



SYSTEMATIC REVIEW

REVIEWED Record linkage of population-based cohort data from minors with national register data: a scoping review and comparative legal analysis of four European countries

[version 2; peer review: 3 approved]

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Abstract

Background: The GDPR was implemented to build an overarching framework for personal data protection across the EU/EEA. Linkage of data directly collected from cohort participants, potentially serving as a prominent tool for health research, must respect data protection rules and privacy rights. Our objective was to investigate law possibilities of linking cohort data of minors with routinely collected education and health data comparing EU/EEA member states.

Methods: A legal comparative analysis and scoping review was conducted of openly accessible published laws and regulations in EUR-Lex and national law databases on GDPR's implementation in Portugal, Finland, Norway, and the Netherlands and its connected national regulations purposing record linkage for health research that have been implemented up until April 30, 2021.

Results: The GDPR does not ensure total uniformity in data protection legislation across member states offering flexibility for national legislation. Exceptions to process personal data, e.g., public interest

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Pieter De Smet, Ghent University, Ghent,

and scientific research, must be laid down in EU/EEA or national law. Differences in national interpretation caused obstacles in cross-national research and record linkage: Portugal requires written consent and ethical approval; Finland allows linkage mostly without consent through the national Social and Health Data Permit Authority; Norway when based on regional ethics committee's approval and adequate information technology safeguarding confidentiality; the Netherlands mainly bases linkage on the opt-out system and Data Protection Impact Assessment.

Conclusions: Though the GDPR is the most important legal framework, national legislation execution matters most when linking cohort data with routinely collected health and education data. As national interpretation varies, legal intervention balancing individual right to informational self-determination and public good is gravely needed for health research. More harmonization across EU/EEA could be helpful but should not be detrimental in those member states which already opened a leeway for registries and research for the public good without explicit consent.

Keywords

Record Linkage, Cohort data, Routine data, GDPR, Data processing, European Union, European Economic Area, Europe

Belgium

3. **Anders Foldspang**, Aarhus University,
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Any reports and responses or comments on the article can be found at the end of the article.



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REVISED Amendments from Version 1

We included the feedback from the three reviewers. Minor changes were done to the text including the abstract, main text and tables. In the abstract, the wording was slightly adapted to meet reviewers' comments (asking for clarity, minor changes to wording, and including why this type of data processing is of interest to this study).

Table were updated: in Table 1 the location of the information source was changed from Norway to Finland; in Table 3 the location of 1 law was changed from European law to Portugal, Finnish laws were also provided in English (besides the Finnish ones), and the table headline adapted per reviewer request). In the main text, the majority of changes done were related to wording, correction of typos, formulations, and clarification as per reviewer request.

Any further responses from the reviewers can be found at the end of the article

Introduction

Improving research on health services requires access to timely, complete, and accurate patient or organizational data¹. Data acquisition via patient registries in routine procedures and systems, or through population-based cohort studies represent important data collection tools for health research, health monitoring, disease prevention, diagnostics, and health improvement²⁻⁶. Routinely collected data are defined as systematic records of patient information gathered in registers/administrative databases such as (non-) electronic patient registries, hospital-based child health and social protection facilities, or educational institutions⁷⁻⁹. A cohort is a group of individuals sharing a statistical factor in a demographic study, and inviting the same individuals to repeated health examinations or other assessments is called a cohort follow-up assessment¹⁰. Whereas routinely collected data cover comprehensive information on individual interaction with cross-divisional facilities, cohort data cover the distribution and determinants of health-related conditions and events in a specific population and explore the longitudinal relationship between a specific exposure and outcome providing high validity, accuracy, and effectiveness in development trends^{2,3,11-14}.

Record linkage – the general merging of data from an individual or an event that are not available in a separate record into consolidate facts – is increasingly used to extend accessible data and to generate complete and comprehensive data for health service organization, policy making, and public health research at comparatively low expenses¹⁵⁻¹⁸. As it enables to respond to research questions that could not have been answered before the merge, it can be of paramount importance for research studies^{14,17,19}. Hence, linking routinely collected data with cohort data presents an asset to research in complementing comprehensive data of individuals on cross-sectoral service interaction with data on the associations between the characteristics in a specifically studied population^{5,6,14,17,20-22}. Health and education data and their multidimensional outcomes are as social determinants of health a vital fragment for public health and biomedical research²³. Moreover, health and education data influence health service provision aiming to improve

population health and responding to user expectations and their needs while reducing inequalities in health and responsiveness leading a basis for policy-making²⁴.

As health data are considered personal data, defined as “an information related to an identified or identifiable natural person [data subject]”, the involvement of the General Data Protection Regulation (GDPR) is required. The GDPR along with the e-privacy directive, covering electronical communication²⁵, functions as the ultimate legal framework on data protection and data privacy that reinforces individual control of data subjects' own data and their associated rights in a digitalized era^{25,26}. The GDPR aimed to build an overarching framework to enhance transparency, support individual rights, and promote the growth of the digital economy²⁷. Its general principles include: Lawfulness, fairness and transparency; Purpose limitation; Data minimisation; Accuracy; Storage limitation; and Integrity and confidentiality²⁸⁻³⁰. After the GDPR was completed in May 2016 and came into effect on May 2018, its direct applicability as a regulation was enforced in all European Union (EU) member states, Iceland, Liechtenstein and Norway, which together comprise the European Economic Area (EEA).

Linking data records falls under data processing, which the GDPR defines as the acquirement and any subsequent operation in the handling of personal data to generate useful information^{1,2}. The GDPR requires that any party that processes personal data to have at least one of the six legal bases: consent, performance of a contract, legitimate interest, vital interest, legal requirement, and public interest³. Though not the only legal basis, when informed consent is used as a legal basis in the sense of the GDPR, it should comply with the criteria of being informed, specific, freely given and demonstratable. Yet, the first two are difficult to meet in longitudinal cohort studies with volunteers where the research questions are broadly defined and several means, which can change over time, might be used to answer that broad range of questions. Moreover, in the context of health data, an additional legal basis is needed, which might be explicit consent but could also be another authorisation based on national law, as the GDPR left a margin in implementing the clauses on health data for the administration of the health care system, public health and research⁴. Thus, the result of the so called triologue between the European Parliament, the Council and the European Commission³¹ left a substantial leeway to the member states in its implementation³². Hence, member states were in charge to implement or leave existing national legislation concerning the processing of health data for public health and research, including exemptions to the informed consent principle and direct applicable research exemptions³². Also, applicable ethically informed legal requirements vary from country to country.

¹ Article 2(b) of the Modernised Convention for the protection of individuals on processing of Personal data, of the 18th of May 2018

² Article 4/2 GDPR

³ Article 6(1) GDPR

⁴ Articles 9.2.h, 9.2.i, 9.2.j, 9.4. GDPR

Since the advent of the GDPR there has been a considerable debate about the relation between the GDPR and research²⁹. Thus, this study investigates law possibilities of linking cohort data with routine health and education data comparing the European countries Portugal, Finland, Norway and the Netherlands for health research purposes.

Methods

A legal analysis and scoping review based on PRISMA-ScR guidelines was conducted between September 15, 2020 until April 30, 2021.

Data selection and eligibility criteria

Countries. We selected four countries that are part of the EU/EEA which are located in the south, middle, and north of Europe to achieve geographic variability: Portugal, Finland, Norway, and the Netherlands.

Population group. We selected children as population group which are by law called data subjects. Children were defined as a human being below the age of 18 years⁵.

Data type. Health (sensitive) and education (non-sensitive) data were included due to their distinct nature in data processing and importance for health research.

Laws and regulations. All published laws and regulations on GDPR's national implementation and connected national regulations in Portugal, Finland, Norway, and Netherlands purposing record linkage of cohort data from minors with routinely collected health and education data for health research that have been implemented up until April 30, 2021 were considered eligible.

Exclusion criteria

Laws and regulations. Register linkage studies that use only register data were not included in this analysis as it would be out of scope of the study's objective. Although the GDPR regulation include, as personal data, all data derived from biological samples, such as those from biobanks, we excluded this data category as it deviates from the main objective of the study and would involve an additional perspective that would lengthen the paper too extensively.

Information sources. Openly online accessible databases EUR-Lex⁶ and national law databases (Table 1) were used. The databases were searched within the time period of September 15, 2020 – April, 30 2021.

Search

EUR-Lex and national law databases were consulted to search for all significant laws on data protection and data privacy for the processing of health and education data. Cross-referencing between the articles allowed to link themes, terms and subjects. Instead of specific search expressions, key words were used when screening the law databases, searching for applicable

laws and regulations and when verifying specific terms. The search string has been adopted based on the local languages (Portuguese, Finnish, Norwegian, English (GDPR), and Dutch). The search was furthermore checked by involved researchers in their respective country of expertise.

Examples of key words used in the Regulation (EU) 2016/679 [General Data Protection Regulation (GDPR)] – EUR-Lex: (“data processing” OR “processing” OR “data”) AND (“operation” OR “collection” OR “storage” OR “recording” OR “organization” OR “storage” OR “adaptation” OR “retrieval” OR “consultation” OR “use” OR “transmission” OR “dissemination” OR “alignment” OR “combination” OR “restriction” OR “erasure” OR “personal” OR “identification” OR “Information” OR “protection” OR “protect” OR “protection” OR “data subject” OR “consent” OR “minor” OR “children” OR “child” OR “subsidiarity” OR “parent” OR “legal person” “subject” OR “scientific research” OR “research” OR “health” OR “education” OR “security” OR “privacy” OR “routine” OR “register” OR “collect” OR “individual” OR “right” OR “principle” OR “duty” OR “duties” OR “population” OR “controller” OR “processor” OR “Pseudomization” OR “Anonymization” OR “data protection impact assessment” OR “Independent supervisory principle” OR “data minimization principle” OR “purpose limitation principle” OR “Storage Limitation Principle” OR “purpose” OR “statistical” OR “freedom” OR “burden” OR “Ethical approval” OR “Ethics” OR “Ethics Committee” OR “sensitive” OR “non-sensitive” OR “safeguarding” OR “provision” OR “administrative” OR “electronic record” OR “electronic” OR “personal information” OR “special categories”).

Data analysis

We investigated the possibilities of linking routinely collected education and health data with cohort data comparing Portuguese, Finnish, Norwegian and Dutch law, and their interplay on record linkage purposing the conduction of research up until April 30, 2021. Data processing findings were analysed and compared across the selected countries from the EU/EEA enabling an overview of the main possibilities of record linkage (Table 2).

Synthesis of results

All data (laws and regulations) that were included are listed in Table 3 and are marked throughout the results section with footnotes. Results were organized and clustered into six main themes: 1) Legal basis for research, 2) Legal basis for registries, 3) Representation of minors, 4) Opportunities to link, 5) Record Linkage with other data bases, and 6) Procedural conditions.

Results

GDPR

The GDPR operates as the chief legal framework for the protection of personal data and data privacy among countries who are part of the EU/EEA given its direct applicability as a regulation, while granting member states a significant margin of discretion in its implementation. The Declaration of Helsinki and other related declarations also play a role in the complete application of the GDPR³³. Data protection, data privacy, and legal contexts for research purposes are constructed

⁵ Article 1, United Nations Convention on the Rights of the Child

⁶ EUR-Lex. Available at: <https://eur-lex.europa.eu/eli/reg/2016/679/oj>

Table 1. Main information sources.

	GDPR	Portugal	Finland	Norway	Netherlands
1	EUR-Lex [Online]. Available at: https://eur-lex.europa.eu/eli/reg/2016/679/oj	Diário da República [Online]. Available at: https://dre.pt/	GlobaLex [Online]. Available at: https://www.nyulawglobal.org/globalex/Finland.html	Access to microdata [Online]. Available at: https://www.ssb.no/en/data-til-forskning/utlan-av-data-til-forskere	Verheid.nl [Online]. Available at: https://wetten.overheid.nl/zoeken
2			DATABASES OF THE FINNISH PARLIAMENT [Online]. Available at: http://www.eduskunta.fi	Lovdata [Online]. Available at: https://lovdata.no/	
3			FINNISH ELECTRONIC STATUTE SERIES. [Online]. Available at: http://www.finlex.fi	Datatilsynet [Online]. Available at: https://www.datatilsynet.no/en/	
4			FINLEX - LEGAL DATA BANK [Online]. Available at: http://www.finlex.fi	Helsetilsynet [Online]. Available at: https://www.helsetilsynet.no/en/	
5			FINNISH LAW INFO [Online]. Available at: http://www.kauppakaari.fi and http://www.lakiverkko.com	Directorate of eHealth – Helsedata [Online]. Available at: https://www.helsedata.no/en/	
6			EDILEX - LEGAL PORTAL [Online]. Available at: http://www.edilex.fi		
7			Data ombudsman [Online]. Available at: https://tietosuoja.fi/en/impact-assessments		

Table 2. Evidence synthesis (based on the Joanna Briggs Institute (JBI) manual). GDPR=General Data Protection Regulation.

Scoping Review Details
Scoping Review title: Record linkage of population-based cohort data from minors with national register data: a scoping review and comparative legal analysis of four European countries
Review objective/s: Investigate possibilities of linking cohort data of minors with routinely collected education and health data comparing EU/EEA member states.
Review question/s: What are the possibilities of linking cohort data of minors with routinely collected education and health data comparing different EU/EEA member states?
Inclusion/Exclusion Criteria
Population: Children (minors), defined as a human being below the age of 18 years, were included as data subjects.
Data type: Health (sensitive) and education (non-sensitive) data were included due to their distinct nature in data processing and importance for health research.
Laws and regulations: All openly accessible published laws and regulations on GDPR's national implementation and connected national regulations in Portugal, Finland, Norway, and Netherlands purposing record linkage of cohort data from minors with routinely collected health and education data for health research that have been implemented up until April 30, 2021 were considered eligible.
Types of evidence source: Openly online accessible databases EUR-Lex and national law databases (see Table 1) were used.
Exclusion: Register linkage studies that use only register data were not included in this analysis as it would be out of scope of the study's objective. Although the GDPR regulation include, as personal data, all data derived from biological samples, such as those from biobanks, we excluded this data category as it deviates from the main objective of the study.
Evidence source Details and Characteristics
Countries: Portugal, Finland, Norway, and Netherlands
Context: Databases have been searched within the time period of September 15, 2020 – April, 30 2021.
Details/Results extracted from source of evidence (in relation to the concept of the scoping review)
Synthesis of results: see Table 3.

Table 3. Main involved legislations, regulations and recitals.

