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WHY SHOULD WE CARE ABOUT THE EUROPEAN HEALTH DATA SPACE REGULATION?

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Public interest versus individual rights and interests

Making health data more accessible (also across borders) has several **advantages**

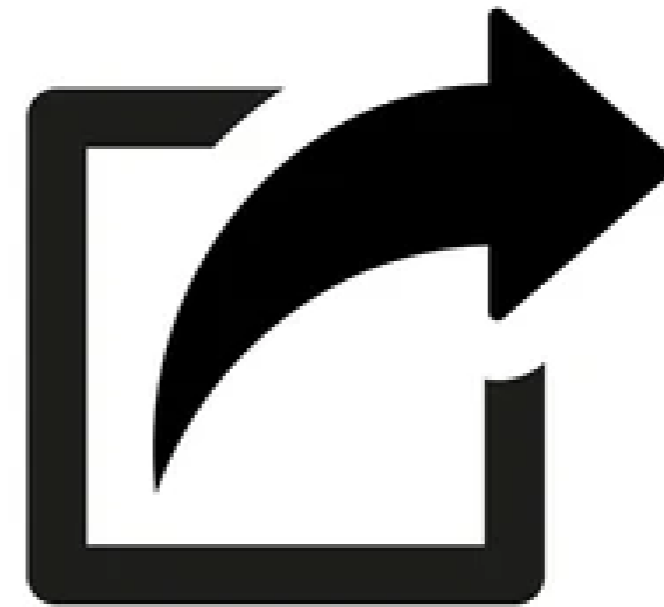
- For the patient whose data is shared: better informed and coordinated healthcare provision, less unnecessary testing, access to prescriptions abroad,...
- For future patients: big data research and better health risk assessments will lead towards predictive/preventive/personalized medicine

BUT: There are **concerns** over privacy, confidentiality, disenfranchisement, stigma and other types of harm to data contributors

Additional difficulty: **power asymmetry** between data subject and data collector

Public interest versus individual rights and interests

So should I put my electronic health data in a private vault, or share it as much as possible?



Public interest versus individual rights and interests

2 responses:

- We need to put the citizen back in charge of their data (cf GDPR).
- We need oversight mechanisms, data stewardship.



Individual control versus collective control



Individual control

- Property rights (data ownership) or civil rights
- Strong consent requirements
- Empowerment (/autonomy), fairness
- Individual responsibility
- E.g. platforms that enable data trading by patients

Collective control

- Data commons, data altruism; several actors have interests – and therefore claims – in health data
- Consent is neither a sufficient nor necessary condition
- Protection, fairness, balancing harm and wellbeing
- Collective responsibility



Individual control versus collective control

Problems related to individual control of health data

- Is individual control more likely to prevent privacy breaches? Individual citizens might be ill-placed to judge whether there is a danger to their privacy in a given situation → see social media use
- Risk of citizens trading away basic rights in their data (e.g. privacy) for little value
- Can a proper informed consent be ensured? Dynamic consent? How to counter consent fatigue? → alternative consent models
- An individual citizen's negotiation capacity is limited compared to that of data users due to the power imbalance

Individual control versus collective control

Challenges for a collective control model for health data

- oversight mechanism would require proper representation / citizen involvement
- systems need to be set up to ensure transparency about (secondary) data uses to avoid a feeling of disenfranchisement
- TRUST!

Individual control versus collective control

TRUST

- Several studies have found that people are open to share their health data for the common good, BUT: they need to trust those who are processing and using their data
 - e.g. industry cannot just make a blanket appeal to data altruism and solidarity while generating great profits from the donated data
- Trustworthiness is dependent on **reliability** and **value congruence**: “the way to build trust in institutions responsible for health data is for those institutions to develop and display values shared by the public” (Holland et al, 2021)
- Requires mitigation of (potential) data harms outlined

Individual control versus collective control

Ideally: health data are shared for the public interest, while safeguarding crucial individual interests of data subjects / avoiding so-called “data harms”

Stratified approach depending on:

- **Type of data** (more sensitive v less sensitive; identifiable v pseudonimized v anonymous; aggregated or not)
- **Type of data user** (government, insurance, health care institution, research institution,...)
- **Goal of data use** (public interest v private interests)
- **Preferences of data subject**

➤ **combination of consent and oversight**

Individual control versus collective control

European Health Data Space Regulation:

- Primary use: strong emphasis on individual control, patient access
- Secondary use: strong emphasis on sharing for the public good
 - compared to GDPR, **less stringent consent requirements** for use of electronic health data for research, innovation, policy making, patient safety or regulatory activities; **public interest** as legal basis
 - **BUT:** (a) with **oversight** mechanisms in place (health data access bodies in member states) and (b) **prohibitions** on certain uses of electronic health data (e.g. use of data against persons, commercial advertising, increasing insurance, develop dangerous products)



Questions?

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