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DIGITAL HEALTH

THE IMPACT OF BIG DATA & AI ON EU HEALTHCARE SYSTEMS

EU STUDY 6.17

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THE IMPACT OF BIG DATA & AI ON EU HEALTHCARE SYSTEMS

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TABLE OF CONTENTS

EXECUTIVE SUMMARY

Chapter 1 focuses on the digital health revolution which brings together eHealth, mHealth and even wearable health. Today, it is difficult to improve healthcare without the help of new technology. Technology is a central part of healthcare development. EHealth and mHealth solutions have a great potential to increase the efficiency of healthcare systems and to transform the face of health service delivery across the EU. They offer many advantages to patients and healthcare providers and the use of ICT in healthcare also allows for the reduction in costs and improvement in treatment and care.

The European Commission's work on digital health goes back to 2004 when the first eHealth Action Plan was brought into play and accepted by EU Member States. Since then, policy initiatives have been developed to foster the adoption of eHealth throughout the EU. The adoption in 2011 of the Directive on the Application of Patients' Rights in Cross Border Healthcare (Directive 2011/24/EU) marked a further step towards formal cooperation on eHealth with the aim to maximize social and economic benefits through interoperability and the implementation of eHealth systems. On 7 December 2012, the European Commission adopted the "eHealth Action Plan 2012-2020 - Innovative healthcare for the 21st century" which clarifies the policy domain and outlines the vision for eHealth in Europe, in line with the objectives of the Europe 2020 Strategy and the Digital Agenda for Europe. On 10 May 2017, the European Commission published the mid-term review of its Digital Single Market strategy. Specifically regarding eHealth deployment, three priorities for EU actions were identified: enable citizen's secure access to and use of health data across-borders; support a cross-border data infrastructure to advance research and personalized medicine; and facilitate feedback and interaction between patients and health care providers, supporting citizen empowerment.

Envisaging a new policy communication by the end of 2017, the Commission launched a public consultation between July and October of 2017 on healthcare transformation in the Digital Single Market to identify the need for further policy measures. The consultation, ended on 12 October 2017, and collected information on three main pillars: 1) citizens' secure access to their health data and the possibility to share it across borders, clarifying citizens' rights and enhancing interoperability of electronic health records in Europe; 2) connecting and sharing data and expertise to advance research, personalized healthcare, and better anticipate epidemics; 3) using digital services to promote citizen empowerment and integrated person-centric care.

All European Member States are aware that eHealth can ensure more effective and efficient health systems, therefore, they are launching several actions and initiatives to encourage the development of eHealth solutions. Estonia is a leader in Europe for e-health solutions. Each person in Estonia, who has been to a doctor, has their own online e-Health record that can be tracked. The National Health Information System integrates data from Estonia's different healthcare providers, creating a common record for each patient. Also the ePrescription model is very advanced in Estonia. According to EU Commission data, 100% of all prescriptions to Estonian patients are issued using a digital prescription. It's a very efficient system connecting every hospital and pharmacy in Estonia, cutting down on paperwork and doctors' visits and saving untold amounts of time and effort.

Other advanced EU countries in eHealth are Finland, the Netherlands, Sweden and Denmark. They show the advanced digital maturity of their citizens and healthcare providers (General practitioners and pharmacists), high level of digitalization in the hospitals and a robust ICT sector. Moreover, these countries have drafted policies to promote the development of the national e-health infrastructures. On the contrary, others countries – especially the Eastern European countries – are still lagging behind in digital health policies.

I-Com drew up a synthetic index in order to give an idea of the level of preparedness for eHealth in the Member States. Obviously it results that the countries that have the best enabling variables for the development of digital health are the northern European countries, instead, most Eastern European countries show resistance to implementing eHealth.

Denmark tops the ranking with a score of 100. Estonia, the Netherlands, Finland and Sweden immediately follow at 91, 90, 88 and 86, respectively. These countries have in common a high level of digitalization in doctors' offices and a high number of patients who use mobile and Internet technologies for searching health information and making appointments online with doctors. Moreover, these countries boast a large infrastructural development and best practices in cybersecurity. France and Italy, unfortunately, do not rank very well (with a score of 61 and 60, respectively), compared to most European countries. In Italy, for instance, patients and doctors are still not accustomed to using the digital channel to interact with each other. Moreover, the digitization of the Italian National Health System is still highly fragmented, especially in some regions and still lags behind most Member States.

In addition to the use of the digital channel in Healthcare, the use of mHealth applications is spreading in Europe and worldwide, and it is having a considerable impact on the medical industry. The market for mobile apps has developed very rapidly in recent years to become a key driver of mHealth deployment facilitated by smartphone penetration. According to the recent estimations of Research2guidance, the number of mHealth apps available to consumers now exceeds 258,000. The demand for mHealth apps also is increasing every year. 2016 was another fascinating year for mHealth with the total number of mHealth app downloads worldwide reaching 3.2 billion.

Finally, Chapter 1 describes the role of 5G in the digital healthcare transformation. The proliferation of machine-type IoT sensor communications poses the challenge of connecting many devices communicating at low-data rates. For instance, in remote health monitoring, wearable devices – such as heart monitors and glucose monitors, require high frequency updates of the central data repository at low-data rates. Experts say that existing networks cannot provide the desired quality of support while connecting a large number of such devices, and they believe that 5G with its ultra-low latency of a few milliseconds and multi gigabit bandwidth can address this challenge. For this reason, it is necessary to invest in this new technology because it can offer a lot of advantages such as remote robotic surgery.

Chapter 2 describes the impact of data and Artificial Intelligence (AI) on healthcare systems. The share of data market value in the healthcare sector was only 3% of total data market value in 2016. In particular, the data market value in the European healthcare industry amounted to almost 1.9 billion euro in 2016 and is expected to grow by 35% to over 2.4 billion euro by 2020. Although the number of data workers and data users in healthcare is lower than in other sectors, the intensity share of data workers – meant as the average number of data workers calculated out of the total number of data user companies – is higher than in most industries. The production, collection, storage, sharing and analysis of Big Data now allows a transition to an outcomes-based system. Outcomes are the results of treatment, and correspond to what is most pressing for the patient, such as pain relief, the return to working life, prevention of complications or restoring physical functionality. This new approach, which provides for outcomes-based healthcare, not only focuses on the actual well-being of the patients but also helps identify and eliminate the technologies that do not give rise to positive outcomes. Outcomes-based healthcare reduces hospitalization, surgeries and long-term care, making the system more effective and sustainable, and allows for investing the resources in products that show better outcomes than the technologies already in use. The transition to an outcomes-based system is possible but remains closely linked to the production and use of health data, which makes it possible to analyze the outcomes themselves.

It is desirable to invest in devices, software, registers and platforms that aim at producing, analyzing, and sharing health data (big data, especially real world data) in a very short time.

Thanks to digitization, a lot of data from citizens, patients, researchers, healthcare professionals, institutions and industries can be collected in large databases and thus become part of registers and platforms that allow for the exchange of information among many actors, for example between pharmaceutical companies and regulators, among more clinicians or between doctors and patients. Consequently, there are many advantages, such as the efficiency and quality of treatment, the prevention of diseases, a better pharmacovigilance and the safety of patients.

The union of Big Data and AI defines a notion of "New Health". Today, thanks to cognitive computers which are able to analyze a lot of health data, it is possible to make early and precise diagnosis and so identify a lifesaving therapy much faster than traditional methods where the patient's genetic data are manually examined. According to the recent estimates, the global market of AI in healthcare was valued at $ 633.8 million in 2014 and is expected to reach $ 6,662.2 million by 2021, at a CAGR of 40%. Among the categories of artificial intelligence, the tools supporting medical imaging analysis and virtual assistants for patients will achieve higher revenues.

Chapter 3 is dedicated to some barriers which hamper the development of eHealth and mHealth and that need to be addressed in order to reap the benefits of a fully mature and interoperable digital health system in Europe. These barriers are: lack of interoperability between eHealth solutions; regional differences in accessing ICT services; lack of IT literacy; the skills gap; and privacy and security of health data. Chapter 3 points out the need for common standards and interoperability among digital health solutions and devices. First of all, it should be crucial, both at the EU level and in Member States, to ensure interoperability of the Electronic Health Records. Moreover, it is necessary to have the appropriate infrastructure in place, specifically high-speed Internet must be accessible in all areas and to ensure that no section of society is excluded from digital services, while at the same time equipping all citizens, including the elderly, with the eSkills to fully benefit from digital health. There is a need to promote IT literacy through specific programs addressed to all citizens and an involvement of the government and the education system.

Chapter 3 draws attention to adequate data protection legislation and the importance of security standards. It is fundamental to increase cybersecurity awareness and technical capabilities. Finally, it focuses on the impact of digitalization on the labor market in the healthcare sector. In this sector too, technical possibilities can lead to staff reduction, even if doctors and nursing staff are far from being replaced.

In the conclusions, the study contains the **policy recommendations**.

To achieve a full leadership in digital health, EU institutions and Member States should act resolutely and fast to ensure the following conditions:

Telecom and ICT infrastructures

- The penetration of digital services requires skills and investments in networks and technologies. Considering that fixed and mobile ultra-broadband network deployment require tremendous investments, it is very important, in general, to create a regulatory investment-friendly environment (also through a stable and predictable telecom regulatory) that encourages the development of new business models and new services.
- 5G will be a key enabler for IoT and new digital service deployment. To accelerate 5G deployment, complying with the Commission's initiatives and planning, it is necessary to accelerate on investments, simplify and remove barriers to small cells deployment, plan a roadmap and a shared timing in Europe, ensure a harmonized and efficient spectrum management, the availability of adequate spectrum bands to 5G

deployment and a close cooperation among all stakeholders.

Interoperability and standards

- With regard to the regulatory framework, it is necessary to reduce and simplify rules, ensuring harmonization and interoperability standards at EU and international levels for health systems that share patient data. Moreover, use of anonymized health data for scientific purposes or international health initiatives relies on data format standardization.
- European Reference Networks (ERNs), launched in March 2017, involving more than 900 highly-specialized healthcare units from over 300 hospitals in 26 EU countries and aiming at tackling complex or rare diseases and conditions that require highly specialized treatment and concentrated knowledge and resources, should become a pilot initiative for a more extensive application of eHealth on a European scale, reducing barriers between different national health systems (and in many cases existing in the same national systems) and testing real standardization and interoperability across the EU.

Skills

- It is important to improve the medical expertise and digital skills of healthcare providers in order to achieve a full development of these technologies and real benefits. Public administrators of the healthcare system should be judged also on the level of digital skills reached by their staff. At the same time, medical education should include knowledge and skills needed to use connected devices and artificial intelligence in healthcare.
- With regards to the demand side, citizens and patients should be encouraged to increase their digital skills and to use eHealth tools through incentives and targeted actions. Users of connected devices should be trained to follow a protocol of usage while, as already occurs in pharmacology and therapeutic education, doctors should be able to set up an ergonomic evaluation of devices depending on each relevant class of users.

Privacy and security

- Data security and privacy are areas that require legal and policy attention to ensure that patient data is properly protected. Legal frameworks that govern the integrity of health data transfer and storage, in addition to identifying access control and medical liability, are critical to enabling the development of eHealth in the Member States. However, at the same time, more cooperation is needed. Respecting the rules established in the General Data Protection Regulation and cooperation in the development of best practices (e.g., data anonymization, encryption, user consent requirements) will ensure that data can move more safely and effectively between different systems and applications. Trust and confidence are key elements for ensuring the swift uptake of mHealth applications by end-users.

- Moreover, the healthcare sector is becoming a major target for cyberattacks. While Member States should fully adopt Directive (EU) 2016/1148 - concerning measures for a high common level of security of network and information systems across the Union (the "NIS Directive"), the cybersecurity package, published by the European Commission on 13 September 2017, should be discussed and approved as soon as possible.
- Clinical use of medical AI would need to be ensured through clear rules, encouraging ethical and responsible use of these technologies and safeguarding the privacy and the security of patients.
- Taking into account that the usage of connected devices could have strong medical implications and technical flaws or shortcomings resulting in serious errors from a diagnostic or therapeutic standpoint, devices with a medical use must be certified before being introduced on the market1.

Towards an outcomes-based healthcare

- Technological innovations are capable of yielding better results (outcomes) than those obtained in the past, offering new solutions to those pathologies where the needs are still unsatisfied, but costs create a sustainability problem. Healthcare systems can reconcile access to care and sustainability developing an outcome-based system. This new approach, which provides for outcomes-based healthcare, not only focuses on the actual well-being of the patients but also helps identify and eliminate the technologies that do not give rise to positive outcomes. Outcomes-based healthcare reduces hospitalization, surgeries and long-term care, making the system more effective and sustainable, and allows for the investment in products that show better outcomes than the technologies already in use. The transition to an outcomes-based system is possible but remains closely linked to the production and use of health data, which makes it possible to analyze the outcomes themselves. For this reason, it would be necessary to define rules governing the process of data extraction/exploration and sharing, data processing and comparing, making this information useful for clinical activities and ensuring the right to information for all.
- The creation of an outcomes-based healthcare is possible only by investing in Information and Communications Technology (ICT), citizen empowerment and improving the doctor-patient relationship. In this way it is possible to create, collect, analyze and share patient outcomes in a very short time, leading to better decisions. An outcomes-based healthcare can respond to the growing demand for care, improving the quality of life of citizens (patients and caregivers), and creating "value", defined as the outcomes achieved relative to the treatment costs.

1 Nokia, White paper on connected health, 2017, https://solutions.health.nokia.com/white-paper-connected-health

PART 1

DIGITAL HEALTH IN EUROPE

1. DIGITAL HEALTH IN EUROPE

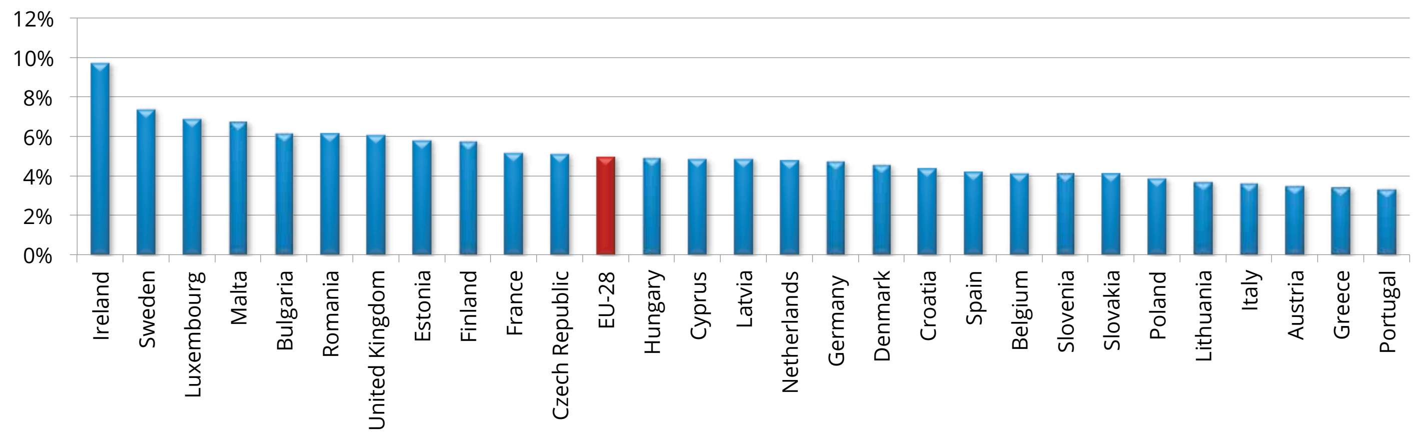
1.1. DIGITAL ECONOMY AND SOCIETY IN EUROPEAN COUNTRIES: A GENERAL OVERVIEW

The digital economy is developing rapidly worldwide and can be found in countless aspects of daily life, impacting sectors as varied as banking, retail, energy, transportation, education, publishing, media and health. Information and Communication Technologies are transforming how social interaction and personal relationships occur, with fixed, mobile and broadcast networks converging, and devices and objects increasingly connected to form the Internet of Things[2].

The economic impact of the Internet is growing and has a huge potential in all European countries. In Ireland, the digital economy contributed to 9.8% of the GDP in 2016, followed by Sweden and Luxembourg (7.4% and 6.9%, respectively), compared to a EU average of 5.0% (Fig. 1.1). Although the European Union as a whole is a net exporter of digital services, the situation among EU countries appears to be quite different. Ireland is a large net exporter of digital services – with a trade balance that has almost doubled in a six-year period and reaching, in 2016, a value of nearly 70 billion dollars – well above other countries such as the UK, Sweden and, Netherlands that follow in the ranking. In 2016, there were only two EU countries which were reported as net importers of digital services – Malta and France (Fig. 1.2).

Fig. 1.1 Contribution of digital economy to GDP (2016)

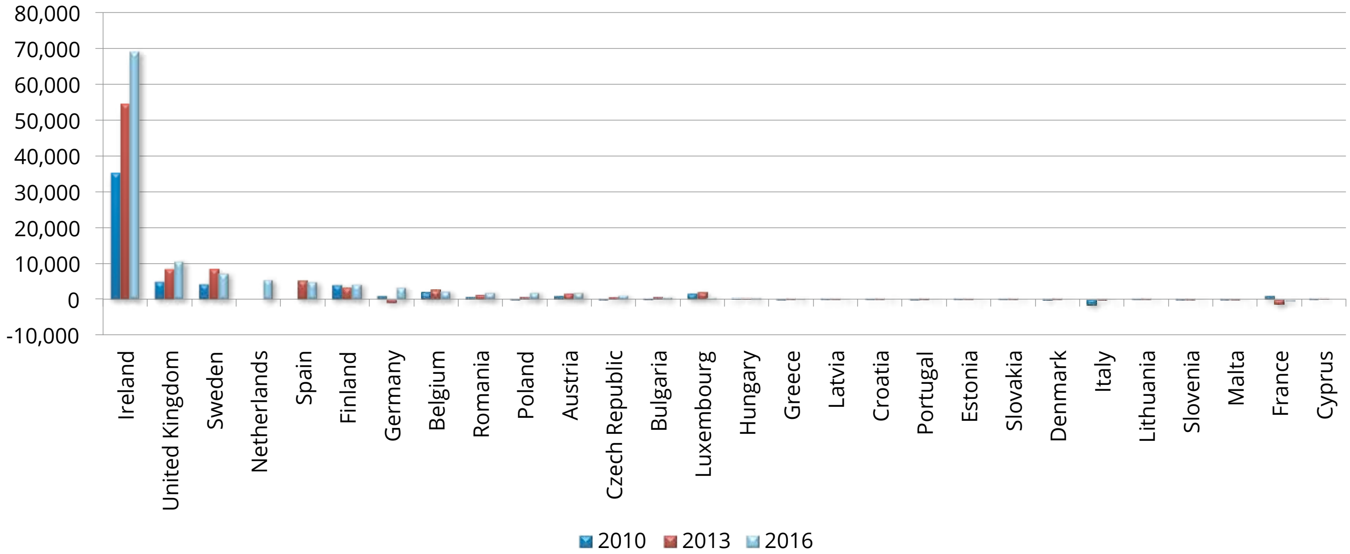
Source: I-Com elaboration on Eurostat data



2 OECD, Digital Economy Outlook 2015

Fig. 1.2 Trade balance of digital services (US$ millions)

Source: I-Com elaboration on UNCTAD data



The Internet is greatly impacting how enterprises do business and interact with one another. Cloud-based data storage, integrated procurement systems, and "enterprise social networks" that facilitate communication within and among organizations in real time are helping companies address a host of procurement, coordination, communication and fragmentation issues. Nowadays, for many businesses, having Internet access is indispensable for their daily activities. This is reflected in the fact that only 3% of businesses in the EU did not have an internet connection at the beginning of 2016[3].

The increasing use of digital technologies appears evident, not only economically, but also socially and politically. For many people in the EU, using the Internet has become an increasingly important part of their daily lives. Indeed, in the EU, the proportion of individuals who have never used the Internet more than halved from 37% in 2007 to 14% in 2016 (Fig. 1.3). This trend has, however, slowed down in recent years – starting in 2013, the share fell by two percentage points each year to reach 14% in 2016 (one percentage point below the Digital Agenda target fixed for 2015)[4].

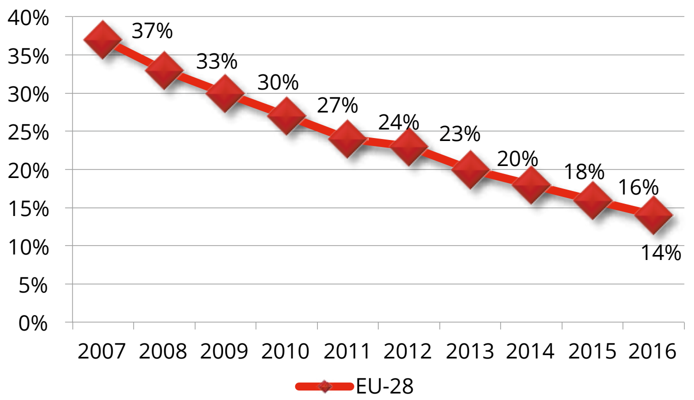
Instead, the percentage of individuals that used the Internet every day or almost every day in 2016 in the

3 Eurostat, Digital economy and society in the EU, 2017

4 Eurostat, Internet access and use statistics - households and individuals, 2017

Fig. 1.3 Individuals who have never used the Internet (2007-2016)

Source: I-Com elaboration on Eurostat data



European countries was 71%. The share of daily users was the highest in Luxembourg (93%), followed by Denmark (89%), the United Kingdom (88%), the Netherlands (86%), Finland and Sweden (85% each). Shares lower than 60% occurred in Greece and Poland (57% each), Bulgaria (49%) and Romania (42%) (Fig. 1.4).

People use the Internet for different purposes, with some of the most common online activities of internet users including sending/receiving e-mails, finding information about goods and services, reading online news sites/newspapers/news magazines and participating in social networks.

