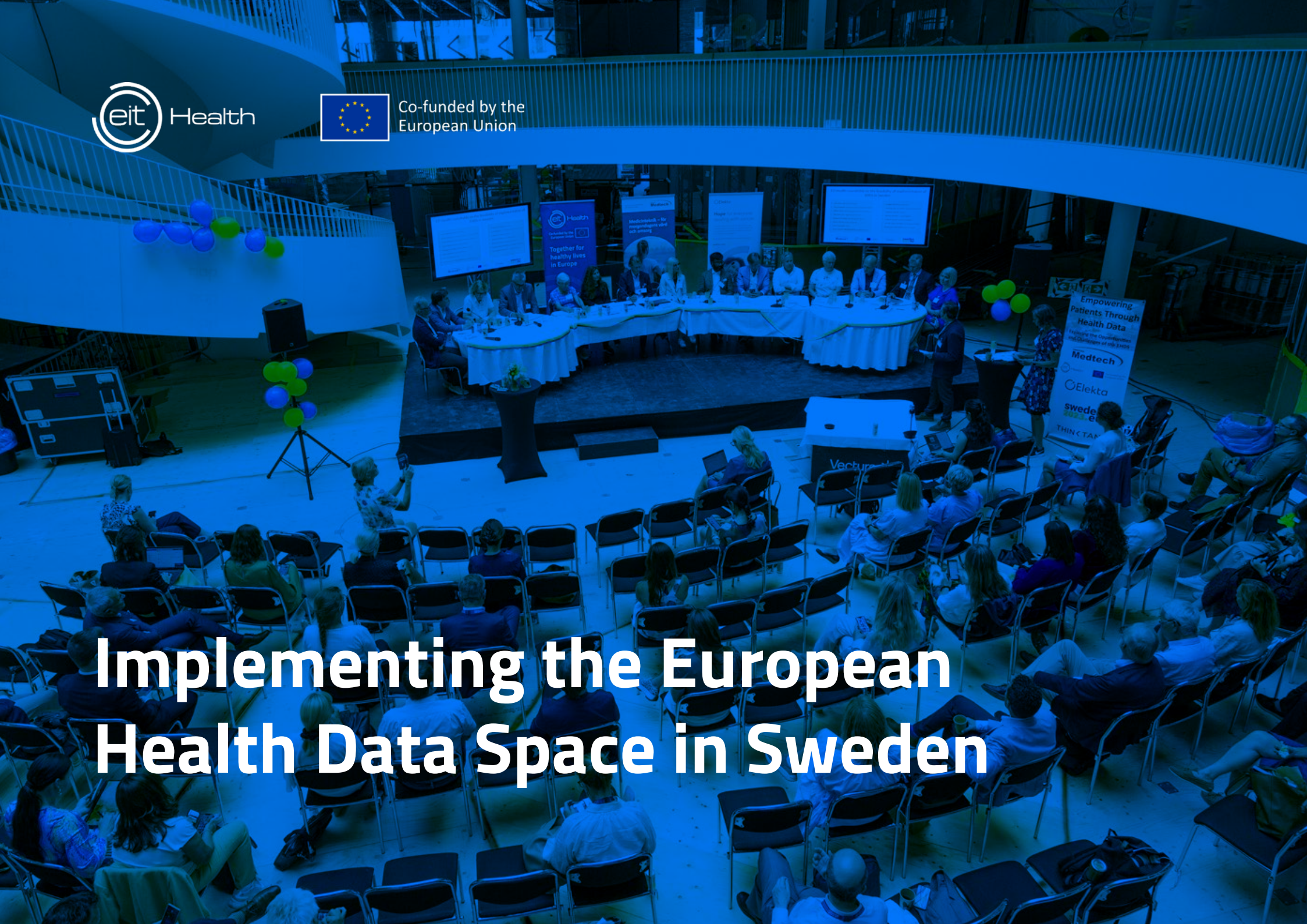


Implementing the European Health Data Space in Sweden

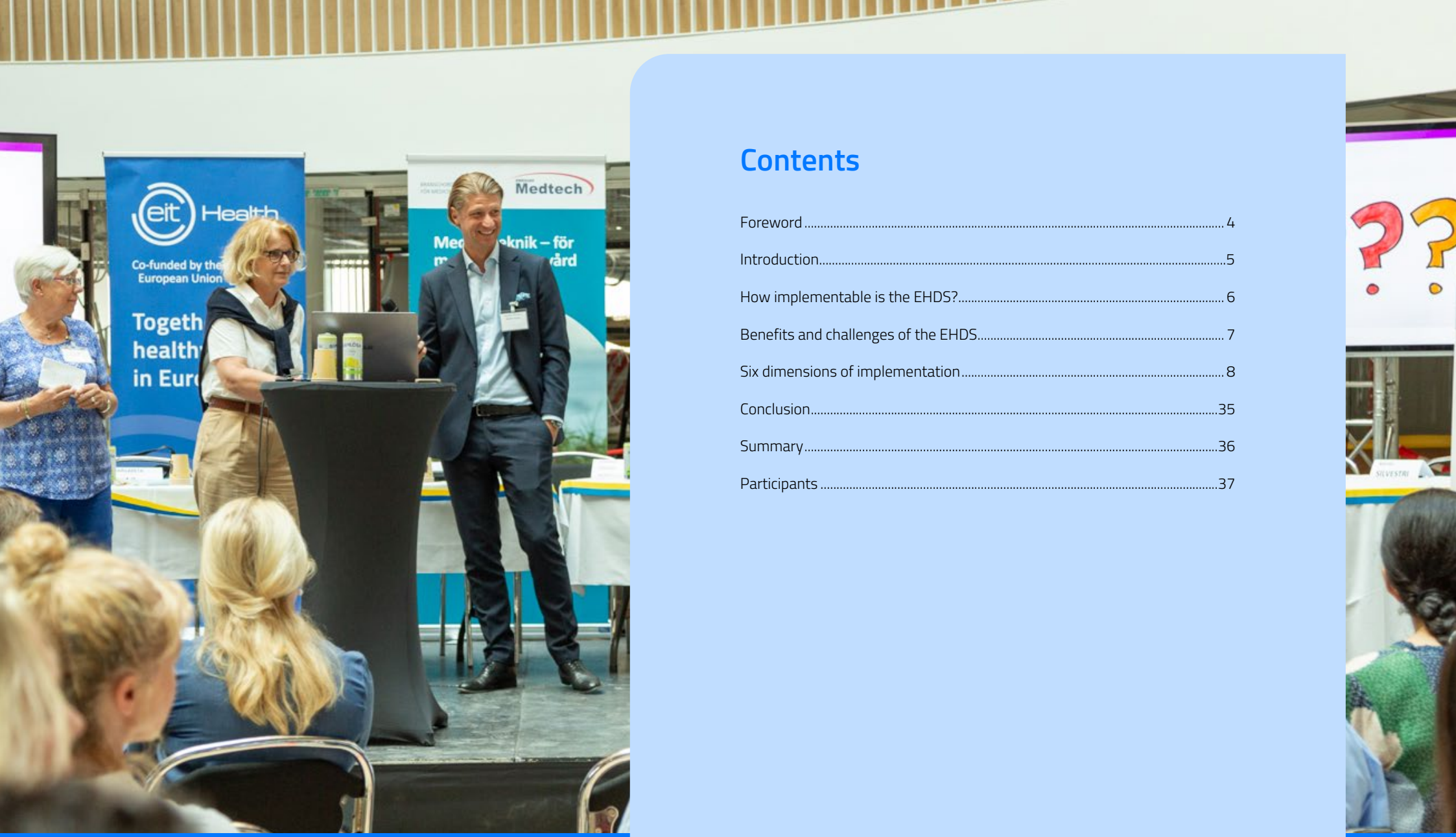
Implementing the European Health Data Space in Sweden

27 June 2023

Co-chaired by: EIT Health Scandinavia and Swedish Medtech

Moderated by: Filippa Kull and Andreas Namslauer,
Stockholm Science City

Photo: ANJA CALLIUS



From the left: Margareta Haag, Clara Hellner and Alexander Olbrechts.

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Foreword

The proposal on health data sharing, EHDS, was presented in May 2022 and it aims to offer people to control and utilise their health data in their home country or in other Member States and offer a single market for digital health services and products. Examples of health data include patient records, e-prescriptions, medical imaging and laboratory results.In a near future a finalised proposal will be ready to be implemented in all EU Member States.

There is a huge potential to use health data to gain more knowledge about diseases and poor health, but also to promote scientific research and optimise care with innovation for increased patient safety and improved quality of care. There are many winners from the proposal, not the least of which are patients and healthcare providers who will have access to more data for better research and better treatments. But of course, there are challenges, such as issues related to privacy and how patient data can be shared and used.

On 27 June, EIT Health Scandinavia, in collaboration with Swedish Medtech, organised a round table to discuss the opportunities and obstacles that exist for the upcoming implementation of EHDS. The round table was one in a series of ten that took place across the EU during 2023, feeding into the final report to be launched in Brussels in December 2023.

The initiative has been led by a steering committee chaired by Dr Andrzej Rys, Chief Scientific Advisor at DG SANTE, European Commission, who also participated in the roundtable in Stockholm. The Swedish representative on the Steering Committee is Dr Clara Hellner, Director of Research and Innovation, Region Stockholm.

