



European Economic and Social Committee

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Digital transformation/health and care

OPINION

European Economic and Social Committee

Communication from the Commission 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

[COM(2018) 233 final]

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1. **Conclusions**

- 1.1 In the course of the changes generated by digital transformation, people must be at the centre of care.
- 1.2 Digitalisation processes must help healthcare professionals to spend more time with patients. It must be ensured that healthcare professions are appropriately staffed with qualified personnel and equipped with appropriate digital skills.
- 1.3 The digital transition is changing the nature of work in health and care. Everyone involved should approach this transformation professionally and with an open mind to achieve high quality standards.
- 1.4 Social dialogue at European level concerning hospitals and healthcare plus social services must be strengthened. Appropriate training and further education programmes are necessary, working conditions and the quality of jobs must be improved and staff data protection must be enhanced.
- 1.5 The EESC knows that Member States are responsible for the organisation and provision of health and social care. Under the directive on patients' rights in cross-border healthcare (Directive 2011/24/EU), an online healthcare network (eHealth network) must be set up to advance the interoperability of eHealth solutions.
- 1.6 Digital tools must be a lever to develop new forms of organisation in health and care systems. They support the potential of individuals, of local communities and social economies. By means of appropriate public investment, values of solidarity and universality must be reaffirmed as the basis of these systems.
- 1.7 Digitalisation processes are not to be misinterpreted as a savings package for health care budgets. They must not lead to personnel cuts or cuts in services. Care must be considered as a personal service and, especially with ageing populations, new concepts of long-term care need to be developed.
- 1.8 The EESC agrees with the vision outlined in the communication, namely to promote health, prevent and fight diseases, help respond to unmet patient needs and make it easier for citizens to have equal access to high-quality care through appropriate use of digital innovations and social economy.
- 1.9 Health literacy in the social and digital context concerns a person's ability to acquire, understand and use information responsibly to promote their well-being and stay healthy.
- 1.10 Citizens should have the right to access their health data. They decide if and when to share their data. It is crucial to take account of the General Data Protection Regulation that guarantees citizens control over the use of their personal data, especially health data.

- 1.11 The EESC suggests that a "right to (free) copying" could be an active form of protection. This concerns all data generated by users when interacting with digital health platforms and permits citizens to reuse their own data.
- 1.12 The original data of users is of useful value for algorithms and platforms; it must be regarded as an original product generated by users and be protected in accordance with laws on intellectual property.
- 1.13 The "right to (free) copying" also helps to involve the protection and promotion of competition, which is now being sorely tested by the systems that digital platforms are currently using to expropriate data and personal histories.
- 1.14 The EESC supports¹ the four-pillar process for cross-border joint work on digital transformation in health and care, including joint clinical assessments, joint scientific consultations, identification of emerging health technologies and voluntary cooperation among Member States.
- 1.15 The EESC suggests taking appropriate action to investigate new ethical, legal and social frameworks that consider the risks associated with data mining.
- 1.16 The EESC suggests promoting research and innovation on the integration of digital technologies in order to renew healthcare processes, e.g. artificial intelligence, Internet of Things and interoperability. The EESC gives full support to the public in secure access to reliable health data across borders to advance research and disease prevention.
- 1.17 The EESC also endorses the EU's support for small, medium-sized and social enterprises that are developing digital solutions for person-centered care and patient feedback.
- 1.18 The EESC supports "rebalancing" the socio-economical asymmetry in data-driven economies by promoting the development of secure platforms and by supporting not-for-profit cooperative organisations to store, manage and share digital copies of all personal data.

2. **Background and general observations**

- 2.1 On 25 April 2018 the European Commission published its Communication on the digital transformation of health and care in the digital single market², which concerns the reforms and innovative solutions required for health and care systems to become more resilient, accessible and effective in providing quality care to European citizens and to create a healthier society. When properly designed and cost-effectively implemented, digital health and care solutions can increase the well-being of millions of citizens and radically improve the efficacy of health and care services that are delivered to patients. Digitisation can support the continuity of cross-border care (Directive 2011/24/EU), an important factor for those who spend time abroad for

¹ [OJ C 283, 10.8.2018, p. 28.](#)

² COM(2018) 233 final.

business or pleasure. Digitisation can also help promote health and prevent diseases, including occupational health at work. It can support the reform of health systems and their transition to new patterns of care, based on people's needs, and allow a shift from systems focused on hospitals to integrated and more community-based welfare facilities. In the course of the changes, it must be ensured that citizens are at the centre of care. Digitalisation processes should help healthcare professionals to spend more time with the patient. It must therefore be ensured that the healthcare professions are appropriately staffed with qualified personnel and equipped with appropriate digital skills.

