eit Health

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Implementing the European Health Data Space in Germany & Switzerland

**Vol. 1:
Partners and Experts
Perspective**

THINK TANK

Implementing the European Health Data Space in Germany and Switzerland

Partners and Experts Perspective

EIT Health Think Tank - EHDS Round Table Discussion

München, October 10th, 2023

Outcome Report v1.8

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Content

Who is EIT Health?

EIT Health is one of nine Knowledge and Innovation Communities (KICs) of the European Institute of Innovation and Technology (EIT), an EU body. EIT Health is 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, its mission is to help overcome the well-known EU paradox whereby state-of-the-art education, excellent research and a dynamic industry are challenged to turn breakthrough ideas into new transformative products and services.

Within the EIT Health network, over 130 partner organisations and institutions from academia, business, research and health care delivery collaborate across disciplines, borders and sectors to reinforce excellence, create knowledge and innovation and encourage greater investment in innovation that delivers the outcomes that matter to citizens and patients. As a result, EIT Health represents a unique match between a sustainable innovation ecosystem model gathering and leveraging different partners and funding sources, and a change agent with extensive capacity to generate real-world data for evidence-based policymaking and the transformation of health care (Figure 1).
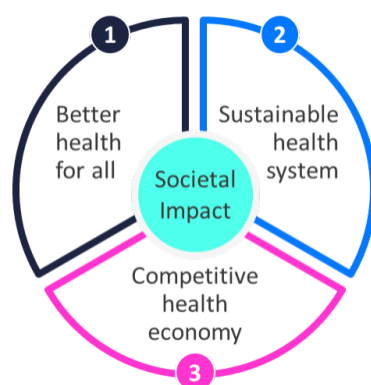
Figure 1: EIT Health main goals.

The EIT Health Think Tank

The EIT Health Think Tank is EIT Health's thought leadership forum. It brings health care leaders together to prepare the ground for life-changing innovation and to identify the next opportunity for a step-change in how health care is delivered. Research participants collaborate across disciplines and borders to explore and assess the most pressing topics impacting health and the uptake and adoption of innovation. This allows for continual assessments of the environmental needs of EIT Health's portfolio of projects and programmes. To facilitate this dialogue and its findings, EIT Health drives a range of activities to generate knowledge and insight, including research, expert Round Tables and interviews, publications, and dissemination of key information.

Previous EIT Health Think Tank projects have focused on determining how to overcome the barriers to, and capitalise on the opportunities of, the adoption of innovation and new technologies in health care, including the harmonisation of digital medical devices, use of Big Data, future-proofing Europe's digital health innovation pathway, the role artificial intelligence (AI) can play in health care workforce and organisational transformation, and the impact of the new Medical Device Regulation (MDR). In 2021, the EIT Health Think Tank produced a report entitled "Learning from health data use cases: Real-world challenges and enablers to the creation of the EHDS" that served as an initial step towards EIT Health's focus on the EHDS regulation, producing an overview of challenges in roles, regulations, and policies and practices. The latest EIT Health Think Tank report focuses on digital medical devices and explores pathways to regulatory harmonisation across Europe.

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

To assess the feasibility of implementing the European Health Data Space (EHDS) in different EU regions and Member States, EIT Health is conducting a pan-European stakeholder consultation initiative. This initiative aims to gather 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 distil 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 held 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.

A roundtable was held on October 10th, 2023, in Munich to discuss Germany's readiness to implement the planned EU legislation for a European Health Data Space (EHDS) and gather insights from Switzerland about its challenges and progress made with respect to establishing a digital health data space aligned with the EHDS. It brought together 9 experts representing the fields of public health, healthcare, academia, and industry/start-ups to discuss six key dimensions of implementation: Capacity and Skills, Resources and Funding, Governance, Data Quality, the relationship between Primary and Secondary Use, and Awareness, Education and Communication. Additional written evidence was collected from Dr. Georg Münzenrieder representing the Bavarian State Ministry of Health and Care.

Roundtable Participants

Public Sector	
Adrian Costea	Swiss Federal Office of Public Health
Dr. Georg Münzenrieder*	Bavarian State Ministry of Health and Care
University/University Hospitals	
Dr. med. Lars Riedemann	University Hospital Heidelberg
René Raab	FAU Erlangen-Nürnberg
Prof. Dr. Oya Beyan	University of Cologne
Harald Wagener	Berlin Institute of Health, Charité
Industry	
Jared Sebhatu	digital health transformation eG
Jakob Defèr	Amgen
Dr. Lena Fanter	Takeda
Start-ups	
Christian Hieronimi	myoncare

* Due to unexpected drop-out, input was collected after the meeting in writing.