The purpose of the roundtable is to provide an overall picture from EU Member States of the obstacles and opportunities for the upcoming implementation of EHDS.

In this report, we have gathered insights into the conditions in Sweden, the opportunities and the most important obstacles. The process was conducted by EIT Health and drafting support was provided by Alison Bouissou.

Many thanks to our panel of experts, our collaborative partners Swedish Medtech, Elekta AB and Vectura for giving us the opportunity to organise this together and to Stockholm Science City for excellent moderation and Anja Callius for capturing the moment with her fantastic photos.

Annika Szabo Portela
Managing Director EIT Health Scandinavia

Introduction

On 3rd May 2022, the European Commission published its plans for the European Health Data Space (EHDS)[1], a new framework intended to make it easier for individuals, doctors, researchers, and regulators to access and use information about the health of millions of citizens across the European Union. The network, which will require actions at the EU and national levels, aims to create a genuine single market for electronic health record (EHR) systems—a key pillar of the bloc's European Health Union—following the EU's high data protection standards. In a statement to mark the launch of the plan, Stella Kyriakides, Commissioner for Health and Food Safety, said, "The EHDS is a fundamental game changer for the digital transformation of healthcare in the EU. It places the citizens at its centre, empowering them with full control over their data to obtain better healthcare across the EU. This data, accessed under strong safeguards for security and privacy, will also be a treasure trove for scientists, researchers, innovators, and policymakers working on the next life-saving treatment. The EU is taking a truly historic step forward towards digital healthcare in the EU."

The EHDS plan has three key objectives:

1. To give individuals better digital access to their personal health data and to support free movement by having that data follow them across the Union.
2. To promote the data economy by fostering a single market for digital health services and products.
3. To set up strict rules for the use of an individual's non-identifiable health data for research, innovation, policymaking, and regulatory activities.

In its proposal, the Commission explains that while the EU health sector is rich in data, it is poor in making it work for people and science. For this reason, the EHDS aims to harness the wealth of health data across the Union to help prevent, diagnose, and treat diseases, support research, improve healthcare delivery, and speed up the development of new medical products and treatments—all while adhering to its strong principles of data privacy and control.

The Commission's EHDS plan covers the use of primary data, secondary data, common governance, and synergies with other health policy priorities. In terms of primary data, the EHDS aims to enable the millions of citizens of the EU to access their own health data and make it available to a health professional of their choice, including when abroad and in other languages, and also enable health professionals to update those records via the common myHealth@EU platform.

In terms of secondary use of data, the EHDS aims to set out a common EU framework allowing for use of anonymised health data of EU citizens for research, innovation in public health, policymaking, regulatory activities, and personalised medicine. It will draw on the creation of a new and decentralised EU infrastructure for secondary use of health data, HealthData@EU, which will connect health data access bodies in all EU member states. This infrastructure, piloted in five concrete use cases under the leadership of the French Health Data Hub, includes plans for permits governing the access to anonymised health data and how it can be used as well as closed, secure processing environments with clear standards for cybersecurity. The data will not be allowed to be used to make decisions that could be detrimental to individuals, to increase insurance premiums, to market health products toward health professionals or patients, or to design harmful products or services.

The proposal will also aim to reinforce the governance of health data at national and EU level. It will build on the current cooperation for primary use of data within the eHealth Network, which helped to build, in record time, two EU-wide infrastructures during the COVID-19 pandemic: the EU Digital COVID Certificate and contact tracing and warning apps. This will include the creation of a new EHDS Board to oversee the system, chaired by the Commission and staffed by representatives of digital health authorities and health data access bodies from the member states.

The proposed regulation is currently under negotiation within the European Parliament and the Council of Europe, whose final positions are expected by the end of this year. Once all institutions have agreed on the final regulation, the European Commission aims to have the EHDS finalised by mid-2024 and running by 2025.

1 https://health.ec.europa.eu/publications/proposal-regulation-european-health-data-space_en

How implementable is the EHDS? EIT Health assesses countries' readiness for the legislation

To assess the feasibility of implementing the EHDS in different EU regions and member states, EIT Health is conducting a pan-European, multi-stakeholder public affairs initiative focusing in particular on provisions relating to the secondary use of health data. The initiative is gathering experiences and real-world insights of EIT Health's partners and other relevant agents of the EU healthcare innovation ecosystem to shed light on what the realities and needs are in the individual countries in relation to adopting the EHDS, but also to distill lessons learnt and best practices from previous experiences of health data sharing for secondary use.

A series of 10 national or regional roundtable discussions is being staged throughout Europe in 2023 to compare and contrast the ability across sectors and borders to put the regulation as it currently stands into practice. A European steering committee made up of experts from different countries and chaired by Dr. Andrzej Rys, Director of Health Systems, Medical Products, and Innovation at the European Commission's Directorate-General for Health and Food Safety, is overseeing the initiative.

On 27th June in Stockholm, EIT Health Scandinavia in association with Swedish Medtech hosted the seminar and roundtable discussion, "Empowering Patients through Health Data: Exploring the Opportunities and Challenges of the EHDS". The roundtable brought together 16 panellists from the fields of academia, EU public policy, healthcare, health data, IT, med tech, patient advocacy, and public health. Participants discussed Sweden's readiness for the EHDS under six dimensions of implementation: Governance; Capacity and skills; Resources and funding; Data quality; Closing the loop: The relation between primary and secondary use; and Awareness, education and communication: Towards a data-driven culture in healthcare. Complementary insights and background were obtained through individual interviews with stakeholders from the healthcare, IT, and health data sectors.

Andrzej Rys

Benefits and challenges of the EHDS: a seminar by Swedish Medtech

In an introductory seminar hosted by Swedish Medtech, three speakers were invited to offer perspectives on the opportunities and challenges of the future EHDS from three different standpoints: patients, research, and industry.

Patients

Margareta Haag, President of the Swedish Network Against Cancer, welcomed the EHDS as an enabler of the kind of data-sharing that patients have been demanding for a long time to improve the care they receive, and the healthcare system as a whole. In particular, Haag saw potential for health-related data to enhance electronic health records and quality registers by integrating medical data with soft values and patient-reported outcome measures (PROMs), and expected that its sharing across organisational and geographical boundaries would improve both patients' safety and their experience of healthcare. She also viewed the EHDS as an enabler for patient empowerment and the exercise of patients' rights, from owning their data and being able to share it according to their wishes, all the way to performing self-monitoring and getting involved in clinical research. As data sharing and monitoring become a routine part of healthcare and health policymaking, Haag hoped that better prevention, precision diagnosis, and precision treatment would ultimately allow more patients to live a good life, both during and after their disease.

Research

For Clara Hellner, Director of Research and Innovation for Region Stockholm, the greatest strength of the EHDS proposal is its vision for the integration between primary and secondary use of data. As a researcher, she reported experiencing first-hand the historical disconnect between efforts to organise primary data collection in healthcare and the needs of secondary users. Although Sweden has a strong track record in registry-based research thanks to high-quality national statistics and databases, Hellner expected that the multitude of new data sources to be made available for secondary use under the EHDS would require novel forms of dialogue and collaboration between the national data governance body and regional points of contact to expedite retrieval and delivery of data from individual healthcare providers. Investments in human resources and skills, especially for extracting data from primary health information systems, will need to be significant. An ability to understand and communicate the quality of the data being shared will also be key to producing meaningful research and valuable innovation for patients. While recognising the possibilities in this area, Hellner highlighted the need to protect the research ecosystem by safeguarding the prerogative to publish scientific results prior to sharing data and recognising that researchers should be free to use the technical solutions for data processing and analysis that best meet their needs.

Industry

Alexander Olbrechts, Director of Digital Health at MedTech Europe, described the EHDS as a turning point in history for how the med tech industry approaches the development and commercialisation of new health technologies for patients, with elements such as interoperable electronic health records creating a single market for digital health in Europe. As an undertaking to unlock the potential of health data to create more sustainable and resilient healthcare systems, Olbrechts emphasised that the capacity of the EHDS to deliver on its promise would hinge on careful implementation that builds trust from the outset. In particular, he called attention to the cybersecurity implications of exponentially adding value to every megabit of data produced within healthcare, thus making that data all the more desirable for ill-intentioned actors. Getting these basics right, he argued, would start a cascade of innovation to strengthen health and healthcare in Europe, from empowering citizens to play an active role in their own health to easing the growing pressure on healthcare providers and addressing medical staff shortages. In a context where small and medium-sized enterprises (SMEs) are the main drivers of innovation in med tech, and the sector has seen more traditional companies enter the digital arena by integrating new technology into conventional medical devices, Olbrechts called for implementation of the EHDS to start with clear definitions—of what constitutes an electronic health record, of what data will be relevant for sharing—and efforts to ensure the legislation integrates seamlessly into the wider EU regulatory landscape and to have alignment with the existing framework, especially with MDR/IVDR and the GPDR.

Six dimensions of implementation

Andreas Namslauer and Filippa Kul

1 Governance

The EHDS will introduce a common system of data governance and rules and guidelines for data exchange in the health sector. This will be coordinated at national level by Digital Health Authorities for primary use of patient data, and by Health Data Access Bodies for secondary use. The ability of different stakeholders in Europe's health ecosystems to apply the EHDS regulation and engage in cross-border sharing of data will, among other things, depend on the conditions prevailing in individual countries in terms of the availability and maturity of electronic health record (EHR) systems as well as rules for health data anonymisation and pseudonymisation, privacy, authorised and prohibited use purposes, and consent requirements under national interpretations of the GDPR. In some cases, changes to existing national legislation may be required. The existence and current capacities of organisations for health data governance, and the different policies and practices surrounding the use of health data within individual organisations, will further determine the ease of implementation in each member state.

