Information Points for Citizens under the EHDS

4-5th September, Brussels

Workshop Report V2.0

Authors: Manuela Pausan, Irene Schlünder, Michaela Th. Mayrhofer
Layout: Verena Borecky

Acknowledgement: The workshop and this report were funded within EHDS2Pilot, a project that has received funding from the European Union's Horizon EU4Health Programme (EU4H) under grant agreement No 101079839.

Table of Contents

Executive Summary of Workshop Outcomes

The aim of this workshop was to analyse how citizens are appropriately informed and involved in the sharing of their health data for research through so called information portals providing ongoing information on data-driven health research. It showcased existing public information initiatives on data sharing activities as well as examples of communication failures.

Following presentations from different initiatives and perspectives COVID-19 campaigns (KRISTIANIA University), ELGA (Austria), French Public Register (HDH, France), Findata (Finland), public portal of Medical Informatics Initiative in Germany (TMF, Germany), Estonian Biobank (Estonia), 1+MG Initiative (LNDS), industry (EFPIA), Multi-Layered Citizen Communication (HDL), Data Saves Lives Initiative (EPF; patients' perspective), Health data sharing from the perspective of rare diseases (EURORDIS; patients' perspective), European Doctors' perspective (CPME), it was concluded that EHDS should build on existing initiatives and should involve in the further development of the information portals for citizens all relevant stakeholders from the beginning.

The outcome of the workshop are recommendations that will inform the implementation of Art. 35 (3) of the future EHDS Regulation. Ideally, national nodes and Health Data Access Bodies will be able to build on existing experience and learn from success factors as well as pitfalls.

This workshop was organised by the EU-Project EHDS2Pilot on 3-4 September 2024 in Brussels and was attended by 50 participants.

This meeting is co-funded within EHDS2Pilot, a project that has received funding from the European Union's EU4Health Programme (EU4H) under grant agreement No 101079839.

Acronyms

BBMRI	Biobanking and Biomolecular resources Research Infrastructure (Austria)
CPME	Standing Committee of European Doctors
DGA	Data Governance Act
EFPIA	European Federation of Pharmaceutical Industries and Associations
EHDS	European Health Data Space
ELGA	Elektronische Gesundheitsakte (Electronic Health Record)
ERIC	European Research Infrastructure Consortium
EPF	European Patients' Forum
EU	European Union
EURORDIS	European Organisation for Rare Diseases
Findata	Social and Health Data Permit Authority (Finland)
GDPR	General Data Protection Regulation
HDH	Health Data Hub
HDL	Health Data Lab
TMF	Technologie- und Methodenplattform für die vernetzte medizinische Forschung (Technology and methods platform for networked medical research)

Workshop on Information Points for Citizens under the EHDS

Purpose

The HealthData@EU Pilot project is a two-year long European project and will build a pilot version of the European Health Data Space (EHDS) infrastructure for the **secondary use** of health data "**HealthData@EU**". The project will connect data platforms in a network infrastructure and develop services supporting the user journey for research projects using health data from various EU Member States. It will also provide guidelines for data standards, data quality, data security and data transfer to support this cross-border infrastructure.

Work Package 7 of the project focuses on legal, ethical and regulatory topics. A major topic is "rights of citizens and transparency about data sharing". This workshop reflects on Art. 35 e of the upcoming EHDS Regulation providing the framework for citizen information portals:

Article 35e

Obligations of health data access bodies towards natural persons

1. Health data access bodies shall make publicly available and easily searchable through electronic means and accessible for natural persons the conditions under which electronic health data is made available for secondary use. This shall include information concerning:

(a) the legal basis under which access is granted to the health data user;

(b) the technical and organisational measures taken to protect the rights of natural persons;

(c) the applicable rights of natural persons in relation to secondary use of electronic health data;

(d) the modalities for natural persons to exercise their rights in accordance with Chapter III of Regulation (EU) 2016/679;

(da) the identity and the contact details of the health data access body;

(db) the record on who has been granted access to which sets of electronic health data and the permit regarding the purposes for processing them as referred to in Article 34(1);

(e) the results or outcomes of the projects for which the electronic health data were used

The workshop included presentation about ongoing public information initiatives on data sharing activities in different European countries but also focused on examples when communication failed but also learnings and future recommendations for the EHDS public information portals.

