Further use of data and tissue for a learning health system: the rules and procedures in The Netherlands compared to Denmark, England, Finland, France, and Germany

Report commissioned by Health-RI

Evert-Ben van Veen (MLCF), Robert Verheij (Nivel),

MLCF

NIVEL
Research for better care

In cooperation with Olenka van Ardenne (Lygature, Appendix F), Kim Bavinck (Health-RI, Appendix F), Daniel Groos (MLCF/Lygature, Appendices B and C), Yvonne de Man (Nivel, Appendices B and C), Beatrice van der Velden MLCF/(Lygature, Appendices D and E).

Colofon

Refer to as:
E.B. van Veen, R.A. Verheij, *Further use of data and tissue for a learning health system: the rules and procedures in The Netherlands, compared to Denmark, England, Finland, France and Germany*, MLCF/Nivel, Utrecht, May 2022.

Graphic design:
Marieke Persoon, www.mariekepersoon.nl

ISBN 978-94-6122-816-1

Acknowledgements:
We thank the various respondents for the interviews at the country studies, Penny Jackson for her language corrections and prof. dr. Gerrit Meyer for his comments to an earlier draft without attempting to influence the direction or conclusions of our study.

About MLCF and Nivel

MLCF

Via its legal, ethical and policy expertise the MLC Foundation (MLCF) operated on the interface of health care and data needed to sustain and improve the health care system. All its activities were guided by the public values which underly scientific research and western European health care systems. MLCF contributed to several national and European projects on responsible processing of personal data for quality assurance, screening and research. The past tense is used here as this is the last report of MLCF. But for this report and its aftermath, all the activities and the staff of MLCF have been transferred to the 'health law, privacy and ethics' portfolio of Lygature.

Nivel

Nivel, Netherlands Institute for Health Services Research, is the national institute for health services research in the Netherlands. It is an independent organisation. Nivel's predecessor was founded in 1965. Its domain is applied and applicable health services research. Nivel has a dual mission: scientific and societal. Increasingly, Nivel has an international orientation.

Each Nivel study is published. In 2021 the annual turnover of Nivel was € 15,8 m. Nivel employs approximately one hundred and seventy persons, of whom about one hundred and ten are researchers. Nivel research is ISO 9001 certified.

About the authors

Evert-Ben van Veen has been active as a policy advisor, lawyer, and researcher in health care for most of his working life. He was the coordinating author of the first Dutch Code of Conduct on health research (2004) and one of the coordinating authors of that of 2022. During the advent of the GDPR he actively contributed to the efforts by the research community and patient organisations to reach a more balanced regulation than as proposed by the European Parliament. In 2017 he wrote a chapter in the yearly proceedings of the Dutch Association of Health Law on big data for a learning health system. At the moment Evert-Ben is part-time employed as a 'fellow' at Lygature in addition to rounding of the activities of the MLC Foundation. His more recent publications and blogs can still be found at the MLCF site.

Prof. Robert Verheij is research coordinator at the Netherlands Institute for Health Services Research, Nivel. His research line focuses on the reuse of health data and learning health systems. Robert has an advisory role at the Dutch National Health Care Institute and is endowed professor in Transparency in health care at Tilburg School of Social and Behavioral Sciences, Tilburg University.

Nederlandse samenvatting

Waarom dit rapport

In een lerend zorgsysteem wordt optimaal gebruik gemaakt van gegevens die de zorg in de vorm van elektronische patiëntendossiers en declaraties, etc., zelf voortbrengt om de zorg beter te maken. Daartoe moeten die in het kader van de zorg en de betaling verzamelde gegevens verder worden gebruikt. Dat is in veel Europese landen een uitdaging gebleken. De uitdagingen gaan deels over de regels met betrekking tot het verdere gebruik van patiëntgegevens en menselijk lichaamsmateriaal (hierna: weefsel).

Dit rapport onderzoekt de Nederlandse regels en discussies over verder gebruik van patiëntgegevens en weefsel voor een lerend zorgsysteem en hoe de toegang tot gezondheidsgegevens en koppeling van gegevens is georganiseerd. De Nederlandse regels en procedures worden vergeleken met Denemarken, Duitsland, Engeland, Finland en Frankrijk. Daaruit worden lessen getrokken voor de Nederlandse situatie.

Modaliteiten voor toestemming van de patiënt voor verder gebruik

De regels voor verder gebruik van patiëntgegevens in de onderzochte landen variëren tussen: 1) altijd verder gebruik als aan bepaalde voorwaarden met betrekking tot het onderzoek met de gegevens wordt voldaan, 2) opt-out, 3) brede toestemming of 4) AVG-toestemming.

Brede toestemming verschilt van AVG-toestemming in de mate van specificiteit. De AVG-toestemming kan een brede toestemming omvatten, maar moet ook de mogelijkheid bieden om de toestemming te specificeren voor bepaalde onderzoeksgebieden, dus een “gelaagde toestemming” met verschillende keuzes over het soort onderzoek waarvoor de gegevens mogen worden gebruikt. De AVG-toestemming is dus de meest strikte optie.

Wij hebben vastgesteld dat, behalve in Duitsland, de regels voor verder gebruik van patiëntengegevens in de andere landen minder streng zijn dan in Nederland. In die landen is het ofwel geen bezwaar voor verder gebruik ofwel helemaal geen toestemmingsmodaliteit. Duitsland kent overigens ook een uitzondering op toestemming voor verder gebruik van declaratiegegevens en voor de nationale kankerregistratie. Wat verder gebruik van weefsel betreft, is de toestemmingsmodaliteit meestal ‘geen bezwaar’, maar ook hier is Duitsland de uitzondering. Daar is het brede toestemming.

Voorkeursmodaliteit nog onderwerp van discussie in Nederland

Het uitgangspunt in Nederland is: toestemming. Er is discussie over de vraag of deze toestemming brede of AVG-toestemming moet zijn. Nederland kent een uitzondering voor verder gebruik voor onderzoeksdoeleinden als het vragen van toestemming onmogelijk is of wanneer redelijkerwijs geen toestemming kan worden gevraagd. In deze situaties is het mogelijk om patiëntgegevens te verwerken voor onderzoek wanneer de patiënt geen bezwaar heeft gemaakt. Onder welke omstandigheden deze uitzondering van toepassing is, staat echter ook nog ter discussie. Ook dit is een verschil met de andere landen. In alle onderzochte landen lijkt het debat over de regels beslecht.

Administratief identificatienummer voor onderzoek

Om gegevens van dezelfde patiënt uit verschillende gegevensbronnen aan elkaar te koppelen of om de patiënt in de tijd te volgen, is een uniek identificatienummer nodig. Nederland is het enige land in onze studie waar het voor administratieve doeleinden in de gezondheidszorg gebruikte identificatienummer (in die landen ofwel het algemene burgerservicenummer ofwel een speciaal sociaal zekerheidsnummer) formeel niet voor onderzoek mag worden gebruikt. Zelfs niet als dit nummer gepseudonimiseerd is in de zin van de AVG. Dat betekent dat de direct identificerende gegevens door de verzender van de gegevens zijn verwijderd maar dat er een sleutel is om van het pseudoniem terug te gaan naar het origineel. De ontvanger heeft die sleutel niet. Bij eenwegcodering ontbreekt zo'n sleutel terug. Het gebrek aan bruikbare alternatieven heeft ertoe geleid dat het eenweg gecodeerde burgerservicenummer in Nederland op vrij grote schaal wordt gebruikt voor koppeling van records, met zogenaamde 'domeinconversie' om het eenzijdig gecodeerde nummer uit verschillende onderzoeken alsnog te koppelen aan de beoogde nieuwe onderzoeksdatabank. De rechtsgrondslag voor deze oplossing wordt echter niet door alle belanghebbenden aanvaard en staat dus nog ter discussie.

In het laatste hoofdstuk stellen wij voor dat Nederland op hetzelfde niveau komt als de andere landen door het gebruik van een gepseudonimiseerd burgerservicenummer voor onderzoek toe te staan.

Centraal toegangspunt voor verder gebruik van gegevens

In alle onderzochte landen heeft de overheid geïnvesteerd in centrale toegangspunten voor onderzoekers om gegevens uit verschillende bronnen te combineren, hoewel de diepgang van de beschikbare gegevens en de rijpheid van die centrale toegangspunten varieert. In Nederland is er geen dergelijk centraal toegangspunt, ondersteund door overheidssteun, hetzij via wetgeving, hetzij via overheidsfinanciering voor die functie. Op basis van de Wet op het CBS vervult het CBS tot op zekere hoogte de rol van centrale hub met een beveiligde omgeving voor de verwerking van gegevens voor onderzoek. Daarbij kunnen gegevens uit een grote verscheidenheid aan bronnen via een door het CBS gegenereerde sleutel worden gekoppeld. Dat is echter niet diens primaire functie. Het CBS moet zijn werkelijke kosten, zoals voor de statistische geheimhoudingscontrole voor de output van het onderzoek, in rekening brengen. Bovendien brengen de gegevensbronnen soms aanzienlijke kosten in rekening om de gegevens, die hoe dan ook aan CBS moesten worden verstrekt voor diens statistische functie, te beperken tot de variabelen die nodig zijn voor een specifiek onderzoek.

Onderzoekers kunnen externe gegevens inbrengen als zij daarvoor een rechtsgrondslag hebben. En zoals gezegd staat deze rechtsgrondslag nog steeds ter discussie. Bovendien zal een volledige koppeling met CBS-gegevens niet mogelijk zijn als die gegevensbron niet het burgerlijke registratienummer of een eenmalig gecodeerd nummer op basis van het burgerlijke registratienummer kan gebruiken dat de genoemde domeinconversie mogelijk maakt.

In het laatste hoofdstuk stellen wij voor de rol van CBS als knooppunt voor onderzoek te versterken en tegelijkertijd de vele gezondheidsonderzoeksprojecten die gebruik maken van veilige gegevensverwerkingsomgevingen en die nog niet via CBS kunnen worden uitgevoerd, zoals met genetische gegevens, radiologische gegevens, enz. niet te belemmeren.

Gefragmenteerde gegevens en toetsing

De Nederlandse discussie over de reikwijdte van de toestemming en de onderzoeksuitzondering vindt plaats in een extreem gefragmenteerd gegevenslandschap. Elke gegevensbron heeft een eigen toezichtstructuur en interpretatie van de regels en voorschriften en hoe zij die vertalen naar de hierboven beschreven toestemmingsmodaliteiten. Bijgevolg is er geen gemeenschappelijk formaat voor de beoordeling van onderzoeksvoorstellen waarbij gegevens verder worden gebruikt. Ethische- of privacycommissies bij elke gegevensbron accepteren vaak geen beoordelingen van andere commissies. Ook hier lijkt Nederland de uitzondering te zijn. De voorstellen in het laatste hoofdstuk moeten leiden tot een minder gefragmenteerd datalandschap.

Voorstellen voor het Nederlandse debat over de toestemmingsmodaliteiten

Naast de hierboven genoemde kwesties gaat het laatste hoofdstuk vooral in op de voor Nederland geprefereerde toestemmingsmodaliteit. Onze discussie in het slothoofdstuk is niet wezenlijk beïnvloed door de "Visie en strategie op secundair gebruik" die de Nederlandse overheid heeft gepubliceerd toen wij dit rapport aan de PDF-redacteur voorlegden. Het belang van secundair gebruik, of "verder gebruik" zoals het in dit rapport wordt genoemd (zie hoofdstuk1), voor een lerend zorgsysteem wordt duidelijk onderkend. Als zodanig is dat een echte vooruitgang voor de Nederlandse situatie.

In het tijdpad staat dat dit jaar de huidige regelgeving wordt toegelicht en dat vervolgens volgend jaar mogelijk wetswijzigingen in gang worden gezet. Wij vinden ook dat de huidige regelgeving en haar problemen aan het parlement moeten worden uitgelegd en hopen via het rapport aan die uitleg bij te dragen. Aan de onderzoeksgemeenschap hoeft dit niet te worden uitgelegd, aangezien de Gedragscode Gezondheidsonderzoek van 2022 dat al doet. In bijlage E bespreken wij die Gedragscode, de brede consensus van alle belangrijke partijen waarop deze is gebaseerd en de reactie van de AP, die in wezen oproept tot een wijziging van de wetgeving.

Daar zijn wij het mee eens. Het debat over het verdere gebruik van gezondheidsgegevens in Nederland loopt al enkele decennia en ondanks de Gedragscode is er nog steeds onzekerheid. Er moeten snel beslissingen worden genomen over de richting van de toekomstige wetgeving. Wij doen daartoe suggesties op basis van onze gedetailleerde analyse van de huidige Nederlandse discussie in bijlage E en wat wij hebben geleerd van de andere landen van onze studie. Op één uitzondering na zijn die afgestapt van het onderscheid: of toestemming vragen of de gegevens anonimiseren. En ook Duitsland is daarvan afgestapt voor declaratiegegevens van de zorgverzekeraars en de nationale kankerregistratie.

Elk debat moet beginnen met het vinden van een gemeenschappelijke basis of uitgangspunten waarover men het redelijkerwijs eens kan zijn. Wij stellen het volgende voor (voor de onderbouwing verwijzen wij naar hoofdstuk 3 van dit rapport):

- De AVG vereist geen AVG toestemming als rechtsgrondslag voor onderzoek met gegevens. Het Europees Comité voor de Gegevensbescherming heeft dat ook afgeraden.
- Een op toestemming gebaseerde aanpak leidt tot onvolledige en bevooroordeelde gegevens, vooral met betrekking tot meer kwetsbare segmenten van de bevolking met een lagere gezondheidsvaardigheden.
- Een op toestemming gebaseerde aanpak leidt ook tot extra inspanningen, kosten en administratieve lasten voor zowel zorgverleners als onderzoekers. Deze zouden verveelvoudigen als deze toestemming geen brede toestemming maar AVG-toestemming zou zijn.

- Strikt anonieme gegevens zijn nauwelijks bruikbaar voor onderzoek. Voor de meeste onderzoeken zijn gedetailleerde gegevens op individueel niveau nodig om geldige resultaten te verkrijgen.
- Deze gepseudonimiseerde of eenzijdig gecodeerde gegevens zijn nog steeds persoonsgegevens al is de patiënt dan niet meer herkenbaar. Zulke onderzoeksgegevens zijn veilig gebleken als de juiste technieken worden gebruikt. Privacygevoelige gegevens van vele miljoenen Europeanen worden al meer dan tien jaar gebruikt voor onderzoek in veilige onderzoeksomgevingen. Voor zover bekend zijn er geen inbreuken op de gegevens geweest die tot negatieve gevolgen voor de betrokken personen hebben geleid.

Deze uitgangspunten bieden geen oplossing voor de ethische kwestie die hier op het spel staat. Elke toestemmingsmodaliteit moet een evenwicht vinden tussen a) de belangen en de autonomie van de huidige patiënten wanneer gegevens die op hen betrekking hebben bij onderzoek betrokken kunnen worden, en b) de belangen van toekomstige patiënten en burgers. Beide groepen zullen profiteren van het delen van gegevens in een lerend zorgsysteem, niet alleen met betrekking tot de behandeling van ziekten, maar ook met betrekking tot ziektepreventie.

Onze uitdaging is een evenwicht te vinden dat aanvaardbaar is voor de samenleving als geheel. Individuele belangen worden altijd beperkt in een samenleving wanneer doorslaggevende belangen van anderen op het spel staan. De discussie gaat over wie wij als anderen beschouwen, wat die doorslaggevende belangen zijn en in hoeverre die inperking kan en mag plaatsvinden. Het gaat erom om een aanvaardbare middenweg te vinden.

Wij stellen voor dat een goed georganiseerd algemeen geen-bezwaar systeem in dit verband een dergelijke middenweg zou vormen, indien aan bepaalde voorwaarden wordt voldaan. Een besluit voor een geen-bezwaar systeem als het uitgangspunt zou veel van de huidige juridische belemmeringen voor een lerend zorgsysteem wegnemen. Toch zou het nog voldoende ruimte laten voor degenen die de privacywaarborgen niet vertrouwen of niet willen bijdragen aan onderzoek.

Geen bezwaar zou dan de standaardmodaliteit worden voor verder gebruik voor een lerend gezondheidsstelsel. Zoals besproken in het laatste hoofdstuk, kunnen er uitzonderingen zijn op deze standaardmodaliteit. Of de gegevens mogen altijd worden hergebruikt, of juist toestemming. Meldingsplichtige ziekten zijn een voorbeeld van de eerste uitzondering.

Een dergelijk systeem is zeker niet onvoorwaardelijk. Elke patiënt moet duidelijk worden geïnformeerd over het verdere gebruik voor een lerend zorgsysteem en dat hij of zij bezwaar kan maken. Er moet worden verzekerd dat het onderzoek in het algemeen belang is, dat wil zeggen dat elke geïnteresseerde groep patiënten of burgers van het onderzoek kan profiteren of dat het onderzoek zal leiden tot een publiek debat over de te nemen maatregel(en). Dat zou betekenen:

- Het verzamelen van gegevens moet in overeenstemming zijn met de FAIR-beginselen[1]
- De veiligheid van de gegevens is gewaarborgd;
- Het onderzoek wordt uitgevoerd volgens wetenschappelijke normen, inclusief vastgestelde normen inzake onderzoeksintegriteit;
- De onderzoeksgegevens worden geen eigendom van de partij die het onderzoek heeft geïnitieerd;

1 FAIR staat voor: findable, accessible, interoperable, reusable. Vindbaar, toegankelijk, uitwisselbaar, herbruikbaar.

- De resultaten van het onderzoek worden openbaar gepubliceerd;
- Het onderzoek is transparant, en onderzoekers en onderzoeksorganisaties zijn verantwoordelijk voor de naleving van bovengenoemde beginselen.

Deze voorwaarden zijn grotendeels al uitgewerkt in de genoemde Nederlandse Gedragscode Gezondheidsonderzoek.

De principiële keuze voor een dergelijk, voorwaardelijk geen bezwaar systeem als uitgangspunt zal, ook als die keuze nog niet in wetgeving is vastgelegd: de huidige terughoudendheid van de gegevenshouders om gegevens vrij te geven verlichten, de discussies in de toetsingsinstanties versoepelen, de huidige registraties in Nederland in stand houden, en voorkomen dat zorgaanbieders onnodige kosten maken voor een ander systeem dat later misschien wordt gewijzigd. Zoals blijkt uit bijlage E zijn veel onderzoek en alle belangrijke registers nog steeds gebaseerd op een geen-bezwaar systeem als uitzondering op het toestemmingsbeginsel in Nederland. Al deze registers en al dat onderzoek wordt momenteel bedreigd.

Via het principebesluit en de andere aanbevelingen van dit rapport zou Nederland een regelgevingsniveau voor een lerend gezondheidsstelsel kunnen bereiken dat vergelijkbaar is met dat van de meeste van door ons onderzochte landen. Natuurlijk dienen deze aanbevelingen onderwerp te zijn van een debat in parlement en samenleving.

Executive summary

Why this report

Opening up health data is essential for a learning health system but is a challenge in many European countries. These challenges are partly about the rules regarding the further use of patient data and human body material (hereinafter: tissue). This report investigates the Dutch rules and discussions on further use of patient data and tissue and how access to health data and data linkage is organised. The Dutch rules and procedures are compared with Denmark, England, Finland, France, and Germany and lessons for the Dutch situation are drawn.

Modalities for patient consent regarding further use

The rules regarding further use of patient data and tissue in the countries studied vary between 1) always allowing further use for research if certain conditions regarding that research are met, 2) opt-out, 3) broad consent or 4) GDPR consent.

Broad consent differs from GDPR consent in terms of specificity. GDPR consent may encompass broad consent but should also have the option to specify the consent to certain research areas, hence be 'layered consent' with choices about the kind of research for which the data may be used. GDPR consent is hence the strictest option.

We found that, except for Germany, the rules for further use of patient data in the other countries are less strict than those in the Netherlands. In those countries, it is either opt-out for further or without any consent modality at all. But also Germany has exceptions to consent for research with claims data and cancer data which are absent in the Netherlands. Regarding further use of tissue, the consent modality is usually opt-out, again except for Germany.

Preferred modality still under debate in the Netherlands

In The Netherlands, the default is consent. Whether the consent should be broad consent or GDPR consent is still under debate. The Netherlands has an exemption regarding further use for research purposes if asking for consent is impossible or when consent cannot reasonably be asked. In these situations, it is possible to use patient data for research when the patient has not opted out. However, under which circumstances this exemption applies, continues to be under debate as well. This is another difference with the other countries. In all countries studied, the debate on the rules seems settled.

Administrative identification number for research

To link data pertaining to the same patient from various data sources or to follow the patient over time, a unique identifier is necessary. The Netherlands is the only country in our study where the identification number used for administrative purposes in health care (in those countries either the general civic registration number or a special social security number) may formally not be used for research. Not even if this number is pseudonymised in the sense of the GDPR (meaning that there is a key back from the pseudonym to the original). With one-way coding such a key back is absent. The lack of usable alternatives has caused a rather widespread use of the one-way coded civic registration number for record linkage in the Netherlands, with so called 'domain conversion' to link the one-way coded number from different data sources to the target research database. However, the legal basis for this solution is not accepted by all stakeholders and is thus still under debate.

In the final chapter we propose that the Netherlands should come to the same level as the other countries by allowing a pseudonymised civic registration number to be used for research.

Central point of access for further use of data

In all investigated countries government has invested in central access points for researchers to combine data from various sources, though the depth of available data and the maturity of those central access points varies. In the Netherlands, there is not such a central access point, backed by governmental support, either via legislation or governmental funding for that function. Based on the Act on Statistics Netherlands (SN), SN fulfils the role of a central access point and offering a secure data processing environment for research to some extent, bringing together and providing a linkage platform for data from a large variety of sources. However, that is not its primary function. SN must charge costs such as for the statistical non-disclosure control for the output of the research. Additionally, the data sources sometimes charge substantial costs to minimise the data, which had to be submitted to SN anyhow for its statistical function, to the variables needed for a specific study. Researchers can bring in external data if they have a legal basis to do so. And as said, this legal basis is still very much under debate. Additionally, complete linkage with SN data will not be possible if that data source could not use the civic registration number or a one-way coded number based on the civic registration number which allows for the mentioned domain conversion.

In the final chapter we propose to reinforce the role of SN as a hub for research while at the same time not hampering the manifold health research projects using safe data processing environments which as yet cannot be executed via SN such as with genetic data, imaging data, etc.

Fragmented data and review

The Dutch discussion about the scope of the consent and the research exception takes place in an extremely fragmented data landscape. Each data source has a separate governance structure and interpretation of the rules and they vary in the way how these translate those into the consent modalities described above. Consequently, there is no common format for reviewing research proposals involving the secondary use of data. Ethics- or privacy committees at each data source often do not accept reviews performed at other committees. Again, the Netherlands seems to be the exception here. The proposals made in the final chapter should lead to a less fragmented data landscape.

Proposals for the Dutch debate on the consent modalities

In addition to the issues mentioned above the final chapter mainly discusses the preferred consent modality for the Netherlands. Our discussion in the final chapter was not substantially influenced by the “Vision and Strategy on secondary use” which Dutch government published when we were ready to submit this report to the PDF editor. The importance of secondary use, or ‘further use’ as it is called in this report (see chapter1), for a learning health system is clearly recognised. As such that is real progress for the Dutch situation. The timeline states that this year the present regulations will be explained and then that next year possibly legislative changes will be set in motion. We support that the present legislation and its problems should be explained to parliament and via the report hope to contribute to that explanation. It does not need to be explained to research community as the 2022 Code of Conduct on health research does so already. In Appendix F we discuss that Code of Conduct, the broad consensus of all

major stakeholders on which it is based and the reaction of the Dutch DPA, in essence calling for a change in the legislation.

We agree that a change in the legislation is needed. The debate on further use of health data in the Netherlands has been going on for several decades and in spite of the Code of Conduct there is still uncertainty. Decisions about the direction of the future legislation need to be made soon. We make suggestions to that end based on what we learned from the other countries of our study, which, with one exception, stepped away from the consent or anonymise approach, and our detailed analysis of the present Dutch discussion in Appendix F.

Any debate should start with finding a common ground or starting points for the debate on which we can reasonably agree. We propose the following (for the underpinning we may refer to Chapter 3 of this report):

- The GDPR does not require GDPR consent as the legal basis for research based on further use of data. The European Data Protection Board advised against that.
- A consent-based approach leads to incomplete and biased data, especially regarding more vulnerable segments of the population with lower health literacy.
- A consent-based approach also leads to extra efforts, costs and administrative burden for health care providers as well as researchers. These would multiply if this consent would not be broad consent but GDPR consent.
- Strictly anonymous data are hardly ever usable for research. Most research requires detailed individual level data to achieve valid outcomes.
- These pseudonymised or one-way coded but still personal research data have proven to be safe if the proper techniques are being used. Privacy sensitive data of many millions of Europeans have been used for research for over a decade in safe research environments. As far as we know data breaches which led to negative consequences for the individuals concerned have not been reported.

These starting points do not resolve the moral issue which is at stake here. Any consent modality must find a balance between a) the interests and autonomy of current patients when data relating to them may become involved in research and b) the interests of future patients and citizens. Both groups will profit from a sharing data in a learning health system, not only with respect to disease treatment but also with respect to disease prevention.

Our challenge is to find a balance which is acceptable to society at large. Individual interests are always mitigated in society where overriding interests of others are at stake. The discussion is about whom we include as others, what those overriding interests are and to what extent that mitigation may and can take place. It is about finding an acceptable middle ground.

We propose that a well-organised general opt-out system would represent such a middle ground in this context, if certain conditions are fulfilled. Formally designating an opt-out system as the default would resolve many of the present legal hindrances for a learning health system. Yet, it would still leave sufficient room for those who do not trust the privacy safeguards or who do not want to contribute to research.

Opt-out would then become the default modality for further use for a learning health system. There may be exceptions to this default, in which either a no-consent or consent would apply, as discussed in the final chapter. Notifiable diseases are an example of the first exemption.

This opt-out is not unconditional. Every patient should be clearly notified about further use for a learning health system and that he or she can opt-out. It should be assured that the research is in the public interest, being that every interested group of patients or citizens can profit from the research or that the research will lead to a public debate what measure(s) to take next. That would mean:

- Data collection must be in line with FAIR principles;
- The safety of the data is assured;
- Research is carried out according to scientific standards including established standards on research integrity;
- The research data will not become proprietary information;
- Results of the research are published;
- The research is transparent, and researchers and research organisations are accountable for adhering to the principles mentioned above.

These conditions have been elaborated in the mentioned Dutch Code of Conduct on health research.

The decision in principle for such a conditional opt-out as the default, even if that has not led to legislation yet, will ease the present reluctance of data holders to release data, will make discussions in review bodies more relaxed, will preserve the present registries in the Netherlands, and will avoid health care providers making unnecessary costs for a different system which might be changed later. As shown in Appendix F, much research and all major registries are still based on an opt-out system as the exception to the consent principle in Dutch legislation. All these registries and all that research are at the moment under threat.

With our recommendations it would be possible to achieve a regulatory level for a learning health system in the Netherlands comparable with that of most of the countries we investigated. Obviously, these recommendations should be subject to a debate in parliament and society at large.

Table of contents

List of abbreviations

BKRG	Bundekrebsregisterdatengesetz, the German Federal Act on cancer registries.
BSN	Burgerservicenummer, the Dutch civic registration number
BYOD	bring your own data
CLDC	Common Law Duty of Confidentiality (England)
CNIL	Commission nationale de l'informatique et des libertés, the French data protection authority (DPA)
CSP	Code de la Santé Publique, the French comprehensive (public) health Act
DARS	Data Access Request Service (England)
DHD	Dutch Hospital Data
DHDA	Danish Health Data Authority
DPA	Data Protection Authority often also referred to as Supervisory Authority
DPIA	Data Protection Impact Assessment
EHDS	European Health Data Space
EHR's	electronic health record
EMA	European Medicines Agency
FAIR	findable, accessible, interoperable, reusable (of data)
FDZ	Forschungsdatumzentrum Gesundheit (the German health data research hub with claims data).
FHDH	French Health Data Hub
FPDA	Federal Data Protection Act (Germany)
FSSA	Federal social security Act, in German 'Sozialgesetzbuch'
GDPR	General Data Protection Regulation
HRA	Health Research Authority (England)
HTA	Human Tissue Authority
ILD	individual level data
LBZ	country wide basic registration care (Landelijke basisregistratie zorg, The Netherlands)
LIL	La loi Informatique et Libertés, The French data protection Act
MII	Medical Informatics Initiative (Germany)
NHS	National Health Service (England)
NIR	numéro d'inscription au répertoire, the French social security number
NKR	Netherlands Cancer Registry (Nederlandse Kanker Registratie)
RIVM	National Institute for Public Health and the Environment (Rijksinstituut voor Volksgezondheid en Milieuhygiëne in Dutch)
RKI	Robert Koch Institute
SES	social-economic status
SHI	social health insurance
SN	Statistics Netherlands, in Dutch : Centraal Bureau voor de Statistiek (CBS)
SNDS	Système national des données de santé, national system of health data (France)
THL	Finnish Institute for Health and Welfare
UAVG	Uitvoeringswet Algemene Verordening Gegevensbescherming, the Dutch GDPR implementing Act
UK-DPA	The UK Data Protection Act, UK implementation of the GDPR
VHI	voluntary health insurance
WGBO	Act in the medical treatment contract (the Netherlands)

1 Introduction

1.1 Background and purpose of this report

Health-RI is a Dutch initiative to establish a national health data infrastructure for research and innovation, to ultimately facilitate the development of a learning health system in the Netherlands. Health-RI is an independent foundation, yet via its governance structure Health-RI has close ties with all major stakeholders in The Netherlands. Health-RI commissioned the MLC Foundation and Nivel to examine the Dutch rules and discussion on further use of patient data and tissue for research against the backdrop of the legal framework on further use of patient data and tissue in a selection of other Western European countries and how this legal framework shapes the data landscape in each of these countries.

The report should provide a mirror and an advice for the Netherlands about possible other ways of approaching the legal framework for a learning health system. The assumption behind the report was that in the Netherlands these rules differ in many aspects from those in the other countries and that the debate about those in the Netherlands is less settled. The first proved to be true to a large extent and the latter certainly proved to be true.

This is why the concluding chapter is only about the Dutch discussion on the rules for a learning health system as we hope that that discussion will unfold in 2023. It also explains why Appendix F on the Netherlands is longer than descriptions of the other countries. The Dutch stakeholders in the debate are the first audience of this report. Secondly, it takes more words to describe a less settled situation than a situation where -as based on our research – the rules seem to be clear.

1.2 Health data and the learning health system

This study is about legal and regulatory aspects of further use of data and tissue in the context of learning health systems. These have been defined as "health system in which progress in science, informatics, and care culture align to generate new knowledge as a natural by-product of the care experience, and refine and deliver best practices for continuous improvement in health and health care".[2] Reuse of health data is at the core of such systems.

Establishing learning health systems, in which health data is constantly generated, reused and learned from is essential to maintain acceptable levels of quality, accessibility and sustainability of care, can improve health protection, can underpin decisions about appropriate use of limited resources, and will further what had been called 'appropriate care' in general.

2 Claudia Grossmann, J. Michael McGinnis, and Brian Powers, *Digital Infrastructure for the Learning Health System: The Foundation for Continuous Improvement in Health and Health Care: Workshop Series Summary* (National Academies Press, 2011).

