SHARING OF SENSITIVE HEALTH DATA

– TWO PRACTICAL EXAMPLES –

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G20 DGI-2 Workshop on Recommendation II.20 “Promotion of Data Sharing”
25 March 2021

Personal Health Data

- Highly sensitive and specially protected
- Creation of absolute anonymity not possible
  - Deeply phenotyped
- Living data sets with need for continuous maintenance and update
- Data usage based on informed consent of participants

➢ **Data protection and ethical issues essential**

Motivation for Data Sharing

- Not possible to fully exploit potential of research data obtained for projects with narrow focus and limited duration
  - Opportunity to investigate research questions that may not have been foreseen at time of project inception
- Investigation of health risks and protective factors highly benefit from large sample sizes
  - Rare diseases
  - Small effect sizes (e.g., genetic risks)
  - Heterogeneous populations
  - Season effects (e.g., dietary and physical activity behavior)
- Record linkage of special interest and with particular challenges
  - Use of secondary data to reduce burden of participants and recall bias

➢ **A matter of efficient use of resources**

IDEFICS – I.Family Cohort

ideficsstudy
Learning healthy living

ifamily

Ahrens W, […], Pigeot I, on behalf of the I.Family consortium. Cohort profile: The transition from childhood to adolescence in European children - How I.Family extends the IDEFICS cohort. Int J Epidemiol. 2017;46(5):1394-5j.

Overview

- **Multi-centre cohort study**
- **8 European countries**
- **Baseline 2007/2008:**
  - 16,228 children, 2-9.9 years
- **1st follow-up 2009/2010:**
  - 13,596 children, 2-12 years
- **2nd follow-up 2013/2014:**
  - 9,617 children, 5-17 years

Ahrens W, […], Pigeot I, on behalf of the I.Family consortium. Cohort profile: The transition from childhood to adolescence in European children - How I.Family extends the IDEFICS cohort. Int J Epidemiol. 2017;46(5):1394-5j.

Funded by the EC, FP 7, Project No. 266044 - Building on ideficsstudy

Aims

- **IDEFICS study**
  - Enhance knowledge of health effects of changing diet & altered social environment & lifestyle of children, 2-9 years, in Europe
  - Develop, implement & evaluate specific intervention approaches to reduce prevalence of diet- & lifestyle-related diseases & disorders

- **I.Family study**
  - Make significant contribution to reduce burden of nutrition-related diseases
  - Focus on individual and his/ her family
  - Assess dynamic nature of causal factors over time and during transition into adolescence

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Data Sharing (I)

- **Based on individual cooperation agreements**
  - Check whether intended usage in line with informed consent
  - Final decision by steering committee
- **Tailored analysis data set**
  - Constrained to variables needed for specific analysis (principle of data minimization)
  - Access via Central Data Server hosted by BIPS
    - Remote access (VPN, firewall-protected)
    - Individual password-protected user accounts
    - Access restricted to analysis data set
    - Download restricted to analysis results (summary statistics)

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Data Sharing (II)

- **Huge international pooling studies**
  - Example: NCD Risk Factor Collaboration (NCD-RisC)
  - Usually based on summary statistics
    - Unified inclusion and exclusion criteria
    - Unified calculations

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German Pharmacoepidemiological Research Database

GePaRD
German Pharmacoepidemiological Research Database

Haug U, Schink T. German Pharmacoepidemiological Research Database (GePaRD). In: Sturkenboom MCJM, Schink T (eds). Databases for pharmacoepidemiological research. Cham: Springer. 2021. p. 119-124

Pigeot I, Ahrens W. Establishment of a pharmacoepidemiological database in Germany: Methodological potential, scientific value and practical limitations. Pharmacoepidemiol Drug Saf. 2008;17:215-23

General Information

- Claims data of **~25 million insurants**
  - 4 statutory health insurances: DAK, hkk, TK, AOK Bremen/Bremerhaven,
- Information on persons who have been insured with one of the providers since **2004** or later
- About **20% of German population**
- As of today: yearly data delivery (most recent 2018)
- Coverage: all geographical regions of Germany
- Contains demographic information, information on hospital stays, outpatient visits and drug prescriptions
- **National reference** for Germany

