

CEN-CENELEC response to the European Commission's Public Consultation on Transformation of Health and Care in the Digital Single Market

October 2017

Executive Summary

CEN and CENELEC welcome the opportunity to respond to the EC public consultation on Transformation of Health and Care in the Digital Single Market.

Modern healthcare is rapidly advancing, adopting digital solutions and relying on electronic communications. The healthcare and medical devices sector, however, suffers from fragmentation of the Digital Single Market, which prevents the industry, consumers and healthcare practitioners to take full advantage of the benefits provided by emerging innovative and digital technologies.

To facilitate further the digital transformation of health and care in the single market and to promote digital innovation in addressing systemic challenges to health and care systems, it will be vital to focus on the harmonization of rules and policies across the 28 Member States. Moreover, it is important to deliver appropriate infrastructure that would ensure compatibility and interoperability between individual Member States.

By way of example, many EU Member States already have electronic systems to record and distribute personal data regarding healthcare (e.g. electronic prescriptions or patient summary data), however, the next step is to ensure synchronization of these systems between different jurisdictions in order to provide for a truly harmonized and interconnected European Single Market. This example demonstrates the limited nature of digital health programs, which is the result of the differences between European healthcare systems, lack of interoperability solutions as well as of appropriate infrastructure.

The creation of a Digital Single Market in the healthcare sector requires a barrier-free Union to ensure an effective uptake of ICT products and services across the European healthcare market.

European Standardization is a powerful tool to help achieve the EU objectives, and the **European Standardization System** provides an adequate framework for setting the right conditions to enable health and care to take advantage of the benefits provided by the Digital Single Market, while ensuring protection of personal data and patient rights.

Voluntary European standards are **innovation-friendly, market-driven** tools that are the outcome of a transparent, consensus based, inclusive, results-driven, dynamic system built on partnerships with all industry and societal stakeholders.

At European level, **CEN/TC 251 'Health Informatics'** addresses standardization in the field of Health Informatics and Communication Technology (ICT) to achieve compatibility and interoperability between independent systems. This includes requirements on health information structure to support clinical and administrative procedures, technical methods to support interoperable systems as well as requirements regarding safety, security and quality. CEN/TC 251 is already involved in several European and international projects linked to the transformation of health and care for the digital age. In particular, the project on **International Patient Summary** serves as a driving force for a broad uptake of the eHealth Digital Services Infrastructure. Meanwhile, it creates a starting point for exploring individual health data and as a platform for innovation. The **eStandards Roadmap**¹, developed in close collaboration with industry standards organizations HL7 and IHE, as well as National eHealth Competency centers, describes the way forward for digital health innovation using standards that are fit for the digital age.

Moreover, given the importance of data protection and privacy with regard to sharing of health data, the work of the joint **CEN-CENELEC Technical Committee 8 'Privacy management in products and services'** in response to the EC Standardization request M/530² will be crucial. The Technical Committee is developing voluntary standards in support of implementing data protection and privacy by design and by default, which will enable manufacturers and/or service providers to incorporate the relevant data protection needs and requirements as part of their design and development processes.

The lack of interoperable solutions, practices (process standards) and trustworthy IT solutions are, among others, gaps affecting the Single Market. On this basis, cybersecurity was identified as one of the ICT Standardization Priorities for the Digital Single Market. In order to address the growing demand of standards in this field, CEN and CENELEC established earlier this year a joint **Technical Committee 13 'Cybersecurity and data protection'**. The objective is to facilitate the development of standards for data and information protection, and security techniques with specific focus on cybersecurity, covering all concurrent aspects of the evolving information society (such as organizational frameworks and methodologies, privacy

¹ ['Roadmap for sustainable & collaborative standards development'](#), eStandards, June 2017.

