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

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Research for better care

Against a background of the European Health Data Space

*"We need to make the most of the potential of **e-health** to provide high-quality healthcare and reduce inequalities. I want you to work on the creation of a **European Health Data Space** to promote health-data exchange and support research on new preventive strategies, as well as on treatments, medicines, medical devices and outcomes. As part of this, you should ensure citizens have control over their own personal data."*

President-elect von der Leyen's mission Letter, 10 September 2019

- Are there differences between MS with regards to interpretation of GDPR on health data processing?
- How does this affect cross-border exchange of health data in the EU?

- Is there appetite for the development of new rules and governance systems at EU level to ensure the safe functioning of the EHDS?

Three data processing functions

- Function 1: Data processing for the purposes of **provision of health and social care** by health and care providers to the patient concerned.

- Function 2: Data processing for **wider public health purposes** including planning, management, administration and improvement of health and care systems, prevention or control of communicable diseases and more.

- Function 3: Data processing for **scientific or historical research by both public and private sector organisations.**

Fragmentation of GDPR

- Some MS have one unified piece of legislation, some MS have multiple laws addressing specific medical areas
- Many national laws on the use of health data predated the GDPR, and have additional restrictions to the use of health data
  - Explicit example: age of consent without parental approval (Art. 8(1) GDPR states from the age of 16)

- Health data exchange is a challenge on a legal and operational level.
  - The use of different legal basis (consent, provision of care, public interest) complicate the sharing of health data for care purposes between MS
  - The use of different EHR systems between and within MS pose challenges on technical interoperability of health data

Data processing for scientific or historical research

- Art 89 GDPR: Processing shall be subject to **appropriate safeguards** for the rights and freedoms of the data subject. […] Where personal data are processed for scientific or historical research purposes or statistical purposes, **Union or Member State law may provide for derogations** from the rights referred to in Articles 15, 16, 18 and 21 subject to the conditions and safeguards referred to in paragraph 1. […]

- Most relevant safeguard: pseudonymisation
  - MS have different interpretation on when data is considered pseudonymised.
- The interplay of data protection and the ethical requirements for research
  - Differences among MS ethical requirements could hamper EU collaboration

Data processing for scientific or historical research

- Differences between public and private sector research

- FAIRness data (Findable, Accessible, Interoperable, Reusable)
  - FAIR principles are not always specified in law but are supported in other ways

- Understanding consent can vary across MS
  - GDPR refers to consent as explicit consent, but there is also informed consent based in national law

- Some MS are working on national institutions to facilitate the use of health data for research

FINDATA

The new authority Findata

One-stop shop for the secondary use of social and health data

- **Grants data permits** when data are requested from multiple registers
- **Collects and links the data**
- **Provides the data** in a secure IT-environment for data users
- **Help Desk** for data users

FINDATA

Goals

- **Enable** effective and safe processing and access to data
- **Enhance** data protection and security
- **Eliminate** overlapping administrative burden
- **Improve** register data quality

FINDATA

Trust is a must.

- A secure remote use environment for individual level data sets
- Data sets are only available without individual's direct identifiers
- Compliance with the Act will be supervised by the Data Protection Ombudsman, Valvira and Findata
- Security in the operating environment will be controlled by an information security inspection body and Valvira

Source: "Implementation of the national Social and Health Data permit authority Findata", Johanna Seppänen 11-2019

SITRA

HEALTH DATA HUB

Our vision.

Ensure a simple, unified, transparent and secure access to health data to improve the quality of care and patient support.

Rights of patients

- Art. 15: Right to access health data
- Art. 16: Right to rectification
- Art. 17: Right to be forgotten
- Art. 18: Right to rectification
- Art. 20: Right to data portability

Take home message

- Though the aim of the GDPR was to harmonize data governance accross the EU, there is variation in interpretation of the law
  - Many MS embedded GDPR concepts within their existing national legislation, and provide extra conditions to the use of health data
- GDPR interpretation and additional national legislation is complex for researchers to navigate through
- Patients do not find it easy to exercise the rights granted by GDPR

Health data could be a rich source of information

- As the current legislative landscape is complex for researchers, a Code of Conduct could support researchers in using health data
  - It should include the perspectives and needs of various stakeholders
- Future international actions should be supportive of how health systems are organized in different MS

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Thank you!

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