

# **SPPS 255: Principles of Pharmacoepidemiology**

Monday, 14 April 2025

# PROPOSED PLAN

## Course Schedule (subject to change)

Week 1 – Introduction to Pharmacoepidemiology / Pharmacoepidemiology study designs

**Week 2 – Discussion on readings**

Week 3 – Administrative databases (e.g., claims, registries, electronic health records)

**Week 4 – Discussion on readings**

Week 5 – Bias and Confounding / Methods to address bias and confounding (e.g., propensity score matching)

**Week 6 – Discussion on readings**

Week 7 – Medication Use Evaluation / Drug Use Evaluation/Drug Use Review

**Week 8 – Discussion on readings**

Week 9 – Pharmacovigilance / FDA and safety

Week 10 – Bioethical issues and Closing Statement

# ADMINISTRATIVE DATABASES TYPES

Not meant for research!

Designed for health-related operations (e.g., reimbursement, delivery of healthcare, documentation)

Validation / Reliability depends on the operational purpose(s)

# TYPES OF ADMINISTRATIVE DATABASES TYPES

Electronic Health Records

Claims / Encounter databases

Registries

Surveillance systems

# CLAIMS / ENCOUNTER DATABASES

Claims data typically include:

- ICD 10 diagnosis
- Diagnosis Related Group (DRG)
- Outpatient encounter codes (HCPSC)
- Pharmacy claims

CMS ([Data.CMS.gov](https://data.cms.gov)) → Medicare Provider Analysis and Review ([MEDPAR](https://medpar.cms.gov))

## DATASET

Medicare Inpatient  
Hospitals - by Provider and  
Service

The Medicare Inpatient Hospitals by Provider and Service dataset provides information on inpatient discharges for Original Medicare Part A beneficiaries by IPPS hospitals. It includes information on the use, payment, and hospital charges for more than 3,000 U.S. hospitals that received IPPS payments. The data are organized by hospital and Medica...

## Quick links

 [Data Dictionary](#)

 [Download](#)

Healthcare Common Procedure Coding System (HCPSC) → Current Procedural Terminology (CPT) ([link to look up CPT codes](#))

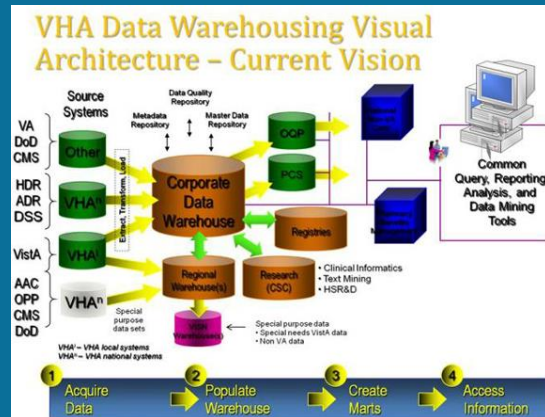
# ELECTRONIC HEALTH RECORDS

Clinically relevant data for the provision of care for the patient (symptoms, family history, social-economic characteristics)

Includes information on billing, provision of care, non-clinical functions

Laboratory, imaging, diagnostic, and pharmacy (outpatient and inpatient) data

Example: US Department of Veterans Affairs, Kaiser, EPIC



VA Corporate Data Warehouse (CDW)

# PATIENT REGISTRIES

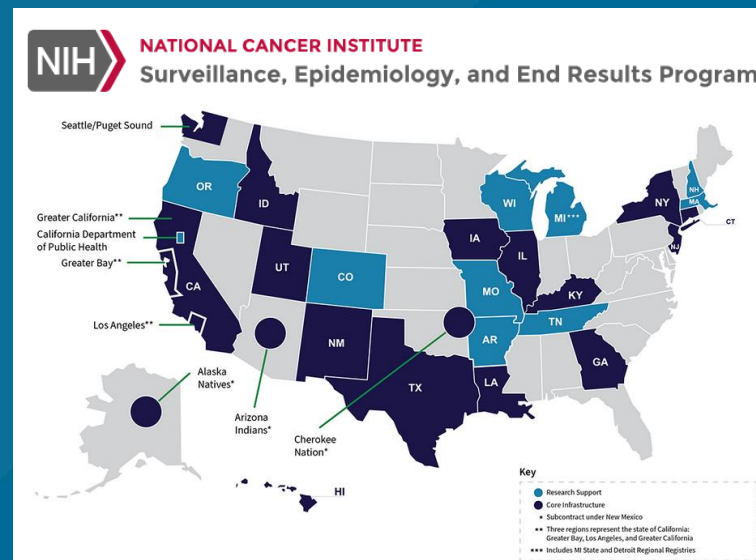
Prospective (on-going) data collection of a specific population

Patient registries can be performed at a single center or part of a population-based, multi-center group

Monitor the longitudinal patterns of treatment, care, expenditures, and outcomes

Provider invaluable information about the specific population's epidemiologic outcomes