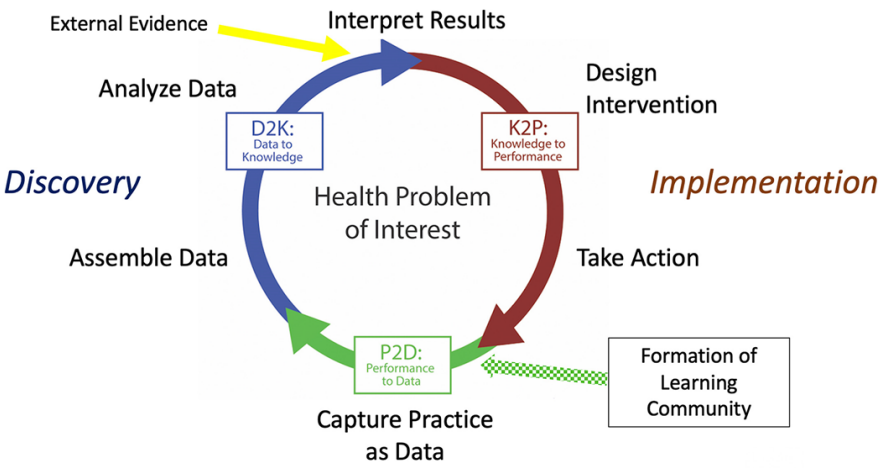


Figure 1. A learning health system as a continuous cycle[3]

Establishing a learning health system is not only an aspiration in the Netherlands. European health care systems must meet certain standards as equitable access, high quality, and long-term sustainability while at the same time they are faced with an ageing population, increasing burden of disease and staff shortages.[4] Hence European healthcare systems face many challenges. A learning health system may help us to face these challenges.

For a learning health system, one needs 'secondary' or 'further' use of patient data and tissue.

Further use versus secondary use

We prefer the term further use above secondary use. The term secondary use can give the impression that there is 'primary use' which is fixed in time. It also implies a certain ranking. Second comes after first. However, what is annotated in the patient file of today, differs from what was annotated even 10 years ago, certainly with more complex diseases. That is largely[5] due to the growing of body of knowledge based on further use or on clinical trials. In that sense there is even a circle. In modern health care there wouldn't be "primary use" if there had not also been 'secondary use'.

The efforts for a learning health system are often associated with 'real world data' or 'real world evidence'. A host of initiatives are taking place under that name, such as by the European Medicines Agency[6, 7, 8] or the BigData@Heart project[9] and its outputs.[10]

1.3 The European Health Data Space (EHDS)

The concept of a learning health system is also at the heart of the plans to develop a European

3 Friedman, 'What Is Unique about Learning Health Systems?'
4 For The Netherlands see: Visser et al., 'Kiezen voor houdbare zorg'.
5 Reimbursement systems also plays a role in how patient files are coded.
6 https://www.ema.europa.eu/en/news/vision-use-real-world-evidence-eu-medicines-regulation
7 https://www.ema.europa.eu/en/news/high-quality-data-empower-data-driven-medicines-regulation-european-union
8 https://www.ema.europa.eu/en/about-us/how-we-work/big-data/data-analysis-real-world-interrogation-network-darwin-eu
9 https://www.bigdata-heart.eu/
10 Kotecha et al., 'CODE-EHR Best Practice Framework for the Use of Structured Electronic Healthcare Records in Clinical Research'.

health data space (EHDS), and then especially the second tier of the EHDS proposal, data hubs for, as it is called there, secondary use.[11] However, the development and direction of the EHDS is still subject to debate and it will take several years to implement.[12,13,14,15,16] Hence the EHDS proposal did not play a major role in this report as this report describes the current situation and aims to further the discussion about that current situation in the Netherlands. Nevertheless, this report is relevant for EHDS implementation in the Netherlands. Dutch government refers to the EHDS in the context of the further use discussion.[17]

1.4 Obstacles for a learning health system

Further use of health data is not self-evident. Health data will have to be brought together in so called health information systems. Such systems are defined as integrated efforts to collect, process, report and use health information and knowledge to support decision making in policy practice and research and the total of resources, stakeholders and activities and outputs to do so. As such, these systems encounter many barriers to coming to fruition.[18]

Health-RI published a document in which it describes the barriers or obstacles for a learning health system in the Netherlands. The obstacles are subsumed under three broad categories and one of those is 'Rules' (see Figure 2).

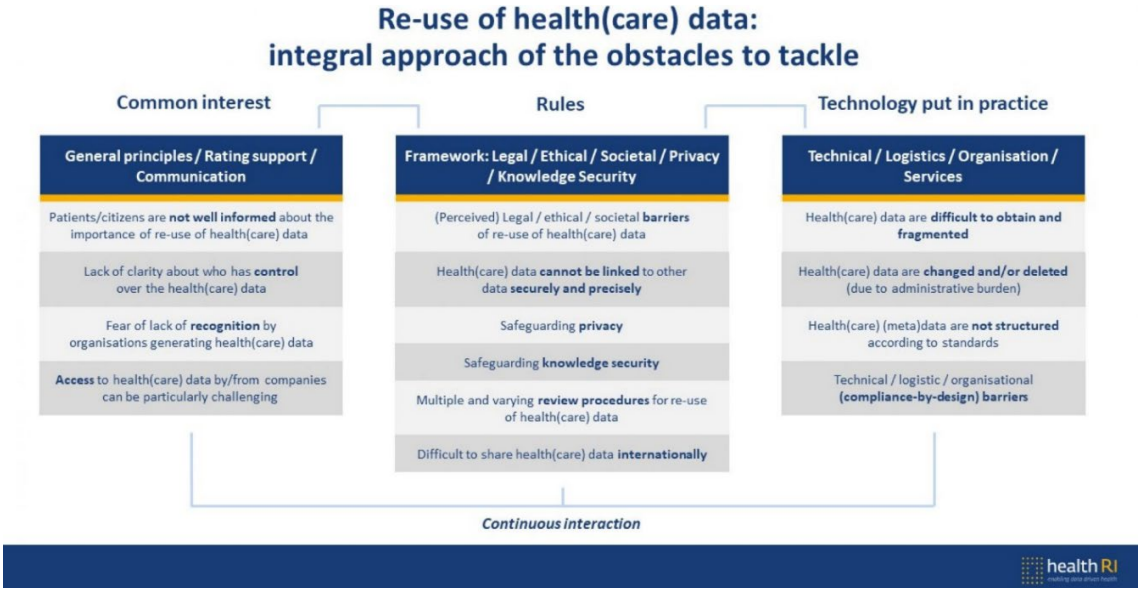


Figure 2. Re-use of health(care) data: integral approach of the obstacles to tackle.

These obstacles are the results of many factors, some of which have been deliberate choices of a specific individual or organisation, while others can be regarded as unintended results of circumstances beyond an individual's or an organisation's control.

11 https://ec.europa.eu/commission/presscorner/detail/en/ip_22_2711
12 EPIC, 'Joint Statement'.
13 Shabani, 'Will the European Health Data Space Change Data Sharing Rules?'
14 European Data Protection Board (EDPB) and European Data Protection Supervisor (EDPS), 'EDPB-EDPS Joint Opinion 03/2022 on the Proposal for a Regulation on the European Health Data Space'.
15 See also: https://tehdas.eu/
16 Marcus et al., 'The European Health Data Space'.
17 Amongst others Kamerstukken 35884, nr. 10
18 Bogaert et al., 'Identifying Common Enablers and Barriers in European Health Information Systems'.

Rules and regulations are not typically put in place with the intention to inhibit the exchange or further use of health data. Similarly, lack of interoperability is often the result of understandable choices made by software developers and healthcare providers within a specific historical context, yet frequently resulting in point solutions. Some obstacles to further use of data may thus also be viewed as safeguards against the misuse of data. In other words, it is important to remember that obstacles can be in place for a reason, even though some of those reasons may have become obsolete. There may have been deliberate choices made under certain circumstances that may or may not be relevant today. If we accept the relevance of learning health systems and the further use of data, the question then becomes how to encourage further use of data without increasing the risk of misuse and without compromising the legitimate interests of individuals and organizations.

1.5 Focus on rules and procedures

Focus of the report is in the middle column in the Health-RI scheme: the rules and regulations regarding further use of health data for research.

We selected a variety of European countries that adhere to (England) or that are subject to the EU General Data Protection Regulation (GDPR), being Denmark, Finland, France, Germany, and the Netherlands. The choice for these countries was made to cover both so-called Bismarckian and Beveridge-like health care systems[19] and based on an initial assessment of their progress towards a learning health system.

In managing further use of health data for research a balance must be struck between data protection with related notions of informational self-determination and the public interest that a learning health system aims to serve. The balance may have been struck differently in different countries. Consent is not the only basis to process special categories of data, such as about health and genetic data. The GDPR has given considerable leeway to the member states to regulate the exception on the ban to process these sensitive data in national law (insofar as specifically relevant here articles 9.2.g till 9.2.j GDPR).[20] We investigated whether the selected countries used those exceptions to consent to achieve a learning health system.

We did not investigate regulations regarding notifiable diseases according to the World Health Regulation, such as Covid 19. Each country will have implemented that Regulation. However, how those data can be linked to other data to, example given, monitor the effects of COVID-19 is within the scope of our study.

The focus is on improving the health care system and health protection via research. Practice feedback to health care providers about their performance on certain indicators as compared to the average of health care providers on the same indicators of appropriate standard of care is an important aspect of a learning health care system as well but is left out of scope. Though this quality feed-back also requires regulation, this way of improvement according to the present standards is much less contested than research leading to new standards.[21]

19 In a Bismarckian system health care is reimbursed via health insurers. In a Beveridge system health care providers are reimbursed by public funds. The distinction is not clear cut. Bismarckian solidirty based system there are risk equalisation schemes on the background and insurers are often also paid via taxation.

20 Research should also meet the standards of article 89.1 GDPR.

21 For an example see: Wierda et al., 'Privacy of Patient Data in Quality-of-Care Registries in Cardiology and Cardiothoracic Surgery'. See also the discussion on the recent draft Act of quality registries in the Netherlands in Appendix F.

1.6 Methods

This report is based on desk research and interviews with researchers in the respective countries. Starting point for the desk research was the report on the implementation of the EU General Data Protection Regulation (GDPR) concerning health data, commissioned by the European Commission and published in January 2021.[22] We delved deeper into the relevant legislation and websites on the further use of health data. We also analysed publications or websites on how the system in each country is being used for research.

Each country chapter starts with a summary of the country and its health care system. We used Wikipedia for the first and most of all reports of the European Observatory on Health Systems and Health Policies[23] for the latter.

For each of the countries studied we answered the following questions, based on desk research and interviews:

- What are in general the rules for data exchange in the context of patient care?
- What are the rules for further use of data and tissue for research?
- To what extent can data from various sources be linked on a subject level via a (pseudonymised) civic registration number or another number used in health care?
- To what extent can patient data from various health care providers and possibly other relevant data sources be accessed for health research via a unified procedure and one or more central access points?
- What are, in general, the procedures for access?
- Are those unified entry points based on legislation or strong governmental support?

In counties where there is such a central access point, we did not attempt to enquire further about various underlying databases. However, in such cases we did try to get a picture about the depth of the data, such as – pseudonymised- full medical records or excerpts or only claims data used for reimbursement of the health care providers. We also investigated whether it was possible to link the data with data outside the health care domain, such as death registries or data about social-economic status (SES).

After gaining a general understanding of each country, we conducted online interviews with researchers to verify the accuracy of our descriptions. We also asked them about their experiences with the further use of health data for research purposes in their country. Respondents were selected based on their experience with actual reuse of health data for research. They were either authors of publications in which health data were further used for research and/or approached through personal networks of the project group. Our goal was to conduct two separate interviews per country, but this was not possible for some countries due to time constraints and lack of responses when requesting an interview. One of the project team members summarised each interview. From these summaries, an anonymized overall description of "how it works in practice" was written for each country and included in this report.

22 Johan Hansen et al., 'Assessment of the EU Member States' Rules on Health Data in the Light of GDPR' (Luxembourg: European Commission, 2021), https://ec.europa.eu/newsroom/sante/items/702120/en.

23 "European Observatory on Health Systems and Policies", 23 November 2022. https://eurohealthobservatory.who.int/.

1.7 Limitations

We aim to provide a general, 'high over' overview of the facilitators and barriers to the further use of health data for research in the countries under examination.

However, it should be acknowledged that, except for the Netherlands, it has been a quick scan and does not cover every aspect of the relevant rules and procedures in each country. We did not visit the countries in question, and the number of respondents is limited. More in depth research could have resulted in a more detailed picture of the ways of working and underlying discussion in each country. This was not possible within the given time and budgetary constraints.

The country reports in the Appendices were completed in January 2022. With a few exceptions possible later developments were not taken into account.

1.8 Build-up of the report

The report became lengthier than expected. We presume that Dutch readers will be most of all interested in this report. Those readers will be interested in the situation in the other countries as shown in the comparative tables and the concluding chapter with recommendations for the Dutch debate. Hence that is the core of this report. The descriptions of the other countries on which the comparative tables are based can be found in the Appendices together with a detailed description of the present Dutch situation and debate.

2 Country comparisons

2.1 Introduction

This chapter gives an overview of the various issues we investigated for each country in comparative tables. For the details about the countries, we refer to the Appendices.

2.2 Conditions for further use of data and tissue for research in general

The table below shows the different legal requirements for further use of health data for research purposes in each of the countries in general.

Country	Data	Tissue
Denmark	Always in, except for genetic data: opt out via a central opt-out registry.	Opt-out, via a central opt-out registry.
England	Opt-out, except for a few selected databases, then always in. Opt-out at the health care provider.	Broad consent, exceptions for residual tissue.
Finland	Always in.	Broad consent
France	Opt-out noted at the health care provider.	Opt-out noted at the health care provider.
Germany	Distinction between EHR data and claims data. EHR data: Layered GDPR consent if the data leave the hospital where patient was treated. Research within that hospital usually allowed without consent. Consent and its scope are noted at the health care provider. Claims data: no consent when analysed at the FDZ processing environment.	Broad consent (noted at the health care provider).
The Netherlands	Consent is default, also for research within hospitals, unless consent cannot reasonably be asked or is impossible to ask. Discussion whether broad consent or GDPR consent should be applied. Consent or opt-out noted at the health care provider. The same applies to claims data.	Consent as specific as possible unless consent cannot reasonably be asked or is impossible to ask. Consent or opt-out is noted at the health care provider.

The conclusion from this table is that most countries studied do not use consent as the basis for further use of data. This is also the case in many other European countries.[24] Within the European context, Germany and The Netherlands stand out as the exceptions. However, it should be noted that in Germany, further use of the data within the hospital is isually allowed without consent while in the Netherlands, that is not the case. Access to the data without consent is limited to the treatment team. In the Netherlands exceptions to the consent principle are possible under certain conditions. One respondent mentioned that occasionally such an exception is made in Germany as well. In the Netherlands circumstances under which

24 See also the Nivel report for some other countries: e.g. Austria, Belgium, Spain.

an opt out system is allowed tend to become more and more strictly applied. Some health care providers, registries and research institutes expressed their worries about this trend. Additionally, there is still ongoing discussion about whether this consent should be a specific "GDPR consent" or broad consent.

Though in Germany GDPR consent is the basis to exchange EHR data, this does not apply to pseudonymised claims data centrally brought together at the recent health data research centre (FDZ). Within the data processing environment of the FDZ, data can be accessed for research. In addition to researchers also patient organisations can use the data.

The situation regarding further use of tissue is more complex. In most countries opt-out or broad consent is the rule. In the Netherlands according to the Bill on control of tissue the consent should be 'as specific as possible'. In that sense the Netherlands would be unique in Europe.

2.3 Data linkage

Record linkage is often a prerequisite for the reuse of health data for research purposes. Many research questions cannot be answered with only one data source. Linkage of health and social care data with for example socioeconomic data (SES) are often required.

The table below indicates what is used as the basis for linking for research in each of the countries studied. Various data security and privacy enhancing measures, such as pseudonymisation, are implemented at the data sources, during the processing of the data. The researcher will thus never have access to the original linking number, but only a derivative, either as a pseudonym or as a one-way hash.[25]

Country	Basis for record linkage for research
Denmark	Via the civic registration number (which is very widely used).
England	Via the NHS number which allows also linking with the social care domain.
Finland	Via civic registration number.
France	Via social security number (allows linking with a wide array of social benefits and allows to assess SES).
Germany	Via health insurance number (limited to health care, does not allow linking with other domains). The central cancer registry does not use a pseudonymised health insurance number but a derivate of certain personal details. In theory that process could be repeated at other data sources.[26]
The Netherlands	The Dutch civic registration number as that is used in health care cannot formally be used for health research. Discussion whether use of one way coded civic registration number is allowed.

The Netherlands is the only country in our study with a prohibition in the law which effectively makes it impossible to use the civic registration number, while that must be used by health care providers, for health research as well, also when that number would be pseudonymised by the health care providers. A one-way coded number is not a civic registration number anymore and that solution is often used, but not uncontested.

25 A one-way hash is not a pseudonym in the sense of the GDPR as the definition of pseudonymised data under the GDPR mention a key back (which must be kept secure). See article 4.4 GDPR.

26 We did not check this. The personal details are rather generic and, in our opinion, might lead to multiples.

In the other countries such a formal prohibition does not exist, but privacy by design must of course be applied by pseudonymisation of the number used in health care when releasing them for research. The hindrances for linking across domains in some other countries arise from the fact that the number used in health care is unique for health care. That creates a practical hindrance for linking, but is not a formal prohibition as in the Netherlands.

2.4 Central databases or one entry point specifically for research (and based on legislation or strongly supported by government)

An important aspect of the health data research infrastructure is the existence, or absence of, one specific access point. If there is one such access point, the following question is to what data it gives access.

As discussed in the Appendices, one entry point does not necessarily mean that all data are collected and made available in a central database. Data may also be federated and remain at their original site, such as at the health care providers. It does mean, however, that access to data is centrally organised. The table below summarizes the situation in the countries studied, with respect to the existence of a central access point and what data can be found there.

Country	Central access point	Richness of clinical data	Causes of death	SES
Denmark	Yes	Yes	Yes	Yes
England	Yes	To some extent. Not the full medical records. Primary care data absent.	Yes	Yes
Finland	Yes	Yes	Yes	Yes
France	Yes	Increasingly more yes	Yes	Indirectly yes[27]
Germany	FDZ	Only claims data	No	No
	IMI	Yes	No	No
	FKR	Yes	?	No
The Netherlands	Statistics Netherlands functions comes closest to a central access point for health data.	Moderate, usually excerpts of clinical files.	Yes	Yes

We see that all countries have one or more central access points. The richness of the data varies.

With the exception of the Netherlands, the trend towards a central access point or access points is supported by explicit governmental policies. On the other hand, it could be said that the Netherlands was ahead of its time by the explicit recognition in the Act on Statistics Netherlands that the data at SN can be used for research as well. However, as discussed in Appendix F, SN only can only give access to data which it has earlier assembled for its statistical mission. Otherwise, it should be 'bring your own data' (BOYD) with a legal basis by the specific data source that these data may be used for research and linked with SN data. In that respect

27 Linking with social benefits as a proxy. Not education or profession.

SN differs from the access points in other countries. It is also important to note that Statistics Netherlands is not officially designated nor designed as a national health data access point.

2.5 Administrative provisions, ethical review

The table below summarises the conditions under which health data can be accessed via the central access point in each country and whether there is a one-site review procedure in place or that each data source should approve the research as well.

Country	Conditions	1 time central review
Denmark	Application at the Danish Health Data Authority. If one needs more data than available at the Danish Health Data Authority, such as the original medical files, then that data holder has to approve as well. Submitting a separate DPIA is not necessary.	Yes, unless the researchers would need data not available already at the DHDA.
England	Application via DARS. Submitting a separate DPIA is not necessary.	Yes
Finland	Application at Findata. Submitting a separate DPIA is not necessary.	Yes
France	A large 'dossier' must be submitted to the FHDH. Two reviews running parallel: • CREES: scientific value, public interest • CNIL: data protection Submitting a separate DPIA is not necessary. If the CNIL does not react within a month, the research is deemed to be approved by the CNIL.	Yes
Germany	The central access points are very recent, we could not check the procedures.	
The Netherlands	There is officially not a central access point yet. However, if research is performed using SN then: • SN will perform a review; • Each data source which had submitted data to SN for its statistical function must approve of the research as well. Submitting a separate DPIA is usually necessary (unless there was a DPIA about research using SN already). Data sources must also agree when the research data are directly assembled from various sources without using SN. The review procedures at the data sources differ and often also their assessments of the same project. Submitting a separate DPIA is necessary and often the DPO at each data source will assess that DPIA as well.	No

For most countries we see that a central entry also means one- time review. With the exception of Germany, the practical experiences of researchers with this review are be described in the next paragraph. For Germany the central access points are too recent for practical experiences.

As far as we could see, when using the central access point, it is not necessary to submit a separate DPIA for this specific project as well.

Here as well, the Netherlands stands out. Each central data source decides and sometimes the health care providers behind the central databases. Additionally, there is the mentioned discussion about opt-out or opt-in. Each committee at the data source has its own opinion whether opt-out is appropriate or that it should have been opt-in. Usually, a DPIA will be required for the specific research project.

2.6 Respondents' views

Here the summary of the reactions from the respondents. For the nuances, we may refer to the respective country Appendices. As mentioned in Chapter One, we did not manage to find at least two researchers-respondents for each country involved. We did not systematically investigate the fees for using the central access point. Yet, it was brought up during our conversations and if a researchers had a remark about it, that was noted.

Country	Observations
Denmark	Researchers not interviewed
England	The system works fairly well. everything goes more smoothly than before. The data are fairly rich but not everything which would be needed for specific protocols.
Finland	In Finland there was a system of linking rich databases already. The Finnish Health data Hub is not seen as an improvement by 3 researchers we interviewed. The throughput time is long, and the file is not dealt with consistently. Another researcher while acknowledging this, remarked that these are 'teething problems'.
France	The French system is moving fast towards opening data via the hub. The richness of the data increases and French bureaucracy decreases. One respondent was more sceptical about the FHDH. Both mentioned that submitting the 'dossier' requires much work. Yet, it goes relatively speedily after submitting the dossier. One respondent mentioned that government invests heavily in the FHDH and the data management behind it. The researcher does not have to pay for the latter and composing the subsequent file with the research data.
Germany	The German system is moving fast as well. The new central access points are too recent for researchers to account for practical experiences. Yet, both respondents were happy with this development. At present it is cumbersome navigating the various databases and slightly diverging legislation at the Länder. The layered consent at the hospitals – seen by one researcher as exaggerated as almost all patients give broad consent - is embedded in an intake process with much paperwork already. The layered consent is now solid law except when there is an exception based on a specific Act as we saw for the FKR. Though there is no legislation that hospital-based ethics committees should accept each other's views, one respondent answered that in practice this is the case. The FDZ open access to pseudonymised claims data without consent. The FDZ is together with the FHDH partner in a consortium where 'use cases' for the EHDS will be tested.

Country	Observations
The Netherlands	As seen in Appendix F, there is still debate in the Netherlands about the conditions for further use of data and tissue for health research. Researchers and registries expressed their concern about the trend towards opt-in. If data are requested from various sources, each data source will have its own opinion whether the data may be used for research, either via its legal department or the ethic- or privacy committee at the data source. This process also applies when using SN which in practice serves as a central access point for research when the necessary data can be found at SN.

Though in our interviews we tried to ask similar and compatible questions, answers diverged as personal views, experiences and interests inevitably played a role. Yet, certain trends are clearly visible in combination with the previous tables. With the exception of the Netherlands, respondents recognise the efforts of their governments to open up data for research. Finnish researchers are less enthusiastic about Findata but that is because of what they had in place already and the 'teething problems' of Findata. That might be a lesson: if one organises a central access point, ensure that it is well equipped and financed.

That would be one of the challenges for SN. Serving as a central access point for research is not its primary function and it is not funded for that function. Additionally, the Dutch researchers mentioned the present discussion about opt-in or opt-out and the scope of consent if it should be opt-in. In all other countries those questions are resolved already.

3 Recommendations for the Dutch debate

3.1 Introduction

As follows from the previous chapter and the Appendices, the Netherlands differs in many respects from the other countries we investigated.

We saw differences in:

- The stage of the debate on further use. In all other countries that debate seems largely settled.[28] In the Netherlands it is not.
- The direction of the debate. With the exception of Germany all other countries have moved away from the consent or anonymise[29] approach for EHR data. And in Germany pseudonymised claims data can be centrally accessed for research without consent, while in the Netherlands that still would be in principle consent.
- Possibilities for linking. In all other countries the unique number used in health care can be used (in a pseudonymised way) for research as well. In some countries that number is the civic registration number. In the Netherlands using that number for research is forbidden (though there is a small and contested work around by one-way hashing of that number).
- The review of research protocols amounts in all other countries to one time review. In the Netherlands all data sources review separately the research protocol with often incongruent outcomes.
- In all other countries government has invested, by legislation or governmental subsidies, and often in combination, in a central datahub for research. That is much less the case in the Netherlands. Statistics Netherlands plays that role in the Netherlands, but that role is formally limited to data that are needed and used for statistical analyses by SN itself. A researcher can bring in data from their own cohort but then then the question of unique linking with SN data (often not possible as the cohort data could not use the BSN) and the legal basis pops-up again.

The regulatory regime in the Netherlands thus is much less advanced in opening up data for a learning health system than in other countries we investigated.[30] The question then becomes how the Netherlands can catch up. That is the challenge to which this final chapter aims to contribute.

3.2 Does the Netherlands catch up with the recent 'Vision on secondary use'?

When this report was ready for the PDF editor, Dutch government published three Visions of the Dutch health information system.[31] This first is a rather 'high over' Vision on how to achieve

28 The limitation of our study did not allow to go deeper than as described in the introduction. There can be 'dissident voices' in all those countries expressed in the press, specialised journals or parliament which we did not investigate.

29 Sethi and Laurie, 'Delivering Proportionate Governance in the Era of EHealth'.

30 There are more parameters to assess a learning health system than those described above, see Lannon et al., 'A Maturity Grid Assessment Tool for Learning Networks'. However, it starts with having the data to perform the analyses and discuss those with the stakeholders.

31 Kamerstukken 2022-2023, 27529, nr. 292 and following

an integrated health information system in the Netherlands. The second is a Vision about how to improve health data exchange between health care providers. The third and last published is a Vision on secondary use.[32] The latter Vision is obviously the most pertinent to our report.

We will come back to some aspects of this 'secondary use Vision' later in this Chapter but at this moment the following observations why the mentioned 'Vision' did not lead to major changes in our recommendations:

- We very much appreciate that the 'Vision on secondary use' clearly recognises the value of a learning health system and that 'secondary use' is necessary to achieve that.
- The 'Vision on secondary use' could be read as stating that many problems for release of data or access to data for research are caused by confusion or misunderstandings about the present applicable law. The Vision seems to indicate that only after government has explained the legislation, and then the legislation is still insufficient to reach the ambitions of a learning health system, a legislative change will be considered.
- However, as we showed in Appendix F, the 2022 Code of Conduct on health research,[33] which represents the consensus of all major stakeholders about the present legislation, already gives a detailed account of how to interpret that legislation. This Code of Conduct is not mentioned in the Vision.
- Hence, to the research community, the present legislation does not need to be explained. If on the other hand, the Vision means that present legislation and its problems should be explained to Parliament, we fully agree. There seem to be many misunderstandings. With this report we hope to have contributed to that explanation.
- The Code of Conduct stranded at the DPA on the interpretation of WGBO consent.[34] The Code of Conduct and all initiatives by stakeholders use broad consent for further use, insofar as they do not rely on the exemption to the consent principle and many still do. However, the DPA concluded that this consent should be GDPR consent (see the discussion in Appendix F). The DPA mentioned that it had discussed this problem with government and had suggested a legislative change. The coordinating authors of the Code of Conduct discussed this with government as well. As shown in Appendix F, unless government would go for GDPR consent, a legislative change is needed anyhow.
- In the same vein, the referral to the DPA's opinion on the use of data for research on excess mortality because of Covid 19[35] is particular. The thrust of that opinion is not that the research could have been easily executed under the present legislation but that such legislation is lacking,[36] and that the present solution could also become a 'back alley'.
- The two other Visions mention 'opt-out' as a possible other way to organise control. That option is not mentioned in the 'secondary use Vision'. It seems to indicate that consent will be the primary basis for further use for a learning health system, such as with the possible "control register" where *consents* will be registered.
- The 'Vision on primary use' refers to the Nivel report[37] in order to show that other

32 For reasons as explained in Chapter 1 we prefer to use 'further use' above 'secondary use' but the terms mean the same.
33 COREON, 'Gedragscode Gezondheidsonderzoek 2022'.
34 It also stranded on the lack of an external supervisory body in the sense of article 41 GDPR. However, that hurdle was a formal one not directed at a main element of the Code of Conduct. Given the text of article 41.1 it may even be questioned whether such an external monitoring body is mandatory.
35 Autoriteit Persoonsgegevens, 'Adviesverzoek Onderzoek Oversterfte'.
36 The press release of the DPA stressed this point most of all. See: https://www.autoriteitpersoonsgegevens.nl/nl/nieuws/ap-onderzoek-naar-oversterfte-kan-cbs
37 Hansen et al., 'Assessment of the EU Member States' Rules on Health Data in the Light of GDPR'.

approaches than consent exist to exchange data between health care providers. The 'Vision on secondary use' does not refer to this Nivel report. However, the mentioned Nivel report shows *more examples of consent **not** being the approach for secondary use* than it does for data exchange between health care providers for primary use.

- The 'secondary use Vision' refers to the 'health data authorities' in Finland and Denmark. However, as shown in the previous chapter and the Appendices, in both countries:
  - The consent system is completely different from that in the Netherlands. From the patient data to registries and/or to research there is no consent at all;
  - In those countries the civic registration number can be used for research while the 'Vision' still not endorses it and mentions that government also looks for alternatives;
  - The 'Vision on secondary use' does not describe how the authority could give access to the data (insofar as they would be available in the Netherlands because of the consent system), while in the mentioned countries these authorities can, as they have these data at their fingertips. A data access authority which cannot give access to data is an oxymoron.
- The 'secondary use Vision' refers to the EHDS and that it will probably have some member states' specific exceptions to the new legal basis for further use provided in the EHDS Regulation. In that sense government seems to come back to an earlier statement to postpone present discussions till the EHDS has come into place. We agree on that point but as discussed below, we would like to go a step further.

In sum, we welcome that the Netherlands has woken up to the call of a learning health system and that government is ready to take steps in that direction. As seen in the previous chapter, the Netherlands has a lot of catching up to do.

However, the Vision on secondary use eschews certain pertinent questions. The Vision can be seen as the first stage of the agenda setting. But we should be more ambitious and act soon. We do not need more explanation of the present legislation and then presumably by government a better explanation than that in the Code of Conduct, but better legislation.[38] For that we need first of all a clear discussion about the legal base[39] for further or secondary use, also in the light of an unbiased view on the systems of other countries.

The remainder of this chapter will be most of all dedicated to that discussion.

3.3 Finding a practical common ground first of all

Any discussion should start with establishing a practical common ground which all parties would reasonably agree on.

This paragraph discusses two of those practical starting points for the discussion. The first is about the disadvantages of a consent system for an inclusive learning health system. The second is about the warranties that not-for profit research for a learning health system has established already without fully anonymising the data, as such anonymous data are in general unusable for research.

38 In a similar vein also: Kist, 'Assessment of the Dutch Rules on Health Data in the Light of the GDPR'.

39 Formally, processing health and -omics data needs a legal base in article 6 GDPR and 'an exception to the prohibition to process these sensitive data in the sense of article 9 GDPR. We group those 2 issues together here.

