Polish EIT Health InnoStars Partners' roundtable on the European Health Data Space

Date: 22 September 2022

City: Warsaw

Venue: The University of Warsaw Biological and Chemical Research Centre

Participants:

EIT Health InnoStars Polish Partners

- Łódź University of Technology
- Łukasiewicz Research Network – PORT (Polish Centre for Technology Development)
- Medical University of Gdańsk
- Medical University of Łódź
- University of Warsaw

European Commission, Directorate-General for Health and Food Safety (DG SANTE)

Polish administration

- Ministry of Health (MoH)
- eHealth Centre
- National Health Fund

The meeting was held under the Chatham House Rule.

Report

The roundtable was organised to involve Polish Partners of EIT Health InnoStars in the discussion on the European Health Data Space (EHDS). Inviting a representative of the European Commission (DG SANTE) and representatives of the Polish administration (MoH, the eHealth Centre, and the National Health Fund) was aimed at making the Polish Partners familiar with the proposal of the EHDS Regulation tabled by the European Commission and the Polish position during the negotiations in the Council of the European Union. Moreover, the Polish Partners had an occasion to present their experience in using electronic health data for the purposes stipulated in the Regulation proposal: provision of health care (primary use) or supporting public health, scientific research, innovation, policymaking, public statistics, patients' safety or regulatory activities (secondary use). This is the first roundtable strictly dedicated to this topic organised by EIT Health and a pilot for the European Commission (DG SANTE) before similar meetings happen in other European capitals.

European Commission

The meeting started with the presentation by the representative of DG SANTE, who talked about the motivations behind drafting the EHDS Regulation proposal and the problems it will tackle. The roundtable in Warsaw was the first of a series of meetings on EHDS. There will be the following ones in the other EU Member States. All of them will serve as reflections on the future of EHDS and be of assistance during the legislative process – the negotiations between the Member States, the European Parliament and the European Commission.

When it comes to collecting and using data, one can distinguish different approaches. Europe is General Data Protection Regulation (GDPR)-driven. It means that protecting personal data is crucial, and it steers its use. In the United States, it is the market that plays the most important role in using personal data. Finally, in China, collecting and granting access to personal data is centralised at the government's level. The government owns personal data and decides on access to it and its use.

The European Health Data Space is the first data space that the European Commission plans to create. They all will have the same goal – supporting data-driven culture in Europe. Broader and more structured access and use of data will be beneficial to EU citizens and the EU economy.

The COVID-19 pandemic turned out to be the testing ground for EU co-operation in the area of data and its electronic use. The EU COVID-19 certificate was created from scratch within a matter of months. It was the result of enormous work done by the national authorities and the European Commission. The certificate functions very well and allowed for faster recovery after the first phase of the pandemic when vaccinations became available. Its holders did not face restrictions when travelling, attending public gatherings, etc. Moreover, it became a world standard, replicated on other continents.

The EHDS proposal is an initial step towards broader and more structured access to and use of data. The Regulation was drafted with the aim of addressing future challenges, e.g., an assumption is that all health data will be digital. This is not the case now and will probably not be when the Regulation enters into force, but this is the direction in which the health systems will go.

According to GDPR, health data belongs to patients and they have free access to it. In some EU countries, this is not so straight forward and the access is blocked by the health care providers. The EHDS Regulation will not only remove these obstacles but will also give the patients immediate access to their data (i.e., just after the data is created). Apart from GDPR, there are other pieces of legislation that are relevant to the EHDS proposal. They are the Data Governance Act, Cyber security Regulation, AI Regulation, Medical Devices Regulation and EU cybersecurity framework.

There are three pillars of the draft Regulation: the primary use of data (for the provision of health care), the secondary use (for purposes like supporting public health, scientific research, innovation, policymaking, public statistics, patients' safety or regulatory activities), and certification of digital medical devices (DMD) to make them reimbursed products in publicly-funded health care systems.

Well-functioning EHDS will mean better access to data and enable data sharing. It will allow the elimination of errors in creating and using data. It will give the patients greater control over access to their data. It will improve the interoperability of data too.

When it comes to using data for primary purposes, nowadays, different health care providers have difficulties accessing patients' health records from other facilities. This threatens the safety of the patients

and has a negative impact on the quality of health care that they receive. This is an example of a problem to be solved by the EHDS.

