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What does it take to create a European Health Data Space? International commitments and national realities

Was ist für die Schaffung eines europäischen Gesundheitsdatenraums nötig? Internationale Ambitionen und nationale Realitäten

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ABSTRACT

Public health concerns in Europe demonstrate the necessity of building a health policy that could contribute to the long-term sustainable development of the European Union (EU), as stated in the European Health Union (EHU) manifesto. The main desire to create an EHU is embodied in the launch of the European Health Data Space (EHDS). The EHDS seeks to foster a genuine single market for digital health services and products by, among other things, accelerating the uptake and implementation of harmonised and interoperable electronic health record (EHR) systems across the EU. In the context of primary and secondary use of EHR data, developments in Europe have thus far resulted in patchy and, in some places, non-interoperable solutions. Taking the gap between international ambitions and national realities as a starting point, this paper contends that both EU level and Member State level circumstances should be considered to make the EHDS a reality.

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ZUSAMMENFASSUNG

Die Sorge um die öffentliche Gesundheit in Europa zeigt die Notwendigkeit, eine Gesundheitspolitik zu schaffen, die zur langfristigen nachhaltigen Entwicklung der Europäischen Union (EU) beiträgt, wie es im Manifest der Europäischen Gesundheitsunion (EHU) heißt. Der Hauptwunsch, eine EHU zu schaffen, wird durch die Einrichtung des Europäischen Gesundheitsdatenraums (EHDS) verkörpert. Mit dem EHDS soll ein echter Binnenmarkt für digitale Gesundheitsdienste und -produkte gefördert werden, indem u. a. die Einführung und Umsetzung harmonisierter und interoperabler elektronischer Patientendatensysteme in der gesamten EU beschleunigt wird. Im Zusammenhang mit der primären und sekundären Nutzung von Gesundheitsdaten aus elektronischen Patientenakten haben die Entwicklungen in Europa bisher zu uneinheitlichen und teilweise nicht interoperablen Lösungen geführt. Ausgehend von der Kluft zwischen den internationalen Ambitionen und den nationalen Realitäten wird in diesem Beitrag die Auffassung vertreten, dass sowohl die Gegebenheiten auf EU-Ebene als auch auf der Ebene der Mitgliedstaaten berücksichtigt werden sollten, um die Ziele des EHDS zu verwirklichen.

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Introduction

Policies of the European Union (EU) in the field of public health have often been the product of crises that allowed the EU to 'fail forward' towards a more integrated Europe [1]. Shortly after cautious reactions by most political leaders to the unprecedented impact of the Covid-19 crisis in the spring of 2020, who sought to tackle the pandemic in a fragmented way, Member States soon turned to the EU, showing solidarity and cooperation [2]. Whilst the joint commitment against Covid-19 has become increasingly apparent, the pandemic also quickly revealed the limitations of the EU for an effective joint response to such public health challenges. Apart from the limited competence of the European Centre for Disease Prevention and Control (ECDC) to ensure comprehensive epidemiological investigations in Member States, their discrepancies on health data quality and methods for collecting data restricted the EU's ability to manage the crisis in a timely manner [2]. If there is one thing that the pandemic confirms, it is that Member States are too closely bound together to lack a shared vision of healthcare. Public health concerns, alongside a number of Europeans living outside of their country and seeking cross-border healthcare, demonstrate the necessity of building a health policy that could contribute to the long-term sustainable development of the EU, as stated in the European Health Union (EHU) manifesto.[1]

Simply put, EHU is a call for new EU competencies in the field of health, supported by a strengthened understanding of the definite impact of EU policies on health. Apart from the proposals of the European Commission (hereafter: Commission) to extend the legal mandates of the ECDC and the European Medicines Agency [3], the desire to create an EHU is embodied in the launch of the European Health Data Space (EHDS). Being the first proposal of a domain-specific common European data space, the EHDS aims to facilitate the provision of health services within and beyond country borders through health data sharing (primary use of health data) and to support better research and policymaking for health, known also as the secondary use of health data [4]. Published in May 2022, the proposal of the Commission for a regulation of the European Parliament and of the Council on the EHDS seeks to i) ensure the people have more control over their health data; ii) contribute to the internal market by accelerating the uptake and implementation of harmonised and interoperable electronic health record (EHR) systems across the EU; and iii) build a framework for the secondary use of health data for research, innovation and policymaking to improve population health [4]. According to the proposal, the establishment of EHR systems in Member States should build one of the main pillars for the exchange of and access to various types of electronic health data across Europe.

