big Data analytics.

[97] W. Gaafmans, F. Abadie, IPTS, Information Society Unit, eHealth team., SIMPHS 3, Guidelines for ICT-supported Integrated Care, 19 May 2015.

4. Economic analysis

Key takeaways

- In essence, telemedicine is generally perceived and judged to be cost-effective in 73.3% of the cases addressed by the literature.
- Neutral effects were discussed in 21.3% of the selected references, mainly in systematic reviews.
- Negative effects account for 5.6% of the studies.
- Further adoption of telemedicine increases benefits: it reduces costs (consultation costs, travel costs, time spend) and increases patient survival and life quality.
- To overcome the barriers there is a need for more scientific evidence for its efficiency and large scale experiments to assess the impact of a wider deployment.
- Raising awareness (patients, doctors), stimulate integration between stakeholders and reimbursement are keys to success.

The present chapter develops an economic assessment framework with the objective of evaluating the potential benefits of future deployment of telemedicine tools and services across the EU. This assessment is relies on the development of an economic decision model[98] based on insights drawn from scientific research.

This economic model enables a cost-effectiveness analysis (CEA) of the future EU-wide deployment of telemedicine solutions under different scenarios; for the sake of parsimony, we analyse two specific cases of potential future deployment: a) promoting telemedicine for any type of disease, and b) promoting the use of telemedicine for major chronic diseases. For each of these two cases, we and investigate the implications of a "baseline" scenario (business as usual) and an alternative scenario (efforts to increase the use of telemedicine tools and services).

The development of this assessment framework is based on a **two step approach**; the first step involves the research design and collection of information on the cost-effectiveness of telemedicine solutions and services adoption. The activities undertaken in during this step are the **literature review on the cost-effectiveness of telemedicine solutions**. The second step of the approach involves the development of the economic model itself, the activities performed during this step include the **implementation of the decision model, and the estimation of the total costs and benefits associated to each scenario** under each particular case of future deployment.

The key objectives addressed by the activities undertaken within the scope of the present chapter are to highlight the evidence and model the cost-effectiveness in using telemedicine to promote health, minimise illness and disability, and generally improve quality of live and longevity.

[98] Morgan, S., *et al.* (2007). Assessing the value of medical devices. University of Nottingham – Brunel University. Discussion document

4.1. Systematic review of cost-effectiveness studies and data collection

The systematic review of cost-effectiveness studies carried out in this section aims at providing an initial insight into the capacity of telemedicine solutions to improve the quality of healthcare services and reduce the costs incurred, in comparison with traditional care. This assessment made it possible to distinguish positive effects in terms of cost-efficiency, from neutral and negative effects raised in the health economics literature.

A five-stage scoping review methodology was implemented to identify and analyse the economic literature on the cost efficiency of telemedicine through the following steps:

1. Identification of the literature sources and repositories in order to ensure access to a relatively wide sample of articles and reports;
2. Identification of relevant studies by interrogating the repositories on several key topics (cost-efficiency and telemedicine, eHealth, mHealth or digital health);
3. Selection of relevant studies for review;
4. Creation of a database from the selected literature for analysis, and
5. Appraisal and analysis of the literature.

The data collection took place between October and November 2017, focusing on electronic searches conducted across several databases referenced in the Tender Specifications for the study and corresponding proposal; namely the Cochrane Database of Systematic Reviews and the Database of Abstracts of Reviews of Effectiveness (DARE), the CRD database of the University of New York, Jstor, Science Direct, and PubMed.

The output of the literature review and research design comprises a database of a total of 190 scientific references whose appraisal was performed on the information present in their abstract, their characteristics on the topic, and information about the study. A PRISMA assessment of the criteria led to the following outcome:

- 44 articles not fit for analysis, as the topic did not match the needs of this study;
- 61 articles fit for analysis;
- 28 articles presenting a systematic review on cost-effectiveness;
- 47 articles addressing seldom benefits or barriers to adoption of telemedicine services without reaching a conclusion on their cost-efficiency.

For the purpose of this analysis, we used the subset of 89 literature references (61 studies and 28 reviews) addressing the cost-efficiency of telemedicine solutions to perform a second appraisal, this time indicating the conclusions obtained.

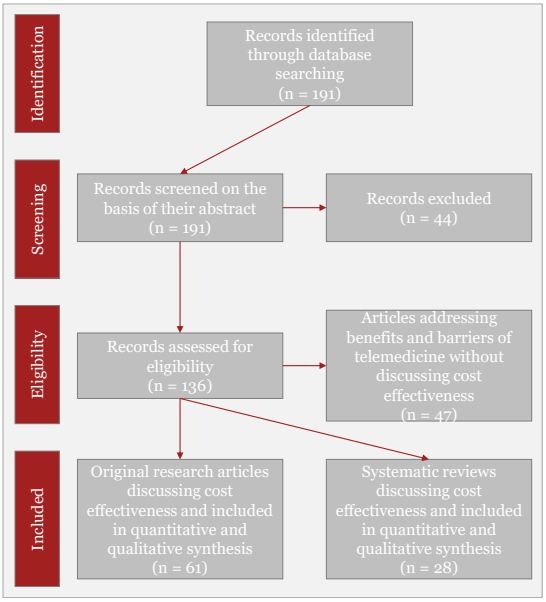


Figure 45 : Screening flow diagram of included literature

The results from this review show that in essence, **telemedicine is generally perceived and judged to be cost-effective in 73.3% of the cases addressed by the literature** while neutral effects were discussed in 21.3% of the selected references. The latter mainly found in systematic reviews that reach a conclusion on the lack of robust and high quality studies on the evaluation of telemedicine services, advocate for further research and evaluation, and do not pronounce in favour of a positive or negative assessment. The following Figure provides an illustration of the results of the sentiment analysis.

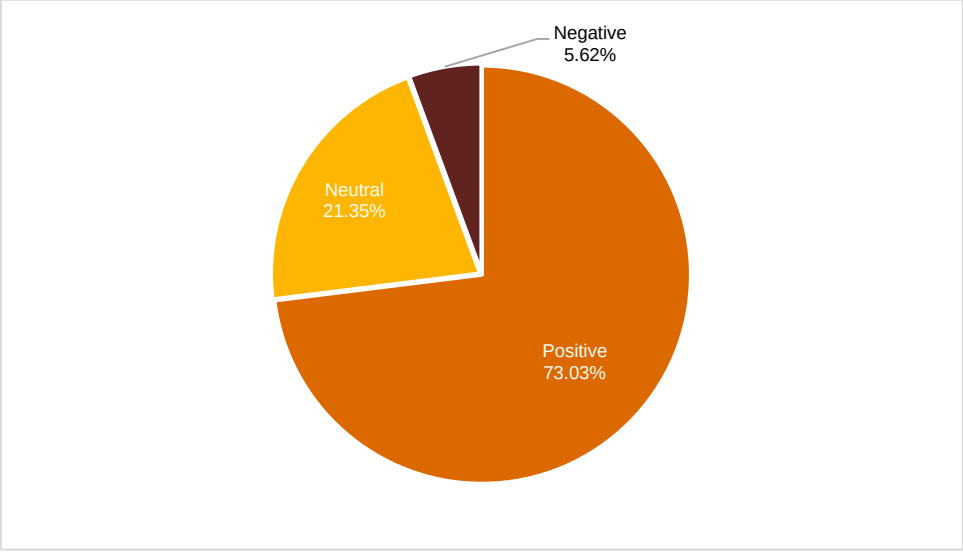


Figure 46: Distribution of cost-effective effects from the assessed literature

Furthermore, the studies under assessment were categorised according to a broad classification of the **type of telemedicine solution addressed**; this classification comprises tele-expertise (interaction only between healthcare professionals), teleconsultation (e.g. selection, diagnosis, and treatment of patients), and telemonitoring (e.g. follow-up treatment, telecare, self-management). The distribution of

