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# The European Health Data Space: An expanded right to data portability?

Wenkai Li *, Paul Quinn

*Health & Ageing Law Lab (HALL), Law Science Technology & Society Research Group (LSTS), Faculty of Law and Criminology, Vrije Universiteit Brussel, Brussels, Belgium*

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ABSTRACT

The European Commission recently released its proposal for a Regulation giving rise to a European Health Data Space (EHDS), as the first domain-specific common European data space under the European Union's data strategy. The proposed EHDS aims to improve access to and control by individuals of their personal electronic health data in primary use and increase data availability for secondary use purposes. This article is primarily concerned with the ambition to enhance the right of natural persons to data portability and promote interoperability in the health sector. This article seeks to delineate to what extent they represent a new and expanded right alongside the right to data portability provided in the General Data Protection Regulation (GDPR). In comparing this new expanded right to the original right outlined in Article 20 of the GDPR, the authors argue that Article 3(8) of the EHDS proposal represents an important expansion with the potential to allow individuals more possibility to control and mobilise their electronic health data, especially those elements located within Electronic Health Records (EHRs). This will also be facilitated by the strengthened interoperability requirements foreseen by the EHDS proposal. However, this paper also identifies several limitations and inconsistencies in the new data portability right which could potentially hinder its functioning. This notably includes the proposal's failure to take into account the need for data portability for secondary use purposes, and the unclear relationship of Article 3(8) of the proposal with Article 9 of the GDPR. It is recommended that these points should be considered carefully in future versions of the EHDS proposal.

## 1. Introduction

The European Commission recently released its proposal for a European Health Data Space (EHDS).[1] It will be the first new data space in line with the EU's proposed data strategy.[2] Its principal aims are to compel far greater sharing of health data for primary use and to make more health data readily available for secondary use purposes. In terms of the former, the EU intends to facilitate an increased level of sharing by creating common technical standards and infrastructure at the European level and imposing an obligation to make certain categories of data from Electronic Health Records (EHRs) available to healthcare providers across Europe. Despite having an implicit link to a common understanding of a notion of data portability, this goal does not however itself constitute an attempt to facilitate data portability as defined in the General Data Protection Regulation[3] (GDPR) (i.e., a transfer of data between two controllers instigated by the data subject).

In parallel to this principal goal, the draft proposal appears (in a non-prominent manner) to suggest a new data portability right that applies

*Abbreviations:* Article 29 Data Protection Working Party, WP29; Data Governance Act, DGA; European Data Protection Board, EDPB; European Data Protection Supervisor, EDPS; European Health Data Space, EHDS; Electronic Health Records, EHRs; General Data Protection Regulation, GDPR.

* Corresponding author: Health & Ageing Law Lab (HALL), Law Science Technology & Society Research Group (LSTS), Faculty of Law and Criminology, Vrije Universiteit Brussel, Pleinlaan 2, 1050 Elsene, Brussels, Belgium

*E-mail address:* wenkai.li@vub.be (W. Li).

[1] European Commission, 'Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space' COM(2022) 197 final <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52022PC0197> accessed 29 June 2023 ('EHDS proposal'). For the avoidance of doubt, all 'EHDS proposal' mentioned in this article refers to this version.

[2] European Commission, 'A European Strategy for Data' (communication) COM(2020) 66 final <https://ec.europa.eu/info/strategy/priorities2019-2024/europe-fit-digital-age/european-data-strategy_en> accessed 29 June 2023. This document is cited with the explanatory materials provided with the proposal.

[3] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) [2016] OJ L119/1 ('GDPR').

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to data being utilised within what it terms the 'primary use' of health data (i.e., loosely related to the provision of healthcare or related services).[4] This new right would seem to go beyond the right of data portability outlined in Article 20 of GDPR in a number of key aspects. The right in question appears to apply in parallel to the main provision on EHR sharing and making secondary data available for research. Though it seeks to go further in a number of ways, it is also explicitly tied to the notion of portability outlined within Article 20 of GDPR.

This article will further explore and analyse the new explicit right to data portability outlined within the EHDS proposal. In particular, it will seek to delineate to what extent it represents a new and expanded right alongside the right to data portability in the GDPR, looking in particular on the limits of the right of data portability outlined in article 20 of the GDPR.[5] Section 2 of this paper will initially explore the concept of portability and how it has evolved in the EU Data protection framework. Section 3 will present an overview of the main elements of the EHDS. Section 4 will look at the seemingly new explicit right to data portability contained within Article 3(8) of the proposal, focusing on how it can be seen as expansive, especially when compared to Article 20 GDPR. Section 5 by contrast will explore the limitations that seem to be foreseen for the application of this right, including most notably that it only applies to data portability requests directed to actors involved in the provision of health care. As the authors of this paper will discuss, this seemingly excludes a range of goals that fall outside of such a context, but which could have scientific, social, and economic benefits for society. Section 6 of this paper will look at new interoperability requirements in the EHDS proposal and their connections to the new right to data portability. The question of whether the new right to portability constitutes a form of *lex specialis* will be approached in Section 7 before the authors present their conclusions in Section 8.

## 2. The right to data portability in the EU data protection legal framework

### 2.1. EU Data Protection Law did not foresee data portability as a right prior to the GDPR

Despite its high profile and existence as a household name, the GDPR did not represent the beginning of the EU's data protection framework. The first initiative was Directive 95/46/EC (Data Protection Directive).[6] This laid down the main pillars of the European data protection framework and elements which to a large extent also formed the mainstay of the GDPR. These include the need to have a legal base for processing, the obligation to respect data processing principles and the requirement to facilitate a number of data subject rights.[7] There was no explicit right to data portability in this first iteration of the EU's data protection framework.

Amongst the rights that were outlined, however, was included a 'right of access' to one's data and the right to rectify it when it is incorrect. [8] Whilst the 'right of access' has some similarities to a 'right of data portability' there are also important differences. Most notably, the latter does not entail providing the data to the data subject but rather transferring it to another data controller of his or her choice. This can have important benefits, in particular, when it is technically or organisationally difficult for a data subject to transfer the data themselves (i.e., after using their right to access). The absence of a right of portability (even where a right of access is foreseen) can therefore represent an important impediment for data subjects wishing to transfer their data from one controller to another. This includes the healthcare sector where inter alia Electronic Health Records (EHR) are complex and may require technical expertise to extract, transfer and integrate them into new healthcare contexts.[9]

### 2.2. Important elements of 'Right of portability' not presented in a 'Right of access'

As one of the authors of this paper has previously discussed,[10] a right to portability must contain a number of elements to be meaningful. The most important of these elements are described below.

#### 2.2.1. An interoperability requirement

A 'right of access' may not provide a right to receive personal data in a form that is 'interoperable' with the processing systems of another potential controller, including those based within the healthcare sector. This was for example the situation with the right to access in the Data Protection Directive.[11] Providing data in a form that is 'intelligible' (as was required by the Data Protection Directive) to the data subject does not entail providing data in a form that is functionally readable by other controllers. 'Intelligibility' is not concerned with the ability of a dataset to be useable by other information processing systems but would rather seem to refer to the ability of humans to be able to comprehend the information that is provided. 'Intelligible' can thus best be thought of as a duty to provide data, even where it is complex in some manner that will allow human data subjects to comprehend it in terms of what can be deduced from it. In the modern information society where data sets may be enormous and complex, this may be in reality translated into a duty to effectively summarise the data in 'human-readable format' so that the data subject can understand it. Providing data in its raw form would be unlikely to meet a duty to provide intelligible data, largely because it would be meaningless to the data subject (given that such data would be stored in a way that is machine-readable). In order to ensure portability, it is thus necessary to make efforts to make data 'interoperable'.[12] This entails providing data to the chosen data controller in a way that it should be possible to make use of it. How this occurs in a specific context is a largely technical matter (and beyond the scope of this paper). This process can be facilitated however by the existence of standards concerning data formats in general and more specifically relating to interoperability. To be most effective, the adoption of such standards should be mandated by law.

[4] The right in question is outlined in Article 3(8) of the EHDS proposal. This article falls within Section 2 which relates entirely to the use of electronic health data for primary use. The definition of 'primary use' is located in Article 2(2)(d). It should be noted that primary use is also described as including 'relevant social security, administrative or reimbursement services'.

[5] Article 20 of the GDPR outlines a general right of data portability. The main contours of this right are further discussed in Section 2.3.

[6] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data [1995] OJ L281/31 (Data Protection Directive).

[7] These are outlined in art 5 (data processing principles), art 6 (the need for a legal base) and ch 3 (data subject rights) of the GDPR respectfully.

[8] Data Protection Directive, art 12.

[9] Aysem Diker Vanberg, 'The Right to Data Portability in the GDPR: What Lessons Can Be Learned from the EU Experience?' (2018) 21 Journal of Internet Law 12.

[10] Paul Quinn, 'Is the GDPR and Its Right to Data Portability a Major Enabler of Citizen Science?' (2018) 18 Global Jurist <https://www.degruyter.com/document/doi/10.1515/gj-2018-0021/html?lang=en> accessed 18 January 2023.