The Commission proposal states that the EHDS would ultimately contribute to 100% coverage of EU citizens having access to their EHRs by 2030, in accordance with the Policy Programme 'Path to the Digital Decade'[2]. In this context, the proposal interprets EHR as 'a collection of electronic health data related to a natural person and collected in the health system, processed for healthcare purposes', and EHR system is defined as 'any appliance or software intended by the manufacturer to be used for storing, intermediating, importing, exporting, converting, editing or viewing electronic health records' [4]. As commonly known, the main function of contemporary EHR systems is the continuity of relevant patient information in which patients' data can be electronically obtained, processed, and stored for providing better healthcare and building a preventive health system. Patients' health information in EHRs typically includes medication lists, vital parameters to monitor, diagnoses, immunisations, medical history, laboratory test results and clinical notes. In more advanced infrastructures, EHR functionalities may moreover cover radiology test images, contraindications and drug interactions [5]. Data from EHRs can be used not only for improving health service quality but also for public health surveillance, especially in the efficient monitoring of disease outbreaks [6]. To date, although the Commission has made significant efforts in EHR deployment and provided guidance, the active introduction of EHRs has mainly relied on the willingness of Member States to adopt recommended policies in their national capacities.

Hence, despite the ongoing efforts for more than two decades at the EU-level towards better harmonisation and integration of health data, wide discrepancies between Member States cannot be overlooked [7]. In the field of primary and secondary use of health data from EHRs, developments in Europe have resulted in patchy and in some places non-interoperable solutions. Indeed, especially during the Covid-19 pandemic, the long lasting debate on health data sharing has gained a new political momentum and revealed how the diffusion of data driven solutions has not been even among industrialised countries [8]. In the face of these challenges, the EHDS will aim to set requirements for EHR systems in order to promote interoperability and data portability [4]. Taking the gap between international ambitions and national realities as a starting point, this paper contends that both EU-level and Member State level circumstances should be taken into account to make the EHDS a reality. Considering the varying pace of developments in Member States regarding the implementation of national EHR systems and the ambitions of the Commission (alongside a number of EU Institutions and Agencies), this study offers a timely contribution to the ongoing debate on the EHDS.

Methods

Based on a theoretical insight offered by Leichter [9], this article elaborates on the Commission's EHDS proposal as an external influence to bring a digital, data-driven approach to European health systems. Leichter argues that national policymakers respond to demands and conditions that happen not only inside but also outside their political systems with increasing interdependence and interrelation among countries in almost all social domains [9]. Known also as environmental factors, international political climate, policy and issue diffusion (borrowing of policy ideas and solutions from other nations), as well as international agreements, obligations and pressures affect national policymaking [9]. These external influences, however, have different impacts on countries with varying starting points; meaning, even in the case of a top-down implementation approach, the outcomes of an international agreement or obligation will not be truly homogeneous across countries [9]. In light of this knowledge, an international expert workshop was conceptualised and applied Leichter's theory to discuss the use and re-use of EHR data at national and European levels in the context of the EHDS.

At the Eighth European Conference on Health Law, the current situation in EHRs implementation and data use in the EU was discussed in a half-day workshop. The workshop, entitled '*What does it take to create a European Health Data Space? Production, use and re-use of Electronic Health Records data*', was attended by almost 50 experts from several European countries and professional backgrounds. Based on the expertise of the authors of this paper, developments in Member States and at EU-level were discussed in four distinct thematic areas with presentations: i) EHR systems in Euro-

[1] See: https://europeanhealthunion.eu/
[2] See: https://ec.europa.eu/commission/presscorner/api/files/document/print/en/ip_21_4630/IP_21_4630_EN.pdf

pean countries; ii) public trust in the context of EHRs; iii) primary use of EHR data; and lastly iv) secondary use of EHR data. After each of these four presentations, participants were given the opportunity to ask questions to the presenters. At the end of the workshop, ample time was provided for an interactive discussion with the participants to develop a conceptual framework that could offer new insights when creating the EHDS. In line with the workshop's main objective, the participants could gain, share and exchange knowledge about feasible policy options to support the EHDS, addressing the topic both from national and international perspectives. Before elaborating on the findings of the expert workshop, the following section provides background information on the EU's continuing commitment to better use and re-use of health data.

Context

For more than two decades, the Commission has been offering funding and guidance to Member States for enabling the establishment of a pan-European medical data-sharing infrastructure. With the first Action Plan on digital health in the early 2000s, the Commission sought to set targets to identify interoperability standards for EHRs by taking into account best practices and relevant standardisation efforts in Europe [10]. A decade after the launch of the Action Plan, Directive 2011/24/EU on the application of patients' rights in cross-border healthcare paved the way for an EU-wide digital health network (eHealth Digital Service Infrastructure; eHDSI) that started to promote cooperation and the exchange of health information of patients among Member States, giving patients access to healthcare in another EU country and facilitating connected digital health systems. The Commission Recommendation (EU) 2019/243 of 6 February 2019 on a European Electronic Health Record exchange format has been central in the context of access to and exchange of EHRs across borders in the EU [11]. Moreover, through various programmes, the Commission has been providing recommendations and financial support to Member States on improving the re-use of health data for research and policy. The following paragraphs will discuss the recent developments concerning the primary and secondary use of health data in the EU, which ultimately built the foundation for the EHDS proposal.

