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Digital health: How can the EU help make the most out of it?

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BACKGROUND

Health in our digital society

Our society is in the midst of a vast and pervasive data revolution. Enormous amounts of data are produced and exchanged daily and people are increasingly using all sort of digital tools in almost any aspects of their life. Health is no exception. A 2013 survey shows that 75% of European hospitals have some type of electronic health records (EHR) system in place.[1] In 2014, six out of ten Europeans have searched for health information on the Internet[2] and the download of health and well-being applications in 2016 has reached 3 billion globally.[3]

This transformation brings about new opportunities for the healthcare sector to become more effective, sustainable and accessible. Digital solutions and data utilisation can help improve people's health and address some of the challenges facing healthcare in Europe. Barriers to the digitalisation of healthcare, however, exist and require adequate attention.

This paper, published ahead of the announced Communication from the Commission on the digital transformation of health and care in the context of the Digital Single Market, lays out the challenges that European healthcare systems are facing in our digital era. It looks into the benefits and limits of the deployment of digital solutions in health, while putting forward recommendations for action at the level of the European Union (EU). A comprehensive approach that takes into account public support, ICT infrastructure development, and data protection and security, should form the very structure of the EU's next steps in this area.

Europe is currently the oldest continent in the world and is expected to hold this record at least until 2060. The old age dependency ratio (people aged 65 or above relative to the working age population) reaches almost 25% in Europe, while it remains below 20% in other regions (Northern America at around 20%, Asia and Latin America slightly above 10%, while Africa remains below 10%).[4] This demographic trend is partly the result of the positive performance of healthcare systems and of medical innovation that have fuelled rising life expectancy across the globe. But it also reflects a disproportion between elderly people (often at higher risk of chronic diseases) and the rest of the population that challenges public budgets, especially pension and healthcare systems.

Healthcare systems are also facing pressures stemming from low economic growth, rising health and care expenditure and remaining inequalities in access to healthcare. As one of the largest items of public expenditure, health and long-term care expenditure in OECD countries is projected to continue to grow, presumably accounting for 9% of GDP in 2030 and as much as 14% of GDP by 2060.[5] These factors pose significant risks in terms of healthcare inefficiency, financial unsustainability, and, what is of more concern to citizens and patients, insufficient and/or unequal access to health services.

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STATE OF PLAY

The benefits of digital innovation in health

Digital innovation in health brings about a range of potential benefits for all stakeholders: patients and caregivers, healthcare professionals and organisations, businesses and public authorities. Digital solutions can help avoid wasteful spending, facilitate inclusion, deliver more patient-centred services, improve people's health and quality of life, empower patients, and enhance access to services and information.

Evidence of such benefits has been found in the field of telemedicine, especially when applied to the management of chronic diseases, mental health, as well as health promotion and prevention. For instance, EU co-funded pilot projects have showed that ICT solutions applied to integrated health and care services improved the quality of life of chronic patients, while reducing hospital admissions and visits to the general practitioner.[6] Encouraging results also come from the implementation of interoperable EHR and ePrescription systems. Analyses of good practices across Europe have showed that long-term socio-economic gains exceeded costs and returns on investment could amount to 200%. Also, the benefits for both patients and healthcare professionals were found to be significant. They included enhanced patient safety, reduced clinical risk, increased continuity of care and improved productivity.[7]

In addition, the emerging big data analytics is expected to have a major impact on healthcare. It could increase the effectiveness and quality of treatments by boosting advances in clinical research, providing a better understanding of health determinants and co-morbidities, and lessening medical errors. Moreover, the analysis of such an amount of information may enhance our knowledge of disease transmission pathways, support chronic disease management and improve patient safety.

Lastly, the market side of digital health should not be overlooked. The connection between ICT, healthcare and well-being has created, and is expected to continue to spur new businesses and opportunities for economic actors.

The limits associated with the deployment of digital solutions in health

To fully reap the benefits, a number of barriers to the deployment of digital health need to be addressed. Both EU institutions and member states have for long been working towards achieving this result, but more needs to be done.

Firstly, a primary challenge relates to the ballooning volume of personal health data, generated either as part of healthcare service provisions, or by the patients/consumers themselves when using personal digital devices to monitor health or lifestyle parameters. From a legal perspective, as of May 2018, the management of personal health data will be subject to the requirements set in the General Data Protection Regulation (GDPR) which imposes rigorous security requirements and prohibits the processing of genetic, biometric or health-related data, outside very specific circumstances. Although the regulation has been adopted more than a year ago, awareness and full understanding of its legal implications is not widespread. Moreover, when considering mobile health (mHealth), there is shortage of guidance on how to comply with the transparency, privacy and security requirements of the GDPR. This is mainly due to the fact that mHealth is a relatively young and rapidly developing business segment. Such limits need to be addressed, both to ensure proper collection, use and management of health data, and to meet citizens' and patients' expectations on privacy and security issues.

From a technical viewpoint, the existing gaps in ICT infrastructure development across and within countries are an obstacle to the broad and effective deployment of digital solutions in health. ICT infrastructures still differ considerably across countries and regions. Broadband penetration, for example, varies significantly, ranging from 97% registered in Luxembourg to 63% in Bulgaria.[8] On top of this, cross-country differences persist in the availability and use of digital health solutions. For instance, statistics on eHealth deployment and use in acute care hospitals in Europe show that, despite growing convergence, Nordic countries continue being the best performers while eastern European countries are less performing.[9] This divide hampers cross-border provision of, and equal access to, healthcare services. Additionally, the lack of data interoperability and common standardisation hinders the effective communication between different healthcare environments, creating scenarios where health data collected, for example, by a hospital are not readable and understandable in another hospital in the same area, let alone in a different region or country.

