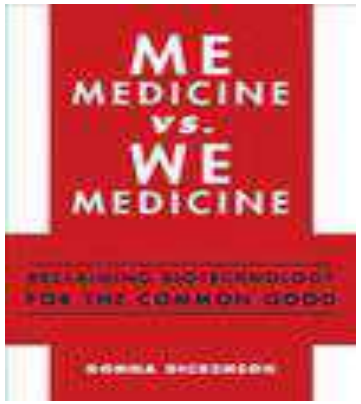
Caring is sharing, privacy is theft.



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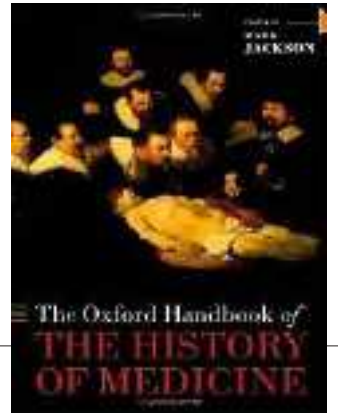

Solidair met patiënten van de toekomst

Informed consent versus *no objection* in the learning health system

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ProgrammaleiderZorgdata & het Lerend Zorgsysteem, Nivel

Hoogleraar Transparantie in de zorg vanuit patiëntenperspectief, TRANZO, Tilburg University

Zorginstituut Nederland

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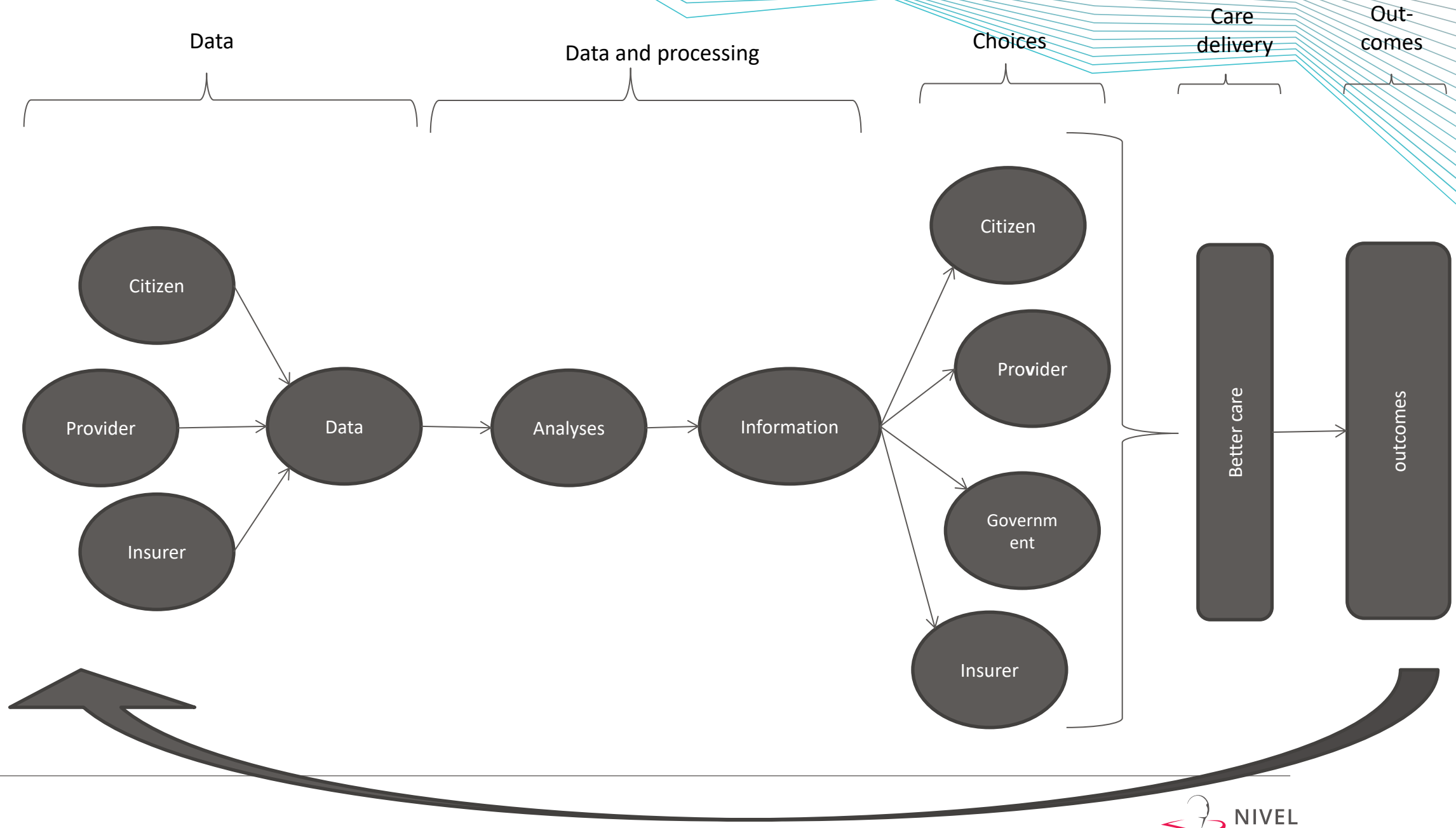
Research for better care