- 2.2 The transition to digital health and care is transforming the nature of work in these areas. This can only be achieved with a high quality standard if everyone involved approaches the transformation professionally and with an open mind. Social dialogue at European level in the health sector and social services must therefore be further strengthened, so that appropriate training and further education must be developed and working conditions, particularly work-life balance, staff data protection and the quality of jobs must be improved.
- 2.3 The European Commission points out that European health and welfare systems face major challenges, such as ageing, multimorbidity, vaccines, lack of healthcare professionals because of difficult working conditions and the growing problem of non-communicable preventable diseases caused by risk factors such as tobacco, alcohol and obesity and other diseases, including neurodegenerative and rare diseases. An additional and growing threat is presented by infectious diseases due to increased resistance to antibiotics and new or re-emerging pathogens. Public costs related to health and long-term care are increasing in the EU Member States and this trend is expected to continue. It is particularly important that the associated costs should be used for improving quality of work for healthcare professionals, avoiding promoting poor pay and onerous working conditions. With ageing populations, new concepts of long-term care need to be developed.
- 2.4 Even when they are available, health data are often tied to technologies that are not interoperable, which is an obstacle to their wide use.
- 2.5 This is why healthcare systems do not have key information to optimise their services, and why it is difficult for service providers to create economies of scale and so offer efficient digital health and care solutions and support cross-border use of health services. The quantified results based on health data need to generate personalised health insights and be accessible to general practitioners, medical specialists and scientists, such that they can be acted on, to perform clustering and predictive modelling and utilise best practices.
- 2.6 As the conclusions of the report on the *State of Health in the EU* show, the use of patient-centred health data is not yet sufficiently developed in the EU.
- 2.7 It is the Member States that are responsible for the organisation and provision of health and social care. In some Member States, particularly those with federal systems, regional authorities are responsible for the financing and provision of healthcare.

- 2.8 Under the directive on patients' rights in cross-border healthcare (Directive 2011/24/EU), an online healthcare network (eHealth network) was set up to advance the interoperability of eHealth solutions.
- 2.9 Cooperation structures have also been developed, such as the European Innovation Partnership on Active and Healthy Ageing, the joint programme to support an active and autonomous life (Active and Assisted Living programme), and public-private partnerships such as the Innovative Medicines Initiative and the Electronic Components and Systems for European Leadership initiative. Regional and national smart specialisation strategies also play a central role in the development of stronger regional ecosystems in healthcare. Since 2004, two eHealth action plans have provided a policy framework for the Member States and the Commission, and the eHealth Stakeholders Group has played an important role.
- 2.10 With reference also to its positions set out in previous opinions³, the EESC believes the Commission's proposed action in three areas should be supported. These are: secure access of the public to – and sharing of – health data across borders; reliable data to advance research, disease prevention and personalised health and care, and digital tools for citizen empowerment and person-centred care. As mentioned above, it must be ensured that digitalisation processes are not misinterpreted as a savings package for health care budgets and do not lead to personnel cuts or cuts in services. Staff shortages lead to poor care and increased morbidity risk. It should not be forgotten that the digital transformation is a two-dimensional phenomenon comprising direction and process. In terms of direction, we focus on the external factors for organisations, constantly looking at "what" the digital transformation is addressing. In terms of process, the focus is on the thinking within organisations, with particular attention to "how" the digital transformation is being carried out. This approach absolutely must therefore be taken into account in examining the subject of the opinion in order to guarantee a patient-oriented approach.
- 2.11 Precisely for this reason, the EESC points out, as it did in its previous opinion⁴, that to take advantage of the digital transformation, EU networks and planned support measures should use digital tools to implement and reinforce, not to weaken, our fundamental rights in respect of health and care. Digital tools must support the development of individual potential and of local communities and social economy; they must be a powerful lever in promoting rights and developing new forms of organisation and governance for health and care; and they must help to reaffirm the values of solidarity and universality that are the basis of our healthcare system. This should be ensured by means of appropriate public investment, as set out in a previous opinion⁵.

