STUDY

Requested by the ITRE committee

European Parliament

The European Health Data Space

Policy Department for Economic, Scientific and Quality of Life Policies
Directorate-General for Internal Policies
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PE 740.054 - December 2022

EN

The European Health Data Space

Abstract

This research paper provides an assessment of the legislative proposal for "The European Health Data Space", including linkages with other EU measures and with Member State rules and laws. It also includes recommendations on further steps needed in order to achieve, facilitate and improve health data sharing, exchange and re-use across the EU.

This document was provided by the Policy Department for Economic, Scientific and Quality of Life Policies at the request of the committee on Industry, Research and Energy (ITRE).

This document was prepared for the European Parliament's committee on Industry, Research and Energy (ITRE).

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Manuscript completed: October 2022
Date of publication: December 2022

This document is available on the internet at:
http://www.europarl.europa.eu/supporting-analyses

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For citation purposes, the publication should be referenced as: Marcus, J.S. et al., 2022, *The European Health Data Space*, Publication for the committee on Industry, Research and Energy (ITRE), Policy Department for Economic, Scientific and Quality of Life Policies, European Parliament, Luxembourg.

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LIST OF ABBREVIATIONS

AI	Artificial Intelligence
API	Application Programming Interface
CBHC	Cross-Border Healthcare Directive
CE	'Conformité Européenne' / European conformity
CEF	Connecting Europe Facility
Chafea	Consumers, Health, Agriculture and Food Executive Agency
DGA	Data Governance Act
EHDS	European Health Data Space
eHDSI	eHealth Digital Service Infrastructure
EHR	Electronic Health Record
EU	European Union
GATS	General Agreement on Trade in Services
FHIR	Fast Healthcare Interoperability Resources
GDP	Gross Domestic Product
GDPR	General Data Protection Regulation
GP	General Practitioner
HIPAA	Health Insurance Portability and Accountability Act
IA	Impact Assessment
MS	Member States
NHS	UK National Health Service
TFEU	Treaty on the Functioning of the European Union
US	United States
WTO	World Trade Organization

EXECUTIVE SUMMARY

Background

The European Commission published a legislative proposal on the "The European Health Data Space" (EHDS) on 3 May 2022. The EHDS proposal seeks to create positive momentum on a number of healthcare interoperability and patient empowerment concerns that have seen scant practical progress for years at European Union level.

The EU has always had a role in public health, but has been constrained by the fact that health is primarily a Member State competence. The EHDS reflects the confluence of several developments: (1) an increased focus on promoting public health at EU level as a result of the COVID-19 pandemic, (2) a recognition that the ability of patients to exercise their rights under the General Data Protection Regulation (GDPR) has been limited in practice in the health sector, (3) efforts to open up as much data as possible (not just health data) for commercial and non-commercial research and use, and (4) a recognition that previous purely voluntary programmes have proven to be ineffective in enabling patients to access and share their health data, and in addressing fragmentation and low interoperability of digital health at national and cross-border level.

Aim

The EHDS seeks to provide rules, common standards and practices, infrastructures and a governance framework for both primary use (using personal electronic health data to provide health services to an individual) and secondary use (using electronic health data for broader needs such as health research or public policy) of public health data. To that end, it (1) strengthens patient control over their data; (2) establishes rules for electronic health records (EHR) systems in order to promote reliability, security and interoperability; (3) establishes rules for secondary use of health data; and (4) establishes mandatory cross-border infrastructures, one for primary use and the other for secondary use.

Key Findings

- Aside from empowerment of natural persons, the economic justification of the proposed EHDS for primary use is largely based on (1) enabling natural persons to obtain better care by reducing information asymmetries between providers and users of health services, and thus facilitating informed choice, and (2) enabling health service providers to provide better care because the individual can grant them access to his or her electronic health data held by others;
- Primary use benefits of the proposed EHDS appear to exceed costs to an even greater degree than estimated by the Commission's Impact Assessment; however, cross-border usage is likely to play only a tiny role in achieving these benefits. Aside from direct economic benefits, patients are likely to benefit from greater transparency, reduction of information asymmetries, and ultimately better care;
- The economic benefits of aggregating data from multiple sources for secondary use (research and public health planning) are clear, notably including faster and more cost-effective development of new drugs and medical procedures, and achieving better public health decisions. Secondary use is also likely to reduce information asymmetries between medical service producers and health insurance providers, thus strengthening competition

between health care providers. That may in turn strengthen incentives to provide more patient-centric health services;

- The EHDS can be expected to have complex interactions with the Data Act, GDPR, DGA, and other current or anticipated EU laws. The EHDS legislative proposal already addresses some overlaps, but the risk of unintended overlaps and incoherence is nonetheless substantial;
- Laws and practices in some Member States already reflect in part the goals of the EHDS, but Member State laws for primary and secondary use of electronic health data vary enormously;
- Privacy for secondary use can be achieved through anonymisation. Decentralised data pools at national level might further contribute to privacy;
- The setting of fees for secondary use entails complex trade-offs. Fees alone cannot provide a sufficient incentive for data providers, so an outright mandate to provide data is unavoidable. Fees should instead enable providers to recover costs;
- The EHDS as proposed is well designed in most respects, but it may be too centralised, and may place too great a burden on the national Health Data Access Body; and
- EHDS defines permitted purposes for the use of secondary health data, but the list of permitted purposes and potential users is very broad, while the list of prohibited purposes may be too rigid.

Recommendations

- Amend the EHDS proposal to clarify the degree to which centralised versus decentralised infrastructure is permissible. A structure that permits full decentralisation, but also enables Member States that desire some degree of centralisation to implement it, appears to have merit;
- The authority and responsibilities of the health data access body should be carefully reviewed, with a particular focus on the proposed Articles 37 and 39 of the EHDS. It may be unnecessary or unproductive to assign too many different tasks to the health data access body. Broadening the scope of exemptions from the procedure required to obtain a data permit via the health data access body should also be considered;
- Expand the Recital 67 discussion of subsidiarity to better link domestic aspects of primary use to the prerogatives of the Union as expressed in the Treaties;
- Consider noting in the recitals the importance of motivating active Member State participation in EHDS by means of EU funding. Moreover, the Commission should be aware of a likely need for follow-up in order to ensure that Member States implement EHDS promptly and fully;
- To facilitate interoperability, the Commission should ensure that a single prominent European or international health data standard (such as the *Fast Healthcare Interoperability Resources* (FHIR)) is adopted at European level. The Commission should push for the standard that is selected to be used as widely as possible for all EHDS purposes in all Member States;
- Mitigate the risk of an implementation deficit by increasing incentives for health professionals to participate in data creation and sharing, and by identifying some large datasets of general interest for healthcare providers;

- Streamline the drafting of the permissible purposes and prohibitions associated with secondary use of health data in order to improve legal certainty. Review the list of prohibited secondary uses of electronic health data to see if all should really be prohibited. Review in particular the restrictions on secondary use of electronic health data by insurance companies, and the prohibition on secondary use of electronic health data for informative marketing campaigns;
- Clarify the meaning of trade secrets for health service providers when data is co-generated between patients and service providers; and
- Take care to ensure that the EHDS as enacted is consistent with other legislative measures, paying special attention to those being enacted in parallel with it.

1. INTRODUCTION

This analysis of "The European Health Data Space", a legislative proposal that the European Commission submitted on 3 May 2022 (COM(2022) 197 final), has been prepared by Bruegel AISBL with support from WIK-Consult GmbH pursuant to a request from the European Parliament's ITRE Committee.

1.1. Objectives and scope of the study

This analysis is intended to provide comprehensive issue-specific analyses, (1) including a critical assessment of key research and data published on the subject, (2) highlighting any strengths and weaknesses, and (3) outlining policy options or issues. By way of a concise summary, we have been called on to provide:

- An analysis of all interlinkages existing between the European Health Data Space (EHDS) regulatory proposal and other relevant European Union (EU) legislation;
- An analysis of the actions necessary to facilitate EU data sharing[1], exchange and re-use, including not only actions in the current legislative proposal, but also considering possible additional actions that might be required;
- An analysis of the likely impact of the proposed actions, and of any additional actions; and
- Recommendations for possible actions to facilitate and improve health data sharing, exchange and re-use across the EU, based on concrete findings (quantitative to the extent feasible) of this study.

1.2. Brief background on the European Health Data Space Regulation

At the sectoral level, the EHDS proposal is an outgrowth of several trends in the health sector that came together at roughly the same time. First, there was a recognition that efforts to foster cross-border health service were generating very little in the way of concrete results. Second, the COVID-19 pandemic brought home the potential value of the EU in terms of public health at EU level, which led in turn to a commitment from the Commission to create an EU Health Union. Third, it became increasingly clear that structural problems were making it difficult for individuals to enforce their rights under the General Data Protection Regulation (GDPR).

The Commission's "European Data Strategy" (2020) announced the creation of several sectoral data spaces with a view to create large data pools that could be used for research purposes. The Data Governance Act (Regulation (EU) 2022/868; DGA) provided legal infrastructure that could be used to create and manage data spaces at EU level. This created an opening to provide for a European Health Data Space.

The EHDS expresses its objectives as being "to empower natural persons through increased control of their personal health data and support their free movement by ensuring that health data follows them; to foster a genuine single market for digital health services and products; [and] to ensure a

[1] It is already often the case today that a second health provider can receive a snapshot of a patient's records, for instance when a doctor makes a referral to a specialist. This is, however, typically a one-time snapshot, not a continuously updated data repository that reflects the evolving status of the patient or his or her records over time. Practices vary greatly among the Member States, and limitations cross-border are widespread.

consistent and efficient framework for the reuse of natural persons' health data for research, innovation, policy-making and regulatory activities" (Recital 67 EHDS)[2].

1.3. Primary use versus secondary use

The EHDS defines primary use of health data as use to support or provide direct individual healthcare delivery to the data subject. Primary use is linked to personal data access and portability rights under the EU GDPR and, by extension, for patients' personal health data. Patients often encounter difficulties in exercising this right. The EHDS seeks to facilitate health data portability and reduce transaction costs associated with this. Secondary use is defined as the use of individual-level (personal or non-personal) health data, or aggregated datasets, for the purpose of supporting research, innovation, policy making, regulatory activities and other uses.

The distinction in the EHDS between primary and secondary use of health data is important because they refer to two distinct underlying economic mechanisms. The main economic justification for primary use of health data is related to economies of scope in re-use of data. Once a data holder has incurred the cost of collecting data, they can easily be re-used by other parties at very low marginal cost. This saves costs in the re-collection of data and represents an economic gain for individuals and for society. In the case of health data, portability facilitates data sharing between several service providers that intervene in often complex health care supply chains. Another justification is that data portability gives patients more choice in health care providers. It prevents lock-in to one provider and can potentially increase competition among health services providers.

The main economic justification for secondary use is based on efficiency gains from economies of scale and scope in aggregation of individual or segmented health datasets into larger datasets. The analysis of related data in aggregated sets usually yields more (accurate) insights compared to the separate analysis of fragmented datasets (Carballa-Smichowski et al., 2022). Economies of scale and scope are however subject to diminishing returns. When the dataset reaches a certain size or complexity, further extensions provide only marginal improvement in the insights that can be extracted. This characteristic enables researchers to extract medical insights from a smaller sample dataset that can be used for the treatment of patients outside that sample. The point at which diminishing returns set in depends on the complexity of the dataset and the diagnostics questions. For some diagnostics, relatively small datasets covering only (a portion of) a single Member State are sufficient; for others, very large multi-country datasets are required.

Another economic justification for secondary use is that it increases transparency in health services markets. Large datasets enable analysts to compare the efficiency of different types of treatments and treatment providers. More transparency on the supply side of the health services market, combined with primary portability, enables patients to make a more informed choice among health care providers based on the quality of their services. That improves health outcomes for patients.

These economic arguments are not fully developed in the EHDS proposal and related documents. The EHDS initiative is presented mainly as an extension and improvement of the EU GDPR. As Recital 11 of the legislative proposal notes, EHDS goes beyond Article 20 GDPR with respect to portability of personal health data. The empowerment of data subjects to effectively exercise their data portability rights could be considered as an objective in its own right. However, it can also be seen as an intermediate objective that gives individuals more choice in the selection of health service providers, reduces healthcare costs, speeds up diagnosis and treatment, and enables individuals to obtain better health outcomes.

[2] See also page 30 of the Impact Assessment.

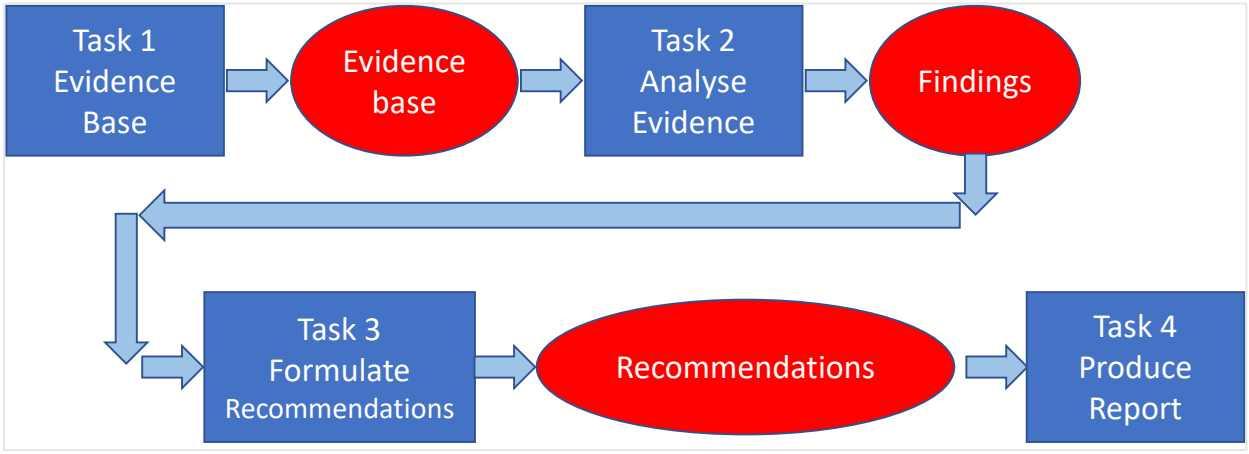
We do believe that the ultimate objective of all health policy initiatives should be to improve health outcomes and the welfare of patients. We therefore pay attention in this report to the economic transmission mechanisms through which the EHDS proposals may contribute to improved health outcomes.

1.4. Our methodology

We followed a straightforward sequence of tasks, as depicted in Figure 1:

- Task 1: the Evidence Base is constructed primarily on the basis of desk research and interviews;
- Task 2: the Evidence Base is analysed in order to generate Findings;
- Task 3: the Findings motivate a series of Recommendations; and
- Task 4: the Evidence, Findings and Recommendations are expressed in a report.

Figure 1. Notional diagram of the project plan.



Source: Authors' own elaboration.

1.5. Structure of this report

This Introduction constitutes Chapter 1. Chapter 2 provides legal and policy background on the EHDS, and the factors that led to this data policy initiative. Chapter 3 presents potential challenges with the proposed approach. We offer possible ways in which to address the potential challenges in Chapter 4. Finally, we very briefly recapitulate the Chapter 4 recommendations in Chapter 5.

