

Citizen participation in the secondary use of health data

What if citizen values were the foundation for secondary use of health data? It would be evident that secondary use is for the common good, there would be less need for individual consent mechanisms and there would be societal pressure against data silos.

HEALTH DATA CULTURE

The establishment of the Belgian Health Data Agency (HDA) and the new European Health Data Space (EHDS) framework provide an opportunity to build a new health data culture based on solidarity and transparency. It is paramount that this culture is based on the values of citizens and patients: they are both the source of health data and their improved wellbeing and health is the end goal of its secondary use.

There will never be a one-size-fits all model for citizen participation in secondary use of health data. Perfection will lay in continuous dialogue and evolution, based on the establishment of a toolkit approach to tackle wicked problems. These are problems that don't have one perfect solution, but require balancing the rights, needs and preferences of different stakeholders to move forward. For example, how to balance privacy protection and scientific progress in the secondary use of health data.

WHY SHOULD CITIZENS BE INVOLVED IN THE SECONDARY USE OF THEIR HEALTH DATA?

1. Secondary health data use is part of our **societal heritage**. As a consequence a robust ethical framework should be defined at the **societal level**, it is not appropriate to lean solely on individual consent.



2. The **justification** for secondary use of health data is **utility and purpose**. Hence, these purposes should be defined and managed in a transparent manner, over the continuum of research, prevention, care, ... in line with societal values.



3. These secondary health data sets would not exist without the contribution of data from **individual citizens**. We should respect these contributions by using them for purposes that are proposed and supported by citizens.



4. The principles and rights constituting the foundation of the ethical, legal and societal implications (**ELSI framework**) for secondary use of health data require constant specification in light of changing societal values and evolving technologies. This framework should be further reinforced on the substrate of responsible research and innovation (RRI) tools and principles (for example: **8 guiding principles for caring technology**). These ethical frameworks for secondary use of health data should continuously be co-created.



5. Citizen engagement is required to maintain – in an ethical way – willingness in the population to produce a **critical mass** of data to inform true evidence-based **healthcare policy** making. This is the fertile substrate that should define how we look at the world, how we build true knowledge to improve it.



6. **Trust** is earned through the development of shared values in a relationship. Health data governance based on trust requires clear communication, transparency and continuous citizen engagement to foster it.



HOW SHOULD CITIZENS BE ENGAGED AND INVOLVED?

1. Consent

The purpose of consent is to inform citizens about the use of health data and to respect their rights. It should not be a barrier to the secondary use of health data. A trustworthy practice of secondary use of health data with good citizen engagement on a societal level can provide a legal and ethical foundation, limiting the importance of consent.



2. Societal debate

a prerequisite for engagement and involvement of citizens and society at large is to embed awareness and education on the use of health data, digital literacy, health literacy (at individual and organizational level), throughout the life course of individuals. For example, (health) data literacy should be part of the high school curriculum and omnipresent in a data culture oriented to the public (e.g. in care organizations). Information should be available structurally, at a low level and visible during organized and recurrent campaigns.



3. Structural deliberation

The HDA should foster a culture of listening and dialogue. It can organize various periodic public engagement initiatives, aimed at different audiences, focusing on specific topics. This toolkit approach will improve the diversity of input and the richness of deliberation.



4. Validated policy output

A clear trace of what is done with citizen engagement outcomes will empower the participants and safeguard societal trust even when citizen recommendations are not fully implemented.



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