Europe	GDPR-specific articles and recitals	Portugal	Finland	Norway	The Netherlands
General Data Protection Regulation (GDPR)- Regulation of the EU 2016/679	Article 4/2 GDPR; Article 4/5 GDPR; Article 4(11) GDPR; Article 4(13) GDPR; Article 4(14) GDPR; Article 4(15) GDPR	58/2019 Act, August 8, 2019; Article 31/4 of 58/2019 Act August 8 2019	Act on the Secondary Use of Health and Social Data (552/2019), March 13, 2019	Act of 15 June 2018 No. 38 on personal data (Personal Data Act) Lov om behandling av personopplysninger (personopplysningsloven)	General Data Protection Regulation Implementation Act, May 25, 2018 "Uitvoeringswet Algemene Verordening Gegevensbescherming" (UAVG)
Article 16 of the Treaty on the Functioning of the European Union, 2000	Article 6 GDPR; Article 6(1) GDPR; Article 6(1)(a) GDPR Article 6(1) b)-c) GDPR; Article 6(1)(e) GDPR; Article 6(1)(f) GDPR; Article 6(2) GDPR; 6(1)(e) GDPR	Article 80 of Portuguese Civil Code, 1966	Data Protection Act (1050/2018), December 5, 2018	Act of 20 June 2008 No. 44 on Medical and Health Research (Health Research Act) Lov om medisinsk og helsefaglig forskning (helseforskningsloven)	Aanpassingswet Algemene Verordening Gegevensbescherming, May 25, 2018
Recommendation CM/Rec (2019)2 of the Committee of Ministers to member states on the protection of health-related data	Article 9 GDPR; Article 9/1 GDPR; Article 9/1/a) GDPR; Article 9(2) GDPR; Article 9/2/i) GDPR; Article 9(2)jj) GDPR; Article 9(2)(h) GDPR; Article 9(2)(j) GDPR; Article 9/1/a) GDPR; Article 9/2/g GDPR; Article 9/2/i) GDPR; Article 9(4) GDPR	Constitution of the Portuguese Republic, 1976; Article 35 Constitution of Portugal, April 10, 1976	Lakiterveydenhuollon valtakunnallisista henkilörekistereistä (556/1989) (Act on the National Health Registries)	Act of 28 April 2017 No. 23 on Ethics and Integrity in Research (Research Ethics Act) Lov om organisering av forskningsetisk arbeid (forskningsetikkloven)	Afdeling 5 van Boek 7 BW
Recommendation No. R(97) 18 of Council of Europe	Article 86 GDPR	Organization and Functioning of the National Commission of data protection – 43/2004 Act, August 18, 2004	Laki sosiaali- ja terveystietojen toissijaisesta käytöstä, 552/2019 (Act on the Secondary Use of Health and Social Data (552/2019))	Act of 15 June 2018 No. 38 on personal data (Personal Data Act) Lov om behandling av personopplysninger (personopplysningsloven)	Article 7:457 lid 3 BW
Recommendation CM/Rec (2010)13 adopted by the Committee of Ministers of the Council of Europe on November 23, 2010	Recital 159 GDPR	Personal genetic information and health information – 12/2005 Act, January 26, 2005	Section 2, Act on the Openness of Government Activities (621/1999)	Act of 20 June 2014 No. 43 on Personal Health Data Filing Systems and the Processing of Personal Health Data (Personal Health Data Filing System Act) Lov om helseregistre og behandling av helseopplysninger (helseregisterloven)	Article 7:458 BW
Convention for the processing of individuals with regard to Automatic Processing of Personal data	Recital 26 GDPR	21/2014 Act, April 16, 2014- legal regime of clinical research	Laki viranomaisten toiminnan julkisuudesta, 621/1999 (Act on the Openness of Government Activities 621/1999)	Act of 1 January 2021 No. 133 on Amendment in Personal Health Data Filing System Act / Lov om endringer i helseregisterloven m.m	Kamerstukken 31765

Europe	GDPR-specific articles and recitals	Portugal	Finland	Norway	The Netherlands
Article 2(b) of the Modernised Convention for the protection of individuals on processing of Personal data, of the 18th of May 2018	Article 89(1) GDPR; Article 89/2 GDPR	26/2016 Act, August 22, 2016	Tietosuojalaki, 1050/2018 (Data Protection Act (1050/2018))	Act of 21 June 2019 No. 32 relating to official statistics and Statistics Norway (Statistics Act) Lov om offisiell statistikk og Statistisk sentralbyrå (statistikkloven)	Article 41 Wet op het Centraal Bureau voor Statistiek
Regulation (EC) No 1338/2008, December 16, 2008	Article 5(1) (b) GDPR ; Article 5(e) GDPR; Article 5 (2) GDPR	Regulation no. 1/2018 by the National commission of data protection, October 16, 2018	Section 1, Data Protection Act (1050/2018), January 1, 2019	Regulation on medical quality health registers - Forskrift om medisinske kvalitetsregistre, of June 21 2019, entered into force on September 01, 2019	Article 7:465 BW
Paragraph 1 of Recommendation No. R (97) 18, September 30, 1997	Article 8 GDPR; Article 8 (1)	Article 31/4 of Law n° 58/2019 Act, August 8, 2019, The Portuguese Data Protection Act	Laki lääketieteellisestä tutkimuksesta, 488/1999 (Medical Research Act (488/1999))	Act of 20 June 2008 No. 44 on Medical and Health Research (Health Research Act) Lov om medisinsk og helsefaglig forskning (helseforskningsloven)	Article 5, GDPR Dutch implementing Act
Article 3(c) of Regulation (EC) no. 1338/2008, December 16, 2008	Article 35 GDPR; Article 35/1 and 2 GDPR; Article 35/3/b GDPR	Law n° 21/2014, of 16 April	Section 2(1) of Medical Research Act (488/1999) October 1, 2010	Forskrift om barn mellom 12 og 16 år sin rett til selv å samtykke til deltakelse i medisinsk og helsefaglig forskning	Article 46 Dutch implementing Act
Paragraph 3.3 of the Recommendation No. R (97)18, September 30, 1997	Article 36 GDPR; Article 36(9) GDPR	Law n°. 12/2005 of 26 January on Personal genetic information and health information.	Section 6, Medical Research Act (488/1999), October 1, 2010	Act of 20 June 2014 No. 43 on Personal Health Data Filing Systems and the Processing of Personal Health Data (Personal Health Data Filing System Act) Lov om helseregistre og behandling av helseopplysninger (helseregisterloven)	
Paragraph 6 of Recommendation CM/Rec (2019)2, March 27, 2019	Recital 32 GDPR	Decree-Law No. 97/95, May 10	Section 44, Act on the Secondary Use of Data (552/2019)	Statistics act §14, Act of 21 June 2019 No. 32 relating to official statistic and Statistics Norway (Statistics Act).	
Working Party (A29WP)	Recital 40 GDPR	Law n° 81/2009, of 21 of August		Act of 21 June 2019 No. 32 relating to official statistics and Statistics Norway (Statistics Act) of 21 June 2019 Lov om offisiell statistikk og Statistisk sentralbyrå (statistikkloven)	
Paragraph 6 of Recommendation CM/Rec (2019)2, March 27, 2019	Recital 162 GDPR	Law n° 53/2017 of 14 July		Regulations to the Statistics Act/ Forskrift til statistikkloven av Dec 11th 2020 No 2731 (FOR-2020-12-11-2731) Forskrift til statistikkloven (statistikkforskriften)	

Europe	GDPR-specific articles and recitals	Portugal	Finland	Norway	The Netherlands
Article 3(c) of Regulation (EC) no. 1338/2008	Recitals 33 GDPR	Law 22/2008, of 13 May		Act of 1 January 2021 No. 133 on Amendment in Personal Health Data Filing System Act / Lov om endringer i helseregisterloven m.m.	
Regulation (EU) 2016/679 of the European Parliament and of the Council, April 27, 2016	Recital 50 GDPR	Article 124 of Portuguese Civil Code		Act of 20 June 2008 No. 44 on Medical and Health Research (Health Research Act) Lov om medisinsk og helsefaglig forskning (helseforskningsloven)	
Regulation (EU)2018/1725; Article 29	Recital 54 GDPR	Article 8º / 3, Decree Law nº 131/2014 of 29 of August		Act of 20 June 2014 No. 43 on Personal Health Data Filing Systems and the Processing of Personal Health Data (Personal Health Data Filing System Act) Lov om helseregistre og behandling av helseopplysninger (helseregisterloven)	
43/2004 Act	Recital 32 GDPR	Article 6/3 "Código dos regimes contributivos do sistema previdencial de segurança social"		Health Research Act §17, §9 and 10	
Article 4/3 of 12/2005	Recital 157 GDPR	14/2013 Decree-law, January 28, 2013;		Forskrift om barn mellom 12 og 16 år sin rett til selv å samtykke til deltakelse i medisinsk og helsefaglig forskning	
	Recital 159 GDPR	Article 99/1 of the 4/2007 Act, January 16, 2007			
	Recital 4 GDPR	Article 3/1 of the 'Despacho n.º 1774-A/2017, February 24, 2017			
		Article 6/5, of 22/2008 Act, of 13 May			
		Article 2º of 22/2008 Act, of 13 May			
		Article 62/2 of 58/2019 Act August 8, 2019			
		Article 9, Law 53/2017, of 14 July			

Europe	GDPR-specific articles and recitals	Portugal	Finland	Norway	The Netherlands
		Article 16, Law 53/2017, of 14 July			
		Article 13, Law 53/2017, of 14 July which Creates and regulates the National Cancer Registry (National Oncologic Registry Act)			
		Article 1/1 of 21/2014 Act, April 16, 2014			
		Article 6 of the 21/2014 Act, April 16, 2014; Article 6/1/b) and Article 6/1/d) of the 21/2014 Act, April 16, 2014; Article 6/1/e) of 21/2014 Act, April 16, 2014			
		Article 16/1 of the 21/2014 Act, April 16, 2014			
		Article 35 GDPR and Regulation 1/2018 CNPD			
		Article 4/4 of 12/2005 Act, January 26, 2005			
		Article 124 of Portuguese Civil Code			
		Official Gazette No. 274/1966			
		Decree-Law No. 47344			
		Decree-Law No. 97/95, May 10			
		Article 4/3 of 12/2005 Act, January 15, 2005			

on each legal setting of EU member states and countries of the EEA. However, given the precedence of EU law principle, as the GDPR is hierarchical higher, its appliance stands above member state law. Partner countries of the EEA agreement are bound by the GDPR in the same manner as EU member states. As a legally binding document it provided technical guidance to all entities that are bound to enforce it^{28,30,34}.

Legal basis for research. The GDPR allows three types of research exception conditional on the obligations inflicted by Article 89(1): i) Exceptions to principles and lawful grounds for data processing; ii) exceptions to data subject rights; iii) national law implementation by member states³⁵. Member states may disclose official documents in accordance with member state law and grant access to official registry data under their member states law⁷.

The GDPR grants the processing of sensitive data with a scientific research purpose under conditions like professional secrecy, Articles 6 and 9 of the GDPR shall be read and interpreted together in this regard. The GDPR states that scientific research and statistical purposes are connected, as statistical results may be used to achieve scientific outcome⁸. While the first provides the six general legal bases⁹ the second sets out a list of ten additional specific conditions, permitting the lawful processing of sensitive data¹⁰. Scientific research is considered a legitimate reason and allows the compressing of the rights of a data subject¹¹. The purpose limitation principle needs to be applied, which enforces that personal data can be collected for a specified, explicit, and legitimate purpose¹². However, the GDPR provides for possible deviations from this principle: further processing for scientific research purposes, when respecting certain safeguards¹³, benefits from a presumption of compatibility with the initial purposes¹⁴. Article 5 provides six principles on personal data processing which inter alia include the purpose limitation principle that data should be “collected for specified, explicit and legitimate purposes” and data minimization principle that is to “limit [to the necessary purpose] [...] for which they are processed”.

The GDPR provides safeguards and derogations from data subjects rights when data is processed for scientific research and statistical purposes including sensitive data¹⁵. The use of information to characterize a collective phenomenon in a given population and the processing of personal data for statistical, scientific, or historical purposes is permitted and subject to

appropriate safeguards and the adoption of technical and organizational measures (e.g., pseudonymization, anonymization)¹⁶. The processing of community statistics on public health and on health and safety at work is granted¹⁷. It is prohibited to take decisions or actions related to a specific individual¹⁸. Public health interest is defined as all essentials that are linked to health (e.g., health status)¹⁹. If a statistical analysis cannot be carried out with anonymized data, collected data for a certain purpose must be anonymized as soon as possible²⁰. Pseudonymization may also be an adequate measure where the purposes of the research can be fulfilled in that manner.

Legal basis for registries. The GDPR specifies that accessing data falls under the overall term of data processing²¹. The GDPR established an inclusive explanation of the personal data processing for scientific research acknowledging the importance of data collection for research purposes in registries²². A registry is a data collection system where official records are kept. In order to access data, a legal basis is needed according to the GDPR (Articles 6 and 9). Member States may introduce further conditions with regards to the processing of health data²³. The acquisition of personal data must also be based on a specific form of consent.

Representation of minors. Data subjects that are considered minors, have no legal capacity and are in need of a higher protection by law²⁴. Therefore, the legal guardian or representative authorizes the processing of personal data or the anonymization of data²⁵ on behalf of the data subject²⁶. Under

¹⁶ Article 4/5 GDPR

¹⁷ Regulation (EC) No 1338/2008, December 16, 2008

¹⁸ Paragraph 1 of Recommendation No. R (97) 18, September 30, 1997;

To understand the distinction between the Council of Europe and the European Union: “The Council of Europe (CoE), an international organization encompassing 47 countries of Europe, was established to encourage democracy and guard human rights and the rule of law in Europe. The CoE Convention for the protection of individuals with regard to the processing of personal data (“Convention 108” of 28 January 1981) and additional protocols is a treaty that is open to any country (it currently counts 54 States). It provides for a legally binding commitment of countries with global dimension and it has inspired for decades a number of legislative processes throughout the world, such as for instance the EU data protection framework (namely the EU Data Protection Directive and the GDPR). The GDPR is an EU legal instrument that is a directly applicable and legally binding to the any EU/EEA Member States. The European Union presently has 27 members that have delegated some of their sovereignty so that decisions on certain issues of shared interest can be made democratically at European level.”

¹⁹ Recital 54 GDPR; Article 3(c) of Regulation (EC) no. 1338/2008, December 16, 2008

²⁰ Paragraph 3.3 of the Recommendation No. R (97)18, September 30, 1997

²¹ Article 4/2 GDPR

²² Recitals 33, 157 and 159 GDPR

²³ Article 9(1/a) GDPR; Recital 32 GDPR; Article 9(4) GDPR

²⁴ Article 8 GDPR; Paragraph 6 of Recommendation CM/Rec (2019)2, March 27, 2019

²⁵ Article 4/3 of 12/2005 Act, January 15, 2005

²⁶ Paragraph 6 of Recommendation CM/Rec (2019)2, March 27, 2019

⁷ Article 86, GDPR

⁸ Recital 159 and Recital 162 GDPR

⁹ Article 6/1 a)-f)

¹⁰ Article 9 GDPR

¹¹ Recital 50 and 54 GDPR; Article 3(c) of Regulation (EC) no. 1338/2008; Article 9/1 GDPR; Article 89/2 GDPR

¹² Article 5/1b) GDPR

¹³ Article 89/1 GDPR

¹⁴ Article 5/1 b) GDPR

¹⁵ Article 89/1 GDPR

the GDPR the minimum of 13 years applies but only for Information on Society Services defined as “any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services³⁶. Apart from that, the age definition of a minor varies across the country-specific contexts.

Opportunities to link. The GDPR generally prohibits the processing of sensitive data unless certain conditions are met [see legal basis for research]. The collection of routine data is part of the classification of substantial public interest and is permitted but is not freely accessible and cannot be shared by third parties²⁷. Routinely collected data can contain non-sensitive (e.g., education data) and sensitive data (e.g., clinical information). If the latter applies, the rules of sensitive data collection are followed.

Health data is considered sensitive data and requires an explicit consent from the data subject whenever consent is the legal basis for processing. Health information collected for health research namely based on consent should also comply with other general data protection principles including the storage limitation principle²⁸. The storage limitation principle follows the idea of keeping the data for not longer than necessary “for the purposes for which the personal data are processed”²⁹. It defines that if the time of storage is unknown, an adequate condition for data storage has to be granted³⁰. The GDPR further states that “personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1)”³¹.