This section will review the governance structures, legislation and formal processes for governing access to health data in Sweden and how they may be used or adapted for implementation of the EHDS.

Laurent Saunier

How ready is Sweden?

Current landscape

In Sweden, the healthcare system is decentralised. Public health and care services are managed and run either by the regions, local authority, or municipality, each of which is responsible for the allocation of its own healthcare resources. This organisation is reflected in the storage and governance of health data: while public health data is collected at national level, for example by the Public Health Agency of Sweden and various national disease registries, most of the data generated in the course of healthcare provision is held and governed locally in the regions.

Challenges

Legal barriers to sharing health data

Sweden's legal readiness to enable the use of health data has historically lagged behind its technical readiness, including in the primary use setting as the country will be one of the last EU member states to connect to the myHealth@EU platform for e-prescriptions and patient summaries. "Despite having all the technical solutions in place for several years, we are still waiting for the legal framework to allow it," emphasised Michel Silvestri, Swedish e-Health Agency, former member of the Swedish negotiation team on the EHDS, advocating for a governmental inquiry to start a comprehensive investigation into the legislative changes that will be required to support secondary use of health data under the EHDS. In particular, it was anticipated that while making national sources of health data available within the future EHDS would pose no difficulties, changes to the current national legislation would be required to integrate the full wealth of data held in Sweden's regions. "When it comes to secondary use of health data specifically, we can probably anticipate that we will need to amend the Patient Data Act, the Ethical Review Act, as well as the Public Access to Information and Secrecy Act."

Recommendation:

- Launch a comprehensive investigation into the legislative changes required to support secondary use of data under the EHDS

National and regional allocation of EHDS roles and responsibilities

Uncertainty remains as to who will take on the responsibilities of the national health data access body. Although the eHealth Agency was cited as one strong candidate among several, the issue is complicated by the fact that the foreseen responsibilities of this EHDS governance body are currently distributed across multiple agencies and authorities in Sweden. "Even within the regions, data governance is decentralised and spread over several different systems and data managers," highlighted Clara Hellner, Director of Research and Innovation for the Stockholm Region. The larger the region, the greater the number of data holders and data managers. Within her own region, Hellner explained that the high share of private healthcare providers adds a further layer of complexity as some data is not owned or governed by the regional agencies but rather by the private institutions commissioned by the region to provide certain health services. These include labs, ambulatory care, vaccination centres, among others.

With a final decision on this matter still outstanding, Silvestri predicted that some level of regional governance with several data access bodies networked in with the national contact point would be needed. Hellner further argued that these regional access bodies should be legally empowered to handle and extract data centrally to enable the sharing and use of data from local sources.

Recommendation:

- Establish a network of regional access bodies legally empowered to handle and extract data centrally

Opportunities

A favourable political climate and a proactive approach

Among the factors that would facilitate the implementation of the EHDS in Sweden, it was noted that a clear signal had been set at a political level in Sweden from the start. "The Swedish government and the parliament are favourable to the EHDS proposal and the topic has had high priority, including during the recent Swedish presidency of the Council of the European Union," Silvestri reported. As a result, roundtable participants agreed that from a data governance perspective, much of what the EHDS foresees is already ongoing or being developed at several government and state agency levels, placing Sweden in a favourable starting position to implement the EU legislation.

Priorities for implementation

Enable data-sharing while protecting intellectual property

Clear and consistent legal guidance

In addition to the necessary legislative review mentioned above to ensure a consistent legal landscape enabling national implementation of the EHDS, Silvestri highlighted the importance of developing clear legal guidance with instructions for the authorities that will be responsible for data governance in Sweden.

Recommendation:

- Develop clear legal instructions for the national (and regional) EHDS governance bodies

Protection of intellectual property

There was also a clear call from several sides to enshrine the protection of intellectual property rights in the final EHDS legislation. Representatives of both industry and academic research proposed that a period of time should be defined during which exclusive access to data is guaranteed for the entity generating it. In particular, a distinction was made between the raw data researchers collect either directly from patients or from the national registries and regional data collections, and the refined datasets that they obtain after processing this data to make it usable for their purposes. "If you spend a lot of your own time and other people's money to work on data, connect it, and increase its value for example by annotating things in medical images, this needs to be protected in some way, for some time," argued Dr. Fredrik Strand, radiologist and researcher at the Karolinska Institute in Stockholm. Hellner advocated for such protection to be extended to the full interval of time it takes for researchers to publish their papers, highlighting that this can sometimes take years. As publications are researchers' livelihood, clear safeguards in this area were also deemed essential to avoid incentivising attempts to hide data and evade sharing obligations.

Similarly, Anders Murman, CEO and co-founder of Deversify, ruled out a mandate for companies like his, which conduct research with their own data and with other open databases, to release all of their datasets in real time. Silja Elunurm, Head of Regulatory Affairs at Migrevention and former member of the e-health team within Estonia's Ministry of Health, commented from a legal perspective that forcing an entity that has invested in creating a new database to release it without delay into the public domain would amount to eliminating their economic right. "This will be an interesting fundamental rights case for the European Court of Justice to discuss, whether it's even possible in this way," she said. "On the other hand, economic rights can be licensed out, so there would be something in it for everybody."

Recommendation:

- Agree at EU level on a protected interval of time during which research and/or private entities retain exclusive access to their datasets

Multistakeholder collaboration to develop the national governance framework

To solve the legal and structural issues described above and develop a national governance infrastructure for the EHDS that corresponds to the organisation of healthcare and health data collection in Sweden, participants emphasised that more ministries and public bodies would need to get involved and collaborate effectively than has been the case to date. "Agencies from the national finances, ethical authorities, and privacy authorities will need to work together with us on this," argued Laurent Saunier, Head of Precision Health at Vinnova, the innovation agency of the Swedish Ministry of Climate and Enterprise. Another participant also called for more active involvement of the interdepartmental Life Sciences office.

In addition to healthcare and industry representatives who already have a seat at the table, several panellists highlighted the importance of giving patients and citizens a say in this process as they were identified as a driving force for implementation of both primary and secondary data use under the EHDS in Sweden. "Patients are pushing for the EHDS to become a reality, so their voices should be heard to ensure that the framework fulfils its promises towards them and the healthcare system," said Margareta Haag, Chair of the Swedish Network Against Cancer.

Recommendation:

- Ensure multistakeholder and cross-government involvement in developing a national framework for EHDS governance. including stakeholders and representatives from patients, citizens, healthcare professionals, industry and academia/research institutes

Key recommendations

- Launch a comprehensive investigation into the legislative changes required to support secondary use of data under the EHDS
- Establish a network of regional access bodies legally empowered to handle and extract data centrally
- Develop clear legal instructions for the national (and regional) EHDS governance bodies
- Agree at EU level on a protected interval of time during which research entities retain exclusive access to their datasets
- Ensure multistakeholder and cross-government involvement in developing a national framework for EHDS governance

Clara Hellner

2 Capacity and skills

Establishing and maintaining infrastructure for the collection, storage, protection, sharing, and secondary use of electronic health data requires specific human resources and skills that are not always readily available. The responsibility of national health data access bodies to examine requests and issue permits, to process the relevant data in more or less centralised pools and deliver access to it for users, as well as to network with their counterparts in other Member States via the core platform HealthData@EU, will require some degree of capacity-building in the public administrations of individual countries. Single data holders such as hospitals, research organisations, and private sector companies will also be required to standardise their datasets and the paths to access it. Finally, the EHDS will bring about significant changes and new opportunities in the way users can interact with health data. For instance, the possibility to bring together large numbers of independent datasets for analysis or the potential to conduct studies on an unprecedented scale with millions of patients will require new skills and changes in existing practices on the part of research communities, innovators, and policymakers.

This section will assess the current capacity within public bodies and healthcare institutions and identify the skills required to implement the EHDS in Sweden.

How ready is Sweden?

Current landscape

A longstanding tradition of secondary use of health data
Sweden has a strong tradition of public health data collection dating back to the 1950s. In particular, the National Board of Health and Welfare has 14 national registries which are mandatory by law. The country also has a strong track record of secondary use of data for research in fields such as epidemiology, thanks to the national registries but also to the official statistics provided through Statistics Sweden in areas including causes of death, health and disease, healthcare and medical services.

Infrastructure for the EHDS is already being built
It was reported that Sweden had a head start in terms of technical capacity for the EHDS, as much of the data infrastructure required is already available or under development. In particular, a national system enabling communication between different hospitals has been in place for years, and infrastructure is currently being built to allow data exchange between the regions. Sweden is also involved in various projects at European level, including the Genomic Data Infrastructure[1] and EUCAIM, the European Federation for Cancer Images,[2] in which actors in the member states are working together to share high-quality, curated data across borders that can be used for other purposes than healthcare provision.

