DATA SOURCES FOR PHARMACOEPIDEMIOLOGY RESEARCH

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DISCLOSURE

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OBJECTIVES

- To describe sources of data for pharmacoepidemiology research
- To highlight the strengths and limitations of these data sources

DEFINITION OF PHARMACOEPIDEMIOLOGY

- Pharmacoepidemiology is the branch of epidemiology that studies the use and effect of medicines in specific populations. It studies the relationships between patients, diseases, and medicines.
- Some examples of applications of pharmacoepidemiology are to:
- Monitor the use and effects of medicines in populations
- Measure the occurrence of diseases
- Study the natural history of diseases
- Measure the characteristics of patients with and without specific diseases

WHAT IS DATA

- Factual information (such as measurements or statistics) used as a basis for reasoning, discussion, or calculation ***(www.merriam-webster.com)***
- Information, especially facts or numbers, collected to be examined and considered and used to help decision-making, or information in an electronic form that can be stored and used by a computer ***(dictionary.cambridge.org)***

TYPES OF DATA

- Primary data:
  - Original data
  - Can involve all cadres of health care workers
  - Can also be gotten from patients and their relatives
  - Documents used include prescriptions, medical records, dispensing records
  - May be through structured instrument/s
  - Used mainly for drug utilization studies

TYPES OF DATA (contd)

- Secondary data:
  - Usually administrative and clinical data
  - Health insurance claims databases
  - Re-imbursement data
  - Electronic medical records
  - Aggregate-level data such as sales data (distribution or hospital based)
  - Can be linked with other databases

TYPES OF DATA USED IN PE STUDIES

- Clinical data
- Field data
- Retrospective observational data
- Registries

SOURCES OF DATA FOR PE STUDIES

- Registries
- Claims databases
- Electronic medical record (EMR) databases
- Hybrid databases

ADVANTAGES OF AUTOMATED DATABASES

- Allow evaluation of health conditions in "real world" settings
- Use of electronic data sources containing medical care data of more than 10-30 years
- Cost- effectiveness (time and resources)

COMPONENTS OF AN IDEAL AUTOMATED DATABASES

- Longitudinal data from all care settings
- Records prescribed, dispensed drugs
- Includes laboratory tests results
- Large representative population
- Linkable to other data sources (via identifiers)
- Confounders of interest available
- Updatable, with access to medical records
- Ideal Automated Data

Shah BR. Am Heart J 2010;160:8 15.

STRENGTHS OF AUTOMATED DATABASES

- Relevant clinical data
- Large, real world clinical population
- Longitudinal and linkable
- Short time frame from design to results

Suissa S. Nat Clin Pract Rheumatol 2007;3:725 32.

LIMITATIONS OF AUTOMATED DATABASES

- Uncertain validity of diagnoses
- Completeness, quality of data
- Instability of population
- Generalizability
- Costs of data

REGISTRIES

- Prospective study of patients with common characteristics
- Developed to evaluate:
  - Natural history of disease
  - Drug effectiveness, safety
  - Quality of life
  - Cost effectiveness of therapies

TYPES OF DATA COLLECTED BY REGISTRIES

- Collect data on:
  - Demographic characteristics
  - Social history
  - Disease specific drug treatments
  - Select disease related outcomes
- Ability to link to other data sources?

REGISTRIES: PROS AND CONS

PROS

- Large patient numbers
- Usual diagnostic, follow up procedures
- Contain "real world" therapeutic effectiveness, safety data
- Heterogeneity among sites

CONS

- Selection bias (non sequential patients)
- Variability in data definitions
- Data may not be validated
- Incomplete data on comorbid conditions,outcomes, mortality
- Inability to link with other data sources

EXAMPLES OF REGISTRIES FOR PE STUDIES

- Cancer registries
  - Gastric Cancer Registry
  - Breast Cancer Surveillance Consortium
- Disease registry
  - Children's Health Foundation Pediatric Asthma Registry (link is external)
- Pregnancy registry