these studies indicates that the majority of solutions are represented by teleconsultation solutions (38.2% share) and telemonitoring solutions (43.8% share) or programs discussed within the sample of literature references. Finally, a 16.8% share of the sample, mainly represented by systematic reviews, discussed either the two main categories (teleconsultation and telemonitoring) or all categories including tele-expertise.

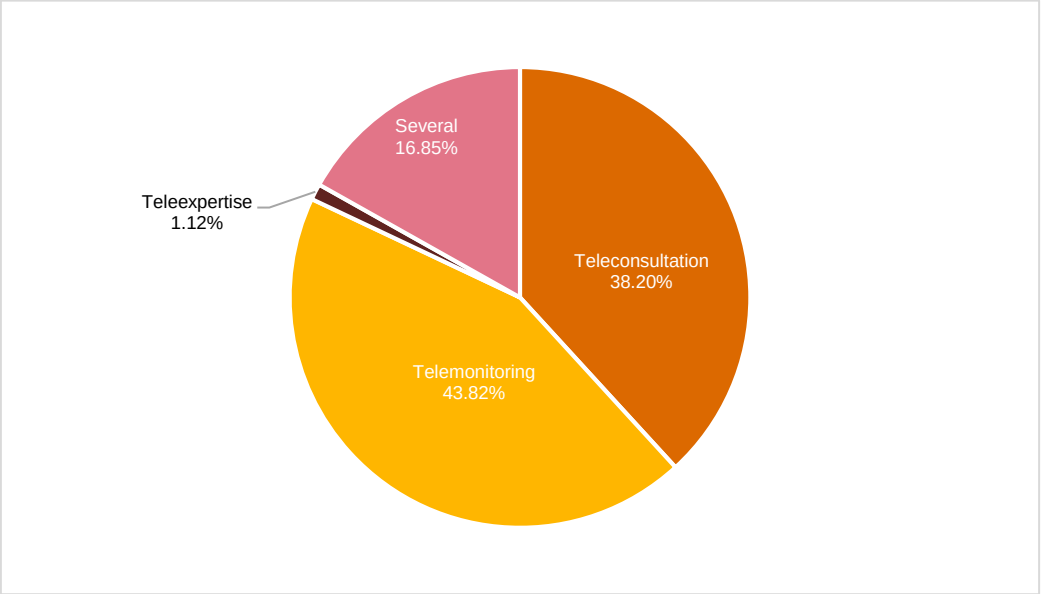


Figure 47: Distribution of telemedicine solutions in the assessed literature

In addition to these descriptive analyses of the study assessment, we focused on the two principal categories discussed in the literature, **teleconsultation and telemonitoring**[99], to better understand their cost-effectiveness and potential differences, as indicated in the conclusions from the assessment of studies. This analysis shows that in general both types of telemedicine solutions are assessed as cost-effective in the literature in a relatively similar proportion, with higher shares in telemonitoring due to the higher concentration of the selected literature on this type of telemedicine solutions. This difference is mainly driven by the neutral conclusions on cost-effectiveness, which are twice as high in teleconsultation as in telemonitoring. These observations and the conclusions observed in, and drawn from the sample of studies under assessment, may point to a longer period of adoption or to major barriers to adoption and scale in the case of teleconsultation solutions. The contingency Table below provides details on this distribution.

[99] Which matches with the findings of the solution mapping exercise where telemonitoring is the predominant type of intervention for telemedicine solutions

Table 3: Contingency table on the distribution of types of telemedicine solution and associated cost-efficiency

Telemedicine\Cost-effectiveness	Positive	Negative	Neutral	Total
Teleconsultation	31.5%	2.2%	4.5%	38.2%
Telemonitoring	34.8%	3.4%	5.6%	43.8%
Teleexpertise	0.0%	0.0%	1.1%	1.1%
Several	6.7%	0.0%	10.1%	16.9%
Total	73.0%	5.6%	21.3%	100.0%

4.2. Cost-effectiveness of telemedicine solutions

The literature review on the cost effectiveness of telemedicine solutions and services led to the collection of data related to monetary costs and benefits (in terms of costs, time and logistics savings, as well as improvement of key performance indicators such as morbidity and quality adjusted life years).

The collected information was used to feed the economic models that allows to evaluate the potential effectiveness of future development. The two models (any disease, or chronic diseases only) were evaluated under two different scenarios for comparison. **Baseline scenarios** denote no intervention and business as usual. **Alternative scenarios** denote an increased rate of adoption of telemedicine.

4.2.1. Baseline scenario – No EU driven efforts to adopt of telemedicine solutions

The baseline scenario represents the current situation on the European telemedicine market; it used as a point of reference for the assessment of the EU wide deployment of telemedicine solutions. Under this scenario, we consider two models, one based on the total population of the EEA area, and the second focused on the chronically ill population.

Under this scenario, even though society, healthcare providers and decision makers know that we need to go through a change of paradigm, decisions concerning the business models to be adopted and actions in favour of the uptake are still hardly taken or difficult to implement.

There is an unclear vision on the utility of telemedicine pointing out to its use to either increase performance (by treating more individuals with less resources), or its use for the provision of optimal care (by increasing its quality and efficiency). Regulators still try to understand better how to manipulate the levers to trigger a wide adoption and implementation of telemedicine.

In this context, the regulator needs to set clear rules in terms of security, confidentiality, and ethics. It is important to understand that the use of telemedicine tools and services require the convergence of different professions, types of organizations and technical infrastructure is often differ and fail to integrate together. This environment creates certain distrust and defiance from the medical professions to the technology itself.

In addition, the human factor is still very important in the healthcare area; patients will only change slowly. However, today patients have started modifying their behaviour, they usually turn first to the internet for comparison of symptoms or plain information, and then consult the doctor with a

preconceived idea on their health status, that may or may not be correct. Changes are starting to take place, although very slowly.

Market characteristics

Under the baseline scenario, without any EU intervention, patterns in the demand for telemedicine solutions will not be affected by the sponsoring effects of the integration of telemedicine within national health systems, or by the harmonisation of standards, regulation, and security requirements. In essence, then demand will not be aggregated at national levels, and therefore no-synergies between private and institutional users, but also between EU MSs will be achieved.