The six dimensions of implementation

1. Governance

Readiness for implementation

Germany and Switzerland are taking steps to provide a legal framework for health data

Acknowledging that Germany's healthcare system is far behind in digitalisation, the Federal Ministry of Health has made some initial steps in order to prepare for the implementation of the EHDS and proposed several draft legislations to support the digitalisation of health data. These legislative proposals include the Digital Act (*DigiG*) as part of Germany's larger digitalisation strategy seeking to progressively digitalise health records and introduce e-prescriptions; the Health Data Use Act (*Gesundheitsdaten-nutzungsgesetz, GDNG*) aims to create a decentralised health data infrastructure to coordinate and facilitate the use of data; finally, the Hospital Transparency Act promotes the publication of structural and performance data of hospitals in Germany. All three legislations are supposed to come into effect in 2024. However, as Georg Münzenrieder from the Bavarian State Ministry of Health and Care pointed out, the GDNG and DigiG proposals are just a first step which should be maintained in a future initiative, but a second step will have to follow to implement the EHDS especially regarding interoperability of EHR systems between member states.

Since the EHDS regulation and therefore the definition of the data holder in the EHDS regulation is still under discussion and has not been finalised, it is not yet clear which data holders will come under the scope of the EHDS. The Health Data Use Act foresees the Health Data Lab (*Forschungsdatenzentrum Gesundheit*) at the Federal Institute for Drugs and Medical Devices to make pseudonymised billing data from people insured in the statutory health system as well as all the data from the German EHR system and the national and federal cancer registries available for research purposes in the near future. The Health Data Act foresees that other data holders shall fall under its scope in the future, but these data holders have not yet been specified.

Switzerland is facing similar challenges like Germany when it comes to establishing a coordinated health data space. It currently ranks at the lower range of digitalisation of healthcare compared to other European countries. Recognising this, the Federal Council mandated the Federal Department of Home Affairs, in collaboration and coordination with other agencies of the Federal Administration, to draw up a program to promote digital transformation in the healthcare sector: the *DigiSanté* program. The aim of *DigiSanté* is to allow for seamless data flows free of media discontinuity in treatment, billing, research and public authority services and the guarantee of data protection, informational self-determination and cyber security. Furthermore, the secondary use of the resulting health data for planning, control and research is to be facilitated within the framework of the legal requirements. With this, Switzerland

aims to define and implement a Swiss Health Data Space be compatible with the EHDS without formally being part of it.

The federal structures of Germany and Switzerland pose challenges to implementation

Germany currently does not have a unified approach to data collection, protection and use. While the Federal Data Protection Authority is in charge of overseeing Federal public entities, each of Germany's 16 Federal States has their own data protection authority (or even two as in the case of Bavaria) in charge of data processing activities of public and private-sector entities within each Federal State.

Switzerland as a federal country with a federal health care structure, distributed among 26 cantons is facing similar challenges when it comes to establishing a seamless data sharing and major steps are needed to streamline and unify data collection and use. In both countries, major efforts have to be undertaken in order to ensure that the EHDS can be implemented.

No agreement yet as to who should take the main responsibility for health data access

The panel discussed the question of who should take the main responsibility for the implementation of the health data framework. The responsibilities of a health data access body could be a state agency (the Federal Ministry of Health is thinking in this direction) initially be affiliated with the Federal Institute for Drugs and Medical Devices (*Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM*), but it could also be an independent body or even serval bodies on regional level. No decision has yet been taken.

Some argued that responsibility should be clearly assigned to one entity responsible to take decisions and next steps. We need to be able to describe who is doing what, otherwise we will not get to the solution. "If responsibility is not identified, everyone can shift the responsibility to the other" Lena Fanter from Takeda said.

Conversely, Harald Wagener of the Berlin Institute of Health at Charité underlined that experts and institutions already more advanced in the digitalisation of data should take on some of the responsibility as well and think how to enable the decision makers in taking the right steps to move forward with the implementation of the EHDS. "It should not primarily be a question of who is responsible but rather a question of what can everyone do with the resources available to support the process".

Implementation is supported if stakeholders offer their expertise

Different observations and experiences were presented by the panellists as to how open decision makers currently are to accept support and expertise from outside stakeholders in the formulation of political decisions. Some observed a clear political will to make things work in practice and argued that the Ministry of Health is willing to work with stakeholders to find the best solutions: What outwardly appears as the Ministry's own proposal, tightly linked to broader European developments and the EHDS is actually based on a lot of direct consultations with the relevant stakeholders at an operational level. The way to go in future implementation stages, it was argued, will be to approach the law maker with kernels of functionality to support the legislative process pro-actively. Other panellists by contrast pointed out that it is difficult to get support from the highest Ministerial level but that this will be necessary to ensure that decisions taken are in the best interest of people working on the ground.