Education data is non-sensitive information collected on education (e.g., educational level, grades) by schools. The collections of non-sensitive information follow for example the same category of protection as the collection of personal information³⁷. Access to non-sensitive data is less limited as it implies lower risks in relation to the rights and freedoms of the data subject.

Record linkage with other databases. Linking cohort data with routine health and education data requires adherence to data privacy protection practices and guidelines. Data privacy protection practices include the provision of an informed explicit consent. Three lawful grounds on sensitive data processing are of main importance for the objective of linking routine health and education data with cohort data: i) explicit consent; ii) reasons of public interest in public health; iii) need for scientific, historical, and statistical purposes³².

Procedural conditions. The GDPR established the independent supervisory principle which defines that the data controller and the data processor must guarantee that the data processing meets the terms of the data protection rules³³. In defined circumstances, regarding processing operations likely to result in a high risk, the data controller has to follow a Data Protection Impact Assessment (DPIA), which implies to carry out an assessment of the resulting risks for data subjects as well as of the appropriate measures to mitigate them, and requires to seek advice from the data protection officer³⁴ (DPO). The data controller defines the purposes and the essential means of the processing of personal data³⁷ while the data processor acts on behalf of the data controller, following its documented instructions.

Portugal

Legal basis for research. In Portugal, the national implementation of the GDPR was finalized on August 8, 2019³⁵. Typically, as per Article 6/1 GDPR, the processing of personal data for research purposes is grounded either on the consent of data subjects (a) the performance of a task in the public interest (e) or the legitimate interests of the data controller. The use and reuse of data for scientific research is not the subject of a dedicated legal instrument regulating it in a comprehensive way. However, the Clinical Research Act³⁶, the Health Information Act³⁷, the data protection act, and several other instruments contain provisions regulating research related matters. The Health Information Act clarifies that health information belongs to data subjects, the health system being its custodian, and can only be used for health care or health related research, except where otherwise provided by law. Access to health records is granted to the data subject, or to a third party with the data subjects’ explicit written consent, through the intermediation of a medical doctor.

For the processing of health personal data held by the national health system in research, explicit written informed consent is required. Without consent, access to health information is allowed for research purposes only if anonymized. The same written informed consent requirement applies to biobanks samples and data, with the exception of retrospective research studies or the collection of epidemiological data, as consent cannot (reasonably) be obtained due to data quantity, number or age of human subjects or similar reason. Therefore, consent requirement may be disregarded only in exceptional circumstances, namely in the case of retrospective use of samples or in special situations where it is impossible to obtain consent. And only through legal interpretation this exception provided for

²⁷ Article 9/2/g GDPR

²⁸ Recital 32 GDPR

²⁹ Article 5/e) GDPR

³⁰ Article 31/4 of Law n°. 58/2019 Act, August 8, 2019, The Portuguese Data Protection Act

³¹ Article 5/e) GDPR

³² Article 9/2/i) GDPR

³³ Regulation (EU) 2016/679 of the European Parliament and of the Council, April 27, 2016; Regulation (EU)2018/1725; Article 29 Working Party (A29WP); 43/2004 Act

³⁴ Article 35/3/b GDPR; Article 35/1 and 2 GDPR

³⁵ 58/2019 Act, August 8, 2019, the new Data Protection Act.

³⁶ Law n° 21/2014, of 16 April

³⁷ Law n°. 12/2005 of 26 January on Personal genetic information and health information.

biological materials and deoxyribonucleic acid (DNA) samples may be extended to routinely collected data in general³⁸. The Health Information Act further specifies provisions on the creation and operation of biobanks³⁹ as well on the processing of genetic information for the constitution of genetic databases, which will not be analysed in this study.

The Clinical Research Act adopts a broad definition of clinical research, comprising a non-exhaustive list of clinical trials and clinical studies⁴⁰, including certain observational studies, and requiring the informed consent from data subjects. The obligation to collect an informed consent for the participation in non-interventional clinical studies can exceptionally be derogated by determination of the Competent Ethics Commission⁴¹; however, the consent for the processing of personal data may only be disregarded under the exceptional circumstances stated above⁴². Similar conditions may be found in the legislative acts creating the existing disease registries. Therefore, in Portugal, health-related scientific research essentially relies on consent, as the legal grounds for the processing of personal data. Following the GDPR approval, the Portuguese new data protection act⁴³ timidly touched upon the subject of scientific research, exception made to the possibility of giving consent to certain areas of research (as in recital 33, GDPR).

Legal bases for registries. In what concerns registries, the recent legislation implementing the GDPR provides a specific provision allowing the processing implied in the organization of centralized health data bases or registries, based on a unique platform, for legitimate purposes under GDPR or national law, provided that the information security requirements resulting from the GDPR are ensured. There is no legal instrument dedicated to regulating the creation of registries, in general, nor registries in the specific field of health. Notwithstanding the above, several health-related systems and (disease) registries were created under a specific legal act respectively, such as

National Epidemiologic Surveillance Information System⁴⁴ and National Oncologic Registry⁴⁵.

However, a National Statistical System was established by law⁴⁶, mirroring the European Regulations on statistical agencies, having generated a comprehensive set of registries in various fields, mostly centralized at the National Statistics Institute. The statistical authorities (including the National Statistics Institute) may require the compulsory provision, from any services or bodies, individuals and legal entities alike, of data relevant for the production of official statistics. The National Statistical System is coordinated by the Superior Council of Statistics, which integrates representatives from the statistical authorities, among other entities, including a representative from the data protection supervisory authority.

The Directorate-General for Education and Science Statistics provides databases in the area of education and science and technology. For research purposes, it also provides the request for accreditation of researchers for access to National Statistics Institute resident databases, in accordance with a Protocol established with the National Statistics Institute and the Foundation for Science and Technology.

Representation of minors. Under Portuguese law, a natural person below the age of 18 years is considered a minor and is legally vulnerable and benefit from greater protection. It requires the authorization or intervention through guardianship of the holders of parental responsibility⁴⁷. The legal guardians or holders of parental responsibilities need to provide the consent and can authorize the personal data processing on behalf of the data subject. The age for consent has not been set in the Implementation Act exception made to implement Article 8 GDPR where it was established at 13 years. Additional requirements may apply in specific contexts where the opinion of minors and incapacitated adults must be considered as a determining factor, in accordance with their age, degree of maturity and capacity for understanding, their opposition must be respected, and at least their assent shall be previously obtained⁴⁸.

Opportunities to link. Portugal has significant resources at its disposal for the collection and linkage of data such as the Ministry of Health, including an e-Health national agency⁴⁹, the Ministry of Education, the Directorate-General of Health and the National Institute of Statistics. Such entities may undertake decisions on data access and sharing to extent allowed by the applicable legal framework, considering the protection of personal data and the safeguarding of the public interest³⁰.

³⁸ Prior to the GDPR, data processing could be authorized by the Portuguese DPA or by Law on the grounds of a “relevant public interest”, pursued directly by the outcome of the investigation, alternatively to consent.

³⁹ According to which, for instance, only anonymized samples should be used in principle.

⁴⁰ Portuguese law defines clinical study as “any systematic study, conducted in humans or from individual health data, intended to discover or verify the distribution or effect of health factors, health status or results, health processes or disease, performance and, or, safety of health interventions or services, through biological, behavioural, social or organizational aspects”.

⁴¹ “Competent Ethics Committee (CEC)” means the committee in charge of issuing the opinion provided for in this law, which may be the CEIC (Ethics Committee for Clinical Research), the Ethics Committees for Health (ESC), established under that name by Decree-Law No. 97/95, May 10), functioning at the clinical trial centre involved, or the ESC designated by the CEIC for that purpose.

⁴² This was the understanding of the data protection Supervisory Authority on its Deliberation No 1704/2015, Applicable to the processing of personal data carried out within the scope of Clinical Research.

⁴³ Law n°58/2019, 8 August

⁴⁴ Law n° 81/2009, of 21 of August

⁴⁵ Law n.° 53/2017 of 14 July

⁴⁶ Currently in force is the Law 22/2008, of 13 May.

⁴⁷ Article 124 of Portuguese Civil Code

⁴⁸ Article 8 / 3, Decree Law n° 131/2014 of 29 of August.

⁴⁹ SPMS – Serviços Partilhados do Ministério da Saúde E.P.E.

Several unique identifiers, which allow the identification of an individual, are specified by law⁵⁰ for numerous purposes, for example: social security number⁵¹, tax number⁵², user number for the National Health Service⁵³, as well as the civil identification number. Those identifiers are contained in the electronic citizens Identification (ID) card through which citizens may exercise data subjects' rights, in particular their access right, in several contexts. For instance, patients can access their electronic health records data through the electronic health registry in the citizen's portal of the National Health Service using their citizen card for authentication purposes. In the health sector an extensive network of Information Technology (IT) systems and databases exist under the supervision of the Ministry of Health.

Several legal provisions define the interconnection and interoperability (at the national and European level) between databases hosted in public entities for specific cases and purposes, including for research³⁵⁻³⁷. Portugal participates in European eHealth Digital Service Infrastructure, allowing the sharing of summary records and prescriptions, and has implemented a national system for the electronic reporting of laboratory notifications for infectious diseases, which ensures the interoperability between the laboratories IT system and National Epidemiologic Surveillance Information System. In specific contexts the use of sensitive data bases was permitted by law for research purposes like was the recent case of anonymized data from patients diagnosed with coronavirus disease 2019 (COVID-19) collected through the Surveillance Information System during the pandemic.

Record linkage with other databases. Linking routinely collected health and education data with cohort data is feasible for research purposes, particularly based on consent, provided that the data subjects' rights, the general principles and certain requirements of data protection law are respected. If data processing involves linkage between special categories of data, such as health data, and non-sensitive data, the legal regime of sensitive data must be complied with, without exclusion of special additional requirements rendered applicable by law, for instance to the usage of specific registries data.

The Law on the National Statistical System provides that individual statistical data relating to natural persons may not be supplied unless the data subject has given his or her explicit consent or with the authorisation of the Statistical Council⁵⁴. Otherwise, individual data may still be shared with universities and other recognized research organizations for

scientific purposes, if data is anonymized⁵⁵ and a contract is in place between the statistical authority and the requesting research entity, establishing the necessary technical and organizational measures required to ensure the confidentiality of data and the respect for the purpose limitation principle. In order to pursue its mission of public interest, the National Institute of Statistics is allowed by law to carry out the processing of personal data, including sensitive data, and data linkage, namely with other statistical authorities.

In the case of the National Oncologic Registry, a centralized national registry of all cancer patients diagnosed and/or treated in Portugal, allowing for the epidemiological surveillance and research as well as the monitoring the effectiveness of medicines and medical devices, it may interconnect with other databases. Also, the interconnection between non-exclusive health databases is allowed⁵⁶, through the Public Administration Interoperability Platform⁵⁷ as well as the interconnection with other European oncology registries, in accordance with the standards and guidelines defined at the European level for this purpose⁵⁸. Access for research purposes from third parties to the data contained in the National Oncologic Registry electronic platform may be authorized by a special committee chaired by the director of the National Program for Oncological Diseases, "provided that, cumulatively, they are duly anonymized, it is not possible to identify the respective holder, and the public interest of the study is recognized"⁵⁹.

It should be noted that while the GDPR allows member state law to impose or maintain special conditions and limitations in what concerns the processing of health data⁶⁰, as well as prior consultation and authorization from the supervisory authority in relation to processing for the performance of tasks in the public interest, "including social protection and public health"⁶¹, none of the relevant national provisions existing prior to the GDPR were subject to revision since the Regulation was put into effect.

Procedural conditions. Portuguese law defines clinical research as a systematic study that analyses the distribution or

⁵⁰ Article 35 Constitution of Portugal, April 10, 1976

⁵¹ Article 6/3 "Código dos regimes contributivos do sistema previdencial de segurança social"

⁵² 14/2013 Decree-law, January 28, 2013; Article 99/1 of the 4/2007 Act, January 16, 2007

⁵³ Article 3/1 of the 'Despacho n.º 1774-A/2017, February 24, 2017

⁵⁴ In the latter case only anonymized data for statistical purposes, on the grounds of sound public health reasons (Article 6/5, of 22/2008 Act, of 13 May).

⁵⁵ It is worth to mention that anonymized data is defined in this law as data modified to minimise, in accordance with best methodological practice and without involving disproportionate effort and cost, the possibility of identifying statistical units (Article 2º of 22/2008 Act, of 13 May).

⁵⁶ In both cases this would be possible only upon the authorization of the supervisory authority; however, the national implementation of the GDPR (Article 62/2 of 58/2019 Act August 8, 2019) determined the revocation of any rules requiring prior authorizations from, or notifications to, the supervisory authority with the exception of specific cases provided in the GDPR or in the new Data Protection Act (v.g. sound recordings in CCTV cameras).

⁵⁷ Article 9, Law 53/2017, of 14 July which creates and regulates the National Cancer Registry (National Oncologic Registry Act).

⁵⁸ Article 16, Law 53/2017, of 14 July which creates and regulates the National Cancer Registry (National Oncologic Registry Act)

⁵⁹ Article 13, Law 53/2017, of 14 July which Creates and regulates the National Cancer Registry (National Oncologic Registry Act)

⁶⁰ Article 9(4) GDPR

⁶¹ Article 36(9) GDPR

consequence of features of health which includes personal data and requires the respect of human dignity⁶². Specific requirements for the conduction of a general clinical study must be met⁶³: 1) comprehensive study information and prior informed consent⁶⁴; 2) guaranteeing liability protection⁶⁵; 3) compliance with ethic committee authorizations⁶⁶; 4) special committees' authorization; 5) the performance of a data protection impact assessment may also be required⁶⁷, in which case the controller shall seek the advice of the data protection officer. A DPIA may be subject to prior consultation of the supervisory authority⁶⁸.

Finland

Legal basis for research. In Finland there are several laws concerning the scientific research and access to public data in addition to the GDPR. The Data Protection Act⁶⁹ specifies and supplements the GDPR as national implementation of the GDPR⁷⁰. The Data Protection Act includes sections that specifies the general conditions to be fulfilled for the scientific research. Medical Research Act⁷¹ is applied to medical research and clinical trials⁷² alongside with other legislation. The Medical Research Act defines specific procedures for medical research, like necessity of informed consent of research subjects⁷³. The Act on the Openness of Government Activities⁷⁴ contains provisions on the right of access to official documents in the public domain, officials' duty of non-disclosure, document secrecy and any other restrictions of access that are necessary for the protection of public and private interests⁷⁵.

The Act on the Secondary Use of Health and Social Data⁷⁶ was finalized on April 26, 2019. The main purpose of this Act

is to simplify processing and access to personal social and health data for steering, supervision, research, statistics and development in the health and social sector. A secondary objective is to assure legitimate expectations of the data subject and its rights and freedoms for personal data processing⁷⁷.

In practice, the legal ground for scientific research in Finland can be based on all sensible options specified in the GDPR Article 6: consent (a), legal obligation (c), scientific research in the public interest (e) or legitimate interest (f). Typically processing of the personal data is based on scientific research in the public interest (e) and in fewer cases on consent (a). Article 9 exemptions applied for processing of special categories of personal data are typically necessity for scientific research (j) or explicit consent (a) and sometimes necessity for reasons of the public interest in the field of public health (i) or necessity for reasons of substantial public interest (g).

Ethical principles defined in the Oviedo Convention and Declaration of Helsinki are implemented in the Medical Research Act. Informed consent is required for participation in medical research, but it is distinguished from explicit consent as only option for legal basis. Therefore, scientific research in the public interest may be valid legal basis even the informed consent is required for the ethical reasons. In this case informed consent may act as additional safeguard.