On the supply side, the market for EU public service users will remain highly fragmented, with telemedicine, e-health and m-health market players segmenting, and mainly investing on more profitable markets defined by catalysing factors for the adoption of such technologies, e.g. demographics, health infrastructure, reimbursement systems, etc.

On the governmental side, national health systems would need to be challenged at some stage regarding the opportunity cost and cost-effectiveness of not- adopting telemedicine solutions at large scale, without any guarantee of meeting the increasing service capacity needed to meet the needs of a growing population.

The demand for telemedicine solutions will thus keep growing over time for as long as the population dynamics, the investment in health infrastructure, and capital and operational expenditure in human resources create the appropriate environment for endogenous growth.

Scenario outlook

Currently, business models behind national health systems differ in many points; for instance, while in some countries the aim is to keep patients away from care services by means of prevention and appropriate care, in other countries the aim is to provide them with more services. In addition, depending on how care services are financed, through insurance or social welfare the optimal business models for the provision of telemedicine will completely differ across the EU territories. Finally, it is worth noticing that the more patients there are, the higher the burden on health systems will be due to more procedures and complexity. Thus, more expenditure will be required from the society. It is also necessary to note, that are the baby boom generation is getting old, the national health systems will be in pressure to provide more services, especially geriatric services.

In several EU health systems, the link between how the system is financed and the need to ensure a revenue from patients implies a business model where health services are pushed to patients therefore creating a barrier for the uptake of telemedicine directly related to the adopted reimbursement model.

Under this scenario, care services are undergoing a transformation process driven not only by technology, but also by the need to cover many more patients as the EU demographic trend increases and a larger share of individuals demand not only base care but also higher quality care services.

The capacity reduction of healthcare providers is illustrated in the development of infrastructure (i.e. hospitals) expected to serve twice as many patients with less resources; this dynamic implies the need to find solutions to provide the same level of services to patients with lower capacity, therefore aiming for the uptake of telemedicine. These solutions need to transform health services and procedures to be more efficient. This is a change in paradigm from a physical presence at the hospital to a technology-based alternative; in the coming years, it will be difficult for healthcare providers in the EU to survive unless they move into that alternative.

Need for evidence and large demonstrators

In order to allow for a natural uptake of telemedicine without the support of coordinated efforts of Member States, a base of clinical evidence is required to demonstrate the actual benefits from adoption. This evidence base is costly and time consuming, and it becomes more and more clear that we are overselling the economic potential of telemedicine without actual evidence. Telemedicine market players are away from good evidence about the efficiency of the service delivery hence failing to convince at a large scale. Even if a lot has been done in terms of specific effectiveness studies in the recent years, the issue is rather about the lack of large-scale implementation and the expected benefits. The literature review on telemedicine cost-effectiveness allows observing many specific studies but lack large-scale demonstrators. Efforts and investments are needed to build good evidence, as it is difficult to implement large-scale solutions unless there is proof about the benefits.
Moreover, it is important to invest in solutions that are easily integrated into the daily operational systems of healthcare. Clinicians should be able to work in the systems that they are used to regardless of the interfaces they are using; today the integration is the most important feature in the process of adoption, but is underestimated and overlooked perhaps due to its complexity. In many cases across the EU, deployment initiatives have lacked good integration. Probably the technical development will probably help trigger the uptake of telemedicine, but the trickiest part will be to change the organisations, the procedures, and the knowledge embedded in the personnel.
Often, barriers are placed on testing pilot deployment initiatives. It is difficult to convince the developers to invest heavily in the integration of the technology in the pilot since the risk of failure is highly expensive, while on the other hand if the integration is not optimal, then the likelihood of failure is important since the pilot would not be able to deliver the expected outcome.

Enabling diffusion and adoption of telemedicine solutions across society

Further adoption of telemedicine under this scenario will require the development of appropriate frameworks to deal with patient's information, its storage, and is permissions of access. The regulator needs to provide clear rules on the rights of the patients and relatives to access and grant permissions to patient data; in essence, the problem is that patients should have the right to decide about the use of their data, but healthcare providers need to be granted access to this data thoroughly.

In addition, the main role of the regulator is therefore to provide clear data utilisation standards as today the telemedicine environment is yet very wild, with many actors start operating in this area for business opportunities, making it hard to assess the quality of their offers for professional and end users. Telemedicine should allow to access data and clear regulations for accessing patient data. While health professionals should be able to access patient data thoroughly, they should also have appropriate training and certification by independent bodies to ensure that patient data is not misused or handed to third parties. On the other hand, the patient, as a citizen, has the right to decide what to disclose on not, and be reassured about data privacy and security measures framing the use of his data.

As an illustration, in the Netherlands, healthcare provision in 2020 will require by law the disclosure of all medical data to the patient in a "personal health environment". This requirement will give the right to citizens to look at and store their health records, and will thus imply a change in the behaviour of practitioners. Consequently, there is a need for a centralized system that sets the rules on the utilization of a public utility, which should not be in private hands. Citizens are entitled to the rights of their health data. In essence, the main role for regulators is to protect the electronic health records of patients to spur optimal healthcare systems aiming at delivering high quality healthcare with lower resources.

4.2.2. Alternative scenario – EU deployment of telemedicine solutions increase by 5% rate of adoption

The alternative scenario is defined by a market set up where demand and supply dynamics are also affected by the sponsoring effects of a technology adoption by national health systems. Under this scenario, we present two models, one based on the total population of the EEA, and the other limiting the scope to the chronically ill population of the EEA (suffering from asthma, COPD, diabetes and heart failure).

According to the first model, telemedicine deployment across the EEA National Health Systems allows to aggregate part of the demand for telemedicine solutions for private and institutional users. However, in this specific case, aggregation is performed indistinctively of telemedicine market segments based on different diseases.

The necessary standards and regulatory requirements will also need to be developed, and differentiated per family of telemedicine solutions. Under this scenario, future health infrastructure investments will also be required to match the needs of a wide scale telemedicine deployment, although the magnitude of such investments will be much higher than those necessary under the previous scenario given the wider scope of solutions included under the present scenario. As described previously, investments will be made by both private companies and health institutions, when they see a viable business case.

Under the second model, the focus is on the solutions for chronic diseases (i.e. asthma, COPD, chronic heart disease, and diabetes) that would bring the most benefits from a societal point of view, since these refer to older people for which remote medical care improves their quality of life.

The necessary standards and regulatory requirements will need to be developed, probably differentiated per family of telemedicine solutions specific to the management, treatment and monitoring of a **specific chronic disease**. Under this scenario, future health infrastructure investments and awareness efforts are necessary to match the needs of a wide scale telemedicine deployment. As these investments could be significant, the role of the state is increased. However, a high initial investment will pay off in the longer term as patients with chronic diseases cost heavily to the health insurance systems.

Since in many cases, the main telemedicine consumers are practitioners themselves (communications between GPs and specialists), the uptake of telemedicine services and tools under this scenario have the potential to increase the quality and speed of diagnosis and treatment, and significantly improve the life style of individuals suffering from chronic diseases.

Under this specific model, the focus on specific chronic diseases is due to the burden these represent for national health systems and to the current dynamics of decreasing amounts of the medical personnel relative to the increasing suffering population.