2. THE EUROPEAN HEALTH DATA SPACE

KEY FINDINGS

- The EU has always had a role in public health, but the EHDS reflects the confluence of several developments: (1) an increased focus on promoting public health at EU level as a result of the COVID-19 pandemic, (2) a recognition that the ability of patients to exercise their rights under the GDPR was limited in practice in the health sector, (3) efforts to open up as much data as possible (not just health data) for commercial and non-commercial research and use, and (4) a recognition that previous programmes to promote cross-border health care in the EU had proven to be ineffective, largely due to their voluntary nature.
- The proposed EHDS addresses both primary use (associated with an individual) and secondary use (associated with broader needs such as public health research).
- Aside from empowerment of natural persons, the economic justifications of the proposed EHDS for primary use are largely based on (1) enabling natural persons to obtain better care by reducing information asymmetries between providers and users of health services, and thus facilitating informed choice, and (2) enabling health service providers to provide better care because the individual can grant them access to his or her electronic health data held by others.
- The economic benefits of aggregating data from multiple sources for research and for public health planning are clear.

In this chapter, we cover the motivations for the EHDS legislative proposal (Section 2.1), and follow with a brief summary of key legislative provisions (Section 2.2).

2.1. Motivations for the EHDS legislative proposal

The EU has always had a role in public health, but COVID-19 has created substantial additional political momentum for an EU Health Union. The need to be better prepared for future health crises, the benefits of information sharing and research at EU level during pandemics, and the success of cooperation in developing digital tools like the EU digital COVID certificate have paved the way for more integration at EU level in the field of health.

The European Health Data Space proposal is one of the initiatives that the Commission has put forward as part of the Health Union package adopted in November 2020. It is the outcome of the convergence of two major policy streams of the last decade: the data economy and eHealth. It can be read as a *lex specialis* and one of the first sectoral applications of the Data Governance Act (2022) that sets a data governance framework for data intermediaries that facilitate data exchanges and sharing between several parties. MyHealth@EU and HealthData@EU are key data intermediary platforms for the implementation of the EHDS. It has links with the Data Act[3] (adoption currently under way) that would promote sharing of personal and non-personal data generated during the use of digital devices and related services, including medical equipment and wellness devices. It also represents an extension of the exchange of patients' electronic health records launched by the 2011 Directive on patients' rights in cross-border healthcare (Directive 2011/24/EU, the CBHC Directive).

The legislation aims at supporting the digitalisation of data in the field of health and promoting their availability and access at the European level.

[3] As proposed by the Commission in document COM 2022/68.

It addresses the exchange of medical data between patients and their healthcare providers and among healthcare providers, the so-called primary use of data. Primary use is about health data portability and builds on the portability put in place by Article 20 GDPR[4]. It seeks to facilitate re-use of health data by consumers, portability between health service providers in support of second opinions, and increased competition between service providers.

The proposed EHDS Regulation also supports the aggregation of health data and other health-relevant data and making them available for research, policy making or other regulatory purposes, the so-called secondary use of data. Secondary use is about health data aggregation in larger national and EU-level data pools. That facilitates the extraction of new insights about health products, services and service providers' performance – insights that cannot be obtained from the analysis of fragmented datasets. It facilitates innovation in health services and creates more transparent services markets to stimulate competition.

The legal, institutional and technical challenges of primary and secondary uses of data are fundamentally different. Combining the two in a single piece of legislation is very ambitious.

Historically, the measures already in place confronted a number of challenges. Notable challenges to date have included:

- Uncertain demand on the part of patients for cross-border delivery of eHealth services;
- Impediments posed by the simultaneous need to maintain the privacy and confidentiality of sensitive health data;
- Insufficient incentives for Member States and institutions to participate in data-pooling arrangements;
- Lack of a strong mandate to proceed at EU level (subsidiarity); and
- The risk of problematic interactions with other EU and national legal instruments.

In the remainder of this sub-section, we reflect on these issues.

For the primary use of data, the draft regulation calls on Member States to develop electronic health records services at national level and to allow exchange of patients' data through the European Platform, MyHealth@EU. This represents a change of gear compared to the current practices: 23 Member States have such systems in place, but with limited functionality, and six of them report a low use of the system. In spite of EU funding being available for the participation in MyHealth@EU since 2014, only 10 countries participate in the cross-border exchange of patients' records, and MyHealth@EU is not yet operational for all categories of data defined in the legislation. In previous work for the Parliament (van Veenstra et al., 2013), we had identified cross-border eHealth as a promising opportunity for the EU, noting however that years of research had been very slow to translate into actual benefits. Yet the results today, many years later, call into question whether there would be much take-up of cross-border eHealth by patients even if it were fully and efficiently deployed. To what extent is the take-up in cross-border health services hindered by incomplete infrastructure that creates obstacles for cross-border portability, versus by weak consumer demand for cross-border health services?

[4] Under Article 20 GDPR, the data subject "… shall have the right to receive the personal data concerning him or her, which he or she has provided to a controller, in a structured, commonly used and machine-readable format and have the right to transmit those data to another controller without hindrance from the controller to which the personal data have been provided …" The right to data portability is in principle already in place, but the GDPR does not clarify how to apply it to health data.

In seeking to promote a global trading system for services, the General Agreement on Trade in Services (GATS) of the World Trade Organization (WTO) has specified four distinct modes of cross-border trade[5]. Any of these four modes could be relevant to a particular instance of the cross-border delivery of health services, depending on the territorial presence of the service supplier and the consumer (patient) at the time of the transaction.

- In Mode 1 (cross-border trade), a health service provider located in one country delivers a health service to a consumer located in another country. For example, a consumer transfers MRI/CT scan images to a doctor in another country who then sends his analysis back to the consumer;
- In Mode 2 (consumption abroad), a consumer goes from one country to another to receive a health service. For example, a consumer travels to a medical doctor in another country, with his EHR, to get a medical diagnosis;
- In Mode 3, a health service provider opens a health service delivery facility in another country. For example, a consumer goes to a foreign health care provider who has opened a care delivery centre in the consumer's country of residence. Primary portability and EHR system compatibility ensures that the foreign care provider has full access to a patient's health data; and
- In Mode 4, a medical service provider moves (as a natural person) from one country to another in order to deliver the service locally. For example, a medical doctor from one country from time to time delivers health services in another country. Again, the doctor should have prior cross-border access to the patient's health data before he travels to another country.

All four modes can benefit from cross-border primary data portability. Health data portability can be a substitute for physical movements of patients or health care providers, unless physical examination of the patient is required. In practice, most cross-border health transactions in the EU are linked to travel abroad for tourism or work purposes (De Wispelaere et al., 2019). This falls under Mode 2. However, the EHDS could also facilitate Mode 1 health services transactions. Digital health data can be transmitted irrespective of borders and distance. Mode 3 and 4 type transactions are not directly linked to digital data.

Health data portability can serve as an enabler for telemedicine[6], which can substitute for physical movements of patients or health care providers when physical examination of the patient is not required.

By making the cross-border exchange of electronic patients' records mandatory, the draft legislation is expected to generate a critical mass of data at EU level, which would be of adequate quality and could be integrated and reused for policy making, research and regulatory purpose at EU level. The specifics of health data, in particular their sensitivity, make it necessary to adjust the general provisions of the GDPR, the Data Act and the Data Governance Act to create European health data spaces. The draft proposal would allow medical research, life sciences and regulation in areas such as pharmaceuticals or medical devices to fully benefit from big data and artificial intelligence

[5] See https://www.wto.org/english/tratop_e/serv_e/cbt_course_e/c1s3p1_e.htm.

[6] Telemedicine or telehealth could be defined as a mode of service delivery whereby the patient and the care provider remain in different locations. Neither moves physically to the location of the other. With telemedecine, all forms of health services that involve the exchange and examination of digital information can be accomplished through distance services, with the exception of those that require the physical presence of the patient.

opportunities and would help the EU to remain a leading region in the medical field, with ultimate benefits for the patients and for the EU economy.

The justification for primary use in the EHDS legislative proposal is presented as a means of making the GDPR effective for health data (Explanatory Memorandum, Section 1). Since personal data protection as defined in the GDPR is a fundamental right, not an economic issue, this justification is not directly invoking any economic justifications. The rationale revolves around the problems that natural persons face in the exercise of their fundamental rights under the GDPR to access and port their personal health data between health service providers at national level, and cross-border, mainly due to uneven application of the GDPR to health data in the Member States (see Hansen et al., 2021). The causes are attributed to regulatory divergence in the implementation of voluntary measures in the relevant directives. In addition to the challenges that patients face in accessing and transferring their electronic health data, substantial variations in the technical data architecture of health data systems between health service providers result in a lack of interoperability within and between Member States. As a consequence, primary and secondary use of health data remains very limited in the current situation. The problem definition presented in the problem tree in the Impact Assessment (IA) (part 1) (European Commission, 2022c) that accompanies the EHDS proposal goes further however and is largely based on economic arguments. It starts from the same observation of regulatory and technical problems that persons face in accessing their health data, but translates this into malfunctioning health services markets. High access costs result in data lock-in and obstacles in accessing alternative medical service providers, in additional costs and waiting times for unnecessary repeated tests, in limited competition between service providers and reduced overall competitiveness, and in limited access to innovative medical services for patients and limited access to relevant data for health policy makers. In other words, combining the reasoning in the Explanatory Memorandum and in the IA leads to the conclusion that weaknesses in the exercise of fundamental rights with respect to health data have a negative impact on the functioning of health services markets and therefore on the welfare of patients as data rights holders. By implication, facilitating the exercise of fundamental personal health data access rights, as proposed by the EHDS, is likely to induce positive economic welfare effects for individuals and for society at large.

This reasoning in the EHDS, and in particular in the IA, can easily be translated in the regulatory intervention terminology of the Commission's own Better Regulation Guidelines and Toolbox[7]. The Toolbox (European Commission, 2021, pp 91-94) explains that regulatory interventions in services markets may be justified by market failures and/or regulatory failures. This market failure logic can easily be reconstructed in three steps:

First, the main economic justification for facilitating primary use of individual health data is the prevalence of information asymmetry among health service providers, and between providers and consumers. In short, there is a lack of transparency in the market for medical services. Health care is a prominent example of incomplete and dispersed information that prevents efficient decision making by several service providers who intervene in the health supply chain. A patient's health care is often delivered by multiple physicians, each having only a partial view of the patient's medical history. If Electronic Health Record (EHR) systems are incompatible, it can be costly to share information across institutional boundaries. Primary use is not an end in itself; it is a means of enabling patients to look for better services and improve their health outcomes, and also a means of enabling health care providers to deliver better and more informed care. In many cases, it is difficult for patients to assess the quality of the services provided by hospitals and individual service providers. Rankings of complex services can be challenging for a patient to interpret. Patients are

[7] European Commission (2021), Better Regulation Guidelines and Toolbox. Available at: https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how/better-regulation-guidelines-and-toolbox_en.

locked in to their provider and cannot easily obtain a second opinion because patient data are not easy to access and port in compatible electronic formats to other service providers. Fragmentation in EHR systems in hospitals and other medical practices reinforce that lock-in[8]. As a result, there is insufficient competition in medical services markets and patients cannot easily relocate to higher quality services. That reduces health outcomes for patients. The health sector is characterised by substantial regulatory intervention in the price, quantity and quality of medical services and products, usually based on equity concerns to ensure affordability and access to health services for all. These regulated input markets make it all the more important for patients to assess and compare the quality of services and health outcomes.

Second, the main justification for secondary use of collective or aggregated health data is the presence of data-driven externalities between patients. The clinical research insights obtained from diagnostics and treatments for one set of patients may be useful for the clinical treatment of other patients. This became very evident during the COVID-19 pandemic when information obtained from tracing infected patients was very useful to design policy measures to contain further spread of the virus. Similar situations occur for most diseases. Medical researchers can extract useful insights regarding diagnostics of pathologies and finding more effective treatment methods from observing samples of patients. These insights can then be applied to much larger groups of patients. Making more and larger samples of data available to researchers accelerates innovation in health sciences and improves health outcomes for patients.

Third, the benefits of primary and secondary use of health data do not emerge spontaneously, or at least not on a sufficient scale, because of incentive alignment problems in health care. As data holders, healthcare providers do not have sufficient incentives to incur costs to adapt their data storage systems and make them interoperable to facilitate access by other parties. The data holder incurs costs while other parties benefit from the spill-overs. It is difficult for the data holder to re-internalise these benefits, for instance by means of a payment or some other form of compensation for the use of data. Consequently, there is underinvestment in interoperable EHR. That, in turn, creates an obstacle to primary and secondary use of health data[9].

As a result of this incentive misalignment, health data exchange markets are largely missing or at least insufficient when relying purely on voluntary initiatives of health service providers. Besides the lack of technical interoperability between EHR systems in hospitals and medical practices, regulatory data access and exchange obstacles may also create obstacles to primary and secondary data use, within and between countries. These data market failures can be resolved through regulatory intervention that by-passes voluntary market mechanisms and mandates all actions required to facilitate primary and secondary use of health data. This is what the EHDS is about. It replaces some earlier voluntary health data initiatives and EU directives that provided greater discretion to Member States regarding implementation modalities, with a set of binding regulatory proposals.

Primary and secondary use are relevant inside a country as well as cross-border. The justification of primary data use within a country is obvious. It enables patients to look for alternative health service providers and brings more transparency and competition in health services markets. Cross-border primary use may be less obvious. The percentage of cross-border health transactions in the EU is currently very low – the Impact Assessment (page 20) makes a very rough estimate that cross-border expenditures represented just EUR 92.1 million out of total expenditures of EUR 882 billion for

[8] For a detailed study of the implications of fragmented EHR systems in the health sector, see for example Competition Bureau Canada (2022) Unlocking the power of health data, digital health care market study, part 1.

[9] In economic jargon, this incentive misalignment can also be summarised under the label of private provision of public goods. There is an extensive research literature on market failures in the private provision of public goods. Private provision of public goods may happen when individuals have a preference for altruism and when they perceive a fair distribution of benefits.

countries that could provide data for 2019 (see also Section 4.3), albeit with a real but uncertain potential to grow over time. Apart from obstacles to cross-border data transfers, there are other obstacles to cross-border health services transactions, including language, transport costs, differences in the organisation of health care systems, and differences in health insurance systems. The EHDS IA claims (page 20) a natural growth rate of 300% in cross-border foreign prescriptions presented to EU pharmacists over the period 2012-2021 as justification, but this is from a very low base. Primary data portability improvements may indeed boost cross-border transactions, especially for cross-border workers, but probably less than in domestic health markets because of the above-mentioned other obstacles. There is a stronger justification for cross-border secondary use of health data, especially for rare diseases where large datasets are usually missing at national level, and to facilitate the creation of cross-border medical research teams and enable specialised researchers in one country to access health data in another country.

At the same time, the potential growth of telemedicine is not fully reflected in current EU data. Comparisons with the United States (US) before and after the COVID-19 pandemic hint at a possibly greater upside potential, which, however, might not be realistically achievable in the EU. Interstate eHealth in the US was also rare before the pandemic due to a combination of legal, regulatory, technological and practical impediments; however, health authorities opened the spigot wide on interstate telemedicine during the COVID-19 pandemic. Per a recent report (Harris et al., 2021), "Based on early evidence, provider licensure flexibilities played a role in helping people access health care services via telehealth during the pandemic. In general, telehealth was an important tool for keeping access to care available, with nearly half (43.5%) of Medicare primary care visits provided via telehealth in April 2020, compared with less than 1% before the pandemic. The Johns Hopkins health system in Baltimore, Maryland, estimated that about 10% of its 330,000 patients who accessed telehealth during the pandemic were from out-of-state".

