TOWARDS THE EUROPEAN HEALTH DATA SPACE: FROM DIVERSITY TO A COMMON FRAMEWORK

By: Minna Hendolin

Summary: Health data plays a crucial role in safeguarding the resilience of society. We need to enhance the use of health data to facilitate better policymaking, to enable a better environment for research, innovation and business, and to provide improved health care for the public. The Towards European Health Data Space (TEHDAS) joint action advances more extensive use of health data across Europe. It supports the European Commission’s aim in creating a harmonised internal market for health data by providing substance to the European Commission’s forthcoming legislative proposal on the Health Data Space.

Keywords: Health Data, European Health Data Space, Legislation

Introduction

The cultural richness and beauty of Europe lies in its heterogeneity. The region consists of over 50 independent countries, with over 700 million people, that together speak more than 200 languages. Dimensions in geography, climate and even outlook combined with a world class research community, booming business ecosystem, and shared European values make our continent a melting pot for creativity and innovation.

But every coin has a flip side. Such diversity can cause challenges when we need to find harmonised ways of working together, and to agree on European policies and guidelines. And undoubtedly, reaching agreement among Member States on health policy is not the easiest task. The variability of European health care systems when it comes to digital health and data sharing maturity has been made clear by a recently published Open Data Institute report on the Secondary Use of Health Data in Europe as well as in the earlier Roche Future Proofing Healthcare – European Personalised Health Index.

Data sharing and use drives the paradigm shift from treatment to prediction and prevention. A need for a radical redesign of how we deliver, practice, and think about health care is emerging worldwide. Health care systems are under increasing pressure in the face of changing demographics and rising costs. Demands from the public, private actors, and public institutions are pushing forward the shift in health care from treating illness towards...
smart, personalised, and preventive health care methods. As we have seen during the COVID-19 pandemic, the world is facing socially complex challenges that are often difficult to define. Furthermore, there are not always clear solutions, nor are they the responsibility of a single stakeholder or country. The last two years have thus emphasised the importance of prediction and prevention, digitisation, and the role of health data.

The European Health Data Space boosts secure and seamless data flow

The European Commission too has recognised the need for digital transformation and the value of data. To secure Europe’s competitiveness and data sovereignty, the Commission launched the European Data Strategy that aims to create a single market for data by enabling easier and secure access and usage of data. The building of a multisectoral European Data Space is one of the priorities of the Commission 2019–2025 and health is one of the sectors involved.

Currently, a researcher may have to spend from a few months up to a year finding and getting access to suitable data. Furthermore, the quality of data varies significantly and there are no harmonised processes. The Health Data Space (EHDS) will enable researchers to focus on solving scientific problems and creating new solutions instead of administrative burden.

The EHDS focuses on enabling health data sharing both in health care as well as for secondary purposes in research, innovation and decision making. EHDS will also contribute to the development of a single market for digital health services and the use of artificial intelligence in health care. The European Health Data Space has four focus areas that will be built on three main principles, as follows:

- Strong system of data governance and rules and guidelines for data exchange
- Data quality
- Solid infrastructure and interoperability.

One concrete tool to develop EHDS and the access to health data for secondary use—such as research, innovation, and policymaking—is the joint action Towards European Health Data Space (TEHDAS). The purpose of TEHDAS is to help Member States and the Commission in developing concepts and guidelines for the governing, usage and sharing of health data for secondary purposes.

Figure 1: Thematic focus areas of TEHDAS joint action

![Thematic focus areas of TEHDAS joint action](Image)
The results of the TEHDAS project will provide input to the European Commission’s legislative proposal on the European Health Data Space. It will also support the pan-European dialogue that will follow the proposed legislation. TEHDAS is carrying out in 25 European countries and coordinated by the Finnish Innovation Fund Sitra. TEHDAS brings together extensive European expertise in project and stakeholder forums as well as advisory groups.

Europe could serve as a lighthouse for the rest of the world

Due to its collaborative nature, TEHDAS joint action is one tool to interconnect several stakeholders for developing the harmonised policies and practices of wider data usage focusing on governance models, data quality and infrastructure (see Figure 1). The project will also produce insights on citizen perception of data sharing as well and develop an economic sustainability plan for setting up the EHDS. The TEHDAS project started in February 2021 and the focus for the first six months was on mapping and analysing the existing health data environment in Europe. The project has produced reports, such as on the specific governance aspects for EHDS, and has identified common obstacles to health data exchange and examined technical solutions for sharing and using health data. The forthcoming reports will focus on such topics as the EHDS data quality framework and options for the minimum set of services for the secondary use of health data in EHDS.

As the recently published report by the Open Data Institute showed, despite improvements undertaken by many European countries in building their competence and capacity for the wider use of health data, there remains much variation in their maturity, both in the strategic vision and implementation of the health data ecosystem. Based on my observation, it seems that there is a considerable appetite in Member States for EU level support and to invest for better technical infrastructure, interoperability, data quality and digital skills of citizens. Strategies and roadmaps are needed in the EU, in country and at regional level.

Concrete steps were shown to have taken place when the first two national centralised health data platforms in Europe – the French Health Data Hub and Finnish Findata – announced a two-year collaboration through a memorandum of understanding. The objective is to provide unified access to health data to researchers and other key stakeholders and to serve as models for other countries to follow.

The vision of TEHDAS is that in the future there will be secure, easy, and seamless access to protected health data for the benefit of the public, researchers, companies, and communities in Europe. Looking ahead, Europe could serve as a lighthouse for the rest of the world by creating health policies and global standards in data use similarly to the General Data Protection Regulation (GDPR). More information on TEHDAS and how to get involved can be found at www.tehdas.eu.

The next step is to bring countries on board

In 2019, Finland was the first country to launch the act on the secondary use of social and health data. Findata, the Finnish Social and Health Data Permit Authority, started operations the following year to promote access and use of data for secondary purposes and to manage data permit services. The Finnish model has also been benchmarked by the Commission as an alternative approach in EHDS for data access and sharing for secondary purposes.

The next step is to bring countries on board

Concrete steps were shown to have taken place when the first two national centralised health data platforms in Europe – the French Health Data Hub and Finnish Findata – announced a two-year collaboration through a memorandum of understanding. The objective is to provide unified access to health data to researchers and other key stakeholders and to serve as models for other countries to follow.

The vision of TEHDAS is that in the future there will be secure, easy, and seamless access to protected health data for the benefit of the public, researchers, companies, and communities in Europe. Looking ahead, Europe could serve as a lighthouse for the rest of the world by creating health policies and global standards in data use similarly to the General Data Protection Regulation (GDPR). More information on TEHDAS and how to get involved can be found at www.tehdas.eu.

References

5. TEHDAS joint action. TEHDAS Report on technical solutions on sharing and using health data, September 2021. Available at: https://tehdas.eu/results/tehdas-identifies-barr