Audience

- Researchers (academia)
- Research Infrastructure Representatives (national and EU)
- EU Commission Representatives from DG Sante
- Patient Representatives
- Doctors' Representatives
- National Ministries and Health Data Authorities Representatives
- Industry Representatives

Outline

Following the welcome note by BBMRI-ERIC's Irene Schlünder and Michaela Th Mayrhofer, Audra Diers Lawson (Kristiania University), expert on risk and crisis communication, held a presentation on communication successes and failures to learn from when wanting to improve citizen engagement. It was followed by the keynote by digitalisation expert Franz Leisch (PRAEVENIRE), the former chief executive of ELGA, who presented the negative campaign of Austrian Doctor's against the Austrian Electronic Health Record (ELGA) in 2014.

The first workshop day proceeded with presentations of existing citizen portals by Yacine Daquin (HDH), Antti Piirainen (Findata), Wiebke Lesch & Sophie Haderer (TMF), Liis Leitsalu (Estonian Biobank), Regina Becker (LNDS) and Aneta Tyszkiewicz (EFPIA).

The second workshop day began with a presentation on ideas and strategies for effective communication with citizens by Rebecca Alvarado (HDL), followed by patients' perspective through initiatives and stories from patient organisations by Gözde Susuzlu (EPF) and Jelena Malinina (EURORDIS) as well as clinicians' perspective presented by Sara Roda (CPME).

The day concluded with a perspective on implementing the EHDS by Mélodie Bernaux (EU Commission) and a podium discussion with all speakers on legal compliance versus best practice communication and further opportunities.

After a podium discussion with all speakers, Irene Schlünder and Michaela Th. Mayrhofer closed the two-day workshop with a summary of success factors.

Summary of the individual sessions

The workshop started with 2 keynotes presentations on communication and failures.

1. **Audra Diers-Lawson** from Kristiania University, Norway gave a presentation about communication successes and failures to improve citizen engagement. She started the presentation by introducing the concept "EPIC" that stands for E – Engaged, P-Positive, I-Informative and C-Communication and its origin story, including the 5 barriers to Risk Communication, Community Engagement and Infodemic Management (RCCE-IM). She continued her presentation with recent findings from the pandemic that pro-vaccine, anti-vaccine and vaccine hesitancy are distinctive attitudes, COVID-19 has worsened vaccine attitudes and continued with presenting one study from England on citizens attitude on vaccination and health, and how people seek, understand and interpret information about vaccination. Some of the outcomes from the first study were: (i) citizens attitude towards vaccination worsened in England during the pandemic; (ii) COVID-19 created health uncertainties and anxiety; (iii) the pandemic affected how citizens trusted the sources of information, trust in social media decreased, while trust in Health Advocacy Groups increased post-vaccine; (iv) the pandemic affected how citizens recognised pro/anti-vaccination messages, especially the ability to attribute anti-vaccination messages to anti-vaccination organisations as well as the believability of the pro- or anti- vaccination messages; The second study, Audra presented, was focused on comparing the information campaigns and messaging between England and Scotland, followed up by European view. The insights of the second study indicated that visual branding, good visuals and good text are needed for risk & crisis communication and that the risk & crisis messaging should be kept positive. Audra concluded her presentation with some recommendations and good practices for being "EPIC" in community engagement.
2. **Franz Leisch** from PRAEVENIRE, Austria presented the negative campaign of Austrian Doctors against the Austrian Electronic Health Record (ELGA) in 2014 and how it was resolved. Franz started his presentation by giving a short introduction about the ELGA

system, its development and legal framework. He then presented the negative campaign of Austrian Doctors against ELGA and their issues from his perspective which included: increased bureaucracy, legal liabilities, past experiences, IT system costs, transparency concerns, medical confidentiality, data security, ambiguity in healthcare provision and messaging strategy. The involvement of doctors through working groups for improving usability and the rollout and funding of the ELGA modules were a few of the steps that helped improve the doctors' perspective about the ELGA system and its implementation. Some of the doctors' expectations where to be included from the very beginning in the development of the system, respect their feedback and proposals, clear and transparent project plan, secure and adequate funding, providing cost-benefit analysis etc. The second part of the presentation was focused on the secondary use of data by providing one example how the acceptance was increased during pandemic for the health data use for COVID-19 research, but also Franz mentioned a second example of data misuse. Franz concluded his presentation with a few takeaways: identify and manage relevant stakeholders; involve stakeholders in implementation from the beginning; communication is key; data should be protected from misuse and funding of IT systems should be adequate.