Coreon workshop WEON


Data
Data and processing
Choices
Care delivery
Out-comes
Citizen
Provider
Insurer
Data
Analyses
Information
Citizen
Provider
Governm ent
Insurer
Better care
outcomes

Note

- **Primary use** of data: use of data of an individual, for the care for that individual.

- **Secondary use** of data: use of data for research, statistics, policy making, epidemiology, health services research.

BOTH are important in the learning health system.

This presentation focuses on **secondary use** for research purposes.

Definition

"integrated health system in which ***progress in science, informatics, and care culture align to generate new knowledge as an ongoing natural by-product of the care experience"***

Friedman et al., 2015

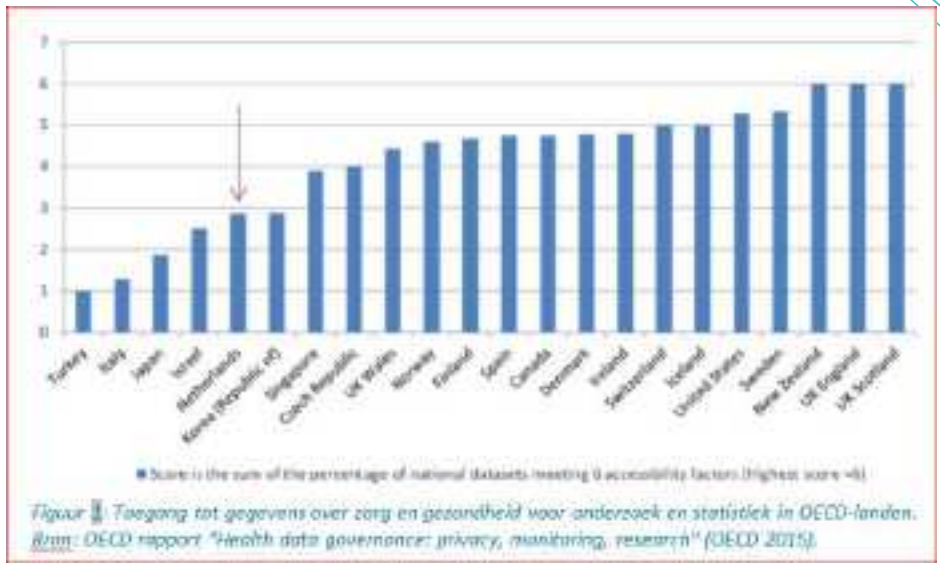
Not as simple as it seems…..

If ever we needed a learning health system, it is now

And yet:

Scattered data landscap and limited use of routine health data.

For example:
Community nursing
Nursing homes
=> Electronic health records that are not yet used for research purposes.



Figuur 1: Toegang tot gegevens over zorg en gezondheid voor onderzoek en statistiek in OECD-landen.
Bron: OECD rapport "Health data governance: privacy, monitoring, research" (OECD 2015).

