CPME/AD/EC/09072020/059_Final/EN

On 9 July 2020, the CPME Executive Committee adopted the 'CPME response to the EUHealthSupport Stakeholder Survey' (CPME 2020/059 FINAL).

CPME response to the EUHealthSupport Consortium on
Stakeholder Survey Assessing Member States' Rules on Health Data in light of the GDPR

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Stakeholder Survey EUHealthSupport

Fields marked with * are mandatory.

Survey assessing the Member States' rules on health data in the light of GDPR

Deadline extension: to allow audiences to respond and share the survey within their networks, the deadline for responses to the survey has been extended till Thursday 9 July 2020 midnight.

The European Commission has initiated a study that aims to examine in which manners the processing of personal health date is governed across the EU and how this might affect the cross-border exchange of health data in the EU.

The present survey is targeted at experts and organisations representing the wide range of stakeholders, including patients, care providers and researchers. Objective of the survey is to identify gaps and needs concerning the use of health data within the EU, the manner in which citizens have control over their health data and to explore strategies and governance structures for the use and re-use of health data.

The survey, among others, seeks your opinion in what areas EU level action might be needed in order to govern the processing of health data across the EU. It also contains a series of statements on data sharing for different types of use, as described below:

- Data processing for the purposes of **provision of health and social care** by health and care providers to the patient concerned. This includes both in-person care and telecare using eHealth or mHealth tools.
- Data processing for **wider public health purposes** including planning, management, administration and improvement of health and care systems; prevention or control of communicable diseases; protection against serious threats to health and ensuring high standards of quality and safety of healthcare and of medical products and medical devices.
- Data processing for **scientific or historical research** by both public and private sector organisations (third parties, not being the original data controller), including the pharmaceutical and medical technology industries and insurance providers.

Results of the study will be used in a report to be submitted to the European Commission in the summer of 2020.

Note. As some questions may require more information about existing legislation or procedures, it is

possible to skip any questions you wish, or to respond 'don't know.

Thank you for your contributions to this study

On behalf of the EUHealthSupport team,

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Section A: Questions about your background when providing answers

The following questions are mandatory to be able to interpret the results of the survey. To guarantee your anonymity we will only report on each of these questions separately. Hence, while we may report how respondents from public bodies perceive the issues or respondents from specific countries, the combination of both will in no way be revealed.

* 1. Please indicate the membership your organisation represents, if any (tap on the box below to choose your answer):

Health professional

Health professionals category:

- [ ] Nurses
- [x] Generalist doctors
- [x] Specialist doctors
- [ ] All
- [ ] Other

* 2. Please indicate the geographical level you or your organisation represents

EU / Multiple European countries

* 3. I live in the following country:

Belgium

Section B: Sharing health related data for the purpose of providing care

In order to provide healthcare to patients, healthcare professional require access to data collected by other healthcare professionals both within their country and in other countries where the patient might have received or want to receive care. This is referred to as data processing for the **primary purpose for which data were collected.**

4. Do you agree or disagree with the following statements, all related to the way in which such data sharing for providing care is possible and how it could be improved? *Note: If the statement concerns 'my country' and you are answering at an EU or international level, please answer for the country in which you currently live. It is also possible to skip a question.*

Data portability allows data subjects to receive personal data they provided to a controller in a structured, commonly used and machine-readable format and to transmit those data to another controller.

Interoperability refers to the ability of different information systems, devices and applications to access, exchange, integrate and cooperatively use data in a coordinated manner, within and across organizational, regional and national boundaries.