As for the primary use of health data in the EU, eHDSI has been central to two electronic cross-border health services. The first service, electronic prescription and electronic dispensation, allows EU citizens to obtain their medication in a pharmacy located in another partnering EU country, using electronic means to issue and transmit medicinal prescriptions between healthcare providers in different Member States. The second service of eHDSI is concerned with patient summaries that allow accessing information on important health-related aspects of patients when they visit a physician in a different EU country. The digital patient summary, which can be considered as a subset of EHR data, provides information on important health-related aspects such as allergies, diagnostic tests, medical problem list, as well as the history of medical use, medical devices use, procedures, patient illness and immunisation. Its content is planned to be expanded to medical images, laboratory test results and hospital discharge reports, enlarging the scope of patient data and bringing patient summaries closer to comprehensive EHRs. For both electronic cross-border health services, the EU aims for a gradual establishment of an electronic data infrastructure in 25 EU countries until 2025 under MyHealth@EU [12]. The EHDS proposal states that the progress in Member States has been far too slow on the use of personal electronic health data for cross-border healthcare purposes. Thus far, the MyHealth@EU platform has been implemented in not more than ten Member States, which motivated the Commission to call for a more coordinated action [4].

The secondary use of health data (organised at the EU-level under HealthData@EU) refers to the use of health data, including EHR data, for any other purpose than the one for which it was collected; such as research, policymaking and regulatory activities [13]. Currently, there is a patchy landscape of secondary use of health data across the EU, and cross-border research projects face challenges due to varying interpretations of legal EU requirements in different countries [14]. Some Member States have well-developed infrastructures and regulatory frameworks, with streamlined processes for data users to access data for secondary use. On the contrary, some other countries show fragmentation in the health data landscape, and users report difficulties in accessing and analysing relevant health data. The Joint Action Towards the European Health Data Space (TEHDAS) was set up in 2021 to support Member States and the Commission in developing and promoting the concepts for the secondary use of health data to improve health policies, research and innovation in Europe. At its core, the aim of TEHDAS is to put forward options and recommendations for the secondary use of health data in the EHDS. As explored in the framework of TEHDAS, the success depends on several factors: i) data governance should ensure trustworthy health data exchange; ii) data must be of high-quality and interoperable; iii) technical infrastructures should allow safe data exchange; and finally iv) there should be mechanisms in place to involve and inform citizens about to the benefits of health data re-use. From December 2021 to December 2022, TEHDAS carried out country visits to map the state-of-play of health data management systems across Member States and identify their needs and expectations at the national level, to be taken into account when implementing the EHDS.

By providing a mechanism for harmonising the EHR systems in the EU, the proposal of the Commission for a regulation on the EHDS aims to reinforce the rights of individuals to use and share their personal health data in their EHRs in cross-border healthcare and foster the re-use of health data for social good [4]. Once adopted by the European Parliament and the Council, the Regulation would be fully applicable four years after its entry into force; however, the foreseen provisions in the proposal, such as the rights of natural persons for obtaining and sharing their health data, certification of EHR systems, and measures for the secondary use of health data, should be in place before that timeframe. The Commission suggests that the EHDS policies should be implemented through national bodies for primary and secondary use of electronic health data, whereas such efforts in Member States should be supported both financially and politically at the EU-level. As the Covid-19 pandemic has created a common political ground for building on the advantages of cross-border health data sharing in Europe, there are good reasons to be optimistic about the mechanisms to create the EHDS, with, however, some differences between EU and Member State levels.

Arguably, the perceived benefits of the EHDS for end-users of EHRs in Member States will be mainly concerned with the primary use of health data in cross-border healthcare (Figure 1). With MyHealth@EU, which should be reinforced by the EHDS, patients will be able to share their health data with healthcare providers in a country other than their own. Whereas the benefits of receiving health services in another country as the primary purpose of sharing health data across the EU may be tangible to many Europeans, the actual patient mobility in the EU has been very low despite Directive 2011/24/EU on the application of patients' rights in cross-border healthcare. For instance, the whole EU (excluding the United Kingdom) received in 2016 only 6 009 requests for patient mobility, of which 3 822 were granted. The figures from 2017, 2018, 2019 and 2020 show a similar tendency: 5 471