[11] Data Protection Directive, art 12.

[12] For a good exploration of these issues, see Wenlong Li, 'Data Portability as a New Means of Data Protection? Examining the Right to Data Portability in the EU General Data Protection Regulation' (PhD thesis, the University of Edinburgh 2019) <https://era.ed.ac.uk/bitstream/handle/1842/36649/Li2019.pdf?sequence=1&isAllowed=y> accessed 29 June 2023.

#### 2.2.2. A duty to facilitate a data transfer

Data portability should allow a data subject to demand data transfer from one controller to another where necessary.[13] This is important for a number of reasons. Perhaps most importantly, the data controller is likely to have a higher level of technical ability and experience than the data subject. It may have numerous personnel and superior technical abilities (in comparison with an individual data subject). It may also importantly possess a key advantage in terms of economies of scale. This is because a single service provider, especially if it is a large one with a key position in the market (including medical services), may receive many requests from individuals who wish that their data be transferred. In such a context it will usually be easier for the data controller to discern the necessary technical and organizational arrangements that must be made in order to facilitate transfer than it will be for the data subject.[14] An alternative scenario whereby things could only go through the data subject and whereby data controllers had to liaise individually with every data subject on technical adjustments that would have to be made in order to facilitate transfer would in reality be much more complex. Such discussions would be time-consuming and likely be difficult given that individual data subjects would not be likely to possess the same technical knowledge or abilities. The ability therefore to keep discussion on technical issues with one or a few data controllers where needed would therefore be advantageous in terms of promoting interoperability.

### 2.3. The right to data portability in the GDPR

Unlike Directive 95/46/EC, the GDPR includes a new right to data portability. Article 20(1) states:

> '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.'*

There are two things that are immediately apparent and of potential relevance given the discussion above in Section 2.2. The first is that there is a right to receive data in a 'machine-readable format'. This appears to supplement the GDPR's right to access (discussed above) and link it firmly with a right to data portability. As discussed above, this is important from the perspective of interoperability of the data in question, including where the data in question concerns human health. The second is that it bestows the right upon a data subject to ask for direct transfer to another controller where 'technically feasible'.[15] Article 20 can therefore be thought of as an improvement of the situation *vis-à-vis* offering data subjects 'interoperability'. It offers inter alia increased possibility for data subjects to transfer their health data from one controller to another. At the same time, there are however a number of important elements that will likely serve to limit the ability of individuals and researchers to use this article, especially in some important areas that concern health data. The most important are summarized in the sections below.

#### 2.3.1. Limits to the concept of 'structured, commonly used and machine readable' data format

Whilst this concept might sound promising, it is important not to read it in a too expansive manner. In particular, a duty upon data controllers to produce data that is 'structured, commonly used and machine-readable' does not entail an obligation to make such data compatible for all purposes that might be desired. As the Article 29 Working Party (WP29) pointed out when discussing Article 20 of the GDPR, 'portability aims to produce interoperable systems not compatible systems'.[16] The latter (i.e., compatibility) would entail an obligation upon the data controller to ensure that the data provided was directly compatible with the intended purposes and processing systems of the proposed new controller (to whom the data was to be passed). Although such a vision would make things easier for both the data subject and the new controller (who would receive data that would be directly ready for use), this would represent a heavy burden (if not impossible) that almost entirely falls on the original controller to ensure that the data that was being transferred was completely compatible (i.e., ready to use) with whatever processing systems were being used by the new controller. Given that there could be numerous different formats and systems used by a new controller, this would effectively mean a duty to modify and tailor data to the needs of any data controller that a data subject demanded transfer to. Such a duty would likely act as a deterrent to data processing in general given that data controllers would have to ensure that they had the capacity (in terms of both personnel and technical expertise) to make such modifications if they were demanded.

It is for such reasons that a duty of 'compatibility' of transferred data was not deemed realistic by the drafters of the GDPR. As for the notion of 'interoperability', the European Commission has defined it as 'the ability of disparate and diverse organisations to interact towards mutually beneficial and agreed common goals, involving the sharing of information and knowledge between the organisations, through the business processes they support, by means of the exchange of data between their respective ICT systems'.[17] Compared to 'compatibility', 'interoperability' represents a lower threshold and consequently poses less of a burden on the original data controller. Such a duty represents a shared burden where not only the original data controller but also the recipient (a research institution in this context) would have to make efforts to ensure compatibility. This is because interoperability normally involves a duty to use one of several commonly available formats. Interoperability thus entails work for both the original controller, who must ensure that the data meets such a format and for the recipient who will have to further process the data into a new form that is compatible with its desired purposes. Nevertheless, Article 20 of the GDPR does not amount to a duty of 'interoperability' either, as confirmed by the opinion of WP29, where it is stated that 'structured' 'commonly used' and 'machine readable' are 'a set of minimal requirements that should facilitate the interoperability of the data format provided by the data controller'[18] In other words, while the three 'means' are mandatory in the GDPR, the outcome of interoperability is only 'suggested'.[19] Therefore, although an advancement on the Data Protection Directive, the GDPR's data portability obligation to provide data that is 'structured, commonly used and

[13] Barbara Engels, 'Data Portability among Online Platforms' (2016) 5 Internet Policy Review <https://policyreview.info/articles/analysis/data-portability-among-online-platforms> accessed 2 March 2023.

[14] Jan Krämer, 'Personal Data Portability In The Platform Economy: Economic Implications And Policy Recommendations' (2021) 17 Journal of Competition Law & Economics 263.

[15] This is explicitly confirmed in art 20(2) of the GDPR which states: 'In exercising his or her right to data portability pursuant to paragraph 1, the data subject shall have the right to have the personal data transmitted directly from one controller to another, where technically feasible.'.

[16] Article 29 Data Protection Working Party (WP29), 'Guidelines on the right to data portability' (2017) 17.

[17] European Commission, Directorate-General for Informatics, 'European interoperability framework (EIF): towards interoperability for European public services' (2011) <https://data.europa.eu/doi/10.2799/17759> accessed 30 June 2023.

[18] WP29 (n 16) 17.

[19] Paul De Hert and others, 'The Right to Data Portability in the GDPR: Towards User-Centric Interoperability of Digital Services' (2018) 34 Computer Law & Security Review 193.

machine-readable' represents a limited vision in terms of what data portability entails.[20]

#### 2.3.2. Article 20 only applies to personal data provided by data subjects themselves

Another important caveat that should be placed on the right of data portability as described by the GDPR is that it applies only to 'personal data provided by the data subject'.

Firstly, it may appear self-evident that the right to data portability doesn't apply to data without a personal nature, including anonymised data, as the GDPR only applies to personal data.[21] In the area of health data, this could exclude for example certain images or test results where relevant metadata have been removed, insofar as the identification of the relevant individual is extremely difficult.

More importantly, Article 20 GDPR requires that the data that is subject to the right to data portability has to be provided by the data subjects themselves. This importantly excludes all other forms of secondary personal data that have been derived from further processing. This includes, most notably in the area of health data, all forms of inferred data, for example, the results of various forms of analysis that have been performed on the original data. In a world where complex processing using inter alia various forms of artificial intelligence is increasingly becoming the norm (including the area of health), this limitation means that a wealth of analysis, inferences and useful conclusions based on further processing (of data that the data subject had originally provided) would be excluded, which will no doubt be of relevance to others who might want to provide services to data subjects in the future, including in the health sector. This important restriction of the right to data portability was seemingly placed into the GDPR to protect the commercial secrets and strategies of data controllers who may have developed innovative forms of data analysis to produce inferred data. Consequently, as Section 4 will discuss in more detail, the inclusion of the inferred data in the form of portability envisaged in the EHDS proposal represents a major innovation.

#### 2.3.3. Article 20 only applies to data processed under a very limited range of legal bases

Article 20 GDPR is also limited given that it only applies to data that is processed on the basis of two (of the many) grounds that are described in the GDPR. These cover data that is processed after obtaining the (explicit) consent of the data subject or alternatively that the processing was 'necessary for the performance of a contract to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract'.[22] These grounds will cover some but by no means all of the potential types of personal data that might be thought to be of relevance in the processing of health data.

The first may for example cover the types of relationships described above where individuals agree through formalised processes of consent to provide their data so as to have it stored and or further processed. This could include for instance lifestyle monitoring services or certain forms of processing related to healthcare (where consent is the basis for processing). It may also interestingly include data that had previously been provided to researchers or scientific institutions precisely for the purpose of research (again where consent was the legal basis for processing).

With regards to the second ground discussed above, one can imagine various contracts that may have been concluded with various organisations to provide services or deliver physical products. Imagine for instance streaming services for movies or music, online stores such as Amazon etc. Whilst such information may appear banal viewed from the perspective of a single individual, on a larger scale (i.e., where such data is available for many individuals), it may provide extremely useful research material, allowing important information relating to socio-economic factors or even health status. Article 20 thus provides the option of transferability for such data.