Example: The Surveillance, Epidemiology, and End Results (SEER) Program

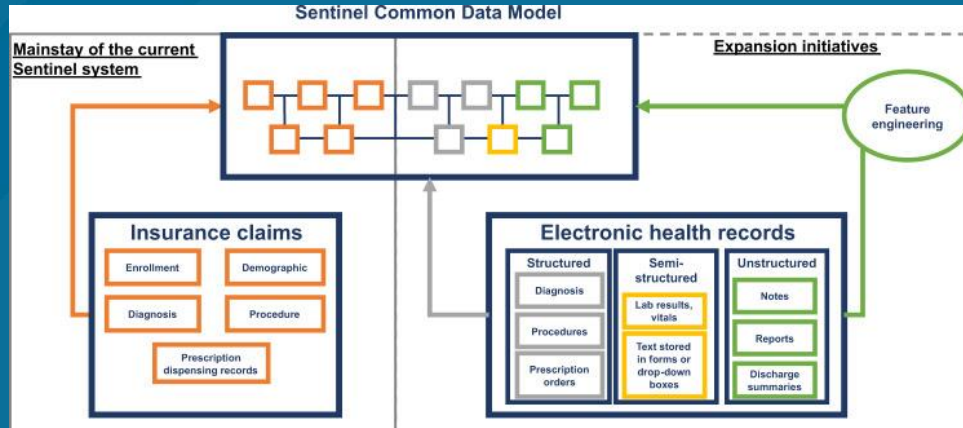


# SURVEILLANCE

FDA's Sentinel system (Pilot started in 2008; official launch in 2016)

Monitors adverse events associated with medical products (e.g., drugs)

Uses real-world health insurance claims data from participating systems to construct a longitudinal picture of cause-and-effect relationship between drugs and adverse effects



Desai RJ, Matheny ME, Johnson K, et al. Broadening the reach of the FDA Sentinel system: A roadmap for integrating electronic health record data in a causal analysis framework. *NPJ Digit Med.* 2021;4(1):170. Published 2021 Dec 20. doi:10.1038/s41746-021-00542-0



# CHOOSING THE DATABASE

Database	Strengths	Weaknesses	Examples
Claims / Encounter (Insurance database)	Information on patient characteristics, prescription fills, and medical services, as part of the routine administration or reimbursement of healthcare; Large sample size; Valid and accurate for some of the data (e.g., pharmacy claims)	Diagnostic information may not be accurate; Missing clinical details (e.g., laboratory findings, demographics); Heterogeneity across systems	Medicare, Kaiser,* Marketscan, IVQIA
EHR	Patient care database; Clinical information about patients (e.g., laboratory findings, demographics); Large sample size; Valid and accurate; Longitudinal;	Incomplete clinical data; Missing data; Complexity necessitating use of SQL / data architects / Relational Database Management Systems / Corporate Data Warehouse	US Department of Veterans Affairs; Kaiser; EPIC
Patient Registries	Efficient enrollment of specific populations (e.g., disease, geography, system); Large sample size;	Lack of follow-up; Missing data; Maintenance requires substantial effort; Lack of a control population	
Surveillance	Large, Accurate and valid; Insurance claims data; Longitudinal;	Requires participation by other healthcare systems; May not be representative of the population; May not be used for hypothesis testing, limited to hypothesis generating; Risk ratio can't be estimated, need to use disproportionality analysis (e.g., proportional risk ratio)	FDA Sentinel, CDC Vaccine Adverse Event Reporting System (VAERS)

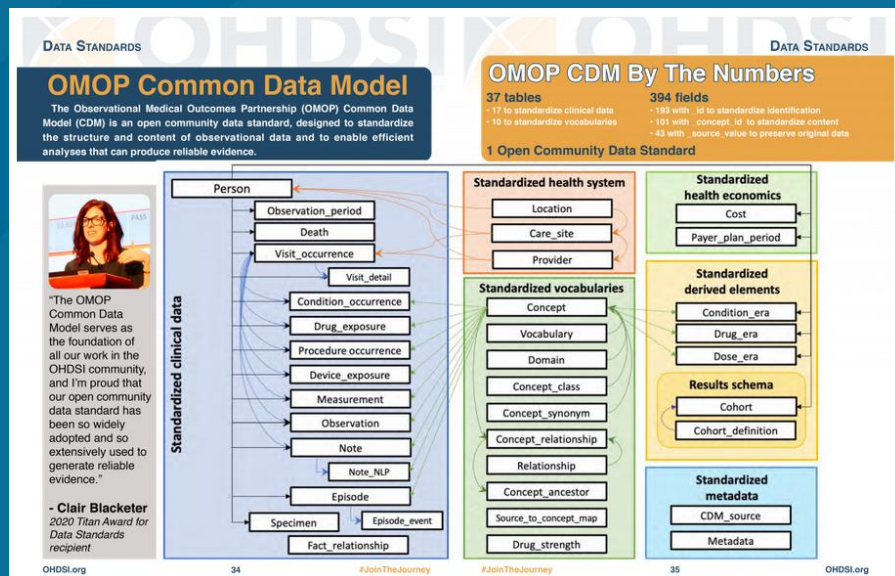
\* Kaiser also has an EHR system

# STANDARDIZATION

## Challenges with healthcare data include standardizing data elements

# Common Data Model

## Example: Observational Medical Outcomes Partnership (OMOP)



## OTHER DATABASES

Agency for Healthcare Research and Quality (AHRQ) Medical Expenditure Panel Survey ([MEPS](#))

National Survey of Drug Abuse and Health ([NSDUH](#))

CDC Wide-ranging ONline Data for Epidemiologic Research ([WONDER](#))

NIH data repositories ([link](#))