The workshop continued with presentations from existing citizens information portals.

3. **Yacine Daquin** from HDH, France presented the French Public Project Register. Yacine started by presenting the Health Data Hub (HDH), which is a public body tasked with facilitating access to health data for projects for public interest. The HDH is also the national body involved in citizen dialogue through regular consultations & public debates and co-creating training and information material for citizens. Most of the health data research projects must publish information about the project on the public projects register. Currently, the health data warehouses are not obliged to share information on the public project register with the public. For the research projects the information currently made available prior to project implementation is a short description of the project, the project stakeholders, project calendar, legal basis and the citizens' rights.

After project implementation, the researchers must share the results with HDH within 6 months. Generally, the results are made publicly available to the public. Although the Public Project Register is a nice portal sharing information about ongoing health research projects, it is not considered a transparent portal and currently in France there is ongoing work on creating a national transparent portal to inform patients & citizens about the use of their data for secondary use.

4. **Antii Piirainen** from Findata, Finland presented the Findata and their approach to public communication as well as presenting a case when media coverage was negative. Findata is a centralised data permit authority for secondary use of Finnish social welfare and health care data. The operations of the Findata are based on the Finish national Act on Secondary Use of Health and Social Data. Antii presented the core services of Findata and some figures on how many applications were received for access to health and social data and how many were granted. Antii shared that Findata has its own section for citizens in accessible language about the projects where access to data was granted and health and social data is being used, they also offer guidance to customers and data holders. He concluded his presentation with one example in which media coverage was unfavorable and tried to spread misinformation about the work of Findata and how this was resolved.
5. **Wiebke Lesch and Sophie Haderer** from TMF Germany presented the public portal of the Medical Informatics Initiative in Germany. They started their presentation with the German portal for medical research data (FDPG), that allows researchers to centrally request health data and biosamples from German university medical centres for research purposes. They then continued by presenting the public information portal of the FDPG that contains information about all research projects approved and their results. The portal shows general information about the different projects such as project description and objectives, scientific background, material and methods, project results and publications. Citizens can also subscribe to a newsletter to receive further information about ongoing activities and projects. The public portal does not offer individual information to citizens/patients about the use of their own data. Moreover, the portal does not offer a central location for opt-out, citizens/patients can opt-out at each location

(hospital) where they have consented. They continued their presentation by sharing some of the activities and communication measures created for citizens and patients' engagement and involvement, such as workshops, communication material (leaflet, website, video) etc. The presentation was concluded with highlighting some lessons learned: Citizen and patient involvement and engagement should happen at an early stage of the development of any information portal; patient information on the public portal should be in a simple language; a centralised opt-out would be desirable for patients/citizens; more websites and portals in the same country about secondary use of data do not create more transparency but can create confusion and EHDS requirements for citizens/patient information and involvement would be useful in order to build a harmonised information infrastructure for citizens and patients.

6. **Liis Leitsalu** from Estonian Biobank, Estonia presented their approach to sharing genetic results with the participants. She started her presentation with an overview of the Estonian Biobank projects and continued her presentation with the MyGenome Portal that they have developed to share the genetics results with the citizens participating in the Estonian Genome project. She presented about the development of the MyGenome Portal and what the participants can see in their portal and also shared the feedback they collected from the 10k participants.

The workshop then focused on some additional topics:

7. **Regina Becker** from LNDS presented the 1+ Million Genomes approach on Informing citizens on secondary health data use. She shortly presented the initiative 1+ Million Genomes and then outlined the legal analysis done within the project leading to the conclusion that general information provided through an information portal is not sufficient to be compliant with the GDPR. Instead, any citizen portal, where it is possible to track back to the data subjects, should offer the opportunity for citizens to receive individual information about the use of their data as granulated as they wish. An important element in offering such information is to design a customisable information portal that allows the citizen to be informed about the data use to the extent and in the

way they prefer. While all information on the data use will be available in the portal, citizens should be able to choose in which cases they want to be informed and what information they deem as relevant. This could prevent information overload / tiredness but allow citizens to get the information they want. APIs between the portal and the information system on data access could be designed to offer such a portal as a scalable implementation. While the management of contact data could be done by the citizens themselves through the portal, the biggest challenge is still reliable and efficient identity management between pseudonym and identity.