I-Com elaborated a ranking (Fig. 1.5) that gives an idea of the level of Internet use in EU countries. The ranking is based on twelve variables that are closely related to the digital society – sending/receiving e-mails; telephoning or video calls; participating in social networks; finding information about goods and services; reading online news sites/ newspapers/news magazines; Internet banking; travel and accommodation services; selling goods or services; making an appointment with a practitioner via a website;

Fig. 1.4 Individuals using the Internet on a daily basis (2016)

Source: I-Com elaboration on Eurostat data

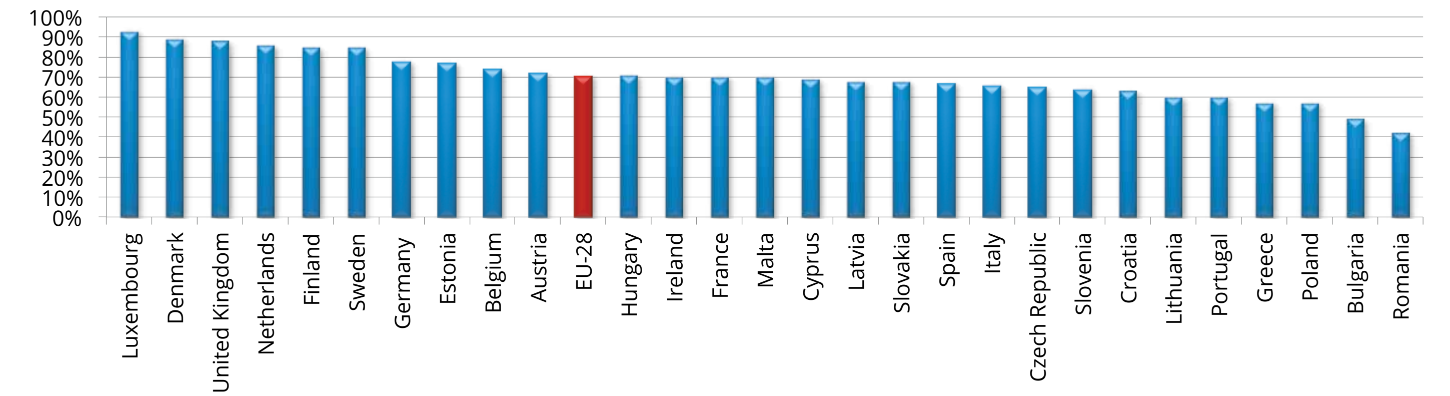
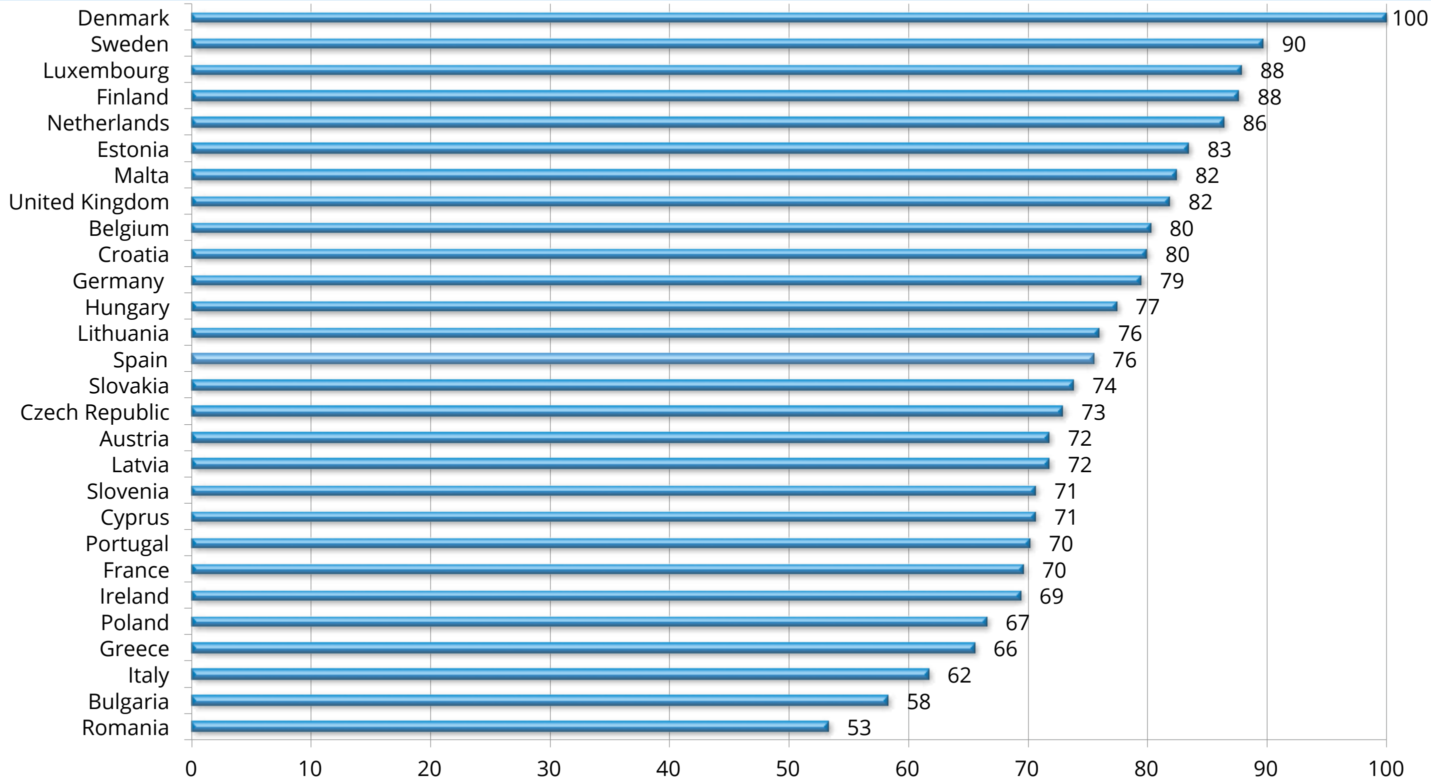


Fig. 1.5 Internet use Index in the European countries (values ranging from 0 to 100)

Source: I-Com elaboration on Eurostat data (2016)



seeking health information; playing/downloading games, listening to music or watching internet streamed TV or videos; and managing a payment account to (potentially) pay for goods or services purchased over the Internet. For each country, an average of the variables was calculated. The values obtained were normalized relative to the best performer country, so as to establish a ranking from 0 to 100. The most advanced country is Denmark, followed by Sweden, Luxembourg, Finland, the Netherlands and Estonia. These countries have in common a high level of digitalization of individuals that use the Internet for various activities, especially sending/receiving e-mails and finding information about goods and services. Italy, Bulgaria and Romania, on the contrary, rank in the last positions.

In such a framework, the ongoing digital transformation is totally changing the healthcare sector, offering opportunities to tackle several of the challenges of health systems (chronic disease and multi-morbidity, health system sustainability and efficiency, cross-border healthcare). In the following pages, I-Com examined the use of digital applications and solutions in healthcare and explains the benefits and risks of the digital tools for patients and healthcare providers.

1.2. EHEALTH AND MHEALTH IN THE EUROPEAN UNION

eHealth[5] and mHealth[6] solutions have a great potential to increase the efficiency of healthcare systems and to transform the face of health service delivery across the EU. They offer many advantages to patients and healthcare providers and the use of ICT in healthcare also allows for cost reductions and care procedure improvements. For example, Information and Communication Technologies (ICT) can help patients manage their own health thanks to a better flow of information and interaction with health professionals (teleconsultations). In this respect, mHealth supports the changing role of patients from a passive to participative, increasing their responsibility for their own health. Moreover, the use of digital devices could help healthcare professionals or paramedic staff reduce medical errors and it could assist governments and healthcare providers in increasing access to care or managing epidemics. Through a greater access to personal health data for patients and health professionals, eHealth and mHealth solutions enable faster diagnosis, improved monitoring, more effective treatment and better health outcomes[7].

The European Commission selected four key indicators to show the performance of European countries in terms of eHealth. In particular, these indicators – listed below – allow a comparison between Member States and illustrate how doctors and patients use Internet to communicate, inform and exchange information about health:

1. Individuals using Internet seeking information about health;
2. Patients making an appointment with a practitioner via a website;
3. GPs (General Practitioners) using electronic networks to transfer prescriptions to pharmacists;
4. GPs exchanging patient medical data with other healthcare providers and professionals.

In 2016, in Croatia, Luxembourg, Malta and Germany, more than 70% of individuals searched for health information over the Internet (Fig. 1.6). These countries, together with

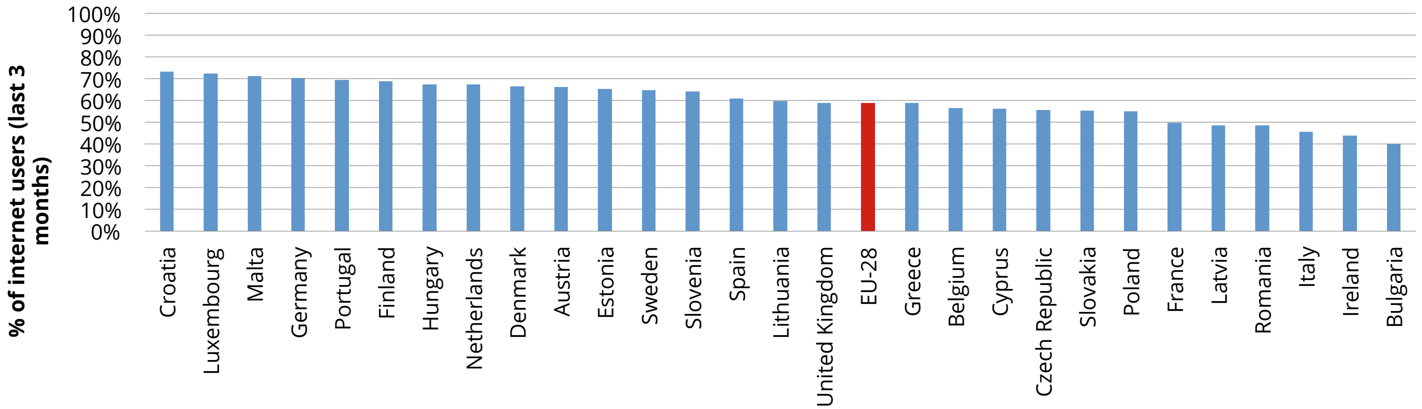
5 The European Commission's eHealth Action Plan 2012-2020 "Innovative healthcare for the 21st century" defines eHealth as "the use of ICT in health products, services and processes combined with organizational change in healthcare systems and new skills, in order to improve health of citizens, efficiency and productivity in healthcare delivery, and the economic and social value of health. eHealth covers the interaction between patients and health-service providers, institution-to-institution transmission of data, or peer-to-peer communication between patients and health professionals".

6 According to the EU Commission's Green Paper and the WHO's definition, mobile Health (or mHealth) is a component of eHealth and refers to medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices. It also includes applications (apps) such as lifestyle and well-being apps that may connect to medical devices or sensors (bracelets or watches) as well as personal guidance systems, health information and medication reminders provided by SMSs and telemedicine provided wirelessly.

7 I-Com, Internet of Things & 5G revolution. The highway for the future of services and industry: energy, healthcare and manufacturing, 2016.

Fig. 1.6 Individuals using the Internet in the last 3 months seeking information about health (2016)

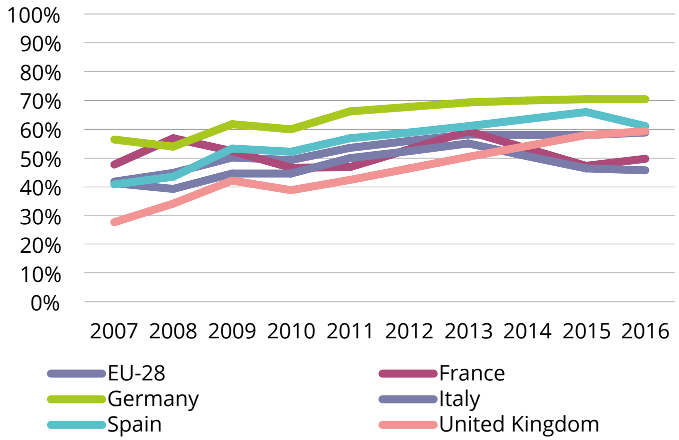
Source: I-Com elaboration on European Commission data



Portugal, Finland, Hungary, the Netherlands, Denmark, Austria, Estonia, Sweden, Slovenia, Spain, Lithuania and the United Kingdom, scored above the EU average (59%).

Fig. 1.7 Number of Internet users seeking information online about health (2007-2016)

Source: I-Com elaboration on European Commission data



Instead, in the rest of the countries, Internet use for searching health information was well below the EU average. For example, in Belgium, France and Italy the percentage of individuals using the Internet to seek information about health was 57%, 50% and 46%, respectively.

Generally, in Europe, the percentage of individuals using the Internet to seek information about health grew from 42% in 2007 to 59% in 2016 (Fig. 1.7). Germany and the United Kingdom showed a positive trend, especially starting from 2010. While in Italy, the percentage of Internet users seeking information online about health decreased significantly in the last three years[8].

8 It should be noted that seeking information over the Internet is not per se a positive activity unless it translates into a proper approach to reliable sources and their right interpretation. If someone is not able to do that, it would be certainly better for him or her to abstain from browsing the Internet and contact a doctor instead. In any case, the relationship between doctors and patients cannot be substituted but only complemented by the Internet.

The highest number of patients making an appointment with a practitioner via a web site can be found in Denmark, Spain and Finland. In 2016, in these countries, more than 35% of patients used the Internet to book a medical examination with a practitioner. In Germany, France and Italy, the percentage of patients fixing an appointment online was less than the EU average (16%), 12%, 11.9% and 10%, respectively (Fig. 1.8)

In 2013, the share of general practitioners who used electronic networks to transfer prescriptions to pharmacies varied from 100% (Estonia) to 0% (Malta). In Estonia, Denmark, Croatia, Sweden and the Netherlands, ePrescriptions were already routinely used, with all prescriptions being transferred to pharmacists electronically and patients also being able to reorder medication via a web-service. There were some countries, including Italy, where ePrescriptions were hardly used (less than 10%) in 2013 (Fig. 1.9).

In 2013, Denmark was the only country where exchanging medical patient data electronically was very common (92%). Other advanced countries, in which doctors exchanged medical data electronically, were the Netherlands, Estonia, Finland and Spain (more than 60% of general practitioners). Italy ranked 12th with 31.2% of general practitioners who exchanged patient medical data with other healthcare providers (Fig. 1.10), followed by Austria and Germany in 13th and 15th position, respectively.

Fig. 1.8 Patients making an appointment with a practitioner via a website

Source: I-Com elaboration on European Commission data

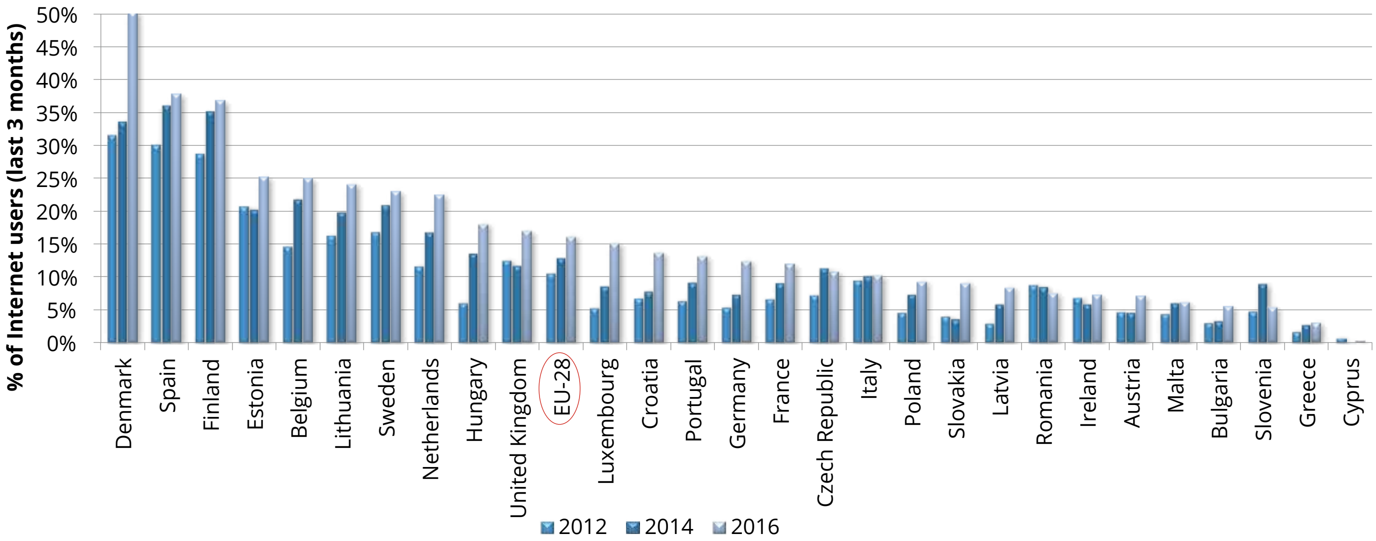
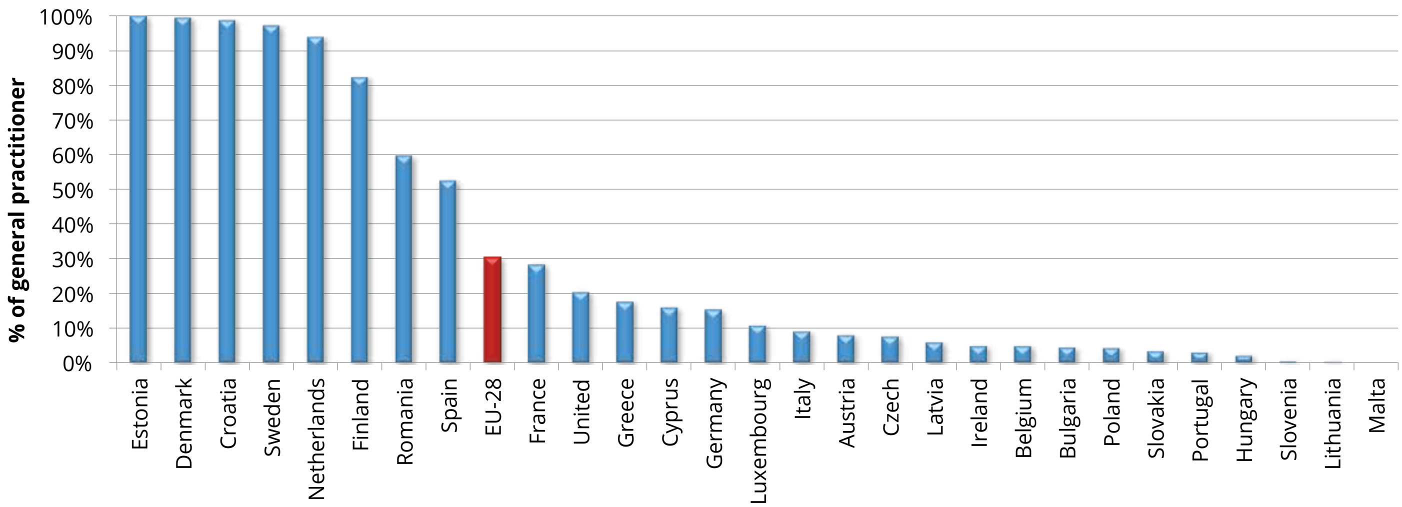


Fig. 1.9 General practitioners using electronic networks to transfer prescriptions to pharmacists (2013*)

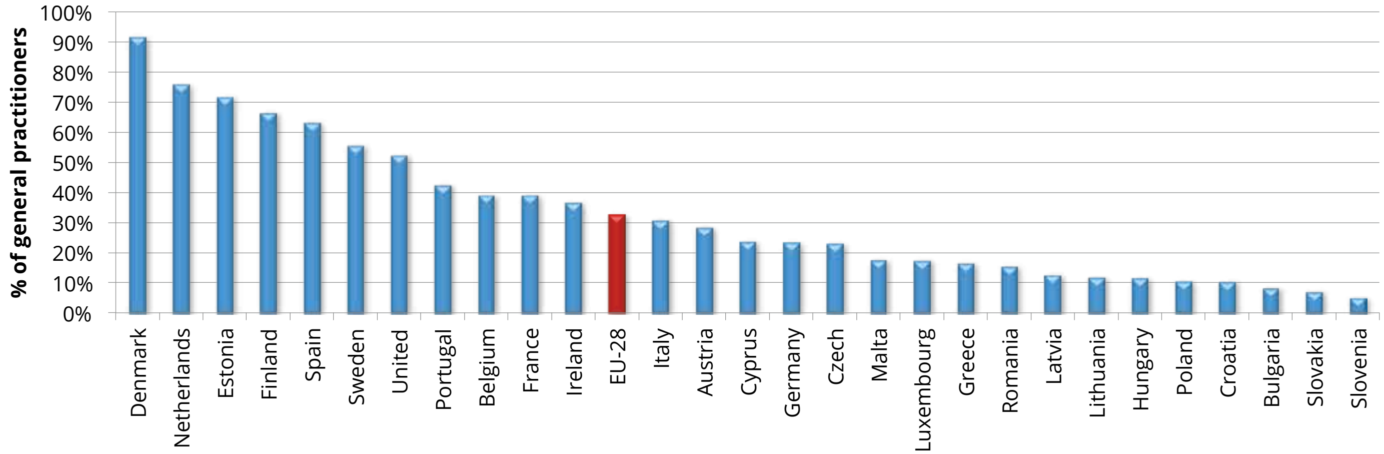
Source: I-Com elaboration on European Commission data



* most recent data available

Fig. 1.10 General practitioners using electronic networks to exchange patient medical data with other healthcare providers and professionals (2013*)

Source: I-Com elaboration on European Commission data



* most recent data available

Fig. 1.11 Number of mHealth apps displayed in app stores (2016)

Source: I-Com elaboration on Research2guidance data

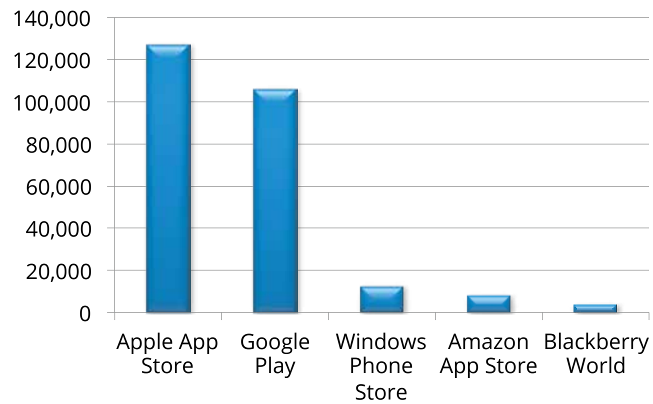
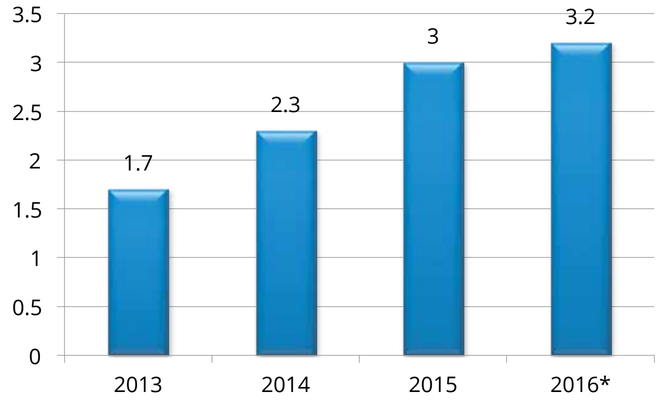


Fig. 1.12 Total downloads of mHealth apps (billions)

Source: Research2guidance, mHealth App Developer Economics 2016, The current status and trends of the mHealth app market, 2016



* estimate

In addition to the use of the digital channel in healthcare, the use of mHealth applications is spreading in Europe and worldwide and the Internet of Things (IoT) is having a considerable impact on the medical industry.

According to the report "Realizing the benefits of mobile enabled IoT solutions" by PwC, commissioned by GSMA, the IoT could save €99 billion in healthcare costs in the European Union and add €93 billion to the GDP, if its adoption is encouraged. The largest savings are expected in the area of wellness and prevention and treatment and monitoring. Moreover, the use of digital applications in healthcare could enable 11.2 million people with chronic diseases and 6.9 million people at risk of developing chronic conditions to extend their professional lives and improve their productivity[9].

According to the recent estimations of Research2guidance, the number of mHealth apps available to consumers now exceeds 258,000. Most apps are published on Apple App Store or Google Play (Fig. 1.11)[10].

Not only the supply, but also the demand for mHealth apps is increasing every year. Global mHealth app downloads have nearly doubled in only four years. The total number of downloads worldwide reached 3 billion in 2016, with an increase of 7% compared to 2015 (Fig. 1.12).