However, Article 20 GDPR does not include a range of other contexts in which health data is commonly processed (and for which different legal bases are used). This includes most importantly where processing in the health care sector is based on Article 9(2)(h), i.e. for occupational medicine.[23] This is a mainstay of data processing in the healthcare sector where the need to continually obtain consent would not be practicable.[24] As a result, vast amounts of health data are obtained and further processed on this basis in healthcare, without the involvement of either consent or a contract.[25] Its exclusion from Article 20 of GDPR means that patients will not be in a position to demand the application of the right of data portability in many circumstances.

## 3. An overview of the European Health Data Space and its new requirements on data portability

### 3.1. Background

The European Commission has the ambition to make Europe a leader as a 'data driven society'. In doing do so, it has, as part of its 'Data Strategy', decided to create a number of 'data spaces'.[26] These represent areas of increased co-operation in terms of data sharing. According to the Commission the concept has three key pillars. They will:[27]

(i) *deploy data-sharing tools and services for the pooling, processing and sharing of data by an open number of organisations, as well as federate energy-efficient and trustworthy cloud capacities and related services;*
(ii) *include data governance structures, compatible with relevant EU legislation, which determine, in a transparent and fair way, the rights concerning access to and processing of the data;*
(iii) *improve the availability, quality and interoperability of data – both in domain-specific settings and across sectors.*

The creation of such spaces will accordingly be facilitated by the creations of new architectures to facilitate data sharing where there is an

[20] See Section 6 which elaborates on the interoperability requirements proposed in the EHDS building on the GDPR.

[21] WP29 (n 16) 9, 'Only personal data is in scope of a data portability request. Therefore, any data that is anonymous or does not concern the data subject, will not be in scope. However, pseudonymous data that can be clearly linked to a data subject (e.g., by him or her providing the respective identifier, cf. Article 11 (2)) is within the scope.' As Section 4 of this paper will discuss, the EHDS proposal seems to go beyond personal data using a definition of 'electronic health data' that includes health data that is not personal in nature.

[22] GDPR, art 20(1)(a).

[23] Art 9(2)(h) provides a legal base for the processing of sensitive data where it is 'necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services'.

[24] Shahid Munir Shah and Rizwan Ahmed Khan, 'Secondary Use of Electronic Health Record: Opportunities and Challenges' (2020) 8 IEEE Access 136947.

[25] Giorgia Bincoletto, 'A Data Protection by Design Model for Privacy Management in Electronic Health Records' in Maurizio Naldi and others (eds), *Privacy Technologies and Policy* (Springer International Publishing 2019).

[26] A European Strategy for Data (n 2).

[27] European Commission, 'Staff working document on data spaces' SWD (2022) 45 final < https://digital-strategy.ec.europa.eu/en/library/staff-working-document-data-spaces > accessed 26 June 2023.

economic, societal, or scientific reason to do so.[28] Such architectures will be regulated by governance frameworks that the EU will outline in forthcoming legislative acts. The aim behind such an ambition is to improve the overall level of data sharing which at present has not been optimised due to a range of legal and technical barriers in addition to a general reticence to share data.[29] This is the main motivation behind the European Health Data Space.

### 3.2. Main structure

The European Health Data Space is the first 'data space' to receive a detailed proposal by the commission. At the time of writing, it was continuing its legislative process through various EU institutions. The proposal aims to primarily increase the sharing of health data in two aspects:

(i) *Primary use*

Primary use is related to the provision of health care, being described as activities involving 'the processing of personal electronic health data for the provision of health services to assess, maintain or restore the state of health of the natural person to whom that data relates, including the prescription, dispensation and provision of medicinal products and medical devices, as well as for relevant social security, administrative or reimbursement services'.[30] In Chapter II of the EHDS proposal, a series of rights and mechanisms for enhancing the individual control over their health data in relation to primary use are outlined to complement the data subject rights under the GDPR. In particular, it foresees the creations of uniform standards and technical requirements for Electronic Health Records (EHRs)[31] and will establish a pan European infrastructure that permits the sharing of central elements of EHRs across Europe.[32] This represents an important shift in the EU's strategy.[33] Previously the EU had only sought to encourage technical harmonization and collaboration in terms of cross-border EHR exchange.[34] Such efforts however have only achieved limited success, providing the motivation for the EU to take a more muscular approach in the EHDS proposal.

(i) *Secondary use*

The secondary use relates to the re-use of electronic health data for a range of purposes that are outlined in Chapter IV of the proposal. Many of these relate to research connected to a wide range of themes and purposes. This includes the classic notion of scientific research[35] but also the innovation of new products or services related to 'public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices'[36]. Other areas of permitted use will relate to the need to deal with public health threats,[37] the need to improve the provision of healthcare delivery and related services and education and training-related activities.[38] To make data available for these purposes, the EHDS proposes to create a mechanism where data users can apply to access certain dataset shared by data holders with a data permit issued by the Health Data Access Body. [39]

### 3.3. Data portability in the EHDS

The European Commission has therefore developed the EHDS with multiple goals in mind, all falling under the broad umbrella of making health data more readily available for selected purposes. Central to this strategy the creation of an EHR sharing architecture, the adoption of harmonized technical standards and the creation of a secondary data platform for the further use of data are the main pillars. Within these broader goals, it also seems clear that one of the aims of the EHDS proposal was to improve the 'portability' of health data. This is clearly described in the explanatory materials to the proposal which state:

> *'The GDPR provides the rights to access, to portability and to accessibility/transmission to a new controller of data. […] The EHDS supports the implementation of the rights enshrined in the GDPR as applied to electronic health data. The EHDS builds upon the possibilities offered by the GDPR for an EU legislation on the use of personal electronic health data for medical diagnosis, the provision of health care or treatment or the management of health care systems and services.'*[40]

The above citation arguably confirms that the Commission sees 'portability' as being a related but distinct concept to 'accessibility' (i.e. in line with how the concepts are seen within the GDPR). In terms of the proposed EHDS regulation, we can see that Chapter 2 of the Proposal (i.e. related to primary use) contains elements that are both implicitly and explicitly linked to the notion of 'portability'. The implicit elements can be linked to a common understanding of the notion of portability but do not relate to the right as it is described within the GDPR. The explicit elements appear however to be a direct attempt to improve upon the rights outlined within article 20 of the GDPR. These are outlined below. After briefly reviewing the elements within the proposal that are implicitly linked to data portability, the remainder of this article will focus on the latter category to determine what the new explicit right of portability in the proposal actually entails and how it may differ from the right outlined in article 20 of the GDPR.

#### 3.3.1. Implicit data portability provisions concerning the transferability of EHR elements

Though not described in terms of a 'portability right', the general aim of making Electronic Health Records (EHRs) available throughout Europe (i.e. the aim of chapter 2 of the proposal which is dedicated to 'primary use') for the process of medical treatment is clearly linked to a loose notion of portability. This is because the aim is essentially to allow patients (who are also data subjects) to have their data (i.e., elements of their EHRs) transferred from one healthcare provider to another (i.e., different data controllers). The provisions in the EHDS proposal on primary use are, in general, intended to allow patients to transfer (at

[28] Inga Ulnicane, 'Artificial Intelligence in the European Union' in Thomas Hoerber, Gabriel Weber and Ignazio Cabras, *The Routledge Handbook of European Integrations* (1st edn, Routledge 2022) <https://www.taylorfrancis.com/books/9780429262081/chapters/10.4324/9780429262081-19> accessed 7 March 2023.

[29] For a wider discussion of this, see European Commission, Joint Research Centre, 'Emerging Approaches for Data-Driven Innovation in Europe: Sandbox Experiments on the Governance of Data and Technology' (2022) <https://data.europa.eu/doi/10.2760/630723> accessed 23 October 2023.

[30] EHDS proposal, art 2(2)(d).

[31] EHDS proposal, ch III.

[32] EHDS proposal, art 12.

[33] Stefano Genovese and others, 'The European Health Data Space: A Step towards Digital and Integrated Care Systems' (2022) 30 Journal of Integrated Care 363.

[34] One of the most important examples of such an approach was the Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare [2011] OJ L88/45.

[35] EHDS proposal, art 34(1)(e).

[36] EHDS proposal, art 34(1)(f). Art (34)(1)(g) also permits the reuse of secondary data for training AI algorithms for similar purposes.

[37] EHDS proposal art 34 (1)(a) for example permits re-use for 'activities for reasons of public interest in the area of public and occupational health, such as protection against serious cross-border threats to health, public health surveillance or ensuring high levels of quality and safety of healthcare and of medicinal products or medical devices'.

[38] EHDS proposal, art 34 (d).

[39] EHDS proposal 71-83 (Ch IV, Section 2 & 3).