8. **Aneta Tyszkiewicz** from EFPIA presented the perspective of industry on building and maintaining trust in data sharing from clinical trials. She started her presentation with a short introduction about EFPIA and how industry uses data for innovation and society benefit. She presented the key principles how industry operates to maintain trust and includes data anonymization, data access control, data encryption, ethical reviews, compliance with GDPR and that compliance is monitored by regulatory authorities, ethics committees and other oversight bodies. The presentation continued with information on how industry already shares clinical data with regulators, public sector, and with different platforms. Aneta concluded her presentation with a few recommendations on the framework of building trust in data sharing in EHDS and includes (i) extensive stakeholder engagement, (ii) harmonized approaches, (iii) building on good practices, (iv) transparency without comprising privacy, integrity but maintaining incentives for innovation and (v) increased understanding of how data can be translated for tangible benefits for the society and citizens & patients.
9. **Rebecca Alvarado** from HDL, Germany presented multi-layered citizen communication. Her presentation focused on important aspects to be considered when communicating with different groups of citizens and which communication tools might be best for each generation. She also indicated that especially negative comments from the public are very important to understand their worries and foster trust and should therefore be taken very seriously into account. Her takeaways message for better communication is (i) know your audience, (ii) start with why, (iii) use the clues.

In order to reflect on what has been said so far, patient advocates presented patient driven information initiatives and patients' viewpoints.

10. **Gözde Susuzlu** from European Patients' Forum (EPF) talked about an initiative they have started named "Data Saves Lives" that is focused on improving citizens' and patients' understanding on health data sharing and how this can help others. She mentioned some of the activities they organised part of the Data Saves Lives with different patient groups and civil societies on Health Data, AI and patient registries and the resulting toolkits they have developed together and that are available for everyone online on the website: www.datasaveslives.eu.
11. **Jelena Malinina** from EURORDIS talked about empowerment vs protection of people living with rare diseases in health data sharing. She shared the perspective of rare disease patients on sharing health data and their activities on informing patients about data sharing for secondary use.
12. **Sara Roda** from CPME presented the European Doctors' perspective on the implementation of the EHDS. She started her presentation with a short introduction about CPME and their key priorities that are grouped into policy clusters. The "Digital Health" policy clusters include the AI, EU Health Data Spaces, Skills and eHealth as priorities. Then, she shortly presented the doctors' ambitions to continue building the European Health Union. One of the ambitions is focused on ensuring a safe digital transformation of healthcare. Part of this is digital health and the EHDS implementation. She presented the EHDS implementation expectations from the perspective of the European Doctors which included: CPME statement on the Electronic Health Record Systems, requesting to prioritise user-friendliness, to minimise administrative burdens, enhance trust and collaboration between patients and healthcare providers, and avoid overwhelming doctors with excessive information. Additionally, the EHR systems should take into account existing national access and coding protocols, and doctors should be consulted on the development and implementation of such EHR systems. Sara then continued her presentation with a focus on information points for citizens and what should be the role of doctors in this regard. CPME noted that the main objectives to

safeguard would be the patient-doctor relationship, medical confidentiality, avoid additional administrative burdens and the need to be mindful of conflicting interests of third persons. However, if doctors would be the first point of contact from patients, CPME recommended that a) the "standard" information to be provided to patients on the secondary use EHDS regime was decided in advance; b) adequate funding for additional communicating tasks was required, as it delayed consultations (these tasks were not directly related to treatment or diagnosis), c) test with specific groups first (soft roll-out), and d) ensure direct involvement of doctors in the implementation process and the system assessment done by end-users. . She concluded her presentation by sharing information about upcoming events of the CPME group.