Challenges

Capacity and skills for data extraction and transfer are lacking
Although technology is constantly evolving, participants explained, the possibility to automate data transfers to a secure processing environment currently still requires data experts to "flip the switch" and set up the processes for what data to make available for each request. Even though the EHDS will give the health data access bodies the right to process data, the data holders will nonetheless need to make data available and turn on that switch. Different data sources can be more or less difficult to access, such as highly structured register data in centralised data warehouses compared to raw data from EHRs. "For example, the Stockholm region's EHR system does not have a clear structure for data extraction, creating a need for highly skilled data extraction experts who can retrieve the requested information," Hellner reported, adding that the relevant skillset in this domain takes years to accomplish. "It's not only a question of programming skills, but also requires deep knowledge of the international, national, and regional medical informatics, the relevant organisational structure and how data is recorded differently in different modules of the EHR."

Further limitations described were a lack of good documentation on what regional health data is actually available, and limited capabilities to satisfy complex requests for data from multiple sources and in different formats—especially within the specified timeframe of two months following request approval by the national health data access body. In addition to providing a further rationale for empowering regional access bodies to support with data cataloguing, extraction, and handling, Hellner expected that each data holder would need to employ dedicated staff to fulfil access requests. Given the scarcity of the skillset required, the time needed to acquire it, and the large number of data holders, estimated at 400 in the Stockholm region alone, Dr. Nasim Farrokhnia, industry advisor at Microsoft and senior lecturer at Karolinska Institute in Stockholm, recommended that hospitals should try to work together to share competences and use synergies across different institutions.

Recommendations:
- Empower regional access bodies to support with data cataloguing, extraction, and handling
- Recruit and train additional data extraction experts for healthcare institutions, pooling resources and sharing competences where possible

Increased risk of security and privacy breaches as more data and new users enter the ecosystem
Another challenge Hellner highlighted concerns the capacity to conduct thorough evaluations of data permit applications, whose complexity will only increase with the multitude of new data sources that will become available through the EHDS. "Our experience from the Stockholm Centre for Health Data is that requests for data are already growing more and more complex, with requests for bigger volumes of data as well as data from multiple

1 https://gdi.onemilliongenomes.eu/
2 https://cancerimage.eu/

sources and in different formats, both structured and unstructured, which may also need to be linked to data from external sources," she explained, emphasising the heightened risk for integrity breaches in these kinds of requests and the need to carefully assess them in that light.

Hellner saw a further risk in the fact that the EHDS will increase the number of data users and include other profiles than just researchers, as secondary use of health data will also be possible for innovation and policymaking purposes. "We will see more 'inexperienced' data users entering the system without necessarily having the knowledge of the confidentiality levels and processes that are required today to handle sensitive personal data. The risk of breaching existing privacy protections due to lack of experience or ignorance may therefore exist," she argued.

Recommendation:

- Anticipate the need for capabilities within access bodies to assess complex data requests and support inexperienced data users to limit the risk of security breaches

Opportunities

Existing experience in centralised health data access: The Stockholm Centre for Health Data

The Stockholm Centre for Health Data is a collaborative organisation within Region Stockholm dedicated to providing a hub for researchers who require access to health data, which could provide a template for managing data access through a single point of contact as foreseen by the EHDS. The department performs a service role for researchers by ensuring they do not have to refer to multiple healthcare providers to gain access to data, providing advice on data availability and quality as well as help with linking data from different sources. For healthcare providers, it offers a one-stop shop with professional, coordinated assessment of the type of data to be shared, and how this should be carried out in accordance with national confidentiality and data legislation. It conducts extensive confidentiality examinations before each release of data to ensure the recipient has the ability to guarantee the privacy and security of the data they obtain, however authorising the access is still within the remit of the healthcare institutions that actually hold the data. Included in the centre's role as intermediary is helping researchers ensure their applications are complete with a clear research assignment and ethical approval for their project from the Ethical Review Authority, sending these to the relevant data holders, and coordinating any requests for additional filings.

Although it does not have its own database, the Stockholm Centre for Health Data centralises access to the Stockholm region's health data by coordinating its release for permitted purposes. The data available covers all healthcare provided to the region's residents, including a limited amount of information on the care they have received in other regions, as well as the care provided by the region's healthcare providers to residents of other regions. The data sources range from a regional patient registry with historic data (VAL databases) dating back to the 1990s, to data from EHRs, lab systems, radiological imaging, and others. Data is typically delivered in encrypted csv files on an external secure data storage media, but there are plans to provide access through so-called trusted research environments in the future. As Hellner reported, however, it currently takes data users up to 18 months to obtain data holders' approval and access data—significantly longer than the three-month application-to-approval period and two-month window to deliver access foreseen by the EHDS proposal.

Recommendation:

- Leverage experience and expertise from existing infrastructure like the Stockholm Centre for Health Data to inform capacity-building and skills acquisition for EHDS access bodies
- Dedicate capacity to reducing the time to access data from months to days or weeks

Significant investment in artificial intelligence

Big data analytics and artificial intelligence (AI) applications will be integral to fully realising the potential of the unprecedented volumes of data that will become available through the EHDS. Although knowledge and experience of these technologies varies between sectors and medical fields, it was noted that a lot of research is already ongoing in this area in Sweden, with some applications like AI-driven analyses of X-rays expected to be ready for

implementation in the near future. Big data analytics and the development of techniques such as AI and machine learning have benefited from significant investment from the Swedish government, private investors, as well as the country's healthcare institutions and universities. Although attention was called to the need to implement quality assurance systems to validate the models, improve knowledge throughout the healthcare and research ecosystem, and proactively address the ethical issues that arise from the use of these technologies, Sweden's progress in this area was considered a positive foundation for utilising the future EHDS.

Recommendations:

- Develop quality assurance systems to validate AI models
- Educate health researchers and healthcare professionals on the use of AI applications
- Establish processes to address ethical issues that arise from use of AI in healthcare

Priorities for implementation

Capacity for guidance and support functions within data access bodies

As Hellner reported from experience within the Stockholm Centre for Health Data, one of the most time-consuming and resource-intensive tasks as a data access hub is processing incomplete or erroneous applications. "Gaps and errors we see in applications range from a lack of clear descriptions of what regional health data are required, through missing information on how researchers will protect the data after they have received it, all the way to asking for data that is not covered by their ethical approval," Hellner said, explaining that a lot of time and effort is subsequently spent by staff to follow up with applicants and make the required changes. "The centre is constantly working on giving clear instructions on our web page as well as offering researchers advisory meetings before they send in their applications. There are also plans to hold educational seminars on how to apply for regional health data." As this phenomenon would likely be compounded by the possibility for users outside the traditional research ecosystem to apply for data permits under the EHDS, the need to build capacity for application guidance and support within the future data access bodies should not be underestimated.

Recommendations:

- Provide data access bodies with sufficient capacity to fulfil guidance and support roles for future data applicants
- Develop supporting documentation and training for data permit applications

Data infrastructure co-developed with its future users

It was observed during the roundtable that the infrastructure needed to implement the EHDS is not something that can easily be bought off the shelf, ready to go into operation at the press of a button. The IT industry will therefore be called on to deliver solutions that do not exist today to build it, but panellists advocated that these should be developed in cooperation with Europe's healthcare systems, the government agencies that control them, and the users of the future EHDS. Farrokhnia added that the process of building the EHDS infrastructure could, and should be used as a means of engaging the healthcare institutions and medical professionals, who will play a key role in making the EHDS come to life, early in the process of implementation. "In terms of technical solutions, the aim of the EHDS to give the individual control over their data and achieve data fluidity requires working with international standards like OMOP, OpenEHR, and FIHR, rather than trying to reinvent the wheel at every local level of implementation," said Farrokhnia. "But developing solutions based on concrete use cases that show data holders how data can be used for secondary purposes will be equally essential to help institutions see how to implement the EHDS. Microsoft works with pharmaceutical companies, healthcare providers, and independent software vendors to build these use cases and demonstrate the value along the patient journey."

Recommendations:

- Foster international collaboration between the IT industry and key EHDS stakeholders to develop technical infrastructure for the EHDS based on concrete use cases
- Promote the development of scalable solutions based on international standards

Key recommendations

- Empower regional access bodies to support with data cataloguing, extraction, and handling
- Recruit and train additional data extraction experts for healthcare institutions, pooling resources and sharing competencies where possible
- Anticipate the need for capabilities within access bodies to assess complex data requests and support inexperienced data users to limit the risk of security breaches
- Leverage experience and expertise from existing infrastructure like the Stockholm Centre for Health Data to inform capacity-building and skills acquisition for EHDS access bodies
- Dedicate capacity to reducing the time to access data from months to days or weeks
- Develop quality assurance systems to validate AI models
- Educate health researchers and healthcare professionals on the use of AI applications
- Establish processes to address ethical issues that arise from use of AI in healthcare
- Provide data access bodies with sufficient capacity to fulfil guidance and support roles for future permit applicants
- Develop supporting documentation and training for data permit applications
- Foster collaboration between the IT industry and EHDS stakeholders to develop technical infrastructure for the EHDS
- Promote the development of scalable solutions based on international standards

3 Resources and funding

Although health data access bodies (HDABs) and individual data holders will be entitled to charge access fees to users, these will likely recover only a small part of the total cost incurred to transform, pool their data, and make it accessible within the EHDS. The resources available for this will vary from one organisation to another and could in practice limit their ability to comply with the new requirements. In its position statement on the EHDS, EIT Health therefore called for support to ensure that the framework represents an opportunity rather than a challenge for stakeholders.

This section will focus on the expected costs, available resources, and areas where investment will be needed to support implementation in Sweden.