AOK Bremen/Bremerhaven

DAK-Gesundheit

hkk Krankenkasse

Techniker Krankenkasse (TK)

https://www.bips-institut.de/en/research/research-infrastructures/gepard.html

Research Aims

- Monitoring of drugs and vaccines after approval
- Analysis of
  - Drug and vaccine utilization, misuse in pharmaceutical therapy of certain indications
  - (Rare) drug/ vaccine risks
  - Drug/ vaccine risks with long latency periods
  - Drug-drug interactions

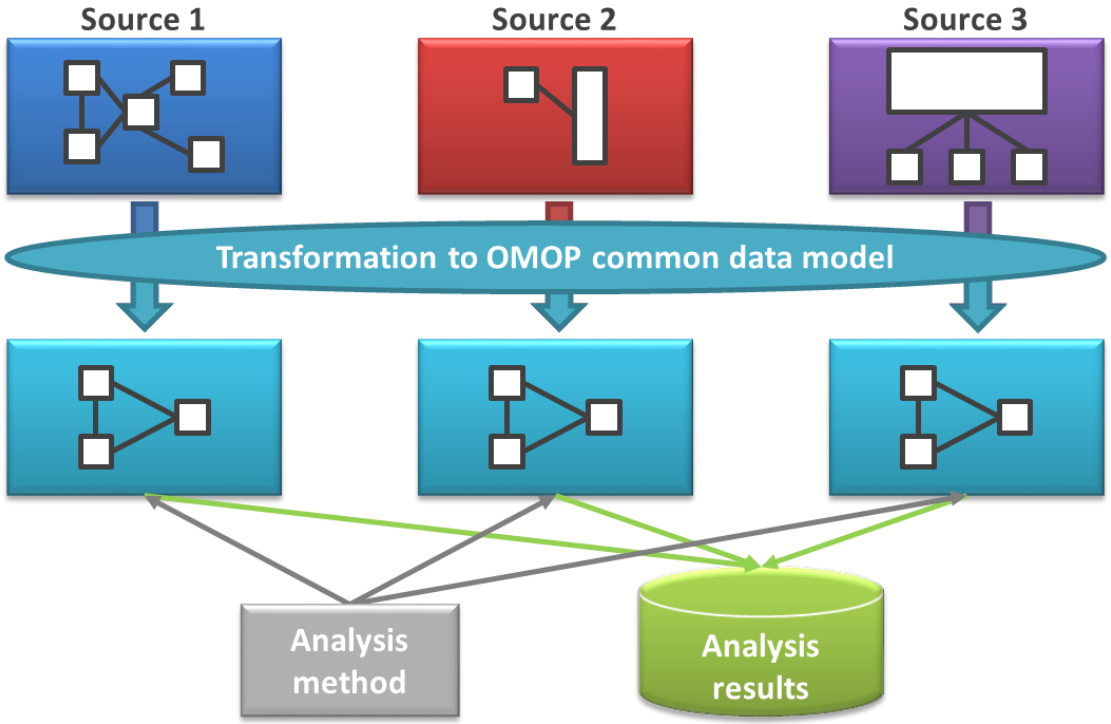
- Often only be possible in cooperation with international consortia

➢ Specific challenges in international projects

- Social data particularly protected in Germany (Social Code Book X)
  - ➢ Data may not at all be analyzed outside BIPS (no remote access)

OMOP – Common Data Model

- Concept:
  - Transform data from different databases into common format and representation (terminologies, vocabularies, coding schemes)
  - Perform systematic analyses using library of standard analytic routines based on the common format



OMOP – Observational Medical Outcomes Partnership; graphic according to https://www.ohdsi.org/data-standardization/the-common-data-model/

Example: Safety of NSAIDs

- EU-project “Safety of non-steroidal anti-inflammatory drugs (NSAIDs)” (SOS)
  - Coordination: Erasmus University Medical Centre, Rotterdam, NL
  - 7th EU Framework Programme
- Five population-based healthcare databases from four European countries (Netherlands, Italy, Germany, UK)
- Revealed more serious cardiovascular side effects for Diclofenac than for other traditional NSAIDs

➢ New safety warning by the European Medicines Agency (EMA)

- Diclofenac subject to the same safety precautions as selective COX-2-inhibitors

Arfè A et al. Non-steroidal anti-inflammatory drugs and risk of heart failure in four European countries: Nested case-control study. Brit Med J. 2016;354:i4857.