Market characteristics

Under this scenario, assuming there is consensus amongst Member States, telemedicine deployment will rely on the harmonisation of standards and regulations for all the commercial solutions available in this specific market segment, which can be identified by national health systems.

Market players willing to take part in the deployment will then need to commit to meet a certain demand and its dynamics in the short, mid, and long term to guarantee the access to these solutions by national health systems. As an incentive to join the deployment, telemedicine market players would receive a commitment (in terms of demand) from the different national health systems. Such interactions between commercial companies and healthcare institutions should be able to guarantee the provision of telemedicine capacity and services at a low prices for the management, treatment and

monitoring of patients suffering from the specific chronic diseases selected for coverage under the deployment initiative.

Scenario outlook

Under this scenario, where investments and efforts are made to partially deploy telemedicine solutions across the EU by focusing on those addressing chronic diseases, benefits for society can be considerable.

These benefits mainly relate to the prevention of productivity losses as people can reduce the time for diagnosis and consultation. In addition, as patient management simplifies thanks to the technology, it is expected that the medical personnel will focus on care activities while reducing the burden of administrative activities. Further benefits for society will include an increase in the base medical resources, knowledge, experience and health that will be made accessible to a wider audience, rendering the patient management and treatment process more fluid, making it more comfortable for individuals to receive care.

The improvement of the quality of healthcare services with an increase in comfort for the patient will be helpful in the reduction of costs because preventive medicine will be widely accessible. This improvement process has the possibility to trigger a virtuous cycle of better information and education of both the medical personnel and the patient. Telemedicine can thus guide people and provide preventive medicine in order to reduce national health expenditure. In addition, as telemedicine is increasingly adopted and gains of knowledge and experience across different professions take place, standards and prevention will also be improved in a virtuous cycle. These increasing returns to adoption will be the base of the future improvement of the healthcare system.

The provision of the infrastructure will be costly in the beginning of the deployment, but in the middle term there are huge possibilities for cost saving and improvement in quality of life. Overall telemedicine will be cost-effective for society, as the deployment telemedicine across the EU will trigger scalability and increasing returns to adoption.

The main or leading market players in Europe will be those who have demonstrated the utility of the technology through evidence. For instance, today, there are many examples in home telemonitoring. These are evolving fast in the technical field, although it is different on the side of the adoption by institutional users.

Indeed, the dynamics of the technology development is faster than the adjustment of behaviour in the healthcare profession in general terms; in addition, since healthcare is about information, support, fears, high expectations etc., and therefore the processes used by the medical personnel evolve at a very slow pace. Furthermore, the lack of awareness and integration issues between technologies and medical personnel can slow down the dynamics of the institutional demand. There is therefore a need for eHealth awareness campaigns at all levels, including trainings for young students in medical professions who are not sufficiently aware of the technologies and the way the can be used.

The demand under this scenario comes from the healthcare systems themselves who need to rethink the how the care services they provide can be better coordinated to suit the total population and its demographic characteristics. The way national health systems take advantage of the enabling technologies in order to optimize their organizations will determine the success of deployment and its related benefits.

In the short term, healthcare providers will need to demonstrate that the technology will reduce relative costs and expenditure associated to any individual of the population. The question is how to measure this cost-effectiveness at such a large scale. In consequence, there is a need to develop better evaluation systems bases on scientific evidence in order to convince the society to adopt and use

telemedicine on a regular basis. It is a challenge to ensure the continuity of healthcare while at the same time asking for performance improvement.

Incentivising healthcare providers to adopt telemedicine solutions widely

Since most of the benefits and costs savings drawn from the uptake of telemedicine will mostly address citizens and municipalities, different players, especially technology market players will observe an uneven distribution of these benefits. It will become difficult to incentives for investment in present of asymmetry of benefits between patients and healthcare providers; indeed the ones biggest investments will be made by healthcare providers, while the biggest benefits will go to citizens in general. In consequence, there is a need to find new ways and incentives to support and deliver care services by leveraging the use of technology to improve patient management and treatment.
Efforts from decision makers will thus be needed to enable ease and speed up the activities of healthcare providers, pushing them rapidly towards saving on low-value time and space. Since the biggest savings will be at the patient level, it will also be important to highlight and better describe the benefits for healthcare providers.

Raising awareness for a better management of the healthcare

Many awareness actions take place at the EU level, although not always focused on chronic diseases. Evidence about the effectiveness of telemedicine is needed in these cases to convince practitioners. Some countries are ahead in terms of support, adoption and willingness such as Estonia and the Nordic countries. As soon as successful cases in a country demonstrate the utility of telemedicine, practitioners accept it as valid and are more likely to engage in the uptake process.
In addition, it is worth noticing that a better coordination of healthcare systems through technology in the case of chronic diseases, in particular telemedicine tools and services for recurrent consultation and prescription, expertise and monitoring will help address the issues related to the appropriate care given to patients and prevent the waste in the medical industry. This feature of telemedicine uptake is related to green care and the capacity of technology to enable a better follow up of the patient and his needs, and limit waste in terms of food, transport, emission, and overconsumption.

Demonstrating the utility of telemedicine solutions across society

Considering the fact that since technology advances quite rapidly, tools are often very advanced but fail to provide evidence of their utility and efficiency. Providers will need to demonstrate the effectiveness of the technology, which as we have discussed in the previous sections, lacks from evidence about its effectiveness, therefore slowing down the telemedicine adoption process. It becomes necessary to better understand whether there may be adverse effects of an increased use of telemedicine, especially when considering a full deployment; for instance, tele-monitoring can easily lead to increased medication and dependence as highlighted by a few studies.

Their main role refers to normalization and standardization. The issue of a reliable exchange of patient information for different means (better diagnosis, patient management, follow-up through telemedicine) is highly political.

4.2.3. Description of variables used for economic analysis

The economic analysis implemented to estimate the costs and benefits associated to each of the scenarios under study relies on a series of parameters gathered from the literature review, as well as studies on the adoption of remote medical technologies and national demographics and health statistics.

Population parameters are based on the total EU population and on the population at risk with the highest weight on national health expenditures. In the latter case, the share of people suffering from diabetes, asthma, COPD, and heart failure represents the population at risk.

Costs and benefits parameters are represented by estimates derived from the information gathered through the literature review. The publications under review were scrutinised for parameters indicating costs, benefits and net benefits under traditional and telemedicine treatments. The parameters collected were aggregated through summary statistics and applied on the population parameters and health survey information to provide a descriptive economic analysis of costs and benefits from the societal and healthcare provider perspective.

In addition, the specific variables and parameters used in the decision model were selected to fit the logic of the model. These variables and parameters are:

- The population of the EEA (EU 28, Norway, Iceland and Lichtenstein), both the total population and the share of individuals suffering from the above-mentioned four chronic diseases.
- The propensity to use remote technologies to consult a doctor gathered from the Eurobarometer survey N° 460 (2017) on the attitudes towards the impact of digitisation and automation on daily life, which comprises a study of the population attitudes on digital health and care.
- The average number of consultations observed for the population.
- The average price of a consultation under both traditional and remote means, gathered from the figures collected from the literature review.
- The estimate of total minutes of consultation under both traditional and remote means, gathered from the figures collected from the literature review.
- The mortality rate under traditional and telemedicine treatment observed from the literature review.
- The total QALYs gained for traditional and telemedicine treatments observed from the literature review.