[40] EHDS proposal 3.

least some data) data from one healthcare provider to another in order to facilitate treatment. Such transmission will be facilitated by the requirements within the proposal on the harmonisation of EHR technical standards throughout the EU (something that hitherto has not been compulsory).[41] Doing this entails the ability to have important segments of one's EHR available upon request for access by health professionals in other institutions.[42] The EHDS proposal importantly does not foresee a right to have all of one's EHR accessible but only what it describes as priority categories of data (outlined in Article 5). At present, these include 'patient summaries', 'electronic prescriptions', 'electronic dispensations', 'medical images and image reports', 'laboratory results' and 'discharge reports'. Although important such elements are far from representing the entirety of a patient's EHRs.[43] It is important to note however that although the chapter II provisions of the proposal are undoubtedly loosely linked with a common understanding of portability, they do not constitute a right of data portability in the strict sense (as understood under Article 20 of the GDPR). This is for several reasons. This includes the fact that the general requirement to share EHRs in Chapter 2 only relates to specific elements of a patient's personal data and not all (or even most of them). Furthermore, such sharing would be triggered by requests made by healthcare providers and not by the data subject themselves. This can be contrasted to the right as outlined in article 20 which is triggered by the data subject.

#### 3.3.2. An explicit new right to data portability?

As Section 4 discusses below, the drafters of the EHDS have also created extra explicit rights of data portability, rights which seemingly augment those contained within Article 20 of the GDPR. In particular, Article 3(8) states:

> *'Natural persons shall have the right to give access to or 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 […]'*

Unlike the general framework for EHR sharing (discussed in 3.3.1), the link between these new rights and the issue of data portability is arguably more explicit (despite the fact that the word 'portability' itself is not explicitly mentioned). The location of these rights within Chapter 2 of the proposal suggests that they only apply within the domain of primary use as outlined above and do not apply for purposes linked to secondary use. Interestingly, they seem to apply in parallel to the general system of EHR exchange foreseen by Chapter 2 of the proposal. This means that these explicit rights of portability apply alongside the more general obligations to make EHRs accessible throughout Europe (i.e., described in 3.3.1). This raises questions as to what the inclusion of this explicit right of portability means. What this limited extension entails and how it is likely to apply are discussed in further depth below.

## 4. An expanded right to data portability?

### 4.1. The scope of the explicit right to data portability in the proposed EHDS

As the first sector-specific EU data space emerging from the European strategy for data,[44] the proposed European Health Data Space is meant to build on the data subject rights set out in the GDPR and further develop them.[45] With respect to the right to data portability, the EHDS proposal made reference to the limitations (on the right of data portability) contained within Article 20 of the GDPR (e.g. applying only where certain legal bases are used, not to inferred data as discussed above in 2.3). It points out that these 'may limit its benefits for the provision of high-quality, safe and efficient healthcare services to the natural person'.[46] As is further discussed below, the explicit right outlined in article 3(8) of the proposal is noteworthy because it seemingly does not contain the same limitations as those foreseen by the GDPR. In particular, the proposal states that data subjects have the right to have their electronic health data transmitted directly to another data holder.[47] The notion of electronic health data includes inferred data, that are processed by any private or public data controllers, irrespective of the legal basis for the processing under the GDPR.[48] Consequently, it could be argued that it represents a substantial expansion of the right to data portability, at least within the scope of electronic health data as defined by the EHDS proposal. The following subsections below will further scrutinize these changes, attempting to delineate to what extent they represent a genuine expansion upon the rights outlined within Article 20 GDPR.

### 4.2. The right to data portability in the EHDS applies to all processing no matter the legal grounds

As discussed above in Section 2.3, Article 20 GDPR is limited only to data that is processed after obtaining the consent of the data subject or alternatively that the processing was 'necessary for the performance of a contract to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract'. Whilst important, these legal bases represent the appropriate processing grounds for only a portion of electronic health data. Most importantly, they do not cover non-consent-based processing for medical use and various types of processing related to public health (e.g., for epidemiological analysis). The legal base outlined in Article 9(2)(h) (relating to occupational medicine), in particular, represents a mainstay in terms of the day-to-day processing of EHRs. Whilst perhaps the most important legal base in mainstream healthcare, it is by no means the only legal base potentially excluded by Article 20 of the GDPR. In addition, it is explicitly stated in Article 20(3) that this right does not apply to processing based on tasks of public interest or exercising the official authority vested in the controller.[49] As discussed in Section 2.3 above, this could include the processing of health data for purposes related to public health or epidemiology. Another important legal base that was excluded by Article 20 is that of 'vital interest'. This is important in the context of health care given that in a number of situations (e.g., emergencies) where patients may require medical treatment but are unable to express consent. Unlike the right of portability described within Article 20 GDPR, the right of data portability outlined in Article 3(8) of the EHDS proposal is not limited by the legal base selected.

This expansion is confirmed by Recital 12 of the proposal, which states that a natural person has the right to data portability no matter what legal basis is used for processing the health data in question. On the face of this, many of the other legal bases that are frequently used in

[41] As art 6 of the EHDS proposal states, the European Commission will through implementing acts outline 'the technical specifications for the priority categories of personal electronic health data referred to in Article 5, setting out the European electronic health record exchange format'.

[42] EHDS proposal, art 4.

[43] It should be noted that art 5(2) of the EHDS proposal allows the Commission to create delegated acts in the future to expand this list.

[44] A European Strategy for data (n 2).

[45] EHDS proposal, recital 6.

[46] EHDS proposal, recital 11.

[47] It should be noted that the right outlined in art 3(8) of the EHDS proposal also obliges data recipient to receive the data that has been transmitted. This is not the case with the right outlined in Article 20 GDPR.

[48] EHDS proposal, recital 12. The term 'data subject' is used in recital 12, but not in the relevant articles of the EHDS, in particular art 3(8).

[49] GDPR, art 20(1)(a) and art 20(3).

health care itself or domains which are directly related will be encompassed. Whereas only a portion of healthcare-related activities would have been engaged in Article 20 GDPR, this appears to no longer be the case, and the vast majority of processing activities will seemingly be engaged by the right as envisaged in the proposal. The authors of this paper would accordingly argue that this would represent an important extension in the domain of health care, though care must be taken when interpreting such a provision given that this right is outlined within the chapter of the proposal dedicated to the primary use, which itself receives a complex definition within the proposal (this is discussed further below in Section 5).

### 4.3. 'All personal electronic health data, including inferred data'

The proposed EHDS extends the application of the right to data portability to 'all electronic health data, including inferred data'. In particular, it is clear from the proposal that inferred data should be included within any right to data portability. This formulation contrasts with the requirement in the GDPR that the right to data portability only applies to data that are provided by the data subject to a controller.[50] WP29 points out that 'data provided by the data subject' does not only amount to 'data actively and knowingly provided by the data subject', but also includes 'observed data provided by the data subject by virtue of the use of the service or the device'. [51] Whether interpreted expansively or restrictively, it is clear that the inferred or predicted data produced by data controllers are excluded from the scope of the right in the GDPR,[52] which puts a limit to the possibilities of exercising the right by individuals in reality. The inclusion of all inferred data in the EHDS proposal is therefore an undoubted expansion of the right to data portability.

WP29 refers to inferred data (and derived data) as the data created by the data controller on the basis of the data 'provided by the data subject', often resulting from the subsequent analysis of one's observed behaviours or certain status.[53] This definition could include a range of important data within healthcare practices. In a broad sense, a doctor's diagnosis can be the most common example of inferred data, as it is based on 'raw data' such as patients' complaints and test results. In addition to such traditional examples of medical inferred data, one can add many examples produced by the ascent of digitised, analytic, and interconnected medicine.[54] These trends have allowed data to be weaved together from various sources and analysed in ways that can provide useful information. The input data that inferences result from could be one's physical or mental parameters, such as heart rate, exercise intensity, daily diet, and sleep-wake schedule, often collected by various wellness and lifestyle apps or wearable devices. In the future, with a potentially increased use of predictive medicine, the range of potentially useful data will increase, potentially including data from further sources, such as purchasing habits (e.g., for food) and even social media content.[55]

Undoubtedly, inferred data has immense potential to be utilised. The quality of care can be improved in a more personalised manner if the health inferences from various sources can be shared among various health and wellness services, especially in the contexts of eHealth and mHealth. In this regard, the proposed EHDS seems to encourage and facilitate the integration of numerous non-traditional sources of health data into their EHRs that can be accessed by healthcare professionals, enabled by the new right to data portability.[56] One could for example choose to import their sleep cycles and exercise level into their EHRs and make them available to doctors when needed. Linking health data produced in both medical and non-medical contexts, despite various challenges such as data quality and system interoperability, helps to build a more holistic view of the patient, and especially takes into account the social and environmental factors that may influence health.[57] Given that it is likely that more health inferences are derived from the analysis of digital traces of individuals outside the traditional medical context,[58] it seems possible that the EHR of the future may contain a wider array of inferred data than it does now. The provisions outlined within Article 3 (8) of the proposal are therefore likely to become increasingly important as medicine makes greater use of such data.