Priorities for implementation

Make sure risks and responsibilities are adequately shared

The question of who should be responsible does not end at the highest level of public authorities. Other stakeholders down the line of implementation also have to be considered. In order to properly prepare the implementation of the EHDS, some thought has to go into the question of how risks and responsibilities, especially in the realm of data protection, can be adequately shared. A data protection officer, for example, has no incentive to share the data if they are liable for the consequences should data leakages or data misuse occur. Therefore, the option of signing an insurance comparable to a business liability insurance for them has to be considered, to avoid that they get punished if something goes wrong.

Increasing the trust in the system in order to encourage sharing of the data might require an increased awareness of the shared responsibility for their quality and use. Data protection is like referring a patient to a colleague: each one is responsible for their own data protection. There was some discussion around whether decentralised data protection reduces the risk.

Implementation should not burden or impair the care processes

At the same time, it will be important to ensure that the implementation of the EHDS regulation regarding the primary use of electronic health data in medical practice does not result in the impairment of the healthcare processes. Obligations of data collection should be sensitive to the constraints and needs of practitioners and informed by the realities of people working on the ground.

Key recommendations

- *Decision makers and experts in the field of health data should work together to ensure that the implementation of the EHDS is running smoothly and not negatively affecting the work of practitioners*
- *Risks and responsibilities have to be considered at all levels of implementation to assure that different stakeholders buy into it*
- *Enough attention should be paid to the needs and constraints of health professionals to avoid that their work is impaired or overly burdened*

2. Capacity and skills

Readiness for implementation

Capacity for health data gathering and use is currently missing

In addition to the gaps in the current legislative framework, Germany and Switzerland are also facing major challenges with respect to the capacity and skills of stakeholders involved in the health data space to collect, store, adequately protect, and share the electronic health data for secondary use.

In order to comply with the requirements of the new EHDS legislation, capacity building will be necessary in all sectors of the health system, from the public administration and official data holders to the users of the system, physicians and patients, but also the various bodies and private companies involved in secondary use of the data.

Tools are not in place for primary and secondary use of health data

While some frameworks for health data already exist in Germany, for example for oncology data (*Krebsregister*) panellists broadly agreed that currently the necessary infrastructure is not in place to allow for a seamless collection and sharing of the health data for primary and secondary use. The federal structure of the German (and likewise the Swiss) state is an additional level of complication and the EHDS is not contributing to the solution of countries' internal challenges. Harald Wagener from the Berlin Institute of Health cautioned that while the EHDS governs the cross—border use of electronic health, it does not give any guidelines on the question of how data is shared nationally.

As Oya Beyan from Cologne University pointed out "We don't have tools to enable people to use the data". Different people have different roles, this needs to be streamlined and we need a good definition of those roles, not only the technicians who set up the systems but also the different users. We also need educational tools and materials to support the implementation.

If you want to change the system, you have to know the system

One of the essential foundations for the successful implementation of the EHDS is to establish a common language and a common understanding of the use of health data. There needs to be a lot of work to understand the different stakeholders' perspective and design a system that incorporates all of them. Practitioners need to be open to show their work to other stakeholders involved. As one panellist mentioned, there are technicians and health economists who have never been to a hospital and the same

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holds for government officials who are too far away from what actually happens inside health providers on a daily basis. Consequently, decision makers and technicians design systems for realities that they have never seen from the inside. People need to be immersed into the system, including in clinics that struggle, not only in university hospitals, not only 9-5 but also night shifts, weekend shifts, show them why doctors cannot spare 10 minutes of their time to fill in a data sheet, be a shadow, to understand the complexity. This should also be financed as part of system development initiatives.

Panellists reported that this concerns not only those who generate and collect the data in primary use but also those concerned with the secondary use of the data. Even many start-ups that want to design solutions for the health sector do not know enough about the reality on the ground. They sometimes cannot explain what exactly they need the patient data for and create solutions for problems that have already been solved.

Adequately dealing with health data requires a major shift of mindset

Germany excels in an engineering and planning approach with very clear processes. However, the implementation of the EHDS will require more of an iterative approach in small steps, learning from failures and through constant experimentation. As Harald Wagener from the Berlin Institute of Health at Charité pointed out, this represents a big cultural shift in ways of working and approaching the task. The agile mindset, an iterative approach to development, learning from errors, keeping what is working and shedding what is not is not currently established in the health system as a whole. "If we wait for someone to come with a grand unified solution, it will never happen."

Priorities for implementation

A strong skill set needs to be established at all levels of the system

In the short and mid-term, capacities need to be built at all levels of the system. Based on a common language and a clear understanding of the purpose of health data actors involved both in primary and secondary use of the data need to be able to navigate the system to take an active part in it. Healthcare professionals need to be able to explain to the patients why and how their data can and should be shared. Similarly, actors concerned with the secondary use of the data need to have a clear picture as to how best to use this data while respecting restrictions to maintain a high level of trust. Decision makers need to be knowledgeable and aware from direct experience how infrastructure needs to be established so that it will support everyone involved. Citizens and patients also need to be educated on topics like data literacy to be able to make informed decisions about their personal health data.

