On 30 August 2017, the CPME Executive Committee adopted the 'CPME response to the Digital Health Society Consultation' (CPME 2017/056 FINAL)

CPME response to the Digital Health Society Consultation

INTRODUCTION

From the 1st of July 2017, Estonia is assuming the Presidency of the EU Council. One of the top priorities defined by the Estonian Government is the development of the **Digital Single Market (DSM)** and the **Digital Economy in Europe**, bringing more services and benefits to EU citizens. The 5th right around the **Free Flow of Data** (beside the free flows of humans, services, products and capital), is a key challenge in order to enable the DSM in Europe. Health and social care services are also going through this digital transformation and the Estonian 2017 EU Presidency aims to move forward the deployment and the implementation of Digital health across Europe.

In preparation of this, the Ministry of Social Affairs of Estonia has appointed the European Connected Health Alliance (ECHAlliance) as its International Strategic Partner in order to develop the activities around the **concept of the Digital Health Society (DSH)** and launch a large collaborative work with the main EU key stakeholders representing policy-makers, citizens, health professionals, scientists, companies and payers.

You can download <u>HERE</u> the latest version of the **Digital Health Society Declaration.**

As a first step, the Ministry of Social Affairs of Estonia and ECHAlliance have decided to launch in July 2017 a **broad consultation across Europe around the Digital Health Society Declaration**. Stakeholders are invited to contribute to the Declaration, expressing their point of view and sharing their ideas and experiences about the opportunities, the barriers to overcome and the existing (implemented) solutions that will allow the development of a real Digital Health Society and of the Free Flow of Data in Europe.

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CPME responses appear in <u>blue font</u>.

1. Please indicate below the organisation you represent.

CPME - Standing Committee of European Doctors

2. The Digital Health Society enabled by the Free Flow of Data will create opportunities for all stakeholders. In your opinion, what are the main ones for each category of the following stakeholders?
   - Citizens
   - Health & Social care professionals and providers
   - Governments & policy-makers
   - Companies
   - Payers & Insurers
   - Research

Bearing in mind that the cornerstone of the physician-patient relationship is the face-to-face contact between them, digital health services can support and enhance communication and sharing of knowledge with patients. Similarly, mobile health (mHealth) services can be useful complementary tools to face-to-face consultations and contribute to patient empowerment (e.g. the management of chronic conditions), provided that both the patient and the doctor have sufficient trust and confidence in the supporting technologies.

Some challenges remain to fully implement the Digital Health Society. Please, comment the challenges mentioned below and share some concrete examples of solutions or actions to overcome it.

3. Lack of awareness and meaning
Citizens are not well enough informed about the benefits of the use of data for healthcare services or research. A lack of understanding (meaning) often leads to the non-acceptance for sharing data.

Acceptance requires not only awareness-raising on the potential benefits related to the reuse of health data for purposes other than care and treatment (secondary purposes), such as medical research, but also transparency on how patient's data are used and by whom. In order to foster acceptance, it must be ensured that personal health data are used only for a meaningful purpose in a manner which is scientifically sound and ethically acceptable. Patients must be informed that appropriate safeguards are in place.

4. Lack of confidence and trust
Citizens should be assured that their data are protected and that all precaution have been taken to guarantee issues around privacy, confidentiality and security.

Because privacy and trust are fundamental in the patient-physician relationship, security and confidentiality are key elements in the provision of eHealth services. Consequently, appropriate data protection and patient's consent rules need to be ensured. On one hand, information must be

securely stored and protected from unauthorised access. On the other hand, appropriate procedures of verification and authentication should be in place (e.g. e-prescriptions).

Transmission of personal health data has to be confidential, secure, purpose-related and based on patient's consent.

5. Lack of interoperability

In order to achieve the free flow of data, health data producers of the European countries and regions should embrace a common strategy regarding the interoperability of data, at the technical and at the semantic level.

The lack of interoperability remains a major barrier to further development of digital health in Europe. CPME very much supports efforts to promote the interoperability of eHealth applications across Europe, the aim however being not only technical interoperability, but also the maintenance of the highest possible standards of usability and, most crucially, data protection and confidentiality.

6. Lack of clear legal framework

Related to the confidence and trust, European countries and regions should define clearly the conditions for health data use, based in the citizens informed consent, (indicating which are the characteristic of data that could be used, for which purpose, by what type of stakeholders).

As stated under section 4, the sharing and re-use of personal health data must be purpose-related and based on patient's consent.

In the context of data collection in medical research, CPME reminds that informed consent is the backbone principle ensuring that research is conducted in an ethically acceptable way. Only when consent cannot be collected due to the fact that it would prove impractical or even damageable to the research study, can derogations be envisaged. In this case, a practical governance system including an approval process by an independent research ethics committee or another relevant body - such as independent review boards entitled to oversee such processes or the Confidentiality Advisory Group in the UK - should be in place, as foreseen in the WMA Declaration of Taipei on ethical considerations regarding health databases and biobanks (see section 13).