MEDICAL INSURANCE CLAIMS DATABASE

- Billing for use of healthcare system
- Diagnoses cannot be verified
- Coding issues with different hospitals
- Pharmacy claims – dispensed?
- Concern for lack of completeness
- No body mass index, BP, tobacco, alcohol data, etc

EXAMPLES OF CLAIMS DATABASES

- US Medicaid, Medicare
- Various Medical Schemes in South Africa, Namibia
- HMOs in Nigeria

ELECTRONIC MEDICAL RECORDS DATABASES

- Generated at the time of visit
- Data include:
  - Medical diagnoses (ICD code)
  - Drug prescriptions (not dispensing)
  - Laboratory results
  - Procedures carried out
- Still have concerns for incompleteness and out of network care

ELECTRONIC MEDICAL RECORDS CPRD

- Clinical Practice Research Datalink
- Sponsored by the UK MHRA and NIHR
- De-identified patient data collected from over 1000 GP practices in the UK
- See https://www.cprd.com/
- Started in 1987
- Patient count now about 35 million

EXAMPLE – NIGERIAN HMO DATABASE

66 Yrs	Female	ASTHMA	IV HYDROCORT.,IV AMINO	Ibuprofen	Prednisolone	Salbutamol (Aerosol)
67 Yrs	Male	ASTHMA	Ibuprofen, prednisolone, ve	Amoxycillin	Aminophylline	Hydrocortisone
70 Yrs	Male	ASTHMA	IV HYDROCORTISONE,CA	Paracetamol	Prednisolone	Salbutamol (Aerosol)
69 Yrs	Male	BENIGN PROSTATE HYPERPI	prednisolone, pcm, ventolin.		Furosemide	
67 Yrs	Male	BENIGN PROSTATE HYPERPI	FRUSEUNIDE,LOSARTAN	Lisinopril	Ampicillin + Cloxacillin	Ascorbic Acid
69 Yrs	Male	BENIGN PROSTATE HYPERTI	10CC N/S DISTILLED WAT	Amlodipine	Ascorbic Acid	
67 Yrs	Male	BRONCHOLITIS	AMLODIPINE-5MG DLY*5/	Omeprazole	Artemeter + Lumefantrine	

HYBRID OR COMBINED DATABASES

- Administrative AND clinical databases
- Reap benefits of claims and medical record data
- Some may have less diverse populations
- Examples:
  - Veterans Affairs, Kaiser Permanente (USA)
  - International Research Consortia for HIV Data

EXAMPLES OF HYBRID DATABASES: Veterans Administration Health Data

- Largest integrated health care system in US
- Available data:
  - Inpatient/outpatient ICD diagnoses, drugs
  - Procedures, biopsies
  - Laboratory data
- Linkable (registries, Medicare, Medicaid)

EXAMPLES OF HYBRID DATABASES: International Epidemiology Databases to Evaluate AIDS

- Collects HIV/AIDS data from 7 regions
- 4 in Africa (Southern, East, West, Central)
- North America, Asia, Central/South America
- Available data:
  - Medical diagnoses, comorbidities
  - Antiretroviral drugs
  - Laboratory data (e.g., HIV RNA, CD4)

SELECTION OF APPROPRIATE DATABASE FOR RESEARCH

- Research questions?
- The absence of automated databases should not deter discourage us from conducting DUR
- Important questions to ask include:
  - What is the population covered?
  - Are there continuous, consistent data?
  - Exposure, outcomes
  - Confounders of interest
  - Is follow up sufficiently long enough?
  - Access to medical records?
  - Ability to link to other data sources?

SELECTION OF APPROPRIATE DATABASE FOR RESEARCH

- Research question dictates database
- Available "checklists" to guide researchers:
  - ISPE guidelines
  - ISPOR guidelines

ETHICAL ISSUES RELATED TO PATIENT DATA USAGE

- Privacy
- Confidentiality
- Security

- There are regulations regulating the use of data in many countries but….
- Usually de-identified data is used but that definition is also debatable…

CONCLUSION

- Data for PE research can be sourced from different types of databases
- Researchers need to consider the strengths and limitations when making their choice

KEY MESSAGE

- Absence of automated databases should not be an excuse for not conducting DUR

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