1 https://eithealth.eu/wp-content/uploads/2022/05/EIT-Health-Statement-on-the-EHDS-proposal_final-05052022.pdf

Niklas Eklöf

How ready is Sweden?

Current landscape

Available funding falls short of expected cost of implementation
As the first of nine planned European data spaces, participants expected that the EHDS would be the most expensive. There was widespread agreement that although funding is available in Sweden, at present it is almost certainly insufficient to cover the full cost of implementation estimated in the billions of euros at EU, and perhaps even at national level. The question of who will shoulder which costs at government, regional, and institutional level has not yet been clearly answered. "Some hospitals are aware of what will be asked of them, but also have very limited resources to actually do it," said Farrokhnia. "Everybody is asking about the funding, whether more will become available and where it will come from."

Insufficient human resources
Similarly, it was noted that the human resources needed to implement the EHDS—including from legal and administrative functions to ensure timely and compliant access to data, as well as technical support to manage IT systems, drive interoperability, and enforce standards—are not currently available in sufficient numbers within the relevant organisations.

Challenges

A difficult cost-benefit analysis for payers
Among the key challenges that panellists anticipated in relation to securing sufficient funding for implementation is that returns in proportion to the investments required will take many years, if not decades to materialise for the payers: government, public agencies, healthcare institutions. Not knowing when in the future they will "break even", as well as not being able to predict the exact nature of the rewards for different stakeholders as new possibilities emerge, for example to connect data across different European data spaces, could inhibit various actors' willingness to pay in the short term. This especially holds true for healthcare providers, which in addition to the expense incurred will likely see an increase in administrative workloads that cannot easily be absorbed by already by their overstretched medical staff. To make the cost-benefit ratio more tangible and more attractive for healthcare institutions, Farrokhnia called for EU funding to support specific research projects through which shared or interconnected infrastructures for the EHDS can be built. "For example, clinicians love doing multicentre studies. So instead of talking generally about interoperability, we could take the use case of AI for diagnosing cancer and ask ourselves how we can train an algorithm in a federated setting, across five different European hospitals in a way that complies with the rules of the EHDS," Farrokhnia suggested. "Then we'll have built that piece of the puzzle, all the while fostering engagement among the clinicians and institutions involved."

Recommendations:
- Combine national and regional funding with EU funding and distribute the financial burden across the health ecosystem
- Provide EU funding for research projects through which healthcare providers can invest in infrastructure for the EHDS and mutualise costs with other institutions

Opportunities

A template for efficient investment: the European Genomic Data Infrastructure
An number of existing EU projects, in which Sweden is also involved, have already delivered solutions and infrastructures that could be leveraged for an efficient and harmonised implementation across Europe. In particular, Elunurm cited the European Genomic Data Infrastructure, which provides not only a technical building block for the EHDS but also an example of best practice in terms of funding and incentive creation. "It was 50% the European Commission's money and 50% the states' money. Estonia, like other member states, participated because it had an interest in enhancing its own health information system to make it functional with the Estonian genomic database," she reported. "There was a pilot project and infrastructure elements were developed which we can now reuse to build our own national node. Developing solutions together and reusing infrastructure components in can make implementation significantly cheaper than if each member state develops its own systems."

Recommendations:
- Create financial incentives for member states to collaborate and pool their resources on projects of common interest
- Reuse technical building blocks from previous EU projects for harmonised and cost-efficient infrastructure development in each country

1 https://tehdas.eu/packages/excellence-in-data-quality/

Priorities for implementation

Efficient investment in a European data infrastructure

According to Alexander Olbrechts, Director of Digital Health at MedTech Europe, a top priority moving forward should be to ensure that any funding provided at EU or national level to implement the EHDS in each country should be channelled towards projects and initiatives that support the development of one integrated European system. "We need to keep in mind that this is supposed to be a single European Health Data Space, not 27 national data spaces, because the power is in having these massive quantities of data," said Olbrechts. "Subject of course to the necessary respect for local organisations, we should avoid fragmentation for both practical and financial reasons."

Recommendation:

- Channel new EU and national funding for the EHDS towards projects that support an integrated European implementation

A common understanding of the resources needed

Several participants highlighted the importance of reaching a clear agreement at EU level about how exactly the EHDS framework will operate, to help national stakeholders better understand which resources need to be mobilised and focus on implementation rather than legal interpretation.

There was general agreement that in Sweden, data infrastructure would require the most urgent investments. Significant funding needs were also expected to arise for data holders and access bodies to recruit and train skilled staff to curate, standardise, and maintain databases as well as expedite data access procedures: experts on the interface between health and technology, data stewards, medical informatics specialists, lawyers, among others. Participants additionally foresaw new collaborations and professions arising with the EHDS, to which resources will need to be allocated.

Recommendation:

- Define the exact functioning of the EHDS as much as possible at EU level to clarify resources needed for implementation in the member states
- Allocate funding at national level for data infrastructure investments
- Allocate budget for new human resources within different organisations

New socio-economic models to secure sustainable funding

To ensure the financial sustainability of the EHDS in the long term, Saunier anticipated that new socio-economic models would need to be developed to secure funding from the stakeholders for whom the costs incurred for implementation generate benefits that they are willing to pay for. "This regulation is supposed to drive the development of value across society, not just in healthcare. Of course, infrastructure, capacity, and skills all have their costs, but they will also create benefits somewhere, so we need to look at this as an equation with two sides and to understand that equation much better," Saunier explained. "We need to find those mechanisms within society at large, so that when we invest money in or around the healthcare system we gain money in some other area."

Recommendation:

- Identify the mechanisms by which long-term funding for the EHDS can be secured from the stakeholders across society for whom benefits are generated

Key recommendations

- Combine national and regional funding with EU funding and distribute the financial burden across the health ecosystem
- Provide EU funding for research projects through which healthcare providers can invest in infrastructure for the EHDS
- Create financial incentives for member states to collaborate and pool their resources on projects of common interest
- Reuse technical building blocks from previous EU projects for harmonised and cost-efficient infrastructure development in each country
- Channel new EU and national funding for the EHDS towards projects that support an integrated European implementation
- Identify the mechanisms by which long-term funding for the EHDS can be secured from the stakeholders across society for whom benefits are generated

Margareta Haag

4 Quality of data

Collection, use, and storage of healthcare data varies between organisations and countries, making it difficult to compare data across different sources and across borders. A common framework is needed to ensure that the data being shared within the EHDS is reliable and meaningful to produce trustworthy and useful research results, yet standards and auditing requirements must be inclusive enough as to allow every member state to participate. In particular, the possibility to use data from EHRs or medical devices for secondary research purposes requires that the reliability of the relevant datasets be scientifically validated.

This section will explore the interconnectedness of data, as well as data standardisation and management.

How ready is Sweden?

Current landscape

Data quality standards differ between primary and secondary use settings
According to Niklas Eklöf from the Swedish National Board of Health and Welfare, data quality frameworks and standards vary across the health ecosystem in Sweden. "At the national level, we are at the forefront when it comes to secondary use of data: we have been collecting data for 70 years, so we have a solid framework and excellent data for secondary use," Eklöf reported, contrasting this with the primary use setting, where his organisation has developed recommendations on data quality and advocated for the adoption of international standards such as ICD10, ICD11, and SNOMED CT, but these are currently not mandatory.

Challenges

Who will assume responsibility for data curation and improvement measures?
Even if the most up-to-date international data quality standards were applied to data collection in healthcare tomorrow, there would still be decades' worth of legacy data from Sweden's regional systems to structure, standardise, and make available for secondary use. As Elunurm pointed out, the fact that data holders, data controllers, and data processors are usually distinct organisations raises the question of who will assume responsibility and, importantly, pay for this data curation and improvement effort. "When I was working at the Estonian Ministry of Health, we estimated that the time and resources required for data retrieval was split 80-20 between the data holders and the data controllers, which were the ministry and the national eHealth Agency," said Elunurm, underlining the inherent imbalance of expecting organisations primarily interested in primary use of health data to shoulder 80% of the burden to allow its use for secondary purposes.

Opportunities

The EHDS as a catalyst for data quality
It was anticipated during the roundtable that the EHDS legislation itself could over time act as a catalyst for data quality, as the current proposal foresees quality and utility labels for the datasets integrated in the network. Silvestri therefore recommended that these concepts be further defined in the final regulation and build on the FAIR principles, according to which data should be Findable, Accessible, Interoperable, and Reusable. "Based on clear definitions, a voluntary system of platinum, gold, and silver tiered labelling of datasets could then be established to foster a degree of benchmarking across different data holders," Silvestri suggested.

The EHDS framework will also likely require some form of certification for EHR systems, which was identified as another enabler of data interoperability and quality as the existing EU Medical Device Regulation (MDR) provides a template for evaluating both of these attributes in health technologies. There were calls for this certification process to be clarified, however, as the European Commission's proposal for a self-certification system has been countered with demands for third-party certification in the ongoing negotiations. Leo Hovestadt, Director of EU Governmental Affairs at Elekta, expressed reservations about the feasibility of implementing third-party certification backed by a sufficient number of notified bodies with the capacity to expedite applications in a reasonable timeframe. "The new requirements of the MDR have already made the procedure for obtaining CE marking unmanageable for SMEs. We need to have a single system with clear guidelines and homogeneous implementation across Europe," said Hovestadt.