Learning health systems are calling for a new ‘commons’ and rules to avoid tragedy of the commons

The **tragedy of the commons** is a situation in which individual users, who have open access to a resource unhampered by shared social structures or formal rules that govern access and use,[1][2] act independently according to their own self-interest and, contrary to the common good of all users, cause depletion of the resource through their uncoordinated action.[3]

Bron: Verheij, Witvliet, Jansen, Hooiveld, Van Hilten. Utrecht: Nivel/CBS, 2019.

Tabel 1: Relevante databronnen/zorgvoorzieningen voor de beide cases

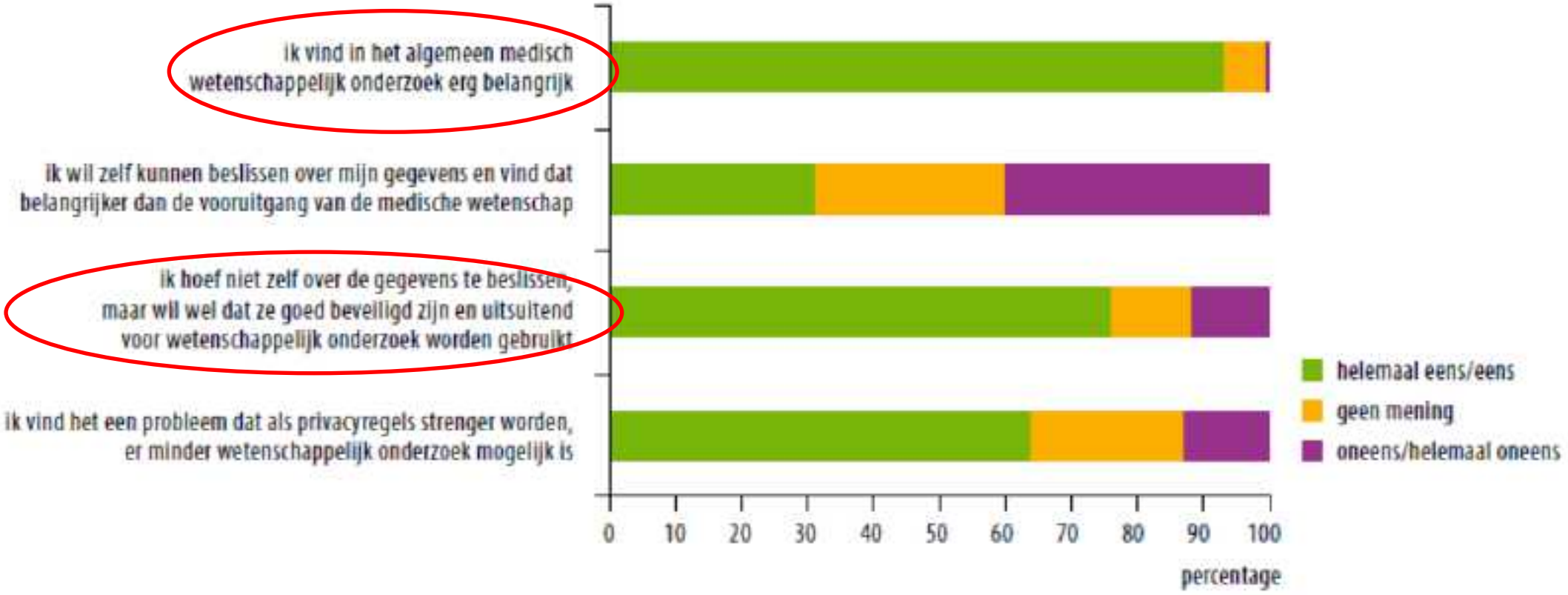
	Kinderen van ouders met psychische problemen (KOPP/KVO)	Kwetsbare ouderen
Declaraties bij zorgverzekeraars	X	X
Huisartsenzorg	X	X
Huisartsenposten	X	X
Ziekenhuiszorg	X	X
Sociaal economische kenmerken	X	X
Ambulancezorg		X
Integraal bekostigde eerstelijnszorg		X
Laboratoriumuitslagen		X
Indicatiestelling langdurige zorg		X
Pathologielaboratoria		
Langdurige zorg registratie		X
Maatschappelijke ondersteuning		X
Paramedische zorg (fysio-oefentherapie, diëtetiek)		X
Wijkverpleging		X
Verslavingszorg	X	
GGD, preventie	X	
Gespecialiseerde GGZ, verslavingszorg (DBC's GGZ)	X	X
Jeugddetentie	X	
Jeugdzorg	X	
Jeugdbescherming	X	

1. **ConclusionFragmented** data landscape.
2. **Statistics Netherlands** *can* act as a research platform, but not all data accessible there.
3. Most data source not completely **FAIR**.
4. Data sources **accessible only with restrictions.**
5. Many stakeholders with own interest => Different **approval and governance regulations**.
6. Data linkage technically possible, but **doubts about legal basis.**
7. Opt-in is the default, **WGBO exceptions** not always used.