Legal basis for registries. Finnish national registries are based on national legislation that stipulates conditions for processing personal data in these registries. Legal basis is legal obligation (Article 6 (c)) or task carried out in the public interest (Article 6 (e)). The processing of personal data in these registries for scientific research is allowed by national legislation. The Finnish institute for health and welfare preserves or manages centralized registries⁷⁸ that contains complete database on all Finnish and foreign people that have used public health and social care services in Finland.

Representation of minors. Under Finnish legislation everybody who is under 18 is considered a minor. However, if the minor is 15 years or older, their own consent is sufficient for participation in the research, if consent is needed. Even if participation requires the approval of parent or legal representative, minors primarily give their own consent⁷⁹.

Opportunities to link. In Finland every citizen and permanent resident has a unique national identification number for all registrations. It is provided at birth or at immigration and

⁶² Article 1/1 of 21/2014 Act, April 16, 2014

⁶³ Article 6 of the 21/2014 Act, April 16, 2014

⁶⁴ Article 6/1(b) and Article 6/1(d) of the 21/2014 Act, April 16, 2014

⁶⁵ Article 6/1(e) of 21/2014 Act, April 16, 2014

⁶⁶ Article 16/1 of the 21/2014 Act, April 16, 2014

⁶⁷ Article 35 GDPR and Regulation 1/2018 CNPD. The latter provides a public list of the kind of processing operations requiring a DPIA. Among other cases such list includes the processing of sensitive data for research purposes, except were regulated by a law which provides appropriate safeguards for the rights of data subjects.

⁶⁸ Article 36 GDPR

⁶⁹ Tietosuojalaki, 1050/2018 (Data Protection Act (1050/2018))

⁷⁰ Section 1, Data Protection Act (1050/2018), January 1, 2019

⁷¹ Laki lääketieteellisestä tutkimuksesta, 488/1999 (Medical Research Act (488/1999))

⁷² Medical research means research involving intervention in the integrity of a person, human embryo or human foetus for the purpose of increasing knowledge of health, the causes, symptoms, diagnosis, treatment and prevention of diseases or the nature of diseases in general" as defined in the Section 2(1) of Medical Research Act (488/1999) October 1, 2010

⁷³ Section 6, Medical Research Act (488/1999), October 1, 2010

⁷⁴ Laki viranomaisten toiminnan julkisuudesta, 621/1999 (Act on the Openness of Government Activities 621/1999)

⁷⁵ Section 2, Act on the Openness of Government Activities (621/1999),

⁷⁶ Laki sosiaali- ja terveystietojen toissijaisesta käytöstä, 552/2019 "Act on the Secondary Use of Health and Social Data (552/2019)"

⁷⁷ Act on the Secondary Use of Health and Social Data (552/2019), March 13, 2019

⁷⁸ Lakiterveydenhuollon valtakunnallisista henkilörekistereistä (556/1989) (Act on the National Health Registries)

⁷⁹ The ethical principles of research with human participants and ethical review in the human sciences in Finland, Finnish National Board on Research Integrity TENK guidelines 2019. FINNISH NATIONAL BOARD ON RESEARCH INTEGRITY TENK 2019. Available at: https://tenk.fi/sites/default/files/2021-01/Ethical_review_in_human_sciences_2020.pdf

reported without necessary consent to the registries as defined by law^{38,39}. The main purpose of registries is administration, monitoring, and quality assurance³⁹. Registry data can be used for further purposes such as scientific or historical research or for statistical purposes⁸⁰.

Accordingly, with the Data Protection Act Section 29, the personal identity code may be processed if the data subject has given consent to it or for the scientific or historical purposes or statistical purposes⁸¹. It is permitted to retrieve data from each of the registry-keeping authorities (e.g., health, social information) for research purposes under special circumstances. If possible, pseudonymized or non-individual-level data for medical research is preferred by authorities. Remote access to pseudonymized data is commonly granted. Consent is not required for individual level data.

Health and Social Data Permit Authority Findata issue permits for social and health data for the scientific research when data is needed from registers of multiple public data controllers, single private data controller or if public body, like the Finnish National Institute of Health and Welfare, have transferred permit authority to Findata^{40,82}. If data is needed from other registries, then usually permits are issued by relevant authorities. Data Protection Ombudsman controls the processing of personal data and delivers permit related statement for the Data Permit Authority if requested.

Record linkage with other databases. Consent is not mandatory for record linkage, but if consent is required for ethical reasons, then consent must include the record linkage. Typically, routinely collected health and education data with cohort data can be linked if a consent is provided. Access to identifiable data can be granted in limited cases, if necessary, for research and if data security is sufficiently high. That implies that either the researcher has already the identification numbers in their own cohort, or researcher will link additional data to their dataset (e.g., medical records from the hospitals)^{40,41}. If Findata grants authorization, then Findata is also responsible for the record linkage in the most cases.

Findata authority takes ultimate responsibility for all research use of the Finnish social and health data requested from multiple data controllers and when single controller has given out authority to Findata. Findata permit and processing of registry data for research purposes requires charges^{38,42}. The authorization and processing of registry data for research purposes requires charges⁴⁰. Information from each registry can be shared and linked to the information from other registries in other Nordic countries. Data from health registries can be shared with research collaborators in other EU/EEA countries⁴⁰.

Procedural conditions. Ethical review is required e.g., if a study involves an intervention in the physical integrity in clinical research, a study deviates from the principle of informed consent or review is needed for scientific publication. If a research study uses only register-based information, the approval of an ethics committee is not required by Finnish law or ethical principles⁸³. Researcher need to apply with a detailed specific research plan on planned data linkages to receive a statement from the regional ethics committee within the hospital district when register data is requested to be used. The application for data permission has to include a data utilization plan, a list of each researcher that will process the data, and a data description. An amendment must be submitted if the application is alternated (e.g., adding researchers)^{38,39}. The DPIA is required prior to processing if data processing is likely to result a high risk to data subjects like processing on large scale of health data⁸⁴.

Norway

Legal basis for research. Norway is not member of the EU but a member of the EEA and bound by the GDPR in the same manner as EU member states. The Act on the Processing of Personal Data (Personal Data Act) incorporates EU's GDPR to Norwegian law and contains national rules in areas where the GDPR allows it⁸⁵. Researcher must comply with both the main rules of the GDPR and the special rules of the Personal Data Act when processing personal data. Other regulations for research using medical data are the Act on Medical and Health Research (Health Research Act) of June 2008⁸⁶ (altered by the Act on Amendment in Personal Health Data Filing System Act of January 1, 2021)⁸⁷, and the Act on Ethics and Integrity in Research (Research Ethics Act) of April 2017 aiming to ensure that research is conducted according to recognised ethical standards⁸⁸. The acts are further specified by regulations and guidelines.

The regulatory bodies of health research are the Norwegian Board of Health Supervision attending the legal reliability of

⁸³ The ethical principles of research with human participants and ethical review in the human sciences in Finland, Finnish National Board on Research Integrity TENK guidelines 2019. FINNISH NATIONAL BOARD ON RESEARCH INTEGRITY TENK 2019. Available at: https://tenk.fi/sites/default/files/2021-01/Ethical_review_in_human_sciences_2020.pdf

⁸⁴ Data ombudsman [Online]. Available at: <https://tietosuoja.fi/en/impact-assessments>. [Accessed: 23-Feb-2021].

⁸⁵ Act of 15 June 2018 No. 38 on personal data (Personal Data Act) Lov om behandling av personopplysninger (personopplysningsloven) – Lovdata (<https://lovdata.no/dokument/NL/lov/2018-06-15-38>) [This is the result of an agreement within EEA/EFTA and an additional protocol: cfr/<https://www.efta.int/EEA/news/General-Data-Protection-Regulation-incorporated-EEA-Agreement-509291>]

⁸⁶ Act of 20 June 2008 No. 44 on Medical and Health Research (Health Research Act) Lov om medisinsk og helsefaglig forskning (helseforskningssloven) - Lovdata

⁸⁷ Act of 20 June 2008 No. 44 on Medical and Health Research (Health Research Act) Lov om medisinsk og helsefaglig forskning (helseforskningssloven) - Lovdata

⁸⁸ Act of 28 April 2017 No. 23 on Ethics and Integrity in Research (Research Ethics Act) Lov om organisering av forskningsetisk arbeid (forskningsetikkloven) - Lovdata

⁸⁰ Act on the Secondary Use of Health and Social Data (552/2019), March 13, 2019

⁸¹ Data Protection Act (1050/2018), December 5, 2018

⁸² Act on the Secondary Use of Health and Social Data (552/2019), March 13, 2019

research⁸⁹, and the Norwegian Data Protection Authority providing guidance and advice on data protection⁹⁰.

According to the Health Research Act, the Regional Committees for Medical and Health Research Ethics (REC) has the authority to evaluate whether research projects fulfil the criteria set for medical and health related projects⁸⁵. The projects must also be compliant with the Personal Data Act⁹¹. The research institutions are responsible for establishing guidelines, procedures, and systems to be compliant with all laws relevant for medical and health research. Research projects that process personal data within other fields than medical and health science have duty to report to the Norwegian Centre of Research Data⁹², a national archive offering help to assess whether research projects meet the requirements of data protection legislation.

Legal basis for registries. Norway holds various national registries storing health related data as well as education and demographic data. The national registries are regulated by the Act on Personal Health Data Filing Systems and the Processing of Personal Health Data (Personal Health Data Filing System Act) of June 2014 to promote health and prevent disease⁹³ (altered by the Act on Amendment in Personal Health Data Filing System Act of January 1, 2021)⁹⁴, and the Act relating to official statistics and Statistics Norway (Statistics Act) aiming to ensure official high-quality statistics to inform public, research and guide decision-making⁹⁵. Registries that are not based on consent to file data are for example the Medical Birth Registry Norway, the Norwegian Patient Registry, or demographics filed by Statistics Norway. Furthermore, several medical quality registers are established⁹⁶, some hold duty to report without consent, such as the Norwegian Cardiovascular Disease registry, while most of them are based on consent, for example the Norwegian Cerebral Palsy Registry.

Representation of minors. According to the Health Research Act §17, the right to consent is generally from 18 years, and from 16 years if research does not involve bodily intervention

or testing medical products, in which case the guardian (legal representative) must consent⁹⁷. According to the regulation and provided that the Regional Ethics Committee approves, minors between 12 and 16 years can themselves consent to research on medical matters if the public utility exceeds the possible disadvantages or if interests may conflict between the child and the parent/guardian (e.g., violence or neglect)⁹⁸.

Opportunities to link. In Norway every citizen and permanent resident has a unique national 11-digit personal identifier for all registrations which is provided at birth or at immigration and reported confidential but without necessary consent to the national registries as defined by §11 in the Personal Health Data Filing System Act⁹⁹. The personal identifier can be used to link personal data with register data if REC approves, either based on consent or for well-founded public, scientific, historical, or statistical purposes. The sharing of indirect identifiable individual level data with other countries is possible through strict regulations.

Record linkage with other databases. Statistics Norway administers official statistics about the Norwegian society. This includes data on education, income, social and work-related information. Access to indirect identifiable data for research purposes is regulated by the Statistics act §14¹⁰⁰. Statistics Norway is given the authority to regulate procedures for access to data¹⁰¹. Linking clinical health data with register data is possible, given that the required ethical and legal regulations are fulfilled, and the researchers are affiliated with an approved research institution by either the Research Council of Norway or Eurostat¹⁰². An overview of data sources is given by Helsedata¹⁰³ which includes more than 40 registers with health data, and guidelines are prepared for access to microdata from Statistics Norway¹⁰⁴.

⁸⁹ Norwegian Board of Health Supervision | Helsetilsynet – Frontpage / Statens Helsetilsyn (or: <https://www.helsetilsynet.no/en/>)

⁹⁰ Frontpage | Datatilsynet (or: <https://www.datatilsynet.no/en/>)

⁹¹ Act of 15 June 2018 No. 38 on personal data (Personal Data Act) Lov om behandling av personopplysninger (personopplysningsloven) – Lovdata (<https://lovdata.no/dokument/NL/lov/2018-06-15-38>)

⁹² Norwegian Centre for Research Data. Available at: <https://www.nsd.no/en/>

⁹³ Act of 20 June 2014 No. 43 on Personal Health Data Filing Systems and the Processing of Personal Health Data (Personal Health Data Filing System Act) Lov om helseregistre og behandling av helseopplysninger (helseregisterloven) – Lovdata

⁹⁴ Act of 1 January 2021 No. 133 on Amendment in Personal Health Data Filing System Act / Lov om endringer i helseregisterloven m.m. – Lovdata (<https://lovdata.no/dokument/NL/lov/2020-12-04-133>)

⁹⁵ Act of 21 June 2019 No. 32 relating to official statistics and Statistics Norway (Statistics Act) Lov om offisiell statistikk og Statistisk sentralbyrå (statistikkloven) – Lovdata

⁹⁶ Regulation on medical quality health registers - Forskrift om medisinske kvalitetsregistre, of June 21 2019, entered into force on September 01, 2019 – Lovdata

⁹⁷ Act of 20 June 2008 No. 44 on Medical and Health Research (Health Research Act) Lov om medisinsk og helsefaglig forskning (helseforskning-sloven) – Lovdata

⁹⁸ Forskrift om barn mellom 12 og 16 år sin rett til selv å samtykke til del-takelse i medisinsk og helsefaglig forskning - Lovdata. Available at: <https://lovdata.no/dokument/SF/forskrift/2017-06-28-1000?q=Forskrift%20om%20samtykke%20til%20forskning>

⁹⁹ Act of 20 June 2014 No. 43 on Personal Health Data Filing Systems and the Processing of Personal Health Data (Personal Health Data Filing System Act) Lov om helseregistre og behandling av helseopplysninger (helseregisterloven) – Lovdata

¹⁰⁰ Statistics act §14, Act of 21 June 2019 No. 32 relating to official statistic and Statistics Norway (Statistics Act). Available at: <https://www.ssb.no/data-til-forskning/utlan-av-data-til-forskere>

¹⁰¹ Act of 21 June 2019 No. 32 relating to official statistics and Statistics Norway (Statistics Act) of 21 June 2019 Lov om offisiell statistikk og Statistisk sentralbyrå (statistikkloven) – Lovdata

¹⁰² Regulations to the Statistics Act/ Forskrift til statistikkloven av Dec 11th 2020 No 2731 (FOR-2020-12-11-2731) Forskrift til statistikkloven (statistik-forskriften) – Lovdata / (<https://lovdata.no/dokument/SF/forskrift/2020-12-11-2731>)

¹⁰³ Directorate of eHealth - Helsedata Front page (helsedata.no) / <https://www.helsedata.no/en/>

¹⁰⁴ Access to microdata (ssb.no) / <https://www.ssb.no/en/data-til-forskning/utlan-av-data-til-forskere>

The Act on Amendment in the Personal Health Data Filing System Act enforced in January 2021 is aiming to make it easier and safer to make health information available for statistics and research¹⁰⁵. The National Health Analysis Platform is a technical platform that will provide researchers with tools to conduct new types of health and medical research. The platform will facilitate complex analysis across the different registries and other relevant sources of health information and improve information security and protection of special data categories.