³ [OJ C 434, 15.12.2017, p. 1](#); [OJ C 13, 15.1.2016, p. 14](#) and [OJ C 458, 19.12.2014, p. 54](#).

⁴ [OJ C 434, 15.12.2017, p. 1](#)

⁵ [OJ C 173, 31.5.2017, p. 33](#).

2.12 In line with previous opinions, the EESC believes that equal access to healthcare, one of the main objectives of health policies, can benefit from digital support provided certain conditions are met:

- equal geographical coverage taking into account areas with poor coverage by digital operators (access, broadband);
- bridging the digital divide in terms of use by the public, health professionals and stakeholders in health insurance schemes;
- interoperability between the various components of the digital architecture (databases, medical devices) to promote continuity of care within and between these facilities;
- protection of health data, which may under no circumstances be used to the detriment of patients;
- electronic distribution of product information approved by drug licensing authorities to improve access (as mentioned in a previous EESC opinion⁶).

2.13 The rapid expansion of telemedicine, connected devices and nanotechnology, biotechnology, information technology and the cognitive sciences (NBIC) must not result in patients being seen as mere connected bodies which can be analysed, monitored and overseen remotely by an all-powerful IT programme. The technical development of health in fact encourages the opposite: it places interpersonal relationships and social ties back at the centre of medical practice and care.

3. Impacts of digital transformation

3.1 Impact of digital transformation on health and care

3.1.1 The Commission communication illustrates how the EU can help to achieve the objectives of the Council conclusions, namely by developing the necessary cooperation and infrastructure in the EU and thereby helping the Member States to fulfil their political commitment in these areas. The proposed actions also support the Commission's commitment to achieving the UN sustainable development goal "Ensure healthy lives and promote well-being for all at all ages" and implementing the principles of the European Pillar of Social Rights.

3.1.2 The EESC agrees with the vision outlined in the communication, namely to promote health, prevent and fight diseases, help respond to unmet patient needs, and make it easier for citizens to have equal access to high-quality care through appropriate use of digital innovations and social enterprises.

3.1.3 The EESC believes that it is essential to increase the sustainability of European health and care systems, helping to maximise the potential of the digital single market through greater use of digital products and services in the areas of health and care. A further objective of the actions proposed must be to stimulate growth and promote European industry in the sector, as well as businesses, both profit and non-profit, which design and manage health and care services.

⁶ [OJ C 13, 15.1.2016, p. 14.](#)

- 3.1.4 Digital transformation enables in particular access to and exploitation of data that can make it possible to reduce healthcare costs as the population grows and life expectancy increases, supporting the optimisation of government action at national and European level.
- 3.1.5 Health digitisation will contribute to not only reducing time spent in hospital, with a direct positive impact on healthcare in hospitals, but also assisting the recovery of patients themselves. In the context of international recognition, the World Health Organization, in cooperation with the International Telecommunication Union (ITU), has proposed the National eHealth Strategy Toolkit, which essentially provides a method for upgrading and developing national eHealth strategies, action plans and monitoring frameworks.