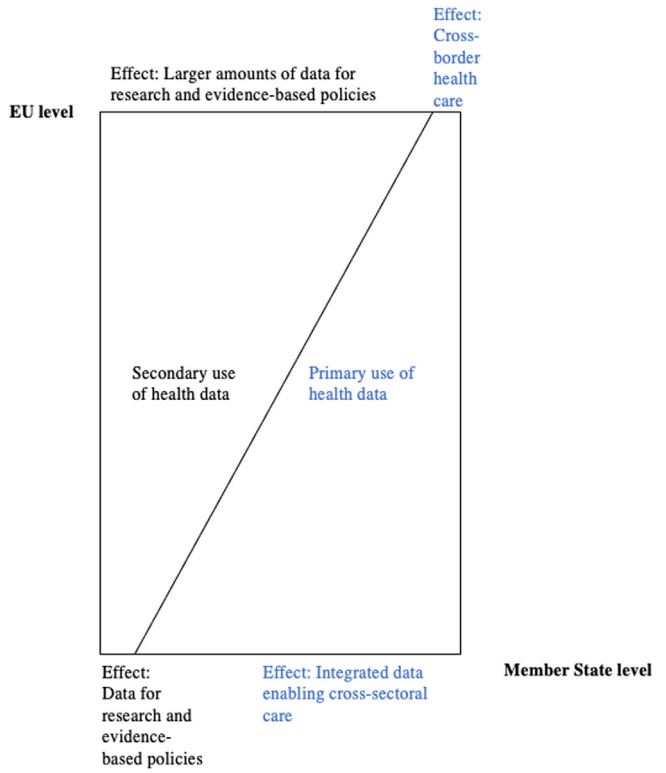

Figure 1. Perceived benefits of health data sharing at Member State and EU levels.

received (3 727granted); 6 301 received (4 447 granted); 5 352 received (3 291 granted); and 5 218 received (3 542 granted), respectively [15]. Based on international patient summary (ISO 27269:2021), electronic exchange of health data in the EU was sought to be harmonised under Directive 2011/24/EU [16]. Even though Directive 2011/24/EU could be the main driver for a strengthened cooperation between Member States in cross-border healthcare and building the EHU, the figures on patient mobility make clear that cross-border healthcare remains very limited, considering the magnitude of the EU with almost 450 million inhabitants [15]. This implies that even though individuals can clearly see the advantage of receiving health services in another country, not many of them would support the EHDS implementation primarily for this purpose.

The situation that the perceived benefit of the primary use of health data, compared to cross-border care, is greater on the Member State level raises a challenge. Because even though receiving good quality health services is ultimately what matters for individuals, the main advantage of EHDS at the EU-level lies in its potential to collect large amounts of health data from EU countries and use these data for better research and policies for the benefit of all (secondary use of electronic health data under HealthData@EU). However, processing personal and sensitive electronic health data of individuals, initially collected in the context of primary use, is highly challenging, even at Member State level [17]. The national context influencing the re-use of EHR data, such as relevant legal frameworks, public communication, data security and management systems, greatly differs from one country to another. This results in a patchy landscape in Europe when it comes to the uptake of data-driven technologies for health [18]. Even though the EHDS regulation comes into force, it will be the role of Member States to take the necessary steps for its proper implementation. It is for this reason that efforts at both EU and Member State levels would be required to make EHDS a reality, to which we now turn.

Findings from the expert workshop

Stakeholder management

The workshop participants emphasised that one of the main factors to consider in the context of the EHDS and EHRs is the varying maturity levels of health data infrastructures in different countries. When introducing complex interventions to European health systems it is of utmost importance to grasp how they work in a specific context and why they might (not) succeed elsewhere. With this in mind, the participants highlighted the importance of context-specific factors and national stakeholders in Member States. They underlined that the digitalisation process entails much more than technical infrastructure, the motivation and collaboration of the main actors in healthcare provision being one of the most preeminent factors. It was emphasised that depending on the health system of countries, healthcare providers can be supportive or reluctant to data integration. To collect EHR data from clinical settings for research and policymaking, the digital health literacy of healthcare providers should be ensured, and they should be offered incentives for providing high-quality and structured data at the source. The workshop participants suggested that reliable clinical data could be collected for research from interoperable data infrastructures, whilst not becoming an administrative burden to health professionals and detracting from patient care.

Trust

The participants stated that laying the groundwork for the secondary use of health data could be challenging to accomplish within a few years, given the necessary time required for establishing trust relationships between the public and policy actors. Some countries, especially those in Northern Europe, follow a liberal approach to personal data exchange and processing; a practice underpinned by trust between their governments and citizens. For instance, in Denmark and Estonia, citizens are given an electronic personal identity at birth by which they can access government services digitally, including those relevant to their health data. Digital interactions between citizens and public officials make the public familiarised with digital government services, which is a key factor for trust. Such digital communications create a high degree of confidence among citizens that the security, privacy and management of their data are ensured according to trustworthy national and European regulations [19]. Strikingly, workshop participants from Denmark challenged this statement and questioned whether public trust plays a role at all in the acceptance of EHRs in the Danish context, given that citizens in Denmark have virtually no other choice than to use EHRs. If they decided to opt out, they would face considerable challenges in access to healthcare services. The Danish example highlights the importance of public trust in overarching governance structures and the state, whilst indicating that attempts to establish trust only in health systems in isolation would be less successful.

