HEALTH DATA TALK SERIES:

Opting-out from secondary use of personal electronic health data within the European Health Data Space

WHAT IS IT ABOUT?

The European Health Data Space (EHDS) aims to unlock the value of health data to the benefit of society whilst safeguarding the privacy of citizens. Therefore, the EHDS imposes an "opt-out" which is the right for citizens to opt-out for certain goals from the secondary use of their personal electronic health data within the EHDS framework.

SITUATION AS IS

Today, it is allowed to process sensitive data such as health data for research purposes under the General Data Protection Regulation (GDPR) when taking into account several conditions. These conditions consist of anonymization[1] or pseudonymisation[2] of the data, having a legal basis (for instance, explicit consent, public interest, or the legitimate interests of the entity using the data), informing the data subject, etc. The GDPR rules are established to create clear terms of use for the secondary use of personal data (including health data).

WHY IS AN "OPT-OUT" IMPORTANT?

The EHDS includes another layer on top of the GDPR rules (a posteriori), which is the right to opt-out from the secondary use of data for certain goals (a priori). The EHDS is a "lex specialis" compared to the GDPR, meaning that health data to be used for goals for which an opt-out has been enabled by a person under de EHDS, can also not be used under the GDPR. The reasoning is to empower citizens by giving them control over their personal data and to create transparency and trust in usage of health data for policy support, statistics and research. Pursuing this important aim is necessary to unlock health data for research, although by using opt-out there are also some pitfalls to take into account.

A first pitfall is of course the one of **data bias**. If, for example, data subjects from a certain age group choose to opt out, the data's representativeness becomes skewed, leading to an underestimation of that age group. As a result, any conclusions drawn from analysing this data may not be reliable or accurate.

Secondly, member states can provide their own opt-out mechanisms or include additional restrictions such as an opt-in from citizens for 4 types of health data (namely genetic, certain human molecular data, biobank, wellness app). Member states can also restrict the opt-out option for certain purposes like public interest, public health matters, scientific research of statistics publicly funded. This freedom of application undermines the goal of the EHDS to bring **harmonisation** in the secondary use of data in Europe.

HOW TO GET TO AN OPTIMAL OPT-OUT FOR SECONDARY USE OF HEALTH DATA?

To allow the opt-out for goals to function at its best for data holders and patients, these are recommendations the member states and the European Commission, during the implementation phase of the EHDS regulation, should take into account:

- Avoid fragmentation: **Standardisation and harmonisation** of opt-out modalities should be key priorities. If not, all stakeholders, notably patients and data holders, will face significant challenges in navigating opt-out systems that vary across different Member States.
- Member States not to introduce even stricter rules (e.g. opt-in) for certain categories of data sharing under the EHDS. Such a requirement would only increase fragmentation in the European Union and would significantly affect the availability and representativeness of the data and as a consequence research opportunities.

1 Data can be considered as anonymous or anonymized, only when it is not possible to "single-out" individuals with the data provided and when the applied mechanisms to anonymise are irreversible. anonymous data is not identifiable data from the start, while anonymized data is data initially identifiable but for which a process has been put in place to make it not identifiable anymore (GDRP: art. 4(5)).

2 Pseudonymisation means processing research data in such a way that they can no longer be attributed to a specific person without the use of additional information like a coding key. This usually involves replacing identifiers from the data with a pseudonym (GDRP: art. 4(5)).

- Strong recommendation to add **information about the percentage of opt-outs** for each goal to data users to assess how representative the data is and how suitable for the research question.
- At this moment there are no current initiatives to add additional restrictions for secondary use of the 4 health data types in Belgium for which additional restrictions can be enabled.
- The opt-out mechanism should **not be a disproportionate burden** on the stakeholders (data holders, clinician, data scientist in hospitals, patients) involved, notably the healthcare system.

Secondary use of health data is an opportunity for Belgium to increase competitiveness in health(care) research. Leveraging this potential should be beneficial for people's health and wellbeing and have a positive impact on the outcome and organisation of healthcare systems.

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