² COMMISSION IMPLEMENTING DECISION C(2015) 102 final of 20.1.2015 on a standardisation request to the European standardisation organisations as regards European standards and European standardisation deliverables for privacy and personal data protection management pursuant to Article 10(1) of Regulation (EU) No 1025/2012 of the European Parliament and of the Council in support of Directive 95/46/EC of the European Parliament and of the Council and in support of Union's security industrial policy.

guidelines, processes and products evaluation schemes, smart technology, objects, distributed computing and data services).

With its **strategic plan for Digital Transformation** adopted in June 2017, CEN and CENELEC aim to meet the needs of the industry to transform digitally, and to undergo their own digital transformation in order to, for example, enable in the future online standards development and digital exploitation of standards' content.

In addition, CEN and CENELEC strongly support the shared vision and values contained in the **Joint Initiative on Standardization (JIS)**, and are fully committed to the implementation of the JIS Actions. This initiative provides a unique opportunity to improve, in a collaborative way, the interaction between standards, legislation and policies for the benefit of the society and the industry. As the lead of the JIS Action 14 'Standardization to support digitization of European industry', CEN and CENELEC together with ETSI seek to cooperate with existing initiatives at national, European and international level in order to create synergies and identify common needs of European industry, including the healthcare sector. Industry, along with non-digital sectors, is undergoing a digital transformation of their processes, systems and supply chains. Standardization, as an interoperability enabler needs to play an essential role.

The EC Communication '**ICT Standardisation Priorities for the Digital Single Market**' (COM(2016) 176 final) of April 2016 identifies 5 ICT 'pillars' being the essential technology building blocks on which the Digital Single Market will be fully realised: 5G communications, cloud computing, the internet of things (IoT), (big) data technologies and cybersecurity. CEN and CENELEC along with ETSI are responding to this Communication, highlighting the vertical sector needs, including that of eHealth.

Finally, CEN and CENELEC will support **standardization of Blockchain technologies** enabling their roll-out in various industry sectors including healthcare. The foreseen benefits are the support of the improvement and authentication of health records through protocols on record sharing; smart contracts where rule-based methods allow permissions to access patient data access to selected health organizations; and precision medicine where patients, researchers and providers collaborate to develop individualised care.

CEN and CENELEC **links with ISO and IEC** are key strengths in international markets and full advantage should be taken of using international standards within Europe, where supported by stakeholders. The eHealth sector is an exemplary case where Europe has the greatest level of alignment with international standards, thereby boosting the global competitiveness of European businesses.

Through 34 national members active in eHealth standardization, CEN and CENELEC have a strong European network with **global outreach** through ISO and IEC that can provide the framework for Europe to capture global market opportunities.

The European Standardization System is a unique asset for Europe that **with the support and engagement of the Commission and the EU institutions will develop the needed standards for eHealth to the benefit of European citizens, healthcare providers and businesses.**

CEN and CENELEC await with keen interest the overall conclusions of the Consultation, the priorities defined by all European stakeholders and their needs for technical standards related to eHealth as well as data protection and privacy.

Detailed replies

Access to and use of personal data concerning health

Q29 Regarding the statement "Citizens should be able to manage their own health data", do you...

Strongly agree.

In digital age, engaged and empowered citizens will increasingly demand ways of using self-collected data, ask for options to feed them into their care process and ways to copy, store and organize health data for their own use. Citizens will wish to receive their health data in an easy to use format, share it with trusted people of their choice and at their discretion.

This is irrespective of the obligations of the healthcare providers to maintain their own electronic health records related to the treatment and interactions with their patients.

eHealth solutions and services that can make citizens more engaged are personal health records, online scheduling services, or self-monitoring and others. In this respect, standardization may enable recorded patient information to be easily filtered, presented and communicated in a way that is safe and understandable for all relevant parties. Moreover, protection of personal information and patient consent require standardization to be effective, when information is shared among various professionals and providers.