	Completely disagree	Slightly disagree	Neutral	Slightly agree	Completely agree	Don't know
It is easy for a patient to access his or her medical record **in my country**	○	○	○	○	○	◉
It is easy for a patient **in my country** to obtain a portable copy of their medical record to take to another healthcare provider in the same country	○	○	○	○	○	◉
It is easy for a patient to obtain a portable copy of their medical record to take to another healthcare provider in **a different EU country**	○	○	○	○	○	◉
The medical records in my country are structured around the patient (e.g as personal data space or patient portal)	○	○	○	○	○	◉
Having health data in a personal data space /patient portal facilitates the transfers between healthcare providers	○	○	○	◉	○	○
Lack of data portability **drives up costs** through repeat testing and examination	○	○	○	○	◉	○
Lack of data portability **slows down time** to diagnosis and treatment	○	○	○	◉	○	○

Lack of data portability **increases the risk of errors**	○	○	○	◉	○	○
Lack of data portability can **limit the rights** of Europeans to seek care in another EU country	○	○	◉	○	○	○
Lack to data portability can **limit the rights** to Europeans to work or go on holiday in another EU country	○	○	◉	○	○	○
Sharing of data for care provision purposes **within my country** is very difficult because of low levels of interoperability between health record systems	○	○	○	○	○	◉
Sharing of data for care provision purposes **with another EU country** is very difficult because of low levels of interoperability between health record systems	○	○	○	○	◉	○
Sharing of data for care provision purposes **within my country** is a major privacy risk because of insufficient security measures (including cloud security)	○	○	○	○	○	◉
Sharing of data for care provision purposes **with another EU country** is a major privacy risk because of insufficient security measures (including cloud security)	○	○	○	◉	○	○
The use of different legal bases (e.g. consent, provision of care, public interest) make it difficult for health-related data to be **shared for care purposes** between EU countries	○	○	○	○	○	◉

Additional measures should be taken at **national level** to enforce patients' access and control over their own health data and portability of this data	○	○	○	○	○	◉
Additional measures should be taken at **EU level** to enforce patients' access and control over their own health data and portability of this data	○	○	○	◉	○	○

5. Would you like to provide further details on data sharing for providing care and control of patients over their own data? E.g., what types of actions are needed to improve, with particular focus on health data sharing at EU level?

Section C: Data processing for scientific or historical research

Health data collected for the primary purpose of providing care are sometimes used for the **secondary purpose of scientific (or historical) research**. This includes research undertaken by public or private sector organisations, including the pharmaceutical and medical technology industries and insurance providers.

6. Do you agree or disagree with the following statements, all related to the way in which such data sharing for scientific research is possible and how it could be improved? *Note: If the statement concerns 'my country' and you are answering at an EU or international level, please answer for the country in which you currently live. It is also possible to skip a question.*

	Completely disagree	Slightly disagree	Neutral	Slightly agree	Completely agree	Don't know
It is easy to gain access to health data for researchers working in the **public domain** in my country	○	○	○	○	○	◉
It is easy to gain access to health data for research for researchers working **in not-for-profit or academic entities** in my country	○	○	○	○	○	◉

It is easy to gain access to health data for research by **commercial entities** in my country	○	○	○	○	○	◉
It is easy to gain access to health data for research by **industry (pharma, medical devices, Artificial Intelligence)** in my country	○	○	○	○	○	◉
The current data protection rules in my country make **data access for research** purposes difficult	○	○	○	○	○	◉
The current data protection rules in my country **do not adequately protect** the interest of patients	○	○	○	○	○	◉
The **time and interaction costs** of gaining access to health data for research are high in my country	○	○	○	○	○	◉
The **financial costs** of gaining access to health data for research are high in my country	○	○	○	○	○	◉
Different rules for access to data for research purposes for **public sector and private sector** researchers should apply in my country	◉	○	○	○	○	○
Different rules for access to data for research purposes for **public sector and private sector researchers** should apply in my country	◉	○	○	○	○	○
There is a need for an **EU level** regulatory and organisational landscape for using health data for research	○	○	○	○	◉	○

A system to allow patients to make data available for research without reference to a particular research project (also known as data altruism) **should exist in my country**	○	○	◉	○	○	○
A system to allow patients to make data available for research without reference to a particular research project (also known as data altruism) **should exist in my country**	○	○	◉	○	○	○
A system to allow patients to make data available for research without reference to a particular research project (also known as data altruism) **should exist at EU level**	○	○	◉	○	○	○
Rules **in my country** make access to data for research organisations unnecessary complex	○	○	○	○	○	◉
EU rules make access to data for research organisations unnecessary complex	○	○	◉	○	○	○
The current **national rules** are outdated, given new developments such as personalized medicine, Artificial Intelligence etc.	○	○	○	◉	○	○
The current **EU rules** are outdated, given new developments such as personalized medicine, Artificial Intelligence etc.	○	○	○	◉	○	○
A single point of contact for the use of health data for research should be supported **in my country**	○	○	○	○	○	◉