To ensure that decisions taken at the legislative level are reasonable and well informed by the reality on the ground and the actual needs and constraints practitioners are facing, those taking decisions should be confronted with the reality on the ground. As Lars Riedemann from Heidelberg University suggested "We need a living lab where we try to create a learning system."

Education institutions need to introduce digital literacy in their curricula

In the longer term, digital literacy, including an understanding of the functioning of the EHDS and its implications for the practical work of physicians and other stakeholders working in the health system, needs to be introduced systematically not only in medical schools but also in engineering schools and other education sectors. This does not only apply to data users and medical professionals but also to the citizens themselves. Data literacy should be a much bigger topic in all school curricula. Education material needs to be made available for everyone outside of school as well.

To spread digital literacy in the current healthcare system and bring practitioners up to speed, lifelong training, upskilling and reskilling initiatives need to be undertaken in various sectors, following the example of countries like France.

Key recommendations

- *Infrastructure needs a major upgrade to support data collection and use*
- *Capacities need to be developed at all levels of the system*
- *Citizens/patients need to be educated on data literacy and enabled to make informed decisions about their health data*
- *Digital literacy, including a solid understanding of the EHDS, needs to be introduced not only in medical schools but also other faculties concerned by the changes*

3. Resources and funding

Readiness for implementation

Major financial investments will be required to bring the system up to speed

There was a consensus among panel discussants that major financial investments will be necessary to support the implementation of the EHDS in Germany and Switzerland. It is difficult to assess how feasible it is for Germany to fund the creation of the central EHDS infrastructure or to put precise numbers as to how much money is needed and where exactly it should go. All levels, EU, national, regional, will need to be involved in allocating funds towards EHDS implementation, it is a collective effort happening at all levels.

Currently, the federal government mainly bears the responsibility for the allocation of funds towards EHDS implementation within Germany. However, the Bavarian State Ministry of Health and Care reported that it already supported an initiative that calls for the financial support of small and medium-sized entities to help them with the EHDS implementation. Apart from that, the Bavarian State Ministry strongly recommends the channelling of funds towards an EU-wide campaign to raise awareness of the advantages of the EHDS framework and to increase the trust in the system to encourage sharing of the data.

Panellists quoted some examples where financial mechanisms have already been established to support the sharing of data for secondary use. For example, the Bavarian Ministry has introduced 'digiOnko' where hospitals are paid to make data available. However, this concerns only the university hospitals in one region and smaller healthcare providers are not involved. On the national level, the Medical Informatics Initiative builds and operates infrastructure for data exchange for secondary use, but as with digiOnko, this is currently limited to university clinics as well.

Ensure that provision of financial resources does not accentuate inequalities

Each region in Germany is already financing its hospitals to support digitalisation efforts but there are differences across regions. Smaller healthcare providers in less well-developed parts of the country with weaker financial resources often face greater challenges in providing the right infrastructure for the implementation of the EHDS. They are less well equipped technically, they lack the expertise, including IT-personnel but also the human resources to ensure that electronic patient records are adequately kept up to date. These healthcare providers are also generally less well equipped financially while being the ones with the biggest needs for financial and human resources to be able to comply with the new requirements. There is a risk that the new requirements for digitalisation will reinforce these inequalities.

As the Bavarian State Ministry of Health and Care pointed out, the decision for an opt-out regarding the secondary use of data will probably affect patients who do not have internet access and/or are not digital natives, i.e., mostly elderly people as well as disabled persons. Moreover, it might become financially and administratively difficult for small and medium-sized entities such as private practices, local hospitals, or start-ups in their role as data holders to comply with the technical and infrastructural requirements of the EHDS when having to transfer their data. Digital literacy must therefore be improved on both the personal and the professional level, especially in these stakeholders.

Additional financial and human resources are needed

However, panellists warned against focussing all the attention only on providing more financial resources. Attention also needs to be paid as to where resources are most needed and how the available resources are spent. For instance, money should be spent to develop the pipeline and improving the processes of data collection and use like in the 'Toyota model' of production mentioned by Lars Riedemann: "Don't take one car and try to make it perfect but work on improving the pipeline on which to produce any kind of car". Based on the agile mindset mentioned above, stakeholders involved in this need to make sure a project ends if something does not work, demonstrate and document failures, "don't hide the mistakes but drop a project rather than fixing it". Knowing what doesn't work will help us to understand where investment should be discontinued.

Only pouring money into the system to support digitalisation will not be enough to ensure an adequate implementation. As Jared Sebhatu from digital health transformation eG underlined, providing the necessary resources is not just a question of money per se but also of manpower. If there are no additional resources to handle the available funds and introduce the necessary organizational and infrastructural changes, they will not have the desired impact.