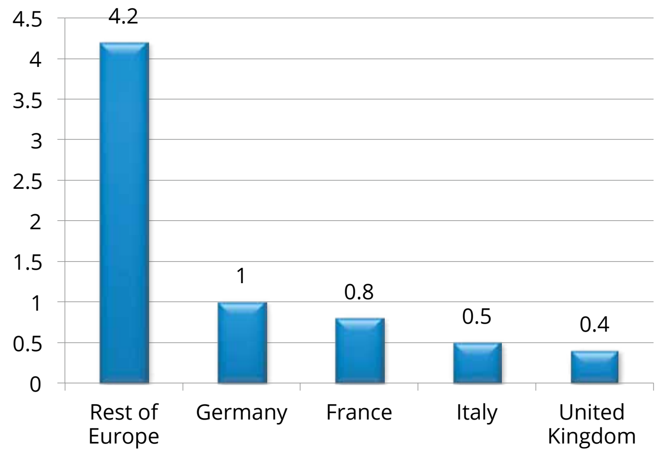
Germany is expected to be the largest market in Europe with revenues of about US$ 1 billion in 2017. Other large markets for mobile health in Europe are France, Italy and the UK (Fig. 1.13).

9 GSMA, Digital Healthcare Interoperability, October 2016.

10 Research2guidance, mHealth App Developer Economics 2016. The current status and trends of the mHealth app market, 2016

Fig. 1.13 Mobile health revenues in Europe in 2017*, by country (in $ billion)

Source: I-Com elaboration on Statista data (2017)



* estimate

1.2.1. European regulatory framework

Internet and digital technologies are revolutionizing our lives, eliminating territorial barriers, simplifying traditional activities and increasing effectiveness and efficiency.

In this changing context, the European institutions and, in particular, the European Commission, are aware of the opportunities connected to the spread of digital technologies. To deal with the barriers to fully exploit the opportunities associated with the digital revolution in Europe, in March 2015, the Commission developed a strategy to create a Digital Single Market. The Digital Single Market Strategy is built on three pillars: 1) better access for consumers and businesses to digital goods and services across Europe; 2) creating the right conditions and a level playing field for digital networks and innovative services to flourish; 3) maximizing the growth potential of the digital economy.

In this new digital society, information and communication technologies applied to health and healthcare systems can increase their efficiency, improve quality of life and unlock innovation in health markets.

eHealth, in particular, offers many advantages and benefits[11]:

- helps patients manage their own health (also known as patient "self-care" or "self-management") thanks to a better flow of information and interaction with health professionals (teleconsultations);
- provides greater access to personal health data for patients and health professionals, enabling faster diagnosis, improved monitoring, more effective treatment and better health outcomes;
- improves healthcare efficiency and thus contributes to alleviating the burden on European health budgets. For example, solutions for patient self-management could contribute to reducing the number and length of hospitalization for chronically ill patients, other eHealth tools, such as electronic health records, could be used to avoid the duplication of medical examinations and to help access patient information faster;
- increases sustainability and efficiency of health systems by unlocking innovation and encouraging organizational changes;
- facilitates access to healthcare services across Europe. eHealth might also support patient mobility and facilitate cross-border healthcare, as laid down

11 European Parliamentary Research Service, eHealth – Technology for health, March 2015; European Commission, eHealth: connecting health systems in Europe, 2016; GSMA, Digital Healthcare Interoperability, October 2016.

in the Directive on patients' rights in cross-border healthcare;

- offers hospitals the possibility to improve care procedures, for instance via patient flow management systems. It could help health professionals reduce medical errors;
- assists governments and healthcare providers in increasing access to care or managing epidemics.

Being aware of the benefits associated with eHealth, European institutions adopted the first eHealth Action Plan in 2004, followed by several policy initiatives to foster the adoption of eHealth throughout the EU.

eHealth can benefit citizens, patients and health and care professionals, as well as health organizations and public authorities being able to deliver more personalized 'citizen-centric' healthcare. This is a toolbox more targeted, effective and efficient and helps reduce errors, as well as the length of hospitalization, facilitating socio-economic inclusion and equality, quality of life and patient empowerment through greater transparency, access to services and information and the use of social media for health.

The adoption in 2011 of the Directive on the Application of Patients' Rights in Cross-Border Healthcare (Directive 2011/24/EU) marked a further step towards formal cooperation on eHealth with the aim to maximize social and economic benefits through interoperability and the implementation of eHealth systems. The Cross-Border Healthcare Directive aims at giving patients the right to receive medical treatment in another EU Member State and its Article 14 establishes the eHealth Network. This Network has the objective to enhance interoperability between electronic health systems and continuity of care and to ensure access to safe and quality healthcare. The eHealth Network is the main decision-making body on eHealth at the EU level and brings together national authorities responsible for eHealth designated by the Member States.

For patients with rare or complex disorders searching for a diagnosis or struggling to access expert care, the dream of cross-border care is about to become a reality, partly thanks to the European Reference Networks (ERNs) (Directive 2011/24/EU).

These Networks, launched in March 2017, involved more than 900 highly-specialized healthcare units from over 300 hospitals in 26 EU countries and aim to tackle complex or rare diseases and conditions that require highly specialized treatment and concentrated knowledge and resources. Using a dedicated IT platform and telemedicine tools, a "virtual" advisory board of medical specialists will link up information and expertise that are scattered across the EU, ensuring that information travels to the patient, who has the convenience of staying in their own supportive home environment[12].

In order to facilitate the mobility of patients seeking cross-border healthcare, the EU Commission is building an EU-wide eHealth Digital Service Infrastructure (eHDSI) allowing health data to be exchanged across national borders with a first focus on ePrescriptions and Patient Summaries. Member States can connect their health

12 European Commission, European Reference Networks, Conference Report, 2017.

systems to the eHDSI through a national contact point for eHealth (NCPeH). When building the necessary NCPeH, Member States are required to take into consideration the guidelines approved by the eHealth Network to support interoperability of national health systems in the EU[13].

The electronic prescription (ePrescription) is defined as *"the use of computing devices to enter, modify, review, and output or communicate drug prescriptions"*[14].

ePrescription should provide[15]:

- computerized entry and management of prescriptions;
- immediate access to information on medicines;
- decision support, aiding the choice of medicines and other therapies, with alerts such as drug interaction;
- support during administration;
- computerized links between hospital wards/ departments and pharmacies;
- links to other elements of patients' individual records.

Furthermore, thanks to ePrescription, patients can travel to another EU country, obtaining their medicines there.

Patient Summary is a standardized set of basic medical data that includes the most important clinical facts about patients and provides health professionals with the essential information they need to provide care in the case of an unexpected or unscheduled medical situation. It can also be used to provide planned medical care[16]. Moreover, through Patient Summary, health professionals can access the data of patients treated in another EU country.

Another important instrument to improve safety, quality and access to healthcare is the electronic health record, which is more detailed than the Patient Summary.

According to the WHO, *"electronic health records (EHRs) are real-time, patient-centred records that provide immediate and secure information to authorized users. EHRs typically contain a record of the patient's medical history, diagnoses and treatment, medications, allergies and immunizations, as well as radiology images and laboratory results. They expand on the information in a traditional paper-based medical record by making it digital and thus easier to search, analyze and share with other authorized parties. An EHR system plays a vital role in universal health coverage by supporting the diagnosis and treatment of patients through provision of rapid, comprehensive and timely patient information at the point of care".*[17]

Moreover, making EHRs interoperable will contribute to more effective and efficient patient care by facilitating the retrieval and processing of clinical information about a patient from different sites.

Direct objectives of interoperable EHRs include[18]:

- direct patient care;
- patient care management;
- patient care support process;
- financial and other administrative procedures;
- patient self-management.

13 European Commission, eHealth: connecting health systems in Europe, June 2016.
14 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4106541/
15 Ingenico, e-Health in Europe, June 2012
16 http://www.epsos.eu/epsos-services/patient-summary.html
17 WHO, From innovation to implementation. eHealth in the WHO European Region, 2016
18 Ingenico, e-Health in Europe, June 2012

Although national plans exist for the introduction of a EHR system, there are still no electronic health records across Europe.

On 7 December 2012, the European Commission adopted the *"eHealth Action Plan 2012-2020 – Innovative healthcare for the 21st century"* which clarifies the policy domain and outlines the vision for eHealth in Europe, in line with the objectives of the Europe 2020 Strategy and the Digital Agenda for Europe, aiming at addressing and removing existing barriers to reap all the benefits from a fully mature and interoperable European eHealth system.

The barriers to deployment of eHealth are identified in: 1) lack of awareness of, and confidence in eHealth solutions among patients, citizens and healthcare professionals; 2) lack of interoperability; 3) limited large-scale evidence of the cost-effectiveness of eHealth tools and services; 4) lack of legal clarity for health and well-being mobile applications and the lack of transparency regarding the use of data collected by such applications; 5) inadequate or fragmented legal frameworks including the lack of reimbursement schemes for eHealth services; 6) high start-up costs involved in setting up eHealth systems; 7) regional differences in accessing ICT services, limited access in deprived areas.

The strategy also underlines the most pressing health and health system challenges – to improve chronic disease and multi-morbidity management and to strengthen effective prevention and health promotion practices, to increase sustainability and efficiency of health systems, to foster cross-border healthcare, health security, solidarity, universality and equity and to improve legal and market conditions for developing eHealth products and services – fixing several clear objectives.

The Commission strategy aims to:

1. achieve wider interoperability in eHealth services, addressing the technical and semantic levels (by fostering EU-wide standards, interoperability testing and certification), the organizational layer and legal issues (reviewing data protection rules and clarifying legal and other issues around mobile mHealth and "health & well-being applications");
2. support research, innovation and competitiveness in eHealth, encouraging Public-Private Partnerships and other actions involving research and innovation and translation of knowledge to clinical trials and demonstration projects, Pre-Commercial Procurement and Public Procurement of Innovation for new products, scalability, interoperability and effective eHealth solutions supported by defined standards and common guidelines and mechanisms such as SME networking, eHealth Week, and business modeling studies to facilitate closer cooperation among stakeholders, research bodies, industry and those responsible for implementing ICT tools and services, to enable faster and wider take-up of research results in the market;
3. facilitate deployment and adoption of eHealth (through CEF, cohesion policy, digital literacy, measuring eHealth added value);
4. promote international cooperation on eHealth at a global level.

On 10 May 2017, the European Commission published the mid-term review of its Digital Single Market strategy. It takes stock of the progress made, calls on co-legislators to swiftly act on all proposals already presented and outlines further actions on online platforms, data economy and cybersecurity.

Concerning eHealth deployment, in the DSM mid-term review the Commission identifies three priorities for EU actions:

1. enabling citizen's secure access to and use of health data across-borders;
2. supporting a cross-border data infrastructure to advance research and personalized medicine;
3. facilitating feedback and interaction between patients and health care providers, supporting citizen empowerment.

Envisaging a new policy communication by the end of 2017, the Commission launched a public consultation between July and October of 2017 on the healthcare transformation in the Digital Single Market to identify the need for further policy measures.

The consultation underlines the importance of ensuring more resilient and financially sustainable heath systems and the role of digital innovation which can encourage the transition from a hospital-based healthcare model to a person-centric and integrated model, improve health promotion, prevention and access to care, and contribute to the sustainability and resilience of healthcare systems.

This consultation ended on 12 October 2017 and collected information on three main pillars: 1) citizens' secure access to their health data and the possibility to share it across borders, clarifying citizens' rights and enhancing interoperability of electronic health records in Europe; 2) connecting and sharing data and expertise to advance research, personalized healthcare, and better anticipate epidemics; 3) using digital services to promote citizen empowerment and integrated person-centric care.

mHealth

The fast spread of sensors and mobile devices is revolutionizing our lives and every economic sector, including the health sector. The Internet of Things (IoT) is changing the medical industry and is improving care systems and cost efficiencies.

Where Solutions across the Patient Pathway is concerned, most mobile health services and applications can be classified into five sub-categories:

1. **wellness**, including self-help services that encourage people to adopt or avoid certain behaviors and practices to maintain or improve their general wellness and fitness levels (information tips, interactive games, applications and fitness monitoring through devices that measure body vitals while exercising, etc.);
2. **prevention**, including services used by government and non-government agencies to raise awareness and encourage people to adopt or avoid certain behaviors and practices to prevent or control disease outbreaks;
3. **diagnosis,** including services and solutions that help healthcare professionals connect with patients geographically distant to provide diagnosis or triage;

4. **treatment**, including services that help treat patients remotely and ensure adherence to the required treatment regimen. Compliance with treatment protocols is paramount to the success of effectively managing chronic diseases such as HIV or other illnesses (tuberculosis) that require patients to take their medication regularly to avoid disease relapse;
5. **monitoring**, including monitoring patients to identify and confirm illnesses and monitoring of the vital parameters of at-risk patients to track basic conditions and take action in order to prevent the situation worsening (for instance, body and heart monitors).

Healthcare Systems Strengthening includes mobile health services and applications aimed at improving the efficiency of healthcare providers in delivering patient care. This category can be classified into four sub-categories – Emergency Response, Healthcare Practitioner Support, Healthcare Surveillance, Healthcare Administration.

- **Emergency Response**: this category includes solutions that enable rapid response in the case of emergencies. They include wireless systems in ambulances to help paramedics interact with physicians in hospitals and send the vital readings of patients to emergency rooms while transporting them.
- **Healthcare Practitioner Support**: this category includes mobile access to Information Technology systems and databases of varying sophistication – from the simple searching for information (medical encyclopedias) to intelligent decision support systems that aid in diagnosis and treatment. It also includes the dissemination of medical information, training and updates to healthcare practitioners.
- **Healthcare Surveillance**: this category consists of services and tools that help healthcare workers collect health-related information of people and track the outbreak of diseases and epidemics. Through smartphones and PDAs with mobile connectivity, it is possible to provide timely information to the central planning authorities about disease outbreaks.
- **Healthcare Administration**: this category includes services such as appointment reminders, which can help reduce non-attendance rates and also improve patients' experience of outpatient care procedures.

The European Commission has highlighted the benefits for health systems associated to mHealth's deployment and the possibility of citizens to play a more participative and responsible role, a big reduction in the time spent by healthcare professionals and paramedic staff on accessing and analyzing information and the opportunity, through the analysis of big data, to improve healthcare effectiveness and disease prevention.

In this respect, the Green Paper, published by the European Commission in 2014, underlines that mHealth solutions can ensure an increased prevention/quality of life through self-assessment tools, remote diagnosis and the promotion of "healthy behavior", a more efficient and sustainable healthcare (through better planning, reducing unnecessary consultations and better prepared professionals receiving guidance on treatment and medication) and more empowered patients.

The same document highlights the importance of guaranteeing an adequate data protection, patient safety, equal access to eHealth solutions, transparency of information, interoperability, incentives to the development and use of mHealth solutions and international cooperation.

Despite the extraordinary benefits connected to mHealth, there are some main barriers limiting the adoption of mHealth solutions[19]:

- *regulatory barriers*: an absence of an adequate regulatory mechanism, lack of clarity on mHealth certification, lack of clarity on data protection legislation;
- *economic barriers*: healthcare providers and policy makers require further evidence of clinical and economic benefits that mHealth can provide to increase its adoption. Other economic barriers are lack of innovative and adequate reimbursement models for patients and limited awareness of the benefits of mHealth;
- *structural barriers*: low cohesion across levels of care and regions and lack of competition;
- *technological barriers*: the absence of protocols to standardize solutions, lack of interoperability and late involvement of doctors in solution design.

National policies

All European Member States are aware that eHealth can ensure more effective and efficient health systems. Therefore, they are launching several actions and initiatives to encourage the development of eHealth solutions. Below we focus on the initiatives of a few Member States, differing significantly from each other, by geography and/or health system. This is not an exhaustive picture, however it provides a view of some noteworthy examples.

Estonia

Estonia is a leader in Europe for eHealth solutions. The Estonian National Health Information System (ENHIS)[20] is the core of Estonian eHealth, being operative since 1 September 2008. It is a national central electronic database for processing health records of all patients receiving healthcare services from any Estonian healthcare service provider. All officially recognized healthcare service providers must by law upload their patients' EHRs on the ENHIS and patients can view all of their EHRs stored on the ENHIS on the patient platform "My E-Health". The identification of the patient takes place by logging in with an electronic national identification card or through mobile phone based identification (mobile-ID).

Patient consent is not necessary in order to create EHRs or share EHRs for the purpose of providing healthcare. Estonian law provides patients with an opt-out for the sharing of ENHIS data so the patient can make all or particular EHRs inaccessible in the ENHIS. In order to invoke that right, a patient must submit an application to his or her healthcare service provider (effective towards ENHIS data created by that provider) or to the Ministry of

19 PwC, Socio-economic impact of mHealth. An assessment report for the European Union, June 2013

20 The main institutions behind the ENHIS are the Ministry of Social Affairs and the Estonian E-Health Foundation (EHF).

Social Affairs (effective towards all ENHIS data).

Any Estonian healthcare professional can access ENHIS data for any patient (only for the purpose of providing healthcare services) if the healthcare service provider that employs the healthcare professional has a valid Estonian activity license or can be denied access if a particular patient has prohibited access to his or her ENHIS data.

In order to keep health information completely secure and at the same time accessible to authorized individuals, the electronic ID-card system uses KSI Blockchain technology to ensure data integrity and mitigate internal threats to the data.

The e-Prescription model is very advanced in Estonia. Its database enables the processing of prescriptions electronically where the patient can present his/her ID card in any pharmacy and the pharmacist can access the digital prescription online. This database is connected to the ENHIS, as some of its content is automatically transferred to the ENHIS, but in order to see the full history of digital prescriptions, the patient has to log in to the state platform www.eesti.ee. Currently, more than 95% of all prescriptions in the country are issued electronically[21].

In March 2015, a National E-health Strategy was launched, establishing several objectives: 1) user-centric and science-based precision services; 2) holistic case management and integrated service network; 3) improved service performance and quality; 4) optimized service access and professional time use via tele-solutions.

21 https://e-estonia.com/solutions/healthcare/e-prescription

Finland

In the 1980s, people engaged in the health system in Finland started to develop local electronic patient records and in 1996 the country adopted an official eHealth strategy many elements still being relevant today.

Since 2004, Finland has been working on eSocial services and, in 2010/2011, it began the very first ePrescribing and eArchiving trials and pilots. Some municipalities started sending data to the archiving systems and new legislation was formulated allowing patients to opt out of the system, replacing the previous model founded on the obligatory opt-in.

The earlier legislation (2007/2011) defined the organizational and structural framework of the new services, i.e. the national lifelong electronic health record system (eArchive), while the Decree on Nationwide Health Care Information System Services (decree 165/2012) set the key milestones for the data to be entered, i.e. it prescribed when each part of the medical record should be entered into the national archive service.

The seven main elements of the Finnish eHealth architecture design are[22]:

1. shared structured (standardized) electronic patient records;
2. national eArchive for the electronic patient records;
3. central consent management;
4. eAccess for patients;
5. ePrescription system (in operation in public health care);

22 https://www.ehtel.eu/references-files/ehtelconnect-support-documentation/EHTELconnect-Finland-PeerReview-Public-Report-RAP2013_11.pdf

6. Patient Care Summary;
7. Information Management System (a new element which was added in 2011).

The Finnish Electronic Patient Record System (KanTa) allows every citizen to access his or her medical records, as well as prescription services. Physicians also utilize this database not only to view patient records, but also to gain access to the Picture Archiving and Communications System (PACS), from which they can see and send relevant information to other entities within the healthcare system. Since 2010, the use of electronic patient records among the primary health centers and secondary care hospital districts has reached 100 percent.

Concerning prescriptions, digitization has introduced a simpler system. Information on patients' electronic prescriptions is recorded in a centralized database, Reseptikeskus, which is part of the KanTa services and includes all electronic prescriptions and markings made by pharmacies. Based on the information in the database, any pharmacy operating in Finland can provide the medication prescribed to patients if they present a patient guide, Kela Card or personal identification.

Citizens can view their own prescription information on the My KanTa pages as well as the healthcare professionals involved, pharmacists and students in the field. Patient consent is necessary to view the information even if the doctor or nurse who prescribed the medication is has the right to view patients' prescribed medications in the Reseptikeskus database.

My KanTa Pages provide citizens with the possibility to perform many activities simply and efficiently.

In My KanTa Pages[23], citizens can view electronic prescriptions, records related to their treatment, laboratory tests and X-ray examinations and other health records. They can also request a prescription, save their living will and organ donation testament, and consent to or refuse the disclosure of their own personal data.

The electronic renewal of prescriptions is one of the most popular functions of My KanTa Pages (which receive about 6,300 renewal requests every day). Electronic prescriptions enter into a centralized database, called the Prescription Centre, which contains all electronic prescriptions and the related dispensing records entered by pharmacies, keeping the prescriptions for 30 months (then they are transferred to another centralized database called the Prescription Archive). Concerning prescriptions, it's very interesting to underline that in Finland electronic prescriptions are the only option for dispensing medication from 2017 onwards.

The Patient Data Repository, instead, is a service in which healthcare units enter patient records from their own data systems in a secure way, offering citizens the opportunity to examine their own medical records on their computer, easily and regardless of time and place.

Italy

In 2008, the Ministry of Health started the "eHealth Information Strategy" – Electronic Health Records (EHRs), e-Prescription, dematerialization, CUP online (Single Booking Centre), telemedicine. Moreover, the regional

23 http://www.kanta.fi/en/omakanta

and central governments recently signed (with a two year delay) the "Pact for Digital Health" (article 15 of Pact for Health 2014-2016), which aims at fostering technological innovation in health through a multi-year Master Plan.

The policy initiatives of the Italian government are in line with the Europe 2020 strategy but the digitization of the Italian National Health System is highly fragmented, especially in some regions and still lags behind most Member States.

The main investments include Electronic Health Records (EHR), document management systems, digital services for citizens and electronic prescription (e-Prescription). On the contrary, the level of investments in solutions for integrating hospitals and communities – such as telemedicine services, ICT solutions for healthcare services provided by local pharmacies or other healthcare providers and home care – is still low.

According to AgID (the Agency for Digital Italy), ten Italian regions have implemented the Electronic Health Record – Aosta Valley, Lombardy, Trentino-South Tyrol, Emilia Romagna, Liguria, Tuscany, Lazio, Molise, Sardinia and Apulia. In Campania, Calabria and Sicily, the Electronic Health Record has still not been implemented, while in the other Italian regions it is underway.

Concerning e-Prescription, all the regions have introduced it and its share is now at 80%.

Not all regions, however, are making progress accordingly. In January 2017, Campania (91%), Sicily (89%) and Trentino (89%) were the best performing, followed by Molise and Veneto. Calabria (26.7%) was in the last position (Promoforma).

In the Conference of 7 July 2016, the government, regions and autonomous provinces of Trento and Bolzano signed the Digital Health Agreement, aimed at achieving the objectives of efficiency, transparency and sustainability of the NHS through the systematic use of digital healthcare innovation. It identified nine macro-areas of action and, in particular, the fifth ("Promotion of quality and adequacy of health care") and the sixth ("Information and Health Statistics System") provide for specific tools dedicated to digital healthcare.

Digitization is described as an opportunity to improve health care and economic growth through: (i) the implementation and use of ICT platforms and ICT solutions interconnected at various levels of government to ensure continuity of care; (ii) adequate levels of care management; (iii) de-hospitalization to reduce health costs; (iv) the use and dissemination of the Electronic Health Booklet; (v) full cooperation between all stakeholders involved in the health and well-being chain.

Among the priorities of the Agreement, services such as teleservice, tele-rehabilitation, tele-consultation, tele-diagnosis and tele-monitoring are included.

In Italy, the process of health digitization must be further speeded up, even if some positive results have been achieved in the last period. It is certain that in the coming years, the Italian National Healthcare Service must invest more financial resources for eHealth to allow for more efficiency, maximization of service supply, a reduction of medical errors, an increase in patient safety, and an improvement in chronic disease management. Moreover, it should draft clear policies for safety and privacy.