Coordinated governance

According to the workshop participants, strict data protection rules and different interpretations of national and European laws build barriers to health data re-use. The EU General Data Protection Regulation (GDPR) shows that even the legal acts that are immediately enforceable as law in all Member States simultaneously can have varying impacts on countries, creating a gap between them. Countries may derogate from GDPR and have different national laws for the re-use of health data in addition to GDPR. Derogations and divergent interpretations of GDPR hamper cross-

border research projects in the EU, especially when Member States have varying data processing requirements. Whereas one country needs the patients' consent, another one may allow using personal health data in research for the public interest without any consent requirement. Combined with a lack of consistent European interpretation on what constitutes sufficient anonymisation, pseudonymisation and secondary use of health data, several Member States adopted risk-averse strategies. The lack of clarity about how to use personal health data for research purposes creates overly cautious data protection practices in Member States, reducing the speed of innovation in Europe. The stagnation within this fragmented landscape suggests the necessity of sector-specific EU legislation and EU-level guidance to support its implementation. To overcome the existing technical, legal and organisational barriers to the secondary use of health data, transparent governance structures at the EU-level are required, with the involvement of a wide range of stakeholders from Member States.

Use-cases

Coordinated governance across the EU should build the basis for harmonised health data systems in Member States and will play an integral role in the development and functioning of the EHDS. However, positive outcomes in health systems resulting from the secondary use of health data are expected to be less tangible to frontline healthcare workers and citizens compared to the primary use of health data, building a potential barrier to the implementation of measures for the re-use of EHR data. This is because the more distant and indirect the benefits of data sharing to the individuals are, the harder it becomes to convince them to do so. Understanding why and how EHR data are used for health at the population level might be more difficult to comprehend than their clinical benefits in healthcare settings. Another major challenge regarding the secondary use is that the available EHR data formats are not always adapted to research and policymaking. The high amount of unstructured data and different interoperability standards reduce the ability to carry out meaningful research based on EHR data. In this context, the workshop participants recommended that the EU should demonstrate the added value of harmonised EHR data across Europe, both for health service provision and the re-use of health data in research and policymaking at the EU-level. Especially for the latter, tangible use-cases with clear benefits to healthcare providers and citizens are needed.

Discussion

The results of our workshop suggest different interventions at the EU and Member State levels (Figure 2). Arguably, when creating the EHDS a standard, one-size-fits-all approach would neither succeed nor satisfy the expectations; even if the regulation comes into force its implementation will require several supporting actions that go beyond technical or financial issues. Our findings imply that it will be primarily the responsibility of the EU to create an overarching framework for a coordinated EHDS governance and show use-cases that could demonstrate the benefits of the secondary use of EHR data at the EU-level. These steps would support the harmonisation of countries on the one hand and create public buy-in during the transition period on the other. In addition to the EU-level actions, Member States should take responsibility to raise public trust in national and European authorities (crucial especially for the re-use of health data) and manage important national stakeholders such as healthcare provider organisations in order to make the EHDS credible and acceptable for them. It is the combination of top-down and bottom-up approaches that will yield successful results.

When comparing European countries with a similar level of innovation overall, it should not come as a surprise that the adoption of digital health solutions does not necessarily correlate with their overall innovation capacity, infrastructure or wealth. The existing gap is rather a reflection of several underlying reasons, such as the differences in administrative structures, level of trust in government or vested interests of some national stakeholders. To make a valid judgement on whether Member States can absorb and implement the measures for creating the EHDS within a short time frame, differences in their legal, social, ethical, or political contexts should be considered. To this end, a flexible governance framework should be created at the EU-level [17]. When developing use-cases about the use and re-use of health data, mapping stakeholders in each country could be helpful. Studies demonstrating the dynamics of institutional pressures and stakeholder behaviours in the context of EHR implementation warn that coercive actions should take power balances into account; political pressures can result in resistance among autonomous, powerful stakeholders, yielding unproductive results in the end [20]. As is mostly the case for other EU health policies, the fate of the EHDS too will mainly depend on the willingness of Member States to implement it successfully. For this reason, the following paragraphs will elaborate on building public trust and managing national stakeholders.

Factors often associated with low levels of public trust in EHRs include inadequate data security, distrust and less patient-centred care [21]. Trust and communication between the public and official institutions are key for the successful deployment of EHR systems and the secondary use of health data [22]. Trust in and of itself is a complex concept with different interpretations and nuances, all of which are based on individuals' cultural views, personal experiences and societal constructs. Therefore, the question of how to foster trust in the use and re-use of EHR data with a single approach would be difficult to answer. Rather, tailor-made solutions for countries should be considered, based on their culture, language and socioeconomic circumstances [23]. Trust is a construct that can only evolve in a free context of choices where it is placed between alternatives [24]. Still, implementation cannot begin without legislation. Legislation is vital for building up and implementing EHRs, especially in the context of handling, security and protection of EHR data [25–26]. Member States should start implementing necessary measures against data misuse and address citizens' concerns in public debates. These dialogues should centre around the balance between the data privacy of individuals and the benefits of sharing them for the common good. Public trust can only flourish if the public understands the potential of EHR data and the rationale behind their secondary use for public health surveillance, and in general, for population health and well-being.