Estimating cost-effectiveness of telemedicine with respect to traditional approaches

The estimation of costs and benefits for each scenario described in the previous section was carried out through the implementation of a decision model whose objective is to simulate the patient journey from an initial consultation to a final treatment and monitoring by means of traditional and remote (telemedicine) healthcare services.

The different possible stages of the patient journey decisions are visualised as a decision tree comprising two initial branches, one for telemedicine/teleconsultation and a second for traditional medical visit/treatment. These two branches are then split into three possibilities of consultation frequencies: one, two, or several consultations.

In each of these branches, we have used as quantification parameters the population likely to fall under in a given branch, the cost of consultation, and the time of consultation. At the final stage of the decision model, we provide an outcome for the patient journey in terms of success and failure and compute the total costs and the total benefits of the journey associated with each path.

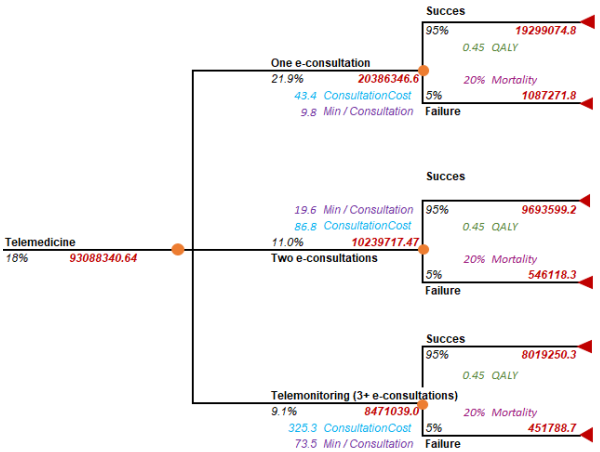
The split of the population moving throughout each branch of the model is the result of the computation of population shares using different parameters drawn from the literature. The model output comprises summary statistics determined by the population likely to be in each final branch. This output comprises the following aggregates:

- Total cost of the patient journey expressed in euros;
- The total QALYs gained;

- The total consultation time expressed in days;
- The potential lives lost expressed in head counts and based on the mortality parameter;
- The total distance saved expressed in kilometres.

The figures below and overleaf provide an illustration of the economic decision model for the case of the deployment for the full population and the case of deployment for the chronically ill population; both under the baseline scenario (business as usual), and the alternative scenario (efforts to increase adoption by 5%). These figures also show how the economic decision models are based on the information collected during the literature review and other statistical sources.

Full population - Baseline



Full population – Alternative Scenario

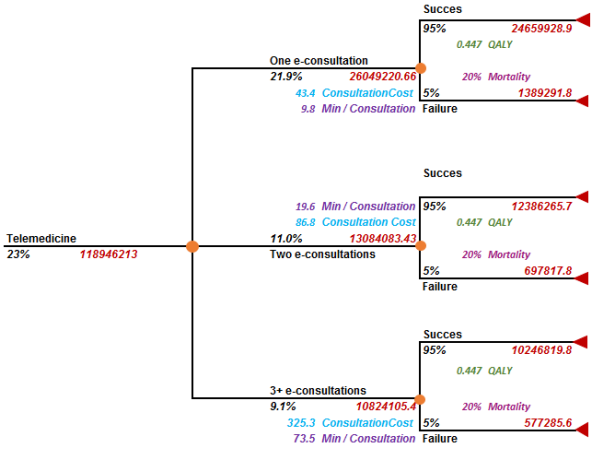
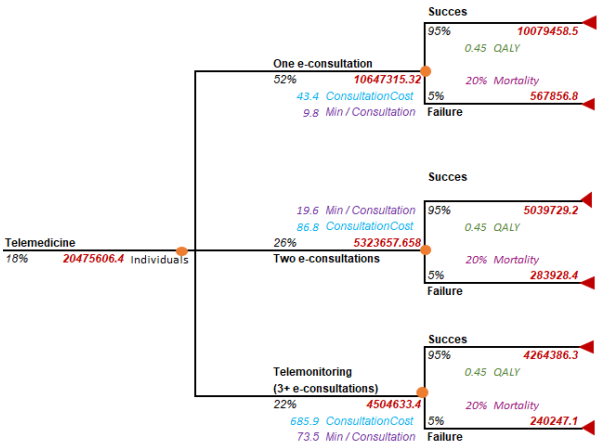


Figure 49: Evaluation model on the total population, decision model's telemedicine branch

Chronically ill population - Baseline



Chronically ill population – Alternative Scenario

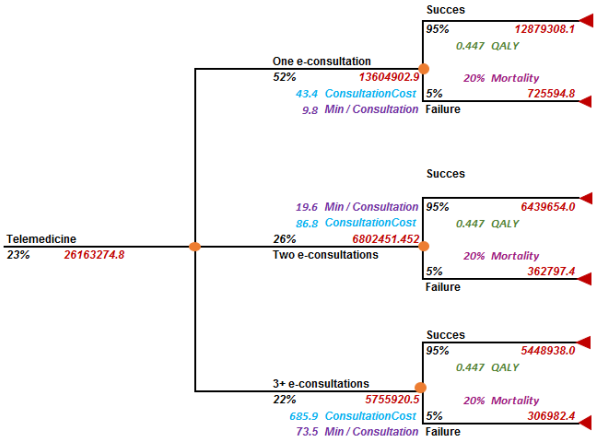


Figure 49: Evaluation model on the chronically ill population, decision model's telemedicine branch

4.2.4. Summary of results

The present section presents a summary of the results drawn from the CEA analysis of future deployment of telemedicine solutions and services across the EU. These results include a comparison between the costs and benefits evaluated under the baseline scenario (business as usual) and those evaluated under the alternative scenario (efforts to increase the adoption rate by 5%). They are presented for each of the two models under investigation: deployment focusing on the total population, and deployment focusing on the chronically ill population.

The case of a full deployment for the total population

After application of the decision model on the total population, the results on the cost-effectiveness analysis on the baseline scenario (business as usual) indicate that **telemedicine healthcare services dominate traditional care today**, at least under the assumptions of the present model, which by simplicity, focuses on the recurrence of consultation. Indeed, **telemedicine is driving down the total costs of healthcare services for society**; today, the mix of telemedicine and traditional medical approaches to patient management and monitoring is of 18% to 82% percent of the population respectively. The total costs based on the full population are lower with the current proportion distribution between telemedicine and traditional approaches (126.4 euros) than the total costs if there were no telemedicine (143.3 euros). In this case, the general costs per patient (standardised by the EU population including the EEA area) represent 8.8 euros per individual under the telemedicine and 117.5 euros under the traditional approach.