There are limits, however, to the applicability of comparison to the United States. Experience in Europe strongly suggests that differences in language and in payment systems (such as health insurance) are important barriers to cross-border trade. The United States has a common language, and many of the payment systems are nationally consistent. In Europe, cross-border trade of all kinds between countries that share a common language (such as Germany and Austria; the UK and Ireland; and Belgium and France) is usually much higher than trade among countries with different primary languages[10]. The strong growth that Johns Hopkins observed in interstate consultations is presumably the result of the absence of language and payment/insurance barriers between states, and a reduction in geographical transport costs to zero as a result of telemedicine, together with the excellent reputation of Johns Hopkins.

Another finding from cross-border online trade is that size of local markets matters. Consumers in small countries tend to shop abroad more than those in large countries, mainly because the variety and quality of services available in small countries is smaller. The role of country size is a general finding in the trade literature[11]. Given that EU Member States are smaller than the United States (in some cases, much smaller), this factor might slightly offset the limitations imposed by language and payment system differences, but the balance among these factors is not clear.

[10] See for example Maciejewski, M., and Wach, K. (2019). What determines export structure in the EU countries? The use of gravity model in international trade based on the panel data for the years 1995-2015. *Journal of International Studies*, 12(1), pp 151-167.

[11] Op.cit.

2.2. Main elements of the proposed EHDS Regulation

The European Health Data Space regulation aims to create a single market for health data. In other words, it would set up a common European space for sharing health data. This would be the first space in line with the Commission's 2020 vision to create a single market for data to generate economic and social values on top of data (European Commission, 2020). In this context, the proposed regulation would unlock the use of health data for primary and secondary use of data. It would build on existing and future European regulations to promote health data-sharing in Europe. In particular, the regulation builds upon the GDPR data portability right that allows individuals to transfer their own personal data from one provider to another. However, the GDPR right is ineffective for sharing health data for two main reasons. First, it restricts sharing of valuable health data inferred by a physician or a machine (so-called "inferred data"), such as diagnosis. Second, it does not mandate that providers can seamlessly read data thanks to a common format (so-called "interoperability"). As a result, users can, in practice, merely access their health data without the ability to use them effectively. Against this backdrop, the EHDS proposes an extension of the GDPR data portability right by allowing individuals to transfer in an interoperable format their health data, including inferred data (EHDS Recital 12 and Article 3). Individuals could then effectively share their health data with a third party of their choice and at their request. In particular, they will be able to access and share the system that stores digital health data (so-called "electronic health record (EHR)" anywhere in Europe. This reduces healthcare costs, increases innovation in the health sector, and helps decision-makers make health-related decisions, such as in the context of a cross-border health crisis. To achieve these benefits, the regulation imposes several requirements related to security, privacy, and governance for using health data for primary and secondary use of data. Security and privacy requirements aim to preserve the fundamental rights of individuals due to the sensitive nature of health data and the risk of data misuse. Governance requirements aim to ensure that health data can freely flow in Europe without hindrance but with some purpose limitations to prevent risks of abuse by data users. However, primary and secondary use of data does not raise the same issues. The proposed regulation would thus set different requirements for each use.

2.2.1. Primary use

The primary use of health data aims to support healthcare delivery, namely the provision of health care by physicians. In Europe, the 2011 directive on the application of patients' rights in cross-border healthcare (the CBHC Directive) established a voluntary eHealth Network to ensure the cross-border exchange of health data. However, the proposed EHDS regulation outlined that the CBHC Directive is ineffective and inefficient due to its voluntary nature. The platform MyHealth@EU for cross-border healthcare enables the exchange of electronic prescriptions (so-called "ePrescriptions") and patient summaries in only 10 Member States. Even for these services, the platform has a very limited impact on cross-border health data exchange. The Impact Assessment (page 21) highlighted that in the last three years, only 21,000 cross-border ePrescriptions were dispensed, and only 300 cross-border exchanges of patient summaries were made. This lack of effectiveness is even more salient considering that the target number was 8 million cross-border ePrescriptions. The reasons are twofold. First, the directive does not mandate that Member States receive their medical records in electronic format. Some Member States still allow medical records in paper format, thus preventing the ability to exchange records cross-border in another language seamlessly. Second, the CBHC Directive only recommends but does not mandate using a standard for exchanging EHR to ensure interoperability, with the result that not all Member States adopted the standard, which led to inability in practice to exchange data among the Member States.

The EHDS aims to fill these gaps. First, it would create pressure for medical records to be in electronic format. Second, it would enable individuals to access and share their health data from the health or social security sector to another in an interoperable format and free of charge. In other words, it would complement the GDPR data portability right by extending it to inferred data and mandating interoperability. It would also reinforce other GDPR rights, including the GDPR rectification right that allows individuals to modify their data. However, not all health data would be available for the primary use of data. The Regulation would establish six priority categories of primary use data, including patient summaries, ePrescriptions, electronic dispensations, medical images, medical reports, laboratory results, and discharge reports, which are subject to amendment through delegated acts by the Commission (Article 5 EHDS). It would also allow and facilitate cross-border use of telemedicine. Implementing and enforcing the application of these rights would be the responsibility of each Member State's data protection authority and digital health authority, where individuals and businesses would be able to lodge complaints.

In addition, MyHealth@EU would be the infrastructure in charge of facilitating the cross-border exchange of health data between national contact points. Participation in MyHealth@EU, currently optional for Member States, would become compulsory. Finally, it would harmonise EHR systems within the EU through a mandatory self-certification scheme and voluntary labelling of wellness applications interoperable with EHR systems, registered in a common EU database. A market surveillance authority would be in charge of enforcing this obligation.

2.2.2. Secondary use

The secondary use of health data aims to support health research, innovation, policymaking, regulatory and personalised medicine. The eHealth Network enables to set some specifications regarding the secondary use of data. However, the Explanatory Memorandum to the proposed Regulation outlined (page 9) that the network is ineffective with a very limited impact due to the non-binding nature of the recommendations. Moreover, other actions, including different bodies and funding, have not been implemented with the eHealth Network.

The EHDS aims to promote the secondary use of health data. First, Member States would determine which data holders from public and private entities in the health or care sectors (with the exception of micro-enterprises) would be obliged to make fifteen categories of data available, even when protected by intellectual property rights and trade secrets (Article 33(4) EHDS)[12], including EHR and genetic data. The Commission is empowered (Article 33(7) EHDS) to adopt delegated acts (following the procedure in Article 67 EHDS) to amend the list of fifteen categories "to adapt it to the evolution of available electronic health data". In addition, health data access bodies might provide access to further data that they hold thanks to voluntary cooperation with data holders or a national law provision (Article 33(8) EHDS).

Second, the EHDS would impose purpose limitations with a list of authorised and unauthorised data processing due to the sensitive nature of health data. It would allow processing for health research, innovation, policymaking, regulatory, and personalised medicine purposes. But it would prohibit secondary users from making detrimental decisions, including with regard to insurance premiums, advertising or marketing activities, unauthorised access to third parties, and the development of harmful products or services. Each Member State will have to establish a health data access body which would be responsible for tasks related to secondary use, including granting a data permit to

[12] Per Article 33(4) EHDS, "Where such data is made available for secondary use, all measures necessary to preserve the confidentiality of IP rights and trade secrets shall be taken."

a natural or legal person for accessing data only for the purpose requested in an anonymised or pseudonymised format. It would have to inform the public on the secondary use of data through an easily searchable database containing several information elements, including the legal basis and the GDPR rights, and issue an annual activity report. Data holders and data altruism organisations would have to respect certain obligations related to data access and security to provide data through a secure processing environment. Health data access bodies and data holders could charge data users for making data available for secondary use. The EHDS proposal sets no restrictions on the entities allowed to request secondary data: any legal or natural person can launch a request. The only obligation for the data users is to publish the outcome of the research based on the data used not later than 18 months after data access was granted. However, a data permit is unnecessary when the data user is a public sector body requesting access to support its tasks as enshrined in its mandate. Moreover, when a data user requests access to a single data holder in a Member State, it could apply directly to the data holder (Article 49 EHDS). Furthermore, the EHDS would allow cross-border data exchange for secondary use in Europe through the infrastructure HealthData@EU and a single data permit.

Finally, the EHDS would also enable sharing of non-personal health data with non-EU countries under certain conditions. It would create (Article 64 EHDS) a European Health Data Space Board (EHDS Board) to facilitate cooperation between digital health authorities in charge of the primary use of data and health data access bodies in charge of the secondary use of data. The Commission would be able to adopt delegated acts to ensure the proper implementation of the Regulation, from the deliverability of its economic and social benefits to the interoperability of electronic health data to technical requirements for data altruism purposes in the health sector.

3. POTENTIAL CHALLENGES WITH THE APPROACH TAKEN

KEY FINDINGS

- EU approaches to health data have struggled due to several key limitations:
- Uncertain demand for cross-border delivery of eHealth services;
- Impediments posed by the simultaneous need to maintain the privacy and confidentiality of sensitive health data;
- Insufficient incentives for Member States and institutions to participate in data-pooling arrangements;
- Lack of a strong mandate to proceed at EU level (subsidiarity);
- The risk of problematic interactions with other EU and national legal instruments;
- The Directive on the application of patients' rights in cross-border healthcare (CBHC Directive 2011/24/EU) facilitates cross-border data sharing, but has had limited effect because it is purely voluntary;
- The EHDS can be expected to have complex interactions with the Data Act, GDPR, DGA, and other current or anticipated EU laws. The EHDS legislative proposal already addresses some overlaps, but the risk of unintended overlaps and incoherence is nonetheless substantial;
- Laws and practices in some Member States already reflect in part the goals of the EHDS, but Member State laws for primary and secondary use of electronic health data vary enormously. Member State practices are also shaped by professional rules and insurer practices. Most Member States in our sample allow for secondary use;
- Aside from empowerment of natural persons, the economic justification of the proposed EHDS for primary use is largely based on (1) enabling natural persons to obtain better care by reducing information asymmetries between providers and users and health services, and thus facilitating informed choice, and (2) enabling health service providers to provide better care because the individual can grant them access to his or her electronic health data held by others;
- Primary use benefits of the proposed EHDS appear to exceed costs to an even greater degree than estimated by the Commission's Impact Assessment; however, cross-border usage is likely to play only a tiny role in achieving these benefits. Aside from direct economic benefits, patients are likely to benefit from greater transparency, reduction of information asymmetries, and ultimately better care;
- The economic benefits of aggregating data from multiple sources for secondary use (research and public health planning) are clear, notably including faster and more cost-effective development of new drugs and medical procedures, and achieving better public health decisions. Secondary use is also likely to reduce information asymmetries between medical service producers and health insurance providers, thus strengthening competition between health care providers. That may in turn strengthen incentives to provide more patient-centric health services;
- Privacy for secondary use can be achieved through anonymisation. Decentralised data pools at national level might further contribute to privacy; and
- The setting of fees for secondary use entails complex trade-offs. Fees alone cannot provide a sufficient incentive for data providers, so an outright mandate to provide data is unavoidable. Fees should instead enable providers to recover costs.

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- Uncertain demand on the part of patients for cross-border delivery of eHealth services;
- Impediments posed by the simultaneous need to maintain the privacy and confidentiality of sensitive health data;
- Insufficient incentives for Member States and institutions to participate in data-pooling arrangements;
- Lack of a strong mandate to proceed at EU level (subsidiarity); and
- The risk of problematic interactions with other EU and national legal instruments.

These limitations manifest differently for primary use versus secondary use, and they have different implications for the degree to which the proposed EHDS Regulation can be expected to be effective, efficient, coherent, and adding European value.

The health sector is characterised by extensive price, quantity and quality regulations for health services and products in all EU Member States. In the wake of rapid digitalisation of health services, many Member States have also introduced a layer of health data regulation on top of product and services regulations. The EHDS complements these developments with data regulation at the EU level.

The EHDS would work in tandem with various European and national data-related policies. In this context, there is a risk of increased enforcement costs for both regulators and businesses resulting from compliance and transaction costs for businesses to comply with multiple health data-related policies and associated administrative costs of various regulators. There is also a risk of inconsistent outcomes due to conflicting rulings (see Sections 3.1 and 3.2).

GDPR data portability rights are limited to primary or raw data, i.e. personal data contributed by the data subject and data on the observed behaviour of the data subject. The EHDS extends these portability rights to processed or inferred data. Portability rights are subject to the user's request and should be in an interoperable format. Inferred data requires investment in data collection. However, the collection of such inferred data will not deter the incentive to collect data because patients (or their insurance companies) have in general already paid for the original compilation of inferred health data through payments for lab analysis, medical imaging and other diagnostic services. If there are incremental costs, they will be associated with making the data portable and interoperable, and most of those costs will be one-time rather than recurring. Consequently, there is little risk of free-riding by third-party data users.

There is possible tension in the interaction between EDHS data portability rights and other data portability rights, including those in the GDPR and in the Data Act, but the EHDS legislation proposal already seeks to address them. Notably, Article 38(6) EHDS takes precedence over the provision in the Data Act that allows data holders to charge for the transfer of primary product data to third parties. The EHDS includes payment provisions only for secondary data use, not for primary use. Under the Data Act, a hospital could charge for the transfer of medical image data to a third-party; under the EHDS, it cannot. The GDPR requires portability only of raw primary data, not of inferred or processed data; under the EHDS, however, processed data is also to be portable. The EHDS thus enables transfers of patients' medical data, including for example scanning data, irrespective of the degree of processing involved.

Both primary and secondary use bring distributional issues to forefront. To what extent do health service providers, innovation producers and consumers benefit from data re-use? How does price regulation in health services affect these distributional effects? While consumer access to primary health data is in principle free of charge, the EHDS introduces some data pricing rules for access to

secondary use data, as well as some restrictions on user access to data. Compilation of health data pools for secondary use is carried out and facilitated by a third party intermediary that incurs costs. It is to be expected that these costs should be recovered somehow from users. It is not clear however if any of these payments will flow to patients or health care providers – most likely, different Member States will develop different arrangements. The Commission has also budgeted some of the cost for secondary use infrastructure at EU level. It is not clear however how these rules will affect health outcomes.

The EHDS Regulation remains somewhat ambiguous with respect to the degree of centralisation or decentralisation of the data infrastructure to ensure cross-border portability and data aggregation. Article 52(9) EHDS says that the Commission shall operate a core platform for HealthData@EU by providing information technology services needed to facilitate the connection between health data access bodies as part of the cross-border infrastructure for the secondary use of electronic health data. A centralised infrastructure raises questions about the relative cost to build the infrastructure in comparison with a decentralised infrastructure. In sub-section a of Section 3.3.2, we explore alternative decentralised data server systems that might offer enhanced security and data protection without reducing the benefits of data pooling.

3.1. Interactions with other EU legislation

The EHDS builds upon several existing and forthcoming EU policies. Indeed, European legislations already offer a framework for the cross-border exchange of health data for primary use, data-sharing of personal and non-personal data, data protection, security, governance, medical devices, digital identity, and the processing of data in artificial intelligence (AI) systems. The proposed regulation would rely on and complement them.