Priorities for implementation

Be smart about providing the right resources

Panel participants pointed to the fact that not all forms of data collection and use have to be costly and cumbersome and that there are ways to be smart about data collection in order to reduce costs to the system. If data is a by-product of certain interactions or if data can be derived from other processes, data can be provided basically for free. For example, involving patients as the originators of the data is still an underserved area of the discussion around the implementation and funding of the EHDS.

Patients need to consent to their data being shared and investments have to be undertaken to build the necessary trust to make this happen. As René Raab from Friedrich-Alexander-Universität Erlangen-

Nürnberg pointed out, we need a system where citizens can adjust their consent on a spectrum: from completely trusting the health data access body and accepting any request for sharing data to completely turning off any data sharing. In between these extremes, citizens should be able to automatically share data with entities or groups they trust (e.g., university research or industrial research) or have the opportunity to decide on a case-by-case basis if they want to share data.[1]

More data are not an advantage per se

Attention needs to be paid to collecting the right types of data. "Collecting data for the sake of data is costly" argued Christian Hieronimi from myoncare. And Harald Wagener cautioned that "data begets more data and data also rots".

To invest not just in more but in better and useful data, we need to know more about intelligent use of data, including in secondary data use. There is willingness to invest if the outcome is clear, e.g., early detection of a complication makes you save money, this is a nice selling proposition to the current payers (health insurance). Very good use cases are needed that can demonstrate these advantages.

Key recommendations:

- *Invest into the right elements, not only technical but also human resources*
- *Explore the possibilities of low cost or no cost data collection*
- *Structure financial support in such a way that it does not accentuate already existing inequalities in the health system*

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[1] Harald Wagener and René Raab pointed to their recent paper which discusses these aspects in the context of a proposed citizen-centric implementation for the EHDS. See references:
R. Raab et al. (2023) "Federated electronic health records for the European Health Data Space"

4. Quality of data

Readiness for implementation

The data collection, coding and storing is not standardised

Panel participants reported various examples of practices that pose challenges to the collection of health data. The electronic health records do not function as a data collector, they are not yet properly established everywhere: "The EHR system in Germany and Switzerland have one thing in common, it is a collection of PDFs, not data." Panellists reported that they often see printouts of medical records and hand-written updates on the record. The key problem is that there is no time to update the records, to record information adequately in the system at the time of treatment or to follow up on it systematically. Information is only updated when someone has the time; there might be a note on paper "needs to be updated!" - but finally this does never happen. These prevailing practices would need to change if a seamless data gathering and sharing is to be established and every stakeholder in the system needs to be involved in this.

As panellists also cautioned, in the processes of data collection and use, meta-data is also to be considered. "Meta-data is data, and we should treat it as such." Meta data often is not less sensitive than the actual patient data, it also involves data protection issues (e.g., in the case of rare diseases).

Systems are not compatible

Another challenge relates to data structure. As panellists pointed out, we do not currently have structured data and therefore we cannot share it between systems. We need a common language, a common data model, a commonly agreed upon semantics and way of collecting meta-data. It is difficult to go from one system to the other when information is not compatible. There are also differences in syntax, e.g., different systems ask for pain levels differently and also in semantics (the values of the data attributes). The international patient summary exists, but is not used everywhere which makes it difficult for anyone who wants to work with the data to coordinate them.

Panellists suggested that the system might be supported with a new code of conduct. Dynamic system needs first the agreement of the patient and then clear roles and rights (patient, doctor, relatives, pharmacist etc.). Adrian Costea from the Swiss Federal Health Ministry reported that in Switzerland, electronic patient records do exist, but they are not linked to the health insurance system. The Swiss Personal Health Network merges data from different hospitals but needs to unify their data models including semantics. A common data model, common data structures and a standardised semantics in Europe would help the local efforts to achieve interoperability. The target architecture of the Swiss Health Data

Space will adopt, among other things, the approach of a Once-Only principle whereby the data generated by the primary systems no longer have to be edited manually, but can be exchanged automatically allowing seamless system interfaces.

There was disagreement as to how structured EHRs should be

The idea of enabling practitioners to use free text for data input in their hospital or practice information systems was introduced by the moderator. René Raab from FAU Erlangen-Nürnberg suggested that while this may be a good solution for practitioners, output of these software systems always need to be structured. Others agree that data output of different software systems always needs to have the same structure to be usable. While input must remain flexible, we need to be careful when implementing the translation systems from free text to structured data to ensure that no information is missing, and that no faulty information is extracted.

Christian Hieronimus from myoncare cautioned that too much data is also a risk because in the end nobody reads it. He pointed to the potential of blockchain to ensure data integrity: blockchain can trace back who owns the data, who accessed the data and from where, only the patient can see the individual data, others can enter the space and see only the general data.