3.2 **Impact of digital transformation on people**

- 3.2.1 Digital transformation gives citizens the opportunity to widely access innovative and more efficient personalised healthcare knowledge, infrastructure and services and also to contribute – as service providers, information producers and data providers – to improving the health of others.
- 3.2.2 It might also be considered that citizens have the right to access their health data and decide if and when to share such data. The EESC also believes it is crucial to take account of the General Data Protection Regulation, which came into force on 25 May 2018 and will guarantee citizens control over the use of their personal data, including health data. In addition, account should be taken of the statement made by the World Medical Association (WMA) on ethical considerations regarding health databases and biobanks in its Taipei Declaration, adopted by the 53rd WMA General Assembly, Washington DC, USA, October 2002, and revised by the 67th WMA General Assembly, Taipei, Taiwan, October 2016.
- 3.2.3 In this respect, it is essential to challenge the risk of a widening gap in people's digital literacy levels. Health literacy in the social and digital context concerns a person's ability to acquire, understand and use information responsibly to promote their well-being and stay healthy. To this end, it is necessary to guarantee a level of skills and familiarity with the new tools that allow people to improve their own well-being and that of the community through measures to improve lifestyle and living conditions.
- 3.2.4 As users are at the centre of design and service, the data they generate should also be considered crucial, with appropriate regulations laid down concerning ownership of the data and the right of the user him/herself and other parties to use them. The questions that should be raised are "who owns the data?", "who has the right to use them?", "under what conditions can other parties providing services use the data?", "can the user freely use the data?", etc. In this regard, an important distinction should be made between data types: raw data, on the one hand, and data generated by algorithms and artificial intelligence services, on the other. If another party generates new aggregate data using proprietary algorithms, how should ownership of the information be managed? How are business models designed to handle the presence of multiple stakeholders, each providing a fundamental part of the service? A distinction should also be made between business models based on services only (more traditional, e.g. support with activities of daily living (ADL)), and those based on patient-centred data with the possibility of

developing new services in terms of tele-health (e.g. services for prevention, treatment support and adaptation).

- 3.2.5 The authentic – i.e., original – data of each user is the only useful value for algorithms, services and platforms, which means that it can/must be regarded as an original product generated by users (and by them and their biological, cognitive, cultural and behavioural characteristics alone) and as such is an "original input" that must be protected in accordance with similar rules, albeit ones based ad hoc on intellectual property. One suggestion could be an active form of protection through a "right to (free) copying" of all data generated by users when interacting with digital health platforms, so as to permit them to reuse it – if deemed appropriate – by reaggregating it through other services/algorithms. The "right to (free) copying" also helps with another problem involving the protection and promotion of competition, which is now being sorely tested by the systems that digital platforms are currently using – on the basis of contracts or otherwise – to expropriate data and personal histories.
- 3.2.6 The EU itself has addressed the matter mentioned in point 3.2.5 on various occasions and in some cases has opted for a right to make data available (copying) (see Article 9 of Directive 27/2012 on energy efficiency: "if final customers request it, metering data on their electricity input and off-take is made available to them or to a third party acting on behalf of the final customer in an easily understandable format that they can use to compare deals on a like-for-like basis").
- 3.2.7 The EESC suggests creating a connected IT infrastructure so that patients with a rare disease can be contacted quickly and can make their health and medical data available for global not-for-profit research. The European Union is promoting the creation of a system of electronic health records by supporting the exchange of information and standardisation and the development of networks for the exchange of information between healthcare providers in order to coordinate actions in the event of a public health risk.
- 3.2.8 This would enable people/citizens/patients/users to take back full control of their digital identity. It would allow them to participate in the acquisition of knowledge obtained from aggregated health data for personalised medicine and prevention, and also to enjoy the considerable economic benefits derived from these aggregated data.

3.3 **Impact of digital transformation on social and health systems**

- 3.3.1 The EESC supports (as mentioned in EESC opinion⁷) the four-pillar process for cross-border joint work on digital transformation in health and care.

⁷ [OJ C 283, 10.8.2018, p. 28.](#)

3.3.1.1 The proposal establishes a coordination group, composed of representatives of the Member States' Health Technology Assessment (HTA) bodies, and describes the four pillars of future cooperation. The joint work would be led by the Member States through the coordination group and would comprise:

- joint clinical assessments;
- joint scientific consultations;
- identification of emerging health technologies;
- voluntary cooperation among the Member States.

3.3.1.1.1 *Joint clinical assessments* concern the most innovative technologies that include: i) medicines undergoing the central marketing authorisation procedure, and ii) certain classes of medical devices and in vitro diagnostic medical devices that make it possible to address unmet medical needs, potential impact on patients, public health or healthcare systems, and significant cross-border dimension. Such assessments would be drafted and defined by the Member States' HTA bodies, pharmaceutical companies or medical devices manufacturers (the "developer"), patients, clinical experts and other stakeholders. Once verified by the Commission, the report would be published and then used by the Member States.