Procedural conditions. All projects that fall within the jurisdiction of the Health Research Act must according to § 9 and 10 apply for pre-approval to the Ethics Committee in order to start the project¹⁰⁶. Informed written consent is a premise for sampling and accessing individual health data. Therefore, the written participant information and consent form, if relevant describing linkage to specified registries and data sharing with other countries, must be approved by the committee. Exemptions from requirements of consent are 1) minimal risk for not ensuring the well-being and integrity of participants, 2) substantial interest for society, and 3) consent is difficult to collect for various reasons, and requiring consent will cause incomplete data set, introduce bias and considerably hamper the research quality. The application must furthermore include: i) a project description with aims and justifications for the need for new knowledge; ii) details on planned data linkages; iii) reasoning on the necessity of using the data for the project; iv) who will have access to data; v) and how data will be stored¹⁰⁷. An amendment must be submitted if the original application is changed.

Linking individual clinical data with register data requires approval from an Ethics Committee and accommodation to the Personal Data Act fulfilling EU's GDPR. Pseudo-anonymised data with low risk for indirect re-identification may be shared with research collaborators nationally and within EU/EEA with a strict control on access to data¹⁰⁸. Registry authorities usually secure only few analysts, ideally one analyst for a study. Such human restriction jointly with data minimisation and adequate technical solution safeguard data protection. For lending individual data on education and demographics, an application must be submitted to Statistics Norway for a specific research project and for a specified period. Researcher affiliated with an authorised research institution may apply.

The Netherlands

Legal basis for research. The national implementation of the GDPR was finalized on March 25, 2018 in the Implementing Data Protection Act called *Uitvoeringswet Algemene Verordening Gegevensbescherming*¹⁰⁹. In addition, several changes have been made to other legislation such as in the Act on the National Institute of Public Health and Environment¹¹⁰. The emphasis in Dutch implementation of the GDPR was first of all not to change the content of existing legislation which was deemed to be compliant with the GDPR. In the second place not to reiterate in Dutch legislation which follows directly from the GDPR already. Hence, the necessity for appointing a DPO or performing a DPIA follows directly from the GDPR and not from Dutch law. The same applies to the principle of data minimisation and other GDPR principles.

Legislation which was not changed involves amongst other the act on the treatment contract, which is part of the Dutch Civil Code and dates from 1995 already¹¹¹. The treatment contract Act covers various patient rights such as informed consent for treatment, the right to a copy of the medical file and the right to professional secrecy. The Act on medical research with human beings was not changed either because of the GDPR. This Act has a limited scope of application applying only to medical scientific research where the participants are subject to procedures or are required to follow rules of behaviour¹¹². Purely observational research does not follow under the remit of the Act, also when that would involve occasionally filling in questionnaires. Hence, in the context of this paper, this Act will not be discussed.

There can be various legal bases to establish a cohort with research participants. A cohort which recruits volunteers obviously would require their consent and several of these large cohorts exist in the Netherlands, either population based¹¹² or targeting a specific group¹¹³. All these cohorts with volunteers are based on broad consent predating the GDPR. Some of those cohorts recruit subgroups for add-on studies which will fall under the remit of the Act on medical research with human subjects when the add-on study involves specific tests or procedures to follow. Such add-on studies there will then be based on specific consent.

Cohorts can also be based on secondary use of health data. While data processing for the provision of health care is not based on consent but on the treatment act which requires the doctor to keep a medical file, in general, the consent of the patient is required to release patient data to a party not involved

¹⁰⁵ Act of 1 January 2021 No. 133 on Amendment in Personal Health Data Filing System Act / Lov om endringer i helseregisterloven m.m. – Lovdata (<https://lovdata.no/dokument/NL/lov/2020-12-04-133>)

¹⁰⁶ Act of 20 June 2008 No. 44 on Medical and Health Research (Health Research Act) Lov om medisinsk og helsefaglig forskning (helseforskningsloven) - Lovdata

¹⁰⁷ Act of 20 June 2008 No. 44 on Medical and Health Research (Health Research Act) Lov om medisinsk og helsefaglig forskning (helseforskningsloven) - Lovdata

¹⁰⁸ Access to microdata (ssb.no) / <https://www.ssb.no/en/data-til-forskning/utlan-av-data-til-forskere>

¹⁰⁹ General Data Protection Regulation Implementation Act (UAVG), May 25, 2018

¹¹⁰ Aanpassingswet Algemene Verordening Gegevensbescherming, May 25, 2018

¹¹¹ Afdeling 5 van Boek 7 BW

¹¹² Examples: Lifelines. Available at: <https://www.lifelines.nl/>

¹¹³ Examples: <https://tweelingenregister.vu.nl/>; <https://generationr.nl/>

in the treatment¹¹⁴. There are exceptions. A breach of professional secrecy can be required by law such in the context of the health insurance reimbursement system¹¹⁵ or with notifiable communicable diseases¹¹⁶. There is also an exception for research. Consent is not required when it would be impossible or when it would be unfeasible to ask for consent, the research serves a public interest, the privacy of the data subject is sufficiently assured (in practice meaning that the data should be pseudonymised), the research cannot be performed without those data and the patient did not opt-out to such use¹¹⁷. These four conditions release data by the treating physician to a researcher are reflected in somewhat different wording in Article 24 (and Article 27 for genetic data) in the Dutch implementing Act as the legal base for the research institution to process health data without consent.

This legal base can in general not be used by a cohort with active volunteers. As there is some form of contact, consent can be asked. Therefore, for linking with data from the health care system and registries, consent will be asked. Usually at the start of cohort on the consent form with tick boxes for various databases.

In 2004 the Dutch health research community issues a Code of Conduct on health research which was approved by the existing data protection authority⁴⁴. That Code of Conduct already had provisions which are now laid down in the GDPR such as that the research protocol should explain how about data minimisation and pseudonymisation of the research data is being applied. The Code of Conduct is at the moment under revision¹¹⁸.

There is substantial discussion whether the existing broad consent cohorts can retain their present procedures and about the relation between the consent to submit data to a researcher for further use for research as follow from the Act on the treatment contract and consent in the sense of the GDPR. Some authors claim that consent according to the treatment contract can be broad but the researchers should still fall back on the exception to the consent principle of Article 24 of the Dutch implementing Act⁴⁵.

Legal basis for registries. Except for a clause in the Act of the National Institute for Health and the Environment relating to not notifiable communicable diseases, the Netherlands has no formal regulation on health registries implementing Article 9.2.i GDPR. Some registries are based on the opt-out system discussed above. Other function on the basis of

disputable controller-processor basis, the registry then being the processor. Legislation regarding quality registries has been announced by government¹¹⁹. Those quality registries are meant to give feedback to health care providers about their performance on certain quality indicators compared to the average of all participating health care providers. Such quality registries will not be based on consent in order to assure their integrity. It remains to be seen whether the non-anonymised data from these quality registries may also be used for research without consent.

The largest registry or a bundle of registries is held by Statistics Netherlands (SN). SN is based on its Act incorporating the European legislation regarding statistical agencies. As any statistical agency SN require citizens, corporations and public bodies to submit personal data to it. SN has detailed data about for example the education, health and welfare consumption and income of citizens. The Act on Statistics Netherlands contains special provisions on the use of the data for research¹²⁰. The data of SN can be used for research if certain conditions are met. If the participant has explicitly consented to linking with SN, the data from SN may be added to the cohort data. If there is not such explicit consent, the cohort data may be submitted to SN which will perform the linking. The researcher can then analyse the dataset within the secure environment of SN also by remote access. SN has then procedures that the researcher can only extract the fully anonymous results of the statistical analyses¹²¹.

Representation of minors. A distinction should be made here between when the minor is also a patient or at other situations. The Act on the treatment contract gives the minor from 12 years onwards a personal privacy right to the medical record¹²², hence, to retrieve data from the health record, the child from 12 years onwards, when competent, should decide. For general purposes the age for consent has been set at 16 years in the Implementation Act¹²³.

Opportunities to link. Use of the national registration number is required for many public functions. Health care providers and health insurers are required to use this number¹²⁴. Data to SN are submitted under the national registration number or a pseudonym which SN can reverse to the national registration number. Within SN the national registration number is then again pseudonymised to the unique SN number.

¹¹⁴ Article 7:457 lid 3 BW

¹¹⁵ Zorgverzekeringswet and executive decrees

¹¹⁶ Wet publieke gezondheid and executive decrees

¹¹⁷ Article 7:458 BW

¹¹⁸ Coreon.org [Online]. Available at: <https://www.coreon.org/codegoedge-drag/>

¹¹⁹ Kamerstukken 31765

¹²⁰ Article 41 Wet op het Centraal Bureau voor Statistiek

¹²¹ Microdata: Conducting your own research. Available at: <https://www.cbs.nl/en-gb/onze-diensten/customised-services-microdata/microdata-conducting-your-own-research>

¹²² Article 7:465 BW

¹²³ Article 5, GDPR Dutch implementing Act

¹²⁴ Wet aanvullende bepalingen verwerking persoonsgegevens in de zorg

However, the national registration number may only be used when explicitly allowed by legislation¹²⁵. There is no legislation which allows that number to be used for research. Hence, linking with SN can never be exact because of wrong spelling etc.

Record linkage with other databases. See above “Opportunities to link”

Procedural conditions. The Act on medical research involving human subjects has a system for accreditation of medical ethical review boards and every protocol falling under the remit of the Act must be approved by such a committee. The Netherlands does not have such a system for observational research. In practice many research institutions have such non formally accredited review boards and so have almost all registries, sometimes named as privacy committees or data access boards. In practice there are no gaps for ethical review but on the contrary because of the lack of a national system there are overlaps where a proposal is reviewed by several bodies, sometimes coming to different conclusions⁴⁶. There is not a requirement to consult the Data Protection Act (2018) for research unless directly following from the GDPR itself, being that the DPIA would necessitate a consultation of the GDPR. A request for linking data with SN will be reviewed by an access committee unless it has approved a similar request from that research institution already. The procedure is known to be rather quick.

Discussion

Summary GDPR application among member states

The GDPR aimed to create a robust and coherent data protection framework across EU/EEA member states by ensuring a constant and high level of protection for the individual and the proper functioning of free movement of personal data within the EU/EEA in order to respond to rapid technological progress, globalization and associated challenges³⁰. The implementation of the GDPR was successful in EU/EEA member states’ encouragement by strengthening the role of data protection authorities and by promoting the allocation of sufficient resources to data protection authorities^{28,30,34}. However, the margin that the GDPR allowed for each EU/EEA member state in the national implementation, as demonstrated in the results, appears to have caused for divergence to remain, discouraging innovative research in particular in states with more restrictive implementation^{29,35,47,48}. Fragmentation originating from different approaches followed at member state level seems to have further created unequal settings for researcher challenging data exchange, record linkage, and generally research collaborations within and across EU/EEA member states³⁵.

Public interest and scientific research

First of all, the principal questions that consider national and cross-national record linkage of cohort data with routinely collected data relate either to the conditions provided for

scientific research and public health¹²⁶ or to the legal basis of public interest¹²⁷. Even though the GDPR lays down specific requirements for the processing of sensitive data, the GDPR does not automatically signify that data may be processed in agreement with these allowances, as the allowances rely on further EU or national legislation. Neither does the GDPR signify that the legal basis always has to be the provision of an explicit consent as there are several other legal grounds in the GDPR to process personal data³⁵. The GDPR generally prohibits the processing of sensitive data¹²⁸ (e.g., genetic¹²⁹, biometric¹³⁰ and health¹³¹) but lifts this prohibition in particular scenarios¹³² such as for scientific research purposes¹³³ which is subject to the imposed obligations¹³⁴. Thus, the GDPR acknowledges scientific research as a legitimate purpose for data processing and as a specific condition for the processing of sensitive data¹³⁵ although requiring further regulation and a legal basis to be used in practice.

A lawful ground of personal and sensitive data processing¹³⁶ must always be fulfilled by the researcher and/or the research institution, acting as a data processor and/or controller. For instance, data processing is permitted if it is necessary for a task carried out in the public interest¹³⁷. Data processing is also permitted if essential to attend the legitimate interests of a controller or a third party¹³⁸, yet, public authorities cannot process data in the performance of their tasks¹³⁹ relying on legitimate interest. Moreover, the GDPR limits the exemption of data processing for scientific research to those cases where a national or Union Law provision regulates it, in accordance with certain technical and organizational measures¹⁴⁰. Hence, research entities cannot solely rely on the research exception³⁵. The GDPR leaves significant room for national (or specific EU) legislation¹⁴¹. In particular, on the one hand, it allows exceptions to the informed consent principle in the context of research which need to be laid down in EU or national member state law¹⁴², while, on the other hand, it allows EU/EEA member states to maintain or introduce further conditions including

¹²⁶ Article 9 GDPR

¹²⁷ Article 6 GDPR

¹²⁸ Article 9(1) GDPR

¹²⁹ Article 4(13) GDPR

¹³⁰ Article 4(14) GDPR

¹³¹ Article 4(15) GDPR

¹³² Article 9(2) GDPR

¹³³ Article 9(2)(j) GDPR

¹³⁴ Article 89(1) GDPR

¹³⁵ Article 9 GDPR

¹³⁶ Article 6 GDPR

¹³⁷ Article 6(1)(e) GDPR

¹³⁸ Article 6(1)(f) GDPR

¹³⁹ Article 6(1) GDPR

¹⁴⁰ Article 89(1) GDPR

¹⁴¹ Article 6(2) GDPR

¹⁴² Article 9 (2) GDPR

¹²⁵ Article 46 Dutch implementing Act

limitations with regard to the processing of genetic, biometric and health data (e.g., explicit consent and written informed consent). The existence of national limitations also conditions the application of the presumption of combinability of secondary use of data¹⁴³. Thus, the GDPR allows substantial national variations and therewith also the possible regulatory fragmentation across EU/EEA member states⁴⁹.

This fragmentation can be seen in our results: The **Netherlands, Finland and Norway and Portugal** have in place some exceptions and derogations from data subjects' rights also applicable to health data related research, which may apply to record linkage. However, only in Finland a dedicated Act on the Secondary Use of Health and Social Data and research was approved that is typically grounded on public interest and the necessity for scientific research as the main legal basis for the use of health data. In fewer cases consent is used. In all the four countries less restrictive conditions apply to non-sensitive data (e.g. education data), without prejudice to the need to ensure lawfulness of the processing. In **Portugal** – which currently seems to be the most restrictive of the four assessed countries—if sensitive or non-sensitive data is anonymized, and therefore cannot be linked to the data subject, its access can be granted for research purposes¹⁴⁴; otherwise, an explicit or an explicit and written consent (the latter in the case of routinely collected data held by the health system) must be given¹⁴⁵ and can only be disregarded in very exceptional circumstances. Yet, particular rights of the data subjects can be derogated in the context of scientific research, subject to certain conditions, when they are likely to render impossible or seriously impairing the objectives of the research in question. Nevertheless, anonymized data falls outside of the scope of the GDPR and member states' personal data legislation, as the GDPR does not apply for anonymized data¹⁴⁶. Thus, even though room for national legislation is granted¹⁴⁷ which to some extent is beneficial, it also implies a potential risk of regulatory fragmentation^{148,35,49}. Even though the GDPR aimed to avoid regulatory fragmentation across EU/EEA member states, any national derogations allowed by the GDPR¹⁴⁹ similarly upsurges this possibility^{35,49}. Thus, we argue that EU national legislatures ought to further collaborate and work jointly together to guarantee consistency^{35,49}. There is also room for further EU legislation in specific matters, as it is the case of the proposed creation of a Health Data Space in Europe for the improvement of data sharing for scientific research purposes^{50,51}.