Apart from this, it will be important for Member States to increase the digital health literacy of the public and healthcare providers and support them with interoperable data infrastructures in clinical settings to reduce burdensome documentation processes. In this context, addressing barriers to health data sharing caused by legal, semantic and technical interoperability must be a priority. When looking at the Commission's proposal for a regulation on the EHDS (whilst noting that the content may change in light of negotiations in the Council of the EU and the European Parliament), some key components to enable the secondary use of health data that require closer attention include i) overall digitalisation of health data; ii) semantic and technical interoperability to allow meaningful data exchange between countries; iii) public metadata catalogue with specific descriptions of the data available in countries; iv) infrastructure for facilitating access to data from different data sources; v) remote secure data processing environments to allow the safe analysis of data; and finally vi) equal access to health data for national and foreign researchers. The final point is fundamental in the context of cross-border access to health data,

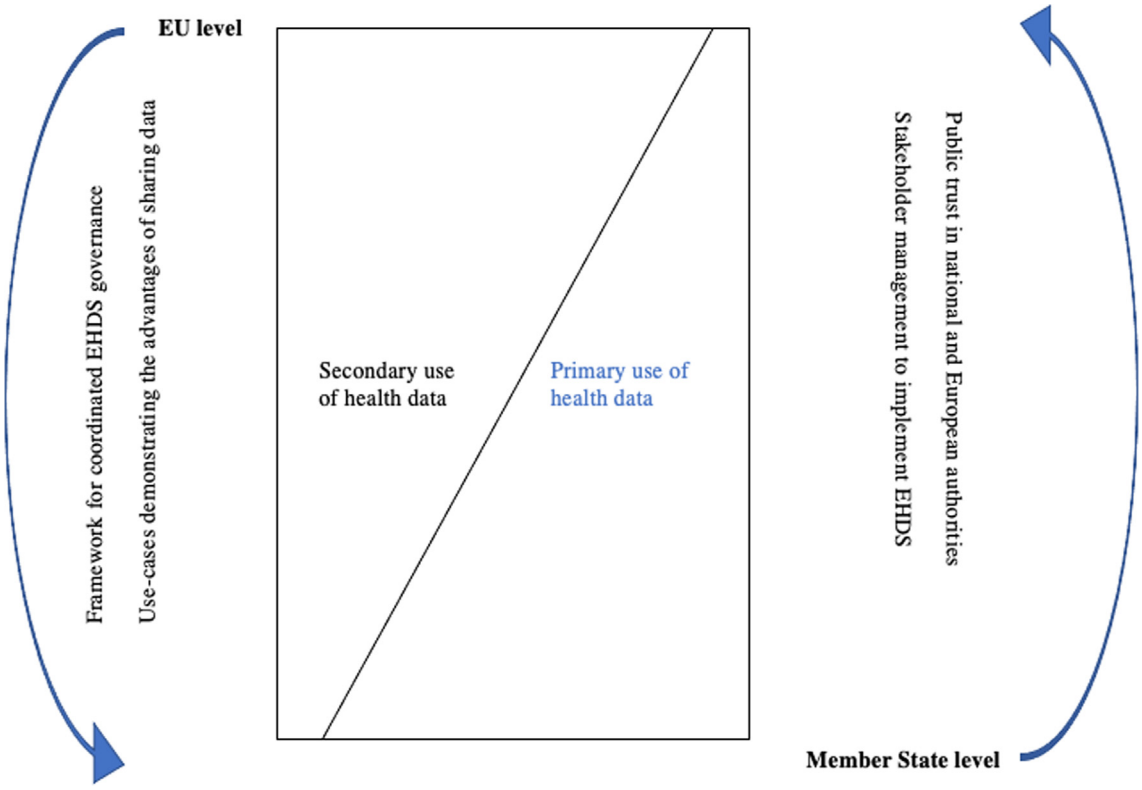

Figure 2. Necessary actions to ensure a successful EHDS implementation.

contributing to the FAIRness (Findability, Accessibility, Interoperability and Re-usability) of health data [27].

Despite the availability of standards for semantic interoperability, such as SNOMED CT, their adoption in European countries has been extremely slow for years [28]. Nonetheless, given the increasing importance of EHR data for health systems and efforts to create the EHDS, Member States have started to take steps to increase the quality of health data they collect. For instance, based on the Patient Data Protection Act (2020), Germany became a member of SNOMED International; this step has been crucial for strengthening semantic interoperability and will enable important developments for a uniform and meaningful use of (exponentially increasing) health data in Germany and Europe. Moreover, the newly published digitisation strategy of the German Ministry for Health from March 2023 lays the foundation for connecting the German health system to the EHDS, facilitating medical care and research across borders. The document states that Germany is making progress towards the European harmonisation of legal and technical framework conditions in health and long-term care, referring to the EHDS in several places and including electronic IDentification, Authentication and trust Services (eIDAS) as well [29]. As also becomes evident in the German case, the EHDS is a major step forward in harmonising Member States' laws and overcoming divergences in data protection rules relevant to health data sharing in the EU [30].