Different roles in the systems makes the implementation of the EHDS more complex

One additional factor is complicating the system and needs to be considered when building new structures: One person can have different roles, be a patient and a practitioner at the same time, work as a scientist as well as physician. This makes the implementation of the EHDS more complicated and needs to be considered to reflect the reality on the ground.

Priorities for implementation

Data curation and quality improvements will happen if it is combined with a clear strategy and goals

As Harald Wagener put it: "Data quality is always terrible until people start using it for a purpose." Just collecting data is not going to solve any problems. You need to implement the data, make actual use of data in rality, and develop concrete use cases in order to identify gaps and malfunctioning, discover regulatory hurdles that you were not aware of. As Lars Riedemann pointed out "More data is often connected to more problems in the realm of science", thus this needs to be explored further to achieve useful solutions.

The current reality was described as a "transactional focus on hospitals, a patient is treated and we get the money for it". There is no real advantage for healthcare providers to focus on longitudinal aspects or to give patients the possibility to update their data and the means to be more involved. This is not currently rewarded by the system. As panellists observed, too often treatment happens in silos, it is not sufficiently cross-disciplinary and approached from a long-term perspective. There needs to be a change of perspective and time horizon as a basis for changes in data collection. We have to put systems in place that connect all the stakeholders.

We need a long-term vision of what happens with the data

To effectively regulate access to data, people need to know what happens to the data along the way. Data collection will need to be interdisciplinary, intersectoral and continuing, travelling with the patient, and allowing for longitudinal monitoring. Data collection systems need to consider different patient journeys and different users need to be reflected in the system structure. A patient journey is potentially complex and long, it goes on after the treatment. The EHDS is currently limited in that respect and does not cover certain possibilities for patients.

As Lars Riedemann from Heidelberg University put it: "To introduce a meaningful system, we need a long-term vision. We must ask ourselves, what is our highest goal? How can we improve treatment, reduce mortality, what is a real concrete primary end goal of the system? We need to have concrete goals that we can test and make progress towards."

Key recommendations:

- *Establish a common language, a common (logical) data model, a common semantic and a set of standards for the EHDS interoperability*
- *Ensure that the way data is gathered does not impair the quality of the treatment or hinder specialised research*
- *Establish a clear purpose and long-term vision for why which data should be collected*

5. Relation between primary and secondary data use

Core element of the EHDS framework is a combination of primary use of standardised health data for individual patient treatment on the one hand and secondary use of aggregated health data for innovation and training on the other hand (Figure **2**).
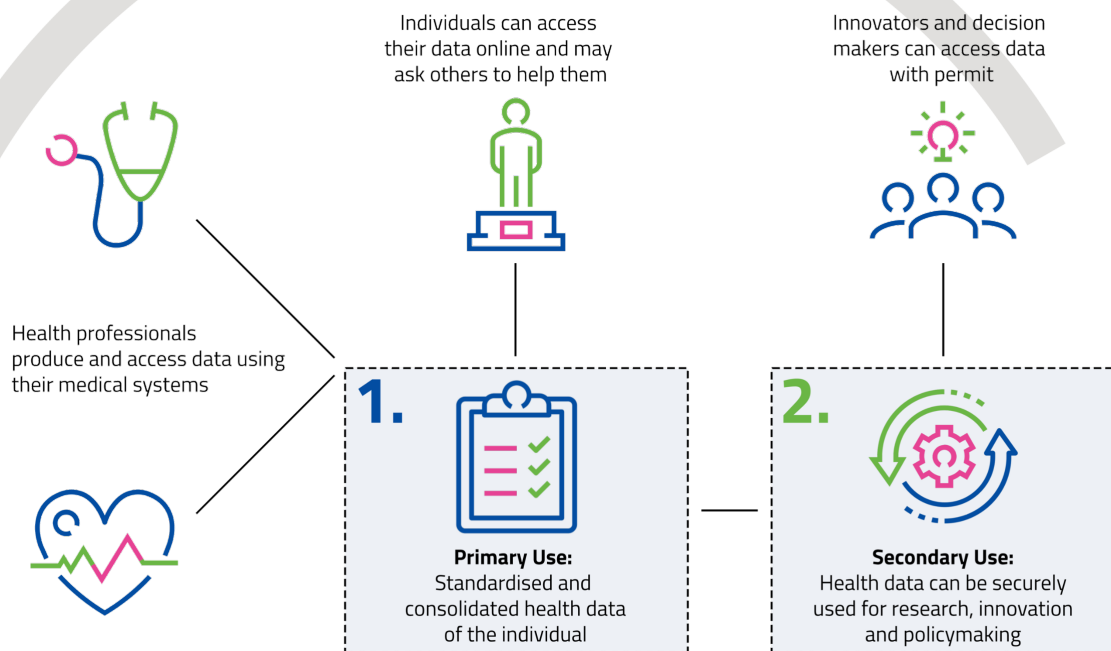
Individuals can access
their data online and may
ask others to help them

Innovators and decision
makers can access data
with permit

Health professionals
produce and access data using
their medical systems

1.