*i*com institute for competitiveness

The Netherlands

The Netherlands is one of the EU's frontrunners in eHealth. The Dutch National Implementation Agenda for eHealth was released in June of 2012 with the collaboration of The Royal Dutch Medical Association (KNMG), the Netherlands Association of Health Care Insurers (ZN) and the Federation of Patients and Consumer Organizations in the Netherlands (NPCF). It set goals around self-management by patients and care substitution initiatives to achieve several ambitious objectives and, in particular, a greater awareness of the benefits connected to eHealth's deployment among physicians and other specialists, the provision of electronic care support (core electronic data sets, care and decision support), the support for safe electronic storage and exchange of patient data, and the development of research on effectiveness of telemedicine and health apps.

The first regional computerized health record system was started in Leiden in the 1970s while an obligatory national electronic health record (Het Electronisch Patiëntendossier) was introduced in 2009 after a public consultation about privacy laws concerning health data. The service is provided by the Dutch government and only accessible to general practitioners, pharmacists, and medical personnel in hospitals. Instead, patients have an opt-out choice enabling them to either automatically participate in the system or object for privacy reasons. Doctors can also access patient data through platforms including Patients and eHealth, iZiekenhuis (eHospital) and regional platforms.

Since 2011, the exchange of medical data between healthcare providers has occurred through a National Switch Point (LSP) which provides a reference index for routing, identification, authentication, authorization and logging. The LSP can be compared to a traffic-control tower which regulates the exchange of patient data among healthcare providers. Authorized care providers can consult this data to obtain a clear picture of a patient's medical history or medication use. Since 2012, the Association of Healthcare Providers for Health Communication has been responsible for the LSP.

On 4 January 2013, the Minister of Health, Welfare and Sport introduced the Proposal on Patient's Rights. This proposal aims at giving clients more rights when electronic records are filled in, when healthcare providers exchange data and when data is requested. The proposal applies to the use of 'electronic exchange systems', i.e. systems which enable healthcare providers to consult records, parts of records or information from records from other healthcare providers, using electronic means.

In November 2013, the Dutch Ministry of Health, Welfare and Sport issued a General administrative regulation with regard to the electronic exchange of data between healthcare providers, supplementary to the Personal Data Protection Act and the Proposal on Patient's rights.

In the Netherlands, most of the medical records are updated electronically and are no longer available in paper. There are also several systems in place for the electronic exchange of patient data inserted in EHRs. For example, at local/regional level, there are systems that connect the information systems of general practitioners, GPs' out-of-hour surgeries and pharmacists who work together in a certain region.

Other regional solutions are[24], for example:

- Zorgdomein (a solution for the exchange of patient data between general practitioners and hospitals in case where the general practitioner refers the patient for further examination to a specialist in the hospital);
- POINT (a solution for the exchange of information between the hospitals and the institutions for care and homecare in the event that a patient leaves the hospital and has to be treated at home or in a nursing home);
- EDIFACT (a solution for the exchange of patient data among general practitioners, hospitals and pharmacists that is used for the exchange of prescriptions and laboratory results).

The government is encouraging the expansion of eHealth services, setting several objectives[25]: 1) **access to medical records**: at least 80% of chronically ill people should have access to their own medical records by 2019, and at least 40% of other members of the population;

2) **health monitoring**: by 2019, 75% of chronically ill and vulnerable elderly people should be able to monitor certain aspects of their own health and share the data with their health provider;

3) **online contact with care provider***:* people receiving care and support at home should have the possibility to communicate with their care provider 24 hours a day via a screen.

To achieve these ambitious objectives, the government is taking several actions to support innovators via an online platform, make digital data sharing easier, share eHealth know-how, raise awareness, and create a personal digital healthcare environment. The government is offering support for healthcare innovators to develop their idea swiftly and effectively into a working application, consulting with healthcare administrators on standards in order to facilitate digital data sharing, creating networks which include healthcare providers, patients and lawyers to allow them to share knowledge and help startups and innovations advance to the next stage and collaborating with various parties in the healthcare sector on a program to give people more control over their own health.

An annual description of the state of digitalization in the health sector is carried out by Nictiz, a Dutch National competence center for expertise and standardization and eHealth. It provides information to health professionals and patients about standards in eHealth as well as possibilities offered by healthcare information infrastructures and monitors research results. Nictiz also produces the annual eHealth Monitor TrendITion which analyzes national and international developments such as registration at source, eHealth, epSOS, blue button and big data, and provides a useful overview of laws and regulations in healthcare as well as an overview of quality marks, certificates and quality statements in healthcare.

24 https://ec.europa.eu/health/sites/health/files/ehealth/docs/laws_netherlands_en.pdf
25 https://www.government.nl/topics/ehealth/government-encouraging-use-of-ehealth

Sweden

Sweden is one of the most digitally advanced European states, showing the advanced digital maturity of its citizens, high level of digitalization in the private and public sectors and a robust ICT sector. Also with regards to eHealth, Sweden is one of the best European performers.

Sweden introduced a national eHealth strategy in 2005 and subsequently revised it in 2010, laying strong foundations for the development of the digital health sector.

More recently, in 2016, Sweden adopted the Swedish Vision for eHealth 2025 – Common Starting Points for Digitization of Social Services and Health Care, which states the common vision for eHealth activities until 2025 by the government and the Swedish Association of Local Authorities and Regions.

It underlines the potential of digital health for increasing an individuals' independence, participation and influence in society, as well as economic opportunities for the industrial sector. It is built on the principles of equality, gender inclusion, protection of privacy and information security, efficiency and accessibility, usability and digital participation.

Considering that Swedish inhabitants are among the most digitally mature in the world and business and public sectors have largely digitized their activities, the strategy underlines that Sweden is a country where digitalization offers great opportunities for the social services and healthcare.

The paper affirms the importance of providing sufficient support to healthcare system staff to enable them to offer high-quality social and healthcare services, opportunities for new career paths and a better working environment for the women and men employed in these services. At the same time, the strategy identifies, as a prerequisite for being able to take advantage of the possibilities that digitalization offers, skills necessary to deal with IT systems at all levels in the services provided.

For the eHealth strategy to be actually effective, the same paper highlights the importance of a clear division of responsibilities between central and local governments and the cooperation among the public sector, professional associations in various occupational categories, organizations representing private and non-profit providers, entrepreneurs and organizations representing patient, user and family organizations, the industry and others.

The strategy identifies several areas for action to achieve this vision:

1) the **regulatory framework** should guarantee the various rights or interests of the individual such as protection of privacy, quality, safety and efficiency;

2) **more consistent use of terms** to ensure that codes, concepts, terms and structures used are valid and usable in the work of responsible entities to enable the exchange of information that is needed to guarantee quality and security;

3) technical **standards** as precondition for interoperability between different actors and interchangeability among different components.

Electronic Health Records (HER) had already been adopted in the late 1990s. In 1997, the Uppsala region began a project called Sustains, an attempt to set up an "internet health account," much like an online bank account. Initially, Swedish data protection laws didn't allow patients to access records but successively, due to increased demands of citizens to access their personal health information, the digitized electronic health records were made accessible to patients in the whole Uppsala region through the portal Minavardkontakter.se ("My Health Contacts"). Today patients can log in to the Journalen system using either an electronic identifier or their Swedish personal identity number and they are able to see notes from all healthcare professionals, a list of prescribed medications, test results, warnings, diagnosis, maternity care records, referrals and vaccinations and they can also add comments to the notes.

The e-Presciptions story is also not so new. Sweden introduced e-Prescription services in 1984. Currently, 90% of prescriptions in Sweden are issued electronically, generated by doctors through the national e-Prescription management system and transmitted to the national prescription database through a secure network. The e-Prescription service is available for clinicians and patients in all Nordic countries but the service enabling patients to view prescriptions is not commonly available yet.

1.3. I-COM INDEX ON THE LEVEL OF PREPAREDNESS FOR EHEALTH IN THE MEMBER STATES

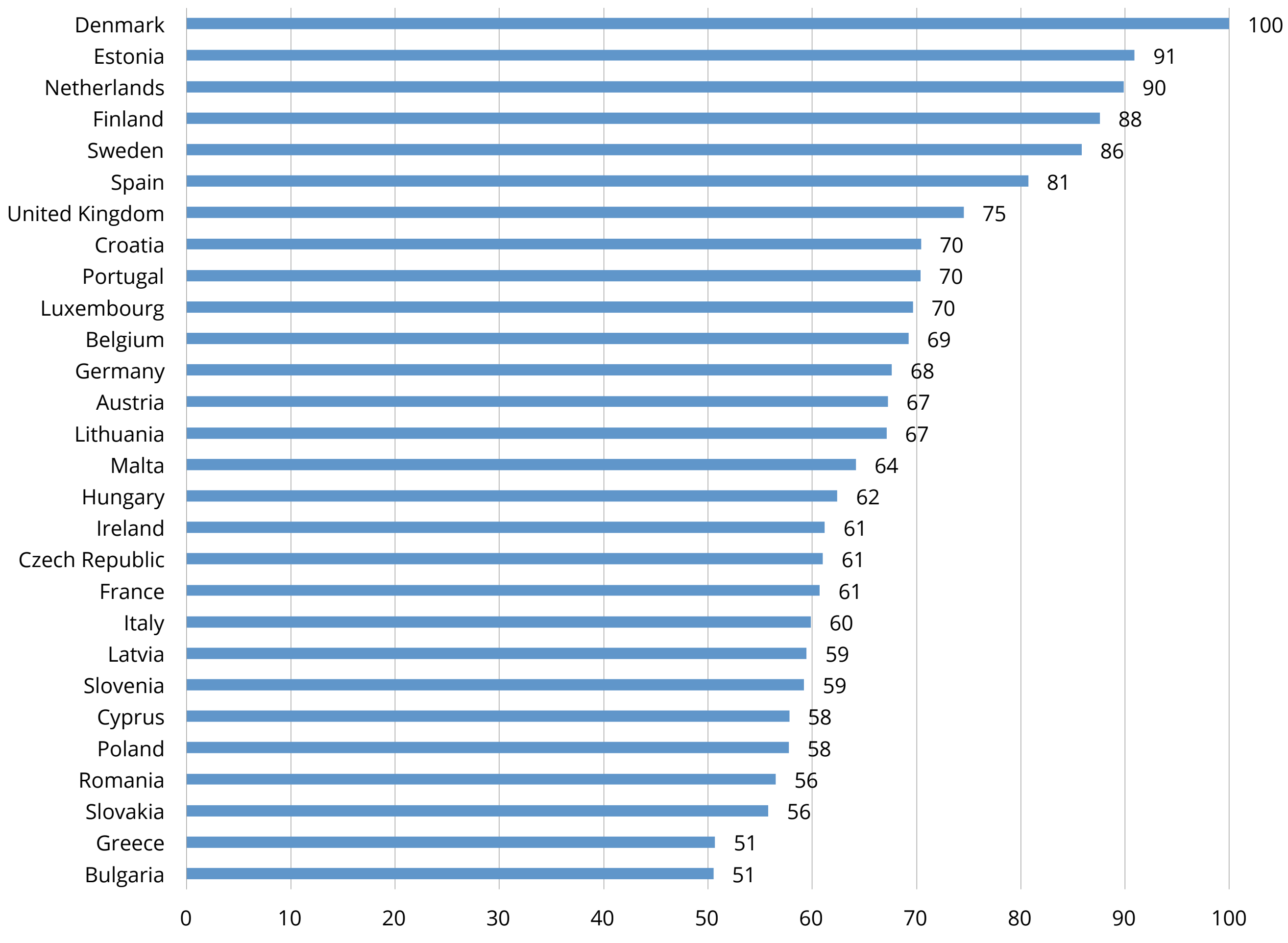
We drew up a synthetic index in order to give an idea of the level of preparedness for eHealth in the Member States (Fig. 1.14). The I-Com index is based on nine variables that are either directly or indirectly related to the development of digital health in Europe. The variables are listed below and refer to 3 categories: Internet use in the healthcare sector, infrastructure development and security and privacy:

1. Individuals using Internet seeking information about health;
2. Patients making an appointment with a practitioner via a website;
3. GPs using electronic networks to transfer prescriptions to a pharmacist;
4. GPs exchanging medical patient data with other healthcare providers and professionals;
5. NGA broadband coverage;
6. 4G coverage;
7. Individuals that haven't experienced abuse of personal information and/or other privacy violations;
8. Individuals that haven't been attacked by a virus or other computer bug resulting in loss of information or time;
9. Individuals using anti-tracking software.

Each variable was weighted. It is worth noting that the variables from 1 to 4 are specific to eHealth. For this reason, a greater weight was assigned to them – 0.5, equally split among the four variables within this category – and 0.25 each to the other two categories (infrastructure development and privacy and cybersecurity). Then, for each country, a compound average of the variables was calculated. The values obtained were normalized relative to the best performer country, so as to establish a ranking from 0 to 100.

Fig. 1.14 I-Com Index 2017 on Level of Preparedness for eHealth in Member States

Source: I-Com elaboration on European Commission data



The countries that have the best enabling variables for the development of digital health are the Northern European countries; instead, most Eastern European countries show resistance to implement eHealth.

Denmark tops the ranking with a score of 100. Estonia, the Netherlands, Finland and Sweden follow with a score of 91, 90, 88 and 86, respectively. These countries have in common a high level of digitalization in doctors' offices and a high number of patients who use mobile and Internet technologies for searching health information and making appointments online with doctors. Moreover, these countries boast a large infrastructural development and best practices in cybersecurity. France (19th with a score of 61) and Italy (20th with a score of 60), unfortunately, do not rank very well, compared to most European countries. In Italy, for instance, patients and doctors are not yet accustomed to using the digital channel to interact with each other.

1.4. THE ROLE OF 5G IN THE DIGITAL HEALTHCARE TRANSFORMATION

Despite the availability of modern and high-performing networks being an indispensable requirement for all European countries, there is still some disparity regarding both fixed and mobile networks. NGA coverage ranges from between 44.2% in Greece and 100% in Malta, with a European average of 76%, while 4G coverage ranges from 45% in Romania to about 100% in Denmark and Sweden, with a EU average of 84% (Fig. 1.15, 1.16).

Fig. 1.15 NGA Coverage (2017)

Source: I-Com elaboration on European Commission data

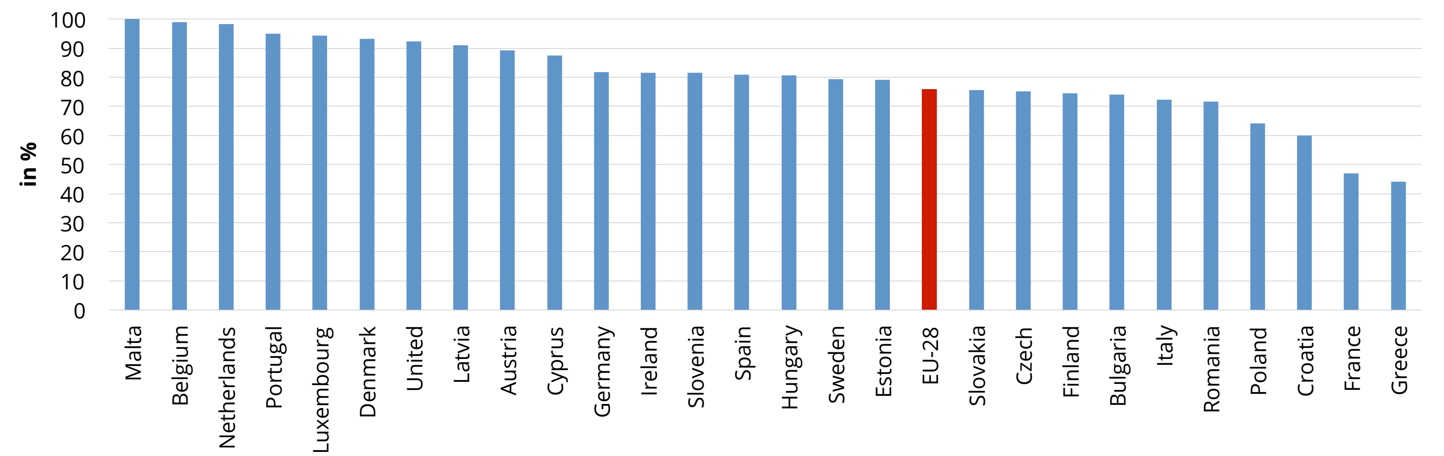
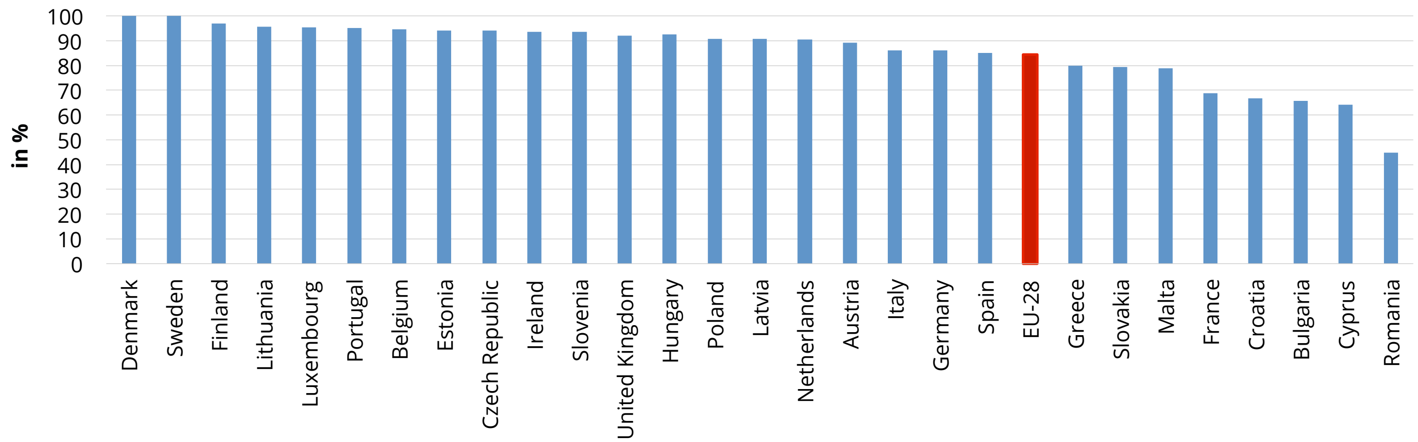


Fig. 1.16 4G Coverage (2017)

Source: I-Com elaboration on European Commission data



The extraordinary growth of mobile data traffic – favored by IoT deployment and the increasing importance of contents – underlines the importance of advanced technologies and performing telecommunication network availability.

In this context, 5G role is crucial. Already, many connected health applications can be done with existing technologies. Yet 5G technology will support applications requiring critical availability and low latency, bringing the required robustness to networks (i.e. providing 5G connectivity to ambulance services, ensuring the best possible patient care outside and inside hospital, whenever connectivity must be ~100%).

5G will enable a far-reaching revolution in the health sector, from remote diagnosis and surgery to constant, comprehensive, reliable and predictive health monitoring, even outside hospitals.

5G is indeed the new generation of radio systems and network architecture that will revolutionize businesses and the lives of citizens/consumers guaranteeing a more advanced and more complex set of performance requirements, being able to support more users, more devices, more services and new use cases through more efficiency and speed. 5G mobile networks represent the next major phase of mobile telecommunication standards beyond the current 4G standards[26].

IHS (2017) estimated that the potential global sales activity in all industry sectors enabled by 5G could reach $12,300 billion in 2035. This represents about 4.6% of all global real output in 2035. In this respect, according to some forecasts, the output enabled by 5G in health and

26 IHS, The 5G Economy: How 5G Technology will contribute to the global economy, 2017

the social sector could reach $119 billion, though only 1% of the overall value sales of 5G ($12,300 billion) across all industry sectors, and it would contribute by 2.3% to the total production in the sector (Fig. 1.17, 1.18).

A wide range of technological advances can be associated to 5G: 1) data rates up to 100 times faster (more than 10 Gbps); 2) network latency lowered by a factor of five; 3) mobile data volumes 1,000 times greater than today's; 4) battery life of remote cellular devices stretched to 10 years or more; 5) increase in the number of devices connected to the network (1 mln per 1 sq km); 6) chance of using several bands from 400 MHz to 100 GHz.