Pillars of trust

- **Start with the WHY.**
- **Governance.**
  - **Transparency**
  - **Legal**
    - **Technical data protection measures**
    - **Organisational**
- **Fitness for purpose** (formerly known as data quality)
- **Citizen 'control over data'**

The patient perspective



FIGUUR 1 Meningen van 731 respondenten over het gebruik van hun gegevens voor medisch-wetenschappelijk onderzoek. Bij elke stelling zijn de percentages van de antwoorden weergegeven.

Coppen, R., Groenewegen, P.P., Hazes, J.M.W., Jong, J.D. de, Kievit, J., Neeling, J.N.D. de, Reijneveld, S.A., Verheij, R.A., Vroom, E. Hergebruik van medische gegevens voor onderzoek: wat vindt de Nederlander van het toestemmingsvereiste? Nederlands Tijdschrift voor Geneeskunde: 2016, 160(A 9868)

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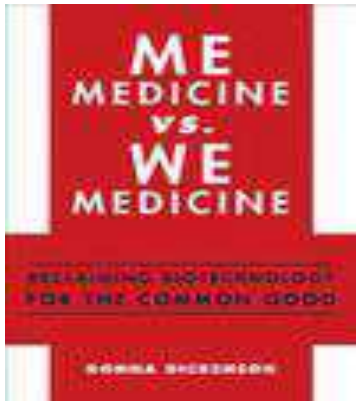

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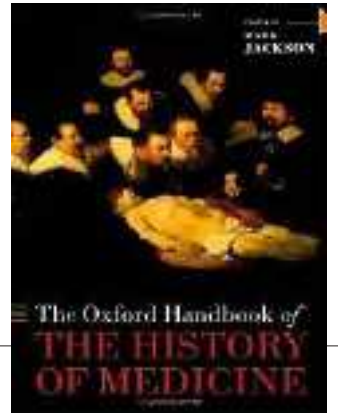


Solidair met patiënten van de toekomst

Datasolidariteit

*"Het principe is dat **alle burgers financieel bijdragen** aan [..] zorg voor anderen en voor zichzelf. [..] Bij data is een **soortgelijke redenering** denkbaar. De gegevens van de ene patiënt kunnen het leven van een ander verbeteren. [..] Het is in dat licht niet onlogisch om van "**datasolidariteit**" te spreken".*

Uit: Data laten werken voor gezondheid, ministerie van VWS 2018

Commissie Van der Zande

- **Aanbeveling 1** (*zie paragraaf 3.1*):
  Zorg voor een duurzaam en gestroomlijnd informatiestelsel in de zorg waar kwaliteitsregistraties integraal onderdeel van zijn, zodat de omslag kan worden gemaakt van meer dan 90% handmatige invoer voor kwaliteitsregistraties, naar meer dan 90% automatische en betrouwbare gegenereerde registratie uit het Elektronisch Patiënten Dossier/ Ziekenhuis Informatie Systeem.

At the same time adequat citizen control over data

*“van groot belang dat burgers en patiënten weten waar hun data zich bevinden, weten wat ermee gebeurt” en dat wordt gestreefd naar “**maximale zeggenschap van een burger over zijn/haar gegevens**”*

Uit: “Data laten werken voor gezondheid”
ministerie van VWS 2018

Maximum control AND data solidarity?

Two possibilities:

- Yes if no objection: opt-out.
- Yes if informed consent: opt-in

Stüssgen, R., Coppen, R., Veen, E-B van, Urbanus, T., Verheij, R. Zorggegevens voor onderzoek: bezwaar of toestemming? De wet en de praktijk. Utrecht: Nivel, 2019.