Conclusion

The Commission has made extensive efforts over many years to promote greater use of digital health technologies in the EU. These efforts include promoting research and developing standards and guidelines in this field, facilitating cooperation between Member States on their own initiatives, and financing their digital health infrastructures. Mechanisms that ensure the exchange of health data between Member States are essential for the sustainability and resilience of European health systems as has been proven in the case of the Covid-19 pandemic. Spanning from the European Semester, the Cohesion Policy Funds, Horizon Europe to the Recovery and Resilience Facility, a number of EU tools support Member States to strengthen and modernise their health systems [31]; still, the European Parliament's newly published draft report on the proposal for a regulation on the EHDS warns that the allocated EU budget may not be sufficient in fully meeting the objectives of the proposal [32]. Given the concern that the EHDS would compete with other actions under the EU4Health and Digital Europe programmes foreseen at the adoption of the 2021-2027 Multiannual Financial Framework (MFF), the European Parliament suggests the Commission to strengthen the budget allocated to the implementation of the EHDS as part of any revision of the MFF and in the proposal for a new MFF in the period after 2027 [32].

This article provided insights into the EU and Member State dynamics in the context of use and re-use of EHR data and recommended measures that should go hand-in-hand with the financial tools. By discussing recent developments in Germany at the end, it presented how external influences can shape national policies. It is without doubt that the endeavours to create the EHDS have been speeding up digital transformation of health systems in Member States; the EU should facilitate this process by providing a framework for coordinated governance and demonstrating use-cases for the (re-)use of health data. Still, even in the form of a regulation the implementation of EHDS legislation will require policies beyond the EU-level; ensuring public trust and managing key national stakeholders are two of the most crucial measures that only Member States themselves can initiate at the country level. Ultimately, the integrity of health data under the EHDS will be achieved by recognising the diversity of European health systems.