Single points of contact should be set up in **all Member States**, making access to health data for research much simpler	○	○	○	◉	○	○
All single points of contact should be **linked at EU level**, to support pan-European research	○	○	○	◉	○	○
One single point of contact should also be set up **at EU level**, in addition to national ones	○	○	○	◉	○	○

7. Would you like to provide further details on data sharing and control of patients over their own data for scientific research? E.g., what types of actions are needed to improve, with particular focus on health data sharing at EU level?

Th Standing Committee of European Doctors (CPME) believes that the same rules for access to data for research purposes should apply for public and private sector, and this throughout Europe.

Section D: Sharing data for the public health purposes of ensuring a safe healthcare system

Health data originally collected for the primary purpose of providing care are sometimes used for wider public health purposes, being:

1. Supporting health care system planning, the planning, management, administration and improvement of health and care systems.
2. Ensuring high standards of quality and safety of healthcare and of medical products and medical devices.
3. The prevention or control of communicable diseases and the protection against serious (cross-border) health threats.

Questions below address all of these three functions.

8. Do you agree or disagree with the following statements, all related to the way in which data sharing is possible for the above mentioned wider public health purposes? *Note. If the statement concerns 'my country' and you are answering at an EU or international level, please answer for the country in which you currently live.*

	Completely disagree	Slightly disagree	Neutral	Slightly agree	Completely agree	Don't know
It is easy **for the concerned professionals** to gain access to health data for public health planning, quality and prevention purposes in my country	○	○	○	○	○	◉
Data access **for public health purposes** is difficult because data sets are scattered over many different providers in my country	○	○	○	○	○	◉
Use of data for **national level** public health purposes is difficult because data are not comparable between different data sets	○	○	○	○	◉	○
Use of data for **cross-border** public health purposes is difficult because data are not comparable between different data sets	○	○	○	○	◉	○
The use of **different legal bases** (eg consent, provision of care, public interest) makes it difficult for health-related data to be shared for public health purposes between EU countries	○	○	○	○	○	◉
Different **interpretations of whether data are considered anonymised or pseudonymised** make it difficult for health-related data to be shared for public health purposes between EU countries	○	○	○	○	◉	○
Epidemiological institutions should have easier and direct access to health data, in order to ensure their task	○	○	◉	○	○	○
Medicine agencies, notified bodies for medical devices or Health Technology Assessment bodies should have easier and direct access to health data, in order to ensure their task	○	○	◉	○	○	○

Governance structures, data permit authorities, or single points of contact should ensure that **public bodies** are allowed to have easier and direct access to health data	○	○	○	◉	○	○

9. Would you like to provide further details on data sharing for one or more of the following types of public health purposes?

9.a. The purpose of supporting health care system planning, the planning, management, administration and improvement of health and care systems.

9.b.The purpose of ensuring high standards of quality and safety of healthcare and of medical products and medical devices.

9.c. The purpose of prevention or control of communicable diseases and the protection against serious (cross-border) health threats.

Section E – Potential EU Level Action

At present, EU level legislation on data use for function 2 or 3 (secondary use) is governed by a combination of the GDPR and national level legislation foreseen in the GDPR to address issues such as the use of data for the purposes of healthcare provision (provided for in Article 9(2)(h)) or in the public interest (provided for in Article 9(2)(i)) or for scientific research (provided for in Article 9(2)(j)). The European Commission's Data Strategy envisions a European Health Data Space which may demand a range of actions at EU level.

10. The statements below represent some of the potential actions that may be taken for the use of health data for healthcare, but also for policy making and research. Please indicate the extent to which you agree or disagree with the potential actions.

EU level action should be taken to..