European law already enables the cross-border exchange of health data for primary use. The 2011 *Cross-Border Healthcare Directive (CBHC Directive)* promotes the cross-border exchange of some health data by recommending interoperability of electronic health data, developing guidelines, and establishing an eHealth Network and a cross-border infrastructure. However, the voluntary nature led to the Network's ineffectiveness and inefficiency due to the Member States' low participation. The EHDS would fill some gaps in the directive by mandating participation in MyHealth@EU, imposing minimum harmonisation of national EHR and interoperability requirements for electronic health data.

European policymakers want to promote data-sharing in Europe. In the last two years, they proposed two major regulations to ensure a single market for data. First, the *Data Governance Act* adopted in 2022 provides a data governance framework for data intermediaries and the use of data for altruistic purposes. It also enables the re-use of some public data protected by the rights of others, including personal data. It seeks to establish data spaces at the EU level, of which the EHDS would be the first. The EHDS Regulation would provide additional requirements for using health data (including public health data) for altruistic purposes.

Second, the *Data Act* would mandate data-sharing of personal and non-personal data generated by digital devices and related services. This includes medical equipment and wellness devices. Moreover, the Data Act would enable the public sector to access data in case of exceptional needs, such as an emergency situation. Individuals could access and share their data with others at their request. The Data Act would also impose some data quality and interoperability requirements. The EHDS would complement the Act by introducing some specifications for sharing electronic data, such as the absence of compensation for sharing data for primary use.

Europe has a robust data protection framework. The 2016 *General Data Protection Regulation (GDPR)* safeguards personal data by imposing substantial requirements for collecting and using personal data and granting individuals various rights. In particular, the GDPR empowers individuals to access and share the personal data they generate (so-called "volunteered data") or that the provider observes from their behaviour (so-called "observed data"). The GDPR mandates interoperability only to the extent that it is technically feasible.

The GDPR imposes some limitations on sharing health data across borders. First, it does not enable the sharing of data that the provider enriches (so-called "inferred data"), thus depriving individuals of the possibility of sharing certain valuable data such as the diagnosis. Second, it does not oblige providers to share data in an interoperable format, thus depriving providers of the ability to read the health data of others. In other words, the GDPR data portability right is merely an access right to some data without the possibility to re-use and derive valuable insights on top of the data. The EHDS would reinforce this right by mandating data-sharing of all types of health data, including inferred data, in an interoperable format for primary use. Beyond this, the GDPR also provides specific requirements for processing health data, which the EHDS would have to rely on to process data.

In addition to data protection, the European Union also has a strong security framework. The 2020 revision of the *Security of Network and Information System Directive* (NIS2) would impose further cybersecurity obligations. The EHDS would impose specific security requirements for health data-sharing for primary and secondary use. The upcoming *Cyber Resilience Act* would impose cybersecurity requirements for digital products and ancillary services. The EHDS would also impose further specific security requirements.

Sectorial regulations offer some specific rules for medical devices. The 2017 *Medical Devices Regulation* imposes obligations for medical devices. The EHDS would impose additional requirements when the software interoperates with EHR systems. Complementary to this, the 2017 *In Vitro Diagnostic Medical Devices Regulation* imposes obligations for in vitro medical devices. The EHDS would support the development of in vitro diagnostic medical devices.

European policymakers also want to promote digital identity. The 2021 *Digital Identity framework* would impose obligations to use digital identity means, including electronic ID cards and digital identity wallets, to enable people and businesses to access online and offline public and private services across borders. The goal is to ensure that at least 80% of citizens use digital identity by 2030. The EHDS would build upon this framework to share health data without providing further specifications on how it will work in practice.

Finally, Europe wants to be the first continent in the world to regulate the use of AI systems. The 2021 *Artificial Intelligence Act* would impose requirements for high-risk AI systems, including in the health sector. The EHDS would impose additional requirements when high-risk AI systems interoperate with EHR systems.

3.2. Interactions with Member State legislation

Each Member State has its own national healthcare policy and organisation model of healthcare services. Moreover, each Member State has defined its own model for developing and using health data[13]. These differences can have strong implications for collecting and using health data for primary and secondary use in a cross-border context.

3.2.1. Primary use

For primary use, rules stemming from professional and ethical codes for health professionals and the rules set by health insurance, like referrals, play a key role in defining the scope of health data and their sharing between health professionals. Moreover, nearly all Member States have developed or updated specific legislation for use of health data and access to it in the last five years. They define compulsory medical records but do not necessarily require these records to be electronic.

In order to assess these interactions, we conducted desk research on current arrangements in eight diverse Member States (Belgium, Denmark, Germany, Estonia, Spain, the Netherlands, Portugal, and Finland). We selected these Member States to reflect geographic balance, to consider both large and small Member States, and to include some states that are known to have well developed EHR arrangements already in place (see Box 1). Our assessment on this basis shows that only five of these eight countries (Belgium, Denmark, Germany, Portugal, and Estonia[14]) mandate medical records in electronic format. The requirement enables those countries to achieve a high level of use of digital health data. More than 75% of the 27 EU Member States have EHR systems (either centralised, regional, or designed for specific health sectors) that connect to a large spectrum of healthcare service providers (GPs, hospitals, specialists, pharmacies, and labs). However, the impact assessment shows that these systems are routinely used only in about half of the countries. The most intensive users of EHR among the eight Member States that we reviewed are Estonia, Finland, and Denmark (see Box 1).

[13] An overview of national legislation and institutions is available in the studies underpinning the Impact Assessment. The current section draws mainly on the data and facts collected in that framework, as expressed in Empirica and Open Evidence (2020), European Commission (2020b) and Chafea (2021).

[14] So far as we can determine, there is not an explicit legal mandate in Estonia to provide all health data in electronic format; in practice, however, all Estonian citizens are covered by EHRs, and the scope of the relevant legislation covers "all medical service providers and related sectors (pharmacy, laboratories, etc.), and all public authorities and institutions". See Rannala, R. (2007), "An Electronic Health Record for every citizen: a global first. Estonia", Brussels, p. 11.

Box 1: Examples of well-developed EHR systems.

Estonia has a centralised national system, the Health Information System (HIS). It contains records relating to health care, including contracts for the provision of health services, health statistics and the management of health care. Healthcare service providers must record data on health care provided to patients on this platform and can use the platform to have access to patients' data. Patients have access to their personal data held on HIS.

Denmark has developed a national portal for EHR managed by the Danish Health Data Authority (Sundhedsdatastyrelsen). Sundhed.dk is the access point to electronic health records for patients and health professionals for clinical purposes for secondary care. It also gives access to the EHR of municipalities that manage primary care, which health professionals and patients can access directly. Denmark has also established multiple applications to allow communication between patients and their GPs, or to facilitate the monitoring of chronic illnesses.

Finland has a central system (KanTa) which collects EHR from municipalities for primary care and other healthcare providers for secondary care (hospitals and special care). Patients have access to services such as electronic prescriptions, records related to treatment, and laboratory results. Unlike Denmark, where the central platform is a portal that does not store data, this system is a national archive of decentralised health records.

A few illustrative examples can serve to demonstrate that Member State EHDS plans for patient rights, security and confidentiality provisions, as well as interoperability obligations, will require substantial changes in national legislation on electronic health data. In most Member States, the systems are not accessible to all types of health care providers, or their use is not anchored in professional practice. In Belgium, for instance, only 26% of licensed physicians and 40% of dentists provided health data in electronic format in May 2019 (Gerkens et al., 2020). The level is likely to increase in the next few years because Belgium mandated the use of the electronic format in 2020. Overall, there is great heterogeneity in the maturity of the primary use of EHR throughout the EU. The adoption of EHDS might provide the right policy incentives for laggards to speed up the development and use of EHR systems.

Most EU national laws facilitate access to individuals' health data via EHR (25 countries). However, not all of the Member States allow full control of where, how (20 countries), and with whom (16 countries) to provide access to their data. For instance, not all Member States allow patients to add to or correct data, or to decide which health care providers can access the data, as would be required under Article 3 of the EHDS proposal. Professional rules also define the ethical framework for confidentiality, as well as rules for patient safety, professional secrecy and medical liability, which might limit the possibilities of sharing data for primary or secondary purposes. Against this background, the EHDS has opted to focus on a harmonised format for health data applications such as patients' summary data.

3.2.2. Secondary use

The Joint Action Towards the European Health Data Space (TEHDAS JA) has identified several obstacles to cross-border secondary use of data[15]: differences in governance; differences in the definition of anonymisation and pseudonymisation; differences in the scope of secondary use; differences in health data and research legislation; differences in the use of GDPR derogations to consent for secondary use; and differences in interoperability and technical standards.

The following examples illustrate the degree of heterogeneity among the Member States:

- Most Member States allow some re-use for secondary use. Out of the eight Member States reviewed in this study, all but Belgium allow re-use for secondary use for improving health and care systems, but only three countries (EE, FI and DK) for market approval of medicines and devices, and five countries (EE, FI, DK, DE and ES) for monitoring of medical device safety/pharmacovigilance, and all countries but Belgium and Spain for protecting against serious cross-border threats to health. All eight countries that we reviewed permit the creation of disease registries;
- Re-use of electronic health record data for research purposes is possible, but only four out of the eight Member States that we reviewed have specific legislation for health data secondary use for research. When there is no specific legislation, secondary use happens through direct application to the data controller or through applications to a local or national ethics committee as required for scientific research;
- GDPR requirements for consent (or derogations to consent) vary among the Member States, and also vary across the nature and uses of data sharing. For instance, some Member States require specific consent of patients for secondary use for research, others apply the principle of broad consent, and several refer to the derogation for public interest or research. Of the eight countries that we reviewed for this study, only Spain and Portugal have not legislated in this respect. The other countries offer different models and have different legislation combining these different legal bases; and
- In the EU, 13 Member States have already established data governance bodies as foreseen in the EHDS proposal: Bulgaria, Denmark, Germany, France, Ireland, Netherlands, Portugal, Slovakia, Cyprus, Greece, Latvia, Malta and Finland. But apart from rare exceptions like FinData in Finland, the Danish health Data authority, the Danish statistical office, or SPMS in Portugal, most of these national experiences are at an inception stage and/or operate on a narrower mandate than that foreseen in EHDS.

The diversity of national laws is such that some degree of harmonisation will be necessary in order to promote the kind of cross-border secondary use of health data that is envisioned in the EHDS proposal.

[15] Joint actions are projects of voluntary cooperation between Member States in the field of health supported by the EU4Health programme and its predecessors. Relevant findings of the Joint Action towards the European Health Data Space appear in the produced TEHDAS JA (2022) report.

3.3. Costs of implementation and their relationship to benefits

The Commission's legislative proposal focuses on the benefits from cross-border portability and aggregation of health data, and pays less attention to domestic health services benefits from interoperable personal health data and centralised health data pools. This is a reflection of the EU's competence under the Treaties – domestic health care is in essence a Member State competence. The Impact Assessment is focused on the cost side and less so on a variety of potential benefits. In this section, we seek to carry out a more comprehensive exploration of potential economic costs and benefits and likely impacts on the economic efficiency and effectiveness (in terms of health outcomes) of health services.

The status of health service providers may affect their willingness to facilitate access to health data. This presumed lack of willingness to contribute data represents a key justification for the mandatory and standardised data portability and pooling rules that are proposed by the EHDS. Incentives can be expected to be different in countries with predominantly Beveridge-type health systems (that focus on the public provision of health services) versus countries with predominantly Bismarck-type health systems (where private providers play a more important role).

At the same time, differences in the structure of health systems across countries may result in differences in the impact that data sharing may have on the structure of health services markets, including markets for health insurance services. We will examine these effects by types of agents in the health sector: citizens as consumers, (private and public) health service providers and product manufacturers, and (private and public) health insurance providers.

The EHDS proposal distinguishes between primary use and secondary use of health data. We address the former in Section 3.3.1 and the latter in Section 3.3.2.

3.3.1. Primary use

Though the Commission's IA does not discuss market failures in data-driven health services markets, we introduce these because they clarify the expected direct and indirect patient benefits and other benefits to be expected from introducing primary and secondary use of health data. A proper identification of market failures also provides us the criteria and policy variables that we should be focusing on to assess the economic benefits of this initiative, including patient benefits from being able to switch doctors and search for higher-quality and lower-priced health services, the benefits of innovation, more market transparency and competition in health services.

First of all, the problems created by ignoring the Commission's own market failure criteria in the Better Regulation Toolbox become apparent when we examine the methods used for the economic cost-benefit analysis of the EHDS (IA Annex 5). The benefit calculations focus exclusively on telemedicine[16].

Telemedicine became more prevalent during the COVID-19 pandemic as a means to avoid unnecessary exposure to infection risks. It may be a partial substitute for offline consultations, and some of that substitution may be facilitated by the availability of EHR for primary re-use. However, it is not a full substitute for physical visits and cannot replace physical examinations.

[16] The IA argues that "further roll-out of telemedicine requires more mature and interoperable EHR and medical devices" (IA part I, p 9). Telemedicine is estimated to be cheaper than traditional doctor consultations. Savings in journey time to visit a doctor are taken into account. More controversially, an alleged higher quality of tele-visits compared to physical visits, and concomitant reduction in mortality, adds Quality of Life Years. These gains are converted into a monetary value, based on the average salary. All benefit estimates in the IA are based on a study by PWC (2018) Market study on telemedicine, carried out on behalf of the European Commission's Third EU Health Programme. Table 4 p 121 in that study presents a quantification of benefits of telemedicine.

Primary re-use has much wider effects on reshaping the market for medical services – as explained in the IA Problem Tree analysis and in the market failure analysis earlier in this section. There are some recent empirical studies that document the benefits of primary use of EHR in accordance with the market failure criteria. Shrank et al. (2019) explore the problems that stem from information asymmetries between health care providers. They find that coordination failures between medical service providers in the US increase health expenditures by 25-32 billion USD per year or about 1 percent of total health expenditure, even without taking into account the largely non-monetised[17] impact on patients' health outcomes. A comparable figure for the EU[18] would be around 18 billion EUR. The monetary benefit from reducing information asymmetries alone would justify the implementation of the EHDS because it exceeds the monetary cost of implementation by a factor of 3 to 6[19].

A proper cost-benefit analysis should also take into account non-monetary benefits that increase patient well-being in terms of health outcomes, on top of monetary benefits. These outcomes may be difficult to quantify in economic terms but should nevertheless be taken into account. While we do not have an exhaustive account of all these benefits, there are a number of studies that estimate at least some of these benefits for patient health outcomes. In line with Shrank et al. (2019), Böckerman et al. (2020) study the benefits of a public policy that overcomes information asymmetries and integrates health information between care providers, using the rollout of a nationwide electronic prescribing system across municipalities in Finland. E-prescribing systems provide more comprehensive information on prescriptions across multiple physicians involved in a patient's care. Böckerman et al. (2020) estimate non-monetary health outcome benefits for patients and find that integrated health information reduces harmful prescriptions by about 35 percent in rural municipalities. Neprash et al. (2022) come to similar conclusions with regard to transparency in prescription drugs in the US. Agha et al. (2019) measure the impact of a patient's healthcare delivery across (uncoordinated) organisations on health outcomes. When patients move to larger healthcare delivery organisations, coordination improves because larger organisations have more specialist providers in-house and usually have better in-house EHR systems. Patients' healthcare utilisation (number of visits) falls. Switching to larger care providers reduces utilisation by 21%, a monetary cost saving. This study also shows that it improves patient health outcomes for diabetes treatment, a non-monetary benefit. This is not an argument for concentration of health services ownership and management in a single entity, but rather an argument for increasing coordination between service providers across organisational borderlines, for the creation of larger pools of medical expertise, and for working in coordination with each other and sharing patient data. We already see this happening in many countries. There is of course the risk of collusion and competition distortion; however, to the extent that health is already a very regulated sector, prices, qualities and quantities of services are fixed and do not allow much margin for collusion.