### 4.4. The right of portability applies to a broad notion of health data

Given the wording of Article 3(8), one might also ask whether the new right of portability applies to non-personal data in addition to personal data (unlike Article 20 GDPR which clearly only applied to the latter). This is because article 3(8) makes reference to 'electronic health data', which is a central concept in the EHDS. This is defined in Article (2)(c) as including both 'personal and non-personal data'. Such an interpretation would be extremely wide-ranging and raise major questions. This is because the domain of non-personal health data is potentially enormous. It would be capable of encapsulating a range of data from devices and include various data generated by the delivery of health care that may or may not have relevance for specific individuals. The application of a right of data portability to both personal and non-personal data would be challenging for two reasons. *First*, the sheer size of the data involved could be enormous. It would go potentially beyond any personal data on the patient's EHRs and include all types of data generated in the provision of health care to an individual. It is beyond the scope of this paper to outline the boundaries of what such data could include but it would seemingly cover all data related to medical devices used in patient care as well as data concerning the functioning of the organisation itself. The application of a right to data portability to such a range of data would pose serious practical challenges, not only in terms of its potential quantity but also in terms of the need to define it. *Second*, it would be difficult to discern what forms of non-personal data were relevant to a particular individual and thus subject to the application of the right to data portability. It is not clear how a data controller could go about delineating what non-personal data (e.g., relating to the organisation of the institution providing the healthcare) was relevant to a particular individual. Even if it was, it would require considerable deliberation on a case-by-case basis. This would add to problems in terms of the practicability of servicing data portability requests.

For the reasons stated above, the authors of this paper would submit that the application of a portability right to non-personal data would be extremely problematic. We would argue that, despite the unfortunate omission of the word 'personal' before 'electronic health data', the provisions outlined in paragraph 3(8) of the proposal are clearly intended to apply to personal data only. This interpretation is arguably supported by the title of Section I - 'Access to and transmission of *personal* electronic health data for primary use' (emphasis added). [59] It is

[50] GDPR, art 20(1).

[51] WP29 (n 16) 9-10; also see Gauthier Chassang and others, 'Data Portability in Health Research and Biobanking: Legal Benchmarks for Appropriate Implementation' (2018) 4 European Data Protection Law Review (EDPL) 296.

[52] De Hert and others (n 19).

[53] WP29 (n 16) 10.

[54] For example, see Mason Marks, 'Emergent Medical Data: Health Information Inferred by Artificial Intelligence' (2020) 11 UC Irvine Law Review 995.

[55] ibid.

[56] EHDS proposal, recital 10; also see art 31, which for instances foresees a proposal for the voluntary labelling of wellness applications to allow integration within EHRs.

[57] Griffin M Weber, Kenneth D Mandl and Isaac S Kohane, 'Finding the Missing Link for Big Biomedical Data' (2014) 311 JAMA 2479.

[58] Marks (n 54). The term 'emergent medical data (EMD)' is used to refer to such health inferences in contrast with 'tradition medical data'.

[59] Also see Section 5.2 of this article.

argued that this is the only way to avoid a potentially absurd breadth of the right to data portability and one that would make it impossible to facilitate in reality. The authors hope that this discrepancy will accordingly be remedied in the final version of the proposal.

Though of course narrower than 'electronic health data', 'personal electronic health data' remains a very broad concept which is primarily based on 'data concerning health' from the GDPR as defined in the proposal.[60] Two factors are central to creating such a breadth. *First*, 'data concerning health' has been defined in the GDPR as any personal data which can provide an indication of the health status of a particular individual.[61] This goes beyond information indicating that an individual may have a particular health condition and can even include probabilistic assessments about developing a certain condition in the future. It has even been stated that an indication of health status could even include information that ascertains that someone is 'healthy'. *Second*, as one of the authors has discussed in a previous paper, the GDPR approaches the notion of health data (or sensitive data in a broader sense) from a highly contextual perspective, in which the existence of health data is determined by the potential availability of complementary data and the processing abilities of those who have access to the data.[62] In modern contexts this means that the definition of health data is extremely wide and constantly expanding.

This is particularly true when taking into account the ever-increasing computational capacity, data mining technologies and big data applications which allow conclusions related to one's health status to be drawn from all kinds of data indirectly, even if the data is not intrinsically sensitive.[63] While these data are conceptualised by *Malgieri* and *Comandé* as 'quasi-health data',[64] the EHDS refers to them in a similar sense as 'data determinates of health',[65] including relating to 'behaviours, environmental, physical influences, medical care, social or educational factors', all falling under the scope of personal electronic health data.[66] This goes far beyond the data conventionally produced in the medical context, such as test results, diagnoses and prescriptions, but also includes user-generated data from medical devices, smart devices and wearables, digital health and wellness applications, and even potentially include social and environmental factors (for example, income, profession and exposure to pollution).[67] Genetic data and other data in relation to the provision of healthcare services (such as administrative data) are also included in this broad notion by the EHDS. The authors would suggest that such a wide definition of 'personal electronic health data' may have been considered in order to reduce the problems the GDPR presents in defining exactly what health data is. The wide formulation opted for by the EHDS proposal seemingly indicates that an expansive notion is to be used. Whilst this may reduce problems in terms of the need to delineate the boundary between health and non-health data,[68] the mere exclusion of non-personal data here does not help much to solve the practical challenges caused by the overbreadth of the concept with the functioning of the EHDS mechanisms, in particular, the implementation of the new right to data portability.

## 5. Limits to the right of data portability

Despite the obvious ways in which the EHDS ambitiously proposes to expand the right to data portability, there are elements in its formulation that raise questions as to the extent of such an expansion. Some of these are linked to uncertainties in the definition of core concepts within the EHDS. These hinder a clear and coherent understanding of the extent of the expanded right to data portability. These factors raise the question of how far one should go in thinking of the portability right outlined in Article 3(8) as representing a separate and parallel right in addition to the main thrust of chapter 2, i.e., making the sharing of EHRs and other personal electronic health data easier. The most important of these factors are outlined below.

### 5.1. *Limited to transfers from 'data holders' to recipients 'in the health or care sector'*

As with other recent legislative initiatives,[69] the EHDS has opted for a more generic term 'data holder' to refer to entities that bear certain obligations in relation to the data under their control. This is ostensibly for the reason that a 'data controller' as defined within the GDPR is not sufficient in contexts where non-personal data need to be included. The EHDS proposal defines a 'data holder' as:

> *'any natural or legal person, which is an entity or a body in the health or care sector, or performing research in relation to these sectors, as well as Union institutions, bodies, offices and agencies who has the right or obligation, […] to make available, including to register, provide, restrict access or exchange certain data'*.[70]

While Recital 12 of the EHDS proposal calls for a right to portability to be applied to any private or public data controllers, Article 3(8) confines the obligation to react to a natural person's data transfer request to data holders 'from the health and social security sector'. This seemingly narrows the application of the expanded portability right to only a portion of potential data holders. The Joint Opinion issued by the European Data Protection Board (EDPB) and the European Data Protection Supervisor (EDPS) has already pointed out that this formulation may cause inconsistency and confusion with the definitions of 'data holder' in the Data Governance Act and the Data Act.[71] Unfortunately, the wording used in the EHDS proposal, fails to clearly define which actors would be responsible for assisting the individuals in terms of data portability requests, in particular because of an ambiguity about what exactly is covered by the term 'health or care sector' (which was not defined in the original proposal.[72]

Three examples can be used to illustrate the difficulties with the ambiguities that are created here. They relate to areas where individuals might want to invoke a portability right to move electronic health data to actors that might be able to use the data to perform non-healthcare-related functions. The *first* relates to businesses and services that are not strictly medical care but are more well-being-orientated. A common example may be the provision of nutritional advice. In many Member

[60] EHDS proposal, art 2(2)(a).
[61] GDPR, art 4(15).
[62] Paul Quinn and Gianclaudio Malgieri, 'The Difficulty of Defining Sensitive Data—The Concept of Sensitive Data in the EU Data Protection Framework' (2021) 22 German Law Journal 1583.
[63] ibid. Also see Gianclaudio Malgieri and Giovanni Comandé, 'Sensitive-by-Distance: Quasi-Health Data in the Algorithmic Era' (2017) 26 Information & Communications Technology Law 229.
[64] Malgieri and Comandé (n 63).
[65] EHDS proposal, art 2(2)(a).
[66] EHDS proposal, recital 5.
[67] Malgieri and Comandé (n 63).
[68] EHDS proposal, art 2(2)(a).
[69] The concept is also central in Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act) OJ L152/1, art 2(8), and Proposal for a Regulation of the European Parliament and of the Council on harmonised rules on fair access to and use of data (Data Act) COM/2022/68 final, art 2(6).
[70] EHDS proposal, art 2(2)(y).
[71] European Data protection Board (EDPB) and European Data Protection Supervisor (EDPS), 'EDPB-EDPS Joint Opinion 03/2022 on the Proposal for a Regulation on the European Health Data Space' para 29 < https://edpb.europa.eu/system/files/2022-07/edpb_edps_jointopinion_202203_europeanhealthdataspace_en.pdf > accessed 30 June 2023 ('EDPB-EDPS joint opinion').
[72] Petros Terzis, 'Compromises and Asymmetries in the European Health Data Space' (2022) 1 European Journal of Health Law 1.