Vertical industries underline the importance of 5G deployment for the future of the European Union. 5G technology will allow for the development of new services – among them the Internet of Things is one of

Fig. 1.18 Share of output enabled by 5G, by the sector (% of all industry sectors)

Source: I-Com elaboration on IHS data (2017)

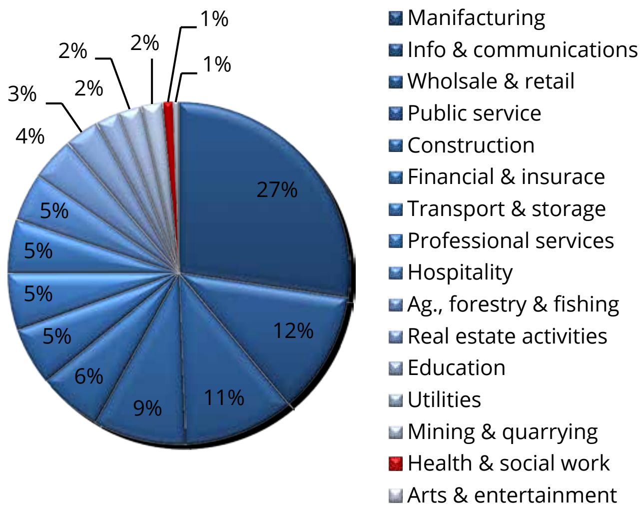
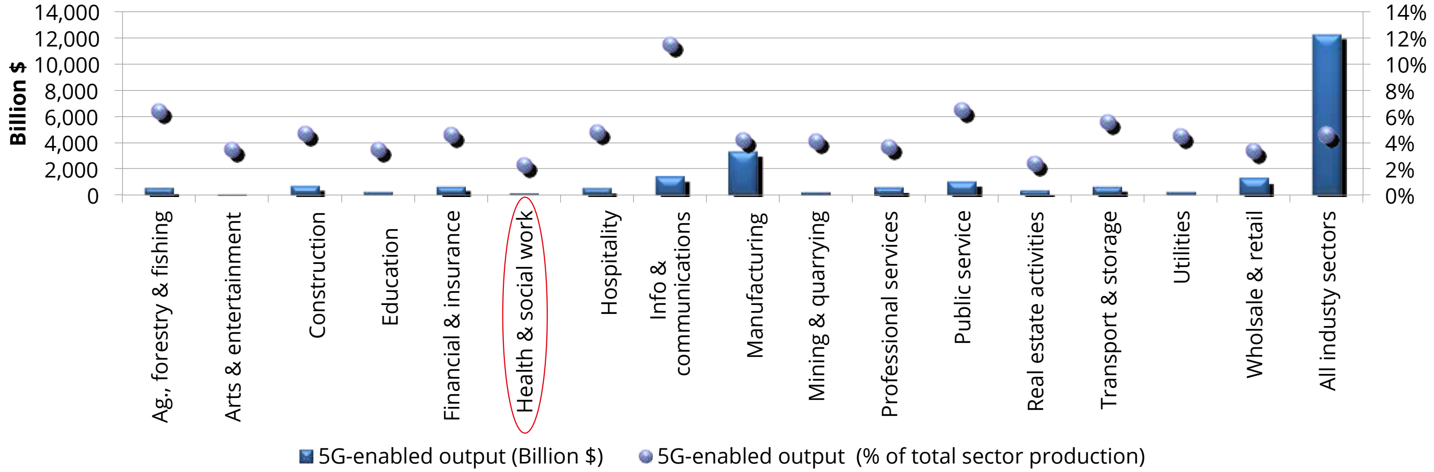


Fig. 1.17 The economic contribution of 5G in 2035, by sector

Source: I-Com elaboration on IHS data (2017)



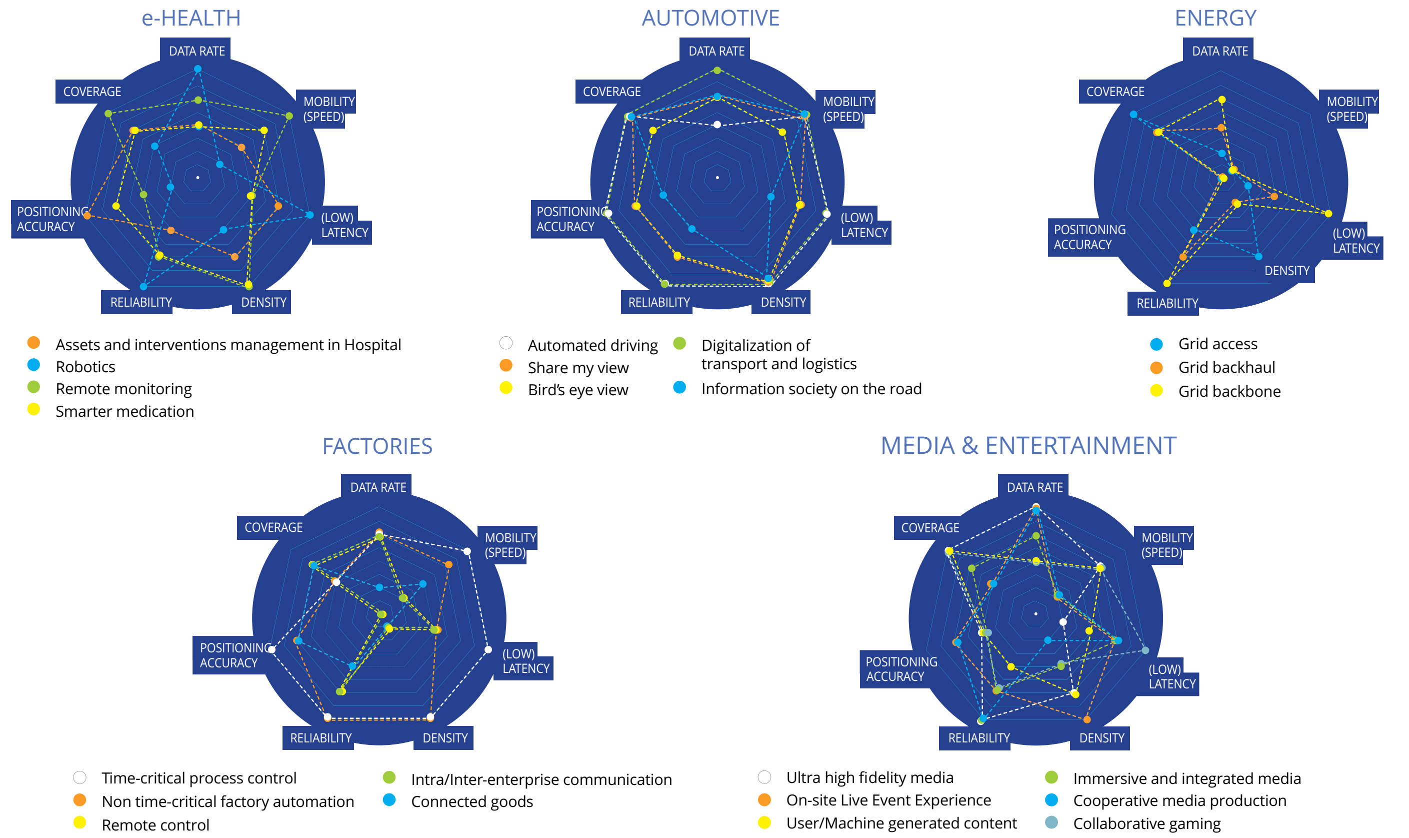
the most important – that will enable the expansion of new services that will bring progress, welfare, jobs and new opportunities for businesses.

The document *"5G empowering vertical industries"* summarizes the opportunities, the critical issues and the actions to be taken to encourage 5G development in Europe underlining that 5G network infrastructures will be a key asset to support the revolution linked to the digitization of society and industry.

This paper analyzes the development prospects favored by technological evolution focusing on the transport sector, healthcare, energy and media and entertainment, showing that, in general, the digitization of factories will be a fundamental step for the 2020s (Fig. 1.19).

Fig. 1.19 Vertical sector technical requirements

Source: 5G Infrastructure Association: 5G Empowering vertical industries



With regard to the health sector, 5G will be instrumental to the main use cases identified, such as assets and intervention management in hospitals, robotics, remote monitoring and smarter medication. The new technological framework will allow for assisted self-management capabilities, the empowering of less qualified personnel to conduct routine tasks on behalf of higher qualified professionals, the massive use of robots by surgeons (by cutting latencies and allowing the remote use of these robots from any place) and a personalized medicine, contributing also to cutting costs.
5G will play the role of an accelerator for the digital transformation of businesses, enabling the development of new advanced services including Massive Machine-type and Critical Machine-type IoT and Enhanced Mobile Broadband (e-MBB) that will represent application clusters in which the impact of such technology will be stronger.
The Massive Machine-type IoT use-case cluster, in particular, includes all network sensors, smart meters, sensors for remote monitoring of strategic assets and structures, with key requirements over battery life of more than 10 years, supported connectivity density of more than one million units per square kilometer, service reliability of 99.99%, but without SLAs particularly challenging in terms of latency and mobility.
In the Mission Critical Machine-Type IoT use-case, instead, we consider all those applications (such as remote surgery and remote monitoring of patients' health status) requiring very high performance in terms of service reliability (99.99%), latency (lower than 10ms) and mobility (even higher 500Km/h.

Finally, Enhanced Mobile Broadband's advanced services include use cases that need to support an extremely high throughput (even +10Gbps) and latency less than 5 milliseconds, also providing reliable, high quality and highly efficient services.
From the recent description of the various use cases, it emerges that Massive Machine-type IoT, not requiring a highly sophisticated performance, can be supported even with the 4G networks available today, while for the full expression of the potential of the clusters IoT Critical Machine-type and Enhanced Mobile Broadband services, the development of 5G platforms is essential.
In the Communication "5G for Europe: an Action Plan" and in the accompanying working document "5G Global Developments" published on 14 September 2016, the **European Commission** identified **8 actions** to promote 5G deployment:

1. launching preliminary trials from 2017 onwards and pre-commercial trials with a clear cross-border dimension from 2018, encouraging the adoption by Member States of national 5G deployment roadmaps and the identification of at least one major city to be "5G enabled" by the end of 2020;
2. identifying, in accordance with Member States, - by the end of 2016, a list of pioneer spectrum bands for the initial launch of 5G services;
3. adopting an agreement around the full set of spectrum bands (below and above 6GHz) to be harmonized for deployment of commercial 5G networks in Europe;
4. setting roll-out and quality objectives for the

monitoring of the progress of key fibers and cell deployment scenarios identifying actionable best practices to facilitate – also incrementing administrative conditions – denser cell deployment;

5. promoting by the end of 2019 the availability of the initial global 5G standard, the standardization on radio access and core network challenges and the conclusion of cross-industry partnerships;
6. planning technological experiments to set be up as early as in 2017 and presenting detailed roadmaps by March 2017 for the implementation of advanced pre-commercial trials;
7. encouraging Member States to consider 5G infrastructure usage to improve the performance of communication services used for public safety and security;
8. identifying assumptions and modalities for a venture financing facility.

To achieve these ambitious objectives, the European states are adopting several important initiatives.

In autumn 2016, the **United Kingdom** created the National Productivity Investment Fund (NPIF), which considered an investment of £ 23 billion between 2017 and 2022 in several areas including communications. The government also planned to invest £ 740 million in fiber development and 5G experiments showing interest in the development of TLC infrastructures.

5G was the subject of a specific strategy launched in March 2017 with the paper "Next Generation Mobile Technologies: A 5G Strategy for the UK", which analyzes possible applications of 5G in the various industrial and economic sectors. The paper sets the following objectives:

1. accelerating the development of 5G networks;
2. identifying benefits and opportunities connected to this technology;
3. encouraging investments.

To achieve such goals and to ensure that the United Kingdom plays a major role in the international context, the Strategy identifies several actions to be launched, including the provision of a "5G oriented" regulatory framework, the identification of the services that 5G will enable and the impact on existing services, the provision of adequate security systems and the targeting of frequency resources allocated to 5G services (including 3,4- 3.6 Ghz, as indicated by the regulator Ofcom in the document "Statement: Award of the 2.3 and 3.4 GHz spectrum bands" of November 2016).

In September 2016, **Germany** launched its 5G strategy aiming to:

1. release frequencies and launch experiments by 2018;
2. create a 5G forum that allows all vertical sectors to understand the technological and economic potential of 5G;
3. enable a 5G city by 2020;
4. provide public funds for research and development and accelerate the 5G commercial launch (forecasting that, by 2025, highways, trains and the 20 largest cities will be covered by 5G);
5. set up a more comprehensive 5G network later on.

Lastly, in July 2017, a detailed 5G plan was announced,

which provides for the release of new frequencies by next year, new fiber projects and the launch of a competition for ideas for new "smart city" applications linked to 5G.
In December 2016, the Bundesnetzagentur, the German regulator, launched a public consultation aimed at identifying and providing the appropriate spectrum for 5G development.
On 27 June 2017, the same regulator published the key elements for delivering the spectrum to be allocated to 5G by analyzing the appropriate frequencies (in particular, 2 GHz, which is due to be allocated, and 3.6 GHz) and asking the companies concerned to notify by September 30 the expected demand for 2GHz and 3.400-3.700MHz bandwidth. Subsequently, the Bundesnetzagentur will take a decision on spectrum release for 5G, based on the demand identified by the operators.
In **France**, the government launched in 2013 a program called *"Nouvelle France Industrielle"* to support new developments and opportunities in 34 growth sectors, including several telecom and technology-related areas, such as the Internet of Things or connected devices. The program gathers industrial players, public institutions, competition committees, operators, and research organizations and is focused on very high speed fixed and mobile broadband (fiber broadband and 5G are key elements), regulation, IoT, security of radio networks, employment/education, SMEs and start-up economic development.
In the government program, "Sovereignty Telecoms" is a specific plan to standardize 5G technology, deploy a European network for the Internet of Things using a mix of French and European players and create a label that will identify connected devices and processes.
Arcep, the telecommunications regulator, launched some pilot projects that will, first of all, involve the cities of Lyon, Nantes, Lille, Le Havre, Saint-Etienne and Grenoble.
Instead, **Ireland** has recently allocated frequencies in the 3.6GHz band, one of the "pioneering" bands for the development of 5G networks. This is a call with 350 Mhz distributed in 594 lots in nine geographic regions (5 urban and 4 rural) and allocated on a contiguous basis.
In particular, the spectrum was split into two batches: the first, 25Mhz in the 3410-3435MHz band (below the band reserved for state services), the second was 65 bits of 5Mhz each in the band 3 475 - 3 800 MHz (above the band reserved for state services).
This procedure saw in Vodafone, Three and Meteor the main operators which have been awarded licenses in all 9 regions for a period of 15 years, with an entry fee of 78 million euros for the state.
As well, **Italy** has shown a keen interest in developing 5G. In March 2017, the Italian government published a public call for pre-commercial trials of innovative 5G networks and services in the 3.7-3.8 GHz spectrum portion. These trials will take place in 5 Italian cities (the metropolitan area of Milan, Prato, L'Aquila, Bari and Matera) with the aim to experiment with the 5G network, not only from an infrastructural point of view but also with regard to underlying services. Therefore, the call was not only aimed at communication carriers but also other national and international players wishing to experience services

with 5G technology, and, therefore, universities and other research entities and companies from other sectors. With a public announcement on 2 August, 2017, the Ministry announced the list of projects that had won the call - Vodafone in Milan, Wind Tre and Open Fiber in Prato and L'Aquila, TIM, Fastweb and Huawei in Bari and Matera.

PART 2

THE IMPACT OF DATA AND ARTIFICIAL INTELLIGENCE ON HEALTHCARE SYSTEMS

2. THE IMPACT OF DATA AND ARTIFICIAL INTELLIGENCE ON HEALTHCARE SYSTEMS

2.1. THE DATA MARKET VALUE IN THE HEALTHCARE SECTOR

The increasing migration of socio-economic activities to the Internet has resulted in a huge data generation, commonly called "Big Data", – characterized by the so-called 5 Vs[27]:

a. **Volume** refers to the huge amount of digital data. It is growing exponentially. While three-fourths of data was analogous in 2000, today more than 99% of all data is digital data

b. **Variety** hints at the fact that there are different kinds of data from diverse kinds of sources. For health care and research, several sources are relevant: medical data from individual patient care, public health data, data from different insurance, research data collected by researchers and scientists, companies or individuals themselves, lifestyle data e.g. from health apps, data from social networks and data from commerce. This data can be classified in different ways and according to different criteria, for example, personal data, anonymized data, metadata, primary and secondary data.

c. **Velocity** means the very high speed at which data can be collected and processed. Real-time-tracking and cloud solutions allow for comprehensive processing within seconds, even producing immediate recommendations, e.g. for medication, behavior or nutrition.

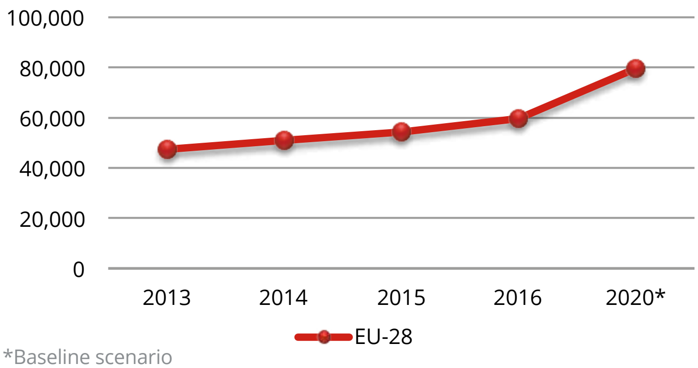
d. **Validity** refers to the quality of the data and the question if it really shows what it is meant to show regarding content and precision. The context of data plays a major role here.

e. **Value**, finally draws attention to the meaning of the data for a specific question e.g. with regard to a certain disease.

The data market value – meant as the aggregate value of the demand for digital data without measuring the direct, indirect and induced impacts of data in the economy as a whole[28] – is expected to increase from 59.5 billion euros in 2016 to approximately 80 billion euros in 2020 (Fig. 2.1)

Fig. 2.1 Data market value in the EU (€ million)

Source: I-Com elaboration on European Data Market Monitoring Tool data, IDC 2016



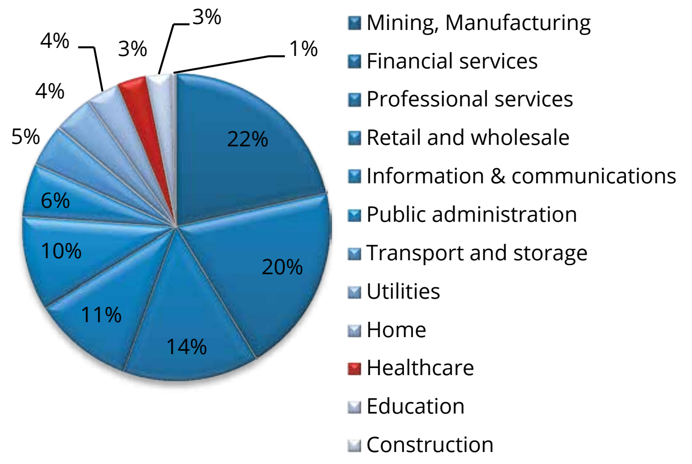
*Baseline scenario

27 Report of the IBC on big data and health, 2017

28 Notice that the data market represents a wider concept than market of Big Data & Analytics (BDA) as it includes not only the value generated by pure data players developing BDA technologies but also the value created by data-related research, business, information and IT services.

Fig. 2.2 Share of data market value in the EU, by industry (2016)

Source: I-Com elaboration on European Data Market Monitoring Tool data, IDC 2016



The top industries in terms of EU data market size are represented by the manufacturing sector and the financial services that, together, accounted for 42% of total data market value in 2016. Instead, the share of data market value in the healthcare sector was only 3% of the total (Fig. 2.2). In particular, the data market value in the European healthcare industry amounted to almost 1.9 billion euro in 2016 and is expected to grow by 35% to over 2.4 billion euro – by 2020 (Fig. 2.3).

Relative to the spending on the data market in percentage of total sectoral spending on ICT, the transport and storage industry spent the most on the data market in 2016 (13% of total ICT spending) while the share of data market spending in the healthcare sector was 11.4% of total ICT spending in 2016 (Fig. 2.4).

Fig. 2.3 Data market value in the EU, by industry (2016 vs. 2020, € mln)

Source: I-Com elaboration on European Data Market Monitoring Tool data, IDC 2016

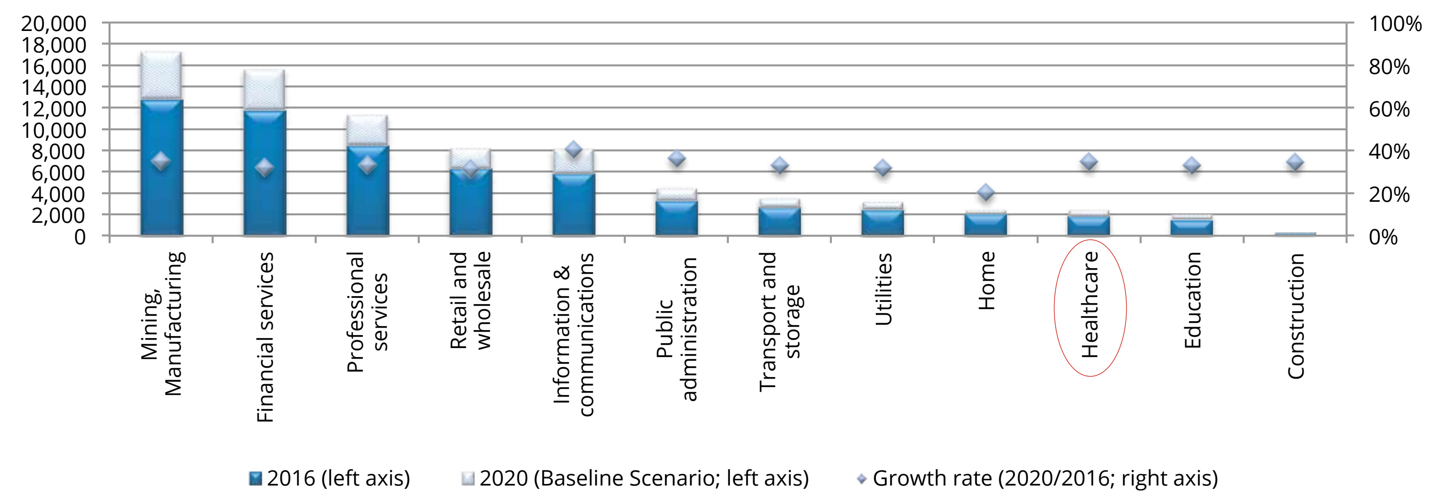
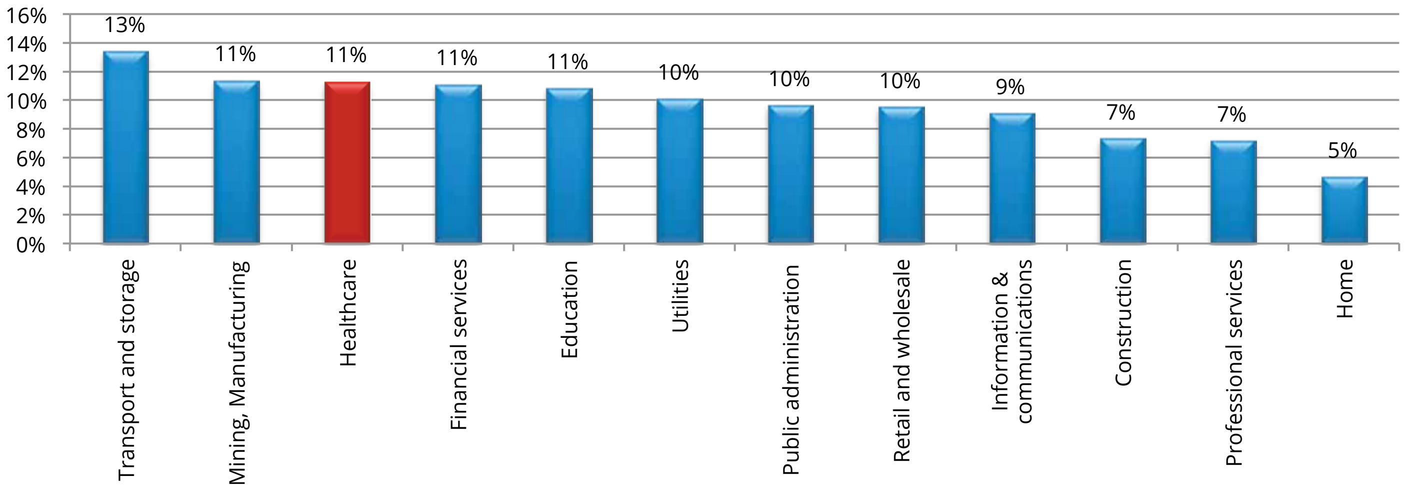


Fig. 2.4 Share of data market on ICT spending, by industry (2016)

Source: I-Com elaboration on European Data Market Monitoring Tool data, IDC 2016



The healthcare industry was the sixth industry for employment of data workers[29] – with a total number of about 485,000 workers in 2016. Nevertheless, the share of data workers on total employment is still low in the healthcare industry (2.0%, compared with 10.7% in ICT or 9.4% in finance, which are typically the most highly digitalized sectors)[30] (Fig. 2.5).

Moreover, the healthcare industry came eighth in terms of data users[31] (29,450) in 2016. Data users are expected to grow, reaching 32,350 units by 2020, a growth of 10%, in line with the other sectors (Fig. 2.6). Finally, in terms of intensity of data workers – meant as the average number of data workers calculated out of the total number of data user companies – in retail and wholesale (87), education (34) and healthcare (17) the intensity share of data workers is higher than in other sectors (Fig. 2.7).

29 Data workers are defined as workers who collect, store, manage and analyze data as their primary, or as a relevant part of their activity.
30 However, it should be taken into account that the healthcare sector is significantly more labor-intensive than both finance and ICT sectors.

31 Data users are organizations that generate, exploit collect and analyze digital data intensively and use what they learn to improve their business.

