HOPE Position Paper

on the Commission Communication on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society (COM(2018) 233 final)

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European Hospital &
Healthcare Federation

On 25 April 2018, the European Commission published a Communication to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on "enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society."

HOPE welcomes this Communication as an opportunity to further clarify certain elements. HOPE agrees of course that Europe's health and care systems face serious challenges: ageing, multimorbidity, health (and social) workforce shortages, rising burden of preventable noncommunicable diseases, neuro-degenerative and rare diseases, growing threat from infectious diseases due to increased resistance to antibiotics and new or re-emerging pathogens.

However, considering differences in epidemiology, wealth, culture and the huge diversity of healthcare system at national and regional level, specificities should be recognized instead of being ignored with a one-fits-all approach. Health and care authorities across Europe face common challenges, which can certainly be best addressed jointly. But the diversity is sometimes more important and would require specific analysis instead of a unique approach.

It is also wrong to say that public spending on health and long-term care have been "steadily" rising in EU Member States as the financial and economic crisis showed in several EU member states drastic cuts and disinvestments. One should be cautious with European averages.
Concerning "eHealth", "digitisation", "digital solution", to use them as mantra or solve-it-all solutions might not be the right approach. As HOPE has been saying to the European Commission for quite some time: the tool should not be mistaken for the goal. The aim of hospital and healthcare services is to provide high-quality care and cure, not to help setting up a digital market and to build economies of scale in this industry.

Digital solutions for health and care can (and already do so) contribute to increase the well-being of millions of citizens but not only by themselves alone. Yes, they certainly could radically change the way health and care services are delivered to patients but this change should mean for good.

Digitisation can support the continuity of care across borders, but the vast majority of patients do not cross borders and optimally should be taken care close to their home. Health care systems should not be viewed only with this cross-border perspective.

As mentioned by the Commission data is not managed in the same way in all EU Member States or within national health systems. It is true that often it is not even available to the patients themselves or to public authorities, medical professionals or researchers to help them develop and deliver better diagnosis, treatment or personalised care. Even where it exists, health data often depends on technologies that are not interoperable, thus hindering its wide use.

Not that we do not ignore or regret market fragmentation and lack of interoperability across health systems. HOPE has been involved in several initiative to create more interoperability such as eStandards and EURO-CAS. But safety matters first.

NEED FOR FURTHER EU ACTION

If the uptake of digital solutions for health and care remains slow and varies greatly across Member States and regions, this needs to be seriously analysed and taken into consideration. Further action at EU level would miss the point by not doing it.

The public consultation carried out by the Commission is certainly not very helpful in this. The responses were of limited representativeness. Anyway, there was no need for a consultation to tell us that data quality, reliability and cybersecurity, standardisation of electronic health records and better interoperability through open exchange formats are important. It is common sense and this was indeed in the Council Conclusions adopted on 8 December 2017.

That the present Communication sets out how the EU can help meet the objectives of these Council Conclusions remains full of uncertainties, in particular by mixing it up with the Sustainable Development Goals on healthy lives, European Pillar of Social Rights, potential of the digital internal market and stimulation of growth and promotion of the European industry in the domain.

CITIZENS' SECURE ACCESS TO AND SHARING OF HEALTH DATA

The General Data Protection Regulation enhances data protection standards, while balancing the need for personal data to be used for health purposes, public health and medical research provided that safeguards are in place.

Data is an essential element of healthcare provision, management and health related research and we welcome the Commission's ambition to enhance technological solutions for developing a European electronic health record. But the most important is that, as mentioned in the Communication, many citizens in Europe and many healthcare providers have limited electronic access to joined- up data to facilitate treatment and care. The data is often untraceable and scattered in different places. Moreover, incompatible formats and standards in electronic health record systems continue to be used across the EU. This is not only a problem for patients, but also for healthcare providers and the clinical teams providing care, or the services managing their care. HCPs will need support through future MFF funding programmes to develop their digital infrastructure.

Safety and quality of information should be the first and the core aims instead of an artificial right that would be jeopardized in reality. Mixing aims and reality will only create dissatisfaction.

As mentioned in the Communication, the current efforts to exchange patient data across borders in the EU rely on the voluntary cooperation of health authorities to connect to the eHealth digital service infrastructure, which is supported by the Connecting Europe Facility (Broadband and Information and Communication Technologies) programme and uses the guidelines agreed by the eHealth network for the governance, establishment and operation of the eHealth digital service infrastructure.

Currently, this exchange is limited to patient summaries and ePrescriptions, and does not cover electronic health records. These two use cases of patient data exchanges are planned to start in 2018 between 8 - 9 Member States, with around 22 Member States expected to join the exchange by 2020. Those are already good steps. The issue is now to go mainstream as always with EU projects and pilots.

Hospitals across Europe are also involved in the secure web-based application called the Clinical Patient Management System for European Reference Networks, which will eventually allow for doctors outside of the ERNs to enrol patients from their healthcare providers (HCPs) in order to seek diagnosis, care and treatment advice from the highly specialized HCP representatives of each ERN. This digital application is critical to the functioning of ERNs and could be a tool which is developed for further use, outside of ERNs in the future. The Commission should monitor this tool and its efficacy and the potential for using this for other purposes.