Another set of barriers relates to the still unequal access to ICT services and low digital literacy among a wide segment of the European population. With the rapid pace of digital transformations, the performance of health systems will be closely dependent on how many people have access to digital solutions. Moreover, beyond the question of equal access, acceptance and trust will also play a crucial role.

Digital health at the policy level

Digital health has been high on the EU agenda for over a decade. The Commission first adopted its eHealth Action Plan in 2004. It then launched a flurry of initiatives to foster the implementation of digital health solutions across the EU.

In 2011, the Cross-Border Healthcare Directive set a milestone in this process by establishing the eHealth Network for formal cooperation between competent national authorities. The network supports member states elaborating common measures to facilitate the exchange of data in cross-border healthcare.

The second eHealth Action Plan (2012-2020) has been complemented in 2014 by the Green Paper on mobile health that looks into the potential of mobile devices in supporting medical and public health practice. Since 2015, furthering the digitalisation of healthcare has been an integral part of the Digital Single Market Strategy that seeks to bring about an inclusive e-society and boost the competitiveness of Europe's industrial and services sectors.

Besides these initiatives, the Commission has also allocated funds to promote innovation and advance the uptake of new technologies in the health sector. For example, the Horizon 2020 Work Programme 2018-2020 allocated an overall indicative budget of EUR 207.5 million to the call *Digital transformation in Health and Care*. Also, strengthening digital literacy and promoting the uptake of digital solutions in health are relevant objectives pursued by the EU cohesion policy for the period 2014-2020. In particular, the second of 11 thematic objectives (*Enhancing access to, and use and quality of, information and communication technologies*) provides funding for the development of ICT tools in the health sector, among others.

At the Council level, the Estonian Presidency has put great emphasis on advancing digital innovation in healthcare, with a particular focus on citizens' right to securely access their health data. It has also promoted better data management to boost medical research and facilitate cross-border data exchange. This is also reflected in the Digital Health Society initiative initiated by the Ministry of Social Affairs of Estonia in July 2017 and in the Council conclusions on digital health adopted on December 2017.

PROSPECTS

Tackling the challenges mentioned above requires a comprehensive approach with particular attention on three key aspects: data security, ICT infrastructure development, and public support.

Firstly, the EU should move forward rapidly in addressing the challenges posed by the ballooning volume of personal health data and the many concerns about data security, especially regarding mHealth Apps. Actions should aim at raising awareness and ensuring clarity about the legislative framework that protects health data privacy. The Commission should promote EU-level communication and social media campaigns to explain to citizens and patients the measures in place to protect their privacy. Similar activities should target the business sector and the organisations processing health data to clarify their obligations and how to comply with the legal provisions protecting data privacy (e.g. GDPR), especially in the field of mHealth. In this area, the Commission has facilitated the drafting of the European Code of Conduct on Privacy for Mobile Health Apps, which represents a good starting point in addressing citizens' and patients' concerns. The Commission should now request the drafting team of industry members to take on board the comments made by the Article 29 Working Party – the independent advisory body of the Commission comprised of representatives from all the national data protection authorities – and thus rapidly finalise the code of conduct. Once completed, such a code could provide a competitive advantage to those industries conforming to it by ensuring a positive image among consumers, thus addressing users' privacy concerns.

Secondly, EU institutions should also address the technical side of the management of personal health data, targeting the existing gaps in ICT infrastructure development across countries and exploring interoperability solutions, always preserving privacy and security. This requires resources and knowledge development, which can be boosted at the EU level. Already under Horizon 2020, the Commission earmarked EUR 30 million for the exercise of prototyping a European interoperable EHR exchange that takes into account innovative technologies, such as the blockchain, the digitalised and distributed ledger of transactions or data mostly known for its application in the financial sector (Bitcoin). This technology is potentially able to allow health data sharing between the various stakeholders, without jeopardising data integrity, security, and privacy.

This represents a promising starting point, but more needs to be done. The Horizon 2020 allocation refers to 2018 and the effort should continue and be extended until 2020. Other funding instruments also play a crucial role, such as the European Structural and Investment Funds and the Connecting Europe Facility. With the proposals on

the post-2020 Multiannual Financial Framework (MFF) expected soon, the EU should allocate the necessary financial resources to ensure continuity and possibly increase today's efforts.

Gathering and sharing knowledge on ICT infrastructures for health should also be put on the agenda. The Commission should support member states, by designing methodologies and providing expertise, to run a mapping exercise of ICT infrastructures in health. Such knowledge, combined with the sharing of best practices at the EU level, would then help national governments to fill gaps and effectively direct investments towards the healthcare structures that are lagging behind in ICT development and/or in the deployment of digital health solutions. This would help ensure the equal access for all EU citizens to innovative and more efficient healthcare services, irrespective of where they are located on the European territory.

Thirdly, access to ICT technology does not depend solely on technical development but also on the digital health literacy of the population, whether patients or health professionals. Accordingly, the Commission should encourage and support member states in implementing awareness raising campaigns and training programmes targeting patients, carers and health professionals. Particular attention must be paid to the older segments of the population as well as the less educated.

As a conclusion, a comprehensive initiative boosting data security, an even development of ICT infrastructure, and stakeholders' awareness and education, should be among, if not at the core, of the EU's next actions. Further measures, for example those which will be proposed by the Commission in the announced Communication on the digital transformation of health and care, should pay particular attention to these aspects. Not only they do potentially represent significant barriers to digital innovation in healthcare, but more importantly they would, if neglected, greatly hamper equal access to and overall trust in our health systems.

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