The COVID-19 pandemic made it very clear how important fast access to data is in health policymaking. Within the course of the pandemic, it was possible to accelerate the publication of mortality data in the EU on a national and regional level. This turned out very helpful in planning the next steps in dealing with the pandemic. With EHDS fully operational, in general, the health data will be available more quickly.

The use of electronic health records for clinical trials is another example of the secondary use of data to be regulated by the EHDS legislation. In this case, it is not only about 'traditional' clinical trials done when producing new pharmaceuticals. It also concerns the development of DMD. This aspect is important for many European start-ups that are active in this field. One of the questions that the EU legislators have to answer when negotiating the final version of the EHDS Regulation is about the role of bioethics committees in DMD clinical trials. Should they decide on the use of electronic health data?

There are different categories of stakeholders who will profit from better regulated but also smoother access to health data used for secondary purposes. They are not only entrepreneurs (including start-ups). The European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control will have privileged access to health data. This will enable them to react faster to health threats. At Member States' level, public institutions will benefit from access to health data too.

When the COVID-19 vaccination campaign started, and there were cases of rare blood clots, it was the EU that reported them first as side effects of using some of the vaccines. It was possible thanks to the analysis of data done by EMA. The data that they used was reported by the Member States regularly and without delays. This example demonstrates the potential for immediate access to well-structured and accurate data.

Research, innovation and development institutions and companies will profit from better access to data as well. It will be especially relevant to data that at the national level in the EU is scarce (e.g., concerning rare diseases), but when the whole EU population is concerned, its amount and, therefore validity are meaningful.

The role of health care providers cannot be ignored when grating access to and use of health data is concerned. Since they play a very important role in producing the data that then is used by others and gives them profit, the health care providers should benefit from that too. It is still under discussion what form (payments, investments or something else) such benefits for the providers should have.

The EU citizens, among them, not only the patients, will benefit from the creation of EHDS in many ways. Each time they will receive any treatment, their health records will be available to their health care providers. They will not have to undergo many times the same diagnostic procedures. Cross-border access to their health data will make their travels more comfortable and safe in case of emergency or when they will seek treatment in other countries; their health records will be available immediately. The individuals will also have better control over their medical records, being able to check who, when and why accessed them.

Since making the European Health Data Space fully operational requires, among other investments, the European Commission has already decided to allocate around EUR 800 million to fund it and its

infrastructure. This money will come from a number of sources like the EU4Health programme, Digital Europe Programme, Horizon Europe, etc.

Ministry of Health

The representative of the Ministry of Health presented the Polish position in the negotiations of the proposal for the EHDS Regulation. The Ministry is a leading institution on behalf of Poland in this process.

In principle, Poland supports the proposal made by the European Commission. EHDS will contribute to the digitisation of the health care sector in the EU, including in Poland. The patients will gain more rights when it comes to the control of their own health data. Co-operation between the Member States will result in, among others, the strengthening of the European economy and the European research and education sectors. The experience that Poland has after engaging in the cross-border exchange of e-prescriptions and the creation of the COVID-19 certificate is very positive and gives prospects for the development of EHDS.

In Poland, 97% of all prescriptions issued are electronic, less than three years after the full rollout of this scheme. In 2022, the 'White Paper on AI in Clinical Practice' was published. The Ministry of Health was one of the public institutions that contributed to its drafting. EHDS proposed by the European Commission fits very well with such projects.

First of all, the EHDS Regulation is about access to health data, including the patients' access to their own health records. For the time being, GDPR is the most important piece of legislation that regulates that. The period since its entry into force (in May 2018), demonstrated that the provisions, though directly binding in all Member States, are interpreted differently. The EHDS Regulation should bring more clarity here.

Currently, it is not possible to give a medical doctor the right to grant access to a patient's data to other health professionals directly, without specific consent from the interested person. This may be an obstacle to a smooth flow of data. On the other hand, the proposed immediate access to data just after it was created poses a risk to the data's quality. Another problem is access to medical records in emergency situations when human life is at stake. In such cases, procedures should be simplified.

These are only some examples of issues that need to be solved during the negotiations. Since the proposal envisages that some aspects will be regulated in delegated acts adopted by the European Commission, questions will remain, because these acts will be adopted after the Regulation enters into force.

The draft Regulation stipulates that all Member States will have to establish bodies responsible for administering access to electronic health data used for primary and secondary purposes. In Poland, the former role will probably be played by one of the existing institutions that already have similar tasks. These proposed institutional changes will require investments in Poland as well as in the other Member States.