3.3.1.1.2 *Joint scientific consultations*, also referred to as "early dialogues", would allow a health technology developer to seek the advice of HTA bodies on the data and evidence likely to be required as part of a future joint clinical assessment. Developers would have the possibility to request a joint scientific consultation from the coordination group. Once approved by the coordination group, the joint scientific consultation reports would be addressed to the health technology developer, but would not be published.

3.3.1.1.3 "Horizon scanning", or the *identification of emerging health technologies* (health technologies that have not yet been adopted in the healthcare system), would help ensure that health technologies that are expected to have a major impact on patients, public health or healthcare systems are identified at an early stage in their development and included in the joint work.

3.3.1.1.4 Member States would have the possibility to continue *Voluntary cooperation* at EU level in areas not covered by mandatory cooperation. This would, among other things, allow for the possibility of performing HTAs on health technologies other than medicinal products or medical devices (such as surgical procedures), as well as for the assessment of non-clinical aspects (for instance, the impact of medical devices on the organisation of care).

3.3.2 The deployment of novel healthcare solutions enabled by digital transformation raises a number of important multidisciplinary issues, including ethical, legal and social issues. Although a legal framework already exists for data protection and patient safety, other matters need to be addressed, such as access to broadband, the risks associated with data-mining and automatic decision-making, guaranteeing appropriate standards and legislation to ensure adequate quality of eHealth or mHealth services, and accessibility and quality of services. Similarly, at the level of services, although there are rules at EU and national level governing public procurement,

competition and the internal market, novel approaches that take account of digital transformation should be discussed and adopted.

3.3.3 Digital transformation will entail a reorganisation of the health care system, with new ways and standards to provide services (e.g. using robots in conjunction with caregivers). Additionally, caregivers should undergo appropriate and specific training programmes (e.g. including social, medical or technical background), and be prepared for new job profiles and transformations in work environments. This will lead to the definition of new service models, support policies, certifications and standards suited to the introduction of digital services and technologies in real care contexts and markets. Their design and development should follow the principles of user-centred design, usability engineering by design, universal design, etc., with users and their needs at the centre of the process avoiding creating digital divide and excluding people from services.

3.3.4 The EESC endorses the Commission's efforts to support the development and adoption of the European electronic health record exchange format and to develop common identification and authentication measures, as laid down in Article 14(2) of Directive 2011/24/EU.

3.4 **Impact of digital transformation on the digital market**

3.4.1 The challenge is that of "rebalancing socioeconomic asymmetry in a data-driven economy"⁸ by means of:

- a legal right to a digital copy of all personal data (medical and non-medical); data portability (Article 20, EU Data Protection Directive);
- a safe and secure platform where people can store, manage and actively share data on their own terms;
- a not-for-profit cooperative organisational structure of personal data platforms so that they are owned by citizens;
- revenues from citizen-controlled secondary use of data being invested in projects and services that benefit members and society at large.

3.4.2 Joint clinical assessments would facilitate faster access, avoid duplication at national level and deliver greater consistency, clarity and predictability for everyone involved in the process. The medical devices industry is overall more sceptical of the proposal. Mandatory cooperation on clinical HTA assessments may slow down market access for devices, rather than streamline it.

3.4.3 As mobile device penetration is growing, eHealth or mHealth solutions will offer novel services with optimised processes. Processes will include facilitating mobility for health and care professionals.

3.4.4 Digital transformation will promote the development of new agile business models, foster participation in the business by various stakeholders and bring about benefits from the quantification of users' experiences. Its success depends on it being customer-centric (or user-

⁸ World Economic Forum – The Global Information Technology Report 2014.

centric), in order to ensure that the user perspective is considered from the very beginning of the design process (design thinking).