Our point here is that the cost savings and benefit indicators for primary use in the Commission's IA are not very relevant in our view. Better studies exist with more relevant indicators on patient benefits and improved health outcomes as a result of primary data re-use between health service

[17] Monetised means that there is a private financial benefit obtained through a market transaction. Non-monetised means that there is no financial benefit but still an economic benefit. Non-monetised consumer benefits occur for example when patients can achieve better health outcomes for the same financial cost. They would probably be willing to pay more for this better outcome but they can get it at the same price as the poorer health outcome.

[18] Based on Eurostat estimates for EU total health expenditure of 1.8 trillion EUR or 10% of GDP (2020). See: https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Healthcare_expenditure_statistics.

[19] The overall EU budget cost of the EHDS is estimated at 0.7-2.5 bln EUR over 10 years (Explanatory Memorandum, p 12). The overall implementation cost for EU Member States is estimated at 3-9 bln EUR over 10 years (IA part I, p 49).

providers. These studies do not undermine the favorable benefit-cost ratio in the IA. On the contrary, they strongly boost that ratio and strengthen the economic rationale for the EHDS proposal.

There are several sources of information asymmetry in health care. Primary data use seeks to overcome information asymmetry between health care providers, giving providers access to medical information compiled by their colleagues, co-providers, and in some cases competitors. There is also information asymmetry between patients (care consumers) and care providers. It may be difficult for patients to find the best doctors, especially for complex pathologies and rare diseases, in order to achieve the best health outcomes. In some countries, patients can already search for medical services on private intermediary platforms. For example, the Doctorialia platform in Spain facilitates search and making appointments with highly rated doctors. Review scores are subjective, based on patients' reviews. Brown et al. (2020) show that, in the UK, there is positive correlation between subjective review scores and more objective indicators of the quality of medical services.

Patients may also delegate the search for quality medical services to their health insurance company. Health insurance companies have an incentive to direct patients to good quality care because poor care may eventually result in higher subsequent medical costs – though price-quality ratios may play a role in insurance decisions. Insurance providers are in any case in a better position than individual patients to scan through large health databases to find the best treatments and service providers. We discuss these benefits for patients further under secondary use of EHR data in Section 3.2.2.

The studies cited above do not distinguish between domestic and cross-border use of primary data. Based on the assumption that cross-border medical services in the EU currently account for much less than 1 percent of all medical services (see for instance Section 2.1), and even allowing for significant growth rates in this figure, we conclude that this cross-border component in itself would not justify the investment cost of a Europe-wide EHDS. The bulk of the benefits of primary use under the EHDS will come from domestic health services. However, there may be indirect spill-overs from the EU level to the domestic level. One important transmission channel could be setting of EU conformity and interoperability standards for EHR systems. Since many EHR providers operate across EU Member States, setting standards at EU level would automatically improve interoperability at Member State level. In our view, the bulk of cross-border benefits from the EHDS are however situated in secondary use (see Section 3.2.2).

3.3.2. Secondary use

Secondary use requires the aggregation of individual (personal or non-personal) health data into larger data pools. Insights obtained from the analysis of EHR from one set of patients have value to improve the treatment of other patients, for medical research and innovation, as well as policy making and regulatory activities.

Secondary use happens in principle on anonymous data. The privacy concerns that are raised by secondary use are substantially different from those raised by primary use, and are amenable to straightforward solutions such as anonymisation, as we explain in sub-section a of this section.

Health service providers have no incentive to incur costs to make data available to a larger pool because another party may reap the benefits, not the data the data provider. Similarly, patients may not have an incentive to share their personal health data because they may not benefit from that. Voluntary sharing may however occur among patients with rare diseases for example (see Courbier et al., 2019), because they constitute a small community with a shared interest and may expect to benefit directly from the research and innovation that can be generated by the data pool. Some patients may also have purely altruistic motives to voluntarily contribute their health data for

scientific purposes, although this altruism is usually conditional on respect for their privacy and for transparency in the usage of the data (Courbier et al., 2019).

In order to overcome these externalities or incentive misalignment market failures, the EHDS introduces mandatory aggregation for secondary use.

The IA estimates the extent to which the economic benefits of secondary use exceed the costs. It skips the market failure approach as well as the drivers presented in the IA's own economic Problem Tree analysis. The total benefit of secondary use of health data is defined as the sum of three components, "the economic value of health data, the savings of more efficient access to data and cost savings thanks to information transparency" (IA part 2, p 49). The first component of that sum, the economic value of health data, is estimated using a study carried out for the Commission in support of the Data Governance Act (IDC and the Lisbon Council, 2022). This study estimates the total value of the data economy based on a number of indicators that cover the number of data supplier and data user firms, employment and turnover in these firms, and the monetisation of data as a share of Gross Domestic Product (GDP). The study bases these estimates on future growth scenarios that depend on EU regulatory intervention to open access to data: more data access accelerates growth in the value of data. The IA calculates the share of health data in the overall data economy and uses the data access scenarios to estimate the impact of the EHDS on the health economy.

Apart from a double-counting problem (health data economy benefits are already subsumed in the benefits of the EU Data Governance Act), this methodology is not very appropriate in our view. Data have no value on their own; their value depends on the additional value that they generate, for instance through their use in data-driven services markets (in this case, health services markets). Consequently, the value of data access policies, like the EHDS proposal can only be assessed by examining how they change value-added and market structure in public and private health services markets, or how they affect patient health outcomes and welfare that are affected by access and wider availability of the underlying data. There can be monetised (cost savings and additional revenue) as well as non-monetised impacts. The IA focuses on monetised benefits only.

The second component of the estimation of benefits used in the IA, savings from more efficient access to data, are attributed to cost savings in the development of new pharmaceutical products. Health data pools make Real World Data available to health researchers. This can result in savings in clinical trials, at least for pharmaceutical products and medical treatment protocols that are already in use. It can also result in better public health policies. Future benefits from secondary use of health data for innovation purposes are inherently difficult to quantify. We consider that the IA's estimated cost savings in medical and pharmaceutical innovation of 1.6 bln EUR per year may be a plausible order of magnitude.

We have no quantification to offer for these innovation benefits because they do not exist for as yet unknown inventions or uses; at the same time, it seems clear that there are potential benefits from use of secondary data, including in ways that were not anticipated when the data was collected. For example, a number of studies combined existing UK health data with vaccination data in order to estimate the emergence, contagiousness and virulence of new variants of the COVID-19 virus (see for instance Nyberg et al. (2022), Ward et al. (2022), and Volz et al. (2021)).

The third component, cost savings from more efficient access to data in centralised health data pools, essentially measures the benefit of overcoming market failure in incentive misalignment that would normally prevent the creation of large health data pools. The EHDS as proposed makes pooling mandatory and forces health services providers to internalise the cost of transforming their

data to make them suitable for pooling. The IA takes into account the fees that central data pools charge to users, which are probably only a small part of the total cost of creating the pools and making them accessible.

Secondary use is beneficial not only for research and innovation in health services. It may also be used to strengthen competition among health services providers. Unlike private providers, public health service providers may not be driven by the profit motive or the desire to expand market shares. However, neither private nor public providers want to dangle at the bottom of the service quality ranking. Access to medical records across hospitals and general practices may enable comparison of health outcomes. In fact, evidence from the UK and Finland shows that a significant share of requests for access to medical data for secondary use actually comes from local hospitals, medical service providers and local health authorities. These requests are driven by a desire to find out about their relative performance in local medical services markets driven, for instance, by a desire to inspire confidence in their service, or to demonstrate (if possible) a qualitative advantage over competitors. While private and more subjective review scores for medical service providers are becoming increasingly available in most countries, more objective reviews based on observed medical diagnostics, prescription behaviour and ultimately patient health outcomes may be an even more reliable indicator[20].

Secondary use can overcome information asymmetry between patients and health care providers, and can increase market transparency and competition between health service providers. Brown et al. (2022) demonstrate how patients respond actively when they get access to quality ratings for health service providers. Poor ratings tend to especially encourage poorer patients to switch to better-rated providers. The relocation effect is much smaller or non-existent for high income patients. High income patients usually already have access to better quality providers.

Kümmer et al. (2022) show how quality ratings increase transparency in health services markets, making it easier to find good medical doctors and thereby improve the quality of services. In this way, secondary use can increase market transparency for medical services, and can help patients to find better doctors and to obtain better health outcomes. This non-monetised benefit of secondary use – a benefit that does not translate into changes in financial expenditure but contributes to consumer welfare and health outcomes – should be taken into account in the economic benefits of secondary use.

Patients can also delegate the search for high-quality medical services to their health insurance provider. Health insurance companies, including public health insurance organisations, have an incentive to ensure that their clients are well-treated. Poor medical treatment at one point in time may lead to higher subsequent medical costs for the insurance company. Health insurance providers are in a better position than individual patients to scan through large secondary use health databases to find the best service providers and treatment procedures. There is a rich health economics research literature that explores how health insurance providers can set up efficient incentive structures for healthcare providers (for an overview, see Vlaanderen et al., 2019). For example, payment by transaction is usually less efficient than payment in function of health outcomes[21].

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[20] Brown et al. (2022) show how subjective and objective health care review scores are strongly positively correlated. Patients respond to the availability of quality information on medical services. The UK National Health Service (NHS) carries out regular quality reviews of its General Practitioners (GPs) practices, using the Quality Outcomes Framework.

[21] Payment by transaction creates an incentive for healthcare providers to maximise revenue by increasing the number of transactions or medical interventions. This may not necessarily improve patient health outcomes and may result in excessive health insurance

Secondary use under the EHDS could potentially narrow the information asymmetry gap between healthcare and health insurance providers, giving the latter much better insight into the efficiency of health services and helping them to improve the financial incentive structure for health providers.

Unfortunately, these important effects are not taken into account in the EHDS proposal and the accompanying IA. Again, we have no quantitative monetary equivalent figure for these benefits; however, that does not make them less important or relevant. Our bottom line here is that there are more important benefits from secondary use that are not taken into account in the EHDS IA. They increase the economic rationale for implementation of the EHDS.

The EHDS IA does not distinguish between domestic and cross-border secondary use. This is essentially a matter of economies of scale or the size of the required data pool to reach statistically significant results. For some common pathologies, a national data pool may be sufficient; for others, a broader data pool may be helpful, and especially so where the genetic distribution of a predisposition to a disease is not uniform across the EU.

For rare diseases where the number of patients in a single country may be very limited, cross-border data pooling may be very valuable. Cross-border data pooling may also facilitate collaboration between international teams of specialists.

Apart from economies of scale, economies of scope may also matter in secondary use of data. Data pools can combine data from different sources that are usually not linked. For example, the analysis of a combined data pool including prescriptions, doctors' visits, health outcomes and social security data, can give more accurate insights than analysing these data sources in separate data silos (Carballa-Smichowski et al., 2022). The possibility to combine EHR data with other types of relevant data for the purpose of secondary use for research is unfortunately not explicitly foreseen in the EHDS.

a. Privacy concerns and secondary use

Health data pooling is often associated with privacy concerns. Individuals fear that their data could be accessed to target them in unfavorable ways. In distinction to primary use, secondary use can however be completely anonymous. Researchers do not need to know the identity of individuals in order to extract useful insights. They can access the raw data pool with anonymised individual data and take out only the derived data and insights, not the primary data. This procedure also mitigates the risk of reverse engineering of identities.

Article 61(2) EHDS explicitly prohibits singling out individuals in the use of secondary data; nonetheless, there is the risk of data leakage from large individual data pools. That risk can be avoided by decentralised or federated data pools, as opposed to centralised data pools (Rieke et al., 2020). Federated machine learning technology connects and enables the extraction of insights from decentralised data pools as if they were a single combined data pool. In decentralised learning technologies, algorithms are brought to the datasets, which differs from the approach used in centralised systems that bring datasets together with the algorithm in a central server. Federated machine learning currently still runs into technological and economic limits, because communication costs tend to increase exponentially as the number of decentralised datasets increases; however, that technological frontier is constantly evolving and should offer ever increasing possibilities.

costs. Payment for patients' health outcomes corrects that incentive bias. For an in-depth discussion of incentive bias in health services, see for example Ma and Mak (2019).

Decentralised data pools mitigate the risk of large data leakages. They are also much cheaper to run because doing so avoids the need to create a new centralised data infrastructure. Many medical service providers are already hosting decentralised datasets. The IA (part 2, section 8.2) estimates the cost of an EHDS centralised data server infrastructure at several tens of millions of euros per year. Much of that could be avoided by decentralised systems. In fact, federated systems transfer at least part of these costs to the researchers because communication costs are much higher in decentralised learning. The message here is that, although the cost of centralised systems is low compared to the potential benefits, there are still additional savings to be made by shifting to a decentralised data architecture for secondary use infrastructure.

The Netherlands represents a rather extreme example of a decentralised health data system. There is strong public resistance against creating central health data repositories[22]. Health data remain in fragmented data silos operated by medical service providers. Switching from current arrangements to a centralised data pool is not, however, the only way to address this fragmentation. Ensuring interoperability between these silos would be sufficient to operate an Application Programming Interface-based (API-based) federated data pool that would enable the extraction of useful insights and knowledge from these decentralised data pools.

The proposed EHDS Regulation already provides mechanisms to promote this kind of interoperability. EHDS Articles 27-35 introduce mandatory certification and interoperability requirements for EHR providers. Voluntary steps in this direction have been promoted for several years through the MyHealthEU initiative.

EHR producers have weak incentives to provide interoperable systems. Market fragmentation increases their market power, pricing and profit margins (Competition Bureau Canada, 2022). Making interoperability mandatory would overcome this market coordination failure. Introducing interoperability standards at EU level is likely to be more effective than at national level because the major EHR producers have strong market positions in most EU Member States. The two largest market operators, Epic and Cerner/Oracle, account for nearly two thirds of the EU market for EHR systems[23]. Getting the largest market operators to set up a common interoperable standard would go a long way towards EHR interoperability in and between EU Member States.

Apart from privacy concerns for natural persons, medical service providers and the legal entities in which they operate may also have legitimate commercial confidentiality concerns. Article 33(4) EHDS mandates the protection of intellectual property rights and trade secrets during secondary use of health data from private entities such as hospitals, medical practices and health product producers; however, it does not protect the identity of these private entities. This would imply that secondary use researchers can access the identities of hospitals and doctors and compare their relative performance, prescription behaviour, etc. This information could be used by commercial suppliers of medical products for market studies and for targeted marketing towards health service providers. Articles 34 and 35 EHDS list allowed and prohibited secondary uses. They constitute an attempt to distinguish between beneficial and harmful innovation from secondary use of health data.

[22] Based on authors' interview with a Dutch health authority representative.

