

The Consumer Voice in Europe

PUBLIC CONSULTATION ON TRANSFORMATION OF HEALTH AND CARE IN THE DIGITAL SINGLE MARKET

BEUC response to the public consultation



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Why it matters to consumers

Digitalisation has the potential to transform the way healthcare is provided. New health technologies and infrastructures can facilitate the production and exchange of health data that can benefit consumers and society as a whole.

Digital solutions can improve safety, quality and continuity of care. They can also help to make health care systems more efficient and more responsive to patients' needs. At the same time, the storage of sensitive health information in an electronic form poses many challenges to consumers privacy that need to be addressed.

Summary

On 20 July 2017 the European Commission launched a public consultation on transformation of health and care in the Digital Single Market. The consultation investigates the need for policy measures that will promote digital innovation for better health and care in Europe and feed into a Communication that is expected to be adopted by the end of 2017.

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.

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

Strongly agree ✓

Agree

Neither agree nor disagree

Disagree

Strongly disagree

2. 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 organisations – e.g. doctors, pharmacists, other service providers, family members, others).

Consumers should always be given the option to get access and manage their own health data. They should also have the possibility to delegate the management of these data to other persons such as a relative, a doctor and/or a pharmacist. A precise definition of "management" should be provided beforehand.

With regard to the type of information collected, we believe that consumers should have access to all data related to their health history. Due to new models of care and more specialisation, patients' information will be more and more shared between many health professionals and consumers should have assurance that what is indicated both about themselves (e.g. contact details) and their medical condition is correct. The patient is the one most concerned about the accuracy of the information and he/she the one who can verify that the information is fully correct.

To ensure that consumers have complete control over their own medical files they should have the option not only to view their record, but also, to add information under certain specific conditions - for example in a dedicated session, with a limited amount of characters available and without directly amending the (electronic) health record or deleting parts - in order not to raise liability issues. Health care professionals should take into account the consumers annotations and if relevant modify the content of the health records accordingly and timely. Moreover, consumers should be informed when the update has taken place. The owner of information should be informed every time a health care professional who is not the one who is directly treating him demands access to his or her file, and should be asked to give the authorisation to access to the whole file, or parts of the file, or no access at all before the information is accessed. According to the survey made by the Belgian consumer organization Test-Achat¹ 95% of the consumers interviewed expressed the

¹ Test-Sante, n.99, November 2010.

desire to view their own medical files. 89% of them believe that it is important to see who accessed their medical file and 74% said they want to be asked for the authorization before their record is shared with other health care professionals.

3. 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

Agree ✓

Neither agree nor disagree

Disagree

Strongly disagree

4. Comments on previous question?

With new drug development models some health data constitute what in jargon is defined as "Real World Evidence", as opposed to data obtained through clinical trials which are not necessarily representative of what will happen later on in real life. Therefore, data obtained from real patients in real clinical practice can offer a more accurate picture on how well new treatments perform.

Sharing data between healthcare services could also decrease health care expenses by decrease unnecessary duplication of diagnostic exams. Data availability could also increase safety by allowing detecting drug interactions and unnecessary drugs intake. However, these data should only be available to the treating physician and should only be used with the consent of their owners. A recent survey conducted by our Danish member Forbrugerrådet Tænk² showed that 73 % of consumers would like their data to be used for research, but 56 % would like be asked the permission beforehand.

Back in 2010 also our Portuguese member DECO conducted a study³ on e-health with consumers and doctors. With regard to the first group, consumers see this application as an advantage, as doctors could have more information that would allow them to provide a better diagnosis and a more safe/accurate prescription (e.g. in case of allergies). However, the risk of lack of privacy is very high among consumers. Also doctors in general believe that compiled health information is an advantage. In their views this would be an easier and faster channel to access patient information that could provide further functionalities (e.g. see the evolution of the patient through graphics and detect mental diseases). Doctors also believe that sharing data would allow a better diagnosis, avoid exams duplication and potentially harmful drug prescription. On line data would also be particularly useful in case the patient is unable to speak and/or express him/her self. Finally, sharing data would facilitate and improve communication among healthcare professionals.

² Forbruggerpanelet om patientdata, Juni 2017.

³ Teste Saúde nº84 April/May 2010, Tecnologias de informação.

5. What are the major barriers to electronic access to health data?

Risks of privacy breaches ✓

Legal restrictions in Member States ✓

Lack of infrastructure ✓

Cybersecurity risks ✓

Lack of awareness ✓

Lack of interest ✓

Others (if so, please specify) ✓

Other barriers include:

- *The low capacity in using new technologies, especially in the elderly population;*
- *Perceived risk of deleting information;*
- *Time consuming procedures;*
- *Lack of awareness.*

The barriers vary according to the EU country considered and the systems they have in place. For example, in Spain health care databases in the public health system have been designed to collect patient's information for administrative purposes, rather than clinical data.