Form and scope of consent

The processing of personal data or special categories of personal data, such as health data, requires the application of the GDPR, as per definition, record linkage is a processing operation which entails higher risks for privacy⁵². The GDPR establishes several legal grounds to process data of which one of them must be fulfilled, except if data is anonymized and then the GDPR is not applicable¹⁵⁰. In practice, regarding scientific research with sensitive data such as health data: i) either an explicit informed consent¹⁵¹ must be provided in oral or written form, ii) or the basis is a task carried out in public interest, in this case either for reasons of public health¹⁵² or because it is necessary for scientific, historical, and statistical purposes based on Union or Member State law¹⁵³. Albeit one legitimate basis for sensitive data processing is consent¹⁵⁴, the GDPR acknowledges that it may not always be possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection¹⁵⁵. The GDPR even states that it should be allowed to give consent to certain areas of scientific research. Hence, on the one hand, the GDPR places a *normative weight* on the consent as a requirement which deviates in light of each health research setting. On the other hand, the GDPR places a more *substantive approach* to consent as it allows research as an exemption⁵³. Thus, in line with Dove and Chen (2020) the question arises: Should consent for data processing be privileged in health research as a lawful basis?⁵⁴.

It appears that there is some political and regulatory divergence emerging from this normative connection that is made between consent as a lawful basis in data protection for the data subject and consent as a research ethics principle⁵⁴. We argue in accord with the European Data Protection Board which inter alia commented, that there are persuasive motives why consent for data processing in the context of health research may not be the suitable lawful basis (reliant also on the kind of project)⁵⁴. This could be seen in the example of **Portugal**, a member state that is more determined to the value of informational self-determination. In cases where cohort data collected, based on consent to participate in a study, is linked with routine data, we argue that consent can be used as one lawful basis signifying respect for the data subject and balancing the communication with the data controller but to the extent that it does not hamper research practices⁵⁴. Thus, stronger emphasis should be placed on the purpose of public interest and the scientific research exemption while not undermining data protection and data privacy.

¹⁴³ Article 5(1) (b) GDPR

¹⁴⁴ Article 4/4 of 12/2005 Act, January 26, 2005; Article 31/4 of 58/2019 Act, August 8 2019.

¹⁴⁵ Article 124 of Portuguese Civil Code

¹⁴⁶ Recital 26 GDPR

¹⁴⁷ Article 6(2) GDPR

¹⁴⁸ Article 6(1)(e) GDPR

¹⁴⁹ Article 9(4) GDPR

¹⁵⁰ Article 9(1)(a) GDPR; Recital 32 GDPR; Article 4/3 of 12/2005

¹⁵¹ Article 4(11) GDPR

¹⁵² 6(1)(e) GDPR

¹⁵³ Article 9(2)(i) GDPR

¹⁵⁴ Article 6(1)(a) GDPR, Recital 40 GDPR

¹⁵⁵ Recital 33 GDPR

In line with Donnelly and McDonagh (2019), we claim that the GDPR articulates research exemption at a more principled and theoretical level, hence, in praxis the research balance is *struck* at national member state level¹⁵³. Consequently, the GDPR not only allows complications and barriers for EU/EEA cross-national record linkage and scientific EU/EEA research projects to remain, it allows to hamper its own aim: to create a harmonised regulatory framework for health research⁵³. Moreover, the fundamental values of the existing legislation in each EU/EEA member state in terms of the equilibrium between individual rights to informational self-determination and the common public good can most likely explain this diversity together with infrastructural constraints. Striking in this regard is also the impact of culture on the concept of patient autonomy and informed consent⁵⁵; therewith, researchers' responsiveness and sensitiveness to cultural differences in national or cross-national studies are key factors in improving study participation and retention and ultimately the quality of research⁵⁶.

The form and scope of consent to access personal data from registries and to undergo record linkage for research purposes varies greatly across member states. In health research, **Portugal** requires explicit (mostly written) informed consent¹⁵⁶, yet, allowing consent given for areas of scientific research. **Norway** requires ethical approval, which demands well-founded research grounds and preferably that linking is explicitly described in the written background information of the consent form (informed consent). **Finland** mainly requires public and legitimate interest for scientific research and less frequent explicit informed consent. The **Netherlands** requires general informed consent with "tick boxes" relying on the opt-out system. Yet strikingly, it could be argued that the GDPR may be more restrictive than any of the member states compared, due to the principle of accountability, which establishes that responsibility must be taken for what is being done with personal data and how other principles are complied with. As appropriate measures and records are needed to validate the compliance, oral consent may rather be seen as a remote scenario as the necessity to record oral consent exists according to the principle of accountability¹⁵⁷.

Despite acknowledging that the opt-in consent is a crucial part of a patient-centred approach in research for those patients who generally do not opt to participate in research⁷, we argue that the opt-out approach — as practiced in the **Netherlands** — is a suitable mean of obtaining consent in medical health research and may facilitate record linkage when based on the data protection and privacy rights of the data subjects as well as may encourage research participation^{57,58}. This should be a factor to consider when aiming to circumvent the growing phenomena of refusals to participate in epidemiological studies^{59–63}. Nevertheless, upcoming opt-out systems should have a focus

on monitoring register performances and the purpose and criteria for evaluation must be determined before the execution⁶⁴. Yet, with regards to the national implementation of the GDPR, it appears that in the **Netherlands** a tendency to curtail the application of the opt-out system and replace it by generic consent at the start of the treatment emerged. Hence, in the **Netherlands** the debate now hinges around the question whether such a generic consent is compliant with the notion of explicit consent in the GDPR¹⁵⁸. The restrictive interpretation of the European Data Protection Board of Recital 33 should then be abandoned, and more emphasis given on how the European Data Protection Supervisor (2020) saw the potentialities of this Recital. Interestingly, also in Portugal the implementation legislation adopted generic consent in line with Recital 33 wording. We recommend aligned to Donnelly and McDonagh (2019), that the European Data Protection Board should offer explicit direction on the process of consent in health research in order to tackle limited research balance at national member states level⁵³.

Representations of minors and the age of consent

The maturity of minors has been highly discussed resulting in deviating opinions and henceforth different implementations and practices across the EU/EEA exist^{27,55,65,66}. The GDPR provides that consent for the processing of a child's personal data, in relation to Information Society Services, can be given from the age of 16 years onwards and that the holder of parental responsibility must give authorization under this age¹⁵⁹. Even though in the majority of the countries consent is qualified from 16 years onwards for most types of health research and regardless of the research topic with 18 years, the assessed countries vary with regards to the representations of minors and the age of consent. **Finland** (15 years)¹⁶⁰, **Norway** (16 years)^{161–163} and the **Netherlands** (16 years)¹⁶⁴ are closer to GDPR's proposal regarding Information Society Services, and seem to be more liberal in involving and allowing minors in consent provision. **Portugal** (18 years, by default)¹⁶⁵ stood out to be most restrictive or protective with

¹⁵⁸ Dutch Code of Conduct initiative. Available at: <https://www.nwo.nl/en/netherlands-code-conduct-research-integrity>

¹⁵⁹ Article 8 (1), Article 6(1) GDPR

¹⁶⁰ The ethical principles of research with human participants and ethical review in the human sciences in Finland, Finnish National Board on Research Integrity TENK guidelines 2019. FINNISH NATIONAL BOARD ON RESEARCH INTEGRITY TENK 2019. Available at: https://tenk.fi/sites/default/files/2021-01/Ethical_review_in_human_sciences_2020.pdf

¹⁶¹ Health Research Act §17

¹⁶² Act on medical and health research (the Health Research Act) of 20 June 2008 No. 44. Lov om medisinsk og helsefaglig forskning (helseforskningssloven) - Lovdata

¹⁶³ Forskrift om barn mellom 12 og 16 år sin rett til selv å samtykke til deltakelse i medisinsk og helsefaglig forskning - Lovdata. Available at: <https://lovdata.no/dokument/SF/forskrift/2017-06-28-1000?q=Forskrift%20om%20samtykke%20til%20forskning>

¹⁶⁴ Article 5 GDPR

¹⁶⁵ Article 124 of Portuguese Civil Code, Decree-Law No. 47344, Official Gazette No. 274/1966

¹⁵⁶ Article 124 of Portuguese Civil Code

¹⁵⁷ Article 5 (2), GDPR

regards to the legal age, even though allowing for a case-by-case assessment of maturity and requiring the assent regardless of minors' age. It means that the Data Protection Law establishes that, offering Information Society Services directly to a child, personal data processing of the data from a child based on consent can be lawfully conducted if the child is at least 13 years old, which is the lowest permitted by the GDPR¹⁶⁶. We argue, in line with GDPR's provision to guarantee that children must understand any information provided to them¹⁶⁷, that the legal age of 18 years – as in Portugal—could be lowered to 16 years providing an opportunity to include mature minors and extend their autonomy^{67,68}. The age of maturity could be scientifically determined^{165,69}.

Scopes of intervention (ethical approval)

In **Portugal** ethical approval from an Ethics Committee must be retrieved before the commencement of research¹⁶⁸. In **Finland** no ethical approval by an Ethics Committee is needed for the pure registry data-based research or if principle of informed consent is not deviated for non-medical research; however, cohort studies that collect data from participants do require consent. In **Norway**, before the initialization of medical and health related research, written participant information and consent forms must be approved by a Regional Ethics Committee¹⁶⁹, and ensuring that the health research is conducted according to ethical standards, including risk-benefit assessment and ethical grounds for data sampling, linkage, sharing with other institutions nationally and internationally. In the **Netherlands**, even though there is no legislation demanding an ethics committee except for scientific health research which includes procedures or requires to follow rules of behaviour, in practice all major research organisations and data holders of databases which can be used for medical research have such a committee which — in the case of multi centre research— do not always reach the same conclusions. Yet, in all four countries assessed different scopes of intervention, DPIA or Ethics Committees, apply.

Whereas **Portugal** appears to be more segmented requiring the approval for research by local, regional or national Ethics Committees depending on the case, **Finland**, the **Netherlands**, and **Norway** appear to be either more centralized so that additional ethical approval is not always

needed (**Finland**), by having one recipient with the authority to approve health research involving collaboration with other institutions (**Norway**), or by not having any legislation in first place that demands an Ethics Committee (**Netherlands**). The paradoxical effect of the seemingly lenient Dutch regime is that researchers have to address various data holders and navigate through various committees if they want to combine data for research. There is not one authority which can state that the research is scientifically valid, ethically warranted and compliant with data protection legislation and hence that the relevant data may be opened up for research. We hence argue that a more uniform process with one recipient having the authority to approve the research so that it is not necessary to send a number of various applications in order to start a research project, as it is the case in **Finland**, may be beneficial for research.

EU-funded projects have commonly opted to not construct a central patient-level database; but instead to store data locally, in view of the data protection and privacy regulations in each EU/EEA member state^{70,71}. Thus, in cross-national projects and multicentre studies involving multiple European institutions from EU/EEA member states, investigators must separately apply to individual Ethical Committees⁷². As initial data analyses are mainly locally executed alike within-country analyses, cross-national analyses are centrally carried out in compliance with a shared analysis plan on the aggregated results of the other countries^{70,73}. However, in some EU/EEA countries current ethical approval processes rather prolong and delay research commencement possibly to an unnecessary extend as well as produce challenges in collecting and extracting data from multiple diverse sources; thus, rather impede national and cross-national record linkage processes^{70,74}. De Lange *et al.*, (2019) concluded that huge variation across Europe in obtaining ethical permission for a non-interventional observational study in Europe exists in the time between application and first approval: 7 days in the **Netherlands**, 50 days in **Norway** and 300 days in **Portugal**⁷². In line with that, international studies recommend national harmonization on ethical, privacy and institutional review for multicentre trials or multicentre studies^{75,76}. Correspondingly, Dove and Garattini (2018) concluded in their qualitative study, that numerous experts that have been interviewed recommended several changes to the present ethics review regime for international research in order to diminish inefficiency and inconsistency⁷⁴. We argue that the current segmentation of ethical committees and approval processes in some EU/EEA countries may rather hinder the incorporation of data subjects and possibly have an adverse effect on external validity⁷². In line with de Lange *et al.*, (2019) in order to promote research, further harmonization between EU/EEA countries in obtaining ethical clearance for observational and non-interventional studies and registries is required⁷². We opt that a more uniform process to improve ethical guidance should be followed across EU/EEA member states. Moreover, European projects should thrive for aiming to produce a centralized and harmonized electronic database of cohort data to facilitate record linkage and data exchange across EEA member states⁷⁷.

¹⁶⁶ Portugal - National GDPR Implementation Overview, May 2020. Available at: <https://www.dataguidance.com/notes/portugal-national-gdpr-implementation-overview>

¹⁶⁷ Article 8 GDPR

¹⁶⁸ "Competent Ethics Committee (CEC)" means the committee in charge of issuing the opinion provided for in this law, which may be the CEIC (Ethics Committee for Clinical Research), the ESC (Ethics Committees for Health, established under that name by Decree-Law No. 97/95, May 10), functioning at the clinical trial centre involved, or the ESC designated by the CEIC for that purpose.

¹⁶⁹ §9 and 10 of Health Research Act

Legal basis for research and registries

The legal basis for research and for registries varies in number, completeness, and accessibility across the assessed countries. The Nordic countries **Finland** and **Norway** appear to be the least restrictive countries which very closely follow the GDPR in their national implementations. **Finland** deviates the least as its legal basis for scientific research mainly requires public and legitimate interest for scientific research and less frequent consent and legal obligations¹⁷⁰. In **Norway**, linkage between various registers is possible but strictly regulated¹⁷¹: While some registries or demographics registered by Statistics Norway, as well as some medical quality registers are not based on consent, others demand consent to allow filing health data. In these registries various health and social information are filed and linked to the unique identification number, making register data accurate and robust¹⁷². In **Portugal**, the national implementation of the GDPR permits data processing necessary for the creation of centralized health data bases or registries for specific purposes under information security requirements and based on a unique platform. The National Institute of Statistics is allowed by law to carry out the processing of personal data, including sensitive data, and data linkage, namely with other statistical authorities and disease registries sharing anonymized data; yet the collection of sensitive data typically relies on the authorization of data subjects. In the **Netherlands**, the legal basis for registries is based on the opt-out system and research is built on a generic informed consent, the opt-out system, and (newly with the GDPR) a DPIA and the involvement of a DPO. However, if consent is not obtainable, data can be used for scientific research if serving the public interest and assuring the privacy of data subjects through pseudonymization. Yet, even though citizens, corporations and public bodies are required to submit personal data to Statistics Netherlands, no legislation exists which allows the usage if national registration numbers for research in the **Netherlands**.

Thus, whereas some legislations in EU/EEA member states do not allow the usage of unique identification numbers for health research, as the **Netherlands** and **Portugal**, in **Finland** the linking of unique identification numbers for research without explicit consent for the majority of register-based research is allowed. In **Norway** filing information on identification number is routine for many registries but linking individual clinical information with these register data requires ethical approval, i.e., generally that the subject gives consent, although with some exemptions. Noteworthy, even though several EU/EEA member states attain ethical approval and introduce

a DPIA complying with the GDPR, registry holders may set different requirements which could be harmonised^{8,78,79}. We further argue, based on the example of **Norway** and **Finland**, that linking unique personal identification numbers across registries and with cohort data for research is a strength and should be further explored. Those identifiers are vital for the operations of national healthcare systems which require to uniquely identify an individual across multiple organizations in order to function properly⁸⁰. Furthermore, those unique identifiers embrace the possibility to link research data, expand data available for individuals, encourage to detect overlap between data collections, and simplify reproduction of research results⁸¹.