Finally, the EU Commission summarised the approach of the EHDS Regulation

13. The last presentation was from the European Commission's point of view, **Mélodie Bernaux** presented the EHDS's approach to transparency and citizen trust for health data reuse. She started by presenting the objectives of secondary use of health data in EHDS and the importance of building trust for health data reuse. She continued her presentation by focusing on the four pillars of trust in EHDS (i) Security, (ii) Privacy, (iii) Transparency and (iv) Ethical Safeguards, followed by the importance of data quality and citizen trust which is at the core of the EHDS.

Reflections from the podium discussion

After a summary of Owe Langfeldt about the transparency concept of the EHDS Regulation, the most important discussion topics was whether citizens and patients would prefer individual information or whether generalised information about the use of their health data through an information portal is acceptable if not preferable. The various perspectives highlight the need for transparency, adaptability and patient-centred approaches:

EPF states that there are pros and cons regarding individual information to citizens about the use of their data for research. Nobody seems to have the final solution. Therefore, she emphasizes the importance of involving patients from the beginning in discussions about information portals

about secondary use of health data, ensuring patient perspectives are considered at the national level. “We should start and learn together along the way through a constant dialogue”.

EURORDIS suggests that there are varying preferences among patients and citizens regarding information about the secondary use of their data. To address this, the system should provide different options to accommodate those who want to know more about their health data use or to exercise their right not to know.

FINDATA highlights the importance of informing data users through early, clear, published information, including data protection assessments, to maintain transparency.

1+ Million Genome representative mentions that in her perspective, citizens are likely more interested in knowing exactly which projects are using their data, rather than receiving general information about all projects without the knowledge, which projects are actually using their data. This highlights the need for an adaptable technical system that can tailor information to individual preferences on their request.

Audra mentioned the importance of the ethics aspects of data use, and particularly the importance of voluntary informed consent. It is important to align data sharing practices with GDPR compliance and provide a centralised system that includes an opt-out option for participants.

EFPIA points out the need for further understanding on what information is most useful to patients and to further improve the current mechanisms for disclosing data. EFPIA also highlights the lack of clarity for industry on what information should be shared with data access bodies, suggesting the need for expert collaboration to ensure workability.

Recommendations

To successfully establish Information Points for Citizens under the EHDS, we strongly recommend considering the following aspects, emphasizing that transparency is key and that there should be no secrets, except for the data itself.

- Why communicate:
  - **“There are no secrets unless the data itself”**
  - **Miscommunication and conspiracy theories will in any event impact public opinion on health data sharing, so be prepared.**
- What to communicate:
  - **Why before What:** always start with the impact of data sharing on public health and then explain how it is done; otherwise, you lose your audience early.
  - **Clear and honest information:** Clearly communicate what citizens can expect from data-sharing practices, clarify the sources of health data.
  - **Active Involvement:** Offer options for citizens to express their information preferences and get active through solid technology (integrate feedback and opt-out functionalities).
  - **Trust Building:** Demonstrate compliance of the data sharing with legal and ethical requirements and restrictions on prohibited uses of data; explain who controls access to data, who has what access rights (i.e., roles and responsibilities).
  - **Openness:** Integrate biobanks and other data repositories into the EHDS framework.
- When to communicate:
  - **Start your communication very early**, i.e. before others do it in a way you will not like.
  - **Risk Management:** Prepare comprehensive plans for crisis situations and miscommunication, they will occur.
- How to communicate:
  - **Positivity:** Emphasize honestly the benefits and positive impacts of data sharing.
  - **Know Your Audience:** Understand the diverse needs and perspectives of diverse groups (i.e., age, gender, disease group).
  - **Co-Design:** Involve citizens in the design process to manage expectations and improve acceptance.
  - **Layered Information:** Provide information in layers to cater to diverse levels of understanding (i.e., citizens with different expertise and interest, researchers, data holders).
  - **Use different communication channels:** Medical doctors are usually the first in line in communication with patients, involve them in your communication.
  - **Harmonised labelling and branding:** Implement clear and consistent labelling and branding practices across Europe (minimal criteria).
- Do not forget:
  - **Resource allocation:** Allocate sufficient funding and expertise for effective information sharing, including communication plans and their execution.
  - **Experts wanted!** Do not underestimate expertise and effort needed for good communication.