Recommendations:

- Further define concepts of data quality and utility in the EHDS legislation, building on FAIR principles
- Design a voluntary data labelling system of quality tiers to foster benchmarking between data holders
- Define an efficient EHR certification system that companies of all sizes can cope with

A European quality framework for the EHDS: Joint Action TEHDAS
The "Joint Action Towards the European Health Data Space" (Joint Action TEHDAS) is an EU project involving 25 countries and coordinated by the Finnish Innovation Fund Sitra, with the goal of developing joint European principles for the secondary use of health data. With one of its eight work

packages dedicated to "Excellence in data quality", Joint Action TEHDAS has over the past two years proposed solutions for the trustworthy secondary use of health and developed guidance on ensuring data quality.[1] "On the basis of the preliminary results of our efforts to data, we have now defined recommendations that will be published within the final TEHDAS quality framework," said Elina Drakvik, specialist at the Finnish Innovation Fund Sitra. "These will include both the technical quality aspects and the utility dimension." Offering some initial insight into the key learnings and recommendations of the upcoming framework, Drakvik highlighted those pertaining to the operational and financial burden that the preparatory to ensure data quality will represent for data holders. "We recommend support for data holders in the areas of data and knowledge management as well as quality assurance, and have developed a data holder maturity model to help increase the maturity of data holders and the quality of their data," she reported. Further guidance will pertain to the labelling of datasets and the publication of data catalogues, and metadata catalogues, following international standards.

Recommendation:

- Adopt and implement the upcoming Joint Action TEHDAS data quality framework at national level to ensure a harmonised European approach to data quality

Priorities for implementation

High-quality, curated data from medical devices

There was agreement among panellists that ensuring the quality of data integrated in the EHDS would require a considered selection of datasets from medical devices rather than opening the floodgates on this potentially infinite source of data. First, Anna Lefevre Skjöldebrand, CEO of Swedish Medtech, advocated that akin to the future certification requirement for EHR systems, only data from CE marked medical devices should be included. "Data quality is one of the key characteristics that CE marked medical devices are evaluated on, but we find that healthcare providers are not always aware of this fact. The assumption is often that any technical device can do the same thing," Skjöldebrand explained, highlighting the importance of laying this down as an explicit rule for data holders.

Second, Olbrechts recommended that only validated output data should be considered for sharing, excluding raw device-generated data on grounds of its limited utility. "We don't have to reinvent the wheel, but we do have to take into account the wide variety of technologies to potentially come under the scope of the EHDS, as well as the complexity within patient pathways," he said. "We're talking about large datasets for secondary use, so we need to be mindful about what we are going to put in: what is actionable data."

Recommendations:

- Exclude all non-CE marked technologies from the scope of the EHDS
- Define more precisely which data from medical devices is relevant and useful for sharing

Stakeholder participation in designing a viable data quality framework

In finalising the common quality framework for the EHDS, confirming its relevance for the intended purposes and its feasibility for the different actors who will have to uphold its standards in the future was considered essential. "The EHDS proposes to create separate frameworks for data interoperability and data utility. For both of these we need to have clarity on what is achievable by the makers of the information systems, as well as ascertain that they are delivering value to the people who will use the data," Saunier explained. He identified a number of stakeholders who would need to be involved in this exercise, including the industry and research communities. Both sectors will also need to be consulted on which existing international health information standards to implement, and which new standards to adopt as they emerge. "One of the actors we often forget is the procurement side," Saunier added. "The people who buy the systems will need to know which standards to specify in their procurement."

Elunurm also cited the users of health information systems and medical devices, be they healthcare professionals, administrative staff, or patients. "When it comes to data quality, asking people to follow specific standards must go hand in hand with a focus on user-centric design for all of these systems into which data is entered," she emphasised. "Today, most of our problems come from this lack of user-friendliness. People try to understand what to enter where and then end up with a myriad of different tables open,

1 https://tehdas.eu/packages/excellence-in-data-quality/

which creates frustration and leads to errors being made. When we don't have an automated quality control function within these systems, that then leads to disparities in quality."

Recommendations:

- Validate the viability of data interoperability and utility frameworks with relevant stakeholders
- Consult industry and research actors on the choice of international data standards to be implemented
- Involve public procurement bodies in defining specifications for health information systems
- Include user-centricity in the data quality evaluation criteria for health information systems

Quality testing for algorithms applied to health data

The vast quantities of data that will become available through the EHDS will require researchers to implement new methods of data processing and analysis, and are expected to accelerate the development of AI technologies for the health sector. As Strand pointed out, this means that quality issues within the EHDS will not be limited only to the data inventory but can also arise in the way an algorithm connects and processes the input information. "In an evaluation[1] of three different AI algorithms for breast cancer detection from three different companies—German, French, and Korean—we noticed biases the manufacturers were not aware of, such as equipment-associated variations in the assessment scores of mammography images," Strand reported. This was expected to be a recurring issue with the secondary use of data from medical devices more generally, because input and output data are not currently harmonised across devices of the same categories. In this context, Hellner saw a need to develop standardised methods of testing algorithms' predictive value: "If we buy an algorithm, we need to know its specificity and sensitivity in the same way as we do for lab tests. This has not been solved on the system basis yet," she explained.

Recommendation:

- Develop and validate methods of quality testing algorithms applied in health research and healthcare

1 https://jamanetwork.com/journals/jamaoncology/fullarticle/2769894

Key recommendations

- Further define concepts of data quality and utility in the EHDS legislation, building on the FAIR principles
- Design a voluntary data labelling system of quality tiers to foster benchmarking between data holders
- Define an efficient EHR certification system that companies of all sizes can cope with
- Adopt and implement the upcoming Joint Action TEHDAS data quality framework at national level to ensure a harmonised European approach to data quality
- Exclude all non-CE marked technologies from the scope of the EHDS
- Define more precisely which data from medical devices is relevant and useful for sharing
- Validate the viability of data interoperability and utility frameworks with relevant stakeholders
- Consult industry and research actors on the choice of international data standards to be implemented
- Involve public procurement bodies in defining specifications for health information systems
- Include user-centricity in the data quality evaluation criteria for health information systems
- Develop and validate methods of quality testing algorithms applied in health research and healthcare

5 Closing the loop: the relationship between primary and secondary use of data

Secondary use of health data will impact the primary use, clinical care process, for instance by accelerating the shift from treatment of illness to prediction and prevention in the way healthcare is delivered. Conversely, effective secondary use depends on the quality of data collection in the primary use setting, as HealthData@EU will interface with MyHealth@EU and interoperable EHRs. The level of detail and choice of semantic standards used when health data is documented in the process of delivering care will determine whether it is reusable for secondary purposes at later stages. In general, a successful integration of data across the primary and secondary use ecosystems will require different actors within these ecosystems to play an active role beyond the interconnected technical infrastructure to be provided at EU level.

This section will examine the current possibilities to transfer data from primary to secondary use environments in Sweden, challenges researchers face, and the preparedness of healthcare professionals to make data reusable.

Michel Silvestri

How ready is Sweden?

Current landscape

EHR systems are widely used

It was reported that digital care records are ubiquitous in Sweden, in primary, secondary, and acute care settings alike, thus fulfilling the first important prerequisite for making primary healthcare data reusable within the EHDS. According to Hellner, the variety of different EHR systems in use could pose difficulties when it comes to extracting and aggregating data in the short term, but not in the long run: "Combining data from different sources is not a major difficulty, researchers have been doing that for decades," she posited. Although Hellner saw a lot of work to be done in the field of standardised reporting and data quality to improve the usability of EHRs for research, she also advocated for recognising and making wise use of the advantages and drawbacks of different data sources according to the research or policy question to be answered. "If what you need is a lot of data that doesn't need to be too granular, EHRs can have high added value. For example, if you want to extract and compare data from the primary care and specialist levels, that is doable in Sweden and in some fields, like depression, it has never been done before," Hellner explained.

Recommendation:

- Educate secondary users of health data on the suitability of EHRs and other primary data sources for different types of research

Challenges

Research needs come after imperatives of care delivery in primary data systems

Even in areas like medical imaging, where the standardisation of primary data is very high thanks to the longstanding and widespread adoption of the DIACOM standard, Strand still expected difficulties to arise from the scale on which the EHDS proposes that secondary users could tap into primary data systems designed first and foremost to support healthcare delivery. "When you extract large volumes of data from radiology systems, the time it takes to transfer that data puts a burden on the clinical workflows: in emergency radiology for example, no one wants to have to wait for extended periods of time just because we need to get some images out for research," Strand cautioned.

Opportunities

New technologies can help healthcare professionals record high-quality, reusable data

There was agreement that to fulfil their critical role in entering high-quality primary data fit for secondary use into the systems, healthcare professionals would need to be supported with efficient processes and tools to alleviate the added burden associated with this. From automating the act of data collection and quality improvement where possible, to improving the user-friendliness and eliminating the redundancies of current systems so that individual data points only need to be recorded once, participants identified various opportunities to enable medical staff to change their ways of working with technology. Elunurm reported from Estonia that a digital strategy in this area had been successfully built around the principle of entering data only once, maximising its potential to be reused with limited hindrances while respecting the fundamental rights of the data subject. Farrokhnia cited novel speech-to-text technology that converts physicians' speech into text and integrates it in the EHR as one of the possible automations that could be implemented to facilitate data gathering, a solution already adopted by certain healthcare institutions in other Nordic countries, including Denmark and Finland.