Primary Use:
Standardised and
consolidated health data
of the individual

2.

Secondary Use:
Health data can be securely
used for research, innovation
and policymaking

Figure 2: Principle of primary and secondary use of health data (K. Höller)

Readiness for implementation

Germany is facing a lot of challenges in integrating primary and secondary data use

Effective secondary use of data depends on the quality of data collection in primary data settings. Currently, the technical standards, data semantics and data quality are not sufficient to allow for a seamless secondary use of the data.

Several panellists quoted that Germany does not have accessible, reliably structured data at the hospitals, there are a lot of silos that do not communicate among each other, paper documentation is a

widespread practice as is manual transformation from one system to the other. Challenges are particularly high in smaller and less well-equipped and well-staffed healthcare providers. They simply lack the capacity and time to do the reporting.

The groundwork has not been laid to allow for effective data sharing

As Jared Sebhatu pointed out, the main challenges are the technical infrastructure and workflow management. Hospitals for the most part do not see themselves as process-oriented organizations. They do not optimise the work processes or put the technical infrastructure in place that would be necessary to allow for seamless data sharing. If funding is available but we do not change the workflows, there will be no improvement. In most cases providers currently do not have a sufficient groundwork to build a health data space on top of it.

Improvements also need to happen on the side of the secondary users of data. Pharmaceutical companies also need to be aware of the advantages of the EHDS, e.g., in getting the treatment solutions faster and safer thanks to better data. And they need to improve the effectiveness and efficiency of how they run their tests and data use to save time and costs in how they use the secondary data. For example, study settings of pharma data are not always effective. Efficiency can be improved which in turn saves time and resources that can be spent elsewhere. In the future, the Federal Health Data Lab (*Forschungsdatenzentrum Gesundheit*) will be implemented as a support structure to make primary data reusable for secondary purposes.

Some AI-based solutions exist

When it comes to AI-based solutions there seems to be no clear agreement as to what can be counted as an AI-based solution in the first place. In theory there are teams that can build totally new models but there is an overly negative view on how complex data systems are or must be. Common perception is that data systems need to be huge and complicated but as panellists pointed out, this does not necessarily have to be the case. If complex situations are boiled down to straight-forward questions, simplest versions of AI can be used to solve these small problems. What will bring Germany forward is not big revolution but more creative use of the data that can already be exploited today. It could be very simple data (e.g., as simple as who wears glasses as a proxy for risk of falling in elderly people) there is no need to dig deep into personal data spaces. In the end, there are already lots of qualified research groups working on AI-based solutions, and as soon as there is structured secondary use data coming out of the EHDS, there are people who would know how to use them wisely.

However, panellists also pointed out that AI-based approaches could be supported by having more streamlined processes and standardised contracts for data use. Data is already there but there are no processes and pipelines to use this data at scale. Long contracting phases and complicated legal processes lead to huge overhead in providing the data. We could free some of these resources by having establish joint systems and standardised contracts for using the data. In short, "there are huge wins to be made by deciding to trust each other."

Some positive examples emerge of linking primary and secondary data use

There are many small and unrelated initiatives that try to reach the same goal of improving availability of data for secondary use, but it often looks like competition which can stifle coordinated action.

However, as Jakob Defèr from Amgen pointed out, there is also hope and good practice is emerging at the regional level. For example, Bavarian hospitals recently agreed to share their data within HiMED Agenda, start small as a first step.

Priorities for implementation

Ensure that stakeholders have the capacity to gather data

Only imposing a new legislation will not be enough to ensure that data are gathered in a way which allows for a seamless use of such data for primary care and secondary purposes. A lot of investments are necessary to lay the right foundations, including reorganising the workflow to ensure that stakeholders have the time and capacity to engage with the system.

Keep implications for secondary use in mind when designing primary use structures

Reasonable secondary use of health data comes with broad coverage. An opt-in solution will capture significantly less population than an opt-out approach. Longitudinal completeness will provide better estimates for future health of individuals, derived from secondary use data. As quick solutions for good coverage in primary use will not necessarily lead to good outcomes for secondary use, it might be better to go an extra mile and optimise primary data collection also for secondary use, ideally aligned across borders.

Key recommendations:

- *Pay attention to building the right capacity and for data gathering*
- *Go in small, manageable steps, simple approaches to data and AI-based solutions can be as effective*
- *Establish joint systems and standardised contracts to decrease overhead in data use*
- *Keep ultimate goals of secondary use in mind when taking decisions for primary use*

6. Awareness, Education, Communication

Readiness for implementation

The success of the implementation of the EHDS depends to a considerable extent on the willingness and readiness of all stakeholders involved to engage with the system and to update and share their data. And this in turn is only a realistic scenario if a corresponding awareness and data culture is established through constructive communication in the short to mid-term and in the longer term through education.