Already now, several European standards exist on personal health device communication, which establishes a normative definition of communication between personal medical devices and managers (e.g. cell phones, personal computers, personal health appliances, set top boxes) in a manner that enables plug-and-play interoperability. Health-device communication standards enable communication between medical, healthcare and wellness devices and with external computer systems by providing automatic and detailed electronic data capture of client-related and vital signs information, and of device operational data. Appropriate use of these standards helps deliver better health, fitness and care, more quickly, safely, and at a lower cost.

Q31 Regarding the statement "Sharing of health data could be beneficial to improve treatment, diagnosis and prevention of diseases across the EU", do you...

Strongly agree.

Sharing of health data would be beneficial in terms of individual care and aggregated use of data for research as well as evidential use of data. Dissemination and availability of knowledge is crucial for better decisions at the point of care and standardization can play a role in this area. For example, linking patient characteristics to the expected effects of treatments relies on formal standards for capturing the distinctive characteristics. In addition, the logic of care plans that links characteristics to expected outcomes requires computable standardization.

Q33 What are the major barriers to electronic access to health data?

- Risk of privacy breaches;
- Lack of infrastructure; and
- Other: Current holders of health data do not see the need and benefits of providing access to data and are scared of the ways in which providing access would change the relationship with the subject of care or with relevant authorities.

IT infrastructure needs to be adapted in order to make import and export of patient-generated data uncomplicated and straightforward for the health professionals.

Q35 What are the major barriers to electronic sharing of health data?

- Heterogeneity of electronic health records;
- Risks of privacy breaches;
- Lack of infrastructure; and
- Lack of technical interoperability and semantic interoperability.

Currently, patient generated data is most often automatically uploaded to vendor-specific portals that act as 'data silos' and may not permit the export of the measured data in any standard format.

Moreover, there is a lack of transparency with regard to ownership and the secondary use of this data, which needs to be addressed. Necessary requirements include clear ID of senders and receivers of the health data.

To ensure that sharing of health data is valuable, the data needs to be processed, which requires homogeneity of the records as well as technical interoperability and appropriate infrastructure. The development and use of appropriate standards can achieve this objective.

Standardization actively supports the facilitation of electronic sharing of health data. Patient Summary for unplanned and emergency care, together with cross border ePrescription, has been a top priority for the European eHealth Network in setting up the eHealth Digital Services Infrastructure and connecting Member States to safely deliver cross border care. Leading the work on European level, CEN/TC 251 is developing a European Standard, which formalizes the dataset required to share information about the medical background and history of a patient across countries in the case of unscheduled treatment. The standard will provide a globally

agreed upon and formalized minimal and non-exhaustive data set that can be used as a reliable and definitive source for data that will support unplanned care of any person requiring a treatment abroad. As such, standardization will provide a core that will support interoperability, providing benefits for patients, providers, clinicians and vendors. In addition, the accompanying Technical Specification will provide guidance for European implementation of the standard, taking into account European specific jurisdictional requirements.

In addition, CEN and CENELEC support the standardization of blockchain technology, which has the potential to improve health IT in the areas of security, storage and healthcare data management.

Q37 What should the EU do to overcome barriers to access and sharing of data?

- Standardize electronic health records;
- Provide the necessary infrastructure;
- Develop standards for data quality and reliability; and
- Other: we would advise to organize more synergy between the European initiatives and current national programmes. In addition, national programmes should provide the incentive to the healthcare professionals to capture and use structured health data in their daily work.

Standards-based interoperability needs to be established across the diversity of eHealth systems involved, in order for the information to be actionable by the systems (e.g. providing alerts and reminders). This is especially important when alerts need to be generated based on self-monitoring data provided by patients.

Moreover, a high degree of standardization of health information exchange will be required when a patient is referred to another professional in a different organization or country (see example above on the International Patient Summary).

The ability to exchange health data depends on the availability of appropriate infrastructure including security and directory services. These need to be incentivized as necessary enablers of a regional, national or European eHealth IT infrastructure.

In addition, privacy issues will need to be addressed in the area of user authentication and consent. Patients shall agree to the exchange of information related to them and to be informed about the way in which the health information will be protected. User authentication shall ensure that access is granted to a verified person.