Fig. 2.5 Number of data workers, by industry (2016)

Source: I-Com elaboration on European Data Market Monitoring Tool data, IDC 2016

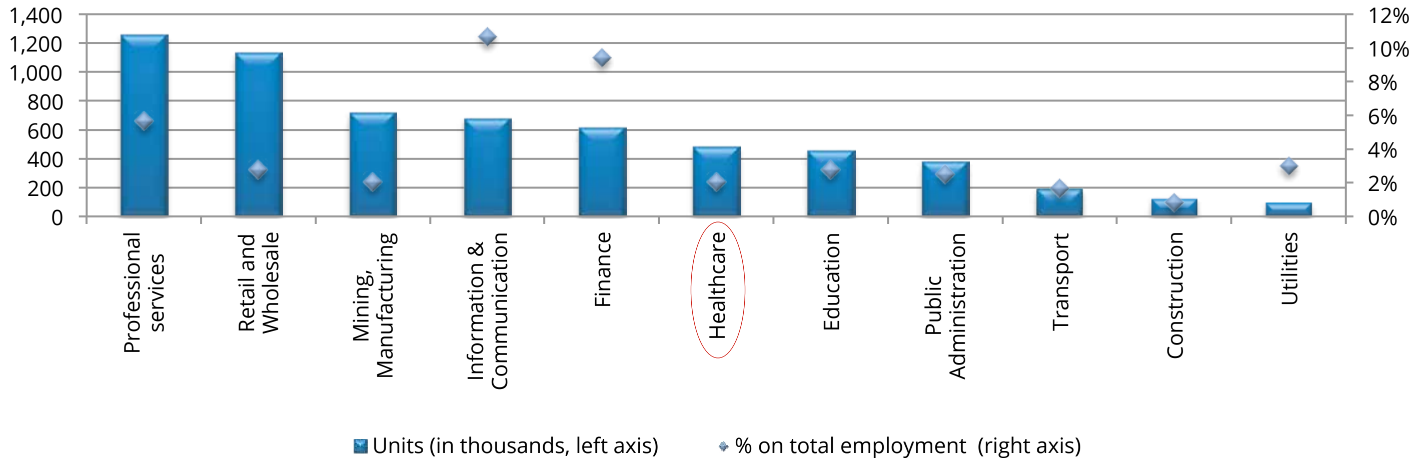


Fig. 2.6 Number of data users, by industry (2016 vs. 2020, units)

Source: I-Com elaboration on European Data Market Monitoring Tool data, IDC 2016

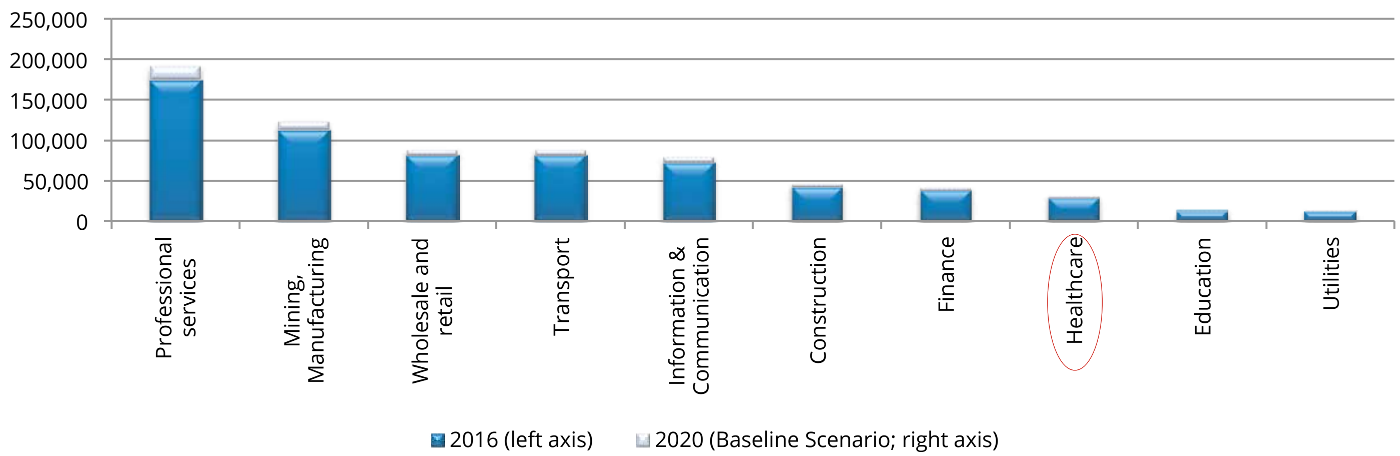
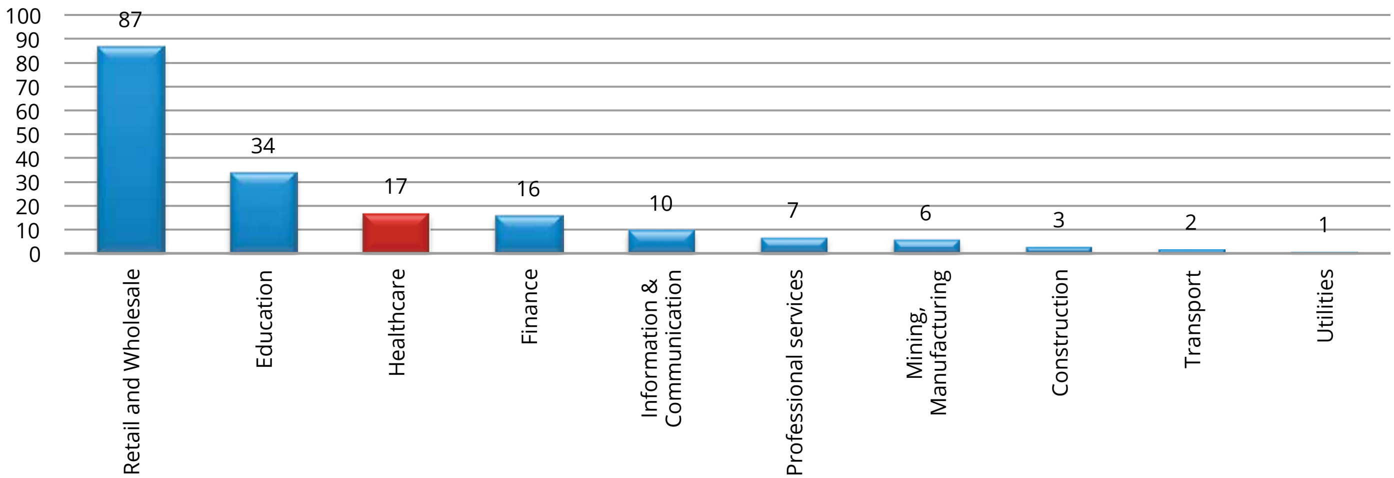


Fig. 2.7 Intensity share of data workers, by industry (2016)

Source: I-Com elaboration on European Data Market Monitoring Tool data, IDC 2016



2.2. THE IMPORTANCE OF DIGITALIZATION AND BIG DATA FOR OUTCOME-BASED, SUSTAINABLE HEALTHCARE

European healthcare systems are facing new challenges, due to the ageing and, consequently, greater prevalence of chronic diseases. At the same time, the development of highly innovative products, such as cellular therapies, gene therapies, and disease-modifying therapies, aims to cure serious pathologies such as cancer, cystic fibrosis and Alzheimer's disease, in response to a wider demand for care. Valuing and adopting highly innovative products is necessary to ensure that European citizens can access better care and achieve a better quality of life. These innovations are capable of yielding better results (outcomes) than those obtained in the past, offering new solutions to those pathologies with needs still unsatisfied, but with costs creating a sustainability problem.

Despite the need to make innovative treatment available to the population, the problem of their cost and, consequently, the different access to care remain a big problem. To date, many health systems have remained focused on inputs rather than on patient outcomes, and this approach, according to EFPIA itself, must change to make health systems not only more responsive to patient needs but also more sustainable.

Outcomes are the results of the treatments, which is what most patients are interested in. Outcomes differ from "outputs", i.e. the results of laboratory tests or diagnostic imaging, because they correspond to what is most pressing to the patient, such as pain relief, the return to working life, prevention of complications or restoring physical functionality. This new approach, which provides for outcomes-based healthcare, not only focuses on the actual well-being of the assisted but also helps identify and eliminate the technologies that do not give rise to positive outcomes.

The outcomes-based healthcare reduces hospitalization, surgeries and long-term care, making the system not only more effective but also sustainable, as it allows for investment in products that show better outcomes than the technologies already in use. The transition to an outcomes-based system is possible but remains closely linked to the production and use of health data, which makes it possible to analyze the outcomes themselves.

There are several big data definitions, but regardless of the scope (for example public health or individual health state), the big data value chain consists of generation and collection of data, storage and processing, and finally distribution and analysis. The European Commission, in its study on *"Big Data in Public Health, Telemedicine and Healthcare"* (2016), shows the importance of big data in health, describing it as *"Big Data in Health refers to a large routinely or automatically collected data sets, which are electronically captured and stored. It is reusable in the sense of multipurpose data and includes the fusion and connection of existing databases for the purpose of improving health and health system performance. It does not refer to data collected for a specific study*."[32]

As famously pointed by the Economist, *"the world's most valuable resource is no longer oil, but data*[33]*"* and this is also true in the healthcare sector. Big data represents a huge resource for both institutions and suppliers of products and/or services, as well as for patients, enabling them to create value through better diagnosis and better clinical decision-making.

Measuring and monitoring health outcomes is a crucial step to building an outcomes-based and, therefore, sustainable healthcare system. Systematically mapping interventions and their impact on outcomes allows suppliers to improve, comparing their performance with technologies that show superior results, while decision makers and patients can opt for the solutions that best fit their needs. We can therefore assert that data digitization, which enables precise and instantaneous collection and analysis of a huge amount of information about the health status of patients and the treatment they undergo, is crucial for the creation of an outcomes-based and sustainable health system.

2.2.1. The potential benefits of big data in healthcare

Technological development guides the evolution of health systems, providing more effective responses to a poly-morbid population with chronic illnesses. Diseases considered incurable, such as hepatitis C, can now be cured with new drugs and the ability to use new devices, often portable and wearable, has led to the creation of

32 European Commission, "Study on Big Data in Public Health, Telemedicine and Healthcare", final report, December 2016

33 The Economist, "The world's most valuable resource is no longer oil, but data", May 2017

new types of data describing the health state of citizens. The relationship between Information and Communication Technologies (ICT) and the healthcare industry has resulted in the digitization of huge amounts of data, which can now be collected, analyzed and shared in a completely different way than decades ago. Today's digitized health data helps improve research activities, prevent and treat illness, promote healthier behavior, improve self-care, and public health activities, and help with clinical decisions. Everyone needs and produces big data, such as academics, industry, healthcare professionals, patients, politicians, and regulator specialists.

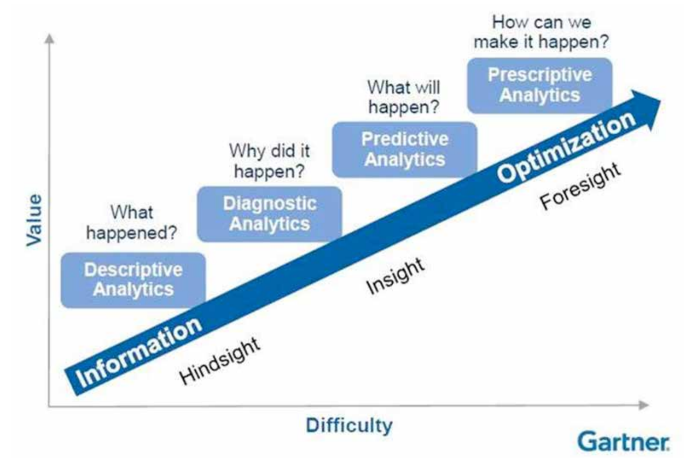
The sources of big data in health are many:

- data on the symptoms, prescriptions and outcomes of patients from electronic health records (EHR);
- outcomes of long-term treatment from real-world efficacy studies;
- data on the performance of administered drugs from random control trials (RCTs);
- biomarker data from genomic and proteomic studies;
- vital data from wearable products and sensors;
- data on social behavior from the social media[34].

According to the Big Data Value Association, Big Data technologies will definitely open up new opportunities and lead to breakthroughs, addressing different perspectives: (i) **descriptive** (what happened?), (ii) **diagnostic** (why did it happen?), (iii) **predictive** (what will happen?) and (iv) **prescriptive** (how can we make it happen?) (Fig. 2.8).

Fig. 2.8 Data patterns including hindsight, insight and foresight

Source: BDV, "Big Data Technologies in Healthcare, needs, opportunities and challenges", 2016



Prospective data monitoring or retrospective analysis can help to:

- increase the effectiveness and quality of treatment (early intervention in case of illness, reducing adverse events due to medicines and medical errors, detecting co-morbidity, linking up the various health figures, intensifying research networks and linking social networks, disease networks or medicine networks);
- improve disease prevention by identifying risk factors at a population, sub-population or individual level, and by improving the effectiveness of intervention that can help people achieve healthy behavior in healthier environments;

34 S. Marjanovic et al., "Understanding value in health data ecosystems. A review of current evidence and ways forward", RAND Europe, 2017

Tab. 2.1 Overview of potential benefits from using data in health

Source: RAND Europe, 2017

POTENTIAL BENEFITS FOR R&D AND INNOVATION	POTENTIAL BENEFITS FOR PUBLIC HEALTH AND PHARMACOVIGILANCE	POTENTIAL BENEFITS FOR HEALTHCARE DELIVERY AND THE WIDER HEALTH SYSTEM
• ***Opportunities to explore new research areas*** could stem from access to richer data sources and new analysis techniques. For example: (i) Linking datasets on genetic profiles with EHR on patient symptoms can help reveal patterns of association or disease causation that it was previously not possible to detect; (ii) access to real- world data from pragmatic trials and other real-world evidence can enable research not possible under an RCT model due to ethical issues (e.g. studies on narcotic abuse) or due to challenges of sample size (e.g. research on rare diseases). • ***Operational and cost-efficiencies*** could stem from: (i) better targeting of R&D investments and more appropriate clinical trial design due to improved patient stratification based on genetic traits and clinical records; (ii) reduced unnecessary duplication in research and enhanced confidence in results due to access to a richer and broader evidence base and enhanced data sharing. • ***Health data can also enhance the quality of research and innovation*** processes and outputs. For example: (i) real-world data from pragmatic trials can increase confidence in study results given that sample populations may be more representative of actual practice; (ii) using real-world data throughout the R&D and innovation cycle could also facilitate reimbursement for products that have a proven enhanced efficacy in a real-life setting and inform value-based and outcome-based payment approaches, as well as adaptive pathways; (iii) longitudinal data on treatment adherence and compliance creates prospects for new outcome measures in research.	• ***Prospects to scale up use of real-world health data in pharmacovigilance:*** Access to more diverse and greater amounts of real-world data than currently practised in pharmacovigilance (drug-safety monitoring), coupled with more granular information on patient profiles, could facilitate quicker and more rigorous learning about how drug safety relates to particular patient groups over time, including in the context of co morbidities. • ***Prospects for enhanced, data-enabled public health promotion and prevention strategies:*** For example: (i) large and integrated environmental, genetic and socio- economic datasets could enable better prediction of risk factors for disease; (ii) data on health apps and portable devices could enable citizen empowerment and proactive behavior in maintaining good health; (iii) computer algorithms and predictive analytics could assist in disease screening and early diagnosis. • ***Emergency-preparedness*** could be improved through more timely data matching disease outbreaks with covariates (such as environmental data from satellite sensors and data on symptoms from both health professionals and social media (although checks on reliability would be needed).	• ***Benefits for healthcare quality:*** For example: (i) more personalised care and enhanced predictive analytics could be enabled by more comprehensive clinical datasets (e.g. improved screening algorithms and integration of imaging data, genomic and proteomic data on new biomarkers, and symptoms data from EHR); (ii) workforce access to more comprehensive evidence could facilitate better-informed care decisions (provided that evidence is presented in a user- friendly manner and trusted). • ***Operational and cost-efficiencies in healthcare delivery:*** For example: (i) easier comparability of outcomes data from different treatments across patient profiles could be enabled by large datasets from EHR, and could allow for more efficient decision-making, reducing wastage and costs associated with administration of inappropriate or inferior treatments; (ii) a reduction in unnecessary hospitalizations could be facilitated through data- and technology-enabled self-care and self-management of risk factors and through remote monitoring of adherence to treatments (this would require careful risk management). • ***Wider benefits for the health system:*** For example: (i) real-world outcomes data for treatments (e.g. clinical and patient experience data) could enable better- informed drug safety regulation, adaptive pathways and innovative reimbursement models; (ii) greater usage of EHR and costs data could facilitate more efficient health systems planning and resourcing, improved workflows and administration efficiency.

- improve pharmacovigilance and patient safety by providing more informed medical decisions with information coming directly to the patient;
- predict outcomes, such as the containment and improvement of chronic diseases, surveillance of infectious diseases through a better understanding of demographic challenges and trends and pathways of disease transmission;
- disseminate knowledge, for example by allowing physicians to stay up to date;
- reduce inefficiency and cut costs.[35]

Transparency and access to big data in healthcare could help experts compare the outcomes from different treatment across distinct patient profiles (e.g. different genotype, phenotype and behavior), through large clinical datasets, such as HER. The possibility to use big data could also help researchers create new and more effective protocols by reducing waste and costs due to inferior or inappropriate treatment.

The use of this data results in significant benefits in R&D, public health and pharma-covigilance and for the entire healthcare system, as described in Table 2.1.

The production, collection, analysis and sharing of big data is necessary to improve on old approaches and create new therapeutic options, but devices, registers and platforms must be used as enabling tools.

35 S. Marjanovic et al., "Understanding value in health data ecosystems. A review of current evidence and ways forward", RAND Europe, 2017

2.2.2. Devices, registers and platforms: from outcome measurement to data sharing

The combination of ICT and health has given rise to products capable of measuring, collecting, analyzing- and sharing many outputs, such as lab and diagnostic imaging results. At present, technological development has enabled products to do this in a very short time, with staff being able to access a huge amount of data, with analysis and sharing now allowing for timely intervention regarding acute conditions and remotely monitor the chronic patient. According to Sonja Marjanovic et al., "health data refers to any health related information that is of relevance to decision making in a health system and that can inform prevention, treatment, cure, health promotion, self-care and wider public health activities and decisions taken by stakeholders (RAND Europe, 2017)", while the European Commission has pointed out that "Big Data in Health refers to large routinely or automatically collected datasets, which are electronically captured and stored. It is reusable in the sense of multipurpose data and comprises the fusion and connection of existing databases for the purpose of improving health and health system performance"[36].

Health informatics data comes from:

- **bioinformatics** which uses molecular level data;
- **image informatics**, which uses tissue level data such as brain image data in neuro-informatics;
- **clinical informatics**, which uses patient level data;

36 European Commission, "Study on Big Data in Public Health, Telemedicine and Healthcare", final report, December 2016

- **public health informatics and pharmacovigilance**, which uses population level data (including via social media);
- **translational bioinformatics (TBI)**, focused on integrating multiple types of informatic data towards improving healthcare outcomes.

This data allows for diagnosing, predicting, and curing many diseases, and nowadays it is possible to understand not only what happened to the patient, but also to predict what will happen to him/her in the future and know how to act as soon as possible.

The development of ICT has led to the creation of a particular kind of data, the real-world data. It refers to health data collected outside the contest of Randomized Controlled Trials (RCTs), stemming from multiple sources, such as patient-reported data, clinical data, payer data and can be collected prospectively and retrospectively. There is a growing attention placed on real-world data applications, for example electronic medical records and observational studies can be used to implement medical research through supplementing data from RCTs and to help doctors in making decisions. Patients can also access the social network and share health information to support diagnosis, self-management and treatment monitoring.

Some real-world data can cover small and structured samples that do not need big-data algorithms for analysis, while other real-world data can be combined to generate big data through the support of specific software and machines to discern patterns.

There are many types of health data:

- Electronic Health Records data (HER-Data) (Symptoms, medical exams, tests, referral patterns, prescriptions, death records, pharmacy records, diagnostic procedures, hospitalization);
- geospatial health data (Health data disaggregated by location);
- omics data (data coming from genomics, transcriptomics, proteomics, epigenomics, metagenomics, metabolomics, nutriomics);
- clinical trial data;
- pharmaceutical data (medicine safety data from pharmacovigilance);
- mobile apps, telemedicine and sensor data;
- social media, web data (Data from patient forums on health topics);
- claims data (nature of service usage, insurance and other administrative hospital data);
- ambient data from “smart” environments (electricity and gate data on the way people walk which can be used to estimate the occurrence of falling);
- well-being, socio-economics, behavioral data;
- other records (occupational records, socio-demographic profiles or environmental).

Health data can also be classified according to who generates it, for example:

- citizen/patient generated data: data from digital devices or media (mobile device, wearable sensors, social media etc.);
- healthcare professionals/provider: data such as HER, hospital performance data, admissions data etc.;
- payer data on claims and costs;

- researcher-provided data such as from scientific studies conducted in research institutes or academia;
- government/provided data such as public health data or epidemiological data;
- industry-/private-sector-provided data, for example from clinical trials, pharmacovigilance or sales data.

Current technological products can be used to measure, collect and share both clinical outputs (e.g. blood glucose, oxygen value, etc.) and health outcomes.

Every day a lot of data coming from patients, doctors, and specialized staff can be collected in large databases and thus become part of registers contained within platforms that allow for the exchange of information among many healthcare actors, for example among more clinicians, between patients and doctors, and between pharmaceutical companies and regulators.

RegistRare is an example of a platform for rare diseases. This is the new Italian Web Platform dedicated to Rare Disease Registries developed by the National Center for Rare Diseases (Centro Nazionale Malattie Rare) of the Istituto Superiore di Sanità (ISS). The Platform allows Patient Associations and Operators in the industry to create their Pathology Register, developing it with the Centro Nazionale Malattie Rare. The platform contains various registers, such as one concerning Cystic Fibrosis (Registro Italiano Fibrosi Cistica) and another for Paroxysmal nocturnal hemoglobinuria (Registro Emoglobinuria Parossistica Notturna).

There are also other examples of registers and platforms at the European level. In the EFPIA paper (2016) "*Healthier future - The case for outcomes-based, sustainable healthcare*", some case studies are reported:

- the Swedish Childhood Cancer Registry has recorded the diagnosis, treatment and outcomes of patients since the 1970s. At 80%, Sweden now has the highest childhood cancer survival rate in Europe, with no significant regional variation. Since 1998, Sweden's National Cataract Registry has collected nationwide data on postoperative endophthalmitis (PE), which, although rare, results in blindness in between 30 and 50 per cent of patients. The Registry enables the identification of specific risk factors, which has contributed to a decline in PE from 0.11 per cent of all cataract surgery cases in 1998 to 0.02 per cent in 2009;
- in the Netherlands, healthcare professionals have helped to develop the outcome indicators for registries of quality and outcome data. In exchange for reported data, hospitals are provided with a weekly dashboard to help identify best practices and how outcomes can be improved. Outcomes have included a 30 per cent decrease in mortality after resection in colorectal cancers between 2010 and 2012.

Portable devices are important tools to generate health data, that can be collected in registers and share in platforms to help researchers, industry and healthcare professionals, patients and the public, regulators payers and policymakers to make the right decisions and improve citizens' health and quality of life.

We have noted that outcomes measurement allows for examining whether therapeutic intervention is associated with a (positive or negative) change in the patient's state of health. The modification can be measured through evaluation scales used not only by the physician but also by the patient. In the second case patients can evaluate directly, without the interpretation of physicians, the effects of treatment received, through Patient-Reported Outcomes (PROs), an important tool to understand and improve the patient Quality of Life, as we can better see in the next paragraph.

2.3. ARTIFICIAL INTELLIGENCE AND ROBOTICS: THE TOOLS OF THE HEALTHCARE REVOLUTION

Artificial Intelligence (AI) is defined as "the use of computer systems able to perform tasks that normally require human intelligence, such as visual perception, speech recognition, decision-making, and translation between languages." Although AI simulates human decision-making, it does not replace human intelligence, rather, it relies on human training[37].

Healthcare is a promising market for AI, thanks to its ability to draw inferences and recognize patterns in large volumes of patient histories, medical images, epidemiological statistics, and other data. AI has the potential to help doctors improve their diagnoses, forecast the spread of diseases, and customize treatment. AI combined with healthcare digitization can allow providers to monitor or diagnose patients remotely as well as transform the way we treat chronic diseases that account for a large share of health-care budgets[38].

AI systems are designed to transform diagnosis and disease treatment and they define a notion of "New Health".