Germany does not have a well-established data culture

Panellists largely agreed that Germany does not have a well-established data culture and there are strong reservations in institutions and the general public alike regarding data use and fears with respect to personal data protection. This is true in general and particularly in the German healthcare system and the wider health ecosystem. Common concerns revolve around the protection of personal data and the prevention of data misuse.

Panellists, however, observed a curious disconnect: while many people seem to be ready to share their basic health data from wellbeing apps through public social media channels, there are strong reservations in the general public to make their health data available in the health system for secondary data use for fear of breaches of data security.

Patients in Germany are neither very active nor empowered to manage their own care

Panellists cautioned that patient consent to share their data should not be taken for granted. Active awareness raising will be necessary to have them on board. Patients need to understand their immediate value added from sharing their data not only that some pharma company has an advantage from using their data.

Patients in Germany are not only reluctant when it comes to making their data available. They are also not particularly involved in their own care or proactive in managing or updating their health-related data and information.

Lot of stakeholders need to be educated, not only the citizens

Awareness of the necessary changes clearly is an area of concern in Germany. While a few stakeholders in government concerned with working on changes in the legislation or negotiating the details of the EHDS and in some more advanced medical institutions might be well aware of the necessary changes and related risks and benefits, this is not the case in the general public nor indeed in the medical personnel more broadly.

Communication in Germany is very risk-focused

As several of the panel participants pointed out, when it comes to data sharing or to dealing with the EHDS in the future, the communication needs to change in order to create trust instead of instilling even more fear by focusing the communication overly on potential risk of data protection. Germany has to understand that it is normal to work with data and this needs to be supported by constructive, benefit-oriented communication. Citizens and other stakeholders need to learn to balance risks and benefits to be able to make good decisions regarding data sharing.

There is no common language of what healthcare data means

Different interpretations of what healthcare data means among the different stakeholders (patients, practitioners, industry) makes it difficult to establish a shared understanding. We need a common language, and this also facilitates the communication about these issues.

Priorities for implementation

Establish concrete evidence and communicate more about those benefits

In order to improve the readiness of the general public to accept and trust the EHDS, panellists pointed out that it will be necessary to change the way of communication and focus it more on the value and upsides than on the risks. To achieve this, it is important to go in incremental steps instead of big jumps that only few people can follow but that would not be understood by everyone and to make use of concrete evidence.

Data is a matter of value creation. So far, Germany and Switzerland have not been active enough to create visible value for the user side (patient and practitioner). Looking into the future, it will be important to get good evidence on the value of data for primary and secondary use and to build on this

evidence to create valid arguments to convince people to take part in the roll out of the health data space.

To be able to show concrete benefits, it is important to go discipline by discipline and make the examples as concrete as possible. We need to be able to explain the benefits and prove it through science. So far, too little is known about how and where data can create value let alone communicated in the general public. To promote this, it was suggested to build in direct feedback channels (the example of Spain was quoted where a blood donator is notified when her or his blood is used) thus establishing an immediate feedback loop. Similarly, patients could be informed what their data is used for and what benefits this generates in order to increase the willingness to share them. All this helps to establish success stories with positive value-risks ratio.

Awareness for the EHDS needs to be addressed in education

As in the case of capacity building cited above, educational needs for awareness raising about the EHDS go far beyond the sphere of Medical Schools but also involve adjacent faculties such as (medical) engineering, pharmacy, or medical care.

Key recommendations:

- *Raise awareness about the changes to come and their benefits*
- *Involve patients more actively in their care*
- *Establish a more constructive communication focussing on concrete advantages instead of risks*
- *Introduce the issue of health data not only in medical schools but also in adjacent fields*
- *Explore if education through EU Pact for Skills is possible in collaboration with industry*

Conclusions

It can be concluded from this round of consultation that both Germany and Switzerland have still a way to go to be ready for the implementation of a comprehensive European Health Data Space. Challenges are numerous and range from providing the right technical infrastructure and improving workflows in healthcare providers to capacity building and the establishment of a more benefit-oriented discourse around health data use. The new structure will need to be collaborative, coordinated, consistent, complete, and clear (also in terms of roles and responsibilities).

Germany's Health Data Use Act (GNDG) and Digital Act (DigiG) proposals are just a first step to be maintained in a future initiative but no reason to reduce speed, a quick second step will have to follow to implement the EHDS especially regarding interoperability of EHR systems between member states.

However, it also became clear that there is a considerable willingness of all actors involved to contribute their expertise to the political process to help moving the EHDS agenda forward. EIT Health Germany Switzerland CLC will continue the dialogue with stakeholders concerned and actively support the implementation of the EHDS by connecting partners and leveraging best practice and relevant expertise.

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