3.3.1 Practical problems because of consent

Regarding the first starting point we are very much helped by Dutch government. In early January 2023 it published a draft Bill for internet consultation which amongst other things would replace the present consent system for feed-back of data of participants to two public health programs (vaccination and public screening) to the respective branches of the RIVM which organises these programs.[40] The arguments for replacing consent by opt-out (vaccination) or nothing at all (the false negatives and false positives in the screening programs) describe the practical problems because of consent:

In the context of vaccination:

Apart from 'real' refusals, there may be other reasons for not obtaining consent that who is vaccinated will be reported to the RIVM:

- The question may not have been asked;
- The answer may not have been recorded;
- The question may have been misunderstood;
- People with language barriers or too little trust in government are not reached by the consent question.

This will create problems in terms of patient safety (e.g. double vaccinations) but also in terms of public health, as vaccination rates cannot be monitored and vaccination campaigns cannot be tailored to specific groups.

In the context of the screening programs the arguments mentioned are in sum:

- As the cases of false negative or false positive results of the screening are rare, a few missing cases can already lead to a biased view;
- Asking all participants to consent at the start of the screening would be at odds with 'data minimisation' as for the vast majority of the participants such feed-back on false positive or false negative results will not be necessary;
- The health care provider could ask for consent but then it remains unclear whether this will actually happen and how. See the dots mentioned at the arguments in the context of vaccination.[41]

Those consent-caused problems are of course not at all new. Many researchers and their counsel have often discussed them with government[42] and they are backed by the literature.[43,44] The arguments about bias in rare cases of in the screening program may at first sight seem less applicable for a learning health system but that is not true. In health research one also needs rare cases in those data. The movement towards personalised medicine necessitates that we can distinguish in a very large datapool between smaller and smaller sub-groups of patients. Personalised medicine is also or perhaps exactly about rare cases. Yet, we do not know upfront who those are.

40 Ministerie van Volksgezondheid, Welzijn en Sport, Verzamelwet gegevensverwerking II.
41 At page 18 of the draft explanatory memorandum.
42 One of the authors remembers an answer by a civil servant when he mentioned 'bias' through informed consent with further use: She said: 'But that is a problem for researchers'. It is of course a problem for those groups who become underrepresented because of the bias and hence will not be able to profit from the results of that research.
43 Rebers et al., 'A Randomised Controlled Trial of Consent Procedures for the Use of Residual Tissues for Medical Research'.
44 de Man et al., 'Opt-In and Opt-Out Consent Procedures for the Reuse of Routinely Recorded Health Data in Scientific Research and Their Consequences for Consent Rate and Consent Bias'.

These practical disadvantages of a consent system do not by themselves lead to another system. They need to be weighed against other arguments which are based on values. That requires balancing and perhaps arriving at a middle ground.

We postpone that discussion till the next paragraph and first discuss aspects of research which all participants in the discussion could also reasonably agree upon. Those are also practical aspects which weigh in the balance.

3.3.2 The nature of health research and research data

Health research should meet a number of requirements. These could also be formulated as conditions for any systems, with opt-out or with consent or with no consent system at all. They are in a way neutral to any of these consent modalities. In addition to that research should be methodologically sound (falling outside the scope of this report) those are:

- A **balance between data minimisation and the methodological requirements** of the proposed research. But in general, one cannot have both, hardly data and good research.[45]
- **Research Integrity**. That aspect is covered by the Dutch Code of Conduct on research integrity. This Code of Conduct goes beyond the prevention of possible scientific fraud. It is about conducting research in an open and transparent manner. Only in very specific cases may the results of the research not be published. Commercial interests or the interests of a specific party which commissioned the research is not one of those.
- **Pseudonymised or one-way coded data**: Researchers do not need to know the identity of the research subjects. And they hardly ever do unless they perform research with their own patients and have the double capacity of treating physician and researcher. But researchers and their software tools do need to uniquely discern one participant from the other to find patterns. Attributes (for example: diagnosis, treatment, response to treatment) need to be assigned the correct patient and not to someone else. Hence each participant must have a unique number but that is an abstract number, not one by which the participant can be recognized.
- **Anonymous data are hardly ever usable for research.** Though the researcher cannot identify the participant via the number, usable research data under that number will always be so granular that as such, when the data were released as 'open data' to which everyone can have access, these data cannot be considered anonymous.
- **With pseudonymised or one-way coded, non-anonymous data the safety of these data can still be assured.** Several research data processing environments where highly granular research data are being processed, have shown that in such environments data breaches are extremely unlikely and, as far as we have seen, in spite of many millions of health and genomic data which are being processed for research all over Europe, a data breach which

45 In the context of AI, see Bak et al., 'You Can't Have AI Both Ways'.

was detrimental to the participants has not been reported yet.[46,47]

- **Transparency**. Researchers should clarify what research they are performing and possible conflicts of interests. The latter is already a condition in all major biomedical journals. Data sources should clarity for which kind of research data may be released for research and under what circumstances. That is already the case for all the major Dutch 'privately' organised databases at the national level (see Appendix F).
- Transparency must be aligned with **accountability**. Accountability can take many forms and here we cannot expand on that in full here. We can say, however, that accountability should follow the whole chain of research data and hence that there will be many parties to whom the researcher should be accountable. Starting with the why of a certain research project and preferable setting that up in conjunction with patient organisations involved and if not, why not. Then assessing 'why these data', as reviewed by an expert committee. A major endpoint is the publication of the results of research which will lead to a debate within the scientific community and with the public at large.

This list is far from new. The Dutch Code of Conduct on health research encompasses them all. The Code of Conduct is endorsed by all not- for-profit health research organisations in The Netherlands. Hence, we can build on that when discussing the balance.

3.4 Balancing

3.4.1 The interests at stake

In this discussion there are usually two types of interests juxtaposed.

First there are the of the 'interests' of patients 'whose' data are being used for research and their 'autonomy' or informational self-determination.

Second there are the interests of patients and citizens whose health can be furthered by a learning health system or that of government which can manage the health system better in the difficult balance between access to all possible new treatments, equity, and affordability. That balance must be struck in transparent and accountable way, must get approval in parliament, but should also be based on the results of research into the functioning of the health care system. That is also our interest as citizens. Together we call these interests of future patients and citizens the 'public interest'.

We must find an acceptable compromise between those two types of interests.

Before we get to that, both types of interests should be explored more, making nuances.

46 Which does not mean that statisticians sometimes show that with research data which are claimed to be anonymous, in some cases 'replay back' may be possible for certain data. The contention here is that they could not have been used by inside or outside adversaries to the detriment of the data subjects. See also the discussion in Appendix F. about how abstract these statisticians' claims usually are. One of us has contended that that a more contextual approach to anonymity of data would be more appropriate and would give more legal certainty, see Groos and Veen, 'Anonymised Data and the Rule of Law'. Here we adhere to the mainstream of the discussion about this issue.

47 This may seem at odds with many accounts of data beaches in health care. But those relate to the delivery of health care where many professionals are involved in the care for the patient and many contacts points of professionals and patients. For research data these problems for organising such multiple interactions in a secure way are absent. And as they contain at least pseudonymised data, the research databases are also not of a great interest to hackers, 'outside adversaries' in the jargon.

Nuances about the first type of interests, that of patients when data relating to them are being used for a learning health system.

- We saw already that any consent modality system is neutral about whether further use is done in accordance with basic principles of responsible data processing and data safety. That should always be the case. Consent can be in some systems a necessary condition, but it is never a sufficient condition. Hence that the research will be responsible and that the data are safe, is not furthered by an opt-in system.
- We mentioned 'whose data' between quotation marks as we would rather speak of 'data about whom'. The "my health, my data (= of the patient)" approach has become the common expression. We submit that though this type of discourse has certain advantages for the patient, it also flawed. The data are just as well the product of present health care because of the contributions of many others than the patient before the data could even be noted in the patient record and have a collective function to maintain an equitable health care system.[48] Dutch government uses the 'the patient owns the data' discourse but cannot be considered consistent in this approach given the many exceptions in the legislation for further use of patient data to maintain the health care system.
- Bioethics and health law refers to the interest patients to decide about data assembled in the course of their interactions with health care as their right to autonomy or self-determination. A full discussion about this value would lead us into the deep waters of philosophy. Autonomy in its crude form is to have the full liberty or freedom to choose your lifepath and as a derivate, also how you contribute to society, as long as you don't harm others. A strong proponent of a self-oriented conception of autonomy is Holm and we may refer to his rich account of this conception.[49] There are other, more moderate conceptions as well.[50]
- Nowadays it is generally accepted that autonomy ends where the more important interests of others start. But what interests count in this respect opens a pandora's box. Take the discussion about our responsibility for future generations, the environment, or animals. A somewhat different approach to nuancing 'autonomy' would be the recognition that we do not lead our life in a vacuum but are always dependent on others, those around us and those before us. That approach leads back to the earlier remarks about the idea that patients are the 'owners' of the dat data that pertain to them. There are others who contributed to those data much more than the patient did. The data would not be there without access to health care and for most that means access due to the equitable health care system to which we all contribute.
- Autonomy is necessarily mitigated by a dependency which you can partially influence but is partially unavoidable. One can choose one's friends but not one's parents. Nobody deliberately chooses to be ill but there is some choice in what treatment you will receive[51] and certainly in whether you want to be treated at all. But then the consequences are all up to you (discarding for the moment your dependency on near relatives and their dependency on you) while in the context of further use the consequences concern most of all others, being those who might profit from those data.[52]

48 E.B. van Veen https://mlcf.eu/about-your-own-data-in-healthcare/

49 Lewis and Holm, 'Organoid Biobanking, Autonomy and the Limits of Consent'.

50 Onora O'Neill, *Autonomy and Trust in Bioethics*.

51 Some but not all possible choices. Health care providers must adhere to the professional standard. 'alternative medicine or healing' should in the Netherlands at least warn the patient that what it offers deviates from the standard of care.

52 This relational aspect of autonomy is amongst others underscored by Barbara Prainsack and Alena Buyx, *Solidarity in Biomedicine and Beyond*.

A proposal for the balance will be influenced by conceptions of autonomy: the more 'liberal' or the more 'relational', as just described. The latter leads more easily to a presupposition of solidarity or 'reciprocity' in the context of further use.

Nuancing the second type of interest', the 'public interest'

We saw that in some of the countries studied (Denmark, Finland, France) the fact that health research can be performed in their country and will attract all kind of research, also commercial, is also seen as a public interest. That confronts us with the fact that also 'public interest' is a very complex concept.[53] All political parties claim that their program serves the public interest. Yet, there wouldn't be so many and such heated debates if there would be an easy Archimedean point to establish that. One aspect of the public interest could very well be that the debate can be held on fair terms. That is the more procedural approach to the public interest discussion in political philosophy.

Suffice to say here that in the above we used a narrow and contextual definition of the public interest. If research could be based on unbiased data (see section 3.3.1 why because of a consent system the data will become biased), that would:

- Further the interests of future patients who can profit from the advances in health care because of the research;
- Especially groups which are left out in the data because of the consent system;
- Further interests of citizens at large because research can also warn about new possible health threats which appeared because ordinary people became patients and then looking back into what may have been the cause;[54]
- Fuel the public debate about an efficacious and equitable health care system and health protection and check the effects of governmental policies in this respect;
- Not overburdening the health care system with intricate systems for consent while health care is much stressed already.

In spite of the lack of an 'Archimedean point' to determine what the public interest actually is, there seems to be no reason why not nearly everybody would consider these objectives a public interest in a democratic society.

But that also means that the data for this research and the results of the research can be used as such. We will come back to that in section 3.4.3, the 'warranty'.

3.4.2 Our proposal for the balance

Weighing these interests and values we submit that an *opt-out system as the default* would provide a better balance for the Dutch legislation than the present system. We would follow the European Patients Forum position on the proposed EHDS in this respect.[55] A well organised opt -out system would still give patients control. No choice left as in the Danish and Finnish system, would lead us too far away from the present Dutch debate. Additionally, it might become a barrier for those with low trust in the system to use health care if they believe that 'their' data are being used for purposes beyond their control in 'a system' which they mistrust anyhow. And access to health care comes first.

53 Boot, 'Public Interest'.
54 From smoking, asbestos to Q fever
55 European Patients Forum, 'EPF's Recommendations on the European Health Data Space (EHDS)'.

Opt-out would then become the default situation for further use, except for the already established rules in the case of notifiable diseases. We can imagine other exceptions to opt-out at the default situation. Those could go two ways. Either no consent at all or opt-in. The first because the data need to be complete and the risk of bias is considered too high in the light of public interest the research will serve. An example could be monitoring and research on rare cancers or bacteria or funghi which are resistant to most treatment regimes. The second because the research is considered too sensitive with possible unforeseen consequences for the patient him or herself[56] or that it does not meet the 'warranty' for the public interest criterion proposed in the next section.

In both cases there should be clear rules when the exception applies. The present legislation with opt-in as the default and opt-out as the exception leaves too much room for interpretation.

Of course, an opt-out system must be well organised. The way many health care providers have organised opt-out at the moment cannot serve as an example. How the opt-out should be organised is beyond the scope of this report. We propose that a central opt-out registry would be helpful and that a public campaign accompanying the system could follow the lines of the campaign used for the opt-out system in organ donation.

3.4.3 A 'warranty' that the public interest criterion in the opt-out system is met

The always applicable conditions for health research should be supplemented with an additional requirement to warrant the 'public interest' as has been defined above. The results of the research based on this opt-out system should be publicly available whether the research has been publicly funded or not. The results of the research should not become proprietary information and the data on which the research is based should be FAIR, hence be opened up under the same conditions as the original research to other researchers as well. The data can be considered a 'commons' to which all contributed and should be used as such.[57]

3.5 The advantages of this system

Following this proposal would have the following advantages:

- With opt-out as the default we are freed from the present discussion whether the exception to the rule of opt-in applies because it is not reasonably feasible to ask for consent:

As we have seen in Appendix F, there are exceptions to the opt-in rule in Netherlands. For the Netherlands we noticed that it gives rise to a constant and nearly endless debate whether the exceptions to the rule, as described in generic terms in the legislation, apply under specific circumstances. With opt-out as the default the complicated discussion about when the exception applies because asking for consent is impossible or cannot be reasonably asked would become completely superfluous. Hence also diverging opinions on this issue by privacy or ethics committees who guard the release of sensitive data for research. While opt-out would decrease the administrative burdens of health care providers, this would also lessen that of all other parties involved, from review committees to researchers. One-time review would become much nearer.

56 See the Code of Conduct on health research at section 5.5.1 referring to section 4.4.

57 See also the statement on the EHDS by the European Patients Forum, 'EPF's Recommendations on the European Health Data Space (EHDS)'.

- Certain health research does not need to be more in the public interest than other health research:

At present when the exemption to consent is applied, such research needs to be in the public interest. That criterion can lead to debate as well. When all health research is in the public interest, if certain broad conditions are met, as described in section 3.3.4, an additional criterion that certain health research is more in the public interest than other health research, becomes superfluous.[58] This is particularly important as there have been some rather peculiar arguments for public interest have been mentioned for the consent exception. For example that it should be in the interest of a large group of patients'. This would imply that research on rare diseases wouldn't be in the general interest as well. Though there is not an Archimedean point for the public interest, it is certainly not the sum of who profit but also how in the broader scheme of an open democratic society, minorities can participate and profit from advances just as well.[59]

This does not imply that we undervalue the value of health research which does not fulfil the 'warranty' criterion. We saw already that in other countries a wider criterion for 'public interest via health data research is being used. Such a wider conception also seems to underly the European Open Data Directive, the Data Governance Act and the EHDS proposal. Yet, such research would not profit from opt-out as the default as we have proposed here.

- Arguments against opening-up data via one or more central data hubs disappear (largely):

A uniform opt-out system will also make obsolete arguments by data sources that 'their' data subjects did not consent to a research project for which data must be combined. However, this does not by itself imply that they will open-up data and submit the necessary dataset for the project. Additional measures will be needed. See paragraph 8 of this chapter.

3.6 Possible counter arguments

Different views in academic health law and ethics

Opt-out as default runs counter to the prevailing views in academic Dutch health law,[60] and of many in bioethics.[61] But views are there to be challenged. Suffice to mention here that, as we have seen, except to some extent for Germany, those views did not play a preponderant role in the legislation of the countries we investigated in this report.

In the same vein, opt-out does not seem compatible with the guidelines of the World Medical Association (WMA).[62] Government referred to those in the WZL discussion.[63] However, important as those guidelines are, they are not based on a democratic process and carry all the problems of non-governmental agencies setting (formally non-binding) rules, such as the selection of who

58 For attempt to make this more concrete and avoid divergent reviews see; Schaefer et al., 'Clarifying How to Deploy the Public Interest Criterion in Consent Waivers for Health Data and Tissue Research'.
59 See also the discussion about public interest in Commissie Regelgeving Onderzoek, 'COREON Statement Wetenschapelijk Onderzoek'.
60 Ploem, 'Gegeven voor de wetenschap, regulering van onderzoek met gegevens, lichaamsmateriaal en biobanken'.
61 For example: Ploug, 'In Defence of Informed Consent for Health Record Research - Why Arguments from "Easy Rescue", "no Harm" and "Consent Bias" Fail'.
62 Most relevant: World Medical Association, 'WMA Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks'.
63 Kamerstukken 2022-2023, 35844, nr. 7.

draft the guidelines, transparency during the process and accountability.[64] Additionally it should be mentioned that the Taipei Declaration leaves room for other options. As mentioned in the Preamble at point 6:

- When authorized by a national law adopted through a democratic process in respect of human rights, other procedures could be adopted to protect the dignity, autonomy and privacy of the individuals. Such procedures are only acceptable when strict rules on data protection are implemented.

This somewhat swollen language seems typical for this type of documents which after Follesdal sometimes end in 'a race to the top'.[65] But when a taking a step back, a democratic process, strict data protection and well organised opt-out (and hence the patient still ultimately decides), is the essence of our proposal.

This is against the commonly held views of individualism and distrust

Opt-out as default is at odds to present individualism and what patients have been repeatedly told about being data their own. It is not to us to bring back a sense of 'the public', in the sense of the common commitment of citizens to participate in society from perspectives which take their fellow citizens and future citizens (and the planet) into account as well. We submit that the 'my data' discourse is both exponent of that trend and reinforces it. As a society we should ask ourselves whether we want to continue on that route.

How can such a system be implemented in a time of distrust? Trust in politics seems at an all-time low though research shows a more nuanced picture.[66] But it is actually not politics which should be trusted but researchers, often as a fact checkers on politics or checking other researchers. Above we briefly described the conditions for trustworthy health research. That cannot happen if data remain in their silos because of privacy arguments. Any change in the legislation and debate about that legislation should be clear about that. The lessons of the debate in England where the proposal for collecting general practitioners data was rolled out to hastily and the public value and security of the data was not sufficiently explained,[67] should be taken into account.[68]

The change proposed here is not to control citizens but to provide researchers with the tools to contribute to our equitable health care system and health protection. That can also mean to provide government with statistics. However, the measures which might follow from those, will always be subject to a public debate. And those researchers' tools can also mean to control government and governmental agencies who should open up their silo's as well.

Some of the arguments against opt-in can also be used against opt-out: certain groups are difficult to reach.

That is a fair point. Just as that with an opt-in system you miss patients who would have opted-in

64 For a brief discussion with references: van Veen, 'Observational Health Research in Europe'.
65 A. Follesdal in Chapter X in: Andreas Follesdal (Editor, Ramses A. Wessel (Editor), and Jan Wouters (Editor), *Multilevel Regulation and the EU: The Interplay between Global, European and National Normative Processes*.
66 https://www.uu.nl/nieuws/betrouwbaarheid-doorslaggevend-voor-vertrouwen-in-overheid..
67 Carter, Laurie, and Dixon-Woods, 'The Social Licence for Research'.
68 Which does not mean that this proposal will probably be nominated for the 'big brother award' or that PrivacyFirst will be negative about the proposal.

but somehow missed this or did not understand it, an opt-out system might not give patients the opportunity to opt-out while they would have wished so. We submit that those will be less. A well organised opt-out system can accommodate this problem to a large extent. Saying no is easier than saying yes. A perfect system will probably never be possible.[69]

The proposed change will take time.

This argument is both true and *completely not*.

It is true that in the end a legislative change is needed. Though that only concerns two Acts and one or two provisions in each of them.[70] However, if government and parliament would choose for an opt-out system in the debate on further use as the principle for a legislative change, that would have the following advantages at present already:

- Health care providers could stop with incurring unnecessary costs and using scarce staff to implement opt-in systems;
- Discussions in review boards would become much more relaxed, as the present exemption for consent can still be used;
- The presents registries which are dependent on unbiased data will be preserved (see Appendix F where these registries express that they are under threat with an opt-in system);
- The Dutch position would be aligned with that of the European Patients Federation;
- The Netherlands would be better prepared for the coming EHDS.

Hence, if a decision for a conditional opt-out as the default would be made, we do not need an immediate legislative change to take the stress out of the present Dutch discussions. As discussed in Appendix F the present Dutch legislation is ambiguous. For a change that would be an advantage then. It can also be interpreted in the light of that decision.

3.7 Linking

The proposal for opt-out as the default will not work if good, unique linking is not possible.

Fuelled by the Dutch DPA[71] the Ministry of Health is reluctant to adopt wider use of the BSN. The recent Bill on quality registries states that the BSN may not be used by the quality registries while in fact almost all use a 2 way pseudonymised BSN at the moment to link data from different health care providers in the patient's trajectory.

In the 'Integraal Zorgakkoord' it is also mentioned that in 2023 a start will be made with removing bottlenecks in sharing health data, starting with limitations on using the BSN.[72] It is difficult to see why that start wasn't made with the Bill on quality registries already which was published by the end of 2022.[73]

The current objections against using the BSN reverse two questions. The first is *whether* linking is allowed. The second is that when linking is allowed, using a pseudonymised BSN poses an additional threat to the privacy of the patient.

69 As a expression goes 'Perfect is the enemy of good'. In Dutch: 'het betere is de vijand van het goede'.
70 Being 7:458 BW (WGBO) and articles 24 and 27 UAVG.
71 College bescherming persoonsgegevens, 'Advies conceptwijziging Besluit gebruik BSN in de zorg', 24 March 2011.
72 At page 97.
73 As shown in Appendix F, according to this Bill, quality registries should not process a pseudonymised BSN. At the moment, most of them do.

Here we separate the two:

1. The fear that using a pseudonymised BSN will make linking easier and hence people can be traced in their path through all possible public entities.
2. Using a BSN will lead to more 'identity fraud' (meaning that someone with the BSN and other data of someone else, can pretend that he or she is that someone else) or is otherwise an additional threat to the privacy of the patient.

Ad 1:

Linking for research is subject to strict rules as laid down in the Code of Conduct on health research.[74] The protocol will describe what type of linking is foreseen, there might be a DPIA if the linking is novel or other circumstances mentioned in article 35 GDPR apply, and the ethics or a similar committee will vet that.

Hence, that linking is made easier is not an argument against using a pseudonymised BSN in health research.

Ad 2:

The other question is that, when linking is allowed, using a pseudonymised BSN in that trajectory imposes an additional threat to the privacy of the patient. Linking for the primary process in health care uses the BSN. Citizen's interactions with health care and with government use the BSN. There is no reason to assume that if the BSN would be used for research as well, that will increase the privacy risks for the patient.

The contrary is the case. Using a pseudonymised BSN can actually be seen as 'privacy enhancing technology' as otherwise more identifiable data must be used to uniquely distinguish the persons concerned, such as parts of the name, gender, birthdate and address while the BSN which is devoid of any such content. Admittedly, also parts of the name, gender, birthdate and address can be pseudonymised, but this is error-prone because of different spellings and annotations of a name and can lead to multi pseudonyms for the same person as the combination of those properties is not always unique. Confronted with multiples (the same pseudonym logically referring to different persons), researchers may want to go back to reach out to individuals, or ask the data sources to go back, to the original data which are quite identifiable while that would not be necessary if the BSN had been used as that is always unique.

The issue becomes even more challenging for researchers who work with established research cohorts involving volunteers. In such cases, participants are asked to engage in research through questionnaires or similar means. However, researchers are not permitted to request the BSN from participants at the beginning of the enrolment process, making it impossible to use the BSN for any purposes. The earlier discussed workaround via a one-way hashed BSN is not applicable since there is no BSN available at the start. Nevertheless, the researchers behind these cohorts with volunteers also need to link with other data sources, such as from health care providers or the data at SN, as consented by the participants. Only probabilistic linking will then be possible which is less reliable. In some cases, they may also want to grant volunteers access to the data, which necessitates two-factor authentication. Currently, the most reliable method for authentication is the Dutch DigID, which is based on the BSN. However, since there is no BSN at the beginning of these cohorts, secure access to the data through DigID cannot be granted.

74 Chapter 4 of the Code of Conduct on health research discusses that situation.

It is impossible to see why health care providers are requested to use the BSN and data breaches because of this use have not happened[75] cohorts with volunteers and who are extremely dependent on the cooperation of their volunteers, their partners in a way, and hence will take all the necessary safeguards, cannot use the BSN.

Hence, we propose that the present restrictions regarding the use BSN for research should be relaxed.

3.8 Central points for access to or release of data for health research

Regarding central access or release of health data for research the results of the country studies can be compared on various criteria as shown in the tables in the previous chapter. Finland, Denmark and France choose for one central - in terms of the EHDS - 'secure processing environment'.[76] England and Germany – with the exception of FDZ - seem to choose a different route. The researchers can analyse the dataset with the variables necessary for the research at an approved environment of their choice, such as that of their university. The German MII system is different from all other systems as it uses a federated approach, with original data remaining in situ and only data needed for a specific project are being released.

The Netherlands has a mix with SN often used as the central access point for the data which are there already because they were required for its statistical function but there are many manifold bi- or multilateral research projects outside SN as well which use a semi-federated approach. Perhaps a choice for one central access point versus the 'fragmented system' should and cannot be made at the moment for the Netherlands as each has its advantages.

We propose an incremental way forward by improving each approach as much as possible.

Processing via SN has many advantages as many types of data can be combined such as SES and the in terms of the Vision of secondary use, 'social domain' data. Improvements can be made:

- At the moment SN is not clearly recognised for this role beyond what is laid down in the act on SN already. The Dutch DPA evenwarned against using SN as a hub for research as a possible 'back alley'.
- In terms of the OECD report[77] the fragmented data landscape in the Netherlands is reflected in how data submitted for statistical purposes can be used for research as well. Each data source must agree and can charge costs that the submitted dataset is narrowed down to the variables necessary for a specific project. As shown in the Appendix on the Netherlands these costs can be quite substantial.

To accommodate both points of improvement, a legislative change is necessary which in our opinion does not need to be complex. If the role of SN for health research is reinforced, we strongly recommend doing so in close collaboration with the research community in order to avoid the problems encountered in Finland where many see Findata as a step back.

75 There have been data breaches but not because of the BSN. Actually, if an inside adversary wants to have access to patient data while not allowed so, he or she will not look under the BSN. Most people don't remember their own BSN let alone that of someone else.

76 In Finland other secure research environments can be appointed as well. CSC is an example.

77 OECD, *Towards an Integrated Health Information System in the Netherlands*.

Hence any new measures should be a step forward and based on a 'no regret' rule. Eagerness to institute a new system should not be detrimental to valuable aspects of the old system. An example of considering each project on its merits is when for ethical reasons feed-back of findings of the results is necessary with all the precautions attached to such a procedure.[78] Research environments which only allow for aggregated statistical output do at present not accommodate such a feed-back procedure.

Another caution not to discard the present solutions is the following. Not all data can and will be available at SN. SN will not assemble genetic data, imaging data, pathology reports, viral or bacterial strains etc., for its statistical function. And even if those very large datasets would be brought to SN specifically for research, SN will in the near future probably not be able to accommodate all the very advanced sometimes muti-computational research pipelines necessary to analyse those datasets. Some universities have instituted the safe digital research environments where there very complex datasets can be analysed.

Many of those data come from the registries as described in Appendix F. Quite rightfully the Vision on secondary use argues that administrative burdens for release data for research should be minimised and that EHR's data should have a multiple use. The Vision also seems to indicate that further use for research will be federated not needing intermediate databases as the registries discussed in the Appendix F. But EHR systems cannot do both: and fulfil its function for the primary process and more or less constantly being questioned for research. For example, the DataShield method as an advanced federated way to combine data for research, uses 'mirrors' of the original databases for the reiterative questioning of databases most of which are already intended to be used for research. Hence the 'bottom-up' developed registries, such as the Dutch Cancer Registry, PALGA, NZR and the quality registries will be needed for quite some time for a learning health system. Also here are improvements necessary, ranging from the issues we discussed already, being a clear legal basis and easy linking via a pseudonymised BSN, to more unified procedures and what may be charged to release data for research. Hence, more unification without denying the efforts which have been made and are still being made for the 'bottom-up' registries in the Netherlands.

On the longer run that should amount to a 'data access authority' proposed in the Vision on secondary use. The comparison made in the Vision to the authorities in Denmark and Finland does not hold as those have the data so to say 'at their fingertips' while this Dutch authority would not. And we saw differences in the approaches in both mentioned countries, with a simple administrative procedure in Denmark – and in England as well – while in Finland the research is reviewed without Findata at the start being adequately equipped for that task. The latter led to complaints of Finnish researchers that the present funnelling of all research via Findata is actually a step back. These lessons should be taken seriously when developing a 'data access authority'. It could be a sort of centralised data release committee for a federated system, comparable to the Central Committee on research involving human subjects (CCMO) for research which falls under the remit of the WMO, finding a proper balance the various interests involved here.

This unification will also require a legislative change and the same caveat as we mentioned for the central database applies here as well: it should not be a step back.

78 See example given and the references in: Geiger et al., 'GBA/GBN-Position on the Feedback of Incidental Findings in Biobank-Based Research'.

3.9 Concluding remarks

In this final chapter we made recommendations which should accelerate the debate for a learning health system, solve the present impasse in the Netherlands and could bring the Netherlands to the same level as many other European countries. Or even beyond that, given what the Netherlands has already.

We strongly recommend that a basic decision about the consent modality will be made soon. We acknowledge that this requires a parliamentary and societal debate. We hope to have discussed all the various aspects necessary for that debate in this report and to have sufficiently explained our view on the preferred outcome. We will be happy to answer remaining questions and to contribute to this debate in the future.

Appendices

A Denmark

A.1 Description of the health care system

A.1.1 General

Denmark is a constitutional monarchy with approximately 5,8 million inhabitants. Greenland and the Faroe Islands are part of Denmark with certain semi-autonomous authority not relevant for the present discussion. Stemming from a long tradition of social welfare,[79] the health care system is based on a Beveridge model via taxation. Hence, solidarity and equal access are prime aspects of the Danish system. Originally, Denmark had a tradition of a decentralised health system with regions and municipalities steering health care providers which, with the exception of primary care, were publicly owned. That system has changed in the last decennia with central government taking more control.[80] Nevertheless, decentralisation remains a hallmark of the Danish system.

A.1.2 Organisation and funding of the health care system

As indicated in the introduction, there is a mix of a centralised and a decentralised approach. Suffice to mention here that health expenditure is, with only a few exceptions, based on taxation by central government and to a much lesser extent via local taxes while the counties in general pay the hospitals. The latter receive funding from central government for the health care expenditures.

General practitioners are the 'gate keepers' before patients can address more specialised levels of care. Patients do not pay for care provided by general practitioners and further echelons of care after referral. Own- or co- payments are limited such as for dental care not covered by the health care system.