States, this is not recognised as falling within the definition of medical practice ('nutritionists' may for example not have formal qualifications as medical professionals do).

The *second* type is related to commercial digital applications, services, or products that although not falling under the concept of healthcare, are clearly linked given the data that is used (e.g., genetic data for online genealogy services) can also be used for health purposes. Such services may be data intensive (both in the input data they require and the inferred data they generate). Individuals may have valid reasons to want to transfer their personal health data from or to such entities and their healthcare providers. Unfortunately, at present, it seems (at least from an intuitive perspective) that such areas would fall outside the scope of the 'health or social sector', meaning that individuals could not invoke a right of portability to transfer their data to entities performing such activities.

A *third* illustration relates to potential requests for transfers of data from EHRs to research institutions that conduct health-related scientific research. One could imagine that motivated individuals (e.g., citizen scientists)[73] might want to be proactive in channelling their data to particular research institutions (i.e., in effect circumventing the need for such institutions to submit data access requestions through the Health Data Access Body to be set up by the EHDS). Again, the ambiguity of the language used casts doubts on whether such a request is possible. If one refers to the definition of 'data holder' in the EHDS proposal, however, [74] one sees the phrase 'performing research in relation to these sectors' is juxtaposed with 'the health or social security sector'. This arguably indicates that the former is not considered to be part of the latter, i.e., excluding health research from the 'health and care sector'. If this is true it would mean that portability requests could not be used in order to facilitate such motivated transfers for research purposes given that the intended recipients would seemingly not fall within the 'the health or social security sector'. One cannot by any means be certain about such an interpretation, however. The authors of this paper would argue that the reasons for such a formulation are not clear. It seemingly excludes the possibility for motivated transfers on the part of citizen science to facilitate research with their own data. If it is the intention of the proposal drafters, one would hope that this is made explicitly clear in later versions. In response to this issue, the European Parliament has proposed an amendment to this provision in its draft report on the EHDS proposal to remove this restriction, in favour of data flows enabled by the data portability request being transferred to other sectors.[75]

### 5.2. Limited to the 'primary use'

Despite Recital 12 of the EHDS proposal which stresses that the right applies to all electronic health data, the location of the new portability right also seems to indicate an important limitation — that it is confined to the 'primary use' of electronic health data. This is because it is located within Chapter 2 which is described as related to the 'primary use of electronic health data'. This is defined as[76]:

> '*the processing of personal electronic health data for the provision of health services to assess, maintain or restore the state of health of the natural person to whom that data relates, including the prescription, dispensation and provision of medicinal products and medical devices, as well as for relevant social security, administrative or reimbursement services*'.

A first reading of the above definition suggests primary use is clearly related to a traditional vision of what the delivery of healthcare is. This essentially encompasses medical consultation, diagnosis, or treatment, including the use of medical devices or medicinal substances involved in such processes. It additionally appears to cover administrative and financial aspects surrounding such processes. It could be argued however that the use of the phrase 'assess, maintain or restore the state of health' could be indicative of a wider coverage than traditional medicine. The notion of maintaining good health, in particular, is not something that traditional medical activities are generally occupied with (for better or worse). How far this can be stretched to cover a wider range of activities that are not strictly speaking acts of medicine but may be closely related to such acts is however questionable. This includes wellness-related activities, other commercial activities related to health data and importantly scientific research. The inclusion of such activities within the notion 'primary use' seems uncertain. Similarly, data collected for the purpose of, for example, clinical trials will constitute 'the secondary use', seemingly excluding them from the new right of portability envisaged in Article 3(8) of the proposed EHDS.

In addition, whilst the explanatory note in the proposal uses the word 'health professionals' in describing Chapter II,[77] this term does not find prominence in the legal text itself. It is not clear whether 'the provision of health services' is only limited to purely professional scenarios, such as medical treatment by a licensed doctor or is capable of covering activities carried out by individuals who may have a less clear legal underpinning. The authors argue that this makes the delineating when and where the data portability requirement in Article 3(8) will apply more confusing still.

A further area of ambiguity that must be resolved concerns the question of whether both the data holder of origin and destination (the initial data holder and the data recipient) must be within the realm of primary care. Can a patient demand a transfer from a health care provider to a non-healthcare provider? At present the ambiguities of the proposal leave room for three potential interpretations. The *first* one is that data holders have an obligation to transfer the data upon request by an individual only if the data are originally from an actor falling within the definition of primary use, but for which the activities recipient makes use of them is irrelevant, i.e., there is no limitation on whether the data under the control of the new data holder are for primary or secondary use purposes. The *second* possible interpretation is that the data eligible for portability request must derive from activities falling within primary use and must be transmitted to an actor that also falls within the area. The third one is that, whilst a portability request can only be made from actors that are not within primary use, the data in question can only be transferred to actors that fall within the definition of 'primary use'.

Of these three possible interpretations the current version of the EHDS proposal appears to point to the most restrictive one (i.e., the second above). This can arguably be seen by the way term 'data recipient' is defined as always falling within the 'the context of the primary use'.[78] This seemingly makes it impossible for individuals to transfer their data to 'non primary use actors' through the data portability request envisaged in article 3(8).

The authors of this paper would argue that such a restrictive approach is unfortunate, as it is seemingly at odds with the overall objective of the EHDS to enhance individual control over their electronic health data, and to facilitate the secondary use of these data through the proposed mechanisms. Whilst the proposal does this through the proposed general framework for secondary data sharing, i.e., through the

[73] Quinn (n 10).

[74] EHDS proposal, art 2(2)(y).

[75] European Parliament, 'Draft report on the proposal for a regulation of the European Parliament and of the Council on the European Health Data Space' 2022/0140(COD) <https://www.europarl.europa.eu/doceo/document/CJ43-PR-742387_EN.pdf> accessed 30 June 2023, see Amendment 46: 'Natural persons shall have the right to give access to or request a controller or a data holder, *including* from the health or social security sector, to transmit […]'.

[76] EHDS proposal, art 2(2)(d).

[77] EHDS proposal 18.

[78] The term 'data recipient' is defined EHDS proposal, art 2(2)(k).

data permit mechanism and the Health Data Access Body that has been set out in Chapter IV od the EHDS proposal, such a mechanism foresees little role for individuals in deciding whether and how their data can be used for secondary purposes, or which data user can do so. This is particularly reflected in the formulation of EHDS proposal, art 33(5), which seems to imply the removal of the requirements in national laws on consent that conflict with the EHDS proposal, and art 38(2), which provides a derogation from the requirement in GDPR to provide information to data subjects at individual level. Whilst many commentators have pointed out that this could make it extremely difficult for individuals to object to their data being processed for secondary use purposes (at the time of writing at least)[79], it is also concerning because it does not allow individuals to take the initiative in transferring their data where they may feel it is in their or society's interests to do so. Individuals are sometimes in a better position to see where a data transfer would allow research opportunities to be realised. They may have connections with particular research outfits that pursue research in areas that are important to them (e.g. this may often be the cases with rare disease).[80] The authors, therefore, endorse the first interpretation where the right to data portability is extended to secondary use.

### 5.3. The right to data portability and data altruism

In the same month that the EHDS proposal was published by the European Commission, the European Parliament and the Council adopted the Regulation on European Data Governance (Data Governance Act, hereinafter DGA) which aims to set conditions for enhancing the establishment of the common European data spaces.[81] One of its key components is to promote 'data altruism' in the EU. As conceived by the DGA, 'data altruism' means voluntary sharing of data based on consent by data subjects to process personal data pertaining to them, or permissions of other data holders to allow the use of their non-personal data without seeking or receiving a reward and for purposes of general interest. [82] The altruistic sharing of data by individuals will be supported by the recognised 'data altruism organisations' which are registered legal entities in the EU responsible for collecting and processing shared data and making them available for the defined purposes.[83] Correspondingly, the EHDS proposal provides provisions for implementing data altruism in the health sector.[84]

Despite various controversies on the concept of data altruism and the model to be imposed by the DGA, the right to data portability is arguably the way in which individuals are able to have their data transferred effectively from the original data controller or data holder to either a data altruism organisation or a research institution in accordance with their preferences and needs, and thus plays an important and practical role in operationalising data altruism.[85] However, the examination of the current version of the EHDS proposal in previous sections suggest that there are considerable difficulties in applying the right to data portability to data altruism activities. First, the EHDS proposal limits the transfers based on data portability request in health and care sector, whereas research purposes appear not be included based on the reading of Article 3(8) in conjunction with the definition of data holder (see Section 5.1). Second, the extended right to data portability only applies to the primary use of data, excluding the possibility of transferring data for secondary use purposes based on this right (see Section 5.2).