OUTLOOK

National Research Data Infrastructure for Personal Health Data

nfdi 4 health

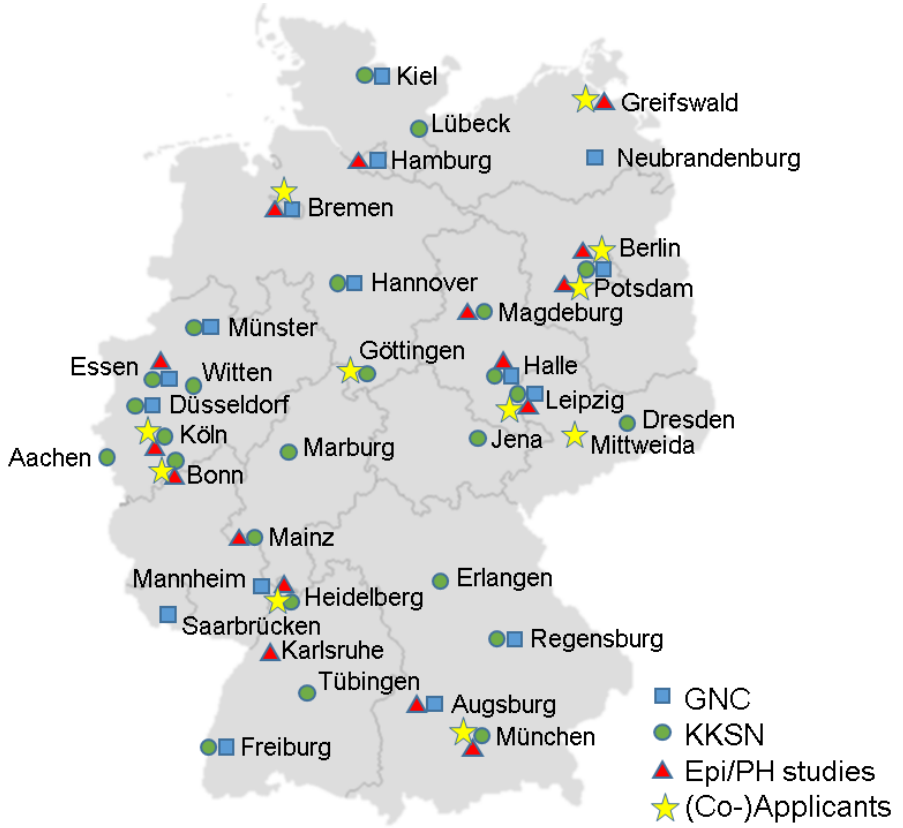
National Research Data Infrastructure

- Initiative of German Federal and *Länder* governments (German Joint Science Conference)
  - Based on recommendations of German Council for Scientific Information Infrastructures (RfII)
- Aims
  - Sustainable securing, indexing and utilization of research data via regional and networked knowledge repositories
  - Establishment of research data management according to FAIR principles
  - Connection and networking to international initiatives such as European Open Science Cloud (EOSC)
- Budget: 90 m€ per year (final stage)
- Up to 30 consortia shall cover science landscape
- First nine consortia started in October 2020

NFDI4Health – Consortium

- Lead: ZB MED – Information Centre Life Sciences
- Co-lead: Leibniz Institute for Prevention Research and Epidemiology – BIPS

- Target data: Health data from registries, cohort studies, clinical trials, administrative health databases, epidemiological and public health studies
- 17 partners and 48 further participants



- Vision: To boost the scientific exploitation of personal health data

NFDI4Health – Aims

- To enable findability of and access to structured health data
- To maintain federated framework of data holding organisations
- To enable privacy preserving exchange and linkage of personal health data
- To develop automated services (e.g., use and access, analysis tools)
- To enhance interoperability and reusability
- To promote use case oriented cooperation between research communities

There is a strong argument to be made that leaving data unshared is an impediment to the scientists of the future.

Nature Communications Editorial

Nature Communications Editorial. Data sharing and the future of science. Nat Commun. 2018;9:2817.

Thank you very much for your attention!

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