A.1.3 The regulatory system regarding data protection

The Danish legislation is systematic in the sense that various versions of Acts are consolidated and that only the central level via Acts and their implementing regulations is relevant for this report. These were described in the country fiche about Denmark in the Nivel report.[81] The Danish Data Protection Act states in article 10 that personal data may be processed without the data subject's consent if that is necessary for statistical or scientific purposes of significant importance to society. The general legislation is the Danish Health Act which regulates all matters concerning the administration of health care including patient rights. We double checked the description of the Danish situation in the very comprehensive Danish country fiche of the Nivel report with an English version of that Act (as generated by google translate) as there seemed to be some new relevant changes. Many of the clauses of the Health Act are further filled-in by delegated legislation by the minister of health and the elderly. We did not check those but relied on the country fiche in that respect. In the following we use that country fiche unless otherwise indicated by a specific referral.

79 As explained in a very different context by Wadmann, Hartlev, and Hoeyer, 'The Life and Death of Confidentiality'.
80 Olejaz et al., 'Denmark Health System Review'. Update in OECD and European Observatory on Health Systems and Policies, 'Denmark: Country Health Profile 2021, State of Health in the EU'.
81 Supplement of Hansen et al., 'Assessment of the EU Member States' Rules on Health Data in the Light of GDPR'.

A.2 Data processing for health care and reimbursement

Denmark has a long tradition of electronic health records and because of its governmental control and even sometimes ownership of health care providers there is high level of uniformity in the electronic health record systems.[82] The health care provider has a duty to annotate his diagnostic findings in the patient's record. Patient records of health care providers are connected via regional systems and a national one. The Danish Health Data Authority speaks of Denmark as 'one cohort'.[83]

Both push (sending a message by the first treating health care provider to the following) or pull (retrieving information by the following health care provider) can be used via this system. In theory the patient can object to both push and pull but in general patient data are exchanged when this is necessary for the situation of the patient and considered to be in accordance with the patient's interests and needs.

Given the taxation-based system patient data are not directly used for reimbursement of the health care provider per patient treatment. Indirectly the aggregated data will be used to fund the health care providers via a lump sum.

A.3 Legal basis for further use for research

A.3.1 Data with the exception of genetic data

The Danish Data Protection Act and the Danish Health Act (hereinafter: DHA) state in conjunction that all confidential information can be transferred to researchers for a – in the translation- concrete health knowledge creating research project.[84] Hence, for such research there is no consent modality applicable.

The research should in principle be approved by the regional ethics committee when competent. However, when the data are in disease registries already (see hereinafter at section 4) such an approval is not necessary.

A.3.2 Genetic data

The DHA makes an exception for genetic data. The treating health care professional must inform the patient that he or she can decide that genetic information can only be used for this immediate treatment. If the patient decides so, he or she has the opportunity to opt out for research using this information as well. The opt-out is to be recorded in the Tissue Use Register. The researcher must consult this register before genetic data can be used for research. The genetic data are available at the National Genome Center.[85] Since its establishment in 2018 all genetic data available at health care provider must be transferred to this center and whole genome analyses are performed at the Danish National Genome Center.[86]

82 Mentioned by Vibeke van der Sprong at the Health-RI 2022 conference. https://www.health-ri.nl/news/setting-data-motion-setting-people-motion These slides cannot be downloaded but we received them.
83 Ibid
84 Article 46 of the DHA.
85 This Center is regulated in par. 223 of the DHA.
86 See https://eng.ngc.dk/

A.3.3 Tissue

For further use of tissue for research the same applies as to genetic data. The patient must be informed that further use for research can take place and opt out of this further use. The refusal will be noted in the Tissue Use Register.

The DHA calls this system 'self-determination'[87] regarding genetic data and tissue. The Minister of Health and the Elderly can establish further rules how the information about this further use is to be provided. We have not been able to find those but asked about it in the interview.

A.4 Personal identification number and linking

Denmark has a civic registration number since 1968. The system can be used for linking various data sources and has been called a 'key tool for epidemiological research'.[88] It should be mentioned that the CPR number, as the number is called in Denmark, is used for a wide variety of purposes, such as (salary) payments, to buy or rent a house, private insurance[89] and obviously health and social care. One of us noticed when inquiring about the CPR, that it is even used in the Danish library card.[90]

A.5 Unlocking data at the national level

In addition to the patient records which as mentioned were electronic from an early stage onwards, health registries for specific diseases were created early on in Denmark.[91] Having these (disease) registries, which also can be used for research, is a trait Denmark shares with many other Nordic countries.[92,93,94]

We will not discuss how linking at the central level was performed before the change of the law which created the Danish Health Data Authority (DHDA) in 2015 which gradually centralised all the registries.[95] This process has not been without its ups and downs as for example mentioned by van der Sprong at her presentation at the Health-RI conference.[96] The system seems to be semi-federated. Apart from registries, which are based on further use, and which are held at the DHDA, the original data remain in situ, such as at the patient files at hospitals, general practitioners and the data of the National Genome Institute. But when needed, they can easily be brought together given the compatible ICT systems.

The data can be accessed for research using one entry point, the Research Health Data Gateway which is held by the DHDA.[97] The system provides access to researchers for approved projects (see the next section) to the necessary pseudonymised data in a secure environment.

87 In our google translation of the Act.
88 Schmidt et al., 'The Danish National Patient Registry'.
89 See in English: https://lifeindenmark.borger.dk/theme/when-you-arrive
90 Personal observation when in Denmark during a meeting. The card was shown to one of us.
91 For an example see: Magyari, Koch-Henriksen, and Sørensen, 'The Danish Multiple Sclerosis Treatment Register'.
92 Laugesen et al., 'Nordic Health Registry-Based Research'.
93 Alriksson-Schmidt et al., 'Flaunting Our Assets. Making the Most of the Nordic Registry Goldmine'.
94 Ludvigsson et al., 'Ethical Aspects of Registry-Based Research in the Nordic Countries'.
95 https://sundhedsdatastyrelsen.dk/da/english
96 Vibeke van der Sprong at the Health-RI 2022 conference. https://www.health-ri.nl/news/setting-data-motion-setting-people-motion These slides cannot be downloaded but we received them,
97 https://www.enindgangtilsundhedsdata.dk/en/About-Us

Researchers are able to add data from other sources there, such from a from a cohort of volunteers. Only the statistical results of the analysis can be exported. All relevant statistical programs can run in this environment such as R.

The DHDA database does not contain the original patient data. These remain federated and are held on location. These data can be added to the research data upon approval of the data holder (see hereinafter). Nevertheless, also without this addition, the depth of the data is quite rich in the DHDA environment, as the registry data which are held at the DHDA already contain quite detailed data and can be linked to Danish statistics data such as about the SES of participants.

A.6 Procedures

The Danish Ethical Review Act exempts observational research with registry data from ethical review. If more data are needed, ethical review by a regional ethics committee is required. This amounts to one time review.

Applicants needs to fill in a form stating amongst other things the purpose of the research and what variables are needed for the research. The DHDA will not review this proposal and a DPIA is not necessary. The DHDA requires an agreement between the DHDA and the applicant before data are made accessible stating amongst things that the data will only be used for the proposed research project.

If data are necessary from other data controllers than those for which the DHDA is responsible, such as the original patient data at a hospital, then that data controller must agree as well.

A.7 Discussion

Denmark's system of further use is even promoted by Denmark as a product: do your research in Denmark', quoting commercial companies who used the Danish system for their research.[98] The consent exception in the phrase' necessary for statistical or scientific purposes of significant importance to society' is apparently taken broadly. Health research which leads to health-related public knowledge, is as such considered to be of significant interest to society.

Regretfully we could not discuss our findings with Danish researchers. The information above is in addition to our desk research based on an interview and written communication with the DHDA. There seems to be opposition in the academic literature to the ease by which patient data can be re-used for research,[99] however we did not find any further proof of that. It would be interesting to know how the opt-out system for the further use of genetic data and tissue is organised in practice and how many patients opt out. Further research and a country visit would be needed for that.

98 https://investindk.com/Set-up-a-business/health-data-denmark
99 Wadmann, Hartlev, and Hoeyer, 'The Life and Death of Confidentiality'.

B England

B.1 Description of the healthcare system and the collection of primary health data

This paragraph provides an overview of the English healthcare system and how health data is collected.

B.1.1 Background

England is one of the four countries that are part of the United Kingdom (UK). Each country has their own health service that oversees healthcare. The National Health Service (NHS) England is the umbrella term for the health and social care system in England and provides free care for approximately 56 million residents in England. NHS England is publicly funded. The government either owns the hospitals and providers of NHS care or commissions them. Except for some specialist services, general medical services contracts (contracts with general practitioners (GPs)), and public health services, commissioning has been at a local level since the 1990s. Primary care services provide the first point of contact in the healthcare system, acting as gatekeepers of the NHS.[100]

B.1.2 Organisation of the healthcare system

Healthcare as covered by the NHS in England is free for all residents, including hospital, physician, and mental health care. People can also take out additional private medical insurance. Benefits of private insurance are more rapid access to care, free choice of specialists, and better amenities, especially for elective hospital procedures. Residents cannot opt out of coverage by the NHS, irrespective of whether they may choose to access services in the independent sector.

Regional NHS teams are responsible for the quality, financial, and operational performance of all NHS organisations in their region. They also support the 42 integrated care systems (ICSs) to provide integrated and sustainable care for patients.[101] ICSs are geographically based partnerships between organisations that meet health and care needs across an area. They coordinate and plan health services to improve population health, reduce inequalities between different groups, and enhance productivity and value for money.[102]

B.1.3 Funding of the healthcare system

Public financing, collected through general taxation, is the primary source of funding for health in England.[103] The United Kingdom's His Majesty's (HM) Treasury allocates a block grant, calculated using the so called 'Barnett formula', to devolved administrations.[104] In England, the

100 Anderson et al., 'United Kingdom, Health System Review 2022'.
101 NHS England. Regional Teams. Retrieved from https://www.england.nhs.uk/about/regional-area-teams/
102 NHS England. What are integrated care systems? Retrieved from https://www.england.nhs.uk/integratedcare/what-is-integrated-care/
103 The King's Fund. (2021). How the NHS is funded. Retrieved from https://www.kingsfund.org.uk/projects/nhs-in-a-nutshell/how-nhs-funded
104 UK Parliament. (2022). The Barnett formula and fiscal devolution. Retrieved from https://commonslibrary.parliament.uk/research-briefings/cbp-7386/

Department of Health and Social Care is accountable to HM Treasury for financial performance and further allocates funding to NHS England and arm's length health agencies (such as the Care Quality Commission and Healthcare Services Safety Investigation Branch).[105] At the local level, ICSs are responsible for commissioning or planning health and care services in England.[106] Healthcare providers can also receive funding from other sources, such as local authorities or people who pay privately for their healthcare.

B.1.4 Relevant characteristics of the regulatory system

In England, and the whole of the UK, the legal frameworks covering how (identifiable) patient data must be organised and processed are the Common Law Duty of Confidentiality (CLDC), the United Kingdom General Data Protection Regulation (UK GDPR), and the Data Protection Act (UK-DPA) 2018.[107]

Additionally, several special acts apply, such as the Human Tissue Act and the Health and (social) Care Acts. The plural is used for the latter as regularly there is an update of this Act, amending the original Health and Social Care Act of 2012. A major one was that of 2022, bringing important changes into the NHS system(reflected above).[108] We mostly used the 2012 consolidated version (called: 'latest version, revised' on the site). But other Acts are applicable as well, such as the Care Act, to which the Health and Care Act refers.

With the constant iterations of most of these acts, cross references to other acts and regulations based on the acts, which were difficult to find, England was not easy to navigate. Hence, we mostly depended on governmental sites explaining the procedures as they were applicable in January 2023. We checked whether we got the general picture correct against the literature[109, 110] and our correspond.

Common Law Duty of Confidentiality

The CLDC states that when information is given in circumstances where it is expected that a duty of confidentiality applies, that information cannot normally be disclosed without a lawful basis.[111] In practice, this means that all confidential patient/client information can only be disclosed with the consent (implied or explicit) of the patient/client, when disclosure is in the overriding public interest, or when there is a statutory basis or legal duty to disclose. It has been suggested that CLDC and the consent and its exceptions as follow from the UK Data Protection

105 The King's Fund. (2022). Where does the buck stop? Understanding accountabilities and structures in the national health and care system in England. Retrieved from https://www.kingsfund.org.uk/publications/understanding-accountabilities-structures-health-care

106 NHS England. What are integrated care systems? Retrieved from https://www.england.nhs.uk/integratedcare/what-is-integrated-care/

107 In the UK, the abbreviation is DPA, We placed UK before that abbreviation to distinguish this from DPA as Data Protection Authority used elsewhere in this report.

108 For a brief description and critique see: https://www.bma.org.uk/advice-and-support/nhs-delivery-and-workforce/integration/the-health-and-care-act#:~:text=The%20Act%20aims%20to%20support,sustainable%20use%20of%20NHS%20resources.

109 As though briefly in: Dove and Chen, 'Should Consent for Data Processing Be Privileged in Health Research?'.

110 Wood et al., 'Linked Electronic Health Records for Research on a Nationwide Cohort of More than 54 Million People in England'.

111 The Common Law Duty of Confidentiality. Retrieved from https://www.health-ni.gov.uk/articles/common-law-duty-confidentiality

Act are not properly aligned.[112]

The UK General Data Protection Regulation and the Data Protection Act 2018

The UK GDPR is the post-Brexit retained the EU law version (with some changes to make it work more effectively in the UK context) of the 2016 General Data Protection Regulation (EU GDPR).[113] The UK-DPA 2018 concerns the UK's implementation of the UK GDPR.[114]

In June 2021 the European Commission concluded that the UK offers the same level of protection concerning personal data as the EU member states to which the GDPR is directly applicable (adequacy decisions).[115]

B.2 Conditions for primary use

Individuals may expect that relevant health information is shared among their care team to ensure high-quality care, integrated services, and a better experience for patients. NHS Digital develops and maintains 'The Spine'. The Spine allows the secure sharing of information between different parts of the NHS and forms the basis of the Electronic Prescription Service, Summary Care Record, and Electronic Referral Service.[116] As far as we could assess, patients are not asked to consent or have the option to opt-out for datasharing via the Spine, however, the CLDC will still apply.

B.3 Conditions for secondary use of patient data and human tissue for research

This paragraph provides an overview of the legal conditions for the reuse of health data.

B.3.1 Patient data

All secondary use of health data must be in line with the UK-DPA 2018 and the UK GDPR. Part 1 of Schedule 1 of the UK-DPA 2018 states that special categories of data such as health or genomic data may be processed without consent if the processing:

- is necessary for archiving purposes, scientific or historical research purposes or statistical purposes,
- is carried out in accordance with Article 89(1) of the [F4UK GDPR] (as supplemented by section 19), and
- is in the public interest.

As we will see, these broad provisions are supplemented by special regulations when it concerns NHS data.

112 Dove and Taylor, 'Signalling Standards for Progress'.we analyse the legal components of disclosing confidential patient information under the UK's common law duty of confidentiality (CLDoC
113 https://www.legislation.gov.uk/uksi/2019/419/regulation/2
114 Data Protection Act 2018. Retrieved from https://www.legislation.gov.uk/ukpga/2018/12/contents/enacted
115 https://ec.europa.eu/commission/presscorner/detail/en/ip_21_3183
116 NHS Digital. Spine. Retrieved from https://digital.nhs.uk/services/spine

B.3.2 Human tissue

There are numerous biobanks in England.[117] For practical guidance on how to comply with relevant legislation, the Human Tissue Authority (HTA) has produced seven Codes of Practice. The Codes give practical guidance to professionals carrying out activities which are within the HTA's remit under the Human Tissue Act 2004. Code E concerning research states that human tissue from the living may be stored and used for research without consent provided the research is ethically approved and the researcher cannot identify the donors. Human tissue removed from the deceased must only be retained for use in research if appropriate consent has been given.[118]

Biobanks need to be licensed by the HTA. Given the preference of the HTA for consent, in practice broad consent will be the basis for further use of tissue for research.

In general, biobanks share data with approved researchers whose research project has been approved under their Access Procedures, which means that the researcher has to be a bona fide researcher and has to undertake health research that is in the public interest.

B.4 Linking

Everyone registered with the NHS in England has their own NHS number, a unique national patient identifier.[119] The NHS Number differs from the National Insurance (NI) number, which is used for tax, benefits, and pensions.[120] We did not inquire whether the NHS number can somehow be linked to the NI number which could be helpful fr research which also needs to assess SES. With the NHS number, datasets can be linked and pseudonymised. Biobanks can also link data to primary and secondary healthcare records.

B.5 Central repositories which can be used for health research

B.5.1 Instituted by law

NHS Digital[121] (the national information and technology partner for the health and care system) has a legal obligation and responsibility for standardising, collecting, analysing, publishing, and sharing data and information from across the health and social care system. All providers of care, and since 2016, all providers of care for privately funded patients across the England, have been mandated to routinely supply data on expenditure, activity, outcomes, and patient experience to NHS Digital. Patient information sharing legislations apply to the routine processing of personal data by NHS England. The Health and Care Act 2022 enables NHS Digital to acquire personal confidential data from General Practitioners (GPs) without seeking patient

117 Tissue Directory and coordination Centre. (2022). A - Z List of Registered Resources. Retrieved from https://directory.biobankinguk.org/Profile/Biobanks

118 Human Tissue Authority. Code of practice and standards. E: Research https://content.hta.gov.uk/sites/default/files/2020-11/Code%20E.pdf

119 NHS England. What is an NHS number? Retrieved from https://www.nhs.uk/using-the-nhs/about-the-nhs/what-is-an-nhs-number

120 NHS England. NHS Number Leaflet. Retrieved from https://www.eastamb.nhs.uk/Downloads/NHS-Number-Leaflet.pdf

121 In February 2023 NHS Digital ceased to exist and became part of NHS England. In March 2023 when this Appendix was last checked, the sites referring to NHS digital still functioned.

consent.[122] However, routine NHS data are collected through different IT systems, which leads to a fragmented data landscape. Some examples of available NHS data are given below.

B.5.2 Primary care

Through NHS Digital, data regarding medicines dispensed in primary care (from the NHS Business Services Authority)[123] is available for research purposes. Also, from the GP medical records, electronic Summary Care Records (SCR) are created. However, only authorised staff in other areas of the health and care system involved in the patient's direct care can access these records. There is no general primary care database with patient data that can be used for purposes beyond direct clinical care. There were plans to bring GP data together across the NHS, to support research and analysis.[124, 125] But this central database, the General Practice Data for Planning and Research (GPDPR), was shelved after widespread criticism from doctors and privacy campaigners. They argued that pseudonymisation of patients could be reversed and that people had not been given sufficient time and information to opt out.[126]

B.5.3 Secondary and tertiary care

The NHS Digital Secondary Uses Service (SUS) brings together a large amount of data across secondary care[127] and is designed to provide anonymous patient-based data for purposes other than direct clinical care. This includes the Hospital Episodes Statistics (HES) datasets for in- and outpatient care, the Diagnostic Imaging Dataset, the Emergency Care Data Set (ECDS) which provides information about the care provided in emergency departments (including capacity and demand) and the SUS Payment by Results dataset. However, these data lack detailed clinical information – being primarily used for payment and activity monitoring.

The Mental Health Minimum Data Set and Mental Health Services Data Set collect data from the health records of individual children, young people and adults who were in contact with mental health services in England.[128]

NHS Digital collects some data from individual community services providers and makes this available for purposes besides direct clinical care through the Community Services Data Set.[129]

B.5.4 Covid Care

NHS England provides data for the NHS COVID-19 Data Store. The datasets are pseudonymised

122 Health and Care Act 2022. Retrieved from https://www.legislation.gov.uk/ukpga/2022/31

123 NHS Digital. Medicines dispensed in Primary Care NHS Business Services Authority data. Retrieved from https://digital.nhs.uk/data-and-information/data-tools-and-services/data-services/medicines-dispensed-in-primary-care-nhsbsa-data

124 NHS Digital. General Practice Data for Planning and Research (GPDPR). Retrieved from https://digital.nhs.uk/data-and-information/data-collections-and-data-sets/data-collections/general-practice-data-for-planning-and-research

125 Carter, P., Laurie, G. T., & Dixon-Woods, M. (2015). The social licence for research: why care. data ran into trouble. *Journal of medical ethics, 41*(5), 404-409.

126 NHS Digital. About the GPDPR programme. Retrieved from https://digital.nhs.uk/data-and-information/data-collections-and-data-sets/data-collections/general-practice-data-for-planning-and-research/about-the-gpdpr-programme

127 NHS Digital. (2022a). Secondary Uses Service (SUS). Retrieved from https://digital.nhs.uk/services/secondary-uses-service-sus#:~:text=The%20Secondary%20Uses%20Service%20(SUS,the%20delivery%20of%20healthcare%20services.

128 NHS Digital. Mental Health Services Data Set. Retrieved from https://digital.nhs.uk/data-and-information/data-collections-and-data-sets/data-sets/mental-health-services-data-set

129 NHS Digital. Community Services Data Set. Retrieved from https://digital.nhs.uk/data-and-information/data-collections-and-data-sets/data-sets/community-services-data-set

prior to going into the NHS Data Store to ensure that individual patients are not identifiable. Examples of available data are:[130]

- Lab test data
- Data from the COVID-19 SARI-Watch database -which includes treatment and outcome information on patients admitted to hospital with a Covid-19 diagnosis
- Intensive Care National Audit and Research Centre – Care provided to COVID-19 patients and discharge data

Additionally, there is a centralised UK database containing x-ray, computed tomography, and magnetic resonance images from hospital patients across the UK: The National COVID-19 Chest Imaging Database (NCCID).[131]

B.5.5 Cohorts and registries

The National Disease Registries Directions 2021 provides NHS Digital with a legal obligation to process confidential patient information, setting aside the CLDC. The legal basis to collect these data is thus a legal obligation and substantial public interest.[132] Anyone can opt out of disease registration at any time. Opting out of the registries is different from the national NHS opt-out.

Three products are available:

- Cancer Registration Data: contains records of cancer registrations, including the registration date and place, but also information about type of cancer or its site (recorded in ICD10 code)
- Civil Registration – Deaths: contains details of all registered deaths in England and Wales
- Demographics: provides information on cohort members' current status (fact of death or exit from the NHS, for example) and to give demographic details such as current name and address

B.5.6 Screening programs

The NHS offers a range of screening tests to different sections of the population. Public Health England (PHE) re-uses the information to ensure that screening services are safe and effective. This is usually anonymous data but sometimes includes identifiable information. Data can also be shared with national disease registers or with researchers outside of PHE.

B.5.7 Administrative data

The Office of National Statistics plays a crucial role in sourcing, linking, and curating public sector data, ensuring that all data can be accessed by researchers in a safe and secure form with minimal risk to data holders or the public. Data can be accessed by accredited researchers for approved research projects that are in the public interest.[133]

130 Retrieved from https://www.england.nhs.uk/contact-us/privacy-notice/how-we-use-your-information/covid-19-response/nhs-covid-19-data-store/

131 NHSX. Covid Chest Imaging Database. Retrieved from https://nhsx.github.io/covid-chest-imaging-database/

132 NHS Digital. National Disease Registration Service. Retrieved from https://digital.nhs.uk/about-nhs-digital/corporate-information-and-documents/directions-and-data-provision-notices/data-provision-notices-dpns/national-disease-registration-service

133 NHS Digital. List of Administrative Sources. Retrieved from https://digital.nhs.uk/data-and-information/find-data-and-publications/statement-of-administrative-sources/list-of-administrative-sources

B.5.8 Conditions for using the central repositories that are instituted by law for health research

As seen, consent not necessary for health and care research in England. The 3 mentioned conditions apply. The UK GDPR and UK-DPA 2018 also provide several rights to data subjects, such as the right to rectification, objection, and restriction of processing. The UK DPA 2018 has implemented Article 89.2 of the (UK) GDPR, which allows a derogation from certain rights (e.g., the data subject's right to object) when the personal data are processed for scientific research purposes. Thus, these rights cannot be applied, if they would prevent or seriously impair the achievement of the purposes of scientific research. However, for NHS data the right to object does apply.

B.5.9 Routine primary, secondary and tertiary care from NHS Digital

All project-based research taking place in the NHS in England and Wales needs approval form the Health Research Authority. If the research project involves accessing confidential patient information without consent in England and Wales, an additional application for approval to the Confidentiality Advisory Group is necessary.

Data from NHS Digital can be requested through the Data Access Request Service (DARS). Within DARS, NHS offers a central De-ID solution which enables de-identified linkage across data sources. Through De-ID, a different pseudonym value is created each time the data is made available through DARS. This allows data to be linked by using the pseudonym rather than a personal identifier, such as the NHS Number, and thus avoiding the risk of directly identifying a person. However, pseudonymisation is a security measure. It does not change the status of the data as personal data.

B.5.10 Covid Care

The Covid-19 Data Store data has a specific application process within DARS and this data is only available for planning and research for COVID-19 purposes.

B.5.11 Screening programs

Approval from an ethics committee and special permission to use this information from the Health Research Authority's Confidentiality Advisory Group is needed.

B.5.12 The National (NHS) data opt-out

Patients have the right to request that their confidential health information is not used beyond their own care and treatment. The national data opt-out allows patients to opt out of the use of their health data for research or planning purposes. Patients, or people acting for them by proxy, have control over setting or changing their own opt-out choice, and can change their minds at any time. The national data opt-out covers confidential patient information collected about care in England. This includes:

- publicly-funded, commissioned, or coordinated health and adult social care
- private care that is given in NHS settings

Anonymous or aggregated data are exempted from the opt-out system. When a patient sets an opt-out choice, unless the patient changes their mind, the data cannot be used for research,

even after the patient has died.[134]

Patients cannot opt out of data being used to deal with emergencies such as the coronavirus. When patients have used the national data-opt out, they can still be invited for screening services.[135]

If any biobank participant elects to use the national NHS opt-out, this will not exclude them from any biobank. To withdraw from a Biobank, any participant has to withdraw by notifying the specific Biobank.

B.5.13 Health Data Research Innovation Gateway

Because there are numerous health datasets available in England, it can be difficult for researchers to discover what datasets exist. The Health Data Research Innovation Gateway, established in 2020, provides a common entry point for researchers to UK health data. The Gateway provides a detailed list of all available datasets and offers a platform to manage and request access to these datasets.

B.6 Discussion

The researcher we interviewed was generally very satisfied with the opportunities for secondary use of health care data. The researcher did raise concerns that England will eventually be leapfrogged by other countries (law of the handicap of a head start).

One of the main issues the interviewee raised was the massive gap in available data in NHS Digital, being primary care data. As of yet there is no central GP database. The communication strategy was severely lacking, as a result of which it turned into a huge national issue fueled by in his words 'privacy activists'.[136] A central GP database therefore remains politically difficult to achieve. According to this respondent the issue is not so much legal but more about optics.

Other issues regarding NHS Digital are that more detailed outcome data can only be found at a regional level, and there is a lack of agreed-upon data standards. Furthermore, many researchers complain about the long waiting times for data access requests.

A federated data platform will be developed in the future, with an investment of 300 million pounds. This will become part of the NHS.

Additional links

Department of Health. The Common Law Duty of Confidentiality. Retrieved from https://www.health-ni.gov.uk/articles/common-law-duty-confidentiality

Health and Care Act 2022. Retrieved from https://www.legislation.gov.uk/ukpga/2022/31

134 NHS Digital. (2022b). Understanding the national data opt-out. Retrieved from https://digital.nhs.uk/services/national-data-opt-out/understanding-the-national-data-opt-out

135 https://www.gov.uk/government/publications/patient-confidentiality-in-nhs-population-screening-programmes/nhs-population-screening-confidential-patient-data

136 For a more nuanced view than this respondent, see: Carter, Laurie, and Dixon-Woods, 'The Social Licence for Research'.

NHS Digital. About the GPDPR programme. Retrieved from https://digital.nhs.uk/data-and-information/data-collections-and-data-sets/data-collections/general-practice-data-for-planning-and-research/about-the-gpdpr-programme

NHS Digital. Community Services Data Set. Retrieved from https://digital.nhs.uk/data-and-information/data-collections-and-data-sets/data-sets/community-services-data-set

NHS Digital. General Practice Data for Planning and Research (GPDPR). Retrieved from https://digital.nhs.uk/data-and-information/data-collections-and-data-sets/data-collections/general-practice-data-for-planning-and-research

NHS Digital. National Disease Registration Service. Retrieved from https://digital.nhs.uk/about-nhs-digital/corporate-information-and-documents/directions-and-data-provision-notices/data-provision-notices-dpns/national-disease-registration-service

NHS Digital. Spine. Retrieved from https://digital.nhs.uk/services/spine

NHS Digital. (2022a). Secondary Uses Service (SUS). Retrieved from https://digital.nhs.uk/services/secondary-uses-service-sus#:~:text=The%20Secondary%20Uses%20Service%20(SUS,the%20delivery%20of%20healthcare%20services.

NHS Digital. (2022b). Understanding the national data opt-out. Retrieved from https://digital.nhs.uk/services/national-data-opt-out/understanding-the-national-data-opt-out

NHS England. Integrated care systems (ICSs). Retrieved from https://www.england.nhs.uk/commissioning/who-commissions-nhs-services/ccg-ics/#:~:text=On%201%20July%202022%2C%20integrated,and%20work%20in%20their%20area.

NHS England. NHS Number Leaflet. In.

NHS England. Regional Teams. Retrieved from https://www.england.nhs.uk/about/regional-area-teams/

NHS England. What are integrated care systems? Retrieved from https://www.england.nhs.uk/integratedcare/what-is-integrated-care/

NHS England. What is an NHS number? Retrieved from https://www.nhs.uk/using-the-nhs/about-the-nhs/what-is-an-nhs-number/#:~:text=An%20NHS%20number%20is%20a,use%20of%20all%20NHS%20services.

The King's Fund. (2021). How the NHS is funded. Retrieved from https://www.kingsfund.org.uk/projects/nhs-in-a-nutshell/how-nhs-funded

The King's Fund. (2022). Where does the buck stop? Understanding accountabilities and structures in the national health and care system in England. Retrieved from https://www.kingsfund.org.uk/publications/understanding-accountabilities-structures-health-care

Tissue Directory and coordination Centre. (2022). A - Z List of Registered Resources. Retrieved from https://directory.biobankinguk.org/Profile/Biobanks

UK Parliament. (2022). The Barnett formula and fiscal devolution. Retrieved from https://commonslibrary.parliament.uk/research-briefings/cbp-7386/

C Finland

C.1 Description of the healthcare system and the collection of primary health data

C.1.1 Background

In this paragraph we briefly describe the Finnish health care system with respect to the collection of routinely recorded health data. Finland is a republic and has approximately 5,5 million inhabitants [The World Bank]. The Ministry of Social Affairs provides a framework for the health legislation at a national level. However, the responsibility for the organization, provision and financials of healthcare lie with the municipalities and must remain within the limits of the central legislation. Therefore, the healthcare and its availability can differ between municipalities. Furthermore, private healthcare is a growing sector in Finland, although still most of the healthcare is owned by the public sector.[137, 138]

C.1.2 Organisation of the Healthcare system

As in many countries the Finnish healthcare system is divided into:

- Primary care: consisting of care such as general practitioners (GPs), physiotherapists and dentists, but also inpatient clinics located in primary health care which are staffed with nurses.
- Secondary care: regional hospitals (inpatient and outpatient specialist clinics), for access a referral from a GP is required.
- Tertiary care: university hospitals, for access a referral from a GP is required.

