Preparing for EHDS on National Level

Concise Comparison of the Health Data Systems in Germany, France and Finland

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Why comparing Germany, France and Finland?

All three are different in terms of

1. Population size
2. Political system in terms of legislative power including data protection law
3. Health care payment system
4. Administration of health care data
5. Administration of health research data: example biobanks
6. Legal basis for access to data for research purposes

All factors are critical to assess the complexity of making data FAIR

Model for a centralised system (and probably model for EHDS Regulation Draft)

1. 5,5 million inhabitants

2. no legislative power on subnational level

3. health care is a public service and paid by taxes („NHS“), it is managed centrally by the National Institute for Health and Welfare (THL) https://www.eu-healthcare.fi/healthcare-in-finland/healthcare-system-in-finland/

4. central administration of health care data (EHRs): Kanta
   https://www.kanta.fi/en/what-are-kanta-services

5. biobanks are all approved, registered and limited in number, THL has the most important epidemiological collection
   https://www.biopankki.fi/en/finnish-biobanks/

Finland

6. Finish legal acts on research, regulating:

- registration and consent for biobanks, no data transfer to European research platforms, but only to single research projects https://www.finlex.fi/en/laki/kaannokset/2012/en20120688.pdf

- consent for access to EHRs in Kanta https://www.kanta.fi/en/consent-to-sharing-patient-data

- no consent needed for secondary use of health care data registered in a centralised data base **Findata** (limited data set, no lab results, comparable to claim data/social security data for example in Germany: dates of visits, diagnosis, therapy). Use of data limited to on-site analysis, transfer of pseudonymised data only exceptional, no transfer to other research resources but only single research projects. https://findata.fi/en/

- Bilateral data sharing remains possible beyond central system

Model for a semi-centralised system

1. 65,5 million inhabitants

2. no legislative power on subnational level, central data protection authority (CNIL)

3. Healthcare payment system: Sécurité Sociale: „Caisse Primaire d'Assurance Maladie“, „Mutualité Sociale Agricole“, „Mutuelle des artisans“, grands entreprise d‘Etat, e.g. SNCF: cover ca 65% du tarif, private health care insurances close some gaps

France

4. Administration of health care data:

- Care data: hospital by hospital
- Claim data: Système National des Données de Santé (SNDS):
  - Data of l'Assurance Maladie (base SNIIRAM) ;
  - Data of all hospitals (base PMSI) ;
  - Cause of death (base du CépiDC de l'Inserm) ;
  - handicap data base (CNSA) ;
  - Subset of data from private health insurance companies

5. Administration of health research data: totally decentralised

6. Legal basis for access to data for research purposes
  - Informed consent for clinical and other studies
  - Legal acts on research on humans for secondary use

Model for a de-centralised system

1. 83 million inhabitants

2. Federal State (“Bund”) comprising 16 Constituent States (“Länder”), each of them with legislative power including administrative law, data protection law and research law.

3. healthcare is paid by various actors:
   - statutory health insurance companies (97),
   - private health insurance companies (43),
   - public budget for civil servants.

   No central registry!

Germany

4. Administration of Health Care Data:

- hospital by hospital (medical records), MII (Medical Informatics Initiative) is making data of all University hospitals available for research through a central national entry point administered by TMF

- insurance company by insurance company (claim data), certain sets of claim data are hold by „FDZ Forschungsdatenzentrum“, a department of BfArM (German EMA) for anaylsis by policy makers, regulators and research.

Germany

5. Administration of Health Research Data:

- totally decentralised
- cancer registries are regulated by law and are obilged to work together German wide, a federal law on registries is in the making
- a number of national initiatives such as NaKo (interesting for epidemiologists! https://nako.de/informationen-auf-englisch/), MII, disease specific research networks, …, all funded by Federal Ministry of Resesarch

Germany

6. Legal basis:

- prevailing legal basis for access to data for research purposes is informed consent!
- only limited exceptions: claim data, if consent is not obtainable
- some standard consent forms for „broad consent“ discussed and approved by all 17 data protection authoritoies
  - Biobanking: https://www.akek.de/biobanken/
  - MII: https://www.medizininformatik-initiative.de/de/mustertext-zur-patienteneinwilligung)

Conclusion

Huge complexity in Europe

More or less centrally available in all countries: claim data

EHDS: implementation hardly feasible anywhere in the EU given the comprehensive definition of health data