Nivel Primary Care Database (Nivel zorgregistraties

- “No objection” system
- 1,7 million individuals
- Electronic health records based
- Representative for Dutch population
- Aims research on:
  - Public health
  - Quality of care
  - Health services research
  - Health monitoring

Juridisch kader: (U)AVG en WGBO:

Explicit consent (opt-in) is de norm. However:

If:

- doel is wetenschappelijk onderzoek in het algemeen belang
- onderzoek kan niet zonder de betreffende gegevens worden uitgevoerd
- toestemming vragen is redelijkerwijs niet mogelijk
- maatregelen om herleiding tot individuele natuurlijke personen te voorkomen (privacy by design).
- patiënt adequaat geïnformeerd.

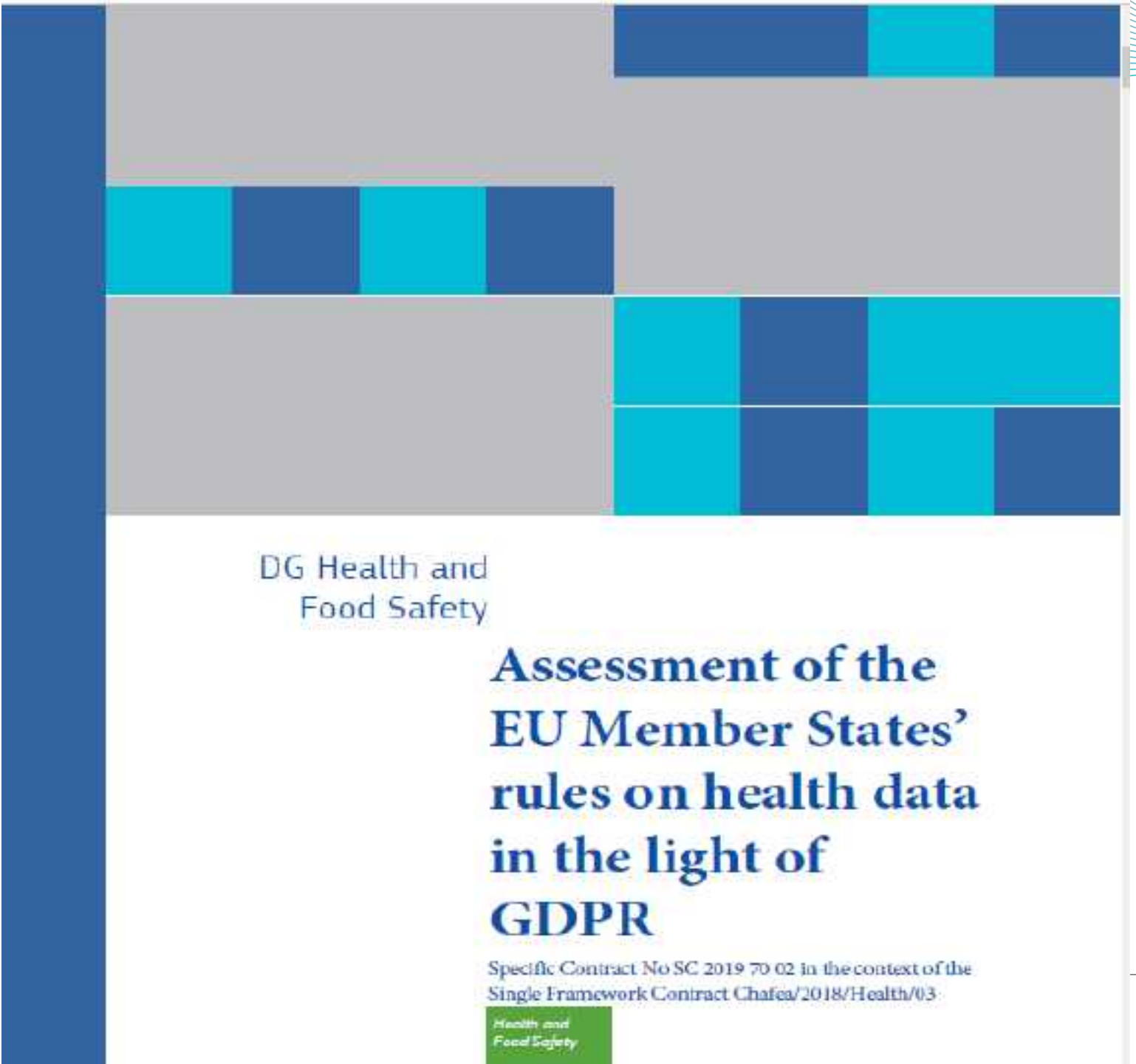
èn

- *patiënt heeft* ***niet uitdrukkelijk bezwaar*** gemaakt.