National Identity Schemes are compound sociotechnical arrangements in which numerous necessities from various stakeholders must be balanced and based on appropriate levels of privacy and security⁸². The protection of data subjects' identity is possible when linking those identifiers, if the data curator allocates random identifiers to survey entities but has no access to the data, making it highly difficult to identification of respondents⁸⁰. Another possible option is the 'Privacy-Preserving Record Linkage' technique aiming to link data records without revealing concrete personal identifying attributes and adhering to data privacy⁸³ and "federated learning technique" (e.g., RECAP preterm platform that allows federated database analysis (see <https://recap-preterm.eu/>)). Even though the GDPR has achieved success for digital health, we recommend the strengthening of countries with the national health identifier system and further security for the protection of personal health information which requires political determination and alliance among all involved stakeholders to function effectively^{84,85}.

Record linkage and harmonization

The comparison of the possibilities in linking routinely collected health and education data with cohort data enables to lawfully understand the barriers, challenges, and opportunities across the EU/EEA region. In **Portugal**, if the basis of the data processing reasoning is scientific research, it is possible to link routinely collected health and education data of children with cohort data if data processing has a lawful ground, follows the rights of data subjects, duties of processors and controllers, and the legal requirements and obligations relative to DPIA. In **Finland**, if data is needed from registers of multiple public data controllers, single private data controller or the Finnish National Institute of Health or if single data controller has transferred the permit authority to Findata¹⁷³. The Data Permit Authority Findata has the right to request a data permit application statement from the data protection supervisory authority Ombudsman, which was mandatory in the previous law prior to the GDPR. However, this statement is not used for record linkage, but for the general permit of data and is

¹⁷⁰ Article 6 GDPR

¹⁷¹ §9 and 10 of Health Research Act

¹⁷² Act of 20 June 2014 No. 43 on Personal Health Data Filing Systems and the Processing of Personal Health Data (Personal Health Data Filing System Act) Lov om helseregistre og behandling av helseopplysninger (helseregisterloven) – Lovdata

¹⁷³ Act on the Secondary Use of Health and Social Data (552/2019), March 13, 2019

in practice hardly ever requested¹⁷⁴. **Norway** allows linking routinely collected cohort data if the Regional Committee for Medical and Research Ethics approved it, and if it complies with the Personal Data Protection Act and the GDPR procedures. In the **Netherlands**, linking routinely collected data at statistics Netherlands with cohort data is possible with a generic informed consent based on the opt-out system and the requirement of the conduction of the DPIA and the appointment of a DPO.

Thus, did the GDPR recognize the importance of health research³¹? The analysis of the four countries revealed that fragmentation and divergence remained, which is not always in favour for linking routinely collected health and education data with cohort data purposing scientific research. One the one side of the spectrum, **Portugal** stood out as the country with the most incomplete national implementation of the GDPR with regards to scientific research compared to any of the other member states assessed²⁸; in part for that reason and the resulting lack of legal certainty it is also considered the most restrictive one, including in what concerns internal and transnational record linkage. Further legislation or the revision of the existing legislation applicable to health-related research would definitely be welcome for the sake of clarity and legal certainty. On the other side of the spectrum, **Finland** appears to be the least restrictive in facilitating record linkage, which amplified the usage of electronic registries comprising sensitive data while maintaining citizen's right to privacy as health care authorities have the right to collect and record health data of individual citizens⁸. It appears that the GDPR rather has brought a more narrowed and restrictive focus in those EU/EEA member states who had followed a more liberal approach up until now, such as the **Finnish** legislation on the processing of health data and the **Dutch** legislation which now requires additionally the conduction of a DPIA and the consultation of a DPO.

We argue in line with Sorbie *et al.* (2021) that even though data ownership and the idea of 'my data' is central for notions of reward, opportunity and control— as executed in **Portugal** —, ethical and social concerns of data that reinforce biomedical research are of greater importance⁸⁶. Thus, based on the **Finnish** example, a centralized management of national data may be beneficial for research outputs serving as a powerful basis of data at national level and will further facilitate cross-national record linkage of data. Moreover, member states that are more committed to the value of informational self-determination, such as **Portugal**, are rather hindered in conducting health research purposing to contribute to the public good. Even as the GDPR may appear discouraging for researcher in some member states, as Cornock (2018) argues, it rather essentially gives existing best ethical practice a legal standing⁸⁷. Hence,

further consistency and harmonization would be beneficial in line with the response of the European Data Protection Board to the European Commission on the subject of health-related research and the GDPR⁸⁸. We argue in line with the European Data Protection Board, which recommends that the European Commission should explore the possibility of providing a uniform regime for health-related research in a future legislative proposal dedicated to the European Health Data Space^{50,51}.

Thus, consistent with Townend (2018) we ask: "Is harmonization an impossible dream"⁸⁹, or actually practically achievable? And if achievable, how can the impossible be made possible? Townend (2018) further argues that harmonization would be possible if the aim of data sharing – and therewith subsequent record linkage processes – is based on public interest, social liberalism as a basis of solidarity, with an understanding of the human rights approach and citizen sensitivities acknowledging the profession of 'researcher'⁸⁹. Moreover, in line with van Veen (2018), 'good research governance' can enable to frontward on consent-based research – as in Portugal with individual informational self-determination – or anonymization²⁹. Hence, harmonization may be achievable while taking the opportunities of the flexibilities of the GDPR into account without undermining data protection and data privacy of data subjects. Scientific research that involves sensitive data should be planned to accommodate the needs of the public good considering that personal data protection is not an absolute right¹⁷⁵. The protection of personal data should be considered with regards to its purpose in society and in relation to the principle of proportionality¹⁷⁶ and be balanced with other fundamental rights⁹⁰, as otherwise harmonization across EU/EEA member states is hampered in disadvantage to record linkage purposing research.

Strengths and limitations

This comparison can assist researchers aiming to establish international collaboration with other countries and help to handle with the technical aspects of the data transfer/processing etc. The comparison allowed to understand the best practices for research from each EU/EEA member state. The study is limited to a lawful view on record linkage.

Conclusion

Even though the GDPR is the most important legal framework for the protection of personal data in Europe, the national execution, when it concerns registries and research, matters most for record linkage. However, this varies: where in some EU/EEA states registers with which one could theoretically link data do not even exist while in other member states the registers exist and linking is possible without explicit consent. Underlying values of the existing legislation in each member states, concerning the balance between the individual right to informational self-determination and the public good can

¹⁷⁴ Section 44, Act on the Secondary Use of Data (552/2019). March 13, 2019. Available at: <https://stm.fi/documents/1271139/1365571/The+Act+on+the+Secondary+Use+of+Health+and+Social+Data/a2bca08c-d067-3e54-45d1-18096de0ed76/The+Act+on+the+Secondary+Use+of+Health+and+Social+Data.pdf>

¹⁷⁵ Article 4 GDPR

¹⁷⁶ Recital 4 GDPR

most probably explain that diversity along with infrastructural limitations and also the pace and completeness or sufficiency of the GDPR implementation reforms. Researchers from member states more committed to the value of informational self-determination, such as Portugal, are often hampered in doing research which in their opinion would contribute to the public good. It will remain a challenge to overcome these variances in Europe. More harmonization could be helpful but should certainly not be detrimental for research in those member states which opened a leeway for registries and research for the public good without explicit consent.

Data availability

All data underlying the results are available as part of the article and no additional sources of data are required.

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Mark Taylor 

Melbourne Law School, Melbourne University, Melbourne, Australia

I've reviewed and think the changes made are adequate.

Competing Interests: No competing interests were disclosed.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 11 October 2021

<https://doi.org/10.21956/openreseurope.15260.r27690>

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Mahsa Shabani

Metamedica, Faculty of Law and Criminology, Ghent University, Gent, Belgium

I have reviewed the responses of the authors and I have no further comments on the manuscript."

Competing Interests: No competing interests were disclosed.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Version 1

Reviewer Report 03 August 2021

<https://doi.org/10.21956/openreseurope.14763.r27015>

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**Anders Foldspang**

¹ Department of Public Health, Aarhus University, Aarhus, Denmark

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Doetsch *et al.* present a thorough, detailed, systematic, legal, comparative analysis and scoping review with the objective to investigate possibilities of linking cohort data of minors (as an example) with routinely collected education and health data, comparing EU/EEA member states, with a central view to the implementation of the General Data Protection Regulation (GDPR) in Portugal, Finland, Norway, and the Netherlands.

Use of registers and data linkage is crucial for the production of knowledge in public health science and practice, including epidemiological population studies as well as studies on health services functioning and studies in clinical epidemiology. Linkage of demographic data with health, social and economic data opens up hitherto non-accessible scientific and practical perspectives – and not least when the complicated phenomenon of cross-border linkage is made possible.

Having considered the special conditions of the implementation of the GDPR in each of the four countries selected, Doetsch *et al.* discuss public interest and scientific research; form and scope of consent; representation of minors and the age of consent; scopes of intervention and ethical approval; the legal basis for research and registries; record linkage and harmonization.

These months, the global Covid-19 pandemic has demonstrated both the use of and the need for high-quality population data – not tomorrow but in time – from all European states and from states outside Europe as well. Register-based information has been crucial to the initiation and implementation of large and extremely expensive anti-Covid-19 programmes. Thus, on one side, removal of obstacles to scientific and practical register use necessarily must be extremely precise and of high quality, whereas it, on the other side, as it seems, can only happen too slowly.

Thus, the detailed problem analysis and discussion presented by Doetsch *et al.* is future-oriented and a gift to the process of development of register refinement and coverage as well as register and data linkage and analysis in research and practice. The Covid-19 pandemic has demonstrated the urgent need for that.

Are the rationale for, and objectives of, the Systematic Review clearly stated?

Yes

Are sufficient details of the methods and analysis provided to allow replication by others?

Yes

Is the statistical analysis and its interpretation appropriate?

Not applicable

Are the conclusions drawn adequately supported by the results presented in the review?

Yes

Competing Interests: No competing interests were disclosed.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Author Response 17 Sep 2021

Julia Nadine Doetsch

The authors' responses to the reviewer report 1 were highlighted in bold.

Doetsch *et al.* present a thorough, detailed, systematic, legal, comparative analysis and scoping review with the objective to investigate possibilities of linking cohort data of minors (as an example) with routinely collected education and health data, comparing EU/EEA member states, with a central view to the implementation of the General Data Protection Regulation (GDPR) in Portugal, Finland, Norway, and the Netherlands.

Use of registers and data linkage is crucial for the production of knowledge in public health science and practice, including epidemiological population studies as well as studies on health services functioning and studies in clinical epidemiology. Linkage of demographic data with health, social and economic data opens up hitherto non-accessible scientific and practical perspectives – and not least when the complicated phenomenon of cross-border linkage is made possible.

Having considered the special conditions of the implementation of the GDPR in each of the four countries selected, Doetsch *et al.* discuss public interest and scientific research; form and scope of consent; representation of minors and the age of consent; scopes of intervention and ethical approval; the legal basis for research and registries; record linkage and harmonization.

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Thus, the detailed problem analysis and discussion presented by Doetsch *et al.* is future-

oriented and a gift to the process of development of register refinement and coverage as well as register and data linkage and analysis in research and practice. The Covid-19 pandemic has demonstrated the urgent need for that.

Authors' reply: We would like to thank the reviewer Prof. Anders Foldspang for their constructive comment and positive response.

Competing Interests: No competing interests were disclosed.

Reviewer Report 19 July 2021

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Mahsa Shabani

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Pieter De Smet

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The manuscript uses scoping review methodology to review the relevant national regulations in four countries related to linkage of registry databases and cohort data (including education and health data) from minors.

Below please see our remarks on the version 1 of the manuscript.

A general remark regarding the writing style/wording choices of the manuscript: attention should be paid to the way that sentences are written. Below I list some examples that require revisions:

- From abstract: "Linkage of data directly collected from cohort participants based on individual consent must respect data protection rules and privacy rights of data subjects." In principle, in processing any type of personal data, regardless of the legal basis for data collection (consent or others), data protection rules and rights must be respected.
- Another example from the abstract: "EU/EEA has limited legislative authority over member states." This is a strange phrase, as EU law is generally considered to have primacy over national law (depending on the subject matter).
- Another example: P. 4: e-privacy regulation: the regulation is not yet approved by the relevant institutions – the replacement of the Directive is thus not (yet) definite.
- Example from P. 21: the legal basis for scientific research is also a public interest basis, so

the comparison/listing is not fully accurate.

- example from P. 16: It's not because Norway forms part of the EEA, that Regulations/Directive of the EU evidently apply. This requires an agreement within EEA/EFTA and an additional protocol – would be interesting to link to that agreement (cfr/ <https://www.efta.int/EEA/news/General-Data-Protection-Regulation-incorporated-EEA-Agreement-509291>).
- This sentence is not correctly written: "As a result, the so called trialogue between the European Parliament, the Council and the European Commission as substantial leeway was left to the member states".
- In table 3, under column "GDPR specific articles" also recitals have been included. this is not fully accurate as in principle recitals are not articles.
- Related to this general remark, the language errors and typos in the text need to be fully addressed.

Here are other comments on the content of the paper:

- Abstract: The abstract is not fully informative. It would be better that to start why this type of data processing is of interest to this study (maybe by reference to the project).
- In the methods section, it should be specified that the search string has been adopted based on the local languages. Also, it would be helpful to include whether the search has been conducted and checked by multiple researchers and how this has been coordinated among various authors.
- In the methods, the review question is quite broad and vague ("what are the possibilities of..."). It is important to nuance this and make it more specific. Otherwise, this can also refer to technical possibilities, etc.

Results and discussion:

- In general, the rationale behind table 3 is not very clear to me. How columns and rows are related to each other? Or this is in principle a table with standalone columns?
- A general remark: in the paper, approvals and requirements from data protection regulations and research with human subjects (ethics approvals for processing health data mainly) have been discussed together, while this has not been adequately explained in the introductory part. For a reader with no prior knowledge on this matter, this lack of distinction can be confusing.
- In the paper has been referred to binary option of anonymisation vs consent as legal basis. However, it has not been adequately explained what are the potential risks associated with re-identifiability of data in this context? is this in principle possible?
- Use of privacy preserving methods has been briefly mentioned in the manuscript. what are the other technical and organisational measures that can/must be used in this context in case data have been processed based on research exemption rules?
- Page 21 out of 27 (under form and scope of consent): The lawful grounds for processing

sensitive data is broader than what is listed there (although these might be the most relevant ones for this discussion). In any case, to avoid confusion, it is important that nuance this paragraph.

- The authors mention that the upcoming European Health Data Spaces can be a potential solution to address the current fragmented regulatory framework in the EU regarding secondary uses of data. It would be interesting to briefly elaborate on that and discuss how this can address the current regulatory fragmentation in the EU on this matter.

References

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Are the rationale for, and objectives of, the Systematic Review clearly stated?

Partly

Are sufficient details of the methods and analysis provided to allow replication by others?

Partly

Is the statistical analysis and its interpretation appropriate?

Not applicable

Are the conclusions drawn adequately supported by the results presented in the review?

Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: My expertise in in the area of health privacy, with focus on processing health data for scientific research purposes.

We confirm that we have read this submission and believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however we have significant reservations, as outlined above.

Author Response 17 Sep 2021

Julia Nadine Doetsch

The authors' responses to the reviewer report 1 were highlighted in bold.

The manuscript uses scoping review methodology to review the relevant national regulations in four countries related to linkage of registry databases and cohort data (including education and health data) from minors.

Below please see our remarks on the version 1 of the manuscript.