Past decades focused on the innovation provided by medical products delivering historic and evidence-based care. The present decade is one of medical platforms focused on real-time, outcome-based care. The next decade is moving towards medical solutions – using AI, robotics, and virtual and augmented reality – to deliver intelligent solutions for both evidence- and outcome-based health, and focusing on collaborative, preventative care. This convergence of technology-based products, platforms and solutions is leading to a previously unimagined precision medicine, down to the familial and individual level, which one day may even be able to predict and thereby prevent diseases[39].

PWC (2017) conducted a survey on a sample of individuals (potential patients) with the aim of analyzing the perception of the advantages and disadvantages related to the use of AI in healthcare.

According to 36% of respondents, thanks to AI, healthcare would be easier and quicker for more people to access. Moreover, advanced computers/robots with AI can make a diagnosis faster and more accurately (according to 33% of respondents) and will make better treatment recommendations (29%). For

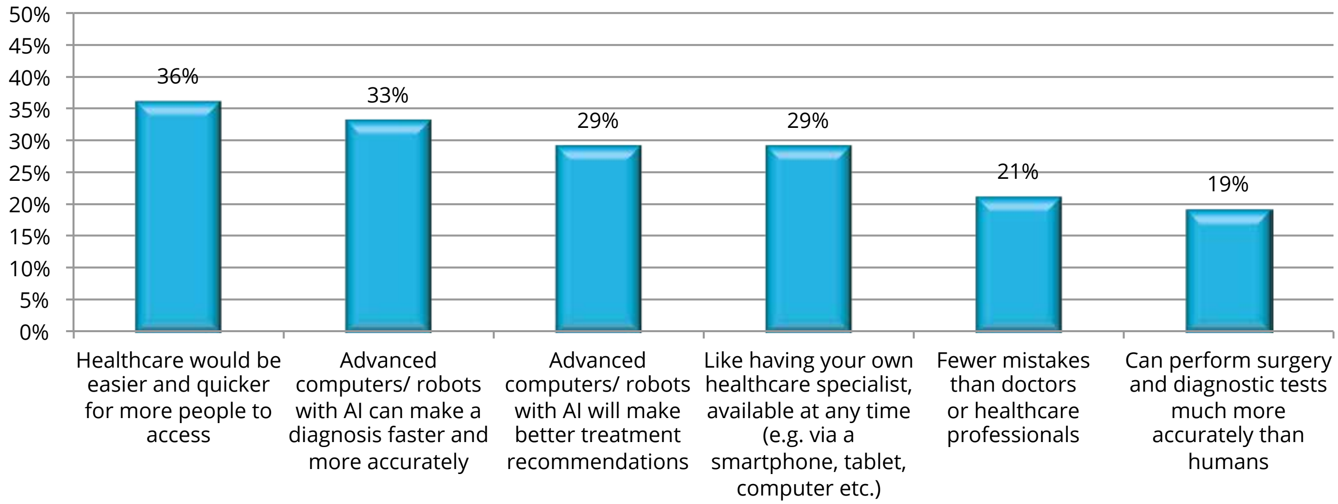
37 Omnicom Health Group, The Power of Artificial Intelligence in Healthcare, 2016

38 McKinsey Global Institute, ARTIFICIAL INTELLIGENCE: THE NEXT DIGITAL FRONTIER?, 2017

39 PWC, What doctor? Why AI and robotics will define New Health, 2017

Fig. 2.9 Advantages of AI in healthcare according to a sample of potential patients

Source: PWC (2017)



29% of respondents another big advantage consists in the possibility to have their own healthcare specialists available at any time. It's also of note that many respondents felt that there would be fewer mistakes (21%) and more accuracy (19%) (Fig. 2.9).

Relative to the disadvantages, the lack of trust (47%) and the human element (41%) are the primary reasons for doubts concerning the use of AI enabled or robotic services. For 40% of respondents, only a doctor or human healthcare professional can make the right decisions for health treatment/procedures. Many respondents (32%) don't understand this kind of technology well enough to infer if it can be beneficial or not. Moreover, according to 17% of respondents, it is too complicated for people to access and use this kind of technology. Finally, many patients interviewed (17%) do not see how this kind of technology can do a better job than a human (Fig. 2.10)

AI is a very broad category with various subfields. There are multiple applications of AI, from sensors and IoT devices, to more complex systems that apply natural language processing and machine learning (Fig. 2.11). The latter is fast becoming transformative for the healthcare value chain.

Some AI applications are exercising a considerable impact on eight "areas of healthcare ecosystem" (Keeping well; Early detection; Diagnosis; Decision making; Treatment; End of Life Care; Research; Training)[40,41].

40 PWC, What doctor? Why AI and robotics will define New Health, 2017

41 PWC, Sherlock in Health How artificial intelligence may improve quality and efficiency, whilst reducing healthcare costs in Europe, 2017

Fig. 2.10 Disadvantages of AI in healthcare according to a sample of potential patients

Source: PWC (2017)

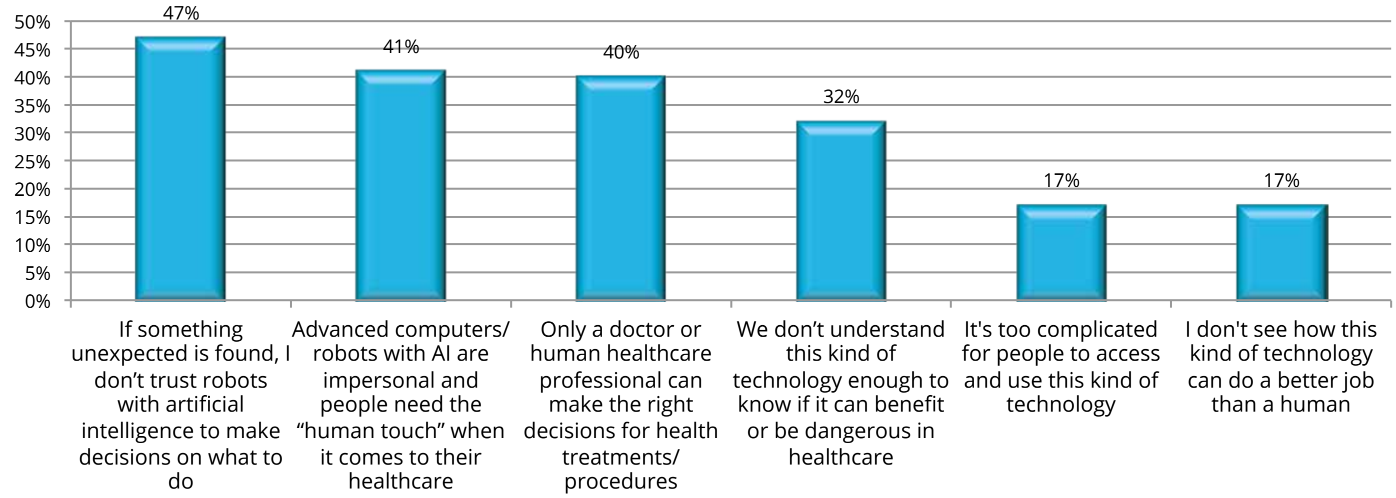
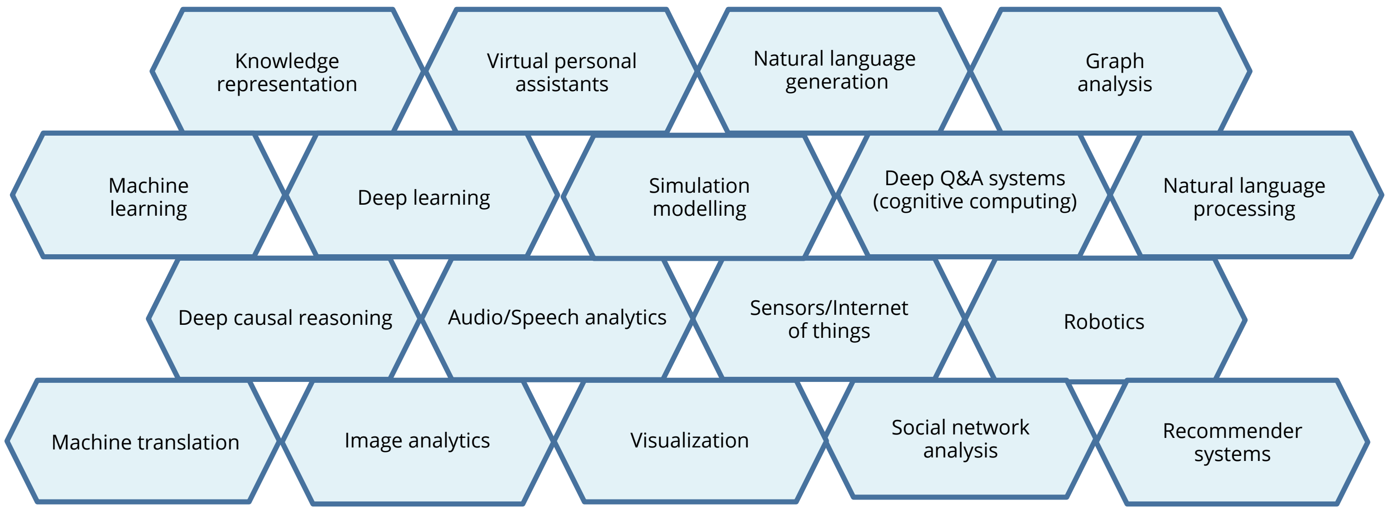


Fig. 2.11 AI subfields

Source: I-Com elaboration on PWC (2017)



1. Keeping well. The use of AI and the internet of medical things in consumer health applications helps people manage their own health and keeps them well. These applications encourage healthier behavior in individuals and help with the proactive management of a healthy lifestyle. Additionally, AI increases the ability for healthcare professionals to better understand the day-to-day patterns and needs of the people they care for, and with that understanding they are able to provide better feedback, guidance and support for staying healthy.
2. Early detection. AI, the use of wearables and other devices can be applied to detect diseases such as cancer, or to monitor cardiac diseases at a very early stage, enabling doctors and other caregivers to better monitor and detect potentially life-threatening episodes at earlier, more treatable stages.
3. Diagnosis. AI is being implemented across different hospitals worldwide to solve issues of misdiagnoses. AI has the ability to process information much faster than any human can, thus increasing efficiencies and accuracy.
4. Decision-making. The innovation of predictive analytics and the alignment of big health data with the appropriate and timely decisions will support clinical decision-making and deliver administration priorities and actions. AI technologies can ingest, analyze and report on large volumes of data, across different modalities, to detect disease and guide[42].

42 Sobia Hamid (The Babraham Institute, University of Cambridge), The Opportunities and Risks of Artificial Intelligence in Medicine and Healthcare, 2016

5. Treatment. AI can help clinicians take a more comprehensive approach for disease management, better coordinate care plans and help patients to better manage and comply with their long-term treatment programs. Moreover, robotics is being widely used in healthcare, from surgery to supporting self-management of patients with long term conditions and for treating psychological conditions.
6. End-of-life care. Robots have the potential to revolutionize end-of-life care, allowing people to remain independent for longer, reducing the need for hospitalization, caregivers and care homes by performing routine tasks such as taking vital signs and prompting for medication. AI combined with the advancements in humanoid design are enabling robots to go even further and have ‘conversations’ and other social interactions with people, keeping ageing minds sharp and solving problems of loneliness and isolation.
7. Research. Applications of AI are increasingly applied in drug research and discovery. Players in the biopharmaceutical industry are looking toward AI to speeding up drug discovery, decreasing failure rates in drug trials and eventually creating better medicines. Moreover, AI has the potential to significantly cut both the time to market for new drugs and their costs, not only for the labs who develop the drugs, but for those people whose health depend on them.
8. Training. The use of AI in healthcare improves training of healthcare professionals through providing

realistic and accurate simulations, thus increasing comprehension and skills.

In short, AI is becoming increasingly sophisticated at doing what humans do but more efficiently, more quickly and at a lower cost. AI is well known for advancing "precision medicine", an emerging approach to disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle. Now, thanks to cognitive computers, it is possible to make early and precise diagnosis and so identify a lifesaving therapy much faster than traditional methods where the patient's genetic data are manually examined.

Another advance in healthcare through the use of AI is the ability to mine information that is held in electronic medical records. AI is also helping to speed up telemedicine.

Finally, AI and robotics will open up new opportunities and will free up clinicians for other types of work that enable them to spend more meaningful time with their patients.

2.3.1. The obstacles to AI in medicine and healthcare

The adoption of AI is not without facing some potential risks. The main risks concern low accuracy, security and understanding that may cause various problems. Accuracy is important to preserve trust in these new technologies. A probable lack of trust in AI systems may significantly impinge on the adoption of technologies that may otherwise offer significant improvements in patient outcomes. Trust can be gained through greater transparency in how results are achieved, as well as putting into place some best practices that increase transparency and the level of information provided to patients relative to their data processing, and avoid collecting an amount of data greater than is required to use AI models.

Moreover, there is a need to draft clear policies that safeguard the privacy and the security of health data. All personal data can be identifiable, therefore, it is critical that all data used is safeguarded. Given that there is an important distinction between clinical and non-clinical use, and the fact that data from non-clinical smart wearables may feed into clinical AI systems, it will be necessary to identify where clinical-level accuracy and reliability need to be implemented.

Another aspect concerns skills of healthcare professionals. Medical education would also need to be broadened to better include new technology and digital skills. For AI systems to be fully appreciated and implemented as they are intended within clinical practice, there would need to be dedicated training in understanding and working with these new technologies which will even take on certain clinical tasks with complete autonomy, such as diagnosis and surgery. Furthermore, as the role of the clinician evolves, medical education will need to focus more on complex disease scenarios, and developing skillsets to navigate, understand and communicate the myriad of data that may be called upon for a given medical scenario. In order to equip medical students with meeting these demands, medical education will need to be more holistic, incorporating a better understanding of technologies and the results they generate.

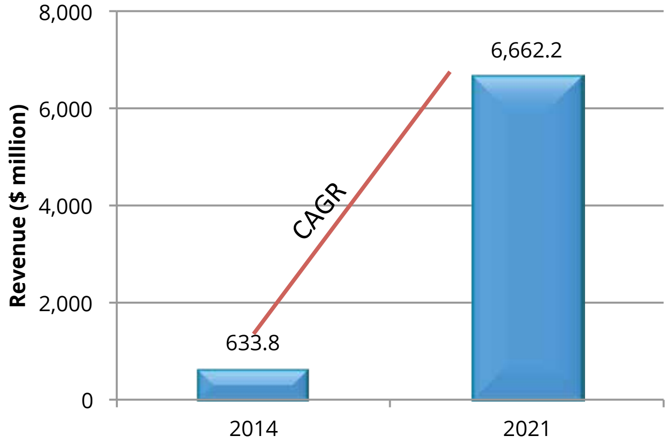
Lastly, it would make sense to define rules governing the use of AI in the healthcare sector. Clinical use of medical AI would need to be ensured through a combination of standards and regulations encouraging ethical and responsible use of these technologies[43].

2.3.2. The current status and trends of the global AI health market

According to Frost & Sullivan (2016), the global market of AI in healthcare was valued at $ 633.8 million in 2014 and is expected to reach $ 6,662.2 million by 2021, at a CAGR of 40% (Fig. 2.12).

Fig. 2.12 Global market of AI applications in healthcare (2014 vs. 2021)

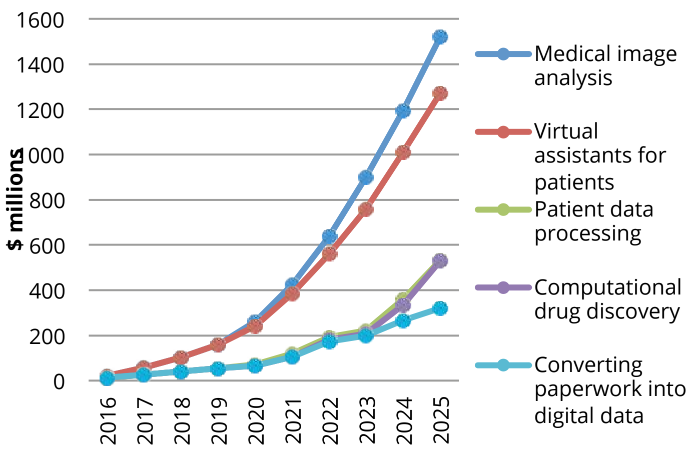
Source: Frost & Sullivan, Trasforming healthcare through artificial intelligence systems, 2016



43 Sobia Hamid (The Babraham Institute, University of Cambridge), The Opportunities and Risks of Artificial Intelligence in Medicine and Healthcare, 2016

Fig. 2.13 Top five AI use case revenues – World Market

Source: Tractica, Artificial Intelligence for Healthcare Applications, 2017



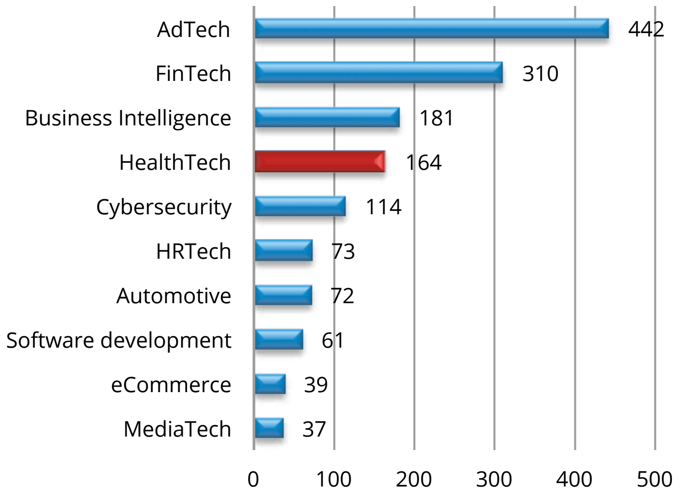
Five categories of AI – according to Tractica (2017) – will achieve higher revenues, especially tools supporting medical image analysis and virtual assistants for patients. The worldwide revenue of technologies for medical image analysis is expected to reach about $ 1,600 million by 2025 while the global revenues of virtual assistant apps could exceed $ 1,200 million by 2025 (Fig. 2.13).

The growth of this market is driven by the growing usage of Big Data in the healthcare industry, ability of AI to improve patient outcomes, the imbalance between the health workforce and patients, reducing healthcare costs, enhancing precision medicine, and significantly increasing venture capital investment in AI in the healthcare sector.

AI is certainly a profitable sector for ICT companies and is also fertile ground for startups and scaleups, which

Fig. 2.14 AI investments in European scaleups (2016, € million)

Source: Sirris, European Artificial Intelligence scaleup report, 2016



are investment targets of Venture Capital, Corporate Venture Capital and M&A. In 2016, European scaleups in the healthcare sector raised € 164 million in financial resources (Fig. 2.14).

Taking into account the enormous advantages, AI market in healthcare is expected to grow at the highest rate in the future.

2.4. THE EFFECT OF DIGITALIZATION ON THE QUALITY OF LIFE

The New England Journal of Medicine (NEJM) reported that measuring patient-reported outcomes (PROs) with standardized questionnaires is one way of measuring relevant outcomes in a timely manner. Measuring the results according to a timely schedule should be a must in health care to understand if a patient is heading in the right direction, especially with a good cost/effectiveness ratio, but the tendency is often focused on more downstream quality assessments, for example on survival. The NEJM invites us to take into consideration the use of PROs to measure the functional outcome, symptoms and quality of life.

Initially successfully used in oncology – where PROs have helped improve the management of symptoms, the quality of life and the survival rate – payers have recently begun to encourage their use in other domains of medicine. A study (L. S. Rotenstein et al., "Making Patients and Doctors Happier — The Potential of Patient-Reported Outcomes", The NEJM, 2017), reports that "the Medicare Comprehensive Care for Joint Replacement model includes financial incentives for hospitals to collect and submit PRO data for patients undergoing elective hip or knee replacement", while the Department of Orthopedic Surgery at the University of Rochester has so far collected more than 1.1 million PROs, currently used to involve patients in shared decision-making on therapeutic options. PROs, which have been cleared in this case by orthopedics, have now entered the clinical practice of another 30 departments and divisions of the same university.

The authors of the NEJM study discuss also their experience at the Partners HealthCare (a large multi-hospital Boston system) and say that the use of PROs increases the degree of medical satisfaction, prevents burnout and improves patient care. Up to now, since 2012, more

Fig. 2.15 Patient-reported outcomes for shared decision-making

Source: Lisa S. Rotenstein, "Making Patients and Doctors Happier — The Potential of Patient-Reported Outcomes", The NEJM, 2017

Patient-reported outcomes data (obtained by the authors from http://caredecisions.partners.org) for total knee replacement. The panel shows the severity of knee pain before and after knee replacement; data is based on the pain subscore of the Knee Injury and Osteoarthritis Outcome Score, with higher scores indicating less severe pain.

than 1.2 million PROs, covering 75 specialties, have been collected, on iPads in the clinic or on patient devices at home. Currently 1,500 physicians at Partners HealthCare use PROs, which are now adopted as feedbacks with the most diverse implications, from clinical management and programming to research (Fig. 2.15).

The medical-patient relationship may result strengthened from this approach, that allows a better understanding of the symptoms. For example, it allows the clinician to understand the outcomes of surgery, in terms of residual pain and disability. As well, PROs also facilitate sharing of decision-making processes and 'conversation' between physicians and patients.

Data digitization makes production, collection, and data sharing immediate, allowing anyone to perform these activities at any time and at any distance. The use of platforms that examine data from multiple sources (genomic data, clinical records, financial and administrative systems) significantly improves health care services. Genomic and HER data can be used to choose the best prescription, the real-world data can be used to adjust the therapies and the use of telemedicine to avoid the patients the need to physically meet their physician. This new approach to healthcare gives rise to a better therapeutic adherence, relapse prevention and reduction of side effects, improving the quality of life of patients and caregivers.

Sensors and smart technologies and virtual communication platforms could also facilitate self-care. Faster information exchange between patients and physicians can support self-care strategies and help caregivers, improving their quality of life. For instance, patients can gain greater knowledge about self-management and risk factors and can be informed about whether to remain at home, avoiding hospital or based care expenses, through a collaboration with health professionals.

Real time data obtained by wearable sensors can help disabled or elderly patients, alerting the physician about high risk situations that would require immediate action. BioSerenity and Dataiku's Neuronaute are wearable devices to improve the diagnosis and real-time monitoring of epilepsy, provide doctors and care providers with more access to information, generating quicker reactions and better outcomes. The platform is available 24/7 and the service is already used by dozens of hospitals in Europe. The apps operate as remote controls for the devices and map the patient pathway and timestamp also through patient feedback and survey.

The ParkinsonNet (2017) initiative is another example of support for self-care strategies. Through a web-based platform, information can be transferred on best practices, enabling interaction between professionals and patients. Sonja Marjanovic et al. report that *"the system originated in California and is now implemented in all Dutch municipalities as well as in parts of Norway. An evaluation of the initiative in the Netherlands found it provided both significant cost savings (€20m annually, equating to four to five per cent of the total expenditure on direct Parkinson's care in the Netherlands) and reduced the occurrence of hip fractures in patients with Parkinson's disease by 55 per cent (Bloem & Munneke 2014; Nijkrake et al. 2010). In a wider study on potential benefits, PricewaterhouseCoopers (2013) estimated that by using mHealth solutions, healthcare systems in the EU could save up to €99bn in total annual healthcare spend in 2017 and help 185 million patients gain 158,000 years of life (PricewaterhouseCoopers 2013)."*

Finally, the use of big data in healthcare can improve citizens' quality of life, allowing them to act promptly, enhancing self-care education and monitoring at a distance the patient's care status.