	Completely disagree	Slightly disagree	Neutral	Slightly agree	Completely agree	Don't know
Increase awareness of citizens rights on **data access** to their medical health records/health data under GDPR	○	○	○	○	◉	○
Increase awareness of citizens' rights on **data portability** under GDPR (being able to transfer one's personal data to another controller)	○	○	○	○	◉	○
Support Member States to reinforce **citizens' access, portability and control** over their health data, for example by guidance or legislation	○	○	○	○	◉	○
Support Member States' healthcare providers to ensure the transfer of health data **between different healthcare providers** and at the request of patients, this to allow patients to provide their health data only once, for example by guidance or legislation	○	○	○	○	○	◉
Support Member States to set up **personal data spaces** or patients' portals centred around patients, for example by guidance or legislation	○	○	◉	○	○	○
Support Member State to put in place structures **allowing for secondary use** of health data for policy making and research, for example by guidance or legislation	○	○	◉	○	○	○
Support Member States to set up **governance structures** for managing data available for research without a reference to a particular research project (data altruism), for example by guidance or legislation	○	○	○	◉	○	○
Set up **governance structures at EU level** for managing data available for research without a reference to a particular research project (data altruism)	○	○	○	◉	○	○

Support the processing of health data by **epidemiological institutions** for the protection against serious cross-border health threats, for example by guidance or legislation	○	○	○	○	◉	○
Support the processing of health data by **medicine agencies, notified bodies for medical devices or Health Technology Assessment bodies** for ensuring high standards of quality and safety of health care and of medicinal products or medical devices, for example by guidance or legislation	○	○	○	○	◉	○
Support the processing of health data for **scientific or historical research or statistical purposes**, for example by guidance or legislation	○	○	◉	○	○	○
Support the processing of health data by **industry (pharmaceutical, medical devices, Artificial Intelligence)** to health data, for example by guidance or legislation	○	○	◉	○	○	○
Set up **governance structures** to support such processing of health data by industry (pharmaceutical, medical devices, Artificial Intelligence)	○	○	○	◉	○	○
Promote the use of the **same legal base** of sharing health data for research purposes	○	○	○	◉	○	○
Provide EU level guidance on **obtaining consent** from patients for sharing data	○	○	○	○	◉	○
Provide EU level guidance on **anonymising/pseudonymising** health data	○	○	○	○	◉	○
Support **interoperability** through the use of open exchange formats / interoperability agreements, for example by guidance or legislation	○	○	○	◉	○	○
Promote **data quality and reliability** through the use of standards	○	○	○	◉	○	○
Promote **data security** through the use of standards health-related cybersecurity standards	○	○	○	○	◉	○
Develop **minimum datasets** for data exchange	○	○	○	○	◉	○

10a. If you would like to propose any other action to be taken at EU level, you can specify this below:

11. How do you think the EU should organise health data sharing for secondary purposes at EU level? *Multiple answers are possible.*

- [x] Non-legislative policy guidance documents
- [x] A set of common rules, put together in a Code of Conduct (soft law)
- [x] New health data specific European level law
- [ ] A structure linking all existing health data of different countries to each other
- [ ] Setting up structures at national level intermediating access to health data (one entry point/data permit authority)
- [ ] A network of Member States representatives, structured along two pillars: use of health data for research and policy making, alongside another pillar aimed at use of data for healthcare
- [ ] A structure intermediating access to health data e.g. a body where a request for access to existing health data can be put forward and managed
- [x] A structure managing data available for research without a reference to a particular research project (data altruism)
- [ ] An EU agency for e-health and health data
- [x] A structure managing the health data based on consent of the patients
- [ ] Set up a network of data permit authorities/one entry points at EU level
- [ ] None of these options, the current set of rules and regulations is sufficient
- [ ] None of these options, I don’t see the value of a common model for health data sharing
- [ ] Other, please specify

12. Who do you think should be involved in setting up regulations for the secondary use of data at European level? *Multiple answers are possible.*