[23] For an overview of market shares in EHR systems, see for example https://www.definitivehc.com/blog/most-common-inpatient-ehr-systems.

b. Fees for access to data for secondary use

Medical service providers incur costs for the setting up and day-to-day operation of their EHR systems that collect, store and curate health data. They have an incentive to invest in EHR systems for internal organisational reasons, because these systems facilitate internal management and operations. EHR costs will be covered by their operational budget and reflected in the prices that they charge for health services to patients and their health insurance providers. Some of these costs may also be borne by government subsidies to health service providers, in particular public sector providers. Whatever the allocation mechanism, it implies that the cost of all health data collection, storage and curation for internal use by medical service providers (for data that are currently being collected and electronically registered) is already covered by the day-to-day operations of medical service providers. Health data production is a by-product of these day-to-day operations.

Making health data available to external parties, for primary or secondary use, may entail additional costs. For example, costs related to introducing standardised data formats, or for ensuring interoperability and access via standardised APIs. Service providers have no incentive to incur these additional costs because they do not benefit from these. Only data recipients outside the provider's organisation benefit from this. Service providers would benefit however when they would receive health data from other providers on a reciprocal basis. Reciprocity requires coordination. Health data markets have however demonstrated that they are prone to incentive misalignment, externalities and coordination failures that create obstacles to reciprocal data exchanges (see for example Vlaanderen et al., 2019). These market failures justify regulatory intervention to set mandatory data standards in EHR systems in order to facilitate health data exchanges for primary and secondary use, as proposed by the EHDS.

Most of these external standardisation costs are fixed costs. For data that are already being collected and registered electronically, the marginal cost for each external data transfer will be close to zero once the initial investments in establishing automated portability have been made[24].

The cost of EHR provision could be covered or at least mitigated in several ways. First, the health service provider could internalise the costs in its operational budget. That should be feasible when standardisation costs are relatively small compared to the running costs for the internal EHR system. Second, standardisation costs could be reduced if EHR software providers offer standardised EHDS-compatible solutions. Since the two largest EHR software providers in the EU account for more than half of the market, substantial economies of scale could be achieved, especially since developing a solution would be a fixed cost for the system provider that can be amortised over a large number of clients. Third, costs could be charged to primary and secondary data recipients.

The EHDS proposals take this third route, at least for secondary use of health data[25]. Article 42 EHDS provides guidance on fees charged by health data access bodies and single data holders for accessing the secondary data pools that they create for third-party secondary use. Any fees "shall include and be derived from the costs related to conducting the procedure for requests, including

[24] Marginal costs will be significant only in case of exceptional demands that go beyond the specified health data domains and that require additional data curation and formatting. This may occur for example when governments request medical service providers to provide additional data related to public health emergency situations – as foreseen in the chapter on business-to-government data sharing in the Data Act.

[25] The EHDS has no provisions for fees for primary use. This is an area where the EHDS is inconsistent with the Data Act, despite the fact that EHDS Recital 62 specifies that fees should be based, among others, on the provisions of the draft Data Act. The Data Act does not distinguish between primary and secondary use. It deals only with the transfer of "product" data to third parties. They are subject to fair and reasonable fees, or a "remuneration of the data holder" in the terminology of the Data Act. Product data under the Data Act includes data from medical machines and wellness devices. The product manufacturer, or the software provider, can be the data holder. In principle, this would enable the manufacturer of a medical imaging machine to charge a fee for any data transfer to a third-party outside the hospital that owns and uses the machine. That would severely upset primary use provisions in the EHDS.

for assessing a data application or a data request, granting, refusing or amending a data permit or providing an answer to a data request" (Article 42(1)). If the data are not already available, additional "compensation for part of the costs for collecting the electronic health data" is permitted. Moreover, Article 42(3) EHDS provides for additional fees for "enriched data". Finally, Article 42(4) EHDS establishes that any fees charged to data users "shall be transparent and proportionate to the cost of collecting and making electronic health data available for secondary use, objectively justified and shall not restrict competition."

The question is whether such a fee system makes economic sense. Medical service providers have an incentive to invest in their internal EHR system, for organisational and management efficiency reasons. This includes the cost of collecting, storing and curating patients' health data, including for the six health data domains covered by the EHDS. Secondary data use requires interoperability between EHR systems of medical service providers. This may entail additional fixed costs to adapt systems to these requirements. These fixed costs will be greatly reduced by the EHDS' standardisation requirements that will force EHR system suppliers to deliver standard interface packages to their clients. Recurrent data access fees in EHDS Article 42 are not an appropriate solution for fixed costs. The data provider does not know how often its data will be re-used for research purposes. It is therefore not possible to calculate a fee rate or marginal remuneration that would completely compensate the data provider for its fixed costs. Fees would be appropriate only when the data provider incurs additional marginal cost.

So far, we have only looked at the cost side of secondary use. We should also look at the benefits side, the value of the health service innovations that are generated by secondary use. The innovator appropriates that value, provided it is privately appropriable[26]. Data providers may want to get a share of the benefits. Data providers could constitute a data cooperative that would allocate participant data providers a share in the innovation value or health services market value to which their data contributed. This approach runs into several problems too, including (a) how to calculate the appropriate share (Mehta et al., 2022) or the marginal value of each data subset, and (b) how to determine the overall value of the innovation. Innovations usually get to the market in several steps. The data analysis is only one part of that production process. Another approach would be to waive fee remuneration for the data provider and leave the entire innovation benefit to the researchers or innovating firm that took the initiative to analyse the data.

From an economic perspective, central data servers or data permit authorities can be considered to be a two-sided market or platform. The server infrastructure brings together data suppliers (including hospitals and medical practices) and data demand (researchers, firms, possibly the same hospitals). Lowering market entry costs on one side of the market (for example waiving fees for researchers) will increase entry costs for the other side (data suppliers), unless government steps in with a subsidy mechanism (Parker and Van Alstyne, 2005; Rochet and Tirole, 2006). With higher entry costs, or lower entry benefits, data suppliers will invest less in supplying data. This is not a problem for the six standard data domains defined in the EHDS. Service providers already have to standardise access and make these data available to national data servers. As argued above, these are mostly fixed costs.

Price incentives will become important however for additional data curation and quality improvement beyond the six standardised domains. For example, hospitals might collect free format text string data that are difficult to use for researchers.

[26] Public health service benefits, such as better public health policies to contain COVID-19, are usually difficult to privately appropriate because they constitute pure public goods.

Curating and standardising these text data may entail a substantial investment cost that data providers will undertake only if they have a guaranteed source of financing or market outlet for the data. Curation incentives will also depend on the uniqueness and monopolistic market value of the dataset. Setting an appropriate and optimal fee structure or remuneration is thus crucial to maximising the data supply and innovation potential of the EHDS. In economic jargon, an optimal fee structure would maximise the data-driven network effects of these health data intermediation platforms. Fee structures may have to vary across different types of data and data sources. There is unlikely to be a one-size-fits-all solution. Existing fee systems in EU Member States span the entire range of options, from waiving all fees to fairly steep data access fees and provisions to remunerate the data provider[27].

3.4. Member State aspects and subsidiarity

The fact that national health systems are primarily a national prerogative has not been conducive to strong coordination of health records across the EU. Under Article 168 of the Treaty on the Functioning of the European Union (TFEU), the EU plays only a limited supporting role. The potential mandate of the Union is wide-ranging, but the carve-outs from the Union mandate are explicit and are even larger: "Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them".

The role of the EU has however been growing over time. The COVID-19 pandemic has tended to bring home to the public and to national governments the potential value of public health initiatives such as vaccine procurement at EU level (Marcus et al., 2021).

In terms of cross-border health services, neither the legislation on coordination of social security systems nor the legislation on patients' rights in cross-border health care have generated a massive demand for cross-border health care to date (see also Sections 2.1 and 4.3). This lack of demand presumably served to limit the degree of interest that Member States have shown to date in engaging in cross-border exchange of electronic health records and in making use of EHR standards recommended at EU level. Whether the EHDS can open the door to greater cross-border use remains to be seen.

[27] In Finland, FINDATA does not remunerate the data provider. In the UK, the NHS is experimenting with various remuneration systems to entice their hospitals to contribute more and better curated high quality data to a central data system.

4. ADDRESSING THE CHALLENGES POSED BY THE EHDS AS PROPOSED

KEY FINDINGS

The overall design of the EHDS as proposed is sensible, but it may be too centralised, and may place too great a burden on the national Health Data Access Body.

EHDS defines permitted purposes for the use of secondary health data, but the list of permitted purposes may be a bit too broad, while the list of prohibited purposes may be too rigid.

The EHDS as proposed seeks to address numerous shortcomings in existing EHR practice at EU level and in the Member States. We view it as a good start, and a positive step overall.

Based on the assessment that we have provided in Chapter 3, however, we think that there are a number of aspects that would benefit from further refinement. We address these in the Sections 4.1 through 4.7, in each case providing a summary of the issue to be addressed, a discussion of ways in which it might be addressed, and a recommendation as to a promising way in which the Parliament might proceed.

4.1. A centralised, decentralised, or federated structure?

The legislative proposal seems to be confused as to whether the infrastructure that is being proposed at EU and at Member State level is intended to be centralised, decentralised, or federated, or some hybrid of these.

Member States were confronted with a similar choice for the development of national COVID-19 contact tracing / exposure notification apps. Two models were chosen at the same time. France went with its centralised implementation, while Germany stepped back from its initially centralised design and changed its app[28]. In the end, the exposure notification app that was used in nearly all of the Member States was implemented by Apple and Google directly at operating system level in a decentralised way. National exposure notification apps operated as user interfaces on top.

The legislative proposal as written provides all of the necessary elements for a system that is fully decentralised both at EU and at Member State level, both for primary use and for secondary use. The proposed Regulation establishes a European electronic health record exchange format (Article 6 EHDS) to facilitate interoperable data interchange. This federated approach is in line with other data spaces currently under development in the EU, including Gaia-X. The decentralised approach is a pragmatic approach, taking into account the fact that data are already scattered across many databases. Private market operators are also increasingly adopting this approach. This pragmatic choice should not lead us to ignore the fact that there are many problems associated with the use of decentralised data, including potential failures in each component database and high communication costs between the databases.

For primary data, natural persons are to have the right to access their data (Article 3(1) EHDS), and the right to receive a copy in the European electronic health record exchange format (Article 3(2) EHDS).

[28] See for example Civil Liberties Union, June 2021, "Covid Contact tracing apps in the EU: lessons from Germany". See also VoxEU, August 2021, "A cross-country comparison of contact-tracing apps during COVID-19", available at https://cepr.org/voxeu/columns/cross-country-comparison-contact-tracing-apps-during-covid-19.

They are also empowered to directly "request a data holder from the health or social security sector to transmit their electronic health data to a data recipient of their choice from the health or social security sector, immediately, free of charge and without hindrance from the data holder or from the manufacturers of the systems used by that holder." There is nothing to suggest that these requests must be routed through any authorities at Member State level.

Article 12 EHDS puts in place MyHealth@EU, which among other duties is to "*support and facilitate* the exchange of electronic health data between national contact points for digital health of the Member States". Significantly, Article 12 EHDS does not say in so many words that MyHealth@EU is to *provide* the exchange of electronic health data.

For secondary data, Article 49 EHDS makes it possible for a data user who desires data from a single holder in a single Member State for secondary use to make the request directly to the data holder, and for the data holder to issue a permit *and to answer the request*. The relevant health data access body need not be involved in satisfying the request; however, the data user must notify the relevant health data access body in order to enable it to meet its requirements under Article 37 and Article 39 EHDS, mainly having to do with reporting requirements.

The EHDS proposal also includes (Sections 2 and 3, Articles 14-27 EHDS) extensive obligations on providers of EHR systems, medical equipment and high-risk AI systems to ensure that their offerings comply with demanding standards. Only compliant offerings are awarded the right to affix a 'Conformité Européenne' (CE) marking (which in most cases will be a prerequisite to making the offering available in the EU). This approach is broadly in line with the overall EU approach to safety of products and services (for an overview of EU safety procedures, see for instance Marcus (2021)). It does not guarantee perfect interoperability, but it potentially takes things a long way in that direction. Once again, this approach is consistent with ensuring interoperability in a fully decentralised implementation; however, it does not preclude a more centralised approach.

For secondary data, the EHDS anticipates a *catalogue* of available datasets. The catalogue should be publicly available and widely accessible. It is not necessarily centralised.

Other elements of the EHDS as proposed seem to imply data centralisation or consolidation. For instance, Article 3(5)(a) EHDS requires Member States to establish "one or more electronic health data access services at national, regional or local level" in order to enable natural persons to access their data, or in order to provide a copy in the European electronic health record exchange format.

Similarly, Article 52(9) seems to clearly imply a centralised EU role: "The Commission shall develop, deploy and operate a core platform for HealthData@EU by providing information technology services needed to facilitate the connection between health data access bodies as part of the cross-border infrastructure for the secondary use of electronic health data." This might not imply that the core platform is the only way to transfer EHDS data cross-border, but it clearly plays a prominent role.

The Commission refers in one document to a "Cross-border digital infrastructure for the exchange of health data, also known as the eHealth Digital Service Infrastructure (previously referred to as "eHDSI")" (European Commission (2022a)); however, neither that document nor the relevant portions of the Commission's "EU4Health Work Programme for 2022" (European Commission (2022b)) shed much light on whether the eHealth Digital Service Infrastructure is intended to provide only support services such as the catalogue of datasets, versus actual data transfer between national data contacts.

Among the tasks that the health data access bodies "shall carry out" (Article 37 EHDS) are to "(d) process electronic health data for [permissible purposes], including the collection, combination,

preparation and disclosure of those data for secondary use on the basis of a data permit; (e) process electronic health data from other relevant data holders based on a data permit or a data request for a [permissible purpose]". It is clear, however, that a range of data holders are also likely to carry out this kind of data processing. Is this really intended to be something that the health data access body *must* do, or is it rather something that the health data access body *may* do?

Moreover, Article 37(1)(p) seems to imply a centralised operational role for the health data access body that is not strictly necessary. The health data access body shall "send to the data holder free of charge, by the expiry of the data permit, a copy of the corrected, annotated or enriched dataset, as applicable, and a description of the operations performed on the original dataset". Why is this a responsibility of the health data access body, and not of the data user?

We suggest that it is helpful to think of the EHDS as a whole as a *federated* structure that can accommodate as much centralisation or decentralisation as the EU or the individual Member States desire.

There are in our judgment some significant advantages to decentralisation, and it more or less reflects current conditions in many of the Member States (see Recital 7 EHDS). Allowing for a fully decentralised federated data system at EU level has the potential not only to save infrastructure costs, but also to assuage privacy concerns and push the privacy-efficiency trade-off further out, generating the same efficiency levels for more privacy. Federated learning systems bring the algorithms to the data, rather than the reverse. Researchers can take out only derived data, not the underlying individual EHR. Drawing inferences from datasets spread across multiple infrastructures, and perhaps not all capturing the same data elements, poses computational challenges; however, the technology of federated artificial intelligence is advancing rapidly, and is likely to make this progressively less of an issue over time.

With all of that said, however, it is not necessary to preclude centralised operation for Member States that desire it, or that already implement centralised systems (Finland, for instance). And there may possibly be scale economies with centralised infrastructure.

Recommendation 1. Amend the EHDS proposal to clarify the degree to which centralised versus decentralised infrastructure is permissible. A structure that permits full decentralisation, but also enables Member States that desire some degree of centralisation to implement it, appears to have merit.

