COMITÉ PERMANENT DES MÉDECINS EUROPÉENS
STANDING COMMITTEE OF EUROPEAN DOCTORS

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On 10 October 2017, the CPME Executive Committee adopted the 'CPME response to public consultation on the transformation of health and care in the Digital Single Market ' (CPME 2017/058 FINAL)

CPME response to public consultation on the transformation of health and care in the Digital Single Market

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.

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CPME responses appear in blue font.

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.

29. 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

30. 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):

As a general comment, it was difficult to answer several questions of this consultation considering that the type of data and the context in which data are accessed/shared/managed are not defined.

Therefore, the following aspects should be clarified:

1. Which data is being accessed/shared/managed?
2. By whom/with whom is the data being accessed/shared? (See questions 31, 33 and 35)
3. Are the data anonymous or may the individual patient be identified?

Before the recording and/or sharing of personal health data, it is good practice to inform and asked patients for consent. If approaches vary from one EU country to another, some general principles should apply:

- Although consent can be presumed for the recording and sharing of information required for healthcare within the immediate healthcare team, it is good practice to obtain specific consent for this process, particularly in relation to sensitive information.
- Specific consent should be obtained for the sharing of information beyond the healthcare team, including for the creation and sharing of a patient summary.

While patients should be able to access their data, it should be noted professional documentation is in principle not subject to change. It should also be highlighted that some health professions, such as doctors, are bound by professional secrecy and are obliged by law to keep records (i.e. for liability reasons). Nevertheless, when technically feasible, patients can request access and ask for changes.

31. 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

32. Comments on previous question:

In general, cross-border data exchange should not be an end in itself. The benefit of any data exchange for patients should be defined first, and depending on that, it should be defined which data, in which format, is shared with whom and at what point of time.

More specifically, research using big data can help improving the quality and effectiveness of diagnostic and therapeutic interventions as well as widening possibilities for diseases prevention and fostering the understanding of diseases. However, research opportunities opened by the use of health data should not hide the ethical challenges surrounding the reuse of personal health data for a purpose which is different

from the one for which the person has explicitly provided its consent. Ethical guidelines are needed to ensure that personal health data are used for a meaningful purpose in a manner which is scientifically sound and ethically acceptable.
To that end, European doctors consider that the WMA declaration of Taipei on ethical considerations regarding health databases and biobanks provides the necessary safeguards.

33. 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

34. Please specify:

The question is not specific enough (please see our general comment under question 30)

35. 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+9
- ☐ Lack of awareness
- ☐ Lack of interest
- ☐ Others

36. Please specify:

Again, the question is not specific enough (please see our general comment under question 30)

37. 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

38. Please specify: With increasing provision of cross-border healthcare services, it is important to address interoperability issues at EU level to reduce fragmentation. Nevertheless, the aim should not only be technical interoperability, but also the maintenance of the highest possible standards of usability and, most crucially, data protection and confidentiality. In addition, a reflexion should be undertaken on specific cybersecurity measures required in the healthcare sector in order to prevent hacking of IT systems.

Finally, the cross-border processing of data (i.e. for public health research) requires standards on data quality and reliability to be defined.

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.

39. 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

40. 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 : N/A

41. Please specify: If research using health data has the potential to increase knowledge for the benefit of society, it is equally important to guarantee patients' autonomy and their right to self-determination. Citizens/patients must give their consent on the way their personal data are used.

42. 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

43. Please specify:

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

✓ Yes

☐ No

Do not know

45. What would be the most important application areas? See question 32

46. 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

47. 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?

There is a need to ensure consistency in the implementation of the General Data Protection Regulation (GDPR) and especially its articles 5 and 89 - in relation with recital 156 - on the processing of health data for secondary purposes. Differing approaches from Member States, including national derogations or safeguards, would lead to legal uncertainty and challenge for cross-border research.

In addition, the Commission should support the development of code of conduct, pursuant to Article 40, to ensure the proper application of the GDPR, and a high level of protection of personal health data.

48. Do you / Does your organisation encounter barriers to using big data analytics for personalised medicine?

☐ Yes

☐ No

✓ Do not know

49. Please explain what prevents the use of big data analytics: N/A

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.

50. 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

N/A

51. 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

☐ No

☐ Do not know

N/A

52. 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

N/A

53. 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

54. 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…).

Several international investigations have shown the need to reduce the number of adverse events in the healthcare sector. In this context, the exchange of information, knowledge and best practices at EU level on the prevention and reduction of adverse events in the healthcare sector should be pursued (see CPME policies on patient safety and quality of care which are accessible here).

55. 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

56. Please specify