7. Lack of training for institutions, healthcare providers and professionals

Data will be collected correctly and used in day-to-day practices of health professionals, if specific training are provided (to students in medical/nurses school and to current workforce).

Acceptance of new ICT tools requires appropriate education, training and support of health professionals. To that end, e-skills need to be integrated at both undergraduate and postgraduate levels in the curricula and Continuing Professional Development (CPD) programs. Regular training for

doctors at the workplace would foster the acceptance of new ICT technologies by the medical profession.

8. Lack of change management strategy in healthcare systems

As in all sectors, the implementation of digital technologies is not only equipping the on-going work process and organisation. It requires a re-think and re-organisation of the whole system, the role of the stakeholders and the approach for the healthcare service delivery. Digital brings a complete transformation.

The development of digital health can only be successful if it can be really and easily integrated in the daily work of doctors and other healthcare professionals.

9. Lack of meaningful and integrated solutions

Simple rough and general data information is not impacting behaviours. The citizens need to understand the meaning of each set of data, to have a view on the impact of their actions and choices on their health status and so on. The basic quantified self, thanks to all personal devices and wearables currently on the market, are not triggering the expected behaviour changes, because of the lack of meaningful information and the lack of integration within the healthcare systems.

The development of eHealth solutions should be based on a user-centred approach. They should be adjusted to the needs of healthcare professionals in order to support and simplify their work (e.g. telemedicine) instead of creating an additional burden (e.g. double reporting of patient data).

When it comes to mHealth solutions, technologies should take into account patient's knowledge and ability. For mHealth solutions which are not qualified as medical devices, CPME considers that an overall independent assessment of mHealth solutions (e.g. certification scheme) is necessary to ensure the safety, quality and reliability of these products. Such solutions should also prove to enhance clinical results and improve the quality of care.

10. Lack of innovation in funding models

Lack of money is also often indicated as one of the main barrier factors but it is debatable. If we observe the allocation of resources in the area of digital health, and particularly related to electronic health data deployment at the EU or at the Member States level, we realise that large sums have been or are being invested. The issue seems to identify creative and innovative funding models. Because EU systems are widely based on fee-for-services models, the added-value of data-based systems and solutions focused on integrated care, services quality, prevention and outcomes of the interventions don't find their place in current purchase processes and contracts model. The challenge is then to break down the budget silos between health and social care or between secondary and primary care, to incentivise the stakeholders, to deploy more widely, innovative public procurement models, and new types of contracts, outcomes-based and involving risk sharing between the parties (suppliers-buyers-care providers).

Proper financing models and reimbursement schemes are certainly needed. So far, only a few limited initiatives have been implemented at national, regional or local level across the EU. Furthermore, questions related with liability aspects should be adequately addressed to ensure legal certainty.

The Digital Health Society has set up Task Forces around specific challenges which need be moved forward in the next months. Please share with us your comments, ideas and initiatives that could generate progresses around the following challenge.

11. Task Force 1 on interoperability standards

This task force 1 is targeting a convergence roadmap for European member states and regions on interoperability standards and Digital Tele healthcare protocol.

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12. Task Force 2 on data donors

This task force 2 is targeting to create Data donors campaigns and tools for EU member states and regions in order to raise awareness of the Europeans about the benefits in sharing personal health data to improve health services and contribute to the European Research.

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13. Task Force 3 on the legal framework to facilitate the free flow of data and the 2nd use of data

This task force 3 is targeting to collect the best practices and design the principles of a legal framework, including the GDPR and local regulations, facilitating the free flow of data and the 2nd use of data.

As mentioned under section 6, a proper governance framework should be in place to allow the reuse of personal health data, in particular for medical research, while protecting patient autonomy and their right to self-determination.

More concretely, the [WMA Declaration of Taipei on ethical considerations regarding health databases and biobanks](#) provides a transparent governance process in cases where obtaining informed consent is impractical. This governance framework includes the securing of an initial consent given on the basis of limited information and a third party oversight by an ethics committee before any re-use of the personal data (consent plus governance solution). This oversight can lead to require additional safeguards or going back to the patients for consent.

CPME considers that this Declaration provides the additional safeguards needed to complement the new EU [General Data Protection Regulation](#) (GDPR) which left to the Member States the possibility to provide for appropriate safeguards for the processing of personal data for secondary purposes, including scientific research.

14. Task Force 4 on the digital transformation in healthcare systems

This task force 4 is targeting to collect the best practices and publish recommendations for the digital transformation & change management in healthcare organisations.

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15. The Digital Health Society has set up several Task Forces, gathering high-level experts and 1st implementers on specific topics.

You will be invited in September to express your opinion on the pre-conclusions of these Task Forces. Please indicate which topic interests you.

Convergence roadmap on interoperability standards and Digital Tele healthcare protocol

☐ *Data donors campaigns*

☑ *Principles of a legal framework facilitating the free flow of data and the 2nd use of data*

☐ *Recommendations for the digital transformation & change management in healthcare organisations*