Why not informed consent system?

- Administrative burden in health professionals and citizens
- Higher costs. Research budgets not sufficient
- Few people will say no if asked, but many people will not be reached.

The European perspective



Study Authors

Johan Hansen[1], Petra Wilson[2], Eline Verhoeven[1], Madelon Kroneman[1], Mary Kirwan[3], Robert Verheij[1,4], Evert-Ben van Veen[5] (on behalf of the EUHealthSupport Consortium)

[1] Nivel, Netherlands institute for health services research,
[2] Health Connect Partners,[3] Royal College of Surgeons in Ireland, [4] Tilburg University, [5] MLC Foundation

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Definitions

Important: this is not about primary use for research, where data are collected ~~specifically for research based on consent~~ (eg RCT's).

- **Function 1:**

Data processing for the **purposes of provision of health and social care** by health and care providers to the patient concerned. Including in-person care, eHealth and mHealth tools.

- **Function 2**:

Data processing for **wider public health purposes** including planning, management, administration and improvement of health and care systems; prevention or control of communicable diseases; protection against serious threats to health and ensuring high standards of quality and safety of healthcare and of medical products and medical devices.

- **Function 3**:

Data processing for **scientific or historical research** by both public and private sector organisations (third parties, not being the original data controller), including the pharmaceutical and medical technology industries and insurance providers.

Categories of data use:

Primary use: for better healthcare

Secondary use: for policy making

Secondary use: for research and innovation

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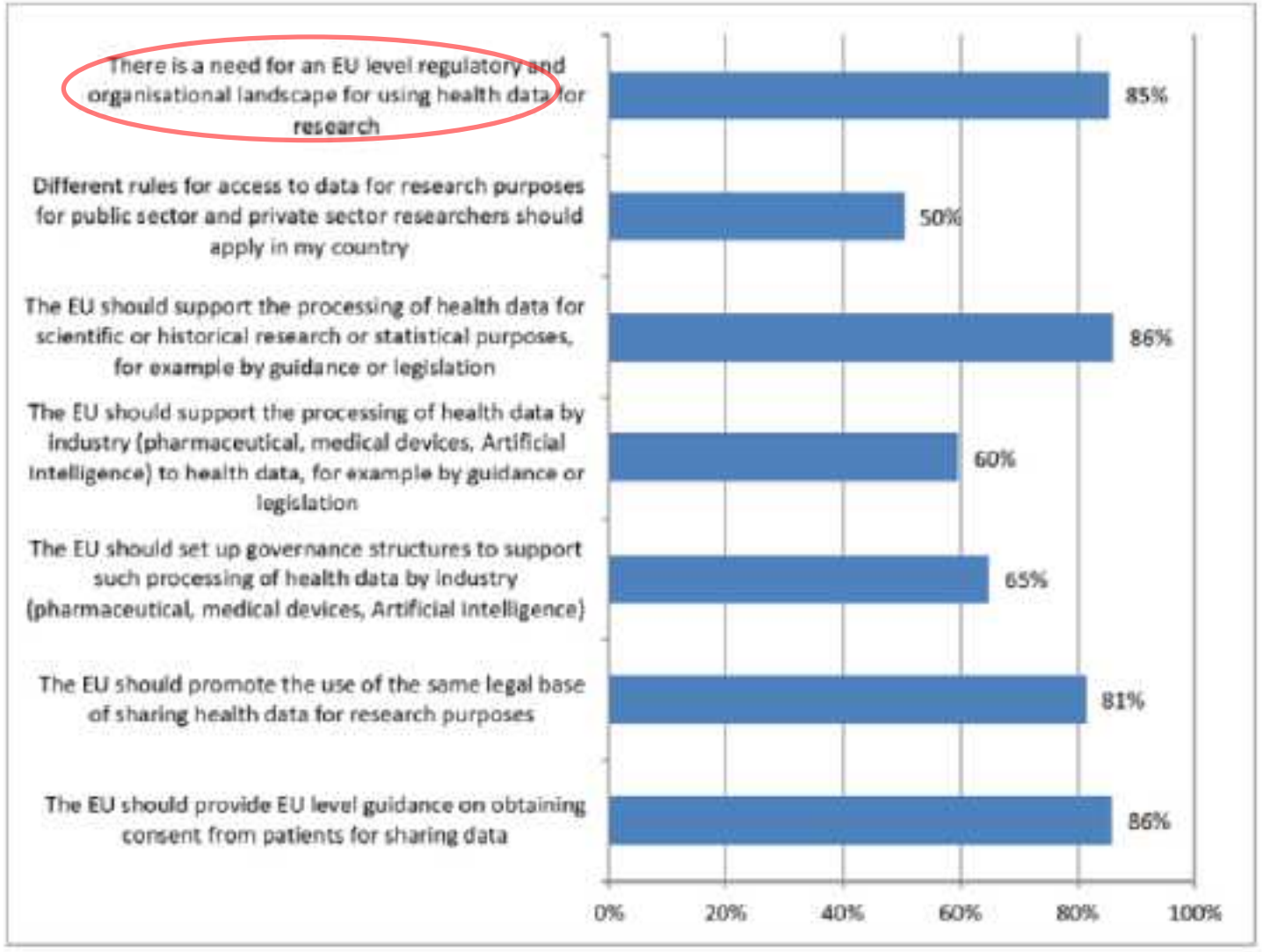
Secondary use for research

