Secondary Use of Electronic Health Data

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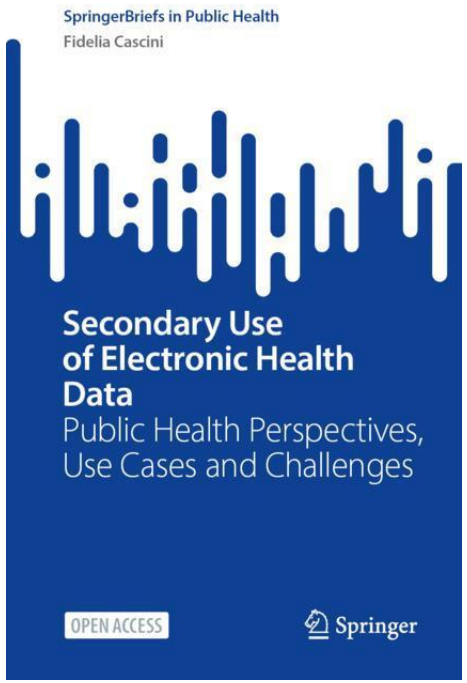

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Secondary Use of Electronic Health Data

Public Health Perspectives, Use Cases and Challenges

- Is the first book that provides an in-depth overview of all secondary applications of all electronic health data
- Embraces the most updated real-world scenarios and use cases including artificial intelligence for public health
- Illustrates new opportunities to maximise the value of health data sources such as the European Health Data Space
- This book is open access, which means that you have free and unlimited access

This open access book provides an in-depth overview of the characteristics, significance, backgrounds and limits of the most relevant electronic health data categories used at a global level for secondary purposes. These include healthcare system improvement, patient safety and quality of care, health policymaking, surveillance of diseases, personalized medicine, research and innovation such as artificial intelligence training for clinical practice.

A detailed and thorough representation of published evidence, practical experiences and concrete examples is offered to the reader who has the opportunity to explore the main areas of utilization of electronic health records, biobanking data, genetic and 'omic' data, real-world data and many other health data from different sources.

The challenges and advantages of health data reuse are explained from a public health perspective that addresses risks, benefits and impacts for different stakeholders such as health data holders (e.g., healthcare providers, pharmaceutical and medical device companies), health authorities and data permit issuers (e.g., health data access bodies), and health data users (e.g., healthcare professionals, researchers, business partners in the healthcare system such as insurers, commercial providers of digital solutions).

Given the increasing expansion of health data used for secondary purposes, Secondary Use of Electronic Health Data: Public Health Perspectives, Use Cases and Challenges serves as a go-to resource to facilitate the implementation of health data reuse ecosystems. In this regard, it also highlights emerging opportunities such as the European Health Data Space which is extensively explained.

Main Categories of Electronic Health Data

electronic health data from **EHRs**;

healthcare-related **administrative data**, including dispensation, claims and **reimbursement** data

human **genetic, epigenomic and genomic** data;

other **human molecular** data such as proteomic transcriptomic, metabolomic, lipidomic and other omic data;

automatically generated personal electronic health data, through **medical devices**;

data from **wellness applications**;

other health data from medical devices.

Data on factors impacting health, including **socio-economic, environmental and behavioural determinants** of health;

Aggregated data on **healthcare needs**, **resources** allocated to healthcare, the provision of and access to healthcare, healthcare expenditure and financing;

Pathogen data, impacting on human health

population-based health data **registries** (public health registries);

data from medical registries and **mortality registries**;

data from registries for medicinal products and medical devices;

health data from **biobanks** and associated databases.

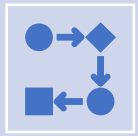
data from **clinical trials**, **clinical studies** and clinical investigations subject to Regulation (EU) 536/2014, Regulation [SOHO], Regulation (EU) 2017/745 and Regulation (EU) 2017/746, respectively;

data from **research cohorts, questionnaires** and surveys related to health, after the first publication of results

Use cases where RWD makes the difference

Main Real World Data Categories

Routinely collected



Electronic Health Records

Patient Generated Health Data

Registries (diseases, trauma, mortality)

Patients' surveys (including PREM, PROM)

Main Use Cases

Clinical research: arms of RCT (external control)

Epidemiology: population health, burden of disease, pattern of treatment, …

Health-economic research: healthcare services evaluation, health technology assessment, …

High-risk AI training and testing: RWD in combination with RCT data (i.e. controlled and structure data complemented by RWD as in the case of AIaMD)

Impacts and limitations of RWD

Impacts

Enabling time and cost efficiency: drug development processes are accelerated (e.g. when RWD are used as an external control/arm of RCT)

Enabling longitudinal analyses of large samples: large amounts of data available for long time support disease discovery (e.g. rare diseases) and population studies

Providing knowledge on patient outcomes: benefits and risks of a medical product after RCT, quality and safety of care

Limitations

RWD are '*by design*': observational, unstructured, incomplete, voluminous.

This means that compared to RCT data, RWD are sub-optimal data types that cause:

- variability in results
- complexity during analyses
- inconsistencies between entry sources

Minimum conditions to achive great impacts

01

Creating good **data models** to reduce mess incompleteness, heterogeneity, errors and biases in measures

02

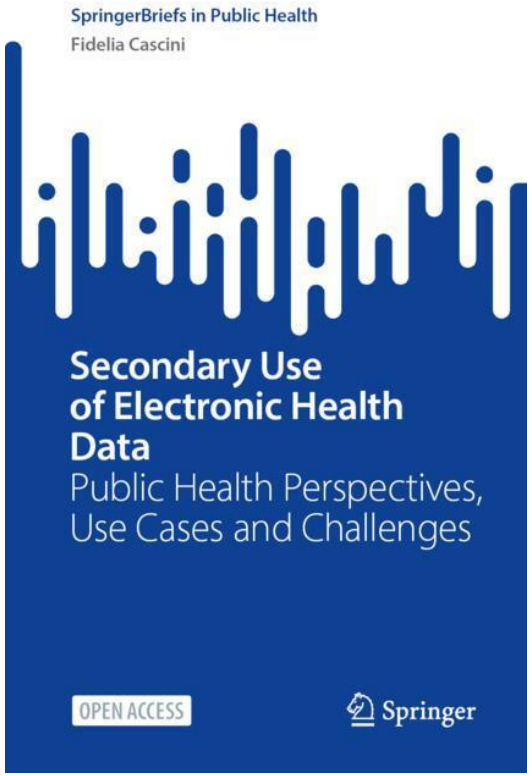
Assessing and ensuring **data quality** (e.g. data quality and utility label) to allow reproducibility and replicability of data

03

Working on **semantic interoperability** to enable collection of data from different sources, merging data not on individual level, mapping datasets and their interpretation.

Thanks!

Key message



To take concrete advantages from digital transformation and the use of AI based technologies:

1. Let's make all the different Electronic Health Data categories FAIR – Findable, Accessible, Interoperable, Reusable

2. Then, let's combine data from different sources and categories each use case, for advancing medical research and healthcare practice through a sinergetic approach.