All patient information in Finland is in an electronic format. The health information systems are developed regionally, as the organization of healthcare is primarily based in the individual municipalities. However, a national information system was introduced gradually between 2010 and 20186 called Kanta Services.[139] The Act on the Electronic Processing of Client Data in Healthcare and Social Welfare [784/2021] regulates the secure electronic processing of client data in healthcare and social welfare sector as it defines the general requirements for data systems and their suppliers. Renewal of this act took place on 1st of November 2022.

Kanta Services

These services were launched in stepwise from 2010-2018 [Jormanainen, 2018]. Kanta services is not an EHR system, but a transmission and archiving service. This is where patient/client data is shared between social welfare and public and private healthcare organizations, pharmacies and citizens. The most known service within the Kanta Services is “My Kanta Pages”, here patients/clients can view their own health data and prescriptions and request repeat prescriptions. Kanta Services is increasingly used by a very large part of the population though less with people with lower digital skills or SES.[140]

137 Keskimäki et al., ‘Health System Review 2019’.
138 Laugesen et al., ‘Nordic Health Registry-Based Research’.
139 Keskimäki et al., ‘Health System Review 2019’.
140 Jormanainen, ‘LARGE-SCALE IMPLEMENTATION OF THE NATIONAL KANTA SERVICES IN FINLAND 2010–2018 WITH SPECIAL FOCUS ON ELECTRONIC PRESCRIPTION’.

Patients do not have the right to forbid the storing of their EHR-data in the Kanta Services. However, patients can give consent to data sharing between service providers. Without this consent, only the healthcare service provider who has recorded the data has access to the patient's data, unless sharing is necessary for treatment of the patient and consent cannot be obtained because of unconsciousness, mental illness or comparable reason. See Act on the Status and Rights of Patients 13 and Act on the Electronic Processing of Client Data in Healthcare and Social Welfare section 10.

The most important aim of Kanta Services is that all original copies of health records are submitted to this national data repository by health care providers who are connected to Kanta Services.[141] Kanta Services is a national digital health data system service, which includes, "My Kanta Pages", Prescription Centre (ePC), Pharmaceutical Database, Patient Data Repository (PDR), Patient Data Management Service (PDMS), Kelain, Client Data Archive for Social Welfare Services (CDA) and Kanta Personal Health Record (Kanta PHR). The new act makes it possible for clients to save their own wellbeing data in the new Personal Health Record (PHR) in Kanta Services.

Kanta is very transparent; patient can see the whole content of his or medical or welfare files. But it is primarily used for patient care, and not research as it is very unstructured. Only the prescription database is a well-structured database that is quite fit for research. One can apply for Kanta content through Findata (see hereinafter).

C.1.3 Personal identification number

To identify patients in EHRs, a personal identification number is used. The personal identification number was introduced in 1964 along with the Finnish Central Population Register[142] and was also needed for an identifier in health insurance, employee pension, population and other registers. The use of the personal identity number in healthcare is documented in the Personal Data Act.

C.1.4 Funding of the healthcare system[143]

The funding of the Finnish healthcare system is primarily tax-based and covers approximately 75% of all health care, which includes access to GP's, hospitals, outpatient hospital clinics, and partial reimbursement of prescribed medications. Furthermore, the following 20% is collected by patient co-payments, primarily for visits and procedure fees, medications costs, or dental care. The last 5% of the health care costs are derived from private insurance. Private healthcare is mainly financed by personal fees, however also partially reimbursed by healthcare insurance.

The public healthcare insurance of Finland, the National Health Insurance (NHI), is managed by the Social Insurance Institution (SII) and it covers all citizens and permanent residents. Population groups that are not covered, such as undocumented immigrants or foreign temporary workers, do still have access to essential emergency care. Approximatly 17% of the Finnish population has coverage by voluntary healthcare insurance (VHI), which is complementary to the NHI.

141 Milieu Ltd and Time.lex, 'Overview of the National Laws on Electronic Health Records in the EU Member States National Report for Finland'.

142 Gissler and Haukka, 'Finnish Health and Social Welfare Registers in Epidemiological Research'.

143 This section is based on: Keskimäki et al., 'Health System Review 2019'.

C.2 Secondary use of health data

C.2.1 Legal basis for further use of health data for research[144]

The most relevant legislation on the secondary use of healthcare data is:

- The legal basis for the processing by Findata is Article 6, Section 1 (e) of the EU's General Data Protection Regulation (processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority). When processing data concerning specific categories of personal data (previously referred to as sensitive data), including personal health data, the processing is carried out on the basis of Article 9, Section 2 (g) (processing is necessary for reasons of substantial public interest) in addition to the aforementioned Article 6.
- The Act on the Secondary Use of Health and Social Data (552/2019): this act specifies the uses for which authorisation may be granted. According to section 2 of the Act, data may be disclosed for the compilation of statistics, scientific research, development and innovation activities, education, knowledge management, steering and supervision of social and health care by authorities and the planning and reporting duty of an authority. No separate consent from patients is needed for secondary use of health data.

C.2.2 Central database for healthcare data

Finland has a central entry for health data for research called "Findata". Findata is an independent central agency which falls under the responsibility of the Finnish Institute of Health and Welfare (THL). Findata consists of multiple data sources, including (but not limited to) data saved in Kanta services (medical record data, prescriptions), public and private service providers of social welfare and health care, Finnish Medicines Agency (Fimea), Statistics Finland (to the extent that access is required to data covered by the act on the investigation of the causes of death).

C.2.3 Conditions for data use and permits for Findata

Researchers can request permits at Findata for using the pseudonymised or anonymous data for their research. Access to data with direct identifiers can only be granted under strict conditions and fitting with the data applicant's processing purposes.[145] It is also possible to combine different data sources, such as data collected by the researchers themselves. Findata can combine these data. However, when data extraction from Findata has already been completed or it concerns other data than that referred to in the Act on the Secondary Use of Health and Social Data (as opposed to the permit granted by Findata), a special amendment application needs to be submitted. [https://findata.fi/en/data/]

Furthermore, it is possible for researchers to access data from the direct source, if they only need data from one data controller, instead of getting access through Findata.[146]

Permits for Findata can be requested in Finnish, Swedish or English via the Findata web portal by not only researchers, but also individual citizens. Aggregated statistical data can be accessed after a data request and sent to researchers, who can analyse the data freely as long as they are in accordance with a data utilisation plan. Non-aggregated data, i.e. data on individuals

144 See also: Southerington, 'Access to Biomedical Research Material and the Right to Data Protection in Finland'.
145 Hansen et al., 'Assessment of the EU Member States' Rules on Health Data in the Light of GDPR'.
146 Hansen et al.

require a different data permit and can only be analysed in a secure environment [https://findata.fi/en/data/#what-data-are-available-via-findata]. To request a data permit, a personal identity code registered in the Finnish Population Information System is required. For foreign researchers, alternative secure identification is being investigated, which will make it possible for foreign researchers to request a data permit.[147] As far as we know this system has not been implemented yet.

Findata checks the research plans. If the research is unfeasible, Findata will advise a revision of the research proposal and permit request. Findata gives detailed information when denying a request. Therefore, it is unlikely researchers will start an appeal process when Findata gives advice to change the research plan. We did not check with our respondents whether 'unfeasible' means that the requested data are not available or that Findata has different opinions about the methodology of the proposed research.

As an exception, the National Institute for Health and Welfare (THL) may grant permission (Act on the National Institute for Health and Welfare (668/2008)) if the applicant works for THL and does not need data from another registrar referred to in the Act on Secondary Use.

C.2.4 Biobanks

Legal basis for use of biobank-data

In September 2013, a special biobank-act has been set in place in Finland (688/2012). The objectives of this act are to support research that utilises human biological samples, to promote openness in the use of these samples and to secure the protection of privacy and self-determination when processing these samples.

In contrast to further use of patient data, further use of bio samples requires the consent of the patients. Donors can withdraw their consent and prohibit further use of their samples at any time. The consent is broad consent. Once consent is given to further use of the samples, not every study has to ask for new consent.

Furthermore, Finland has multiple biobanks by health care districts and catchment areas, universities, and the Finnish Institute for Health and Welfare (THL). As there are multiple Biobanks, the National Biobank Register contains information on the owners and custodians of such biobanks. In addition, the register has general information on the number of samples stored in biobanks, the research areas of biobanks, the conditions for obtaining samples and other factors related to the usability of the samples and the data associated with them as well as any information on possible decisions taken by authorities. "Every Finn can donate samples to a biobank. Therefore, biobank research requires samples collected from population cohorts to reflect the health of the population as well as samples from patients treated in hospitals."

There is no separate consent for reuse of biosamples. When patients consent to the bio samples being stored in a biobank, this implies consent for the reuse for research purposes (broad consent). Also in the upcoming new Finnish biobank law, the fact that only one consent is needed will not be changed. The hospital or university where the applicant resides is responsible for the study. The biobank will need to see this approval and review the proposal before giving access. Analysis of biobank samples can be done both on-site or in an approved laboratory at a research facility or university.

147 Hansen et al.

Conditions for data use and permits for biobank-data

A biobank may grant access to, study or otherwise process the samples and information stored by it, provided that:

1. The intended use corresponds to the research area defined for the biobank and the criteria and conditions established for the processing of the sample;
2. Terms and restrictions provided in this act or elsewhere in law and determined by the biobank are observed in the research and in the processing of samples and information
3. The individual who is granted access to the samples or data, holds the appropriate professional and academic qualifications for processing the samples and information, and the granting of access to the sample or information is in connection with the duties of the recipient.

The data will be coded (pseudonymised) and personal information can only be granted based on consent from the registered individual or some other person qualified to provide consent in the event that no other criteria are provided in this act for granting access to the information [Biobank law].

C.2.5 Population-based registries

Under Finland's national screening programme, municipal health centres must arrange screening for the early detection of

- breast cancer
- cervical cancer
- colorectal cancer
- foetal chromosome and growth defects during pregnancy

The data from these screening programmes are collected in national registries. Other Finnish registries are the causes of death registry, statistics on reimbursements for prescription medicines and the Care Register for Health care (includes data on inpatient care in health centres, hospitals, and other institutions, day surgeries and specialized outpatient care, providers of those services, patients, admission and discharge, diagnoses, and treatments provided. Primary health care is not included). Data from these registries can be accessed through Findata.

C.3 Discussion

Findata is seen as the one-stop-shop in Finland for data requests by the researchers we interviewed. Findata was implemented to make the data request procedures straightforward and easy. But in the experience of one of our interviewees, it has not. When submitting a request for data through Findata, each project is assigned an advisor. However, due to a high turnover and long lead time, this advisor might change several times throughout the process. This further slows the process (which can last from several months up to more than a year) and also jeopardizes continuity. Data requests are also quite costly contrary to what researchers were used to. Additionally, instances are known where, when the data was finally received by the research team, variables would be missing, or other mistakes were made by Findata. Especially for a not a full-time researcher, the process is quite cumbersome, not so straightforward and takes a lot of time. We also received a mail of early 2021 which stated that

Findata was actually a step back in comparison to what was possible in Finland before Findata.

The primary care data that can be requested through Findata is not always complete and detailed enough. Primary care data is not meant for research, lots of aspects tend to be missing.

Not needing consent for research is not a recent development in Finland.[148,149] As far as the interviewed researchers know, there have not been any unwanted side-effects from the lack of consent for further use of data. It was a political, top-down decision to implement the current consent modality where patients automatically agree to the reuse of health data for research. However, overall, the trust of the population in the government is high. There might be some people who do not agree with their data being used, but according to the respondents this is a very small fraction. No instances are known where patients avoid health care services because they do not want data to be reused for research.

For observational, biobank and registry data, there is no ethical approval needed, except when data from various sources are combined data, there is some kind of intervention or it is necessary to take extra samples for the research. Findata does not perform ethical reviews but does advise whether an ethical approval is necessary.

Findata provides a secure remote access platform to analyse data. It is also possible to analyse the data at other, Findata-approved, remote access platforms. The interviewed researchers stated that the remote access platform by Findata works quite well but that is does not support all statistical programs used for research.

Additional links

https://www.kanta.fi/en/professionals/secondary-use-of-kanta-data

https://aineistokatalogi.fi/catalog/studies

https://eurohealthobservatory.who.int/countries/finland/

https://findata.fi/en/data/#what-data-are-available-via-findata

https://www.biopankki.fi/en/what-is-a-biobank/

148 Alriksson-Schmidt et al., 'Flaunting Our Assets. Making the Most of the Nordic Registry Goldmine'.
149 Laugesen et al., 'Nordic Health Registry-Based Research'.

D France

D.1 Description of the healthcare system and the collection of primary health data

D.1.1 Background

France is a Republic which has approximately 65 million inhabitants.[150] France has several 'oversea regions' where the regulations are slightly different. We concentrate on mainland France. The jurisdiction of the healthcare system is divided among;[151]

- The state: the parliament and the government, specifically the Ministry of Health
- National Union of Social Insurance Funds (SHI)
- local authorities, particularly at the regional level.

For the purpose of regulation and planning, the state, SHI and health care provider's representatives negotiate. The outcomes of these negotiations are translated into administrative decrees and laws passed by the parliament and collective agreements signed by SHI and health professionals' representatives.[152]

D.1.2 Organization of the healthcare system

The French healthcare system is based on a Bismarckian approach with Beveridge goals. A Bismarckian model is characterised by an insurance system usually financed jointly by employers and employees through payroll deduction. In the Beveridge model, health care is provided and financed by the government through tax payments.[153] The Beveridge goals are reflected in the single public payer model, the current increasing importance of tax-based revenue for financing health care and strong state intervention.[154]

The French health system is based mainly on a SHI system, with a traditionally strong role for the state.[155] Enrolment in France's statutory health insurance system is mandatory. The system covers most costs for hospital, physician, and long-term care, as well as prescription drugs. Most voluntary health insurance (VHI) is complementary, covering mainly co-payments and balance billing, as well as vision and dental care, which are minimally covered by SHI.[156]

Delivery of care is shared among private, independent physicians, public hospitals, private non-profit-making hospitals and private profit-making hospitals. Alongside the health care sector and the social sector, there is a combined health and social care sector, the "third sector",

150 https://www.nationsonline.org/oneworld/france.htm
151 Chevreul, K., Brigham, B., Durand-Zaleski, I., & Hernández-Quevedo, C. (2015). France: Health system review. *Health systems in transition*, (17/3) p.15 (zit in Z. maar daar heet het dan HiT ....)
152 Chevreul, K., Brigham, B., Durand-Zaleski, I., & Hernández-Quevedo, C. (2015). France: Health system review. *Health systems in transition*, (17/3) p. 20
153 *Health Care Systems - Four Basic Models | Physicians for a National Health Program*. (z.d.). Geraadpleegd op 27 september 2022, van https://www.pnhp.org/single_payer_resources/health_care_systems_four_basic_models.php#:%7E:text=The%20Beveridge%20Model,force%20or%20the%20public%20library.
154 Bolliger, A. (2019, 12 juni). *FRANCE*. eanamed.eu. Geraadpleegd op 27 september 2022, van https://www.eanamed.eu/index.php/free-practice-all-over-europe/france
155 OECD/European Observatory on Health Systems and Policies (2021), *France: Country Health Profile 2021*, State of Health in the EU, OECD Publishing, Paris, https://doi.org/10.1787/7d668926-en. P. 8
156 Durand-Zaleski, I. (2020). International Health Care System Profiles, France. *The Commonwealth Fund*.

that provides care and supportive services to elderly and disabled people.[157]

D.1.3 Funding of the health care system

Approximately threequarters of total healthcare expenditures are funded publicly principally through SHI. SHI resources mainly come from income-based contributions from employers and employees.[158] The central government allocates budgeted expenditures among different sectors (hospitals, ambulatory care, mental health, and services for disabled residents) and regions.[159]

VHI provides complementary insurance, such as for co-payments and better coverage for medical goods and services that are poorly covered by SHI. Complementary insurance is provided mainly by not-for-profit, employment-based associations or institutes.

D.1.4 Characteristics of the French regulatory system

France may be seen as the cradle of the modern Western European tradition of codification of the prevailing law. However, when that started during the Napoleonic area the regulatory and welfare state hardly existed. It started with 2 codes, the Civic Code and the Penal Code which at the time were an example throughout continental Europe. Currently, laws and regulations are broken down into 78 Codes, each defined by a broad subject area. The social security code, the mutualities code, the public health code (Code de la Sante Publique, hereinafter referred to as the CSP) and the social action and families code all apply to health care directly or more indirectly. Additionally, there is a Code on research (CoR).[160] These codes are quite lengthy and also contain the delegated legislation. Specific legislation usually leads to a change in one the codes. On certain points the Codes refer to each other and it must be noted that rules from several codes might together be applicable to a certain topic.[161] For our purposes the CSP is most relevant but for human samples also the Code on Research is applicable. The CSP contains provisions which in the Netherlands are spread over various Acts, such as professional qualifications of health care professionals, medicinal products, public health and patient rights, though the Code Civil contains provisions on those as well. For the object of the present report the French Data Protection Act (Loi Informatique et Libertés (hereinafter referred to as LIL) crosscuts the applicable provisions of the various Codes.

Additionally thereis certain French tendency towards 'bureaucracy'[162] with resulting regulations and agencies which such as the CNIL, the French data protection authority, can issue very elaborate bylaws or pseudo-legislation, tumbling over each other. This makes the French system difficult to navigate in spite of the 'codification'. This is exacerbated by the fact that relating to the objective of this report the French system is in a flux.

157 Chevreul, K., Brigham, B., Durand-Zaleski, I., & Hernández-Quevedo, C. (2015). France: Health system review. *Health systems in transition*, (17/3) p. 52

158 Chevreul, K., Brigham, B., Durand-Zaleski, I., & Hernández-Quevedo, C. (2015). France: Health system review. *Health systems in transition*, (17/3) p. 59

159 Durand-Zaleski, I. (2020). International Health Care System Profiles, France. *The Commonwealth Fund*.

160 In French it is the Code de la recherche, with this abbreviation we remained close to the French title. It should be mentioned that in the first section 'research' is added with 'and technological development'. Amongst other things, the CoR also lays down how French government should establish and fund a research agenda and several advisory bodies in that respect. Unlike the CSP the oversight of the French legislation did not show the implementing legislation of the CoR.

161 Chevreul, K., Brigham, B., Durand-Zaleski, I., & Hernández-Quevedo, C. (2015). France: Health system review. *Health systems in transition*, (17/3) p.7

162 For a slightly one sided view but in our opinion with a valid kernel of truth see: https://www.gisreportsonline.com/r/french-bureaucracy/

As an example (legislation and sites last accessed January 2023). Even though updated in 2021,[163] the CSP refers in a clause about health research with solely data[164] to article 54 of the LIL which mentioned a committee which should approve such health research and then send its approval to the CNIL. We use the past sense here as that section of the CSP refers to the version of LIL *before* the LIL was considerably changed, coming into effect into May 2018, following the GDPR.[165] At the moment article 54 of the LIL refers to a completely different subject. With the new LIL a new committee was set in place. However, when visiting the site of that newer committee, that committee was again very recently replaced by the committee set up under the new French Health Data Hub (hereinafter: FHDH).[166]

Apart from this confusion, the question then arises which committee would approve, if that were necessary, health research with data which does not use that FHDH. We will come back to the FHDH and mentioned questions later in this chapter.

D.2 Conditions for primary use

The CSP contains several provisions on the topic of further use for primary use in conjunction with the LIL. In general consent is not necessary to process data in the medical file (article 65 jo. Article 44 LIL) by professionals under an obligation of medical confidentiality. France has instituted a system of shared medical records between health care providers. The patient is informed about this shared medical record and is explicitly notified that he or she can opt out from this.

D.3 Conditions for secondary use of patient data and tissue for research

D.3.1 Patient data

Such research is per R.1121 section 3 of the CSP exempt from the provisions on research in the CSP. Hence only the provisions of the LIL apply though different conditions may be set by the committee which supervises the further use of the data for research which can be made available via the FHDH.

The LIL uses the research exemption in article 9.2.j GDPR and hence consent is not necessary for further use of health data for research in the public interest (article 66-71 and 73-79 LIL). Yet, everybody can object to the further use of the health data concerning him or her (article 74 LIL). The CNIL has issued a 'methodologies de référence' on this further use.[167] When using this methodology, one does not need to apply for an approval by the CNIL. Hence otherwise and in the absence of other exemptions (see hereinafter) one would (article 66 II and III LIL).

When using the methodology, one still must notify the CNIL confirming that the processing of health data for research is in accordance with the methodology.

163 Décret n°2021-848 du 29 juin 2021 - art. 1
164 Article R 1121, section 3
165 https://francearchives.fr/fr/authorityrecord/FRAN_NP_003875
166 https://documentation-snds.health-data-hub.fr/glossaire/inds.html
167

Two methodologies are particularly relevant here:

- MR 0004, relating to studies which use one single data source
- MR 0005, relating to studies which use the centralised hospital "Standardised Discharge Summary" system[168] (PMSI) and/or the centralised summaries of emergency admittance system. Both are available at the ATIH.[169] As we will see, these 2 centralised systems may largely have been superseded by the FHDH. We will discuss the approval process for studies using the FHDH later.

Methodology MR004 is extremely detailed, even listing the personal data which may be used in the research by the research team and how long these data may be stored, namely 5 years. As mentioned, if data from multiple sources are being used, MR 0004 does not apply (dot 3 and 4 of article 1.2 MR 0004). A DPIA is necessary before the research may start. Each person whose data are being used for research should be notified about the research, hence about each new project, and then can object. He or she can also inquire what data are being processed for the research (although the methodology also states that the data should be pseudonymised) and can ask for correction. So, **it seems** that France did not make use of the exemptions provided in 89.2 GDPR.

The data assembled for the research may only be processed until 2 years after the last publication, which seems to make later validation of the research or FAIR impossible.

Studies which neither use one data source or the FHDH, would need approval of the CNIL. Probably one would need to follow the details of MR 0004 for the application but then adding more data sources. Or, if one does not need to combine the data pertaining to the same patient, from the various sources, one could use MR0004 repeatedly.

Or one would use the MR 005 to access data at the FHDH platform. MR005 is detailed as well. Instead of MR 0004, where the exemption to ask for approval by the CNIL is directed at researchers, here that exemption is given to organisations. The French umbrella organisation of comprehensive cancer centres[170] is amongst them. Organisations mentioned in MR 0005 can get a license for access by the ATIH/FHDH.[171] The data may only be analysed at the secure ATIH Platform and only the fully anonymised results of the analyses can be exported. In this case the patients whose data can be analysed for a specific research project do not need to be individually notified. That would also be impossible as the direct identifiers from the data source are one-way hashed. Notification and the possibility to object may take place at the data source, hence the hospital. We will discuss those options when discussing the various national databases in France.

Again, the data assembled for the study may only be stored for 2 years.

In order to increase transparency all studies must be notified at the ATIH site.

The conclusion of this section is that further use of patient data for research in the public interest is allowed in France unless the patient has opted out. Sometimes this is an opt-out to a specific study or it can sometimes be an opt-out to a central assembly of data which we discuss later.

168 Boudemaghe and Belhadj, 'Data Resource Profile'.
169 Agence Technique sur l'Hospitalisation, see : https://www.atih.sante.fr/
170 https://www.unicancer.fr/en/
171 See : https://www.atih.sante.fr/acces-aux-donnees-pour-les-bureaux-d-etudes-ou-laboratoires-de-recherche

In principle the CNIL should approve this further use unless the research felt under one of the "methodologies de référence". As we will see, further use via the new FHDH does not fall under these 'MR's' and a double control will be performed.

D.3.2 Biosamples/biobanking

Human tissue may be further used for research if the patient did not opt out from this use. In this a regional research ethics committee must approve the project and most often also the CNIL for the data processing unless MR 0004 were applicable.

D.4 Linking

In France the 'social security number' (numéro d'inscription au répertoire, NIR) is used to uniquely identify patients in health care. But probably as there seem to be only 3 numbers which are unique,[172] for the central assembly of data, we saw also other data being used for linking.[173]

Article 30 of the LIL allows the NIR for linking for research if the NIR has been substituted by – in short – a random number. When done frequently this number should be renewed (hence a new number) at a certain interval. The interval should be laid down in an Administrative Degree of the higher order.[174]

D.5 Centralised databases

In addition to thementioned ATIH France has created the national system of health data (SNDS). In the SNDS pseudonymised data about the functioning of the health care system are assembled. The pseudonymisation seems to be same as with the ATIH, namely based on the RIN and some additional data.[175]

The SNDS contains three principal databases:

1. SNIIRAM
   The SNIIRAM database contains all data linked to health insurance reimbursement. The data has been collected since 2006.
2. PMSI
   Each healthcare establishment records each hospital stay, known as a "Standardised Discharge Summary", which are classified in Diagnosis Related Groups (DRGs) according to medical and economic criteria.
3. CépiDc
   Inserm's CépiDc manages the Causes of Deaths database (BCMD). It only processes the medical component of the death certificate. The database does not contain any names. Additionally, the SNDS also contains data about long term care as collected via the social security system (CSP L 1461 and following).

172 https://www.service-public.fr/particuliers/vosdroits/F33078
173 See Thierry Boudemaghe and Ihssen Belhadj, 'Data Resource Profile: The French National Uniform Hospital Discharge Data Set Database (PMSI)', *International Journal of Epidemiology* 46, no. 2 (1 April 2017): 392–392d, https://doi.org/10.1093/ije/dyw359 for how the unique number in the
174 Décret en Conseil d'Etat, a comparible with a 'algemene maatregel van bestuur' in the Netherlands.
175 https://www.snds.gouv.fr/SNDS/Qu-est-ce-que-le-SNDS

- Information on health as well as on the provision and quality of health care and medical and social care;
- The definition, implementation and evaluation of health and social protection policies;
- Knowledge of health expenditure, health insurance expenditure and medico-social expenditure;
- Information for professionals, health or medico-social structures and establishments on their activity;
- Surveillance, monitoring and health security;

We found it difficult to understand whether *every* patient or client of the social (long term) care system is also pseudonymised were assembled in the SNDS. The part on data protection on the site of the SNDS[176] refers to the LIL and a change of the law which expanded the remit of the EHDS. The latter does not specifically mention opt-out. The referral to the LIL mentions the generic opt-out as the right to object under the GDPR.[177] Exempt from that right to object is data processing for public services. Further use for research on data in the SNDS would not fall under that, hence the right to object remains. See also article 74 LIL. It is unclear to us how that right to object can be executed in practice.

The SNDS data is made available via the Health Insurance portal. For research first the positive opinion of the CEREES scientific council must be obtained and then that of the CNIL. We did not find any reference to the CEREES in the legislation.

A publication in 2018 showed that for research the SNDS can only be meaningfully used for research in combination with other data sources.[178] However, since 2019, the SNDS has been expanded with a larger number of health data, data from registers, research cohorts, hospital data warehouses, etc., leading to the FHDH.

D.5.1 French Health Data Hub

The Health Data Hub is a public interest group created by Article 41 of the Law on the Organization and Transformation for Healthcare. It is established between 56 actors represented in its General Assembly, as set out by ministerial decree, mostly from the public sector but also some private actors. The funding of the FHDH is mainly public. It is an enlargement of the SNDS also containing data from cohorts, registries, and the content of hospital data and general practitioners.

The data will be accessible to all project coordinators contributing to public interest research after a positive opinion from an independent committee, the mentioned CESREES authorization and by the Data Protection Authority (CNIL). It should be mentioned that the CNIL authorisation procedure has a fatal deadline. If the CNIL has not respondend within a month, the proposal is deemed to be approved.

Data are to be analysed in the safe data space provided by the FHDH which is still under development. All major statistical and other research software can run on that safe space.[179]

176 https://www.snds.gouv.fr/SNDS/Protection-de-la-donnee
177 Article 56 LIL, the referral on the site mention 3 alinea's of the article but we only found 2 in the most recent version of the LIL.
178 Scailteux et al., 'French Administrative Health Care Database (SNDS)'.
179 https://www.health-data-hub.fr/offre-technologique

D.6 Discussion

We interviewed two researchers. They could not explain all the details of the complexities we discussed earlier but spoke from experience how they navigate through the system. Both mention the large file which has to be submitted when requesting data from the central repositories. Preparing the file is time-consuming. Yet, the approval process after that, if all the tick boxes are correct, goes smoothly. They did not mention any specific problems with the necessary CNIL approvals. De facto the proposals are often deemed to be approved because of the mentioned fatal deadline in the approval process.

One researcher was somewhat sceptical about the new FHDH and mentioned positive experiences with the existing databases. The other researcher on the other hand was even moderately enthusiastic. This respondent mentioned that under president Macron France is working hard on eliminating 'red tape'. We noticed an example of this with the mentioned 'fatal deadline' of the CNIL approval. This respondent sees the FHDH as France moving towards one big cohort. We saw already that Denmark is considering itself as such but, as the respondent remarked, France has many more inhabitants and that will give many more opportunities for research. This opportunity to become a major player in the health research data market is also why the FHDH is backed by government funding and legislation.

Additional links

https://www.connexionfrance.com/article/Practical/Health/A-guide-for-residents-and-second-homeowners-to-the-French-healthcare-system-in-2021

https://healthmanagement.org/c/it/issuearticle/the-healthcare-system-in-france

https://wagner.nyu.edu/files/faculty/publications/French.health.system.03.2018%20%281%29.pdf

https://www.cleiss.fr/particuliers/venir/soins/ue/systeme-de-sante-en-france_en.html

https://www.nationsonline.org/oneworld/france.htm

https://www.legifrance.gouv.fr/liste/code?etatTexte=VIGUEUR

http://www.civitas.org.uk/content/files/france.pdf

https://www.french-property.com/guides/france/public-services/health/system-overview

E Germany

E.1 Description of the healthcare system

E.1.1 Background

Germany is a federal republic consisting of 16 federal states and has a population of 83 million people. The states of have legislative authority, except in cases where this authority has explicitly been reserved for the federal level. There are also areas where the states and the federal level have concurrent powers.[180,181,182] Public welfare (except for the law on social care homes) is one of the concurrent powers.

This has important implications for the governance of the health care system and the subject of this report. Care sectors are subject to different legislation and separated in terms of organisation, financing, and reimbursement, making governance complex and decentralised.[183] There are several sickness funds each pertaining to a group of society and for a minority which is not covered by one of these groups, there is voluntary health insurance offering the same coverage. Within the boundaries set by the federal Social security Act[184] (hereinafter: FSSA) sickness funds have regulatory powers, including regulating details of the benefits. Also other organizations have been given formal rights to influence decision-making through consultation, participation, proposals or becoming a deciding and financing partner.[185]

E.1.2 Organization of the healthcare system

The German healthcare system is based on five principles.[186] First, the principle of mandatory insurance entails that every resident in Germany is required to take out health insurance, either through one of the statutory sickness funds (SHI) or private health insurance (PHI). Both SHI and PHI are funded through the premiums or contributions from their members and this is known as the second principle. The principle of solidarity plays an important role, as all those with statutory health insurance receive the same medical care regardless of their financial status through contributions to an income-based common fund.[187] This means that, just as in the Netherlands, there is a risk-equalisation system running in the background which compensates insurers with a population with higher costs than the average.[188]

180 Blümel et al., 'Health System Review 2020'.
181 Constitution of Germany, article 70 and following version as made available via the federal governmental hub to access legislation https://www.gesetze-im-internet.de/englisch_gg/englisch_gg.html#p0014 (last accessed on 15-11-2022)
182 Blümel M, Spranger A, Achstetter K, Maresso A, Busse R. Germany: Health system review. Health Systems in Transition, 2020; 22(6): p. 1
183 LINK "https://www.gesetze-im-internet.de/englisch_gg/englisch_gg.html" \l "p0014"https://www.gesetze-im-internet.de/englisch_gg/englisch_
184 Blümel et al., 'Health System Review 2020'.
185 For example the German Medical Association: https://www.bundesaerztekammer.de/en/german-medical-association
186 Bundesministerium für Gesundheit. (2022, april). *Das deutsche Gesundheitssystem*. https://www.bundesgesundheitsministerium.de/service/publikationen/details/das-deutsche-gesundheitssystem-englische-ausgabe.html
187 Germany Healthcare System - Health Insurance in Germany. (2022, 25 juli). VisaGuide.World. Geraadpleegd op 28 juli 2022, van https://visaguide.world/international-health-insurance/germany/#:%7E:text=The%20German%20public%20health%20care,fund%20where%20everyone%20contributes%20to.
188 Schneider, Ulrich, and Wille, 'Risk Adjustment Systems in Health Insurance Markets in the US, Germany, Netherlands and Switzerland'.