PART 3

POLICY CHALLENGES TO BE ADDRESSED

3. POLICY CHALLENGES TO BE ADDRESSED

3.1. HEALTHCARE CHALLENGES: AGEING, CHRONIC DISEASES, POLYMORBIDITY AND ACCESS TO THERAPY

Eurostat data[44] show that low birth rates and higher life expectancy are transforming the EU-28's age pyramid, underlining that *"probably the most important change will be the marked transition towards a much older population structure, a development which is already apparent in several EU Member States."* The increased number of over-65s gives rise to an increase in chronic diseases and contributes to creating a polymorbid population. The WHO shows that in Europe *"the proportion of people aged 65 and older is forecast to almost double between 2010 and 2050 and the number of people aged 85 years and older is projected to rise from 14 million to 19 million by 2020 and to 40 million by 2050."*[45]

In the above mentioned EFPIA report ("Healthier future – The case for outcome-based, sustainable healthcare", 2016), Joe Jimenez, EFPIA President, wrote that *"the demands on Europe's healthcare systems are evolving rapidly, driven by an ageing population and increasing prevalence of chronic disease. At the same time, significant advances in medical science are delivering more and more innovative treatments that need to be assessed, adopted and delivered for patients across Europe to benefit. All of this is happening in the context of a challenging economic environment".*

44 Eurostat website, "Population structure and ageing", 2017
45 WHO website, "data and statistics"

Currently, healthcare systems have to respond to increased demand for care by using very effective treatments. Physicians can now use more effective, but also more expensive treatments, compared to the past, indicating the need to use an innovative approach in understanding how to respond to this new demand for care. Today, it is necessary to choose treatment that leads to better outcomes and shifts the focus towards "value", defined as the outcomes achieved relative to the treatment costs.

The current challenge for healthcare systems is to provide good quality care at a reasonable cost for their citizens. This situation can be represented by the iron triangle of healthcare (Fig. 3.1), reported and explained by the Big Data Value Association, in the "Big Data technologies in healthcare-needs, opportunities and challenges (2016)" report. Where it is pointed out that *"the three components of the triangle are quality, access and cost. Efficacy, value and outcome of the care reflect the quality of a healthcare system. Access describes who can receive care when they need it. Cost represents the price tag of the care and the affordability of the patients and payers. The problem is that all the components are typically in competition with one another in the healthcare sector. Thus, while it may be possible to improve any one or two components, in most of the cases this comes at the expense of the third as illustrated in the figure. However, while the present healthcare optimization approaches may help introduce minor changes in the balance of the Iron Triangle of Health, only a radical breakthrough has the potential to totally disrupt the Iron Triangle of Health such that all three components including Quality, Access and Cost are all further*

Fig. 3.1 How current approaches to healthcare improvement often lead to suboptimal solutions

Source: BDV, "Big Data technologies in healthcare-needs, opportunities and challenges", 2016

optimized simultaneously. Given that healthcare is one of the most data intensive industries around, the multitude of high-volume, high variety, high veracity and value of data sources within the healthcare sector has the potential to disrupt the Iron Triangle. While most of this healthcare data was previously stored in a hard copy format, the current trend is towards digitization of these large amounts of data, which can facilitate this process."

Finding the right outcomes and standardizing them is the first step to promoting the introduction of treatment that can generate more value. In this way, using big data, will make it possible to achieve better results by spending less and obtaining wider access to care, but in order to achieve this, health systems have to overcome several barriers.

3.2. THE BARRIERS TO DEVELOPMENT OF DIGITAL HEALTH

Digitization has had a considerable impact on the global economy, through the transformation of various sectors, including healthcare. Smart devices, IoT, Big Data and artificial intelligence are transforming the medical industry, improving care systems and reducing costs.

However, there are some issues which hamper the development of eHealth and that need to be addressed in order to reap the benefits of a fully mature and interoperable eHealth system in Europe:

- lack of interoperability between eHealth solutions;
- regional differences in accessing ICT services;
- lack of IT literacy – the skills gap;
- privacy and security of health data.

The Europe 2020 Strategy and the Digital Agenda for Europe aim at addressing and removing these barriers. In particular, the eHealth Action Plan 2012-2020 establishes operational objectives to remove barriers to the development of eHealth, enhancing quality, access and safety in healthcare across Europe and encourages all stakeholders to work together.

3.2.1. Interoperability in Digital Health

Interoperability in digital health means the ability of health information systems to work together within and across organizational boundaries in order to advance the health status of and the effective delivery of healthcare for individuals and communities. Moreover, it is the ability of two or more systems or elements to exchange information and to use the information that has been exchanged, supporting the electronic transmission of health-related financial data, patient-created wellness data, and patient summary information among caregivers and other authorized parties. This level of interoperability – known as semantic interoperability – is possible via potentially disparate EHR systems, business-related information systems, medical devices, mobile technologies, and other systems to improve wellness, as well as quality, safety, cost-effectiveness and access to healthcare delivery.

Benefits of interoperability include an easier and faster access to patient information; better diagnosis, quality of treatment and patient safety; cost effectiveness; increased consumer choice and enhanced competition[46].

Unfortunately, the lack of interoperability among eHealth solutions is one of the key barriers to the development of digital health in Europe.

Standards[47], which enable interoperability in Digital Health, are essential to ensure the exchange of data between machines, systems and software and to facilitate the introduction of innovative products by providing interoperability between new and existing products, services and processes. The role of European standardization organizations (CEN, CENELEC and ETSI) in achieving EU-wide quality standards or reliable digital health solutions needs to be promoted. The impact of standards is particularly important as standards may provide for a technical means to tackle the lack of harmonization at other levels, e.g. legal and institutional, across Member States[48].

46 GSMA, Digital Healthcare Interoperability, 2016

47 More specifically, standards are defined by the International Organization for Standardization (ISO) as "documents, established by consensus and approved by a recognized body, that provide for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context".

48 Michał BONI, Member of the European Parliament, mHealth Position paper, 2016

The absence of regulations or standards that drive interoperability among digital health solutions and devices limits the scope of innovation and economies of scale to be achieved. It has also a negative impact on ease of use and limits scalability.

On March 23, the European Commission published a new version of the European Interoperability Framework (EIF), together with an "Interoperability Action Plan". The framework gives specific guidance on how to set up interoperable digital public services.

It offers public administrations 47 concrete recommendations on how to improve governance of their interoperability activities, establish cross-organizational relationships, streamline processes supporting end-to-end digital services, and ensure that both existing and new legislation do not compromise interoperability efforts.

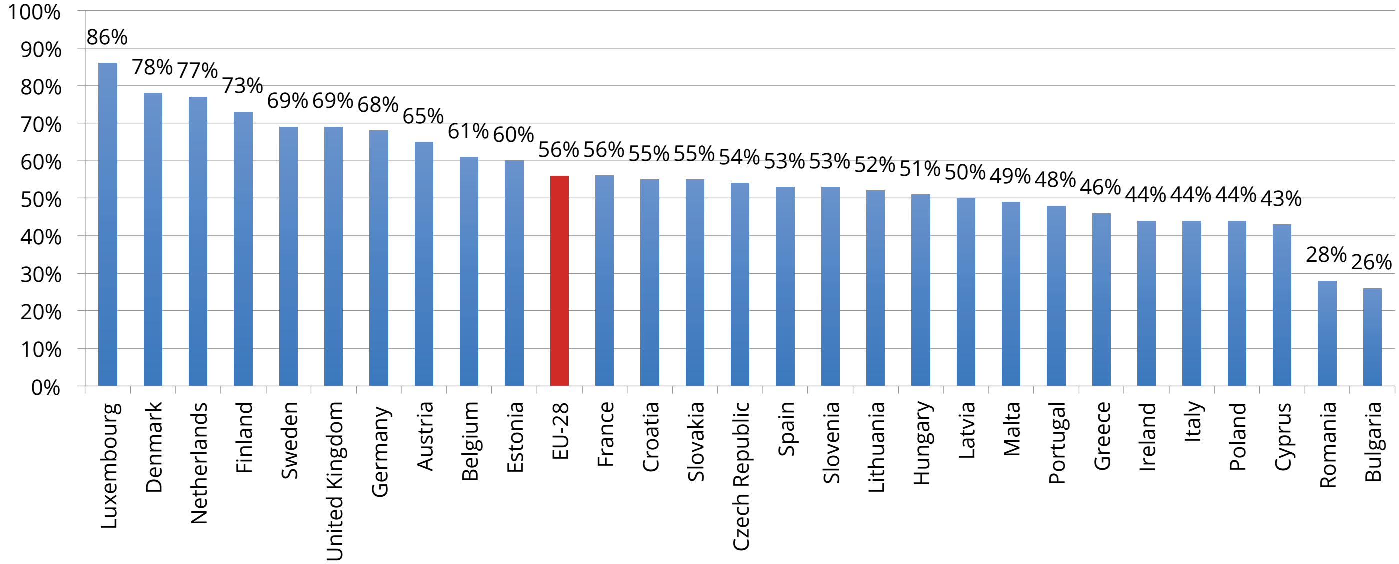
The new EIF is undertaken in the context of the Commission priority to create a Digital Single Market in Europe.

3.2.2. Digital divide and eSkills

E-health has a great potential to increase the efficiency of healthcare systems but this potential can become a reality only with the appropriate infrastructure in place, specifically high-speed Internet must be accessible in all areas and to ensure that no section of society is excluded from digital services, while at the same time equipping all citizens, including the elderly, with the eSkills to fully benefit from digital health. In the EU, only 56% of all individuals had basic or above basic overall

Fig. 3.2 Individuals who have basic or above basic overall digital skills (2016)

Source: I-Com elaboration on Eurostat data



digital skills in 2016. 18 out of 28 countries were below the EU average (Fig. 3.2).

There is a need to promote IT literacy through specific programs addressed to all citizens and with the involvement of the government and education system.

Avoiding the digital divide is one of the most important challenges. Recognizing the crucial role of digital competence in today's society, the European Commission's 2010 Digital Agenda for Europe devoted a whole pillar to digital literacy, skills and inclusion. Furthermore, recognizing the need for indicators to measure the extent of digital competence in Europe, one of the actions of the Digital Agenda was to propose EU-wide indicators of digital competence and media literacy[49].

In 2013, the Digital Competence Framework for Citizens, also known as DigComp, was first published by the European Commission. It is a tool to improve citizens' digital competences, help policy-makers formulate policies that support digital competence building, and plan education and training initiatives to improve the digital competence of specific target groups. DigComp also provides a common language on how to identify and describe the key areas of digital competence and thus offers a common reference at a European level. In 2016,

49 Measuring Digital Skills across the EU: EU wide indicators of Digital Competence, 2014

the EU Commission published the second version of the Digital Competence Framework for Citizens – DigComp2.0. DigComp 2.0 has maintained the same overall structure of 5 competence areas identified by the European Commission in the first version though some changes were adopted.

3.2.3. Privacy and cybersecurity

Data security and privacy are areas that require legal and policy attention to ensure that patient data is properly protected.

Legal frameworks that govern the integrity of health data transfer and storage, in addition to identifying access control and medical liability, are critical to enabling the development of eHealth in the Member States. However, at the same time, more cooperation is needed. Respecting the rules established in the General Data Protection Regulation and cooperation in the development of best practices (e.g., data anonymization, encryption, user consent requirements) will ensure that data can move more safely and effectively between different systems and applications. Trust and confidence are key elements ensuring the swift uptake of mHealth applications by end-users.

Moreover, the healthcare sector is becoming a major target for cyberattacks. The rise and sophistication of ransomware attacks that hold IT systems and patient-critical device hostage continues to grow. The trend began in the first quarter of 2016 when numerous hospitals around the world suffered ransomware attacks.

The Union has already taken important steps to ensure cybersecurity and increase trust in digital technologies. In 2013, an EU Cybersecurity Strategy was adopted to guide the Union's policy response to cybersecurity threats and risks. In its effort to better protect Europeans online, in 2016 the Union adopted the first legislative act in the area of cybersecurity – Directive (EU) 2016/1148 – concerning measures for a high common level of security of network and information systems across the Union (the "NIS Directive"). The NIS Directive put in place requirements concerning national capabilities in the area of cybersecurity, established the first mechanisms to enhance strategic and operational cooperation between Member States, and introduced obligations concerning security measures and incident notifications across sectors which are vital for the economy and society, such as energy, transport, water, banking, financial market infrastructures, healthcare, digital infrastructure as well as key digital service providers (search engines, cloud computing services and online marketplaces). A key role was attributed to ENISA in supporting the implementation of this Directive. In addition, an effective fight against cybercrime is an important priority in the European Agenda on Security, contributing to the overall aim of achieving a high level of cybersecurity[50].

On 13 September 2017, the Commission adopted a cybersecurity package, including important draft legislation. The package builds upon existing tools and presents new initiatives to further improve EU cyber resilience and response, also in the healthcare sector.

50 REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on ENISA, the "EU Cybersecurity Agency", and repealing Regulation (EU) 526/2013 and on Information and Communication Technology cybersecurity certification ("Cybersecurity Act")

To increase cybersecurity in the healthcare sector, several principles[51] must be implemented:

1. define and streamline leadership, governance, and expectations for health care industry cybersecurity;
2. increase the security and resilience of medical devices and health IT;
3. immunize against cyber threads not only devices, sometimes very simple from an IT standpoint, but also telecommunication networks;
4. develop the health care workforce capacity necessary to prioritize and ensure cybersecurity awareness and technical capabilities;
5. increase health care industry readiness through improved cybersecurity awareness and education;
6. identify mechanisms to protect R&D efforts and intellectual property from attacks or exposure;
7. improve information sharing of industry threats, risks, and mitigations.

The healthcare system cannot deliver effective and safe care without stronger digital connectivity. If the healthcare system is connected, but insecure, this connectivity could betray patient safety, subjecting them to unnecessary risk and forcing them to pay unaffordable personal costs. Therefore, it is important to prevent patients from being forced to choose between connectivity and security and support the development of digital health.

51 HEALTH CARE INDUSTRY CYBERSECURITY TASK FORCE, Report on improving cybersecurity in the healthcare industry, 2017

3.2.4. Lack of available, adequate digital infrastructure

The availability of an ICT infrastructure that would provide reliable and affordable connectivity is a first step on every country's road to digitalization, even in the healthcare sector. Telecom and ICT infrastructure is the basics of digitalization. As has been recently stated in a report published by the Broadband Commission for Sustainable Development[52], infrastructure can be seen as the global nervous system of a modern world that underpins our digital lives.

Some areas or applications of digital health require only some connectivity, e.g. providing statistical information. However, the quality of connectivity is becoming more and more decisive also for eHealth development concerning:

- **bandwidth**: needed to provide massive volumes of data (e.g. from CT images, etc.);
- **availability**: monitoring of health data can be critical, in some cases bringing health care to remote areas for the first time (also in Europe);
- **latency**: future applications as remote surgery will be possible only if latency is below 5ms;
- **reliability**: achieved only through the above-mentioned;
- **security**: if connectivity is not secured then privacy can be compromised; as well, data can be compromised or not available leading to no or not adequate medical treatment.

52 Working Group on the Digitalizazion Scorecard, Which policies and regulations can help advance digitalization, June 2017, http://www.broadbandcommission.org/Documents/publications/WG-Digitalization-Score-Card-Report2017.pdf

All these factors, put together, explain why 5G will allow for qualitatively new applications in the area of digital health and why, next to 5G, ultra-broadband should be ubiquitous.

However, despite the availability of modern and high-performing networks being an indispensable requirement for all European countries, there is still some disparity regarding both fixed and mobile networks, causing discrimination in the access of European citizens to eHealth.

3.3. THE IMPACT OF DIGITALIZATION ON THE LABOR MARKET IN THE HEALTHCARE SECTOR

Digital technologies will most probably drive economic growth, but their potential impact on employment is less clear. There are two schools of thought.

According to the first, many jobs are at risk because of digitalization and automation. The primary assumption of this body of research is that new digital technologies cause an adverse effect especially on low and middle skilled workers. High-routine occupations will probably be eliminated. In the future, simple work mostly carried out by mere physical strength will be increasingly, but never completely, performed by machines. The decisive factor remains the level of routine. The efficient use of a machine rather than a human employee is possible only if the process can be made independent and is repeated with certain regularity.

On the contrary, the second school of thought refers to the fact that there has always been some kind of change in qualifications throughout history – one need only think of the First Industrial Revolution –, therefore, this is just another new era, which requires adaptation in training and development. As a result, it may be more beneficial to focus on how employees can adapt to the new skills which will be required for tomorrow's jobs.

However, regarding the healthcare sector, doctors and nursing staff are far from being replaced. But, in this sector too, technical possibilities can lead to staff reduction. In some cases, machines are able to work faster, more accurately, and more efficiently than the most efficient humans. It will no longer be possible to imagine hospitals without robots in the future. Their tasks will be, for example, to move people out of their wheelchairs or their beds or even help the doctors to perform surgery. Additionally, software technology based on artificial intelligence will help doctors to diagnose various illnesses by reconciling patient data with medical knowledge collected in a cloud. Finally, the demographic change, at least in Western Europe, will lead to an increase in jobs in this sector because the population is constantly ageing, modern medicine being one of the reasons for this[53].

53 IBA Global Employment Institute, Artificial Intelligence and Robotics and Their Impact on the Workplace, 2017

CONCLUSIONS AND POLICY RECOMMENDATIONS

The widespread application of ICT technologies (Internet of Things, wearable devices, Robotics, Big Data, Artificial Intelligence) is expected to bring to healthcare a vast array of benefits, such as enabling faster diagnoses and better therapeutic results, improving the quality of life for patients and their families, and making the provision of services more cost-effective.

The production, collection, storage, sharing and analysis of Big Data thanks to AI models could lead to an outcomes-based system reducing hospitalization, surgery, and long-term care, and making the healthcare system more effective and efficient, as well as financially sustainable.

Indeed, outcomes-based healthcare allows for investing resources in products that show better results compared to current technologies.

Thanks to digitization, a lot of data from citizens, patients, researchers, healthcare professionals, institutions and industries can be collected in large databases and thus become part of registers and platforms that allow for the exchange of information among many actors, for example between pharmaceutical companies and regulators, among clinicians or between doctors and patients. Consequently, many advantages can be gained at the same time, such as the increasing quality and effectiveness of treatment, disease prevention, a more effective pharmacovigilance system and patient safety.

Moreover, genome sequencing, revealing mutations in DNA that influence diseases ranging from cancer to diabetes, allows for a personalized treatment, a concept that has been well known to researchers and practitioners for long time. This is a powerful tool, along with other techniques such as RNA-seq, which are more responsive to the environment. Collecting large quantities of data and elaborating it, using computing and predictive models, are instrumental in making personalized medicine a reality.

Of course, apart from the initial significant investments in ICT, many other challenges need to be properly addressed, from privacy and cybersecurity to ethical and legislative issues, from the skills gap to the possible replacement of professionals and workers with machines and algorithms. It is, however, evident how Europe may benefit by leading a transformative process of healthcare-based digital technologies.

To achieve a full leadership in digital health, EU institutions and Member States should act resolutely and fast to ensure the following conditions:

1. TELECOM AND ICT INFRASTRUCTURES

- The penetration of digital services requires skills and investments in networks and technologies. Considering that fixed and mobile ultra-broadband network deployment require tremendous investments, it is very important, in general, to create a regulatory investment-friendly environment (also through a stable and predictable telecom regulatory) that encourages the development of new business models and new services.
- 5G will be a key enabler for IoT and new digital service deployment. To accelerate 5G deployment, complying with the Commission's initiatives and planning, it is necessary to accelerate on investments, simplify and remove barriers to small cells deployment, plan

a roadmap and a shared timing in Europe, ensure a harmonized and efficient spectrum management, the availability of adequate spectrum bands to 5G deployment and a close cooperation among all stakeholders.

2. INTEROPERABILITY AND STANDARDS

- With regard to the regulatory framework, it is necessary to reduce and simplify rules, ensuring harmonization and interoperability standards at EU and international levels for health systems that share patient data. Moreover, use of anonymized health data for scientific purposes or international health initiatives relies on data format standardization.
- European Reference Networks (ERNs), launched in March 2017, involving more than 900 highly-specialized healthcare units from over 300 hospitals in 26 EU countries and aiming at tackling complex or rare diseases and conditions that require highly specialized treatment and concentrated knowledge and resources, should become a pilot initiative for a more extensive application of eHealth on a European scale, reducing barriers between different national health systems (and in many cases existing in the same national systems) and testing real standardization and interoperability across the EU.

3. SKILLS

- It is important to improve the medical expertise and digital skills of healthcare providers in order to achieve a full development of these technologies and real benefits. Public administrators of the healthcare system should be judged also on the level of digital skills reached by their staff. At the same time, medical education should include knowledge and skills needed to use connected devices and artificial intelligence in healthcare.
- With regards to the demand side, citizens and patients should be encouraged to increase their digital skills and to use eHealth tools through incentives and targeted actions. Users of connected devices should be trained to follow a protocol of usage while, as already occurs in pharmacology and therapeutic education, doctors should be able to set up an ergonomic evaluation of devices depending on each relevant class of users.

4. PRIVACY AND SECURITY

- Data security and privacy are areas that require legal and policy attention to ensure that patient data is properly protected. Legal frameworks that govern the integrity of health data transfer and storage, in addition to identifying access control and medical liability, are critical to enabling the development of eHealth in the Member States. However, at the same time, more cooperation is needed. Respecting the rules established in the General Data Protection Regulation and cooperation in the development of best practices (e.g., data anonymization, encryption, user consent requirements) will ensure that data can move more safely and effectively between different systems and applications. Trust and confidence are key elements for ensuring the swift uptake of mHealth applications by end-users.

- Moreover, the healthcare sector is becoming a major target for cyberattacks. While Member States should fully adopt Directive (EU) 2016/1148 - concerning measures for a high common level of security of network and information systems across the Union (the "NIS Directive"), the cybersecurity package, published by the European Commission on 13 September 2017, should be discussed and approved as soon as possible.
- Clinical use of medical AI would need to be ensured through clear rules, encouraging ethical and responsible use of these technologies and safeguarding the privacy and the security of patients.
- Taking into account that the usage of connected devices could have strong medical implications and technical flaws or shortcomings resulting in serious errors from a diagnostic or therapeutic standpoint, devices with a medical use must be certified before being introduced on the market54.

5. TOWARDS AN OUTCOMES-BASED HEALTHCARE

- Technological innovations are capable of yielding better results (outcomes) than those obtained in the past, offering new solutions to those pathologies where the needs are still unsatisfied, but costs create a sustainability problem. Healthcare systems can reconcile access to care and sustainability developing an outcome-based system. This new approach, which provides for outcomes-based healthcare, not only focuses on the actual well-being of the patients but also helps identify and eliminate the technologies that do not give rise to positive outcomes. Outcomes-based healthcare reduces hospitalization, surgeries and long-term care, making the system more effective and sustainable, and allows for the investment in products that show better outcomes than the technologies already in use. The transition to an outcomes-based system is possible but remains closely linked to the production and use of health data, which makes it possible to analyze the outcomes themselves. For this reason, it would be necessary to define rules governing the process of data extraction/exploration and sharing, data processing and comparing, making this information useful for clinical activities and ensuring the right to information for all.
- The creation of an outcomes-based healthcare is possible only by investing in Information and Communications Technology (ICT), citizen empowerment and improving the doctor-patient relationship. In this way it is possible to create, collect, analyze and share patient outcomes in a very short time, leading to better decisions. An outcomes-based healthcare can respond to the growing demand for care, improving the quality of life of citizens (patients and caregivers), and creating "value", defined as the outcomes achieved relative to the treatment costs.

54 Nokia, White paper on connected health, 2017, https://solutions.health.nokia.com/white-paper-connected-health

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