	Completely disagree	Slightly disagree	Neutral	Slightly agree	Completely agree	Don't know
Patients/patient representatives	○	○	○	○	◉	○
Researchers in the area of public health	○	○	○	○	◉	○
National statistics offices	○	○	○	◉	○	○
International statistics offices (such as Eurostat, WHO, OECD)	○	○	○	○	◉	○
(Representatives of) healthcare professionals	○	○	○	○	◉	○
Regulators (medicine agencies, Health Technology Assessment and notified bodies, etc.)	○	○	○	○	◉	○
Data protection authorities	○	○	○	○	◉	○
National policy makers	○	○	○	◉	○	○
EU policy makers	○	○	○	○	◉	○
Public bodies ensuring the prevention of diseases (such as centres for disease control, national health institutes, institutes monitoring infectious diseases)	○	○	○	○	◉	○
Biobanks	○	○	○	○	◉	○
Commercial parties, such as pharmaceutical industry, manufacturers of wearables, tech industry, insurers	○	○	◉	○	○	○

12a. If other than the above, please specify:

13. If an EU level data sharing infrastructure for secondary purposes were set up, what functions should it have?

	Completely disagree	Slightly disagree	Neutral	Slightly agree	Completely agree	Don't know
A structure linking all existing health data of different countries to each other	○	○	○	◉	○	○
A structure linking the one entry points/data permit authorities of different countries, other research infrastructures and data sources and EU institutions /agencies	○	○	○	◉	○	○
A structure intermediating access to health data e.g. a body where a request for access to existing health data can be put forward and managed	○	○	○	○	◉	○
A structure managing the health data based on consent of the patients	○	○	○	○	◉	○
None of these options, the current set of rules and regulations is sufficient	○	○	○	○	○	○
None of these options, I don’t see the value of a common model for health data sharing	○	○	○	○	○	○

14. If an EU level data sharing infrastructure were set up, how should it be organised? *Multiple answers are possible.*

	Completely disagree	Slightly disagree	Neutral	Slightly agree	Completely agree	Don't know
A voluntary network, for both primary and secondary use of health data	○	○	○	○	◉	○
Two voluntary networks, one for primary use and one for secondary use of health data with some common activities	○	◉	○	○	○	○
A form of public-private partnership	◉	○	○	○	○	○
An EU committee	○	○	◉	○	○	○
An EU agency	○	○	◉	○	○	○
None of these options, because in my view this should not be set up at EU level	◉	○	○	○	○	○

14a. If other than the above, please specify:

15. If an EU level data sharing infrastructure were set up, how should its governance/rules be assured? *Multiple answers are possible.*

	Completely disagree	Slightly disagree	Neutral	Slightly agree	Completely agree	Don't know
A code of conduct put together by representatives of all relevant national authorities	○	○	○	○	◉	○
A code of conduct put together by a board of stakeholders	○	○	○	○	◉	○
EU level legislation	○	○	○	◉	○	○
Other	○	○	○	○	○	○

15a. If other than the above, please specify:

16. The COVID-19 pandemic has demonstrated that access to data for responding to communicable disease outbreaks is very important. To be able to respond better to such situations in the future the EU should take action to:

	Completely disagree	Slightly disagree	Neutral	Slightly agree	Completely agree	Don't know
Ensure that pseudonymised health data on affected citizens can be shared with public health authorities without consent on the basis of public health need for public health purposes	◉	○	○	○	○	○
Ensure that only non-identifiable health data on affected citizens can be shared for relevant public health purposes with public health authorities	○	○	○	○	◉	○
Facilitate reporting of pseudonymised data of national and regional public health laboratories directly to ECDC without going through a reporting cascade	○	◉	○	○	○	○
Facilitate direct reporting of national and regional public health authorities to public health institutions dealing with epidemiological aspects, without going through a reporting cascade	○	○	○	◉	○	○
Set up a system at EU level to allow patients to make data available for research without reference to a particular research project (also known as data altruism)	○	○	○	◉	○	○
Set up an EU level governance managing the data altruism	○	○	◉	○	○	○
Such a data altruism system should also be used for pandemics	○	○	◉	○	○	○

Thank you for completing our questionnaire.

If you would like to receive information about the results of the study, we kindly ask you to send a message to contact@euhealthsupport.eu

In case of any comments or suggestions, we would be grateful if you could fill them in here

Contact

contact@euhealthsupport.eu