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Conflict of interest

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References

[1] Brooks E, de Ruijter A, Greer SL. The European Union confronts Covid-19: Another European Rescue of the Nation-State? In: Coronavirus Politics: The Comparative Politics and Policy of COVID-19. University of Michigan Press; 2021. https://doi.org/10.3998/mpub.11927713.
[2] Forman R, Mossialos E. The EU Response to COVID-19: From Reactive Policies to Strategic Decision-Making. J Common Market Stud 2021;59(S1):56–68. https://doi.org/10.1111/jcms.13259.
[3] European Commission. European Health Union. https://ec.europa.eu/info/strategy/priorities-2019-2024/promoting-our-european-way-life/european-health-union_en, n.d. (Accessed 14 March 2023)
[4] European Commission. Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52022PC0197, 2022 (Accessed 14 March 2023)
[5] European Commission. Benchmarking deployment of eHealth among general practitioners - Final report. https://data.europa.eu/doi/10.2759/511610, 2018 (Accessed 14 March 2023)
[6] Haneef R, Delnord M, Vernay M, Bauchet E, Gaidelyte R, Van Oyen H, et al. Innovative use of data sources: a cross-sectional study of data linkage and artificial intelligence practices across European countries. Arch Public Health 2020;78(1):55. https://doi.org/10.1186/s13690-020-00436-9.
[7] OECD. Survey results: National health data infrastructure and governance. https://www.oecd-ilibrary.org/social-issues-migration-health/survey-results-national-health-data-infrastructure-and-governance_55d24b5d-en, 2021 (Accessed 14 March 2023)
[8] Bogumil-Uçan S, Klenk T. Varieties of health care digitalization: Comparing advocacy coalitions in Austria and Germany. Rev Policy Res 2021;38(4):478–503. https://doi.org/10.1111/ropr.12435.
[9] Leichter HM. A Comparative Approach to Policy Analysis: Health Care Policy in Four Nations. Cambridge: Cambridge University Press; 1979.
[10] European Commission. e-Health - making healthcare better for European citizens: An action plan for a European e-Health Area. https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2004:0356:FIN:EN:PDF, 2004 (Accessed 14 March 2023)
[11] European Commission. Commission Recommendation (EU) 2019/243 of 6 February 2019 on a European Electronic Health Record exchange format. http://data.europa.eu/eli/reco/2019/243/oj/eng, 2019 (Accessed 14 March 2023)
[12] European Commission. Electronic cross-border health services. https://ec.europa.eu/health/ehealth/electronic_crossborder_healthservices_en, n.d. (Accessed 14 March 2023)
[13] TEHDAS Consortium Partners. TEHDAS Joint Action Glossary. https://tehdas.eu/results/tehdas-glossary/, 2022 (Accessed 14 March 2023)
[14] European Commission. Assessment of the EU Member States' rules on health data in the light of GDPR. https://health.ec.europa.eu/system/files/2021-02/ms_rules_health-data_en_0.pdf, 2021 (Accessed 14 March 2023)
[15] European Commission. Commission Staff Working Document accompanying the document: Report from the Commission to the European Parliament and the Council on the operation of Directive 2011/24/EU on the application of patients' rights in cross- border healthcare. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=SWD:2022:200:FIN, 2022 (Accessed 14 March 2023)
[16] ISO. Health informatics - International patient summary. https://www.sls.se/globalassets/sls/sls/remissvar/remisser/2021/iso_27269_2021.pdf, 2021 (Accessed 14 March 2023)
[17] Schmitt T, Haarmann A, Shaikh M. Strengthening health system governance in Germany: looking back, planning ahead. Health Econ Policy Law 2023;18:14–31. https://doi.org/10.1017/S1744133122000123.
[18] OECD. Health Data Governance: Privacy, Monitoring and Research. https://www.oecd.org/els/health-systems/health-data-governance-9789264244566-en.htm, 2015 (Accessed 14 March 2023)
[19] Nøhr C, Parv L, Kink P, Cummings E, Almond H, Nørgaard JR, et al. Nationwide citizen access to their health data: analysing and comparing experiences in Denmark, Estonia and Australia. BMC Health Services Res 2017;17:534. https://doi.org/10.1186/s12913-017-2482-y.
[20] Klecun E, Zhou Y, Kankanhalli A, Wee YH, Hibberd R. The dynamics of institutional pressures and stakeholder behavior in national electronic health record implementations: A tale of two countries. J Informat Technol 2019;34(4):292–332. https://doi.org/10.1186/s12913-017-2482-y.
[21] Lounsbury O, Roberts L, Goodman JR, Batey P, Naar L, Flott KM, et al. Opening a "Can of Worms" to Explore the Public's Hopes and Fears About Health Care Data Sharing: Qualitative Study. J Med Internet Res 2021;23(2):e22744.
[22] Bogaert P, Verschuuren M, Van Oyen H, van Oers H. Identifying common enablers and barriers in European health information systems. Health Policy 2021;125(12):1517–26. https://doi.org/10.1016/j.healthpol.2021.09.006.
[23] Gille F, Smith S, Mays N. Evidence-based guiding principles to build public trust in personal data use in health systems 20552076221111947. Digit Health 2022;8. https://doi.org/10.1177/20552076221111947.
[24] Luhmann N. Familiarity, Confidence, Trust: Problems and Perspectives. Trust: Making and Breaking Cooperative Relations. Blackwell; 1988.
[25] Gille F, Smith S, Mays N. What is public trust in the healthcare system? A new conceptual framework developed from qualitative data in England. Soc Theory Health 2021;19(1):1–20. https://doi.org/10.1057/s41285-020-00129-x.
[26] Wellcome Trust. Enabling Data Linkage to Maximise the Value of Public Health Research Data: full report: March 2015. https://wellcomecollection.org/works/zymnf3ka, 2015 (Accessed 14 March 2023)
[27] Wilkinson MD, Dumontier M, Aalbersberg IJJ, Appleton G, Axton M, Baak A, et al. The FAIR Guiding Principles for scientific data management and stewardship. Sci Data 2016;3(1). https://doi.org/10.1038/sdata.2016.18.
[28] Thiel R, Birov S, Piesche K, Højen AR, Gøeg R, Dewenter H, et al. The Costs and Benefits of SNOMED CT Implementation: An Economic Assessment Model. Stud Health Technol Inform 2016;228:441–5. https://doi.org/10.3233/978-1-61499-678-1-441.
[29] BMG. Gemeinsam digital - Digitalisierungsstrategie für das Gesundheitswesen und die Pflege. https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/D/Digitalisierungsstrategie/BMG_Broschuere_Digitalisierungsstrategie_bf.pdf, 2023 (Accessed 14 March 2023)
[30] Molnár-Gábor F, Sellner J, Pagil S, Slokenberga S, Tzortzatou-Nanopoulou O, Nyström K. Harmonization after the GDPR? Divergences in the rules for genetic and health data sharing in four member states and ways to overcome them by EU measures: Insights from Germany, Greece, Latvia and Sweden. Sem Cancer Biol 2022;84:271–83. https://doi.org/10.1016/j.semcancer.2021.12.001.
[31] European Observatory on Health Systems and Policies. European support for improving health and care systems. https://eurohealthobservatory.who.int/publications/i/european-support-for-improving-health-and-care-systems, 2021 (Accessed 14 March 2023)
[32] European Parliament. Draft report on the proposal for a regulation of the European Parliament and of the Council on the European Health Data Space. https://www.europarl.europa.eu/doceo/document/CJ43-PR-742387_EN.pdf, 2023 (Accessed 14 March 2023)