In addition, there is the principle of no direct payments by patients. Individuals who are covered by SHI receive medical treatment without having to pay the costs themselves. Lastly, there is the principle of self-administration. This means that the state provides an overall legal framework at the federal level, but state governments themselves are responsible for hospital planning and public health services.[3] Corporatist bodies such as associations of sickness funds and providers oversee most of the decision power within the SHI system, thereby organizing and structuring the healthcare system. Corporatist bodies as such serve as organs of political representation and exercise control over persons and activities within their jurisdiction.[189] These corporatist bodies set out regulations together in its supreme decision-making body, the Federal Joint Committee.[3, 190]

E.2 The regulatory system regarding data protection

The federal structure of Germany also applies to the data protection legislation. There is a data protection Act at the federal level and one at the level of each state. The latter differ slightly from each other.

This complex arrangement reflects the German Constitution and how EU law is reflected in German law. Certain basic rights are the regulatory domain of the federal insofar as necessary for the national interest. Data protection is not explicitly addressed in the German Constitution. However, in 1983 the German Constitutional Court recognised the right to 'informational self-determination' as embedded in the German constitution, though as any basic right not without limitations.[191] This leads to a system where the legislation of all states should reflect EU data protection law.

The Federal Data Protection Act (BDSG) applies to all private entities[192] and, insofar as relevant here, in essence to public bodies of the federal government or other public bodies insofar as this is not regulated at the state level and as they execute federal law. As all major hospitals and certainly the university hospitals are public bodies, they will be subject to state level data protection regulation. Hence, to get the full picture of Germany one should look at each state. We only investigated that of Bayern, given a publication that Bayern both intends to foster biomedical research as a new industry and is very much consent-orientated to open up data for research.[193] Which is, as will see, also the case for the rest of Germany.

In addition to the generic acts of data protection also specific regulations in special laws such as state hospital legislation, specific acts (such as the Federal Act on cancer registries) and even church law can play a role which data may be processed under what circumstances. This together with the circumstances mentioned in the previous paragraph make Germany extremely difficult to navigate when it comes down to the details. But the broad lines are clear and will be explained in the following paragraphs.

189 Britannica, T. Editors of Encyclopaedia (2014, February 13). *corporatism*. *Encyclopedia Britannica*. https://www.britannica.com/topic/corporatism

190 Gemeinsamer Bundesausschuss, https://www.g-ba.de/

191 BVerfG, Urteil des Ersten Senats vom 15. Dezember 1983, 1 BvR 209/83 u. a. – Volkszählung –, BVerfGE 65, 1.

192 Except for the 'household exemption', see article 2.2.c GDPR and the Lindqvist case ECLI:EU:C:2003:596 for the limited scope of that exception.

193 McLennan et al., 'Practices and Attitudes of Bavarian Stakeholders Regarding the Secondary-Use of Health Data for Research Purposes during the COVID-19 Pandemic'.

E.2.1 Data processing for health care and reimbursement

The German federal data protection Act allows for data processing for the delivery of health care without consent (article 22 BDSG). The same applies for data processing in the context of social security such as by the mentioned sickness funds (art 22 BDSG). The FSSA lays down which data may by processed by the sickness funds in great detail. (par. 282 and following of Book V of the FFSSA).

The sickness funds use a common data information platform as regulated in the FSSA (par. 306 and following FSSA). Via this data information platform patients should also be able to get access to a record or app which combines all the data of the health care providers they have visited (par. 341 FSSA and following).

E.3 Legal basis for further use for research

E.3.1 Data

Though the FDPA allows for an exception to use personal data for research without consent, the general norm is consent. For example, the Bayern data protection Act states that though personal data may be used for statistical output by the Bayern cancer registry,[194] research with these data should be based on consent. In some cases, state hospital and state data protection laws provide in their research clauses possibilities for secondary use of health data for research purposes without consent. However, these regulations can differ considerably, making it difficult to use data across the states.[195] In general, the picture is, as mentioned by our respondents, that researchers employed at a hospital can access patient data for research, but that as soon as personal data leave the hospital, consent would be needed.

Consent or opt-out was intensively discussed in the context of the German Medical Informatics Initiative (hereinafter: MII) which we will discuss in detail later. The choice was made for opt-in via written consent at the admission of the (University) hospital.[196] The patient is offered a table of choices, from broad consent to narrow. Hence, we should speak of 'layered consent'. The German DPA's accepted this procedure including the option of broad consent as long as the consent question is asked in a different room and by a different staff member than the staff helping the patient fill in other forms. As the admission procedure is, except in emergencies, charged with paperwork already.

Human samples

There is no specific human tissue regulation.[197] The legal framework is primarily derived from

194 Bayern was chosen because of a publication describing the situation in Bayern, McLennan et al.benefiting from this data requires accessing and sharing the data. Health care organizations focusing on individual risk minimization threatens to undermine COVID-19 research efforts, and it has been argued that there is an ethical obligation to use the European Union's General Data Protection Regulation (GDPR(waarom neemt Z. deze niet helemaal mee?)

195 Gerlach, F., Greiner, W., Jochimsen, B., Von Knalle, C., Meyer, G., Schreyögg, J., & Thürmann, P. (2021). Digitalisierung für Gesundheit–Ziele und Rahmenbedingungen eines dynamisch lernenden Gesundheitssystems. *Sachverständigenrat zur Begutachtung der Entwicklung im Gesundheitswesen, Bonn*. P. 205

196 Zenker et al., 'Data Protection-Compliant Broad Consent for Secondary Use of Health Care Data and Human Biosamples for (Bio)Medical Research'.in Europe

197 Hoppe, N. (2021). The Regulation of Biobanking in Germany. In: Slokenberga, S., Tzortzatou, O., Reichel, J. (eds) GDPR and Biobanking. Law, Governance and Technology Series, vol 43. Springer, Cham. https://doi-org.eur.idm.oclc.org/10.1007/978-3-030-49388-2_15

the general norms of civil, criminal, professional and data protection law. In biobank-specific guidelines important principles are summarised, which, however, are not legally binding.[198] The informed consent of the donors of biospecimens is considered key for the ethical and legal admissibility of the operation of biobanks. According to § 15 (1) of the German professional code for doctors,[199] research with human tissue falls under the obligation to consult the competent ethics committee. As a result, the working group has developed a series of sample texts for the information and consent of sample donors depending on the situation at hand.[200]

E.4 Personal identification number and linking

To uniquely identify a person in the healthcare system, the insurance number (KVNR) is used. The KVNR contains personal data about the insured person and must therefore be considered as personal social data. The processing of personal social data as such is only permissible insofar as the legal provisions of the FSSA allow or order it (§ 67b FSSA). Under current data protection law, it is not possible to use the KVNR directly as a patient identifier in the context of medical research, even if the patient has given his/her consent. Yet, in a pseudonymised form it can. The FSSA V mentions some explicit exemptions for the direct use of the KVNR outside the health insurance context, for example for the consolidation of cancer registry data for the comparison of cancer registry data with data from organised cancer screening programmes.[201]

E.4.1 Unlocking data at the national level

Data at the central level

There are only a few medical registries in Germany for which data collection is prescribed by federal or state law. These registries are subject to special framework conditions due to their special legal basis.[202] Also these reflect the layered system of legislation (at the state and at the Federal level).

The legal basis for the national cancer registry in Germany is the recent Bunsdeskrebsregisterdatengesetz (BKRG).[203] This Act assigns the Robert Koch Institut (RKI) as the responsible body for the national cancer registry. The BKRG lays out in detail what data may be collected by the registry. This can be divided into data which are meant to uniquely distinguish between patients, as a pseudonymised national number cannot be used for this purpose, and data about the diagnosis and treatment. The latter type data are spelled out thoroughly in the Act and can be supplemented by a ministerial decree. The collected data must, since the recent change in the Act (entry into force in 2022),[204] be submitted by the cancer registries of the states, based on the respective laws of each of the states. The RKI checks the data from regional registries on completeness and quality and performs what might be

198 https://www.akek.de/biobanken/
199 Munster BerufsOrdnung which counts as as professional law (see the section on corparatist bodies.
200 https://www.akek.de/biobanken/
201 Niemeyer, A., Semler, S. C., Veit, C., Hoffmann, W., Röhrig, R., Gurisch, M. S. C., ... & Beckedorf, D. P. F. I. Gutachten zur Weiterentwicklung medizinischer Register zur Verbesserung der Dateneinspeisung und-anschlussfähigkeit.
202 Niemeyer, A., Semler, S. C., Veit, C., Hoffmann, W., Röhrig, R., Gurisch, M. S. C., ... & Beckedorf, D. P. F. I. Gutachten zur Weiterentwicklung medizinischer Register zur Verbesserung der Dateneinspeisung und-anschlussfähigkeit. P. 46
203 https://www.gesetze-im-internet.de/bkrg/BJNR270700009.html
204 For a critique on the outcomes of German cancer registries before the changes in the German law see: Andersen and Storm, 'Cancer Registration, Public Health and the Reform of the European Data Protection Framework'.

called 'data cleaning'. Additionally, the RKI performs various analyses to generate statistics on prevalence, incidence but also on survival etc.

The data may be used for research by third parties, also commercial parties, if the requested dataset is in short necessary and proportional. In principle the research should be performed with anonymised data and the RKI will only transfer anonymised data. If pseudonymised data are necessary, the research must be performed in a safe data space under supervision of the RKI. The RKI should consult the Ministry of Security and Information technology first about the technical and procedural measures of the safe data space. Further conditions apply in this case such as that all who have access to the data are subject to a professional or contractual duty of confidentiality.

As mentioned, the data for the federal cancer registry come from the cancer registries of the states which in their turn receive the data from health care providers as regulated by state law. For example, the Bayern Act on a cancer registry[205] lays down which data should be transmitted by health care providers to this regional cancer registry. These do not seem to exactly mirror the provisions of the BKRG. The Bayern Act is based on distinction between epidemiological surveillance of cancer and research. It states that all research with the Bayern cancer registry must be based on consent. Additionally, it stipulates that each data subject can opt out of being entered in the registry but that does not seem to mean that such an opt-out system must be implemented at each health care provider before the patient is entered in the registry. It remained unclear to us how the provision on research in the Bayern Act relates to the new BKRG where the data submitted to the federal cancer registry can under the circumstances mentioned above, also be used for research without consent.

E.4.2 Claims data

The mentioned legal framework of articles §303a to FSSA makes it possible to use claims data from the outpatient and inpatient sector for scientific purposes[206] without consent.

Again, there is a new central development here. § 303b (1) SGB V regulates that the Central association of statutory health insurance companies (*GKV-Spitzenverband*) is to act as the data collection agency for the data delivered by the statutory health insurances. The scope of the data to be collected is explicitly defined by law in § 303b (1) SGB V, and the actual scope of the data to be transmitted to the central level is defined in § 3 (1) Data Transparency Ordinance (DaTraV).

The new Research Data Centre Health (*FDZ Gesundheit*)[207] makes it possible to access the billing data of all people with statutory health insurance in Germany. The FDZ Gesundheit receives the billing data annually in pseudonymised form from the German National Association of Health Insurance Funds.[208] Access to the health data of the FDZ Gesundheit is only granted to institutions authorised to use it, as stipulated in § 303e paragraph 1 SGB V. In addition to approved research organisations, those also include patient organisations.

The data can only be analysed within the processing environment of the FDZ.

205 https://www.gesetze-bayern.de/Content/Document/BayKRegG/true

206 Gerlach, F., Greiner, W., Jochimsen, B., Von Knalle, C., Meyer, G., Schreyögg, J., & Thürmann, P. (2021). Digitalisierung für Gesundheit–Ziele und Rahmenbedingungen eines dynamisch lernenden Gesundheitssystems. *Sachverständigenrat zur Begutachtung der Entwicklung im Gesundheitswesen, Bonn*. P. 222

207 https://www.forschungsdatenzentrum-gesundheit.de/

208 https://www.tmf-ev.de/News/articleType/ArticleView/articleId/4764.aspx

It should be mentioned that this new central collection and opening up data for research has been challenged before at least one court.[209]

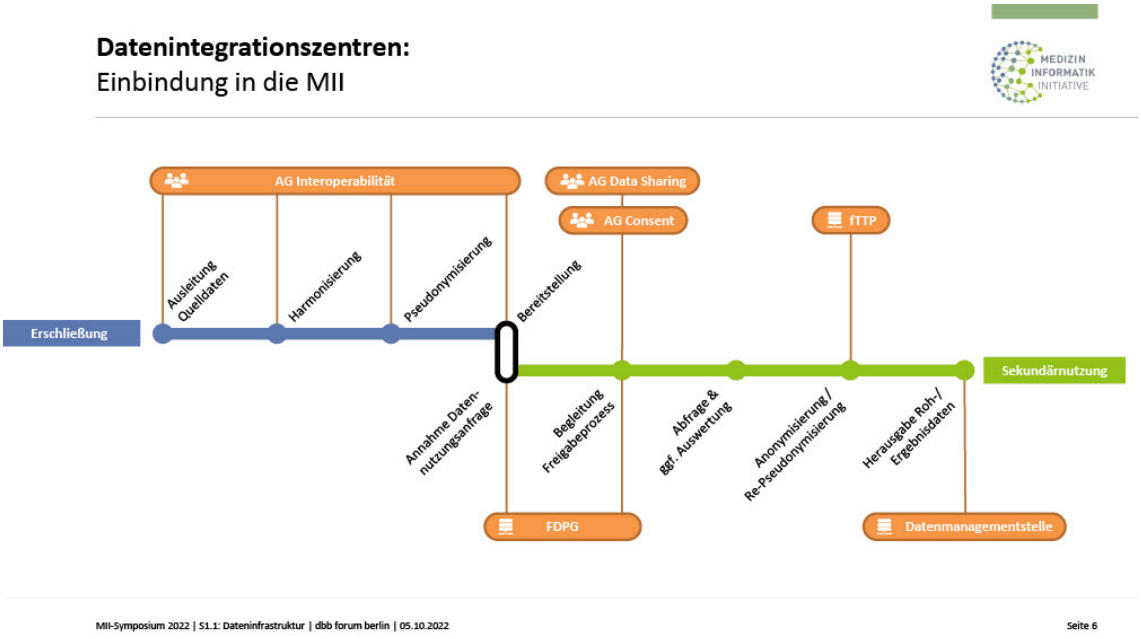
A federated system via the Medical Informatics Initiative (MII)

The MII is a 'bottom up' initiative (though financially supported by the Federal government) by all university hospitals and other organisations to create a harmonised framework and standardised rules at the national level for research for which data form several sources are necessary. Though originating from the University hospitals also other data sources can be opened up via the MII framework, though as yet not primary care.[210]

The MII explicitly acknowledges that health data are heterogenous and accommodates for that by setting rules, which are continuously developed further for common datasets and data harmonisation before data are released.

The MII procedure is described in the following scheme. Though in German, the steps are easily recognisable and understandable. Dataquellen means data sources and AG stands for 'Arbeitsgruppe' meaning working group. There are several of those. The MII is under constant development but alreadyfunctions for agreed use cases. The research should be approved first by the ethics committee of the researcher requesting the data. Though there is no formal harmonisation of the approval system of these committees for observational research, one of our respondents remarked that de facto all other committees accept such a decision. Given the standard contracts agreed upon in building the MII one model DTA covers the release from all data sources. Each release of a dataset for research should meet stringent procedures for data protection, meaning double pseudonymisation of the number by which a subject can be distinguished from another subject in the dataset, and consent. As we have seen, in Germany release of EHR data for research must be based on consent and the broadness of the consent can differ. Hence, for each record it must be ascertained whether the research is covered by the consent of the patient. We did not investigate how this works in practice. Also, the length of the process if the research is not covered by one of the established use cases would require further investigation. As mentioned, the MII is still in its building phase.

209 Richter zweifelt an zentraler Massenspeicherung von Gesundheitsdaten | heise online
210 https://www.medizininformatik-initiative.de/en



Further conditions, ethical review

As we have seen, the German deontological code prescribes that every research with data should be reviewed by an ethics committee. That is by the ethics committee of the institute of the researcher initiating the research. There is no legislation that the ethics committee at the health care providers which have been asked to release data should accept that decision but as noticed earlier, de facto they do. We did not investigate the relation between these committees and the authorities or in the case of MII, the procedures, which release data at the central level.

E.5 Discussion

E.5.1 The interviews

The general impression is that Germany is in transition to a system which aims to facilitate better use of patient data for research. Some legal texts reflect the future reality of a system that is still in its implementation phase. This applies to the comprehensive overview of their health data which the patient should be able to see via the common data platform of the sickness funds (see section 3). One of our respondents was very sceptical about whether this works in practice, the other was unaware of it. This respondent remarked, however, that the system of exchange of data from the sickness funds via a common data platform is very recent and still in its implementation phase. This respondent mentioned that at the moment using these data for research the researcher needs to apply at the supervising body of each sickness fund. While this is going to change because of the mentioned data platform, the procedure to apply for data from this platform is still unclear.

Regarding the consent question one of our respondents remarked that 'if Germans don't see forms which they must sign, they don't believe the procedure to be legit'. Hence, the written consent with an explanation resembling the patient information form in clinical trials has been made an integral though distinct part of a, to Dutch standards, already complex admission procedure. In one room they sign informed consent for the planned procedure and other forms.

Nearly all patients visit a nearby room for the consent form that data may be used for research. One of the respondents remarked that as most patients also sign that broad consent, the form could be made less complex with only that broad consent. However, exactly the fact that also other options are open, made the DPA's agree with the procedure. Though in our opinion, the respondent is correct that the form is complex and signing might better be seen as an act of trust than true informed consent. This respondent also remarked that waiting rooms are full and the consent is not always asked for and as far as known not from patients who only visit ambulatory care. Emergency admissions are also an issue according to this respondent. The other replied that if really necessary, those data could be released on the basis of a consent exemption for observational research. The former respondent also remarked that consent should be given at each hospital. Her experience is that also with a cohort with volunteers, consent given at the level of the researcher that data may be released to the cohort database, is not seen as consent given at the hospital.

That Germany is in transition was reflected by the respondent doing cancer research. The cancer registries at the state level are set up for quality control and general statistics, not for research. Without consent data cannot be used for research and linking with other data is not really possible, even if it were allowed. We saw that in the Bayern legislation. This respondent remarked that the new federal registry at the RKI is also still in its implementation phase.

Another sign of transition is the discussion about disease registries other than cancer in Germany. Both respondents mentioned a recent paper by the Ministry of Health. Discussion is still ongoing. One of our respondents predicted that such registries will be established for generic statistics and quality control without consent but that for research with these data, the usual German system of consent of the patient would kick in.

Transition is also shown by the MII. One respondent mentioned MII might be overtaken by the network of university medicine, established to gather timely data during the Covid epidemy. MII is more technically oriented, the network more driven by clinicians. The other respondent saw this more as merging both initiatives. The researcher among the respondents did not have actual experience with a request via either MII or the university medicine network. It is all rather new. For the selected use cases it is working.

One respondent had high hopes that this federated system with various stakeholders from within the field having the lead, could be a valuable alternative to the 'national datahubs' as proposed by the EHDS.

None of the respondents mentioned problems with more than one ethical review of a proposal. One respondent remarked that in practice they respect each other's decision. The other respondent remarked, however, that in spite of the nationally agreed layered consent form, ethics committees tend to 'tweak' that form to their liking before it is implemented at the hospital.

E.5.2 Reflection

As Germany seems to be an 'outlier' compared to the other countries in this report, some comments.

The mentioned federal cancer registry, the common data platform of the sickness funds and the MII are signs that Germany is a system in transition. All are in their implementation phase and practical experiences cannot be reported yet.

A large clinician- and researcher- driven (though supported by the federal government) project to overcome existing hindrances is the MII. In our opinion the MII shows that 'bottom-up' initiatives when properly funded and with sufficient time and 'Ausdauer' to reach consensus, also with the regulators, can in principle work. However, the result seems to remain a time consuming and hence expensive procedure, starting at the hospital already with the layered consent form and the various steps which must be taken before data are released. Before data are released a check must be made not only whether there is consent but also given the layered consent whether this protocol fits the specific consent of each patient to be included. We did not investigate how the EHR systems of the hospitals accommodate for this layered consent. The potential 'bias' in the research data because of underrepresentation of certain groups remained undiscussed as well.

It should also be mentioned that the MII is limited to data of the major, almost all university hospitals. Primary care as from general practitioners cannot be centrally opened up for research yet. We did not come across any regional initiatives in this respect.

Hence, the overall picture seems to be that Germany is well aware of the value of patient data for a learning health system and that various initiatives have been taken in this respect but that many hindrances seem to remain as well.

F The Netherlands

F.1 Description of the healthcare system

F.1.1 Background

The Netherlands is a constitutional monarchy with a parliamentary system of government and has a population of approximately 18 million.[211]

The Netherlands is divided into provinces at the regional level and municipalities at the local level. The central government holds legislative authority, but other bodies under public law also have regulatory authority on a regional or local level or as national specific regulatory authorities, instituted by specific Acts.

F.1.2 Organisation of the healthcare system

The central government holds ultimate responsibility for providing safe, accessible, affordable, and high-quality healthcare. However, many responsibilities are delegated to regulatory bodies such as the health inspectorate (Inspectie voor de gezondheidszorg en jeugd), National Healthcare Institute (Zorginstituut Nederland), Dutch Healthcare Authority (Nederlandse Zorgautoriteit), healthcare providers, and health insurance companies. In 2006, a two-tiered system of public and private insurance was replaced by the universal social health insurance scheme, while regulated competition was introduced in the healthcare system, supervised by the central government and newly instituted regulatory authorities such as the mentioned Dutch Health Care Authority, based on the Healthcare Market Regulation Act (Wet marktordening gezondheidszorg).

Within the parameters of various laws (such as the Health Care Insurance Act, Zorgverzekeringswet), health insurers (which must be non-profit organizations) play a significant role in directing the provision of healthcare. They are responsible for ensuring that every insured person receives care in accordance with the provisions of the Health Care Insurance Act. Every resident is required to be insured for the basic insurance scheme according to this Act. Health insurers are obliged to provide the care that is covered under the basic insurance scheme. The nominal fee that the insured person has to pay differs slightly between health insurers and most health insurers offer two types of policies:[212] the insured can only seek care from a healthcare provider with whom the insurer has a contract or the insured has free choice of healthcare providers. In December of each year, the insured can choose to change their health insurer. The insurers pay the healthcare providers. Payment is made on the basis of contracts between the healthcare provider and the insurer or on the basis of the maximum fees set by the Dutch Health Care Authority.

In addition to the Health Care Insurance Act, there are acts on long-term care (Wet langdurige zorg, Wlz), youth care (Jeugdwet) and social support (Wet maatschappelijke ondersteuning, WMO), which also cover certain aspects of long-term home care. These services are not directly paid for by health insurers. Youth care and social support are paid by local governments

211 Netherlands, Statistics. “Population Dashboard”. Statistics Netherlands, 13 October 2022. https://www.cbs.nl/en-gb/visualisations/dashboard-population.

212 some health care insurers only offer the free choice policy

(gemeenten) and do not count as an entitlement by social security.

As a general rule, general practitioners (huisartsen) play a gatekeeping role in the Dutch healthcare system when it comes to accessing secondary care. This requirement means that a referral is necessary to receive medical specialist care. This means that GPs have a more or less complete overview of the use of health services and health problems present in their patient populations in their electronic health records systems (EHRs).

F.1.3 Funding of the healthcare system

Different sources contribute to the funding of healthcare, with varying percentages. In 2020, 85% of healthcare and welfare expenditure was paid for by the government and/or covered by compulsory health insurance. Households contribute to nearly half of this expenditure, through premiums, contributions, compulsory deductibles, taxes, and direct payments. The largest portion of this funding is intended for expenditure on providers of medical specialist care, such as hospitals and clinics.

In addition to direct payments made by households to health insurers, healthcare expenses are also financed through the Health Insurance Fund (zorgverzekeringsfonds) and the Long-term Care Fund. These funds are managed by the National Health Care Institute. Ultimately, all collective healthcare expenses are paid for by citizens and companies through the nominal premium, compulsory deductibles, out-of-pocket payments, and taxes.[213]

F.1.4 Characteristics of the regulatory system

The Dutch health care system is regulated by a variety of Acts. Though there is considerable overlap, these acts can be broadly categorized into four types. The most important are:

1. Acts that regulate entitlements, such as the Health Care Insurance Act and other acts mentioned above on long term care, youth care and home care.
2. Acts that regulate the organization of the health care system, such as the Healthcare Markets Regulation Act and the Gezondheidswet (Generic Health Act) which primarily regulates the Inspectorate for Health and Youth.
3. Acts that regulate the quality of health care, such as the Wet op de geneeskundige behandelingsovereenkomst (WGBO) (Medical Treatment Contract Act), the Act on Quality, Complaints and Disputes in Health Care (Wet kwaliteit, klachten en geschillen zorg, hereinafter: Wkkgz), the Wet aanvullende bepalingen verwerking persoonsgegevens in de zorg (Act on Supplementary Provisions for Processing of Personal Data in Health Care), and the Wet beroepen in de individuele gezondheidszorg (Act on Professions in Health Care).
4. Acts that regulate patient rights, including the Wet op de geneeskundige behandelingsovereenkomst (WGBO), the Wkkgz, the Wet aanvullende bepalingen verwerking persoonsgegevens in de zorg (Act on supplementary provisions for Processing of Personal Data in Health Care), and the Wet verplichte ggz (Act on Compulsory Psychiatric Care) and the Wet zorg en dwang (Act on care and coercion) for patients suffering from dementia or severe mental disabilities.

For the topic of this report, the Dutch General Data Protection Regulation implementing act

213 Petel, Vincent Van Polanen. "Hoe betalen wij voor de zorg?" Centraal Bureau voor de Statistiek, 23 May 2022. https://www.cbs.nl/nl-nl/longread/statistische-trends/2022/hoe-betalen-wij-voor-de-zorg-?onepage=true.

(UAVG) is also of particular importance. Additionally, there are acts on specific topics, such as the Act on Medical Screening (Wet op het bevolkingsonderzoek) and the Public Health Act (Wet Publieke Gezondheid).

Three relevant bills are currently pending in parliament:

- The Act on the exchange of data in healthcare (Wet gegevensuitwisseling in de zorg, Wegiz) which sets standards for electronic exchange of health information.
- The Act on Control of Human Tissue (Wet op de zeggenschap lichaamsmateriaal).
- The Act on Quality Registries in Health Care (Wet kwaliteitsregistraties in de zorg, which will change the Wkkgz.

As mentioned, self-regulation or co-regulation (regulation within the boundaries of the law) plays an important role in Dutch healthcare.[214]

Professional standards are set by professional societies. If these standards meet certain criteria, they will be accepted as such by the National Health Care Institute. Professional societies also set the standards for the renewal of the license for certain basic professions under the Act on Professions in Healthcare.

There is not an act that regulates ethical review of health research in general. The Act on Medical Research with Human Subjects (Wet Medisch-Wetenschappelijk Onderzoek met mensen, WMO) does not apply to the further use of data or tissue.

F.2 Legal basis for primary use of health data

The WGBO requires all healthcare providers to maintain a medical record for every patient, and this act serves as the legal foundation for the primary use of health data. Access to the medical record is only granted to professionals who have a treatment relationship with the patient, to the extent that it is relevant for their role in the treatment. Access for other healthcare professionals, even within the same healthcare provider, must be based on either the patient's consent or a legal requirement. There is an exception for health research, which will be discussed in the following paragraph.

If a patient has been referred to another professional and has consented to this referral, the referring professional can share the necessary information with the new professional based on the assumption of consent. The same applies for the new professional to share information with the referring professional.

The Act on Supplementary Provisions for the Processing of Personal Data in Healthcare (wet aanvullende bepalingen verwerking persoonsgegevens) primarily regulates the following:

- Healthcare providers and professionals, health insurers, and the bodies responsible for admission to long-term care are required to use the Dutch civic registration number (BSN).
- Standards for the security of electronic health records (EHRs) and the electronic exchange of data between healthcare providers are set by a Royal Decree based on this Act. EHR systems must comply with standards equivalent to ISO 27001/2.
- If an electronic exchange system is used between different healthcare providers, the patient

214 Specifically for privacy legislation, see Dennis D. Hirsch, "Going Dutch? Collaborative Dutch Privacy Regulation and the Lessons it Holds for U.S. Privacy Law", *Michigan state law review* 2013, nr. 1 (1 januari 2013): 83.

must give their consent for their data to be made available to new professionals (pull method, as opposed to push/sending as mentioned under the WGBO).
- Patients have the right to an electronic copy of their medical file and to a log of which professionals have accessed the file.

F.3 Further use of patient data and bio samples for research

F.3.1 Patient data

All further use of health data must be in line with the WGBO, the GDPR and the UAVG.

The Code of Conduct for Health Research encompasses all mentioned legislation in one comprehensive document and aims to clarify the sometimes multi-interpretable terms of the legislation.

The relation between the various legislation is as follows:

- The WGBO holds rules when someone from the treatment team (see the description supra at section 2 about that definition in the WGBO) can share the EHR's data (or parts thereof) with a researcher.
- The GDPR holds general rules about data processing and contains research exemptions to those general rules. Some of those exemptions must be implemented in national legislation.
- The UAVG is the main Dutch national legislation where the GDPR research exemptions have been laid down.

Hence, there are always 2 steps and two different types of legal provisions applicable:

- For the treatment team to give a researcher access to the data[215] according to provisions in the WGBO, *and*
- For the researcher to have a legal basis to process the data for research (as per article 6 GDPR) and if the research not based on GDPR consent *an exemption to the prohibition of processing sensitive data, according to the provisions of the GDPR or UAVG*.[216]

This also applies when treatment team and researchers are employed at the same organisation, such as a hospital.

WGBO

The WGBO entered into force in April 1995. Electronic exchange of data was not an option at that time, at least not on a large scale. Health records were mostly kept on paper.

The general rule of the WGBO, only access by the treatment team, unless there is a legal obligation to transfer to the data such as in the case of notifiable transmissible diseases applies to research as well. Hence the general rule is that patients[217] must give consent for use of health data for research purposes if the researcher is involved in the patient's treatment.

215 access can also mean sending those data to a researcher.

216 The italics here as will we only discuss that part. The general legal basis as per article 6 GDPR is not typical for the Dutch situation and hence is not discussed in the following. However, as side remark, it should be mentioned that because of the Dutch bottom-up approach of national health data bases via private foundations, the either article 6.1 e or 6.1.f GDPR basis often raises discussions.

