October 5, 2017

Re: Public Consultation: Transformation of Health and Care in the Digital Single Market

Dear Sir or Madam,

On behalf of the Center for Data Innovation, we are pleased to submit the following response to the European Commission's public consultation on Transformation of Health and Care in the Digital Single Market.

The diversity of European health systems and high degree of regulatory fragmentation creates a strong argument for EU-level intervention when it comes to ensuring clinicians can use health care data to deploy the latest data-driven technologies in patient care. These technologies include diagnostic tools that use artificial intelligence and wearable devices that help manage chronic health problems. In particular, policymakers should introduce legislation requiring all member states to create electronic health records, and to remove regulatory barriers to the testing of new data-driven health care tools.

Yours faithfully,

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INTRODUCTION

The purpose of this consultation is to define the need and scope of policy measures that will promote digital innovation in improving people's health, and address systemic challenges to health and care systems. Those measures must be aligned with legislation on the protection of personal data, patient rights and electronic identification. The consultation collects views on:

- Cross-border access to and management of personal health data;
- A joint European exploitation of resources (digital infrastructure, data capacity), to accelerate research and to advance prevention, treatment and personalised medicine;
- Measures for widespread uptake of digital innovation, supporting citizen feedback and interaction between patients and health care providers.

The European Commission reserves the right to publish all contributions to the consultation unless non- publication is specifically requested in the general information section of the questionnaire.

The public online consultation will close on the 12th of October 2017.
In case your response includes confidential data please provide a non-confidential version.

ACCESS TO AND USE OF PERSONAL DATA CONCERNING HEALTH

A major change in the way we receive and provide health and care services is giving citizens the possibility to effectively manage their health data i.e. to grant access to this data to persons or entities of their choice (e.g. doctors, pharmacists, other service providers, family members, insurances) including across borders, in compliance with EU data protection legislation.

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

-Agree

Comments on previous question (e.g. what kind of information, obligatory self-management of data access vs optional, delegated management only to certain persons or organizations – e.g. doctors, pharmacists, other service providers, family members, others):

Citizens should have the right to access their health data, and must be consulted before the data is shared with any third party for purposes other than those necessary for the running of the health service. However, relatively few citizens are in a position to make informed decisions

about day-to-day data management, such as how and where it should be stored or by what technical methods it should be processed.

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

-Strongly agree

<u>Comments on previous question</u>

Data analytics software, particularly artificial intelligence, holds great promise for health care. For example, AI tools can help identify abnormalities in scans. However, AI tools are almost always developed by third parties, usually businesses. Unless health-care providers have a straightforward means by which they can share health data strictly for the purposes of testing or deploying new technologies, subject to appropriate controls and precautions, then they may be reluctant to make use of data-driven health-care technologies without of falling foul of data protection rules.

<u>What are the major barriers to electronic access to health data?</u>

-Lack of infrastructure.

<u>What are the major barriers to electronic sharing of health data?</u>

-Legal restrictions in member states
-Lack of infrastructure

<u>What should the EU do to overcome barriers to access and sharing of data?</u>

-Standardize electronic health records
-Propose health-related cybersecurity standards
-Support interoperability with open exchange formats
-Provide the necessary infrastructure for Europe-wide access to health data
-Develop standards for quality and reliability
-Propose legislation setting the technical standards enabling citizen access and exchange of Electronic Health Records amongst EU Member States

-Other (please specify): Ensure that member states' health care regulations do not become an obstacle to data-driven health care. For example, hospitals should be able to test AI tools for use in treatment using real data prior to deploying them in direct care. A Directive may the most appropriate means of achieving this: full regulatory harmonization may be unworkable, given the diversity of European health-care systems.

MAKING USE OF PERSONAL DATA TO ADVANCE HEALTH RESEARCH, DISEASE PREVENTION, TREATMENT AND PERSONALIZED MEDICINE

The increasing amount of data on the health and lifestyle of individuals has the potential to advance research, improve disease management and support health policy, notably if exploited in a coordinated way across Europe and in compliance with EU data protection legislation.

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

For which purpose would you agree to make your health data available provided this is in compliance with data protection legislation? (Choose as many as you wish)

-Improving health care organization
-Improving clinical practice
-Improving social care organization
-For your own treatment
-Developing health insurance schemes
-Informing public health programs
-Supporting public health policy making
-Helping products development
-Helping developing countries' health care systems

If you share your health and/or lifestyle data for research, the following preconditions have to be ensured. (Choose as many as you wish)

-My data is secure and only accessible to authorized parties

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

-Yes

What would be the most important application areas?

Artificial intelligence and connected wearable devices are especially important. The latter generates valuable healthcare data, such as with regard to chronic health conditions, while the former adds a new layer of analysis to the information health-care practitioners collect.

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)?

-Agree

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

Remove regulatory barriers to data-driven health care, such member state rules that allow data sharing for direct care, but not for testing tools intended for direct care.[1]

Do you / Does your organization encounter barriers to using big data analytics for personalized medicine?

-No

PROMOTING UPTAKE OF DIGITAL INNOVATION TO SUPPORT INTERACTION BETWEEN CITIZENS AND HEALTH CARE PROVIDERS

This section looks at the current status of digital services in health and care. It also addresses the role that individual citizens, health and care providers, industry, public policy authorities and the EU can play in the improvement of disease prevention and treatment in Europe.

Do you currently have access to digital health services (e.g. remote monitoring, consultation with doctors or any other kind of service provided through digital means)?

-No

Would you like to have access to digital health services (e.g. remote monitoring, consultation with doctors or any other kind of service provided through digital means)?

-Yes

As a citizen, are you able to provide feedback to your health care provider on your treatment through electronic communication channels?

No

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.

Agree

Please describe other factors you consider essential or more important than citizen feedback in order to improve health and care services (e.g. statistics and other evidence collected by public authorities and insurers, research, public health initiatives, education, cost-efficiency, the sharing of best practices...).

Policymakers should ensure the availability of open data on the performance of hospitals and healthcare facilities. This data should include details such as whether the facility is using the latest data-driven tools to provide health care. Policymakers should also consider new pathways for approving data-driven medical innovations that have a faster development cycle than traditional interventions. The PreCert program at the U.S. Food and Drug Administration provides an example of an innovative attempt to rethink oversight of medical devices.[2]

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)?

-Provide support for knowledge transfer between member states and regions

-Support regions and municipalities in rolling out new services

-Support EU associations of patients and clinicians to improve clinical practices

-Support further research

-Promote common approaches for feedback mechanisms about quality of treatment

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1. Nick Wallace, "UK Regulations Need an Update to Make Way for Medical AI" (Center for Data Innovation, August 12, 2017), https://www.datainnovation.org/2017/08/uk-regulations-need-an-update-to-make-way-for-medical-ai/.

2. "PreCert Pilot Program - Frequently Asked Questions" (U.S. Food & Drug Administration, Last updated August 14, 2017), https://www.fda.gov/MedicalDevices/DigitalHealth/ucm570617.htm.