Furthermore, other benefits include the amount of QALYs gained, which are still superior under the use of traditional medical approaches, the time of consultation expressed in days, which is higher for the traditional medicine approach, the mortality rate, and the distance saved. According to these results, telemedicine is cost-effective with respect to traditional medical services in terms of costs, logistics, and mortality.

The results from the evaluation of costs and benefits under the alternative scenario (increase adoption by 5% rate) indicate that an increase of 5% in the utilisation rate of telemedicine services and tool by the total European population (including the EEA area) is cost-effective. Indeed, the share of the population going through telemedicine accounts for lower patient journey total costs with respect to the share of the population going through traditional medicine approaches. The total costs (standardised by the total EU and EEA area population) associated with the 23% of the population using telemedicine amounts to 11.31 euros per inhabitant, while the total costs associated to the 77% of the population using traditional medical approaches amounts to 110.39 euros per inhabitant. In total, the cost for society associated with an utilisation rate of 23% of telemedicine is of 121.7 euros per inhabitant.

When compared with the baseline scenario, an EU intervention to spur investments and efforts to increase the current adoption rate by 5% is preferred to the baseline in the light of the difference between societal costs of 126.4 euros per inhabitant under the baseline and 121.7 euros per inhabitant under the full deployment scenario.

In addition, in terms of benefits we observe the following evolutions with respect to the baseline scenario:

- An increase of 1.7% QALYs gained per inhabitant,
- A decrease of 1.7% time spent in consultation,
- A decrease of 3.6% in the mortality rate in case of failure, and
- An increase of 27.8% in distance saved.

These results indicate that the democratisation, awareness raising and final uptake of telemedicine services can provide considerable benefits for society by improving the way healthcare service are organised and delivered. The human factor will always be important in any patient-doctor interaction, but logistics benefits can considerably drive costs down enabling the medical personnel to focus on the most valuable tasks, hence improving the quality of life of the population.

Table 4 : Cost-effectiveness results from the baseline scenario (standardized by the total population – EEA area)

Full population - Baseline	Telemedicine	Traditional Medicine	ICER (for total benefits only)	Total scenario costs/benefits	Total costs for 100% traditional medicine
Cost of patient journey	8.85 €	117.55 €		126,41 €	143,36 €
QALYS gained/individual	0.0323	0.1082	1,432.39 €	0,1406 €	0,1320 €
Days of consultation/ individual	0.0042	0.0277	4,620.54 €	0,0319 €	0,0338 €
Mortality%	0.0815%	1.0411%	11,327.98 €	0,0112 €	0,0127 €
Distance (Km)/individual	0.1408	0.0000	772.11 €	0,1408 €	0,0000 €

Table 5: Cost-effectiveness results from the partial deployment scenario (standardized by the total population – EEA area)

Full population – Increase adoption by 5%	Telemedicine	Traditional Medicine	Total scenario costs/benefits	Evolution with respect to baseline	Telemedicine preference
Cost of patient journey	11.31 €	110.39 €	121,70 €	-3,7%	Yes
QALYS gained/individual	0.0413	0.1016	0,1430	1,7%	Yes
Days of consultation/individual	0.0053	0.0260	0,0313	-1,7%	Yes
Mortality%	0.1042%	0.9776%	1,0818%	-3,64%	Yes
Distance (Km)/individual	0.1799	0.0000	0,1799	27,8%	Yes

The case of a partial deployment focusing on the chronically ill population

Under the model focusing on the chronically ill population, the results from the analysis on the baseline scenario also indicate differences between the total costs for society. The **total costs under the current situation** (mix of 18% share of the population suing telemedicine approaches *vs.* 82% using traditional approaches) **are lower than the total costs in a situation with 100% individuals using traditional approaches** (81.2 euros and 89.4 euros respectively), indicating a clear dominance of telemedicine solutions over traditional approaches for diagnosis, treatment and monitoring. In this case, the general costs per patient (standardised by the EU population including the EEA area) represent 7.8 euros per individual using telemedicine tools and services and 73.3 euros using traditional approaches for diagnosis, treatment and monitoring.

Furthermore, in the case of analysis under the alternative scenario (increase adoption by 5% rate), and according to the proportions on the frequency of consultations observed from national statistics data, we compute the proportions associated with one, two or several visits to a doctor for individuals suffering from the specific chronic diseases. The economic evaluation under the alternative scenario assumes that 52% of the chronically ill population visits a doctor at least once during a year, 26% visits a doctor at least twice, and 22% visits a doctor three or more times.

The results from the evaluation of costs and benefits under the alternative scenario indicate that telemedicine dominates traditional medical approaches throughout the patient management and follow up process. Indeed, the overall cost for society (standardised by the total EEA population) for the patient journey is of 10 euros per inhabitant while under traditional medical journeys it is of 68.9 euros per inhabitant. In addition, the time spent on consultations is also lower in the case of telemedicine

(0.003 days per inhabitant *vs.* 0.014 days per inhabitant). In addition, other benefits are also superior in the case of telemedicine approaches to patient management and monitoring. These results indicate that investments and awareness raising efforts made to increase the uptake of telemedicine is cost-effective under a scenario focusing on the chronically ill population.

With respect to the baseline scenario, a focus on chronic diseases and the population suffering from them indicates that actively investing in the uptake of telemedicine, at least by 5%, is cost-effective as the evolution of total costs savings and benefits (standardised per inhabitant) improve the situation. Indeed, the total costs of a mix of 23% telemedicine and 77% traditional medical approaches, with respect to the baseline scenario (18% to 82%) are lower by 2.8%, while in terms of benefits, QALYs gained increase by 1.7%, the time spent on consultation decreases by 1.7%, the mortality rate decreased by 3.6% and total distance saved by 27%.

Table 6 : Cost-effectiveness results from the baseline scenario (standardized by the total population – EEA area)

4.3. General conclusions

The analysis of costs and benefits from the wide deployment of telemedicine indicate that no matter the path chosen by decision makers, the main benefits and savings will rather be in the hands of society, mostly citizens and municipalities through logistics savings and productivity gains. Indeed, even if the time of a consultation, as adopted by the decision model, is in average 14 minutes, it usually costs the patient about a half or a third of the day in productivity, hence increasing the burden on society through the reduction of the economic activity. However, with telemedicine solution, the effective productivity losses are associated with less than 30 minutes away from economic activities.

This distribution of benefits seems uneven, making it difficult to explain why healthcare systems should heavily invest in technologies that will only provide benefits for the patient and not the institutions or hospitals themselves. However, as demonstrated above, national health systems can benefit from productivity gains from equal levels of expenditure at a higher quality of service and at an increased time spent by human resources focus on value added care.

The preference for a wide deployment of telemedicine implies the need to find new ways to deliver high quality care services to optimize the organization of health systems to reduce the scope of non-value-added activities through the proper use of telemedicine technologies. The organizational change has the potential to optimise consultations from the perspective of a personalised care approach taking into account the real needs of a patient.

In general, the outlook of a wide telemedicine deployment seems positive and promising because there is an increasing awareness of the need; today the EU is in the very early days of adoption, and just the fact that there is an absence of a harmonized reimbursement system indicates that it is far away from full potential. However, individual Member States are moving forward with the UK promoting teleconsultation as a way to save costs for the NHS while in France teleconsultation is going to be reimbursed from September at the same amount as for a physical visit to the doctor (€25 for a general practitioner and €30 for a specialist doctor)[100].