217 In the following everywhere when 'patient' or 'donor' is mentioned, his or her representative should be read instead.in case of incompetence of the patient or donor.

The exception to this main rule, which allows the use of health data without consent, is set out in the subsequent article on medical confidentiality and contains the following condition:

Patient data may be made available to a researcher if:

- asking consent is not possible and, in the execution of the research, there are safeguards such that the data subject's privacy is not disproportionately harmed; or
- considering the nature and objective of the research, asking consent is not a viable option (literally: it is reasonably feasible to ask for consent) and the physician has ensured that the data be issued in such a way that the reidentification of the data to the patient is reasonably prevented.

When one these circumstances applies, the data can only be made available, provided that:

- the research is carried out in the public interest;
- the research cannot be carried out without this data; and
- the patient concerned has not expressly objected to the use of this data for research.[218]

In general, the Dutch call this the 'opt-out system'.

GDPR Implementation Act (UAVG)

The UAVG stipulates that the further processing of sensitive personal data for research, such as health data, is permitted in the absence of GDPR consent under the following conditions:

- These data are is necessary for scientific research;
- The research serves the public interest;
- It appears to be impossible to request consent or asking consent requires disproportionate effort;
- The privacy of the data subject (in the case of further use: the patient) may not be disproportionately harmed.

Code of Conduct on Health Research (Gedragscode Gezondheidsonderzoek)[219]

The Dutch Code of Conduct of Health Research of 2022 (hereinafter: the Code of Conduct) discusses all privacy aspects of data processing for health research, starting with the plan to collect the data and ending with storage of the data after the specific research project has ended. It is based on a consensus of all major stakeholders. The Code of Conduct was drawn up via a representative group of lawyers and an ethicist and an intensive dialogue with all major stakeholders in not for profit health research and represents the consensus of the stakeholders about the present applicable legislation. Chapter 5 of the Code of Conduct discusses the conditions for the further use of patient data and tissue.

It offers a nuanced approach within the limits of various acts, as interpreted by the drafters.

According to the Code of Conduct the WGBO consent can be broad consent for research related to the disease area for which the patient was admitted unless the research is particularly sensitive. In that case GDPR consent would be needed. Broad consent in the WGBO context is not equal to GDPR consent. GDPR consent must be layered consent, offering a choice of possible research which is allowed by the patient.

218 Kist, 'Assessment of the Dutch Rules on Health Data in the Light of the GDPR'.
219 'Gedragscode Gezondheidsonderzoek', *Coreon* (blog), https://www.coreon.org/gedragscode-gezondheidsonderzoek/.

Hence, this WGBO consent is not GDPR consent and the researcher who has access to the pseudonymised data, should still fall back on the consent exemption in the UAVG.

This broad WGBO consent should preferably be asked when a patient is registered at a health care provider, described as "consent at the gate". If a patient cannot be reached or did not make a decision, an explicit reminder should be sent, stating that if the patient does not make a decision, the data may be further used for research. These patients are thus presumed not to have opted out.
The Code of Conduct gives indications of when 'consent cannot possibly be asked for' or when it is not 'reasonably feasible to ask for consent'. One of those is that when retroactively asking for consent, this would lead to bias in the resulting data. The researchers must justify this claim. Additional conditions for the use of the exception are mentioned as well:

- The research must be related to the area of the disorder or the disease areas of the patient's illness or request for help;
- The research must not entail any special risks or consequences for the participant;
- The research cannot be carried out without that data;
- The data or bodily material is provided to the researcher under a code. That means that research may only be conducted with coded data or executed with coded bodily material.[220]

F.3.2 Human tissue

The laws and regulations mentioned above are also of importance for the use of human samples for research as there cannot be research with tissue without data: data which accompany the sample, data which are derived from the sample or data which will be linked to the data derived from the sample.[221]

In addition, there is a Bill that specifically regulates the question of control in the context of the use of human tissue.

Draft act on control on human bodily material (WZL)

The proposed act intends to regulate storage and use of human tissue and other human bodily material which has not been regulated elsewhere, such as the Act on foetal tissue.[222]

The starting point of the draft WZL is that the consent of the donor is required for the storage and (further) use of human tissue. In the discussion we will come back to how 'broad' this consent may be. The exception is when requesting consent is impossible or requires a disproportionate effort. In that case information must have been provided about, among other things, the purposes of use, and the patient should not have opted out. Some applications with bodily material can be regarded as sensitive for society or the donor and then consent is always required.[223]

An ethics committee according to the Act on medical scientific research with human subjects (WMO) must approve the research projects. However, it can delegate some tasks to a subcommittee.

220 Chapter 5 of the Code of Conduct on Health Research
221 van Veen et al., 'TuBaFrost 3'.
222 Wetsvoorstel Wet zeggenschap lichaamsmateriaal. Pub. L. No. 35844, https://zoek.officielebekendmakingen.nl/dossier/35844
223 Memorie van toelichting.

F.4 Personal identification number and linking

The Dutch civic registration number (BSN) is a national, unique and personal number and anyone who is who has legal residence in the Netherlands has a BSN. As such, the BSN is content-free. The generic Act on the BSN stipulates that the BSN can be used by governmental bodies for the execution of their tasks. As we have seen, the special Act on processing of personal data in health care stipulates that the BSN must be used in health care.

Just like its predecessor the UAVG forbids that a number which has been assigned by law, is used for another purpose than that law. Hence, the BSN cannot be used for further use.

It should be mentioned that in practice many research databases use a workaround. A one-way hashed BSN is not a BSN anymore. A Dutch Trusted Third Party[224] (Zorg TTP) offers such a hashing service for direct identifiers such as the BSN. When repeated at several data sources, the same code number arrives at the research database allowing that the patient is followed over time and across various health care providers. This one-way hash is performed separately for each project and consists of two steps, a first hash at the data source via ZorgTTP software and a second hash followed by a research project or client dependent AES encryption performed by ZorgTTP.[225] This results in the same pseudonym for a BSN for a (specific) research project or client (a so called 'domain') and a different pseudonym for a another (non-related) project or client.[226] The created pseudonym is not convertible to the original BSN.[227] However, this would have rendered it impossible to link different pseudonymised datasets. This is problem is solved by the TTP by using so-called 'domain conversion'.[228] ZorgTTP can convert the pseudonym from one datasource to a pseudonym generated in another domain without using a non-pseudonymised BSN or other identifier. Without this possibility one could doubt whether the process of ZorgTTP is pseudonymisation in sense of the GDPR. According to the GDPR definition of pseudonymised data, there must be a key to reverse/undo the pseudonymisation which must be kept secure.[229] Such a key would be completely absent with one-way coded data without the possibility of 'domain conversion'. But as seen, a key to original BSN is also absent when using domain conversion'.

F.5 Central repositories which can be used for health research

In the Netherlands there is a number of domain specific repositories of (health) data collections that can be used for health research. However, most of these repositories are initialized and maintained by private organisation(s). Statistics Netherlands brings together data from different sources and makes these accessible for researchers outside Statistics Netherlands, through their microdata services. This, however, is in principle limited to data that are needed for Statistics Netherlands to perform the legal tasks laid down in Act on Statistics Netherlands.[230]

224 "ZorgTTP | Data veilig delen", n.d. https://www.zorgttp.nl/.
225 Factsheet pseudonimisatie ZorgTTP may 2021 https://www.zorgttp.nl/wp-content/uploads/2022/05/Factsheet_pseudonimisatie_ZorgTTP_2021.pdf
226 ZorgTTP | pseudonymisation method description, https://www.zorgttp.nl/wp-content/uploads/2023/01/NEN-pseudonimisering-specificatie-voorstel-VWS-1.0.pdf
227 The Dutch DPA has once asserted that 'replay back' would still theoretically possible but failed to give a concrete example in the ZorgTTP case.
228 "Pseudonimisatie | ZorgTTP", n.d. https://www.zorgttp.nl/pseudonimisatie/.
229 Article 4.5 GDPR.
230 See also the THEDAS report on the Netherlands ...

We will first briefly discuss the specific national databases set up by governmental bodies following from their specific role in the health care system and provide a summary of 'not for profit central databases organised by foundations which play a role in the. After that we will discuss SN in some detail.

F.5.1 Central databases by governmental bodies in the context of the health care system

The Health Care Authority can request data from health care providers including sensitive patient data to monitor the functioning of the health care system in view to setting the tariffs. This data may only be used to fulfil the Health Care Authority's legal tasks and is not accessible for researchers outside this Authority. Recently the Dutch DPA stressed that the detailed data collected about psychiatric care (which is faced with various problems at the moment, especially for the more severe cases[231]) can only be used for setting up a new tariff system. According to the Dutch DPA patients should have the possibility of opting out for this data collection, in spite of the legal basis for the Health Care Authority.[232]

The National Health Care Institute has several legal tasks requiring the use of health data.[233] It is allowed to process pseudonymised sensitive data, each with their own purpose in the sense of article 5.1.b GDPR and sometimes legal basis. Also these databases are not meant to be opened to researchers other than those invited by the National Health Care to assist in its analyses.

The National Institute for Public Health and the Environment (RIVM) has various databases. Part of those are based on its legal tasks (especially the Public Health Act and the Act on the RIVM), because the Minister of Health assigned a specific task to the RIVM or based on voluntary cooperation between stakeholders in the field, such as the sexually transmittible disease registration,[234] or about antibiotics resistance.[235] The RIVM is in many cases allowed to use pseudonymised patient data for its function which is also research, but that does not mean that there is a basis of the health care provider to submit those data. At that level, the WGBO will come first. We will come back to this in the concluding chapter.

F.5.2 Major central domain-specific databases by non-governmental bodies

There are many central domain-specific health databases. Those are all the results of non-governmental and mostly not-for-profit initiatives[236] instituted by private parties in the Dutch health care system. Often, they have different legal bases. We make a selection in the context of this report, meaning that those have a function for research and are often used as such. We briefly discuss the legal basis of each.

- **VEKTIS**. Vektis is the data processor of all health insurers in the Netherlands and processes

231 Haan, 'Een derde van specialistische ggz- bedden opgeheven, "zorg zakt door ondergrens"'. See also: https://www.nrc.nl/nieuws/2023/02/12/zorgautortiteit-wil-persoongegevens-om-te-weten-hoe-duur-een-patient-is-campagne-van-bezwaren-2-a4156894#/krant/2023/02/13/#108

232 Autoriteit Persoonsgegevens, 'Eindbrief NZa aanlevering Honos + gegevens nieuw stelsel zorgvraagtypering ggz', 7 October 2022.

233 "Tasks of the National Health Care Institute". About us | National Health Care Institute, 22 November 2021. https://english.zorginstituutnederland.nl/about-us/tasks-of-the-national-health-care-institute.

234 https://www.rivm.nl/publicaties/registratie-van-soa-en-hiv-consulten-bij-ggds-en-soa-poliklinieken-jaarverslag-2000

235 https://www.rivm.nl/antibioticaresistentie

236 For a private initiative see: https://logex.com/

all claim data. As a processor it does not need a legal basis of its own. As the health insurers are obliged to use the BSN, Vektis processes the BSN of the insured. As a controller in the sense of GDPR, Vektis also registers health care providers to match those with health insurers. Vektis has an active policy in opening fully anonymised claims data under the Open Data directive.[237] Such aggregated data are important for the public debate but do not allow nuanced research for a learning health system. For that Vektis is dependent on the legal basis of the controllers, hence the health insurers. Whether non-anonymised claim data may be opened up for research, will depend upon whether the insured has given consent or that the exception to the consent principle can be applied. Vektis has increasingly become reluctant to share claims data for research. The Vektis claims data are also submitted to SN based on the legal mandate of SN to use these data. See the section on SN.

- **DHD and the LBZ dataset**. Also, Dutch Hospital Data acts as a processor, being of all Dutch health care providers which provide intramural care. One of their main 'products' is the country wide basic registration care (Landelijke basis registratie zorg, LBZ). LBZ is a rich database with, amongst others, diagnoses with the ICD 10 codes, procedures, the administration of expensive medicines.[238] They are primarily used for benchmarking and quality control. DHD increasingly cooperates with specific quality registries and the Dutch cancer registry (see the next bullet) to get a richer picture of the data for the purpose mentioned and to avoid double registration. The LBZ data are sent to SN and the Health Care Authority based on their respective legal bases and thus lead to less administrative burden for each hospital which would otherwise have to submit those data separately. The LBZ data are obviously important for research as well. For example, a publication describes how by using the LBZ data the growing incidence of pulmonary diseases might have led to an earlier detection of Q fever caused by goat farms with free- ranging goats.[239] DHD has clear policies about how and when data can be released for research.[240] In principle only anonymised data are upon request released for research. Once the data are at SN a somewhat different procedure applies, see at the discussion of SN.
- **The Netherlands Cancer Registry (NKR)**. The NKR is held by the Netherlands comprehensive cancer organisation (IKNL)[241] which is the controller of the NKR in the sense of the GDPR. The NKR holds very detailed data about incidence and prevalence of cancer and the accompanying data including the staging and follows the patient through his or her whole trajectory of diagnosis and treatment of the disease. The NKR is used for a variety of purposes, from assisting professionals and patients in making better treatment decisions to research. The anonymised data of the NKR are published on the public website kanker.nl.[242] A recent addition is the 'cancer atlas' which describes which cancers are more prevalent in which region. The atlas is based on the NKR data which also contain 4 numbers of the Dutch zip code of each patient (the total zip code has 4 number and two letters) but in order to increase anonymity in the atlas those are levelled up to regions containing several 4 digits

237 Directive (EU) 2019/1024 of the European Parliament and of the Council of 20 June 2019 on open data and the re-use of public sector information (recast). Implemented in the Netherlands in the Wet open overheid.

238 DHD. "Ontdek de mogelijkheden van de LBZ", 3 januari 2023. https://www.dhd.nl/producten-diensten/registratie-data/ontdek-de-mogelijkheden-van-de-lbz.

239 Wijngaard et al., 'In Search of Hidden Q-Fever Outbreaks'.

240 DHD. "Aanvraag van ziekenhuisdata", 11 October 2022. https://www.dhd.nl/producten-diensten/registratie-data/aanvraag-van-ziekenhuisdata.

241 "About IKNL", n.d. https://iknl.nl/en/about-iknl.

242 "Kanker.nl - we zijn er voor je | Kanker.nl", n.d. https://www.kanker.nl.

zip codes.[243] The NKR is largely funded by Dutch government but does not have a basis in a specific act. At presents it gets the pseudonymised data based on the research exception discussed in section 3.1. The pseudonymisation is not based on the BSN.

- **Quality registries**: the Netherlands has many quality registrations which were all initiated by professional societies.[244] However, these quality registries lacked a clear legal basis for the organisers (either foundations or professional societies) who decided upon purposes and means on the quality registration, often together with other stakeholders as hospitals and health insurers. Recently, a bill on quality registries was submitted to parliament which should address that situation.[245] Quality registries are mainly meant for practice feedback against a background of the average of all participating health care providers (benchmarking). The quality registrations only hold data which are relevant for the quality indicators which the quality registration is intended to measure. But those data are complete as almost all health care providers participate and are relatively rich as they must allow for case mix control. Obviously, such data are important for research as well and research is performed with the data of most quality registrations. Yet, each has its own governance when that research is allowed, and the proposed Act on quality registries does not contain provisions about research with these data. We will come back to this in the discussion paragraph. Pseudonymisation of patients in the quality registries is usually based on the BSN.
- **PALGA**, the Dutch nationwide pathology databank: Palga may probably be the oldest nationwide health databank in the Netherlands. It was established in 1971, at the time using paper-based patient files. At the moment Palga contains two databases. Relevant here is the research database which contains excerpts of pathology reports all Dutch laboratories. Each patient is entered via de ZorgTTP one- way code and on the basis of opt-out. Hence, just as the NKR, the PALGA research database does not contain directly identifiable data. The Palga procedures are transparent for patients.[246] If the researcher requests possibly indirectly identifiable data from the Palga registry, in principle the pathology departments which submitted the data should agree.
- **Nivel primary case database (NZR)**: Primary care health care providers are invited to contribute to this database with data from their electronic health records. This data is used for epidemiological and health services research. Nivel primary care database is based on the research exception to consent. Patients can opt-out at the primary care professional. Nivel informs patients via leaflets which the professional must distribute and on its website which gives additional information.[247] The Via ZorgTTP it uses a one-way coded pseudonymised BSN. The data in the Nivel database are submitted to SN based on the legal mandate of the latter. Just as in the case of the hospitals via DHD, thus leading to much less administrative costs for the required statistics as otherwise SN could potentially require those data to be submitted by each or a representative sample of those health care providers. SN considers the data of the Nivel primary care database sufficiently representative for all primary care professionals.

243 "Nederlandse Kankeratlas", n.d. https://iknl.nl/kankeratlas.

244 The history of the quality registries in the Netherlands is briefly described E.B. van Veen, 'Big Data Voor Een Lerend Zorgsysteem'.

245 Wetsvoorstel Wijziging van de Wet kwaliteit, klachten en geschillen zorg in verband met het regelen van regie op kwaliteitsregistraties in de zorg en grondslagen om ten behoeve van die kwaliteitsregistraties bijzondere persoonsgegevens te kunnen verwerken.

246 See: https://www.palga.nl/voorlichting/patienten.html

247 https://www.nivel.nl/nl/nivel-zorgregistraties-eerste-lijn/over-nivel-zorgregistraties-eerste-lijn/privacybescherming

F.5.3 Statistics Netherlands (SN)

SN collects many data about individuals, companies and governmental bodies for its statistical tasks. The Act on SN states that SN can use the BSN and can process sensitive personal data. Once at SN certain pseudonymisation techniques are applied.[248] Based on the Act on SN, the Director General of SN can issue decrees which organisations should submit what data for its statistical functions. As seen above (DHD, Nivel) SN can request these data from intermediary organisations to mitigate the administrative burdens of organisations or professionals. Individual citizens are not requested to submit data. SN knows sufficiently about Dutch citizens already via their interactions with governmental bodies and other organisations.

Researchers can request to use the SN data. They can also bring their own data in that respect (BYOD), for example if they have organised a cohort with volunteers. As that cohort will not be able to use the BSN or a BSN derivate, linking will then be probabilistic.

The research can only be performed on the SN platform, using the so-called remote access facility.[249] Only fully anonymised data, the statistical output of the research, can be exported. As this facility is offered by SN outside its primary task and it is not funded for this facility, SN charges costs. We will come back to SN in the discussion.

F.6 Review and administrative conditions

See the discussion paragraph.

F.7 Discussion

This paragraph differs from those of the other country appendices. The drafters of this report are very well informed about the Dutch discussion and the possibilities for further use. There was no need to consult researchers. Additionally, as will be shown below, the Dutch discussion is much less settled than seems to be the case in the other countries. This applies first of all to legal conditions for further use of data and tissue.

F.7.1 From opt-out to consent and then what consent?

General observations

Until recently, many health care providers used the research exemption in the WGBO and hence the opt-out system to submit pseudonymised or one-way coded EHR data for research or to further analyse pseudonymised or one-way coded residual tissue for research. Reaching out to every patient was deemed not to be reasonably possible. The Code of Conduct as a consensus document stressed that according to Dutch legislation consent is the basis and that the exception should be well motivated. The Code of Conduct also gave more substance to the exemptions to consent. In spite of this consensus, there is considerable discussion on two topics.

248 Centraal Bureau voor de Statistiek, 'Antwoordbrief van het CBS over verzoek om informatie van de vaste commissie VWS over pseudonimiseren medische gegevens voor onderzoek.', 14 November 2022.

249 Netherlands, Statistics. "Microdata: Conducting Your Own Research". Statistics Netherlands, 23 February 2022. https://www.cbs.nl/en-gb/our-services/customised-services-microdata/microdata-conducting-your-own-research.

First, how much extra effort to ask for consent can be considered as still reasonable. Asking for consent means reaching out to each patient, either in person (via the professional, and we may safely assume that the treating physician does not have time for this, so via secretaries at the reception desk) or via digital means. And then to register consents. As, given the general opinion of patients towards further use,[250, 251] it may be assumed that more people will consent than refuse to give consent. Next, to adjust their systems accordingly, with tags for those who have consented and reminders for those who did not decide. Hence much more needs to be done under a consent system than under an opt-out system. The costs will be made by health care providers. In a different context, government has acknowledged these and other problems with a consent system. We discuss that in de concluding chapter.

And the initial assumption has changed in two aspects: more data are needed and less data can be considered to be anonymous.

More data are needed

As mentioned in the first chapter, everyone wants 'real world data'. The data are not needed occasionally but all EHR's data are needed at some time for a learning health system. University hospitals whose mission is, in addition to teaching and specialised patient care, also research, are increasingly organising 'consent at the gate'. The Code of Conduct warns about the possible consequences of this approach for registries which need to be as complete as possible, such as the NKR. In one of our interviews the NKR expressed their serious worries about a consent system for the future of the NKR. Worries were also expressed by research organisations which are dependent on data from primary care. Primary care, especially GP practices, are under much stress and cannot be expected to make extra effort described above for research which will only help them and their patients in the longer run (for example by improved practice guidelines or health protection measures which would lead to less patients).

Less data can be considered anonymous

Anonymous data can always be used for research. This also applies to anonymised EHR's data. They both fall outside the scope of the GDPR. Anonymisation is itself processing of personal data and hence falls within its scope. Yet, this can be legitimatised under article 5.1.b last part of the GDPR insofar as this research can be considered 'bona fide' research. The Code of Conduct refers to the Netherlands Code of Conduct on Research Integrity[252] in this respect. The threshold to consider data anonymous has been raised. A Dutch recent report claims that individual level data (ILD) cannot be considered anonymous whatever obfuscation or other smart statistical techniques are being used. There will always be other statisticians who state that they can crack those,[253] though it seems to us in rather unrealistic scenarios and far beyond the common sense of researchers working those data. We come back to the seemingly fruitless discussion about anonymous or not in the concluding chapter. Suffice to mention here:

- the GDPR and Dutch legislation in its wake only has two tastes: data are anonymous or not.

250 Coppen et al., '[Re-use of medical data for research. What do the Dutch think of the requirement for explicit consent?'within the framework of protection of their personal data?\nDESIGN: Survey among 731 members of the Healthcare Consumer Panel of the Netherlands Institute for Health Services Research (NIVEL

251 More conditionally: Patiëntenfederatie, 'Delen van Uw Data. Hergebruik van Gezondheidsgegevens En Lichaamsmateriaal Voor Wetenschappelijk Onderzoek'.

252 https://www.nwo.nl/en/netherlands-code-conduct-research-integrity

253 van der Sloot, van Schendel, and Fontanillo López, *The Influence of (Technical) Developments on the Concept of Personal Data in Relation to the GDPR.*

In the latter case all the major provisions of the GDPR apply.
- DPOs and privacy or similar bodies who supervise or who need to approve that data may be released for research, have increasingly become more reluctant to consider data anonymous.

The scope of consent

These problems are exacerbated by the discussion about the scope of consent, as introduced by the recent changes in the draft WZL. As seen, there is a two-tiered approach for further data use based on consent in the Dutch system. Firstly, the legal basis for a treating professional to submit not fully anonymous data to a researcher based on the WGBO of 1995. Secondly the legal basis for a researcher to process the data is based on the GDPR or its Dutch implementing act. The Dutch Code of Conduct states that the first tier can be based on broad consent, though limited to the disease area for which the patient is or was treated. However, this broad consent would not be sufficient for the second tier, given the GDPR's requirement for specific consent. GDPR consent must at least be layered consent. As we saw in Germany, DPA may accept broad consent but only if other options are available as well to narrow down the type of research the patient deems acceptable.

When the first WGBO tier is only broad consent, then for the researchers the exemption to GDPR consent in the implementing Act becomes relevant to process these data for research. As seen, that view is expressed in the Code of Conduct.

However, according to the DPA during an informal meeting[254] consent under the 1995 WGBO should also meet the 'specific' requirements of the article 7 of the GDPR. This aligns with the position of the EDPB on consent.[255] Recital 33 of the GDPR would only play a minimal role in this context. The DPA also noted that they are not fundamentally opposed to this solution of broad consent as the first tier and would not publicly reject the Code of Conduct. To those present at the meeting, it seemed that the DPA favoured this solution above the present situation which formally would require specific consent. The DPA expressed that this solution requires a much-needed legislative change using article 9.2.j GDPR.

However, the opposite has happened. As seen, one of the objectives of the draft WZL is to change the current system in most hospitals, for research where the researcher cannot reasonably know the identity of the patient, from opt-out to opt-in. Researchers can only resort to an opt-out procedure when obtaining consent is not reasonably possible.

In this context, the parliamentary documents which accompany the Bill recognise that consent systems and their exceptions should be similar for data and tissue. The Dutch government also stated, in response to questions from parliament, that consent for the use of patient data and tissue in research should be 'as specific as possible'.[256]

This is extra striking as the drafters of the Bill on the WZL are aware of the discussion with the Dutch DPA about the Code of Conduct and its opinion that if the phrase 'consent' is used, that should be GDPR consent. They were also aware of the DPA's more implicit recommendation that also other phrases are available and that this would require a legislative change which the

254 One of the drafters of this report was present at that meeting.
255 European Data Protection Board and EDPB, 'Guidelines 05/2020 on Consent under Regulation 2016/679 | European Data Protection Board'.
256 Nota naar aanleiding van het verslag.

Dutch DPA would – in principle, but depending on the wording etc. – not oppose.[257] We could use a term such as 'authorisation' or 'assent'.

But that has – as yet – not happened in the WZL. Hence, unless a change in the draft WZL is being made, the Netherlands would be heading towards GDPR consent as requested by the Dutch DPA in all cases when the term 'consent' is used. Yet, those (university) hospitals which are now introducing consent for research (both data and tissue) when the patient is admitted to the hospital or outpatient clinic, organise the relatively broad consent outlined in the Code of Conduct. Not the 'as specific as possible (GDPR) consent' outlined in the WZL.

For those health care providers, this broad consent would then be a sort of safeguard, 'ethical consent' but not consent in the sense of the legislation. They would argue that it is impossible to ask for such a GDPR consent 'at the gate'. Against this government might probably respond that 'as specific as possible' could involve adopting a system of layered consent similar to that used in Germany, as discussed in Appendix F.[258] The costs for health care providers implementing such a system of GDPR consent would multiply.

The government has announced that it will issue a Royal Decree once the WZL has been adopted by parliament, outlining the concept of consent and its exceptions. This is because not only the breadth of consent is still under discussion, but also the exception to the consent principle. The Code of Conduct elaborated on these exceptions, clarifying the broad and somewhat vague terms of the WGBO contract and the GDPR implementing Act. However, this clarification is not mentioned in the government's statement on the WZL to parliament. It is likely that the government either considers the current specification to be too broad or not specific enough.

Government does recognise however that the EHDS might change the rules of further use. Hence it has postponed the WZL discussion till the end of this 2023.[259]

F.7.2 Avoiding the issue with quality registers

In the section on national hubs, we mentioned the quality registries and that the recent Bill explicitly does not regulate research with the data in the registry. When an earlier draft of the Bill was submitted for 'internet consultation' the combined quality registries reacted amongst other things that the new Act also should give a legal basis for research with these data. The Explanatory Memorandum which accompanied the Bill does not recognise the value of these data for research. It briefly states that the prime objective of government was to regulate quality registries for the primary function on the shortest possible notice (which still took several years). It should be mentioned that some of the examples of the added value of quality registries for quality assurance according to the present standards[260] seem to be based on research with the data in the quality registry about underlying mechanisms why certain health care providers

257 The DPA made similar remarks in it legislative advice on an earlier draft of the WZL before it was submitted to Parliament Autoriteit Persoonsgegevens, 'Advies Wet Zeggenschap Lichaamsmateriaal'.

258 It may be doubted whether the government itself or the stakeholders are aware of these implications. The Bill was accompanied with an assessment of the costs for hospitals and researchers. As usual when government imposes new measures, that assessment was optimistic. But more importantly, it was based on 1 time broad consent. Not on specific consent. One should multiply the costs in that case.

259 Kamerstukken 35844, nr. 10.

260 We make a distinction here between benchmarking which allows health care provider to reflect on how they are doing compared to others according to presently known standards for treatment improve care and improve their care accordingly and research which aims to provide generally applicable novel insights.

performed better on the quality indicators than other health care providers.

F.7.3 Preliminary conclusions

In sum, the Netherlands is struggling with the conditions for further use of patient data for research. Government seems to have a restrictive view and insists on a form of individual control as the first option. In the so called "Comprehensive agreement on health care in 2023" (Integraal Zorgakkoord)[261] it is stated that "To support the reuse of data for secondary purposes, VWS tries to remove existing bottlenecks, for example by creating legal bases and/or adjusting or clarifying existing ones. The basic principle here is that the protection of the data of citizens and the control over it are paramount, taking account of proportionality and purpose limitation."

The lessons from the Code of Conduct do not seem to have been learned. If that control should be in principle an explicit affirmative decision and that decision is framed as 'consent', the patient should have a table of possible options about the possible research or in other words, layered consent. Otherwise, it is not consent in the sense of the GDPR.

F.7.4 Linking

As seen in section 4, the BSN cannot be used for research. Not all data sources are assured that the 'work around' discussed in that section will not ultimately be disavowed by the Dutch DPA. When drafting this report, there was even discussion amongst the authors whether we should mention this 'work around' at all as that would make explicit what happens on many occasions and hence would invite the DPA to make an explicit statement which could end all linking which happens at the moment. Such policy considerations would be contrary to the objective account of the Dutch situation which this report attempts to give and hence the observation was retained in this report.

We come back to linking via the BSN in the final chapter.

F.7.5 Administrative procedures

As seen, the Act which organises ethical review of research, the WMO, does not apply to further use of data or tissue for research. Each data source will have its own privacy or ethics committee which assesses whether 'their' data can be used for research. Their assessments often differ for the same proposal. The problems have been described in a report of February 2021[262] but thus far not much progress has been made. The Department of Health is coordinating a working group from parties involved in ethical review which should issue recommendations on the sometimes grey area between research under the WMO and other research, and about the proportional review of research not within the remit of the WMO.[263] These recommendations will need certain incentives to make local review boards comply and it is unclear yet what those incentives would entail. Additionally, the recommendations cannot solve the present discussions about consent or opt-out and then, if consent, what type of consent, as described above.

261 https://www.rijksoverheid.nl/documenten/rapporten/2022/09/16/integraal-zorgakkoord-samen-werken-aan-gezonde-zorg

262 MLC Foundation and Antoni van Leeuwenhoek Nederlands Kanker Instituut, 'Niet-WMO-Plichtig Onderzoek En Ethische Toetsing'.

263 Kamerstukken 2019-2020, 29963, nr. B

The mentioned WZL will make ethical review of research with residual tissue mandatory, appointing the under the WMO recognised ethical review boards for that task. As under the WMO one review suffices, that would at least solve the problem of multiple and sometimes contradictory reviews.

F.7.6 The national databases

We distinguished 3 types of databases:

- The data of governmental agencies which as such cannot be used for research by third party researchers.
- There are many databases which are created by, so to say, bottom-up initiatives. These navigate the strict Dutch rules by either presenting themselves as processors or falling back on the research exemption. Each have their own governance. This leads to a data landscape which is very diverse and difficult to navigate. As discussed in the section on conditions for research, registries which are not using the processor route or are not based on consent, are seriously worried about the move form opt-out to opt-in. That worry is acknowledged in the Code of Conduct. In that sense the Dutch cancer registry but also Palga[264] is under constant threat. Again, The Netherlands is an outlier here. All other countries have organised 'something' for reliable cancer statistics. Such statistics and research based on them are essential to control cancer[265] and cancer screening programmes.[266,267]
- SN which was not created as a central datahub for research but in practice serves that purpose.