4.2. Authority and responsibility of the health data access body

Closely related to the question of infrastructure centralisation is the issue of the degree of control to be exercised by the many control bodies envisioned by the EHDS legislative proposal. This is most notably visible as regards the health data access bodies that are put in place by Article 37 EHDS. The twenty enumerated duties of the health data access bodies (Article 37(1)(a) through (t)) are wide-ranging. One has to ask whether this many distinct duties are really necessary or productive.

The EHDS proposal is based on a model of intensive control at Member State level, with each health data access body acting as a gatekeeper for permit issuance, and for the use of data. The EHDS as proposed foresees only two exceptions to a request for permits through the health data access authority: one is when the data user requests data from a single data holder in a single Member State and can in that case request it directly from the data holder (Article 49 EHDS), and the second is for public sector bodies and EU institutions (Article 48 EHDS) where a data permit is not required.

Even in the case of the exception under Article 49 EHDS, there is a requirement to notify the relevant health data access body within three months in order to enable it to meet requirements, mainly reporting requirements, under Articles 37 and 39 EHDS, thus imposing an administrative burden that might not truly be commensurate with its cost. Exemptions such as those under Articles 48 and 49 EHDS are fully justified and will greatly ease the work of data permit authorities. Given that secondary use of data is already operational in some form in many Member States, the new Regulation should build as much as possible on successful experience at national level. For instance, existing research consortia or networks, which involve partners who are both data holders and data users, could also benefit from a lighter procedure for data permit requests and uses. The EHDS proposal should leave the scope to Member States to identify exceptions to the data permit procedures. It would reduce red tape for both the data access authorities and the potential data holders and users.

A careful review of the twenty prerogatives and responsibilities of the health data access body as expressed in Article 37(1) would appear to be in order, together with an exploration of the possibility of expanding the exceptions to the requirement to obtain a data permit. Section 4.1 expressed concerns about three of the enumerated duties (Article 37(1)(d), (e), and (p)), and there are likely more that are candidates for trimming back.

For analogous reasons, the fourteen reporting requirements mandated on in Article 39(1) would likely benefit from a careful review. Are all of them really necessary? What is the likelihood of capturing reliable data? Are the benefits worth the administrative cost? Three that might be considered are "(j) satisfaction from applicants requesting access to data; … (m) number of peer-reviewed research publications, policy documents, regulatory procedures using data accessed via the EHDS; (n) number of digital health products and services, including AI applications, developed using data accessed via EHDS; …". The value of indicators like this is clear – they are valuable for an understanding of the degree to which EHDS is generating benefits, and are thus important for the eventual evaluation of the programme. But where are these data supposed to come from (i.e. from whom)? How long after data is acquired will this be known? How likely is it that reliable data can be collected?.

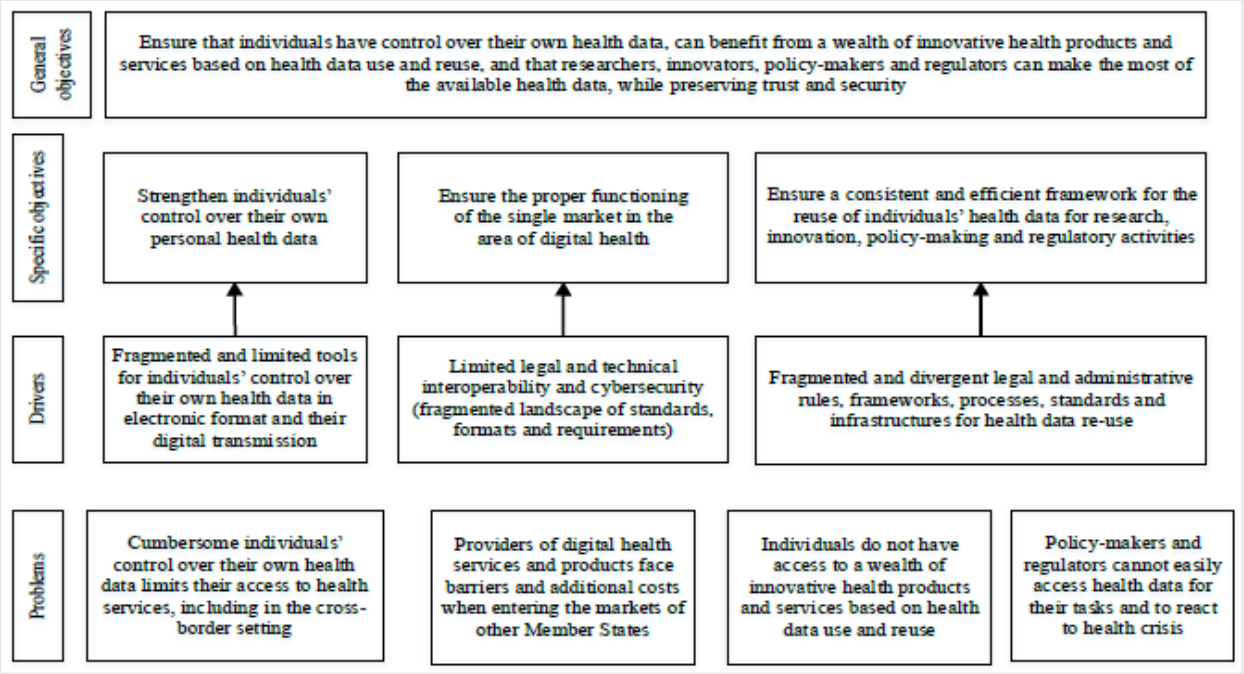
Recommendation 2. The authority and responsibilities of the health data access body should be carefully reviewed, with a particular focus on the proposed Art 37 and Art 39 EHDS. It may be unnecessary or unproductive to assign too many different tasks to the health data access body. Broadening the scope of exemptions from the procedure of obtaining a data permit via the health data access body should also be considered.

4.3. Greater clarity needed as to subsidiarity

There is no question that the EHDS addresses a number of long-standing problems that deserve to be addressed; however, greater clarity in the arguments would be useful in ensuring legal certainty, especially as regards the arguments concerning subsidiarity.

The general objectives of the EHDS as proposed are "to empower natural persons through increased control of their personal health data and support their free movement by ensuring that health data follows them; to foster a genuine single market for digital health services and products; [and] to ensure a consistent and efficient framework for the reuse of natural persons' health data for research, innovation, policy-making and regulatory activities" (Recital 67 EHDS). The Impact Assessment presents the objectives and the associated intervention logic as depicted in Figure 2.

Figure 2. Objectives tree and intervention logic of the proposed EHDS.



Source: Impact Assessment, page 31.

The EU's role in promoting the single market, and in promoting innovation, are firmly rooted in the Treaties (especially Articles 26 and 114 TFEU). Among the four freedoms that undergird the EU single market, at least two are key here: the freedom to establish and provide services, and the free movement of persons. More specifically, the role in promoting free movement cross-border, as a complement to national policies, by ensuring that health data follows the individual would appear to be clearly rooted in Article 168(2) TFEU: "[The Union] shall in particular encourage cooperation between the Member States to improve the complementarity of their health services in cross-border areas." It is thus reasonably clear that cross-border movement is within the competence of the Union, and it is clear that the solutions that solve the cross-border movement problem by enhancing the interoperability of EHR systems can also mitigate barriers to movement within a Member State, but do these observations provide a basis for a legislative proposal whose largest effects relate to free movement *within a Member State*?

The document that contains the EHDS legislation proposal asserts: "The proposal does not aim to regulate how healthcare is provided by Member States." That may be the intent, but it is not the effect, at least insofar as health data is concerned (rather than the delivery of healthcare services). Consider for example Article 3(1) EHDS, which confers on all natural persons "the right to access their personal electronic health data processed in the context of primary use of electronic health data, immediately, free of charge and in an easily readable, consolidated and accessible form". That right is not limited to cross-border usage.

The EHDS proposal does not provide logic that would clearly link the domestic health care aspects that EHDS seeks to address to the powers conferred on the Union as expressed in the TFEU. The "empowerment of natural persons" is a seemingly desirable characteristic, but reasoning that would explicitly link it to EU competence as expressed in the Treaties does not appear to be presented in the legislative proposal.

The EHDS seeks to make the GDPR more effective as regards health data. This is a laudable goal, but whether it flows from the main justification for GDPR in Article 16 TFEU can be debated. Article 16

TFEU states: "Everyone has the right to the protection of personal data concerning them". Article 16 TFEU calls for laying down rules for "the protection of individuals with regard to the processing of personal data by Union institutions, bodies, offices and agencies, and by the Member States when carrying out activities which fall within the scope of Union law, and the rules relating to the free movement of such data". Whether these provisions adequately address all possible concerns over subsidiarity as regards primary use in the EHDS as proposed is not immediately clear.

The Impact Assessment makes clear that there are problems with domestic health services in general and EHRs in particular that deserve to be solved, many of which have been long-standing, and there is obvious benefit in solving the domestic problems together with cross-border aspects. "A recent study on interoperability of EHRs shows that access to health information for citizens has been facilitated nationwide in seventeen EU/European Economic Area (EEA) countries, while six countries have ongoing pilot projects, three countries do not offer access to health data for patients, four countries offer mobile access, and two countries still use paper print-outs. In addition, citizens of 12 countries are not entitled to choose which healthcare professional or other party can access their EHR (often, general practitioners act as "data gatekeepers", allowing additional parties to access another's EHR, while in other countries, this is not technically possible). The study also shows that 18 Member States allow the exchange of health data across borders and that almost half of the Member States have devolved powers in digital health to decentralised governments, often further exacerbating the current fragmentation and patchwork of incompatible health data exchange formats and networks. Three Member States do not have rules in place for the identification and authentication of healthcare professionals. Patient Summaries and ePrescription exists in two-thirds of the Member States. When it comes to connecting healthcare providers to the national EHRs, general practitioners are largely connected in 20 Member States, pharmacies are connected in 19 Member States and labs are connected in 20 Member States. Several Member States score weak on the connection of different healthcare providers to the national EHR system." (Impact Assessment, page 20)

But cross-border health care represents a negligible portion of health care expenditure today. Per a very rough estimate in the Impact Assessment (page 20), cross-border expenditures represented just EUR 92.1 million out of total expenditures of EUR 882 billion for countries that could provide data for 2019. There is, to be sure, room for growth in the medium to long term. The number of foreign prescriptions per pharmacy per month quadrupled between 2012 and 2021 (Impact Assessment, page 20, see also Section 2.1), and the scope for increased cross-border care through telemedicine might possibly be substantial. Even so, using cross-border health considerations to justify a substantial intervention in domestic health care practices could be debated in light of the relative magnitude of the two.

There thus appears to be a need for a stronger grounding for the domestic aspects of EHDS objectives in Union prerogatives under the Treaties.

Article 114(3) might provide a basis for strengthening the subsidiarity argument as regards primary use within the Member States. In proposals "concerning health, safety, environmental protection and consumer protection, [the Commission] will take as a base a high level of protection, taking account in particular of any new development based on scientific facts". Enhancing portability of EHR data presumably contributes to this goal both within and among the Member States, for instance by enhancing the ability of patients to obtain more meaningful specialist opinions or second opinions.

To the extent that enabling data sharing for primary use might be viewed as a prerequisite to implementing data sharing for secondary use, that dependency might simplify the justification

greatly; however, while it is clear that there are synergies, it is not self-evident that the linkage is strong to warrant basing the justification for primary use mainly on the need to enable data sharing for secondary use.

If a clear justification cannot be established, there is a risk that these aspects could be challenged under the principle of subsidiarity in general, and under Article 168(7) TFEU in particular: "Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care." Or perhaps the proportionality of the EHDS would be challenged if data sharing for secondary use were well justified, but data sharing for primary use less so. This might also be used by recalcitrant Member States as a defence (in infringement proceedings, for instance) to justify deficient implementation of EHDS.

Recommendation 3. Expand the Recital 67 discussion of subsidiarity to better link domestic aspects of primary use to the prerogatives of the Union as expressed in the Treaties.

4.4. Ensuring compliance at Member State level

Efforts at EU level to facilitate cross-border use of health services are not new – they have been ongoing for at least a decade. Nonetheless, there has not been much to show for them (van Veenstra et al., 2013). There are many reasons – the problems to solve are genuinely hard, the benefits to a Member State are unclear (or possibly negative if the use of cross-border services reduces demand for services within the Member State), and Member States' authorities have had little incentive to invest time and effort in fostering cross-border health care.

For the EHDS to be fully effective, it will be necessary to bring the Member States fully on board. We suggest that both carrot and stick, both incentives and penalties, will need attention in implementation.

In terms of incentives, the EU has multiple means of contributing to the financing of EHDS implementation, including for instance the Connecting Europe Facility (CEF).

In terms of penalties, the EU has been limited in the past. The past programmes were generally voluntary. Moreover, the EU had only limited ability to act in areas that are primarily Member State competence, as is the case with health under Article 168 TFEU. The European Semester for instance affords very little power to the EU.

The European Health Data Space Board (EHDS Board), established "to facilitate cooperation and the exchange of information among Member States" in Article 64 EHDS, should be useful for coordination to the extent that the interests of the Member States are sufficiently aligned.

If the EHDS is implemented as a Regulation, then a failure to implement in timely fashion and in good faith could, if needed, be addressed by means of infringement proceedings, thus providing for the first time some serious prospect of bringing enough of the Member States on board to make EHRs and cross-border services effective at EU level.

Even if the Member States implement promptly, the EHDS will not deliver the benefits that are desired and expected unless standardised data formats for health data records are agreed on at European level (or ideally, at an even broader level that also enables international cooperation). The EHDS as proposed already appears to provide the Commission with sufficient delegated powers to achieve this (notably in Articles 3(12), 6(2), 7(2), 45(6), and in the committee procedures of Article 68), but the success of the EHDS will be in doubt unless the Commission is energetic and effective in pursuing the adoption and use of health data interoperability standards.

We emphasise that this is a known issue. Efforts to develop common definitions for electronic health data have been ongoing in the EU for many years. Notably, the Commission Recommendation of 6.2.2019 on a European Electronic Health Record exchange format (C(2019) 800 final) "sets out a framework for the development of a European electronic health record exchange format in order to achieve secure, interoperable, cross-border access to, and exchange of, electronic health data in the Union". That Recommendation puts in place a process that seeks in turn to build on the previous work of the eHealth Network's Common Semantic Strategy task force, together with a range of Horizon 2020 pilot projects.

The *Fast Healthcare Interoperability Resources (FHIR)* is a candidate to play a key role. It is an *application programming interface (API)* for exchanging electronic health records (EHR). It includes descriptions of data formats and elements (profiles), and appears to have the potential to reach critical mass in terms of usage. The United States has been making production use of FHIR for many years.

How a standard such as FHIR might be put in place in the EU is well beyond the scope of the current study, but we can offer a few thoughts and point to a few resources that might be of interest. Wide scale adoption in Europe would presumably require agreement to adopt FHIR as the common framework, and creation of a common core profile to be used across the whole of the EU. Member States and institutions might then develop more specialised variants to meet their respective needs. This process could draw on work that is already ongoing in the EU, and could be implemented following the general procedures that are already in place under the aforementioned Recommendation on a European Electronic Health Record exchange format.

The common profile might benefit from work that is already ongoing to create an *International Patient Summary (IPS)* based on the current version of FHIR in order to have a basic set of data definitions that would be minimal and non-exhaustive, but still clinically relevant[29]. Meanwhile, our understanding is that various FHIR data profiles are already available for instance in Denmark, Germany, France, Italy, and the Netherlands[30].