Yet, it is necessary to involve the companies driving innovation in the actual design of processes, such as regulatory processes with CE Mark. This is necessary in order to ensure that innovation is being promoted. In order to spur efforts for the uptake of telemedicine, it is necessary to better assess what is useful for society in terms of cost-effectiveness based on scientific evidence as well as people's

[100] https://www.connexionfrance.com/French-news/French-healthcare-to-cover-remote-consultations

perceptions. Indeed, there are occasions where tools from big companies that are not scalable and therefore only benefit a few at high costs find support for deployment, while scalable or more useful tools from innovative SMEs do not. Today, there are non-for-profit organisations trying to make the voice of innovative start-ups heard on the policy making field, to proactively involve them in the process of EU harmonization.

What is also important is raising awareness about the potential benefits of the adoption of telemedicine, to the public and their representatives (elected politicians), policy makers and those working in health related professionals.

Conclusions from the analysis of primary data

From our discussion with key experts in the telemedicine field, we concluded that some challenges offer opportunities for assisting the wider deployment of telemedicine. One notable example is the need to make a bigger effort to encourage heterogenic groups of professions (medical doctors, nurses, ICT professionals in health) to develop a common language so that can integrate better, develop a holistic understanding of the needs of a patient and help in the design and deployment of telemedicine solutions.

One way to achieve the smooth collaboration of different groups is for them to meet in workshops so that they can communicate, understand each other and generative innovative ideas through brainstorming. One such idea would be regulators, nurses and medical doctors to develop a data bank (in which patients can find accurate medical information), a collaborative platform for medical professionals to share knowledge, etc. The EU and individual Member States could financially support and encourage the sincere dialog between different stakeholders. Such dialogue would allow stakeholders to understand each other, especially now that the digital disruption and the increased complexity of systems makes it difficult for individuals to follow and adopt.

Another example of action that would increase the use of telemedicine is to simplify the tools at the development stage so that all medical and paramedical personnel can actually use them within the frame of their known procedures. This also need a significant degree of communication and coordination.

Finally, as new technologies allow more efficient treatment, it is the responsibility of all stakeholders to test, adopt and put the new approached in production. One example is that it is now possible to make a heart surgery with alternatives to an open operation, using more efficient techniques enabled by the recent technology. This has reduced the post-surgery stay length for the patient from 8 to 3 days demonstrating a clear benefit for both the patient (recovery speed) and the health care system (cost reduction, treat more patients).

5. Conclusion

The following main findings and considerations can be derived from the analysis conducted in chapters 1, 2, 3, and 4. These represent the key messages for decision-makers to keep in mind when considering further policy developments or initiatives at EU level to support telemedicine uptake, if desirable.

5.1. Main findings

Finding 1	➢ **Solutions**: The telemedicine solutions landscape is concentrated in a number of MS, and primarily targets the telemonitoring and prevention space in primary care, and in relation to main chronic diseases. A great number of solutions target well-being and self-care, especially mobile health applications.

Most telemedicine solutions available on the market are deployed at national or regional level, while few are in use in multiple MS or have international penetration beyond the EU. This is due to the significant differences in national regulations and social security schemes (see "Barriers" below). While these remain a national competence, **interoperability between solutions** – which is another challenge to cross-border use – **can be addressed by policy-makers at EU level and should remain a priority in the coming years, to stimulate the market**. Still, the majority of solutions have been in use for over five years, which testifies to stable demand and future potential.

Software and medical devices are the predominant solution types, but typically, solutions comprise several components: hardware, a supporting platform, application, database and/or services. Considering a 'solution' as an entire ecosystem and the related data flow end-to-end are also key in effective regulation and market facilitation. Therefore, **a new 'solution' definition may be required** to reflect this complexity. At the same time, different companies offer the individual solution components, so **fragmentation between legal frameworks regulating different components must be eliminated**.

The proliferation of well-being solutions, i.e. those that are not related to a (prior) medical condition/disease, suggest that there are more possibilities in this segment at present, while wider uptake of telemedicine for monitoring, prevention and treatment of medical conditions is to be expected in the longer term. **Specific challenges and policy recommendations related to these types of solution merit a separate analysis, as they were outside the scope of the present study**.

Finding 2	➢ **Standards and guidelines**: The applicable standards and guidelines mostly address technical requirements.

It is not surprising that most standards and guidelines are set by international bodies and are of a technical nature, given that technology is at the core of telemedicine practice. However, at times these are not specific enough; in these cases, Member States set their own national standards, especially to provide precise requirements for telemedicine solutions related to given medical specialties. It is

important to tackle this going forward, especially as it directly links to the need for interoperability**. In this regard, the role of EU policy makers would also be to:**

- Better understand current limitations and needs,
- Offer more detailed specifications,
- Work with the entire range of stakeholders (SDOs, market players, healthcare providers, etc.),
- Raise awareness and support capacity-building related to the use of standards and guidelines,
- Link legislative effort with necessary supporting measures related to standards and guidelines.

Beyond standards definition, **testing, classification and certification processes are also essential to prepare the deployment of telemedicine services on a large scale**.

As regards other types of guideline/rule, there seems to be good coverage of all relevant domains at present: data protection, organisational, human resources, ethical and EHR.

Finding 3	➢ **The market**: The market potential of telemedicine is strong. It is expected to grow at a compound annual growth rate of 14% in the coming years. The well-being market enabled by digital technologies (mobile applications, devices) is rapidly growing as well.

The uptake of information technologies in Europe, which has enabled the remote transmission of information at ease, speed and at marginal cost, is the main accelerator telemedicine, which is currently experiencing rapid growth. This is facilitated by two key preconditions: access to the technology or infrastructure, and favourable financial conditions for telemedicine programmes.

Indeed, we observed that demand outpaces supply, but this should be read with care, as there are many telemedicine initiatives but adoption is at early stages, since hospitals and clinics are in demand of these solutions, but do no currently have the appropriate means to pay for the technology by leveraging on well-designed reimbursement systems. Here, there is only a limited role for EU decision-makers in harmonising approaches and enabling reimbursement schemes at EU level to facilitate adoption. However, **there is a role for the European Commission in identifying good practices in MS related to funding schemes for telemedicine and in supporting their adoption by other interested countries**.

A wide range of market players is active, including: telecommunication companies, ICT tools and electronics manufacturers, device manufacturers, pharmaceutical industry companies, and start-ups. They are concentrated in countries with relatively high healthcare expenditure per inhabitant, and we note a trend towards partnerships between healthcare and technology players. **This and other business models should be studied further by policy-makers to enable better regulation.**

Finally, it emerged from our research that the US and Canada have outperformed the EU, whilst Japan has the lowest volume of users of telemedicine. **Factors that contributed to success in North America and a lag in Asia are relevant, and exchange of experience at policy-maker level should take place.**

Finding 4	➢ **Barriers**: Difficulties relating to access to telemedicine in Europe exist in all countries, with: the lack of acceptance of telemedicine solutions by stakeholders; the unfavourable regulatory framework; the insufficient funding; and the inadequate IT infrastructure being the most prevalent ones.