This does not mean by the way that data remain in their 'silo's, as stated in the OECD report.[268] We are aware of many research projects where the data of these or some of these sources were combined. Dutch health research would stop if that would not be the case. An interesting example is research into faster and more reliable recognition of cancer on mammograms processing at the breast cancer screening for which data from the screening organisations, Palga and NKR needed to be combined.[269] The digital research environment of the Radboud UMC is used to combine these complex datasets.

Sometimes SN is used as the platform to combine the data. We will expand on SN as again a typical Dutch workaround to make data available for research in the context of the intended research on unexplained 'excess mortality' during the COVID-19 epidemic. The vaccination data from the National Institute for Public Health and the Environment (RIVM) were the main bottleneck for the intended research. The RIVM had stated that it could not submit the data for research at SN, as is believed not to have a legal basis to do so. RIVM had received those data only after consent from the vaccinated persons given at the health care providers who had administered the vaccination (usually the regional public health bodies or general practitioners).

264 For an example where the complete unbiased database was used for research see Inturrisi, *HPV-BASED CERVICAL CANCER SCREENING*.

265 Coebergh et al., 'EUROCOURSE Recipe for Cancer Surveillance by Visible Population-Based Cancer RegisTrees® in Europe'.

266 Arbyn et al., 'Cervical Cytology Biobanking in Europe'.be integrated in a national or regional screening registry, and be linked to other registries (histology, cancer, vaccination

267 Májek et al., 'The Legal Framework for European Cervical Cancer Screening Programmes'.decision-making structures and legal framework was developed. The primary responses were collected by September 2016.We sent the questionnaire to representatives of 35 European countries (28 countries of the EU, with the United Kingdom included as 4 countries; 4 EFTA member countries: Iceland, Liechtenstein, Norway, and Switzerland

268 OECD, *Towards an Integrated Health Information System in the Netherlands*.

269 See: https://www.kwf.nl/onderzoek/onderzoeksdatabase/gerichter-verwijzen-bij-screening-op-basis-van-mammografische

The privacy statement of the RIVM mentions that those data can be used for research after pseudonymisation, suggesting *only* for research by the RIVM, and that the data would only be processed on the secure servers of the central government. For any other use consent would be asked.[270] There was discussion in the press and in Parliament about this research not being performed. Government asked its main law firm (the State Advocate[271]) for advice.

That advice was that if SN requested the data based on the Act on SN, the RIVM had to submit those data.[272] And as far we can see, that has happened.

However, the solution is particular for two reasons:

- SN only requests data if they are necessary for its statistical function. It usually does not request data which are available as statistics already. And the RIVM provided statistics about the vaccination rate at least of those who had consented that the data could be send to the RIVM. To request data now as those are needed for research could be challenged in Dutch administrative law as 'detournement du pouvoir'.
- As we have seen, once data are at SN for its statistical purposes, the data source still has to agree that the data can be used for research as well. It can only do so if there is a legal basis that the data can be used as such. Article 24 UAVG would then come to the rescue of the RIVM and the research but is at odds with the previous statements of the RIVM both in context of this research as with its privacy statement.

When this Appendix on the Netherlands was nearly finished, the advice of the Dutch DPA on this issue became available, requested by Parliament. The DPA made similar remarks, but also underlined the inadequacy of Dutch legislation for research such as this.[273]

With these observations we do not intend to complain about the procedure. It shows that in the Netherlands sometimes pragmatic solutions are found which navigate around the strict and not really settled rules. And we are actually satisfied that the data are being analysed and one of the authors of this report is even involved the analyses.

Connected to the fact that in principle data can only be analysed at SN when SN had requested them for its statistical purposes, there is also a lag time. Data are usually requested once a year by SN, following the year when the data were assembled at the data source.

Additionally, as SN is not funded for this auxiliary function for research, SN charges their actual costs. These are made transparent on the SN microdata site.[274] However, it seems as if the costs of the data-sources which must submit data to SN and then minimise the data on the SN platform for the specific research questions, in some cases and depending on the data source far exceed the costs of SN. A researcher involved in the research into hospital procedures near the end of life, for which Nivel and DHD/LBZ (both already at SN) needed to be combined,[275]

270 https://www.rivm.nl/documenten/privacyverklaring-covid-19-vaccinatie
271 https://www.pelsrijcken.nl/en/about-us/state-advocate-nations-attorney
272 The State Advocate also suggested another secondary option being to submit those data based on article 24 UAVG. Pels Rijcken Landsadvocaat, Bijlage: Notitie inzake Verstrekking van vaccinatiegegevens door het RIVM aan het CBS ten behoeve van statistisch onderzoek en terbeschikkingstelling van die gegevens aan academici ten behoeve van onderzoek naar de redenen en oorzaken van de oversterfte.
273 Autoriteit Persoonsgegevens, 'Adviesverzoek Onderzoek Oversterfte'.
274 See: https://www.cbs.nl/nl-nl/onze-diensten/maatwerk-en-microdata/microdata-zelf-onderzoek-doen/diensten-en-kosten
275 For an earlier overview of the results of this research see: https://www.nivel.nl/nl/publicatie/factsheet-4-ic-opnamen-en-andere-potentieel-niet-passende-behandelingen-het-ziekenhuis

mentioned that DHD charged around Euro 15.000 for this service. We did not inquire at DHD how these tariffs are calculated.[276] The fee Nivel would charge is much less as explained on its site.[277]

F.8 Conclusion

In the Netherlands there is as yet not a comprehensive approach to further use. Discussions are still ongoing and sometimes workarounds are found. The observed trend from op-out to opt-in is worrisome for those databases which aim for inclusion of all relevant patients.

We come back to the Dutch debate in the concluding chapter where we also discuss that government has announced a white paper on further use in the context of the EHDS discussions.[278]

276 Further information cannot be found at the DHD site. See: https://www.dhd.nl/producten-diensten/registratie-data/aanvraag-van-ziekenhuisdata

277 https://www.nivel.nl/nl/nivel-zorgregistraties-eerste-lijn/over-nivel-zorgregistraties-eerste-lijn/informatie-over-het-aanvragen-van-gegevens-nivel

278 Bijlage: Impactanalyses op het Commissievoorstel omtrent een European Health Data Space.

Cited literature

(the websites referred to in the country studies have not been indexed)

Alriksson-Schmidt, Ann I., Ira F. D. Jeglinsky-Kankainen, Reidun B. Jahnsen, Sandra J. Hollung, Guro L. Andersen, and Gunnar V. HÄgglund. 'Flaunting Our Assets. Making the Most of the Nordic Registry Goldmine: Cerebral Palsy as an Example'. *Scandinavian Journal of Public Health* 48, no. 1 (1 February 2020): 113–18. https://doi.org/10.1177/1403494819829338.

Andersen, Mette Rye, and Hans H. Storm. 'Cancer Registration, Public Health and the Reform of the European Data Protection Framework: Abandoning or Improving European Public Health Research?' *European Journal of Cancer*, Cancer Registries in Europe for Cancer Surveillance and Research: EUROCOURSE Perspectives for Unity in Diversity, 51, no. 9 (1 June 2015): 1028–38. https://doi.org/10.1016/j.ejca.2013.09.005.

Anderson, Michael, Emma Pitchforth, Nigel Edwards, Hugh Alderwick, Alistair McGuire, and Elias Mossialos. 'United Kingdom, Health System Review 2022', n.d.

Andreas Follesdal (Editor, Ramses A. Wessel (Editor), and Jan Wouters (Editor). *Multilevel Regulation and the EU: The Interplay between Global, European and National Normative Processes*. Leiden, Boston: Martinus Nijhoff, 2008.

Arbyn, Marc, Evert-Ben Van Veen, Kristin Andersson, Johannes Bogers, Gaëlle Boulet, Christine Bergeron, Magnus von Knebel-Doeberitz, and Joakim Dillner. 'Cervical Cytology Biobanking in Europe'. *The International Journal of Biological Markers* 25, no. 3 (September 2010): 117–25.

Autoriteit Persoonsgegevens. 'Advies Wet Zeggenschap Lichaamsmateriaal', mei, Kenmerk z2019-28996 2020.

Autoriteit Persoonsgegevens. 'Adviesverzoek Onderzoek Oversterfte', 13 February 2023.

Autoriteit Persoonsgegevens. 'Eindbrief NZa aanlevering Honos + gegevens nieuw stelsel zorgvraagtypering ggz', 7 October 2022. https://autoriteitpersoonsgegevens.nl/sites/default/files/atoms/files/brief_nza_aanlevering_honos_gegevens_nieuw_stelsel_zorgvraagtypering_ggz.pdf.

Bak, Marieke, Vince Istvan Madai, Marie-Christine Fritzsche, Michaela Th. Mayrhofer, and Stuart McLennan. 'You Can't Have AI Both Ways: Balancing Health Data Privacy and Access Fairly'. *Frontiers in Genetics* 13 (2022). https://www.frontiersin.org/articles/10.3389/fgene.2022.929453.

Barbara Prainsack and Alena Buyx. *Solidarity in Biomedicine and Beyond*. Cambridge Bioethics and Law. Cambridge, UK: Cambridge University Press, 2017.

Bijlage: Impactanalyses op het Commissievoorstel omtrent een European Health Data Space, Pub. L. No. 22112, 3576 (2022). https://zoek.officielebekendmakingen.nl/kst-1066094.pdf.

Blümel, Miriam, Anne Spranger, Katharina Achstetter, Anna Maresso, and Reinhard Busse. 'Health System Review 2020', n.d., 308.

Bogaert, Petronille, Marieke Verschuuren, Herman Van Oyen, and Hans van Oers. 'Identifying Common Enablers and Barriers in European Health Information Systems'. *Health Policy* 125, no. 12 (1 December 2021): 1517–26. https://doi.org/10.1016/j.healthpol.2021.09.006.

Boot, Eric R. 'Public Interest'. In *Oxford Research Encyclopedia of Politics*, by Eric R. Boot. Oxford University Press, 2022. https://doi.org/10.1093/acrefore/9780190228637.013.2044.

Boudemaghe, Thierry, and Ihssen Belhadj. 'Data Resource Profile: The French National Uniform Hospital Discharge Data Set Database (PMSI)'. *International Journal of Epidemiology* 46, no. 2 (1 April 2017): 392–392d. https://doi.org/10.1093/ije/dyw359.

Carter, Pam, Graeme T Laurie, and Mary Dixon-Woods. 'The Social Licence for Research: Why *Care. Data* Ran into Trouble'. *Journal of Medical Ethics* 41, no. 5 (May 2015): 404–9. https://doi.org/10.1136/medethics-2014-102374.

Centraal Bureau voor de Statistiek. 'Antwoordbrief van het CBS over verzoek om informatie van de vaste commissie VWS over pseudonimiseren medische gegevens voor onderzoek.', 14 November 2022. https://www.rijksoverheid.nl/documenten/brieven/2022/11/14/bijlage-cbs-antwoordbrief-verzoek-om-informatie-vaste-commissie-vws.

Coebergh, Jan Willem, Corina van den Hurk, Marieke Louwman, Harry Comber, Stefano Rosso, Roberto Zanetti, Lidia Sacchetto, et al. 'EUROCOURSE Recipe for Cancer Surveillance by Visible Population-Based Cancer RegisTrees® in Europe: From Roots to Fruits'. *European Journal of Cancer*, Cancer Registries in Europe for Cancer Surveillance and Research: EUROCOURSE Perspectives for Unity in Diversity, 51, no. 9 (1 June 2015): 1050–63. https://doi.org/10.1016/j.ejca.2015.02.017.

College bescherming persoonsgegevens. 'Advies conceptwijziging Besluit gebruik BSN in de zorg', 24 March 2011. https://www.autoriteitpersoonsgegevens.nl/sites/default/files/downloads/adv/z2011-00063.pdf.

Commissie Regelgeving Onderzoek. 'COREON Statement Wetenschapelijk Onderzoek', 17 December 2018.

Coppen, Remco, Peter P. Groenewegen, J. M. W. Mieke Hazes, Judith D. de Jong, Job Kievit, J. N. D. Nico de Neeling, S. A. Menno Reijneveld, Robert A. Verheij, and Elizabeth Vroom. '[Re-use of medical data for research. What do the Dutch think of the requirement for explicit consent?]'. *Nederlands Tijdschrift Voor Geneeskunde* 160 (2015): A9868.

Coreon. 'Gedragscode Gezondheidsonderzoek'. Accessed 7 January 2023. https://www.coreon.org/gedragscode-gezondheidsonderzoek/.

COREON. 'Gedragscode Gezondheidsonderzoek, Verantwoord Omgaan Met (Persoons)Gegevens En Lichaamsmateriaal Bij Gezondheidsonderzoek', 2022. https://www.coreon.org/gedragscode-gezondheidsonderzoek/.

Dove, Edward S, and Jiahong Chen. 'Should Consent for Data Processing Be Privileged in Health Research? A Comparative Legal Analysis'. *International Data Privacy Law* 10, no. 2 (mei 2020): 117–31. https://doi.org/10.1093/idpl/ipz023.

Dove, Edward S, and Mark J Taylor. 'Signalling Standards for Progress: Bridging the Divide Between a Valid Consent to Use Patient Data Under Data Protection Law and the Common Law Duty of Confidentiality'. *Medical Law Review* 29, no. 3 (1 August 2021): 411–45. https://doi.org/10.1093/medlaw/fwab014.

E.B. van Veen. 'Big Data Voor Een Lerend Zorgsysteem'. In *Big Data in de Zorg*, 105–40. Preadviezen Vereniging Voor Gezondheidsrecht. den Haag: SDU, 2017.

EPIC. 'Joint Statement: Stakeholders' Consensus Response to the Proposed European Health Data Space'. *DIGITALEUROPE* (blog). Accessed 24 November 2022. https://www.digitaleurope.org/news/joint-statement-stakeholders-consensus-response-to-the-proposed-european-health-data-space/.

European Data Protection Board and EDPB. 'Guidelines 05/2020 on Consent under Regulation 2016/679 | European Data Protection Board'. Brussel: EDPB, 4 May 2020. https://edpb.europa.eu/our-work-tools/our-documents/guidelines/guidelines-052020-consent-under-regulation-2016679_en.

European Data Protection Board (EDPB) and European Data Protection Supervisor (EDPS). 'EDPB-EDPS Joint Opinion 03/2022 on the Proposal for a Regulation on the European Health Data Space', n.d.

European Patients Forum. 'EPF's Recommendations on the European Health Data Space (EHDS)', November 2022.

Friedman, Charles P. 'What Is Unique about Learning Health Systems?' *Learning Health Systems* 6, no. 3 (2022): e10328. https://doi.org/10.1002/lrh2.10328.

Geiger, Joerg, Joerg Fuchs, Madeline Starke, Michael Neumann, Ronny Baber, Sara Y. Nussbeck, Michael Kiehntopf, et al. 'GBA/GBN-Position on the Feedback of Incidental Findings in Biobank-Based Research: Consensus-Based Workflow for Hospital-Based Biobanks'. *European Journal of Human Genetics*, 3 February 2023. https://doi.org/10.1038/s41431-023-01299-8.

Gissler, Mika, and Jari Haukka. 'Finnish Health and Social Welfare Registers in Epidemiological Research'. *Norsk Epidemiologi* 14 (1 January 2004): 113–20.

Groos, Daniel, and Evert-Ben van Veen. 'Anonymised Data and the Rule of Law'. *European Data Protection Law Review* 6, no. 4 (2020): 498–508. https://doi.org/10.21552/edpl/2020/4/6.

Grossmann, Claudia, J. Michael McGinnis, and Brian Powers. *Digital Infrastructure for the Learning Health System: The Foundation for Continuous Improvement in Health and Health Care: Workshop Series Summary*. National Academies Press, 2011.

Haan, Bas. 'Een derde van specialistische ggz- bedden opgeheven, "zorg zakt door ondergrens"', 13 January 2023. https://www.nrc.nl/nieuws/2023/01/13/een-derde-van-specialistische-ggz-bedden-opgeheven-zorg-zakt-door-ondergrens-a4154152.

Hansen, Written Johan, Petra Wilson, Eline Verhoeven, Madelon Kroneman, Robert Verheij, and Evert-Ben van Veen. 'Assessment of the EU Member States' Rules on Health Data in the Light of GDPR'. Luxembourg: European Commission, 2021. https://ec.europa.eu/newsroom/sante/items/702120/en.

Hirsch, Dennis D. 'Going Dutch? Collaborative Dutch Privacy Regulation and the Lessons It Holds for U.S. Privacy Law'. SSRN Scholarly Paper. Rochester, NY, 1 November 2013. https://papers.ssrn.com/abstract=2393707.

Inturrisi, Federica. *HPV-BASED CERVICAL CANCER SCREENING: FROM 'ONE-SIZE-FITS-ALL' TOWARDS RISK-BASED STRATEGIES*. s.n, 2022.

Jormanainen, Vesa. 'LARGE-SCALE IMPLEMENTATION OF THE NATIONAL KANTA SERVICES IN FINLAND 2010–2018 WITH SPECIAL FOCUS ON ELECTRONIC PRESCRIPTION'. 2023. https://helda.helsinki.fi/handle/10138/353785.

Keskimäki, Ilmo, Liina-Kaisa Tynkkynen, Eeva Reissell, Meri Koivusalo, Vesa Syrjä, Lauri Vuorenkoski, Bernd Rechel, and Marina Karanikolos. 'Health System Review 2019', n.d.

Kist, Irith. 'Assessment of the Dutch Rules on Health Data in the Light of the GDPR'. *European Journal of Health Law* 1, no. aop (19 October 2022): 1–23. https://doi.org/10.1163/15718093-bja10096.

Kotecha, Dipak, Folkert W Asselbergs, Stephan Achenbach, Stefan D Anker, Dan Atar, Colin Baigent, Amitava Banerjee, et al. 'CODE-EHR Best Practice Framework for the Use of Structured Electronic Healthcare Records in Clinical Research'. *BMJ*, 29 August 2022, e069048. https://doi.org/10.1136/bmj-2021-069048.

Lannon, Carole, Christine L. Schuler, Michael Seid, Lloyd P. Provost, Sandra Fuller, David Purcell, Christopher B. Forrest, and Peter A. Margolis. 'A Maturity Grid Assessment Tool for Learning Networks'. *Learning Health Systems* 5, no. 2 (April 2021). https://doi.org/10.1002/lrh2.10232.

Laugesen, Kristina, Jonas F Ludvigsson, Morten Schmidt, Mika Gissler, Unnur Anna Valdimarsdottir, Astrid Lunde, and Henrik Toft Sørensen. 'Nordic Health Registry-Based Research: A Review of Health Care Systems and Key Registries'. *Clinical Epidemiology* 13 (19 July 2021): 533–54. https://doi.org/10.2147/CLEP.S314959.

Lewis, Jonathan, and Søren Holm. 'Organoid Biobanking, Autonomy and the Limits of Consent'. *Bioethics* 36, no. 7 (2022): 742–56. https://doi.org/10.1111/bioe.13047.

Ludvigsson, Jonas F, Siri E Håberg, Gun Peggy Knudsen, Pierre Lafolie, Helga Zoega, Catharina Sarkkola, Stephanie von Kraemer, Elisabete Weiderpass, and Mette Nørgaard. 'Ethical Aspects of Registry-Based Research in the Nordic Countries'. *Clinical Epidemiology* 7 (23 November 2015): 491–508. https://doi.org/10.2147/CLEP.S90589.

Magyari, Melinda, Nils Koch-Henriksen, and Per Soelberg Sørensen. 'The Danish Multiple Sclerosis Treatment Register'. *Clinical Epidemiology* 8 (25 October 2016): 549–52. https://doi.org/10.2147/CLEP.S99500.

Májek, Ondřej, Ahti Anttila, Marc Arbyn, Evert-Ben van Veen, Birgit Engesæter, and Stefan Lönnberg. 'The Legal Framework for European Cervical Cancer Screening Programmes'. *European Journal of Public Health* 29, no. 2 (1 April 2019): 345–50. https://doi.org/10.1093/eurpub/cky200.

Man, Yvonne de, Yvonne Wieland-Jorna, Bart Torensma, Koos de Wit, Anneke L. Francke, Mariska G. Oosterveld-Vlug, and Robert A. Verheij. 'Opt-In and Opt-Out Consent Procedures for the Reuse of Routinely Recorded Health Data in Scientific Research and Their Consequences for Consent Rate and Consent Bias: Systematic Review'. *Journal of Medical Internet Research* 25 (28 February 2023): e42131. https://doi.org/10.2196/42131.

Marcus, J. Scott, Bertin Martens, Christophe Carugati, Anne Bucher, and Ilsa Godlovitch. 'The European Health Data Space'. *SSRN Electronic Journal*, 2022. https://doi.org/10.2139/ssrn.4300393.

McLennan, Stuart, Sarah Rachut, Johannes Lange, Amelia Fiske, Dirk Heckmann, and Alena Buyx. 'Practices and Attitudes of Bavarian Stakeholders Regarding the Secondary-Use of Health Data for Research Purposes during the COVID-19 Pandemic: A Qualitative Interview Study (Preprint)'. Preprint. Journal of Medical Internet Research, 14 April 2022. https://doi.org/10.2196/preprints.38754.

Memorie van toelichting, Pub. L. No. 35844, 2020–2021 3 (2021). https://zoek.officielebekendmakingen.nl/kst-35844-3.

Milieu Ltd and Time.lex. 'Overview of the National Laws on Electronic Health Records in the EU Member States National Report for Finland', 3 March 2014. https://health.ec.europa.eu/system/files/2016-11/laws_finland_en_0.pdf.

Ministerie van Volksgezondheid, Welzijn en Sport. Verzamelwet gegevensverwerking II (2023). https://www.internetconsultatie.nl/3629/b1#header1.

MLC Foundation, and Antoni van Leeuwenhoek Nederlands Kanker Instituut. 'Niet-WMO-Plichtig Onderzoek En Ethische Toetsing', 14 February 2020. https://www.rijksoverheid.nl/documenten/rapporten/2020/02/14/niet-wmo-plichtig-onderzoek-en-ethische-toetsing.

Nota naar aanleiding van het verslag, Pub. L. No. 35844, 2022–2023 7 (2022). https://zoek.officielebekendmakingen.nl/dossier/kst-35844-7.

OECD. *Towards an Integrated Health Information System in the Netherlands*. Paris: Organisation for Economic Co-operation and Development, 2022. https://www.oecd-ilibrary.org/social-issues-migration-health/towards-an-integrated-health-information-system-in-the-netherlands_a1568975-en.

OECD and European Observatory on Health Systems and Policies. 'Denmark: Country Health Profile 2021, State of Health in the EU'. OECD Publishing, Paris/European Observatory on Health Systems and Policies, Brussels, 2021.

Olejaz, Maria, Annegrete Juul Nielsen, Andreas Rudkjøbing, Hans Okkels Birk, Allan Krasnik, and Cristina Hernández-Quevedo. 'Denmark Health System Review'. Health Systems in Transition. Copenhagen: European Obervatory on Health Systems and Policies, 2012.

Onora O'Neill. *Autonomy and Trust in Bioethics*. Cambridge, UK: Cambridge University Press, 2002.

Patiëntenfederatie. 'Delen van Uw Data. Hergebruik van Gezondheidsgegevens En Lichaamsmateriaal Voor Wetenschappelijk Onderzoek', 2019.

Pels Rijcken Landsadvocaat. Bijlage: Notitie inzake Verstrekking van vaccinatiegegevens door het RIVM aan het CBS ten behoeve van statistisch onderzoek en terbeschikkingstelling van die gegevens aan academici ten behoeve van onderzoek naar de redenen en oorzaken van de oversterfte (2022). https://www.rijksoverheid.nl/binaries/rijksoverheid/documenten/publicaties/2022/11/09/advies-inzake-verstrekking-vaccinatiegegevens/advies-inzake-verstrekking-vaccinatiegegevens.pdf.

Ploem, M.C. 'Gegeven voor de wetenschap, regulering van onderzoek met gegevens, lichaamsmateriaal en biobanken'. In *Wetenschappelijk onderzoek in de zorg*. Preadviezen Vereniging voor Gezondheidsrecht. Den Haag: Sdu Uitgevers, 2010.

Ploug, Thomas. 'In Defence of Informed Consent for Health Record Research - Why Arguments from "Easy Rescue", "no Harm" and "Consent Bias" Fail'. *BMC Medical Ethics* 21, no. 1 (20 August 2020): 75. https://doi.org/10.1186/s12910-020-00519-w.

Rebers, S., E. Vermeulen, A. P. Brandenburg, T. J. Stoof, B. Zupan-Kajcovski, W. J. W. Bos, M. J. Jonker, et al. 'A Randomised Controlled Trial of Consent Procedures for the Use of Residual Tissues for Medical Research: Preferences of and Implications for Patients, Research and Clinical Practice'. *PloS One* 11, no. 3 (2016): e0152509. https://doi.org/10.1371/journal.pone.0152509.

Scailteux, Lucie-Marie, Catherine Droitcourt, Frédéric Balusson, Emmanuel Nowak, Sandrine Kerbrat, Alain Dupuy, Erwan Drezen, André Happe, and Emmanuel Oger. 'French Administrative Health Care Database (SNDS): The Value of Its Enrichment'. *Therapies* 74, no. 2 (April 2019): 215–23. https://doi.org/10.1016/j.therap.2018.09.072.

Schaefer, G. Owen, Graeme Laurie, Sumytra Menon, Alastair V. Campbell, and Teck Chuan Voo. 'Clarifying How to Deploy the Public Interest Criterion in Consent Waivers for Health Data and Tissue

Research'. *BMC Medical Ethics* 21, no. 1 (20 March 2020): 23. https://doi.org/10.1186/s12910-020-00467-5.

Schmidt, Morten, Sigrun Alba Johannesdottir Schmidt, Jakob Lynge Sandegaard, Vera Ehrenstein, Lars Pedersen, and Henrik Toft Sørensen. 'The Danish National Patient Registry: A Review of Content, Data Quality, and Research Potential'. *Clinical Epidemiology* 7 (17 November 2015): 449–90. https://doi.org/10.2147/CLEP.S91125.

Schneider, Udo, Volker Ulrich, and Eberhard Wille. 'Risk Adjustment Systems in Health Insurance Markets in the US, Germany, Netherlands and Switzerland'. *Research Report*, n.d.

Sethi, Nayha, and Graeme T. Laurie. 'Delivering Proportionate Governance in the Era of EHealth: Making Linkage and Privacy Work Together'. *Medical Law International* 13, no. 2–3 (June 2013): 168–204. https://doi.org/10.1177/0968533213508974.

Shabani, Mahsa. 'Will the European Health Data Space Change Data Sharing Rules?' *Science* 375, no. 6587 (25 March 2022): 1357–59. https://doi.org/10.1126/science.abn4874.

Sloot, Bart van der, Sascha van Schendel, and César Augusto Fontanillo López. *The Influence of (Technical) Developments on the Concept of Personal Data in Relation to the GDPR*. WODC/TILT, 2022.

Southerington, Tom. 'Access to Biomedical Research Material and the Right to Data Protection in Finland'. In *GDPR and Biobanking*, edited by Santa Slokenberga, Olga Tzortzatou, and Jane Reichel, 43:243–56. Law, Governance and Technology Series. Cham: Springer International Publishing, 2021. https://doi.org/10.1007/978-3-030-49388-2_13.

Veen, E. -B. van, P. H. J. Riegman, W. N. M. Dinjens, K. H. Lam, M. H. A. Oomen, A. Spatz, R. Mager, et al. 'TuBaFrost 3: Regulatory and Ethical Issues on the Exchange of Residual Tissue for Research across Europe'. *European Journal of Cancer* 42, no. 17 (1 November 2006): 2914–23. https://doi.org/10.1016/j.ejca.2006.04.028.

Veen, Evert-Ben van. 'Observational Health Research in Europe: Understanding the General Data Protection Regulation and Underlying Debate'. *European Journal of Cancer* 104 (1 November 2018): 70–80. https://doi.org/10.1016/j.ejca.2018.09.032.

Visser, Marianne de, Arnoud Boot, Gijsbert Werner, Arthur van Riel, and Merove Gijsberts. 'Kiezen voor houdbare zorg. Mensen middelen en maatschappelijk draagvlak'. Den Haag: Wetenschappelijke Raad voor het Regeringsbeleid, 2021. https://www.wrr.nl/publicaties/rapporten/2021/09/15/kiezen-voor-houdbare-zorg#:~:text=In%20het%20rapport%20Kiezen%20voor,Leidend%20zijn%20hierbij%20twee%20uitgangspunten.

Wadmann, Sarah, Mette Hartlev, and Klaus Hoeyer. 'The Life and Death of Confidentiality: A Historical Analysis of the Flows of Patient Information'. *BioSocieties*, 29 January 2022. https://doi.org/10.1057/s41292-021-00269-x.

Wetsvoorstel Wet zeggenschap lichaamsmateriaal, Pub. L. No. 35844. Accessed 19 January 2023. https://zoek.officielebekendmakingen.nl/dossier/35844.

Wetsvoorstel Wijziging van de Wet kwaliteit, klachten en geschillen zorg in verband met het regelen van regie op kwaliteitsregistraties in de zorg en grondslagen om ten behoeve van die kwaliteitsregistraties bijzondere persoonsgegevens te kunnen verwerken, Pub. L. No. 36278 (n.d.). https://www.tweedekamer.nl/kamerstukken/wetsvoorstellen/detail?cfg=wetsvoorsteldetails&qry=wetsvoorstel%3A36278.

Wierda, E, D C Eindhoven, M J Schalij, C J W Borleffs, G Amoroso, D van Veghel, C R Mitchell, B A J M de

Mol, A Hirsch, and M C Ploem. 'Privacy of Patient Data in Quality-of-Care Registries in Cardiology and Cardiothoracic Surgery: The Impact of the New General Data Protection Regulation EU-Law'. *European Heart Journal - Quality of Care and Clinical Outcomes* 4, no. 4 (1 October 2018): 239–45. https://doi.org/10.1093/ehjqcco/qcy034.

Wijngaard, C. C. Van Den, F. Dijkstra, W. Van Pelt, L. Van Asten, M. Kretzschmar, B. Schimmer, N. J. D. Nagelkerke, P. Vellema, G. A. Donker, and M. P. G. Koopmans. 'In Search of Hidden Q-Fever Outbreaks: Linking Syndromic Hospital Clusters to Infected Goat Farms'. *Epidemiology & Infection* 139, no. 1 (January 2011): 19–26. https://doi.org/10.1017/S0950268810001032.

Wood, Angela, Rachel Denholm, Sam Hollings, Jennifer Cooper, Samantha Ip, Venexia Walker, Spiros Denaxas, et al. 'Linked Electronic Health Records for Research on a Nationwide Cohort of More than 54 Million People in England: Data Resource'. *BMJ* 373 (7 April 2021): n826. https://doi.org/10.1136/bmj.n826.

World Medical Association. 'WMA Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks'. World Medical Association, October 2016. https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/.

Zenker, Sven, Daniel Strech, Kristina Ihrig, Roland Jahns, Gabriele Müller, Christoph Schickhardt, Georg Schmidt, et al. 'Data Protection-Compliant Broad Consent for Secondary Use of Health Care Data and Human Biosamples for (Bio)Medical Research: Towards a New German National Standard'. *Journal of Biomedical Informatics* 131 (1 July 2022): 104096. https://doi.org/10.1016/j.jbi.2022.104096.