- 3.4.5 Digital transformation will enable the widespread use of health and social data, fostering the integration of systems and devices with machine learning services and the necessity of interoperability and interaction capability (M2M) that must take into account the variety of user requirements and preferences, the development of "future proof" systems, the possibility of integration with existing infrastructure and with local service providers, and any disruptive and unplanned technologies and services with new standardisation requirements.
- 3.4.6 Novel key enabling technologies, such as 5G, will create opportunities for enhanced mobile broadband products and services, thus supporting the deployment of millions of connections for Internet of Things (IoT) devices on a massive scale. With the proliferation of 5G and the IoT, digital transformation strategies are crucial for many stakeholders acting in the healthcare domain, particularly as new consumer behaviour and needs will demand new digitised offerings.
- 3.4.7 The EESC supports services related to: health information, disease prevention, development of tele-counselling systems, online prescribing, referral, and reimbursement of medical expenses. Existing platforms such Alfred, Big White Wall, Medicine Patient Portal, Empower etc. can be regarded as enabling the digital transformation in the digital single market. Interestingly, on 29 May 2018, it was announced that the European Open Science Cloud would support EU science in world-leading position by creating a trusted environment for hosting and processing research data. The Cloud should be a broad, pan-European federation of excellent existing and emerging infrastructures that respects the governance and funding mechanisms of its component parts; membership in this federation would be voluntary; and the governance structure would include Member State ministries, stakeholders and scientists.

3.5 **Impact of digital transformation on service providers**

3.5.1 In this context, the EESC agrees on the following objectives:

- a focus on healthcare providers;
- a focus on patients when entering the healthcare system;
- efficient data transfer within primary care (eHealth, Electronic Patient Dossier/EPD);
- patients provide consent to their data being used for research; incentives to provide additional data (mHealth);
- reducing the difficulties of involving patients in research.

3.5.2 Recent technological, social and economic studies highlight that artificial intelligence, Internet of Things and robotics will make it possible to design and develop new approaches in the fields of personalised and precision medicine, cognitive frailty and cooperative robotics. Their take-up in healthcare will mean adapting and developing all processes relating to service design, provision and evaluation. In this context, digital transformation represents a fundamental but also an enabling (or "accelerator") factor in the integration of innovative technologies in the healthcare domain.

- 3.5.3 Digital transformation has the potential to make available a large amount of data allowing the investigation and development of novel and ambitious service solutions based on artificial intelligence. This could be the basis for creating a framework to objectively quantify chronic diseases and identify opportunities in early diagnosis and therapy monitoring. Additionally, recent advances in artificial intelligence would take advantage of data availability to develop systems that can learn and then adapt to the ways in which diseases evolve.
- 3.5.4 The widespread use of data, and the ability for stakeholders to use and transform them according to users' needs, open new scenarios for sharing data, knowledge and expertise, as already supported by the European Reference Networks, which provide a governance structure for knowledge sharing and care coordination across the EU in the field of rare diseases. If a specific location (area or country) has no expertise in a specific disease, the network can help doctors to obtain knowledge from other centres of expertise in other locations. Similarly, hospitals all over Europe can make use of the digital connecting systems to share knowledge and provide support to each other.
- 3.5.5 One obvious consequence of the previous points is that cybersecurity is a key priority. As pointed out in an ENISA report (*ENISA Threat Landscape Report 2017: 15 Top Cyber-Threats and Trends*, European Union Agency For Network and Information Security), the complexity of attacks and sophistication of malicious actions in cyberspace continue to increase. In the healthcare landscape, where many pervasive systems are connected and significant assets are at stake, for example patient life, sensitive personal information, financial resources, etc., information security is a key issue. In the context of digital transformation, new methods and guidance are needed for modelling cybersecurity assessment frameworks, organisational countermeasures and interoperability conformance based on cybersecurity.
- 3.5.6 The EESC also endorses the EU's support for small and medium-sized enterprises that are developing digital solutions for person-centred care and patient feedback. The cooperation will of course involve public authorities and other stakeholders committed to promoting shared or mutually recognised principles for validating and certifying digital solutions for adoption in health systems (for instance, mHealth and independent living).
- 3.5.7 The EESC also believes that previous initiatives to issue health care cards by the European Member States must continue under the prism of the digital transformation of health and care in the digital market. Given the sensitive nature of the medical data that can be stored in such eHealth cards, they must offer robust privacy protection.

Brussels, 19 September 2018

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