According to the study conducted by DECO in 2010, risk of privacy breaches was among the main concerns for consumers, who fear the access of this information by insurance companies and employers. Another issue was related to the influence that the diagnosis of the first doctor could have on that of a second one. Information in the health record about lifestyle and social conditions were also seen as factors that could influence the treatment of the doctor.

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

Heterogeneity of electronic health records ✓

Risks of privacy breaches ✓

Legal restrictions in Member States ✓

Lack of infrastructure ✓

Cybersecurity risks ✓

Lack of technical interoperability ✓

Data quality and reliability ✓

Lack of awareness

Lack of interest

Others

Privacy is the number one concern with regard to the sharing of their data. A recent investigation conducted by the Norwegian Consumer Council⁴ on 22 health connected devices confirmed the risk when it comes to consumers' privacy. Among the findings, the results show that some of these devices transmit health data to companies outside Europe without notifying the users, while many others allow health data to be shared via email.

The investigation also notes that the terms of use for these services are long and indecipherable. For instance, it is unclear how personal data may be used, and all of the suppliers are free to amend their terms of use without notifying the user. Overall the investigation confirms that the standards of security for internet-connected healthcare products are often too low and that consumer privacy rights are being compromised.

Interoperability and different kind of electronic record and data quality are also barriers for its full use. In Spain for example 17 autonomous regions exist, each with their own health system and therefore their own electronic health database system. Even within the same

⁴ <https://fil.forbrukerradet.no/wp-content/uploads/2017/09/2017-09-06-report-privacy-eng.pdf>

region, primary and secondary care have different electronic health systems that make impossible the communication between databases. As a consequence, a Spanish consumer living in one region and moving to a different one has got to carry his own medical history with him/her as the electronic communication between the different health systems is currently impossible. Such fragmentation is even more apparent at European level, when consumers data are processed in a Member State which differs from that of consumers' residence.

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

The EU should:

- Standardise electronic health records ✓*
 - Propose health-related cybersecurity standards ✓*
 - Support interoperability with open exchange formats ✓*
 - Support health care professionals with common (EU-level) data aggregation ✓*
 - Support patient associations with common (EU-level) data aggregation ✓*
 - Provide the necessary infrastructure for Europe-wide access to health data ✓*
 - Develop standards for data quality and reliability ✓*
 - Increase awareness of rights on data access under European law ✓*
 - Focus on access in cross-border areas ✓*
 - Propose legislation setting the technical standards enabling citizen access and exchange of Electronic Health Records amongst EU Member States ✓*
- Other

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

8. 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

Agree ✓

Neither agree nor disagree

Disagree

Strongly disagree

9. 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 organisation* ✓
- Improving clinical practice* ✓
- Improving social care organisation* ✓
- For your own treatment* ✓
- Progressing research and innovation* ✓
- Developing health insurance schemes*
- Informing public health programmes* ✓
- Supporting public health policy making* ✓
- Helping products development* ✓
- Increasing efficiency of health and social care* ✓
- Helping developing countries' health care systems* ✓
- None of the above
- Other* ✓

Make available one's health data can be considered ethical as long as it serves the common good and benefits public health care systems and medical research. Additionally, the use of electronic records could function as a data source to gather and run observational studies which could improve knowledge about disease causes, prevention factors as well as drugs adverse effects.

10. 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 authorised parties* ✓
- My data is encrypted and cannot be traced back to me* ✓
- My data is only used in 'not for profit' activities* ✓
- My data is only shared between societies and institutes researching my disease area
- Other

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

- Yes
- No
- Do not know* ✓

12. 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
Agree
Neither agree nor disagree ✓
Disagree
Strongly disagree

13. 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?

It should ensure adequate budget not only to stimulate research but also to increase consumers' awareness. There is still a huge gap between scientific advancements and public knowledge about them.

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.

14. 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)?

Yes
No ✓
Do not know

The access varies depending on the country

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

Yes ✓
No
Do not know

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

Yes

No

Do not know ✓

Answers vary according to the countries. Moreover, this question addresses individual citizens and not organizations.

17. 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 ✓

Agree

Neither agree nor disagree

Disagree

Strongly disagree

18. 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...).

We believe that the following factors are essential:

- Quality indicators to measure quality of care and transparency;
- Publicly funded research on services, medication, medical devices and IT that bring real meaningful innovation to patients;
- Better coordination between the different types of care;
- Regular monitor of doctors and other healthcare professionals to ensure high quality work and their accountability to patients and authorities (e.g. mechanisms to examine malpractices should be put in place);
- Disinvestment policies in proven ineffective or inefficient health technologies, whose cost opportunity can be put back into the public health system to fund efficient health technologies.

19. 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 ✓

Other



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