Adoption of a standard is not alone sufficient – the standard must also achieve widespread use. The Commission must take an active role in promoting the use of whatever standard is ultimately adopted, but the cooperation of the Member States is sure to be needed as well.

These are very important considerations, but the degree to which they need to be reflected in the operative text of the EHDS Regulation is unclear. It may be more important to note the potential availability of funding in the recitals. The potential need for follow-up is primarily a consideration for the Commission, not necessarily something that needs to appear in the Regulation.

[29] HL7, "International Patient Summary Implementation Guide ", available at https://hl7.org/fhir/uv/ips/.

[30] A list of FHIR packages appears at: https://registry.fhir.org/results?latestFilter=true&fhirVersionFilter=%5B%22R4%22%5D&jurisdictionFilter=%5B%22http%3A%2F%2Funstats.un.org%2Funsd%2Fmethods%2Fm49%2Fm49.htm%23001%22%5D.

Recommendation 4. Consider noting in the recitals the importance of motivating active Member State participation in EHDS by means of EU funding.

Recommendation 5. The Commission should be aware of a likely need for follow-up in order to ensure that Member States implement EHDS promptly and fully.

Recommendation 6. To facilitate interoperability, the Commission should ensure that a single prominent European or international health data standard (such as FHIR) is adopted at European level. The Commission push for the standard that is selected to be used as widely as possible for all EHDS purposes in all Member States.

4.5. Implementation incentives and risks

The EU framework for health data uses is ambitious and entails several implementation challenges, which the current proposal does not fully address. Given the diversity of national policy on health data and the likely resistance of Member States on subsidiarity grounds, the negotiations will have to aim at delivering a balanced proposal with incentives for all actors to deliver a European Health Data Space.

Sections 4.1 and 4.2 have highlighted the heavy burden on public authorities with the establishment of health data access bodies which will have to request data from data holders, to issue permits, to implement privacy and security provisions, and to supervise secondary uses. With that in mind, Sections 4.1 and 4.2 have made proposals to lighten the tasks of the health data access bodies.

This report has highlighted the lack of incentives for healthcare providers to use EHR and to share data as a market failure, and has made the point that this legitimises the approach of mandating the supply of primary and secondary uses of health data. Healthcare professionals and healthcare providers will have to change their medical practices and administrative systems in order to meet the new obligations for both primary and secondary uses. Progress in the Member States is likely to be very uneven: the ways in which Member States will implement the exemption of microenterprises for data sharing, and the difference between Member States mandating or not the use of EHR by health professionals, will reflect different degrees of national ambition in the EHDS project. Will GPs and family doctors have to use EHR, or will they keep permanent exemptions? Member States will have to develop EHR systems, but the sectoral legislation might not allow them to mandate electronic formats for medical records; consequently, the evolution to EHR might meet with resistance from healthcare professionals. All of this implies that the outcome of the EHDS might very well prove to be a very patchy European data space with large segments of EU health systems either not connected to the EHR, or connected for only a limited scope of data.

The success of the EHDS legislation will depend on its ability to provide more incentives for health professionals to participate. In other words, the proposal should generate some key improvements in healthcare systems and healthcare outcomes. More thought should go into a strategic view on how to build a digitised health services sector on top of a data infrastructure network.

Even a perfectly interoperable EHR system would likely not be sufficient in and of itself to achieve better health outcomes at lower cost. Jacobides et al. (2021, p 29-30) argue that "value-based health delivery networks will need to rely on an ecosystem of federated platforms that can connect care pathways and exchange data in an interoperable way – rather than the winner takes all model typically associated with multi-sided platforms". The authors argue that ecosystems require an orchestrator. Health insurers which have a strong network potential within health systems have played a role, and could play an even greater role in that respect. University hospitals, which are both data holders and users, could also play a leading role.

An additional response to the lack of incentives to data generation and sharing would be to make sure that the EHDS provides some key deliverables that would provide broad benefits to the general community of healthcare providers. In the overall approach to the EHDS, EU4Health funding is an essential add-on to the legislative proposal. Funding can speed up implementation and can help to create a critical mass of European information commons as proof of concept through support and joint efforts in some areas (registries, genomics, image libraries, pharmacovigilance, and more). However, EU4Health funding alone will not suffice for a successful implementation of the EHDS. In the United States, the 21st Century Care Act has specific provisions aiming at creating an Information Commons for research and clinical purposes purposes (Majunder et al., 2017). While Article 33 of the EHDS defines data for secondary use that include such datasets, it does not commit to deliver any key large datasets. This avenue could be explored to build a successful implementation roadmap for medical research.

Recommendation 7. Mitigate the risk of an implementation deficit by increasing incentives for health professionals to participate in data creation and sharing and by identifying some large data sets of general interest for healthcare providers.

4.6. Purposes of secondary use

Articles 34 and 35 of the EHDS present lists of respectively permitted and prohibited secondary use. It is unusual for a regulation to contain both a positive and a negative list. There are likely to be uses that are not mentioned in these lists and would fall into a legal void. A single list of prohibited uses might therefore be sufficient, especially because Article 35 includes a general provision that prohibits any uses that may be harmful to persons. The main purpose of prohibitions here is to avoid harmful innovation.

The permitted purposes are very broad (Article 34(1) EHDS), and include "development and innovation activities for products or services contributing to public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices". Commercial application is thus permitted. The breadth of permitted secondary use potentially raises risks as well. Any natural or legal person can request data for purposes of secondary use (Article 45 EHDS).

These lists reflect a prescriptive and precautionary approach, as opposed to an innovation approach that leaves freedom to innovators and seeks to maximise health data-driven innovation. It is important to keep in mind that there is a negative trade-off between precaution and innovation. More stringent precautionary measures will reduce the extent of innovation that can be produced with the data. A fine-tuning of these lists together with additional flanking measures could push that negative trade-off boundary outwards, towards more innovation for the same degree of precaution.

For example, the prohibitions focus very much on harm to individuals as patients or consumers. The impact of some types of secondary use on the position of health service providers is not considered. While secondary use data are in principle anonymous (unless consent has been given) and therefore protect the identity of patients, anonymity is not guaranteed for health service providers. Medical doctors' liability may be at stake, and rightly so, when researchers discover service providers with inappropriate diagnostics and prescription behaviour.

Going beyond liability, Article 33 EHDS specifies that data containing trade secrets shall be made available, but confidentiality should be preserved. It is not clear here what is meant by trade secrets in the context of digital data in general (Radauer et al., 2022) or health data in particular. Contrary to production data in industrial firms, health services production data are usually co-generated by

medical service providers and patients. Both parties have a claim to the data. Excluding one party, the patient, by granting an exclusive trade secret right to the other party, the service provider, would represent a denial of the co-generated status. The reference to trade secrets in health could imply that technical details on medical treatments and diagnostics procedures that could be considered as trade secrets of medical service providers (doctors and hospitals) are excluded from the patient's personal dataset. Recital 64 refers to trade secrets in clinical trial data. Secondary use generates Real World Data that can be used to redo trials. On the other hand, protection of trade secrets in medical treatment procedures can be achieved by means of anonymisation of the identity of the medical service provider in secondary data use. Service provider identities are useful however when a researcher wants to compare performance across service providers. In short, it is not clear what interpretation should be given to trade secrets in Articles 33(4), 34(4) and 37(1)(f) EHDS. Note that the EHDS mentions trade secrets only in the context of secondary use, not in the context of primary use.

Introducing supply side confidentiality may become important when we consider the prohibition of secondary use for advertising and marketing purposes (Article 35(c) EHDS). Research for advertising and marketing purposes may still be useful (because it has an informative component, besides a persuasion component) if the identity of service providers is hidden, so that it cannot be used for targeted advertising but could still have value for overall planning of advertising and marketing campaigns. Market research on prescription behaviour may bring more transparency in pharmaceutical product markets; it increases competition and may improve the quality of medical services.

Similarly, research for insurance purposes can be useful when not targeted at specific persons. Insurance companies may offer clients rewards for more healthy behaviours, or increase premiums for risky behaviours – just as car insurance companies may reward safe drivers with discounts. More importantly, insurance companies could make use of secondary health data to narrow the information asymmetry gap and to design more efficient incentive structures for healthcare providers (Fainman et al., 2020). It is not clear to what extent the Article 35(b) EHDS prohibition on the secondary use of electronic health data to modify insurance premiums would also apply to modifications in pricing of reimbursements of specific treatments. Such modifications would be the normal outcome of improvements in incentive structures for healthcare providers, in particular if an insurance company were to decide to move from payment-per-transaction to outcome-based payment systems (Fuloria and Zenios, 2001; Ma and Mak, 2019).

The EHDS as proposed obliges public and private health authorities to make health data available to private commercial firms for secondary use, but it places no corresponding obligations on commercial firms to make their data available. This approach risks exacerbating information asymmetries between the commercial firms and the public sector. In fact, the borderline between private and public health services providers, and thus between organisations that should (not) provide access to EHR data, is not very clearly defined in the EHDS.

Moreover, while the purpose of secondary uses such as policy making, other regulatory activities and research have well-defined perimeters either through legislation or because they are performed by actors who are easy to identify, the concept of innovation is much more difficult to interpret in practice. Its operationalisation might differ across Member States.

Taking all of this together, the current draft proposal does not provide legal predictability and might be undermined by diverging national practices.

The decision on how broad the purpose for secondary uses should be, and how specific prohibited uses should be, is political. Examples show a wide variety. In the United States, they have opted for the principle of "no information blocking" with a list of exceptions to this principle. In Germany, the health data access body deals exclusively with permits for public research. It is legitimate for the EU to target high ambitions through a broad scope for secondary use of health data. But the current list of services permitted for secondary use (Article 34 EHDS), and a list of prohibited activities (Article 35 EHDS), can lead to potential lacunae or inconsistencies, and ultimately to legal uncertainty.

Recommendation 8. Streamline the drafting of the permissible purposes and prohibitions associated with secondary use of health data in order to improve legal certainty. Review the list of prohibited purpose to see if all should really be prohibited. Review in particular the restrictions on secondary use of electronic health data by insurance companies, and the prohibition on secondary use of electronic health data for informative marketing campaigns.

Recommendation 9. Clarify the meaning of trade secrets for health service providers when data are co-generated between patients and service providers.

4.7. Coherence

The EHDS is one of the first proposals for a vertical (sectoral) data access regulation, to be introduced after the Data Act proposals for horizontal or cross-sectoral data access rules. It also interacts with several other data regulation initiatives, including the Data Governance Act and the GDPR. Interaction with the Digital Markets Act may also become more relevant as the gatekeepers targeted by that Act become more active in the health sector. It is important to ensure coherence and consistency between all these data policies and regulations. For example, the Data Act entitles product manufacturers and other *data holders* to remuneration for third party primary use of the data generated by their products. The EHDS refers to fees for *data providers* only in the context of secondary use in health data pools, not in the context of primary use. Are EHDS data providers equivalent to data holders in the Data Act? Who are the third parties in primary use and how do these provisions affect the rights of health product manufacturers?

Another example relates to the distinction between raw and processed data. The EHDS extends data portability from raw personal data (as foreseen in the GDPR) to processed data. For instance, doctors' diagnostics or processed machine and laboratory data are included in the scope of data portability. The Data Act focuses on primary data while the DMA seems to ignore that distinction. Since the EHDS is the first in what is expected to be a long series of EU sectoral data space regulations, it would be advisable to consider under which conditions this distinction still makes sense.

The EHDS proposal takes pains to reconcile the proposed Regulation with GDPR, DGA, and with pending legislative measures, but the Data Act and the Artificial Intelligence Act represent "moving targets".

The question of which act takes precedence in the event of an inconsistency is crucial. The EHDS legislative proposal notes in many instances that it has proposed something in *derogation* from some other legislative measure, which is clear. It would also be possible to specify that the EHDS is *lex specialis* relative to some other legislative measure, which would also be clear.

Despite the care that the Commission has taken in drafting, there may be cases where two laws conflict due to concerns over fundamental rights. For instance, the DMA prohibits data combination, even if users agree; the GDPR, however, allows data combination under the user's voluntary consent. One might argue that GDPR prevails over the DMA because it protects the fundamental rights of data subjects (consent is a fundamental element of the GDPR). Therefore, while the DMA provision

is specific to some firms in the digital sector, the fundamental rights of the GDPR might prevail. Issues like these might need to be resolved by the courts.

Recommendation 10. Take care to ensure that the EHDS as enacted is consistent with other legislative measures, paying special attention to those being enacted in parallel with it.

5. RECOMMENDATIONS

In this section, we collect the recommendations that were developed elsewhere in this report, along with the number of the page on which they are explained.

Recommendation 1. Amend the EHDS proposal to clarify the degree to which centralised versus decentralised infrastructure is permissible. A structure that permits full decentralisation, but also enables Member States that desire some degree of centralisation to implement it, appears to have merit. 41

Recommendation 2. The authority and responsibilities of the health data access body should be carefully reviewed, with a particular focus on the proposed Art 37 and Art 39 EHDS. It may be unnecessary or unproductive to assign too many different tasks to the health data access body. Broadening the scope of exemptions from the procedure of obtaining a data permit via the health data access body should also be considered. 42

Recommendation 3. Expand the Recital 67 discussion of subsidiarity to better link domestic aspects of primary use to the prerogatives of the Union as expressed in the Treaties. 45

Recommendation 4. Consider noting in the recitals the importance of motivating active Member State participation in EHDS by means of EU funding. 47

Recommendation 5. The Commission should be aware of a likely need for follow-up in order to ensure that Member States implement EHDS promptly and fully. 47

Recommendation 6. To facilitate interoperability, the Commission should ensure that a single prominent European or international health data standard (such as FHIR) is adopted at European level. The Commission push for the standard that is selected to be used as widely as possible for all EHDS purposes in all Member States. 47

Recommendation 7. Mitigate the risk of an implementation deficit by increasing incentives for health professionals to participate in data creation and sharing and by identifying some large data sets of general interest for healthcare providers. 48

Recommendation 8. Streamline the drafting of the permissible purposes and prohibitions associated with secondary use of health data in order to improve legal certainty. Review the list of prohibited purpose to see if all should really be prohibited. Review in particular the restrictions on secondary use of electronic health data by insurance companies, and the prohibition on secondary use of electronic health data for informative marketing campaigns. 50

Recommendation 9. Clarify the meaning of trade secrets for health service providers when data are co-generated between patients and service providers. 50

Recommendation 10. Take care to ensure that the EHDS as enacted is consistent with other legislative measures, paying special attention to those being enacted in parallel with it. 51

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This research paper provides an assessment of the legislative proposal for ''The European Health Data Space'', including linkages with other EU measures and with Member State rules and laws. It also includes recommendations on further steps needed in order to achieve, facilitate and improve health data sharing, exchange and re-use across the EU.

This document was provided by the Policy Department for Economic, Scientific and Quality of Life Policies at the request of the committee on Industry, Research and Energy (ITRE).

PE 740.054
IP/A/ITRE/2022-06

Print ISBN 978-92-848-0031-5 | doi: 10.2861/09933 | QA-03-22-242-EN-C
PDF ISBN 978-92-848-0030-8| doi: 10.2861/88936 | QA-03-22-242-EN-N