Decision-makers should be attentive towards barriers preventing the wide deployment and adoption of telemedicine, and pursue actions to overcome these (*an exhaustive list of proposed countermeasures is include in Chapter 3 and will thus not be repeated here*). In particular, conservatism or resistance to adopting new medical processes, integration between technology and medical practitioner's procedures, and (data protection) regulations are delaying the generation of the base of evidence necessary to convince all actors, and EU level policy-makers should prioritise these actions in the upcoming period. In addition, **attention should also be given to regulatory approval for solutions, to streamline and make it less costly**.

If not addressed, current barriers will delay the deployment and adoption of telemedicine solutions in Europe by years, and as a consequence, the EU also risks seeing market players going to the US or other more favourable economies.

Uptake of telemedicine solutions across national health systems will also only be successful if key institutions in the medical community, such as recognised clinics and hospitals, establish new partnerships. These institutions will only be incentivised to do so if national decision-makers allow health systems to properly pay the utilisation of the technology, meaning developing reimbursement schemes for telemedicine utilisation. Further to this point, it is important to highlight that today, only direct consumer models have some degree of success, only because institutional players cannot pay for or are not always reimbursed for telemedicine tools and services.

Finding 5	➢ **Cost factors**: Telemedicine is generally perceived and judged to be cost-effective, as evidenced by trials documented in academic literature.

Our systematic review of the reported cost-effectiveness of telemedicine was carried out by means of a structured inventory of the existing published data and statistical comparisons.

In essence, we confirmed that telemedicine is reported cost-effective in 73.3% of the cases covered by the literature. Neutral effects were discussed in 21.3% of the selected references, mainly in systematic reviews. Negative effects account for 5.6% of the selected studies.

An additional outcome of this review was the identification of cost factors or cost parameters, which have strong impact on the cost-effectiveness of telemedicine solutions. These include: distance between patient and nearest healthcare professional; time required per consultation; cost of a doctor visit; QALY; mortality rate. The values of these cost parameters prove to directly affect projected cost-effectiveness of telemedicine solutions. Indeed, we used the cost factors identified as a basis in performing a cost-effectiveness analysis of the deployment of telemedicine on a wide scale.

The literature suggests that telemonitoring solutions are proven or indicated as being the most cost-effective in relation to a broad range of diseases, with an emphasis on chronic medical conditions.

While the review shows robust results, they are linked to individual solution trials, and not to wide-scale solution deployment. Hence, broad conclusions regarding cost-effectiveness of telemedicine based on this study of literature should be made with caution.

Finding 6	➢ **Large-scale deployment**: Further adoption of telemedicine is cost-effective, though benefits from wider uptake will be tangible for patients and society at large through logistics savings and productivity gains, and less so for healthcare providers or social schemes. More scientific evidence is needed from larger scale trials and telemedicine programmes to conclude on this definitively.

In general, the trend of telemedicine adoption will continue to increase and is likely to generate considerable savings and benefits for society, though adoption is at an early stage and it may take some before wider uptake can be measured.

Under two scenarios: one, of telemedicine adoption at a rate of 18%, and another – where we simulated telemedicine would be preferred by 23% of the population, we compared the costs and benefits of telemedicine to the traditional face-to-face patient journey. To further differentiate possible alternatives, the scenarios looked at the cost efficiency when telemedicine would be used by the population of people suffering from chronic diseases, and by the total population of potential patients. We also examined various scenarios for up to a 48% share of telemedicine. We were able to observe clearly that the higher the share of telemedicine – the more cost-effective wide-scale deployment becomes. An increasing share of telemedicine decreases the total cost of the patient journey, total consultation time, distance travelled and mortality rates, while increasing QALYs gained.

Further adoption of telemedicine increases benefits: it reduces costs (consultation costs, travel costs, time spend) and increases patient survival and life quality. However, policy-makers need to invest in obtaining more scientific evidence for its efficiency and large scale experiments to assess the impact of a wider deployment. Raising awareness (patients, doctors), stimulating integration between stakeholders and reimbursement are keys to speeding up success.

5.2. Additional considerations

The opportunities for the deployment and adoption of telemedicine across the EU are triggered by a changing demography of both individuals and medical professions; these changes call for a search for optimization of the healthcare service provision driven by the perspectives of **self-management** and **prevention**. In consequence, the EU needs to have an ambitious target with respect to implementation and deployment.

Policy designs need to take into account the **specificities of each country and region**, providing not only the idea and vision and strategy, but also narrowing them down to actual projects that can reflect tangible benefits for the public. When assessing the uptake of telemedicine across different countries, with different cultures and technology maturity, projects need to be tailored to the specificities of the country and the interests of the local population. Although common interests across EU populations can focus on two groups of people:

- The elderly and the chronically ill population which will drive telemedicine consumption, and
- The young or healthy population that cans benefit from prevention and management to stay healthy and economically active.

The benefits must be communicated at local level since it is potential patients who need to be convinced about the utility of telemedicine. **Raising awareness** among the stakeholders of the value chain of telemedicine and the public is key and the European Commission can play an important role in supporting this exercise.

Indeed, citizens need to be better informed about the novelty of the technology and how it will impact them; if possible, changes to the national healthcare systems need to integrate a degree of **co-development with different actors** of the process, decision makers, market players and institutional and end users.

Today there is no clear set-up on the **adoption model** the EU wants; whether it is based on performance improvement or better quality of service, decision-makers will still need to make it clear to generate enough confidence for the adoption process to take place.

The fundaments of **interoperability, secured data transmission, storage, handling and accessing permissions** for health data are not clearly defined either; even if new regulations in place have set clearer rules about private data, these are still not tailored for patient data.

Telemedicine has been discussed for nearly 40 years, but even if today the technology and social conditions for its uptake are met, there is still a **lack of evidence** to support it. When taking national decisions affecting directly the health of the population, decisions need to be taken on the basis of scientific facts. At present, we lack this base of evidence to prove the effectiveness of telemedicine.

Another key consideration is the importance of the **human factor**. Face-to-face interactions are necessary and relevant in clinical caregiving, therefore any discussion about the widespread deployment of telemedicine should consider this.

The dynamics of the medical profession, including nursing, is pressing governments to accelerate adoption, but barriers on the use by the profession are still standing, whereas all medical professions will need to have the competence and knowledge to do telemedicine and telenursing. As an example, from the professional perspective in several countries, nurses are not allowed to perform certain medical procedures (e.g. give advice to patients, prescribe); this represents a barrier closely related to the professional culture, procedures, and data handling permissions. This represents a weakness for the national health system. **Convergence of the medical and paramedical professions** in terms of training can trigger the change of culture to solve this weakness. In addition, **better communication between technical developers and the medical professions** would be necessary.

In essence, telemedicine promises a huge potential for patients and society as a whole. It will help improve the quality of diagnosis, treatment and quality of life throughout the patient management process.