Policy forum discusses European health data space proposal and its financial sustainability

Representatives of government ministries from 21 European countries state that both national and EU funding is needed for the European health data space. To avoid discrepancies between member states, price policies need to be aligned if fees to access data are implemented.

TEHDAS hosted its third **policy forum** online, 29 June, and brought together 60 representatives of the ministries of health, research and finance from 21 European countries. The discussions focused on the progress made by the member states in assigning a national contact point for the secondary use of health data in the European health data space (EHDS), the financial sustainability of the EHDS, potential data access fees, and mutual recognition of data access application evaluation.

National Directorate General for Hospitals (OKFŐ) is a consortium partner in the project and together with the French partner (French Data Hub) is leading work package (WP) 8, which aims to analyse and promote good practices of data altruism in order to integrate population health data into EHDS. Health Services Management Training Centre (EMK), Faculty of Public Health of the Semmelweis University, is participating in the project as an affiliated entity (AE) contributing to the WP 4 and WP 8 work packages.

Support for combining national and EU funding for the EHDS

Most participants were in favour of combining both EU and national funds to build a European health data access and sharing system. EU funding will be required at the start for the implementation of the EHDS in member states, after which national funding will be needed to ensure long-term sustainability.

On national funding, there was a discussion on public-private models, including examples from some countries' successes in combining different sources of financing. It was stressed that it is important to balance funding with public trust in how people's data is used.

Differing views on fees for data access

Participants had different views on whether data users should pay to access data. Some participants were in favour of fees as long as pricing policies are transparent. Others voiced concerns that fees could become a barrier to research in some member states and said that data access should be free if it is in the public interest.

Participants said that fees should be for the work required to prepare data and make it available for research, rather than paying for the actual data. They stressed the importance of aligning price policies across member states to avoid discrepancies.

Mutual recognition of data permits

Most participants were in favour of the concept that a data permit issued by one health data access body in one member state would be recognised by an access body in another member state. This would avoid duplicating work and reduce the time required to access data. But this mutual recognition, as described in the EHDS proposal, and how it would be applied in practice needs further elaboration.
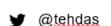
Finland's health data sharing model as a benchmark for the EHDS

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Joni Komulainen from the Finnish Ministry of Social Affairs and Health and **Johanna Seppänen**, Director of Findata, shared experiences and lessons learnt in Finland in setting up the national data

permit authority, Findata, and drafting and implementing **a law on the secondary use of health and social data(open in new window)**, which entered into force in 2019.

Findata is a one-stop shop for access to health and social welfare data. Its services include granting data permits, collecting data and providing researchers with a secure processing environment for analysing it.

Establishing Findata required a systemic change in the data sharing environment in Finland, including new duties for entities collecting data, in addition to financial resources and capacity. It also brought about a vast change in data security, as the law requires data to be uploaded in audited environments to be analysed. Among the lessons learnt, Komulainen and Seppänen highlighted the importance of cooperation between all parties involved in the data sharing process, such as data controllers, permit authorities and lawyers."Get all stakeholders involved as early as possible and maintain that cooperation throughout the legislative process and even after the law has been adopted", said Joni Komulainen.

It is also crucial that the authority granting permits for the secondary use of health data has a solid legal mandate to operate, and sufficient financial resources. The EHDS will likely create a legal mandate, but authorities set up before the EHDS takes effect would need to develop such a mandate in national legislation.

Cross-border data use should be piloted soon

Karina Zalite and **Licinio Kustra Mano** from the European Commission presented the EHDS legislative proposal. They highlighted the financial support that will be provided to EU member states through direct grants to set up the health data access bodies. Applications for grants will open in mid-September.

A pilot project should be launched in September to test the implementation of the legislative proposal through case studies. The purpose is to examine how data access requests requiring data from multiple countries can be handled and establish secure processing environments to analyse data.

Taking stock of progress made by the member states

The forum opened with a greeting from **Mélodie Bernaux** from the French Presidency of the EU Council. She presented the **European ethical principles for digital health(open in new window)**, adopted by the member states earlier this year, which set the course for the EHDS proposal. "The European ethical principles for digital health are a major pre-requisite for citizens to trust digital health and to be supportive of the EHDS," said Bernaux.
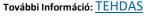
Participating countries also discussed the progress made since the **previous policy forum** of November last year in establishing a national contact point for the secondary use of health data in the EHDS. Countries are at different points, with some starting to discuss the establishment of a contact point, while others have already established institutions likely to take on the role.

The TEHDAS policy forum aims to bring together and engage member states and associated countries in shaping the European health data space legislative proposal and its implementation."Thanks to TEHDAS policy forums I have started communicating with the other ministries in the Czech Republic and getting informed about the EHDS. I appreciate this push to bring together these three ministries. Regarding the EHDS regulation, the Ministry of Health has chosen the EHDS as one of the priorities of the Czech Presidency to the EU", said **Marta Vandrovcova** from the Czech Ministry of Ministry of Education, Youth and Sports.

The next policy forum will take place in November 2022, scheduled be organised in collaboration with the project piloting data sharing for secondary use.

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