It is true that for the purposes of mobilising one's data, the right of access can still be relied on. However, as explained in Section 2, the added value of the right to data portability in facilitating data flows and data reuse cannot be overlooked. One of the most important reasons is that the right to data portability mandates machine-readable data format and requires greater interoperability between systems. These technical specifications are central to supporting data transmission and analysis, from which enormous economic, scientific, and social value can be derived. Therefore, the failure to take into account data altruism further illustrates the need to address these limits of the new right to data portability in the EHDS proposal.

## 6. The interoperability requirements in the EHDS proposal

The above section discusses the scope of the new right to data portability in the proposed EHDS in comparison with Article 20 of the GDPR. However, the core of GDPR's right to data portability lies in the requirement for data to be provided and transmitted 'in a structured, commonly used and machine-readable format',[86] which, as argued in the above section, is an important basis that distinguishes the right to data portability from the right of access.[87] the WP29's guideline opines that 'structured', 'commonly used' and 'machine-readable' are a set of 'minimal requirements' from which interoperability is the 'desired outcome'. But from the reading of Article 20,[88] it is agreed that, besides the three mandatory requirements, achieving interoperability is not a legal obligation. Also, Article 20(2) of the GDPR refers to the term 'technical feasible' when determining whether one data controller must transfer the requested data directly to another (without passing through the data subject). To explain what 'technical feasibility' entails, the WP29 suggests, that while the assessment should be made on a case-by-case basis, direct transmission should take place 'when communication between two systems is possible, in a secured way, and when the receiving system is technically in a position to receive the incoming data'.[89] Despite the unclarity whether there should be other elements involved in the notion of 'technical feasibility', at least it can be agreed that interoperable systems are crucial to making direct data transmission technically feasible. However, the GDPR does not impose an obligation for data controllers (or recipients) to achieve such technical feasibility either.

To take a step back, even as to the question of what the required data format exactly is, the GDPR itself does not provide any technical specifications as to which data formats meet the requirements, only encouraging data controllers to develop such interoperable formats.[90] The data controller who receives the data is not obliged to support a certain data format used by the sender, either.[91] Despite the guidance by the WP29 on what is the appropriate data format that enables data portability[92], there are still not sufficiently clear and binding standards in this regard due to technologically neutral language of the

[79] Luca Marelli and others, 'The European Health Data Space: Too Big To Succeed?' (2023) Health Policy 104861; Santa Slokenberga, 'Scientific Research Regime 2.0? Transformations of the Research Regime and the Protection of the Data Subject That the Proposed EHDS Regulation Promises to Bring Along' (2022) 2022 Technology and Regulation 135.

[80] Quinn (n10).

[81] Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act) [2022] OJ L 152/1 ('DGA').

[82] Data Governance Act, art 2(16).

[83] Data Governance Act, ch IV, also see recital 45-46.

[84] EHDS proposal, art 40.

[85] Teodora Lalova-Spinks, Janos Meszaros and Isabelle Huys, 'The Application of Data Altruism in Clinical Research through Empirical and Legal Analysis Lenses' (2023) 10 Frontiers in Medicine <https://www.frontiersin.org/articles/10.3389/fmed.2023.1141685> accessed 13 October 2023.

[86] GDPR, art 20(1).

[87] De Hert and others (n 19).

[88] ibid.

[89] WP29 (n 16) 16.

[90] GDPR, recital 68.

[91] WP29 (n 16) 16.

[92] WP29 (n 16) 16-18.

legislation.[93] Research also found that, although the commonly used data formats used in reality by various data controllers satisfied the minimal requirements under GDPR, the data usability might be hampered by the differences in the ways data are structured and the lack of contextual information.[94] In fact, the WP29 suggests that the most appropriate format should depend on the specific sector,[95] which is something that the EHDS proposal is currently promoting.

Dating back to 2012, the draft proposal of the GDPR at first took a more progressive approach to implement effective interoperability by tasking the Commission to 'specify the electronic format […] and the technical standards, modalities and procedures for the transmission […]'.[96] But in the final adopted version of the GDPR, this standard-making role of the Commission was removed, which to some extent reduced the certainty of the provisions for the data controllers to implement the data portability requirements. However, in the proposal of the EHDS, this important role of the Commission is re-introduced in the EHDS proposal by the creating 'the European electronic health record exchange format'. As set out in Article 6 of the proposed EHDS, the European electronic health record exchange format, to be laid down by the Commission by means of implementing acts, should include technical specifications for making available and transferring electronic health data. Considering the current insufficient guidance for data controller's compliance to the right to data portability,[97] this is no doubt an important step to increase the legal certainty for what data format should be used with regard to electronic health data, and facilitate the interoperability of data processing systems, especially the EHR systems, in the healthcare sector across Europe.

It should be noted that, as Article 3(8) subparagraph 2 of the EHDS proposal states, the adoption of the European electronic health record exchange format is mandatory when (1) the data holder and data recipient are located in different Member States; (2) the electronic health data in question falls into the 'primary categories of personal electronic health data for primary use' prescribed in Article 5, which are specified in Annex I of the proposal. These data include patient summaries, electronic prescriptions, electronic dispensation, medical image and image report, laboratory result and discharge report, which are considered most relevant in healthcare scenarios and have high priority in terms of the improvement of interoperability.[98] Despite an important step forward compared to the GDPR, it is not clear how the data portability request concerning data beyond the primary categories should be handled in terms of the appropriate data format.

Contrasting with the GDPR's reserved attitude on the question of interoperability, the EHDS proposes to impose an explicit obligation on the manufactures (and the importers) of EHR systems to ensure their interoperability. Such requirements are set out in Annex II of the proposal as part of 'the essential requirements' for the EHR systems. The European Commission will also be mandated to develop 'common specifications', including technical specifications, for the interoperability of the EHR systems.[99] In addition, the EHDS also envisage a larger scale of interoperability to include wellbeing apps which exchange information with EHR systems in the form of voluntary conformity with the Annex II requirements to be indicated by labelling.[100]

To some extent, with the specification of the European electronic health record exchange format and the mandatory interoperability requirements for the EHR systems, the proposed EHDS seems to be able to remedy the GDPR's lack of certainty on the issue of interoperability. If interoperability of EHR systems and well-being apps, driven by the legal requirements, can be improved at the technical level, it will certainly facilitate the enforcement of data portability rules in both the GDPR and the EHDS, and hence the empowerment of the individuals in terms of more flexible and functional control of their electronic health data. However, at this stage, the consideration of interoperability by the EHDS seems to be only limited to the primary use of electronic health data, with little vision of the role of interoperability legal requirements in the secondary use as argued in the last section. The authors argue that to realise the proposed data access mechanism for secondary use in the EHDS, a higher level of interoperability than what is foreseen now is likely to be needed for a secondary-use ecosystem involving much more diverse types of data, data processing systems and data users. Moreover, increased interoperability could entail complex implications on other aspects, such as privacy, data quality and market competition,[101] which will not be elaborated on in this paper but also deserve proper consideration.

## 7. The question of *lex specialis* and the compatibility with Article 9 GDPR

Since the creation of the EHDS proposal, there has been much discussion about its nature, in particular, the question of whether it as a whole or in part forms *lex specialis* to data protection law. Much of this discussion relates to whether the EHDS proposal will itself provide new legal grounds for the processing of personal data or whether it will simply facilitate those grounds already delineated within the GDPR. On the one hand, a motivation behind the proposal appears to be to further facilitate rights and possibilities that have already been created by the GDPR in the specific context of sharing data from EHRs for primary and secondary use. The explanatory materials in the EHDS state: [102]

> *'Considering that a substantial amount of electronic data to be accessed in the EHDS are personal health data relating to natural persons in the EU, the proposal is designed in full compliance not only with the GDPR but also with Regulation (EU) 2018/1725 (EU Data Protection Regulation). The GDPR provides the rights to access, to portability and to accessibility/transmission to a new controller of data. It also designates data related to health as a 'special category of data', affording it special protection through the establishment of additional safeguards for its processing. The EHDS supports the implementation of the rights enshrined in the GDPR as applied to electronic health data…'*

On the other hand, there are a number of areas where the EHDS proposal appears to create new legal grounds for the processing of personal data. This notably includes Article 33(5) where the proposal

[93] Janis Wong and Tristan Henderson, 'The Right to Data Portability in Practice: Exploring the Implications of the Technologically Neutral GDPR' (2019) 9 International Data Privacy Law 173.

[94] Harshvardhan J Pandit and others, 'An Exploration of Data Interoperability for GDPR' (2018) 16 International Journal of Standardization Research (IJSR) 1.

[95] WP29 (n 16) 17.

[96] European Commission, 'Proposal for a regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation)' 2012/0011 (COD), art 18.

[97] Wong and Henderson (n 93); Sarah Turner and others, 'The Exercisability of the Right to Data Portability in the Emerging Internet of Things (IoT) Environment' (2021) 23 New Media & Society 2861.