Member State has adopted sectoral legislation or authoritative guidance specifying safeguards to be applied in line with Art. 89 in the context of health research	Total MS	
No	9	CZ, FR, CY, LT, HU, NL, PL, PT, SK
Yes	18	BE, BG, DK, DE, EE, IE, EL, ES, HR, IT, LV, LU, MT, AT, RO, SI, FI, SE, [UK]
If yes, the following issues are addressed specifically in that legislation		
Scientific research by public sector organisations	12	BG, DK, DE, EE, EL, ES, HR, LU, MT, AT, FI, SE
Scientific research by private sector organisations	9	DK, DE, EE, ES, LU, MT, AT, FI, SE
Research for development of national statistics	12	BG, DK, DE, EE, EL, ES, HR, LU, MT, AT, RO, FI
Research for authorities' planning	9	BG, DE, EE, ES, HR, LU, MT, RO, FI
Other, please explain	6	BE, IE, ES, IT, LV, RO, [UK]

Where no specific legislation has been adopted, 14 MS rely on Art 9(2)(j) - research purposes, 13 on explicit consent and 9 on Article 9(2)(i) – public interest

Attitudes to data sharing for research



% stakeholders agreeing with the statements related to

"whether data sharing for research purposes should be improved"

Key Takeaways

- GDPR did **not** provide a fully **harmonised** approach to the **rules** on processing of data in the area of healthcare provision, administration or research.
- This has led to to a **fragmented data landscape** which makes cross-border cooperation for care provision, healthcare system administration or research difficult.
- **Researchers** in particular **struggle** to understand how the law applies to them.
- **Patients** do **not** feel **empowered** to exercise their rights - in particular the rights to data access and portability.

This is what should worry us:

We know that people's health condition is related to: **old age, migration background socioeconomic status, health literacy, mental capacitie, people in acute care situations.**

These factors are also related to people's ability to process information, and to make decisions in general and also with respect to the use of their data.

Migrating to an informed consent system will mean that two types of study may become impossible

- Studies where representativeness for the whole population is important.
- Studies focusing on any of the subgroups mentioned.

And also:

- Who should decide on the use of data pertaining to individuals that could not be reached or who did not respond to the informed consent question?

- Can we rightly assume that these individuals would **NOT** have given consent if not give permission if they could have been reached?

- Can we rightly assume that these individuals **WOULD** have given consent if they could have been reached.
- => Can we extend the reasoning behind the **Duty of easy rescue**?

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