Going one step further, Farrokhnia expected that the potential of AI technology in particular to optimise care flows and save doctors time in other areas, such as detection of diseases and health incidents, could enable a deeper transformation of processes in healthcare that would benefit not just the secondary users of data, but also the healthcare providers and staff directly. In this context, Drakvik reported from Finland that national recommendations had been developed to create concrete incentives to use healthcare data in a better and more efficient way and demonstrate its benefits at the hospital level.

Recommendations:

- Automate the primary data collection and improvement process as much as possible with technology
- Design health information systems around the principle of entering data only once
- Demonstrate to clinicians the benefits and time savings that can be achieved for them overall through the digital transformation of healthcare processes

Priorities for implementation

Clearly defined primary data requirements and standards

To ensure the feasibility of creating an interface between the primary and secondary use ecosystems, participants saw a need to define more precisely at EU level which categories of primary data should be shared in this context—some, for instance, saw value in including physicians' personal notes in addition to more standardised data points like diagnosis—and clearly identify where these are to be found. "If they are in the EHR systems, what qualifies as an EHR system? These are things we need to clarify," Olbrechts emphasised. Based on well-delineated data requirements, Eklöf advocated that data standards should be implemented or developed as needed for each category of primary data falling within the scope of the EHDS. "Just as the introduction of the DIACOM standard effectively improved data quality in the med tech sector in the 1990s, it would be desirable to develop standards in other relevant areas for the EHDS, such as lab test data and even free text sections within EHRs," said Eklöf.

Recommendations:

- Define the requirements for sharing primary data for secondary use purposes more precisely at EU level
- Implement existing international standards or develop common European data standards (where no international standards exist) for each category of primary data to be shared for secondary use

Automated data extraction and transfer across primary and secondary use systems

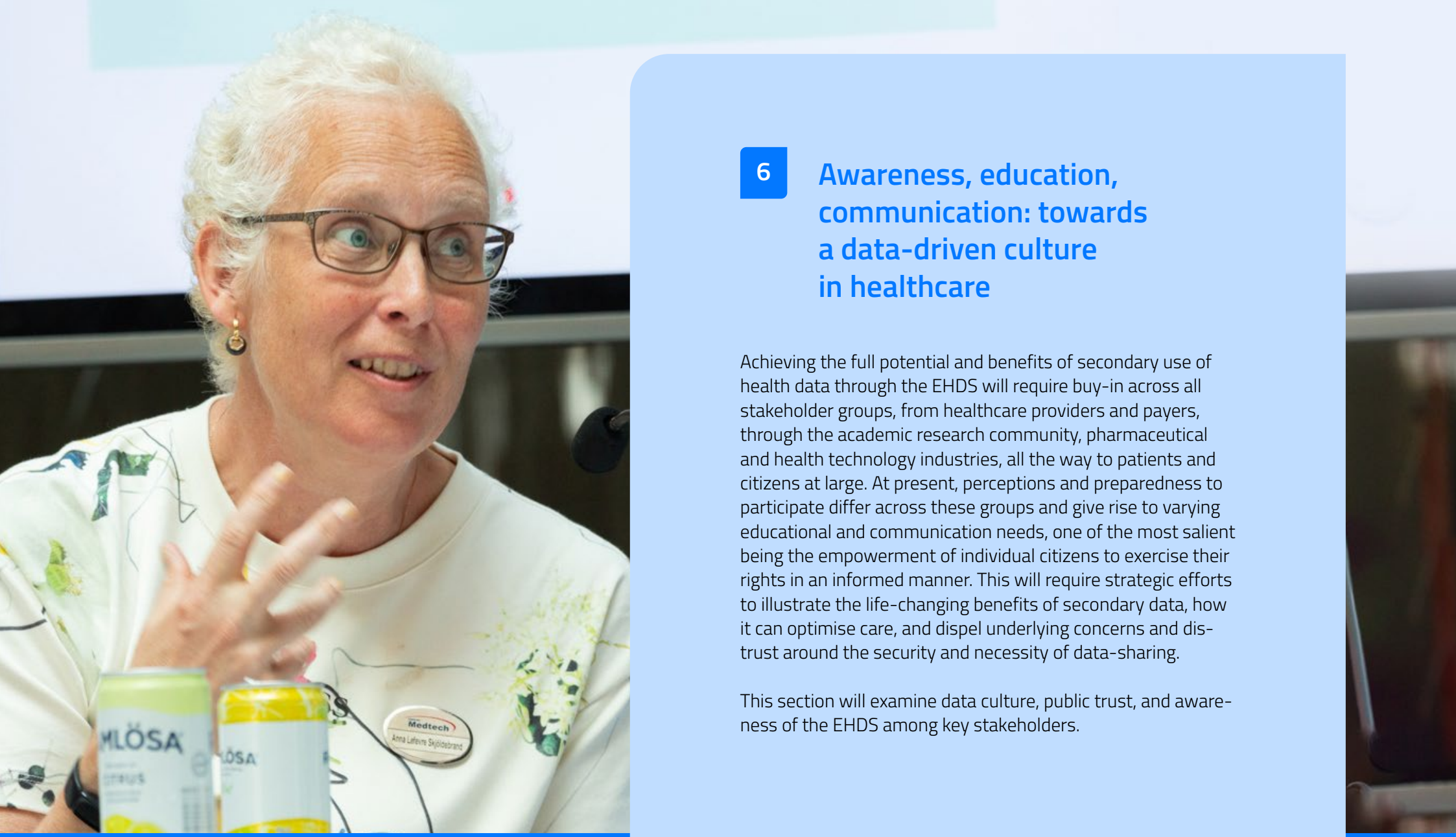
If the standardisation of EHR systems across Europe is one important pillar of an integrated primary and secondary use EHDS infrastructure, a second pillar was said to be the development of solutions for automating the extraction and transfer of EHR data for secondary use to make the process sustainable at scale. Dr. Andrzej Rys, Director of Health Systems, Medical Products and Innovation at the European Commission's Directorate-General for Health and Food Safety, saw a template in the picture archiving and communication systems (PACS) now ubiquitous in the field of medical imaging and which consolidate data acquisition, storage, and transmission functions thus allowing automated data transfers across different systems. However, it was anticipated that attempts to automate the export of EHRs to secondary use environments would likely have a number of legal and privacy-related barriers to overcome. Regarding the cybersecurity implications, one panellist pointed to the EU Medical Device Regulation as a source of guidance on how to mitigate potential risks.

Recommendation:

- Develop a technical-legal approach to automate the transfer of EHR data from primary to secondary use systems
- Draw on the EU Medical Device Regulation to manage cybersecurity risks

Key recommendations

- Educate secondary users of health data on the suitability of EHRs and other primary data sources for different types of research
- Automate the primary data collection and improvement process as much as possible with technology
- Design health information systems around the principle of entering data only once
- Demonstrate to clinicians the benefits and time savings that can be achieved for them overall through the digital transformation of health-care processes
- Define the requirements for sharing primary data for secondary use purposes more precisely at EU level
- Implement existing international standards or develop common European standards for each category of primary data to be shared for secondary use
- Develop a technical-legal approach to automate the transfer of EHR data from primary to secondary use systems
- Draw on the EU Medical Device Regulation to manage cybersecurity risks



Anna Lefevre Skjöldebrand

6 Awareness, education, communication: towards a data-driven culture in healthcare

Achieving the full potential and benefits of secondary use of health data through the EHDS will require buy-in across all stakeholder groups, from healthcare providers and payers, through the academic research community, pharmaceutical and health technology industries, all the way to patients and citizens at large. At present, perceptions and preparedness to participate differ across these groups and give rise to varying educational and communication needs, one of the most salient being the empowerment of individual citizens to exercise their rights in an informed manner. This will require strategic efforts to illustrate the life-changing benefits of secondary data, how it can optimise care, and dispel underlying concerns and distrust around the security and necessity of data-sharing.

This section will examine data culture, public trust, and awareness of the EHDS among key stakeholders.

How ready is Sweden?

Current landscape

High digital literacy
Swedish citizens were deemed to be very digitally literate and avid users of mobile applications in a various domains including health, especially for self-monitoring and self-care. According to Haag, this phenomenon and the benefits it is expected to have for the health system have significantly contributed to changing the culture in healthcare in recent years.

A disconnect between patients and the health system
Conversely, health literacy was found to be lacking among the general population, as was a mutual understanding between patients and healthcare professionals. "Healthcare needs to understand patients better in order to be able to communicate better with them and make shared decision-making a reality," said Haag. "As patients, we are also becoming increasingly aware of the fact that we need to be trained not only in receiving health messages, but also in how we actually talk to healthcare professionals." Haag also noted that positive steps had been taken in this area, from the European Patients' Academy on Therapeutic Innovation (EUPATI) training patients to become more aware of how the healthcare system works, how new medicines are introduced in Sweden, to some initial examples of collaboration between patients and healthcare to improve health research and care delivery.

Challenges

Low awareness and preparedness of key stakeholders
Farrokhnia reported that although clinicians working in fields such as oncology, where precision medicine is becoming a reality, tend to be very attuned to the need to share data and to welcome developments related to the EHDS, awareness of the upcoming framework across the medical profession is low. She also warned that because the innovation taking place in healthcare is often coming from actors, like technology companies, that doctors and nurses are unaccustomed to dealing with, many feel excluded from the transformation process, leading to widespread frustration. Getting these professionals involved early on in national, regional, or hospital platforms that make tangible what the EHDS is intended to achieve with health data would therefore be essential to bringing them on board as active participants.