Authors' reply: We would like to thank the reviewers Prof. Mahsa Shabani and Dr.

Pieter De Smet for their thorough revision and detailed comments.

A general remark regarding the writing style/wording choices of the manuscript: attention should be paid to the way that sentences are written. Below I list some examples that require revisions:

- From abstract: "Linkage of data directly collected from cohort participants based on individual consent must respect data protection rules and privacy rights of data subjects." In principle, in processing any type of personal data, regardless of the legal basis for data collection (consent or others), data protection rules and rights must be respected.

Authors' reply: That is correct, data processing of any type of personal data, regardless of the legal basis for data collection (consent or others), must respect the data protection rules and rights. As we focus on this particular scenario, we narrowed it down in the text to data directly collected from cohort participants. We cut out the "based on individual consent" to avoid misunderstandings, as here we referred to ethical approval.

- Another example from the abstract: "EU/EEA has limited legislative authority over member states." This is a strange phrase, as EU law is generally considered to have primacy over national law (depending on the subject matter).

Authors' reply: Despite being a Regulation (directly applicable), the GDPR does not ensure total uniformity in data protection legislation across member states. It contains a significant number of provisions either permitting or requiring Member States to make their own national implementation in specific fields. As a result, national variations remain in some areas." We adapted the sentence to make it clearer. Another example: P. 4: e-privacy regulation: the regulation is not yet approved by the relevant institutions – the replacement of the Directive is thus not (yet) definite. Authors' reply: We agree the way it was written may have led to potential misunderstandings. We adapted the sentence to: "The GDPR along with the e-privacy directive, covering electronical communication to be replaced by the e-privacy regulation, functions as the ultimate legal framework on data protection and data privacy that reinforces individual control of data subjects' own data and their associated rights in a digitalized era.

- Example from P. 21: the legal basis for scientific research is also a public interest basis, so the comparison/listing is not fully accurate.

Authors' reply: We adapted the enumeration to be more precise.

- Example from P. 16: It's not because Norway forms part of the EEA, that Regulations/Directive of the EU evidently apply. This requires an agreement within EEA/EFTA and an additional protocol – would be interesting to link to that agreement (cfr/<https://www.efta.int/EEA/news/General-Data-Protection-Regulation-incorporated-EEA-Agreement-509291>).

Authors' reply: Thank you, we adapted the sentence to make it clearer. We also included this explanation in the footnotes.

- This sentence is not correctly written: "As a result, the so called trialogue between the European Parliament, the Council and the European Commission as substantial leeway was left to the member states".

Authors' reply: We adapted the sentence to: Thus, the result of the so called trialogue between the European Parliament, the Council and the European Commission left a

substantial leeway to the member states in its implementation".

- In table 3, under column "GDPR specific articles" also recitals have been included. this is not fully accurate as in principle recitals are not articles.

Authors' reply: We agree that the headline should be more inclusive and adapted the titles.

- Related to this general remark, the language errors and typos in the text need to be fully addressed.

Authors' reply: We proofread the manuscript again for typos.

Here are other comments on the content of the paper:

- Abstract: The abstract is not fully informative. It would be better that to start why this type of data processing is of interest to this study (maybe by reference to the project).

Authors' reply: We adapted the second sentence to highlight this study's interest: "Linkage of data directly collected from cohort participants, potentially serving as a prominent tool for health research, must respect data protection rules and privacy rights."

In the methods section, it should be specified that the search string has been adopted based on the local languages. Also, it would be helpful to include whether the search has been conducted and checked by multiple researchers and how this has been coordinated among various authors. Authors' reply: We added to the methods that the search string has been adopted based on the local languages (see page 5, paragraph "Search"). We also added that the search was furthermore checked by involved researchers in their respective country of expertise. In the methods, the review question is quite broad and vague ("what are the possibilities of..."). It is important to nuance this and make it more specific. Otherwise, this can also refer to technical possibilities, etc.

Authors' reply: The research question was on purpose held broad to cover all sub scenarios involved. We adapted the research question to "law possibilities" to make it more distinct that we discuss law scenarios from a legal perspective.

Results and discussion:

- In general, the rationale behind table 3 is not very clear to me. How columns and rows are related to each other? Or this is in principle a table with standalone columns?

Authors' reply: Yes, table 3 is a table with standalone columns. The same applies for table 1. The format of the tables was determined by the editorial staff of the journal after submission. We asked to strengthen the vertical lines to highlight that the columns are standalone.

- A general remark: in the paper, approvals and requirements from data protection regulations and research with human subjects (ethics approvals for processing health data mainly) have been discussed together, while this has not been adequately explained in the introductory part. For a reader with no prior knowledge on this matter, this lack of distinction can be confusing.

Authors' reply: Thank you for this remark. To not cause confusion we did not explore this into depth in the introduction. Later on in the main text, we differentiate in the country specific sections. We added an explanatory sentence in the end of the

paragraph to make it clear in the introduction: "Also applicable ethically informed legal requirements vary from country to country."

- In the paper has been referred to binary option of anonymisation vs consent as legal basis. However, it has not been adequately explained what are the potential risks associated with re-identifiability of data in this context? is this in principle possible?

Authors' reply: This is a very interesting thought. As the article refers to the possibilities of linking data, this is unfortunately out of the real scope of the article. We did not cover this aspect into depth as it is also not possible to explain this in a concise way and another article on this specific topic would be needed. The identification of risks itself is part of the privacy assessment which we mentioned in several occasions as one of the applicable legal requirements.

- Use of privacy preserving methods has been briefly mentioned in the manuscript. what are the other technical and organisational measures that can/must be used in this context in case data have been processed based on research exemption rules?

Authors' reply: The privacy preserving methods is just one of multiple examples. There are plenty of other methods but that would be the subject of another article. The federated learning technique that was mentioned, is practiced in the RECAP preterm project through data analysis in a federated database, which has inspired the motive for this article. We added a footnote.

- Page 21 out of 27 (under form and scope of consent): The lawful grounds for processing sensitive data is broader than what is listed there (although these might be the most relevant ones for this discussion). In any case, to avoid confusion, it is important that nuance this paragraph.

Authors' reply: Thank you. Yes, indeed the ones listed were the most relevant ones for the discussion. We adapted the text to avoid confusion.

- The authors mention that the upcoming European Health Data Spaces can be a potential solution to address the current fragmented regulatory framework in the EU regarding secondary uses of data. It would be interesting to briefly elaborate on that and discuss how this can address the current regulatory fragmentation in the EU on this matter.

Authors' reply: We agree that this would be very interesting, but as this topic is very extensive, it would require further explanation that would need to be covered in another article.

Competing Interests: No competing interests were disclosed.

Reviewer Report 19 July 2021

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Mark Taylor

¹ Melbourne Law School, Melbourne University, Melbourne, Australia

² Melbourne Law School, Melbourne University, Melbourne, Australia

This is an interesting discussion that helps to illustrate the limitations of the GDPR when it comes to establishing regulatory harmonisation between Member States in relation to the processing of personal data for the purposes of health research. It provides interesting summaries of the regulatory position in four countries that are part of the EU/EEA (namely, Portugal, Finland, Norway and the Netherlands) and usefully signposts relevant primary material.

With regards to the scope of the scoping report, as the study was designed to investigate the possibility of linking cohort data with routine health and education data (comparing the four countries identified) (stated second column, page 4) it is not made clear why personal data derived from the analysis of biological samples is excluded from scope. It is stated that such personal data are excluded as a data category “as it deviates from the main objective of the study” (first column, page 5) but it is not made clear why. It is not stated why personal data derived from analysis of biological samples are to be considered a separate and excluded category as a function of how they were derived.

There are occasions when the legal analysis is not entirely clear or accurate. As a non-exhaustive list of illustrative examples,

1. The definition provided of personal information (toward the bottom of first column, page 4) does not correspond with the definition of personal data provided in the GDPR (Article 4(1)). There is a material difference with regards to the need for an individual to be identifiable *from* information classified as personal information (with GDPR defining personal data as data *relating to* an identified or identifiable natural person as personal information. To be personal data under the GDPR the data itself need not necessarily contribute toward identification).
2. The legal analysis occasionally moves back and forth between legal instruments produced by the European Union (such as the GDPR) and those produced by the Council of Europe (CoE) (such as the Recommendation No.R(97)18 of the Committee of Ministers to Members States concerning the protection of personal data collected and processed for statistical purposes) (see bottom of first para, page 11, fn 16-19) without acknowledging the distinction between EU and CoE and the nature of the interplay between these different sources of law.
3. Under the sub-heading ‘Legal basis for registries) it is stated (apparently in reference to GDPR) that “In order to access data, either an explicit informed consent provided in an oral or written format is required, or the anonymisation of personal data of the data subject” (column 2, page 11). The citation provided in support of this claim is “Article 9/1/a) [sic] GDPR; Recital 32 GDPR; Article 4/3 of 12/2005” (fn 23). There are a number of difficulties with this. The legal basis for processing is established in part by Article 6 GDPR, which is not referenced but provides more alternatives than consent. Article 9 GDPR establishes a number of derogations to the general prohibition on the processing of personal data and the alternatives listed in Article 9 as permitting the processing of special categories of personal data also extend beyond consent. The Article 4/3 of 12/2005 cited is not fully referenced and so it is not clear what law is being referred to here. Table 3 “Main Involved Laws” provides only the reference Article 4/3 of 12/2005 Act, January 15, 2005. A more

comprehensive analysis of GDPR is provided elsewhere but this illustrates one of the difficulties with the paper's rather staccato structure.

There are also a number of typos (e.g. "sued" instead of "used", toward top of second column page 4) and some odd syntax that can obscure meaning (e.g. in reference to Portuguese law it is stated that the legal capacity of a person below the age of 18 "must be suppressed through guardianship by holders of parental responsibility" (second column, page 13). I don't know what that means, but it does not sound good!

Despite some qualifications and reservations with regards to the legal analysis, the paper represents a useful contribution as a stimulation to debate, source of reference to national law, and comparison of the legal situation across four countries, helping to illustrate and confirm the limitations of the GDPR with regards to achieving harmonisation in this context.

Are the rationale for, and objectives of, the Systematic Review clearly stated?

Yes

Are sufficient details of the methods and analysis provided to allow replication by others?

Partly

Is the statistical analysis and its interpretation appropriate?

Not applicable

Are the conclusions drawn adequately supported by the results presented in the review?

Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Health Law and Regulation

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 17 Sep 2021

Julia Nadine Doetsch

The authors' responses to the reviewer report 1 were highlighted in bold.

This is an interesting discussion that helps to illustrate the limitations of the GDPR when it comes to establishing regulatory harmonisation between Member States in relation to the processing of personal data for the purposes of health research. It provides interesting summaries of the regulatory position in four countries that are part of the EU/EEA (namely, Portugal, Finland, Norway and the Netherlands) and usefully signposts relevant primary material.

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Authors' reply: We would like to thank the reviewer Prof. Mark Taylor for their constructive feedback and thorough revision. With regards to your point raised on including biological samples, we had decided it would be too extensive. Therefore, this data category was excluded. We added a short explanation to the text: “and would involve an additional perspective that would lengthen the paper too extensively.”

There are occasions when the legal analysis is not entirely clear or accurate. As a non-exhaustive list of illustrative examples,

1. The definition provided of personal information (toward the bottom of first column, page 4) does not correspond with the definition of personal data provided in the GDPR (Article 4(1)). There is a material difference with regards to the need for an individual to be identifiable *from* information classified as personal information (with GDPR defining personal data as data *relating to* an identified or identifiable natural person as personal information. To be personal data under the GDPR the data itself need not necessarily contribute toward identification).

Authors' reply: We adapted the sentence to the exact quotation of Article 4(1) from the GDPR: “an information related to an identified or identifiable natural person [data subject].”

2. The legal analysis occasionally moves back and forth between legal instruments produced by the European Union (such as the GDPR) and those produced by the Council of Europe (CoE) (such as the Recommendation No.R(97)18 of the Committee of Ministers to Members States concerning the protection of personal data collected and processed for statistical purposes) (see bottom of first para, page 11, fn 16-19) without acknowledging the distinction between EU and CoE and the nature of the interplay between these different sources of law.

Authors' reply: Thank you for this comment. We included the distinction between EU and CoE and the nature of the interplay between these sources of law. We added: “The Council of Europe (CoE), an international organisation encompassing 47 countries of Europe, was established to encourage democracy and guard human rights and the rule of law in Europe. The CoE Convention for the protection of individuals with regard to the processing of personal data (“Convention 108” of 28 January 1981) and additional protocols is a treaty that is open to any country (it currently counts 54 States). It provides for a legally binding commitment of countries with global dimension and it has inspired for decades a number of legislative processes throughout the world, such as for instance the EU data protection framework (namely

the EU Data Protection Directive and the GDPR). The GDPR is an EU legal instrument that is a directly applicable and legally binding to the any EU/EEA Member States. The European Union presently has 27 members that have delegated some of their sovereignty so that decisions on certain issues of shared interest can be made democratically at European level.”

3. Under the sub-heading ‘Legal basis for registries) it is stated (apparently in reference to GDPR) that “In order to access data, either an explicit informed consent provided in an oral or written format is required, or the anonymisation of personal data of the data subject” (column 2, page 11). The citation provided in support of this claim is “Article 9/1/a) [sic] GDPR; Recital 32 GDPR; Article 4/3 of 12/2005” (fn 23). There are a number of difficulties with this. The legal basis for processing is established in part by Article 6 GDPR, which is not referenced but provides more alternatives than consent. Article 9 GDPR establishes a number of derogations to the general prohibition on the processing of personal data and the alternatives listed in Article 9 as permitting the processing of special categories of personal data also extend beyond consent. The Article 4/3 of 12/2005 cited is not fully referenced and so it is not clear what law is being referred to here. Table 3 “Main Involved Laws” provides only the reference Article 4/3 of 12/2005 Act, January 15, 2005. A more comprehensive analysis of GDPR is provided elsewhere but this illustrates one of the difficulties with the paper’s rather staccato structure.

Authors' reply: Thank you. We adapted the text to: “In order to access data, a legal basis is needed according to the GDPR (Articles 6 and 9). Member States may introduce further conditions with regards to the processing of health data.” The article 4/3 of 12/2005 was removed as by mistake national Portuguese law was included. We instead included article 9 of the GDPR. Table 3, Article 4/3 of 12/2005 Act, January 15, 2005. This is the Portuguese law that is also referred to in the comparative section. It was moved to the Portuguese section. With regards to the paper’s structure, we chose this structure to ease comparison between countries. There are also a number of typos (e.g. “sued” instead of “used”, toward top of second column page 4) and some odd syntax that can obscure meaning (e.g. in reference to Portuguese law it is stated that the legal capacity of a person below the age of 18 “must be suppressed through guardianship by holders of parental responsibility” (second column, page 13). I don’t know what that means, but it does not sound good! Authors' reply: Thank you, we corrected the typos. The sentence “must be suppressed through guardianship by holders of parental responsibility” was adapted to “It requires the authorization or intervention through guardianship of the holders of parental responsibility” to be more neutral and avoid misunderstandings.

Despite some qualifications and reservations with regards to the legal analysis, the paper represents a useful contribution as a stimulation to debate, source of reference to national law, and comparison of the legal situation across four countries, helping to illustrate and confirm the limitations of the GDPR with regards to achieving harmonisation in this context.

Authors' reply: We thank the reviewer for his comprehensive feedback and constructive comments. We have adapted the paper accordingly.

Competing Interests: No competing interests were disclosed.