HOPE intends to monitor the implementation of the General Data Protection Regulation and how it impacts digital data sharing within and across HCPs and will flag to the European Commission any barriers to secure data sharing that this creates and give recommendations on practical solutions on how to address these problems.

HOPE will also monitor with its members the use of the funding from the Connecting Europe Facility, Horizon 2020 programmes for the European electronic health record exchange format and the further development of the eHealth digital service infrastructure, European Structural and Investment Funds and the European Fund for Strategic Investments, for the deployment of interoperable electronic health records at national and regional level.

And additional funding for this should (and not "might") be considered under the next EU multi-annual financial framework.

HOPE would like more clarity on what means "reviewing Commission Implementing Decision 2011/89037 pursuant to Article 14 of the Directive on patients' rights in cross-border healthcare, in order to clarify the role of the eHealth Network in the governance of the eHealth digital service infrastructure and its operational requirements, as well as to improve the interoperability of patient data and access by the citizen."

HOPE will follow closely the process of adoption of a Commission recommendation on the technical specifications for a European electronic health record exchange format.

BETTER DATA TO PROMOTE RESEARCH, DISEASE PREVENTION AND PERSONALISED HEALTH AND CARE

HOPE has been working on personalised medicine as an emerging and challenging new approach. New technologies enable indeed a wider use of genomic and other information to help doctors and scientists better understand disease and how to better predict, prevent, diagnose and treat.

Several national and regional initiatives already support the pooling of genomic and other health data to advance research and personalised medicine. HOPE agrees with the need to better coordinate these existing initiatives to reach the necessary critical mass at EU level and match similar initiatives in other world regions.

HOPE welcomes a coordinated EU action in this area also responds to the Council Conclusions on personalised medicine, which called on the Commission to help achieve the potential of "Big Data".
HOPE welcomes the Commission intention to support the pooling of the EU's data resources and to facilitate their use for research and health policy.

HOPE welcomes the Commission intention to test specific practical applications of cross-border health data exchange for research and health policy to improve treatment, diagnosis and prevention of diseases. Several HCPs across Europe are involved in the national genome programmes, providing critical access points to patients and thus supporting the declaration of cooperation signed by 15 EU member states aiming at 1 million sequenced genomes by 2022.

HOPE will monitor the set up of a mechanism for the voluntary coordination of authorities and other stakeholders to share data and infrastructure for prevention and personalised medicine research. It is important to include all healthcare providers in discussing this matter. As medical research has a derogation for EU MS in the GDPR, HOPE will monitor implementation of the GDPR across members and how differences in approach impact on data sharing. The Commission, working with the relevant stakeholders and the EDPB may need to provide legal clarity for medical researchers, while allowing flexible interpretation of the GDPR to enable life saving cross border research.

DIGITAL TOOLS FOR CITIZEN EMPOWERMENT AND FOR PERSON-CENTRED CARE

HOPE agrees that to better advance health promotion, prevent disease and deliver integrated services based on people's needs, new technologies and products could help.
But digital solutions, such as wearables and mHealth apps, by which citizens can actively engage in health promotion and self-management of chronic conditions should be carefully handled.
So far, such new care models have typically been deployed on a small scale, then initial evidence is limited their benefits for both patients and health and care systems. Therefore, full-scale deployment of new care models needs more evidence.

HOPE will be interested on the work of the Commission with relevant actors (such as Member States,

regions, technology and service providers, health and care professionals, civil society organisations, academia, investors and existing stakeholder platforms) to support more cooperation across borders and enlarge the deployment of digitally-enabled care models.

HOPE welcomes support of cooperation to stimulate the supply and uptake of digital health by promoting common principles for validating and certifying health technology and the support to the exchange of innovative and best practices, capacity building and technical assistance for health and care authorities (for using open standards and interoperable digital solutions to promote health, prevent and manage chronic conditions, empower people and centre care on the person), with financial support from Horizon 2020, the Structural Reform Support Programme and the third "Health" programme, within the current budgets, while considering making proposals for further support under the next multi-annual financial framework.

More than raising awareness about innovative procurement and investment possibilities for digital transformation in public health and healthcare, it is important to find ways to mobilize relevant EU programmes and financial instruments, collaborating with the European Investment Bank and investor networks, and considering further support, including possible co-investment approaches, under the next multi-annual financial framework. But coordination is the foremost issue instead of piling up projects.

THE WAY FORWARD

Digital technologies should be seen as an integral part of health and care and geared towards the wider objectives of health systems. It is not yet clear how the actions put forward in this Communication will be able to significantly support the Member States' strategies on reforming health systems.

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HOPE is the acronym of the European Hospital and Healthcare Federation, an international non-profit organisation, created in 1966. It represents national public and private hospitals and healthcare associations, national federations of local and regional authorities and national health services from 30 European countries. It covers more or less 80% of hospital activities in the European Union.

HOPE mission is to promote improvements in the health of citizens throughout Europe, high standard of hospital care and to foster efficiency with humanity in the organisation and operation of hospital and healthcare services.