[98] EHDS proposal, Annex I; also see EHDS proposal, recital 17.

[99] EHDS proposal, art 23.

[100] EHDS proposal, art 31.

[101] For example, see Petros Terzis and Enrique Santamaria Echeverria, 'Interoperability and Governance in the European Health Data Space Regulation' [2023] Medical Law International 0; Argyro Mavrogiorgou and others, 'IoT in Healthcare: Achieving Interoperability of High-Quality Data Acquired by IoT Medical Devices' (2019) 19 Sensors 1978; Taxiarchis Botsis and others, 'Secondary Use of EHR: Data Quality Issues and Informatics Opportunities' (2010) 2010 Summit on Translational Bioinformatics 1.

[102] EHDS proposal 3.

appears to suggest that national laws requiring consent for the processing of personal data will not apply where they conflict with the operation of the EHDS.[103] In addition, the proposal itself appears to envisage that a legal base will be created for the processing of electronic health data by the various Health Data Access Bodies.[104]

As far as this paper is concerned, the key question is whether the enhanced right to data portability outlined in Article 3(8) itself represents a new legal basis for the processing of personal electronic health data. Article 3(8) is ambivalent about this. This question is important because for one data holder to transfer personal electronic data to another, a legal base will be required. The authors of this paper would submit that in the absence of further explicit wording, it would not be wise to view article 3(8) as itself providing a legal basis for processing. The EDPS and EDPB have seemingly indicated in their opinion that the provisions contained within Article 3(8) itself do not form *lex specialis*.[105] Their opinion on the proposal raised concerns about the compatibility of Article 3(8) of the EHDS proposal with Article 9 of the GDPR. More specifically, their opinion stated that the data holder must be compliant with Article 9 of the GDPR when executing a request for data portability.

At present, this does not appear to be the case, given that compliance with such a data portability request does not appear to be synonymous with any of the legal bases outlined in the article. This includes explicit consent given that a data portability request alone would not appear to meet the conditions for such consent, in particular, the idea that it should be 'informed'.[106] The authors of this paper would argue that portraying a data portability request as representing a form of explicit consent would in effect be turning the traditional consent paradigm on its head. This is because consent normally represents a response to a specific and detailed proposal on the part of the data controller. In many circumstances this takes the form of accepting an offer to process data in a certain manner on the part of the data controller. In the case of Article 3(8) this does not appear to be the case, with the proposal for action effectively coming from the data subject. There is no requirement on the part of the data holder foreseen within article 3(8) to provide the relevant information required to give informed consent. The result is that a request for portability under article 3(8) of the proposal would seemingly not meet the conditions of explicit consent under article 9 of the GDPR.

In order to rectify this, the authors of this article would recommend that there is a need to reword article 3(8) before the definitive text is agreed by the EU institutions. One possibility is to require the data holder, upon reception of a 'portability request', to make a 'portability proposal' to the data subject. In this proposal they could outline what data would be transferred, to whom and how.[107] It could also be tailored to comply with the informational requirements outlined in Article 13 of the GDPR. Once the 'portability proposal' had been formulated, the data subjects could consent in a way that would comply with Article 9 of the GDPR. Re-crafting Article 3(8) in this way would make the article compatible with the GDPR.

The only alternative would be to acknowledge that article 3(8) represents a form of *lex specialis*, meaning it is not necessary to demonstrate compliance with a legal base rooted in the GDPR. The authors however do not think that such an option is desirable, given that a certain amount of clarificatory information (on the part of the data holder) is arguably needed to avoid individuals making decisions that are not in their best interest. For this reason, the option to re-format Article 3(8) to make it consent compatible is more desirable, given that it would come with an obligation to comply with the informational requirements within Article 13 GDPR. In any event, even Article 3(8) if were to be seen as *lex specialis*, the authors of this paper would at the very least suggest that the legislator should make this explicit within the text.

## 8. Conclusion

The proposed EHDS can in general terms be thought of as a framework that will increase the portability of health data throughout Europe. This includes provisions designed to make the transferability of key elements of EHRs across Europe. Beyond the relationship of many parts of the EHDS with the common understanding of the word 'portability', the proposal also contains a provision that will seemingly expand the right to data portability as understood in data protection law (in particular, Article 20 of the GDPR). This provision is primarily contained within Article 3(8) of the EHDS proposal. Despite being given a low level of prominence within the proposal, it seemingly represents an important expansion of the rights outlined within Article 20 of the GDPR. It appears, *prima facie* at least to create a parallel right of data portability in that it applies alongside the general framework of the EHDS that seek to increase the transferability of EHRs and to make more data available for secondary use purposes. In this way, Article 3(8) appears to allow data subjects the possibility of taking the initiative to transfer their data directly to a third party (i.e., not needing to wait upon or go through the general EHDS architecture).

The right as outlined in the EHDS proposal contains several elements that seemingly go further than the form of the right to data portability outlined in Article 20 GDPR. Most notably, it applies to electronic health data no matter the legal base used for processing (unlike a portability request based on Article 20 GDPR, which only applies to data processing based upon consent or a contractual agreement). This represents an important expansion because it means that inferred data derived from analysis of the data that was originally provided by the data subject can also form the subject of a request. This will include increasingly important conclusions based on AI-driven analysis of patient data. Another important development lies in the interoperability requirements proposed in the EHDS — the European electronic health record exchange format to be specified by the Commission that seemingly goes beyond the notion of 'machine-readable', and obligations on the EHR system manufacturers to ensure the interoperability of their products. Such requirements seemingly put a greater onus on the data holder to ensure that the data that is being transferred will work with the systems of the data recipient. It is argued that the new expanded right to data portability foreseen in the EHDS will empower individuals in the primary use of electronic health data and improve the quality of care by facilitating EHR exchange in cross-border healthcare and enabling the integration of electronic health data produced in non-medical contexts, e.g., user-generated data, into the EHR systems.

Despite these clear expansions, there are a number of seemingly important limitations that will limit the extent of this expanded right. This includes for example that the requirement will only apply to personal electronic health data (likely ruling out application to non-personal forms of personal data). Perhaps more importantly, it seems to be limited to only primary use of the data by data holders that fall within the 'health or social security' sectors. As discussed in this paper, this seemingly limits portability requests to transfers only between

[103] EHDS proposal, art 33(5) 'Where the consent of the natural person is required by national law, health data access bodies shall rely on the obligations laid down in this Chapter to provide access to electronic health data.'

[104] EHDS proposal, art 37.

[105] EDPB-EDPS joint opinion (n 71), para 57.

[106] The authors note in particular the requirements to comply with the informational requirements that should accompany consent laid down in art 13 of the GDPR.

[107] The authors of this paper provided such a recommendation to the EU Parliament's LIBE committee during its review of the first draft of the EHDS proposal.

medical institutions involved in patient care (primary use). Though it is difficult to be certain at this stage (in large part due to ambivalent definitions used within the proposal), the authors would submit that it is disappointing that a range of potentially relevant applications for an expanded right to data portability are excluded. It excludes portability requests to or from instances of scientific research (seemingly including clinical trials). This is regrettable in that it means that this new right will do nothing to assist citizen science initiatives. This is difficult to understand given that boosting data altruism, in general, is an identified goal in both the EU's data strategy and the EHDS in general. Further, non-altruistic transfer purposes also seem to be excluded, including those relating to well-being and others related to the use of health data for commercial non-health-based purposes. This could include online genealogical services that make use of genetic data. The authors of this paper would argue that the reasons for such limitations are not clear, especially given the scientific, social, and economic advantages that could be realised if the right to portability was of a greater extent. Similarly, the interoperability requirements proposed in the EHDS appear to lack consideration of the data portability request beyond the priority categories in the primary use. For these reasons, it is hoped that later iterations of the proposal will foresee a more expansive version of the right to portability, taking into account the various scenarios where the new right to data portability can be used.

Additionally, although it is beyond the scope of this article, the expansion of data portability obligations, together with the general data sharing obligations foreseen by the EHDS could encounter resistance from data holders in possession of electronic health data, in particular, where it is alleged that intellectual property (e.g., in the form of trade secrets may apply).[108] In other cases, healthcare professionals may be reluctant to disclose all information in their possession, including notes they have made about the patient.[109] In order to balance the different interests, the authors of this paper recognise that more limitations are very likely to be introduced in the upcoming versions of the draft legislation. These will require further research in order to determine their impact.

## Declaration of Competing Interest

The authors have no competing interests to declare.

## Data availability

No data was used for the research described in the article.

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[108] Timo Minssen and Justin Pierce, 'Big Data and Intellectual Property Rights in the Health and Life Sciences' in Effy Vayena and others (eds), Big Data, Health Law, and Bioethics (Cambridge University Press 2018) <https://www.cambridge.org/core/books/big-data-health-law-and-bioethics/big-data-and-intellectual-property-rights-in-the-health-and-life-sciences/35C0A03D803719176BE225F249746A97> accessed 12 October 2023.

[109] Marelli and others (n 79).