To ensure the proper flow of electronic health data both nationally and between the countries, not only dedicated bodies must exist but process too. Once again, this calls for financing that goes beyond the establishment of specific institutions and concerns their functioning in a longer perspective.

When the use of data for secondary purposes is concerned, the catalogue proposed in the draft is very wide. In Poland's opinion, it should be narrowed down, and the national authorities should be able to decide about the catalogue's details.

For the time being, there is no procedure for certifying wellness applications in Poland similar to the one proposed in the draft Regulation. Establishing it will require time and effort. The users of wellness applications should actively give consent to use the data coming from them for purposes other than connected directly with their functioning.

To sum up, the adoption of the EHDS Regulation will not mean the end of the story. Next steps will be needed, usually relying on the efforts of the Member States. The *vacatio legis* in the draft is too short and should be extended. Investments are another factor on which the success of establishing the European Health Data Space will heavily rely.

EIT Health InnoStars Polish Partners

The Partners' representatives shared their experience in using electronic health data for secondary purposes (as described in the EHDS Regulation proposal).

Examples of the use of electronic health data included:

- Modelling of the course of the COVID-19 pandemic to envisage its impact on the Polish health system.
- Research on paediatric inflammatory multisystem syndrome (PIMS) caused by SARS-CoV-2 infection among children in Poland.
- Doing research and conducting clinical trials, including the use of samples and data from biobanks.
- 'Teaching' and 'training' AI algorithms in medical devices and applications.

Conclusions

During the discussion that followed the presentations, the participants highlighted to following issues concerning the use of electronic health data.

Quality of data

In Poland, there are many institutions that record health data and use different IT systems, so the data is in silos, and it is difficult to merge different data from different sources. Moreover, they collect data for different purposes, therefore, it may not be very useful for others. There was an example of the daily number of COVID-19 infections. For modelling the course of the pandemic, also information about circumstances in which people got infected would be needed. This was lacking.

Motivation to collect and share data

Collecting and storing data requires a great amount of work and capacity (e.g., servers, expensive IT systems, and data specialists). It is key to convince those who do that work that it is useful. Not only serves others but can be beneficial for them.

In relation to that, usually, the data producers and collectors (e.g., public institutions) are not those who benefit from its commercial use. The lack of mechanisms that reward them is a serious obstacle to increasing data availability. What is more, it is not clear if the data collected thanks to publicly-financed projects can be re-used for commercial purposes.

Consent to use data

In principle, the consent given by the patients to use their health data relates to one specific purpose. It means that for instance, the samples taken for testing against COVID-19 cannot be then used for validating COVID-19 tests since this is a different purpose. Each of the tested people would have to give another specific consent if they could be used for the latter. Such rules narrow the use of the samples stored in biobanks only to the purposes communicated during their collection. It is impossible to use them for anything else.

Education on the use of data

Raising awareness about the profits of the wide use of health data could help in solving some of the issues signalled, like the existence of barriers to access to data or low motivation to share it. Research on PIMS, which started as a bottom-up project, resulted in a number of scientific publications and clinical guidelines that are very useful in treating this health problem. Not only the researchers benefited but also the patients and their families. If this project is developed further, it may even help in modelling future demand for specific health care services. This would improve health policymaking. Showing such examples would make the case for propagating the use of data. Education should relate as well to data protection topics to show that it is possible to respect the privacy of the patients on the one hand and to widely use their data on the other.

Regulation and business models of the use of data

The existence of a rapidly growing amount of electronic health data is a consequence of the digitisation of health care and other sectors. This process cannot be stopped. The question is if it will continue to be controlled in a structured way or not. Work on EHDS should be an occasion to steer it for the benefit of society. However, if the negotiations on the draft Regulation are slow, the authorities may face *faits accomplis*.

There was a proposal to think about the data as a public road system. Should anyone who meets minimal conditions (has a ‘driving licence’ and a ‘car’) be able to use it for any purpose that is legal? Another question was whether there should be motorways that are paid but offer a fast ride and free roads where the speed limits are lower.

The next steps

There is an interest in continuing the reflection on the draft EHDS Regulation and, in a broader context, on the future use of electronic health data in Poland, also on aspects that were not discussed during this roundtable. The EIT Health InnoStars and its Partners will continue this and organise debates on commonly agreed topics. The details have not been decided yet.