Here, the future work of CEN-CENELEC/TC 8 'Privacy management in products and services' and CEN-CENELEC TC/13 'Cybersecurity and data protection' will be crucial for developing the necessary standards addressing the lack of interoperable solutions and practices, trustworthy IT solutions, and data protection requirements.

Relying on the European Standardization System to provide the ICT standardization solutions will help achieve the European policies for a strong digital economy and a truly connected

European Digital Single Market, as European standards ensure the interoperability of products and services.

Making use of personal data to advance health research, disease prevention, treatment and personalised medicine

Q39 Would you agree with the principle that personal health data should be made available for further research, on a case-by-case basis, in a secure way, and in compliance with data protection legislation?

Strongly agree.

Q40 For which purpose would you agree to make your health data available provided this is in compliance with data protection legislation?

- Improving clinical practice;
- For your own treatment;
- Progressing research and innovation;
- Informing public health programmes; and
- Increasing efficiency of health and social care.

The focus should be on common themes across Europe that are scientific in nature.

Q44 Should high-performance computing, big data analytics and cloud computing for health research and personalised medicine be advanced?

Yes.

The most important application area would be the collection of practice-based evidence and investigation of personal and social determinants for diseases and treatment results.

Q46 Would it be useful to further develop digital infrastructure to pool health data and resources securely across the EU (linking and/or adding to existing infrastructure capacity)?

Strongly agree.

Q47 What, if anything, should the European Commission do to stimulate the use of data and digital tools to advance research, disease prevention and personalised medicine?

The European Commission should support the development of an infrastructure and build upon the notions of FAIR Data Approach, such as the personal health train initiative (www.dtls.nl/join-the-personal-health-train-initiative).

The EC should take advantage of the previously mentioned blockchain technology to enable anonymous population health and clinical studies, which can be vital for both healthcare providers and health insurers. Standardization forms an essential part in a technology's adoption curve and blockchain technology is no exception.

Promoting uptake of digital innovation to support interaction between citizens and health care providers

Q53 Please indicate to what extent you agree with the following statement: Citizen / patient feedback to health care providers and professionals on the quality of treatment is essential to improve health and care services.

Strongly agree.

Shared decision-making between citizens and healthcare providers will drive down cost and increase adherence to therapy regimes. Feedback also includes patient reported outcome measures, which are a key indicator of the value of treatment from the perspective of the patient.

Q55 What should the EU do to support the goals of disease prevention, better treatment and giving citizens the means to take informed decisions on health issues (by means of digital innovation)?

- Support regions and municipalities in rolling out new services; and
- Support EU associations of patients and clinicians to improve clinical practices.

We would advise to take notice of the eHealth Task Force Report (2012) 'Redesigning health in 2020' and/or the eStandards project deliverable "[Roadmap for collaborative and sustainable standards development \[in eHealth\]](#)" (July 2017).

About CEN and CENELEC

CEN (European Committee for Standardization) and **CENELEC (European Committee for Electrotechnical Standardization)** are recognized by the European Union (EU) and by the European Free Trade Association (EFTA) as European Standardization Organizations responsible for developing and defining standards at European level. These standards set out specifications and procedures in relation to a wide range of products and services.

The members of CEN and CENELEC are the National Standards Bodies and National Electrotechnical Committees of 34 European countries including all of the EU member states plus Iceland, Norway, Switzerland, Turkey and the former Yugoslav Republic of Macedonia.

European Standards (ENs) are developed through a process of collaboration among technical experts nominated by business and industry, research institutes, consumer and environmental organizations and other societal stakeholders. Once adopted, these standards are implemented and published in all of the 34 countries covered by CEN and CENELEC.

CEN and CENELEC also work to promote the international harmonization of standards in the framework of technical cooperation agreements with ISO (International Organization for Standardization) and IEC (International Electrotechnical Commission).

For more information, please see: www.cencenelec.eu