Similarly, panellists anticipated that challenges would arise from a lack of awareness and understanding among elected officials and other public decision-makers, especially at the regional level where healthcare is managed in Sweden. In particular, educational needs identified for the country's political class included, on a high level, conveying the value of data-sharing and its potential benefits for research and public health, and on a technical level, familiarising them with the standards that will need to be upheld to implement it, which will require more involvement than simply signing an agreement with an EHR vendor.

Recommendations:
- Engage with healthcare professionals and involve them in data-sharing platforms early on to foster trust and active participation in the EHDS
- Educate regional elected officials and decision-makers on the objectives of the EHDS and on their role in implementing the standards required to make it a reality

Opportunities

Citizens' trust in existing health data sharing practices is high
In Sweden, citizens' and the health ecosystem's experience with data-sharing for secondary use purposes goes back 70 years, and openness to releasing personal health data for research and other health-promoting purposes was rated as high enough to allow the country to lead the way and serve as an example for citizens in other member states. However, communication measures are needed as most members of the general public were thought not to be aware of the upcoming EHDS.

Patients in particular were identified as a potential driving force in the implementation of the EHDS, if efforts are made to raise awareness and mobilise them on the basis of clear expectations of what can be achieved.

Recommendations:
- Raise awareness of the EHDS among the general public
- Mobilise patients to act as drivers of implementation

Priorities for implementation

A transparent and inclusive framework

Although the Swedish public's trust in data-sharing may be high today, this can disappear much faster than it developed—if sensitive data ends up being leaked, or if citizens lose sight of how and why their data is used. High rates of disengagement from the system, in turn, could lead to biases in the datasets contained within the EHDS and undermine its potential to produce valuable and representative research insights. In the move to implement the EHDS by 2025 as proposed by the European Commission, several participants therefore emphasised the importance of planning the process in ongoing, transparent consultation with all stakeholders from the outset: to ensure the framework meets their needs, but also to understand the implications of the future regulation for them. "Sweden, like many other member states, has large population groups with roots in other cultures where the trust in government is not as high. We must allow ourselves to move slowly forward and learn as we go," said Hellner.

Two key enablers of public trust were identified. The first is legal clarity and security on exactly what types of secondary uses of health data are permitted, which uses are prohibited, and how data-sharing should be done, an example of which is provided by Finland, where the Act on the Secondary Use of Health and Social Data provides the legal basis for data-sharing via FinData, the Social and Health Data Permit Authority. The second is the assurance of a strong ethical basis for the issuance of data access permits under the EHDS to prevent patients' data from being used inappropriately. "As a researcher, you always need to obtain an ethical approval for your entire research idea. There are both national and European bodies that issue this type of approval, because it needs to be clear why you are using people's data," Farrokhnia explained, and suggested that these bodies should be networked in to provide ethical oversight of all secondary uses of data within the EHDS.

Recommendations:

- Design the national EHDS implementation roadmap in consultation with all stakeholders, including through public debate
- Ensure clear communication to all stakeholders on the requirements for secondary use of health data at EU and national levels to minimise legal uncertainty
- Establish a transparent system of ethical oversight for all secondary use applications, networking in existing ethics committees as needed

A digitally literate and data-savvy healthcare workforce

To bridge the current gap between the digital innovation taking place in the health sector and the daily medical practice of healthcare professionals, Olbrechts argued that training in digital skills and data literacy would need to become an integral part of the latter's higher education. To effectively and safely integrate new tools such as AI-based disease detection or clinical decision-making support systems into healthcare delivery, for instance, doctors will need to familiarise themselves with the concepts of sensitivity and specificity that were previously more relevant to lab staff than to medical practitioners. Drakvik reported that data analysis training programmes for healthcare workers have already been launched in Finland, and recommended the same initiatives be taken in other member states.

Recommendations:

- Integrate training in digital skills and data literacy in medical and healthcare curricula
- Launch upskilling programmes for practicing healthcare professionals

Proof of tangible value for stakeholders

Finally, given the magnitude of the transformation at hand, which was compared to the societal changes brought about by the arrival of railways, the combustion engine, or the broadband internet, Saunier argued that a indispensable step in the implementation process would be for alliances of the willing to lead the way by quickly starting specific projects that could then be used to communicate and illustrate tangible value for different categories of stakeholders. These could be academic, clinical, government-led, but also commercial, for example showing a clear path—especially for European SMEs, which currently face difficulties in this field—from gaining access to data on European citizens to actually reaching the EU market with innovative products and services that can benefit European patients.

Recommendation:

- Illustrate tangible value from the EHDS to different stakeholders through concrete projects

Key recommendations

- Engage with healthcare professionals and involve them in data-sharing platforms early on to foster trust and active participation in the EHDS
- Educate regional elected officials and decision-makers on the objectives of the EHDS and on their role in implementing the standards required to make it a reality
- Raise awareness of the EHDS among the general public
- Mobilise patients to act as drivers of implementation
- Design the national EHDS implementation roadmap in ongoing consultation with all stakeholders, including through public debate
- Ensure a clear framework for secondary use of health data at EU and national levels that minimises legal uncertainty
- Establish a transparent system of ethical oversight for all secondary use applications, networking in existing ethics committees as needed
- Integrate training in digital skills and data literacy in medical and healthcare curricula
- Launch upskilling programmes for practicing healthcare professionals
- Illustrate tangible value from the EHDS to different stakeholders through concrete projects

Conclusion

As it begins its journey towards implementing the EHDS, Sweden finds itself in a privileged position. The country will be able to build on strong technical foundations that include ubiquitous electronic records in its regional healthcare systems, long-established national data collections, and infrastructure for secondary use of health data that Sweden is already developing at local, national, and international levels. Seven decades of experience with sharing health data have also fostered high public trust and openness towards its use for research and public health purposes, something which decision-makers will be called on to nurture and protect by ensuring legal clarity, transparency, as well as strong security, privacy, and ethical safeguards in the implementation process.

Challenges remain, such as aligning the national legislation with the requirements of the future EU regulation, or designing the governance structure for the Swedish health data space in a way that allows the country's seamless integration into the wider European data space while reflecting its regional organisation of healthcare.

Creating data fluidity at the interface between primary and secondary use environments will require both new technical solutions and an adaptation of healthcare providers to their future role, no longer as mere users of patient data, but also as enablers of its potential to accelerate innovation and improve future population health.

Educational needs should not be underestimated, for both future users and operators of the EHDS, in areas ranging from regulatory affairs, through digital literacy, cybersecurity, data quality management, all the way to data analytics and AI. In this area and in others, Sweden can build on the initiatives and best practices implemented by its European neighbours.

However, the EU will also have a crucial role to play in mapping a common path forward, enabling synergies, and mobilising existing funding instruments to help each of its member states weather the tremendous investments that the EHDS will require.

Summary

EIT Health is one of eight Knowledge and Innovation Communities (KICs) of the European Institute of Innovation and Technology (EIT) and an Institutionalised Partnership under Horizon Europe's Pillar III – Innovative Europe. Established in 2015 to tackle the societal challenges of 'health, demographic change and well-being' within the EU.

The EIT Health Think Tank is a thought leadership forum that brings together experts to prepare the ground for life-changing innovation and to identify the next opportunity for a step-change in how health care is delivered.

In 2023 a pan-European, multi-stakeholder, initiative was conducted to support knowledge sharing and capacity building for a fully operational EHDS that is favourable to health innovation and research. The focus is, in particular, on the secondary use of health data and to shed light on what the needs are in the individual countries in relation to adopting the EHDS. This report focuses on the feasibility of implementation of EHDS in Sweden only.

The Swedish government and parliament support the European Health Data Space (EHDS) but face challenges in its implementation. While Sweden is making progress in building the necessary infrastructure, its legal readiness lags behind the technical readiness. Sweden will be among the last countries to join myHealth at EU[1] for this reason. No comprehensive assessment has been conducted yet on the changes to regional legislation that will be required.

Sweden has a strong track record of secondary use of data for research: national registries, statistics, epidemiology, but there is a shortage of skills for extracting data from electronic health records (EHRs). Investments in data infrastructure are needed also new types of collaboration and professional profiles will be needed.

The EHDS is expected to be the costliest among European data spaces. Healthcare professionals are already burdened and need to minimise additional administrative tasks.

Immediate investments are needed in data infrastructure to reduce data access time. Funding should be a collective effort across the health ecosystem, and socio-economic models should be developed to secure financing from stakeholders who benefit from the EHDS.

While Sweden has robust national data quality standards for secondary use, primary use settings lack mandatory data quality recommendations. The EHDS can drive improved data quality, but the roles and responsibilities of data stakeholders need clarification.

Efforts to bridge the gap between primary and secondary data use are necessary. Incentives for healthcare professionals, automation of data recording, and improved digital literacy are crucial. Ensuring EHR interoperability and patient privacy is essential.

Both patients and healthcare professionals need training to understand the health system and improve communication. Demonstrating value for stakeholders, offering legal clarity, and providing guidance are essential steps.

1 https://eithealth.eu/wp-content/uploads/2022/05/EIT-Health-Statement-on-the-EHDS-proposal_final-05052022.pdf

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