Data Sources for Medical Device Epidemiology

Kaiser Permanente
Surgical Outcomes & Analysis

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National Implant Registries
Today’s Talk*

I. Necessary data elements for device surveillance

II. Types of data sources
   A. Examples

*Focus is in orthopedic devices.
Necessary Elements for Device Surveillance

Population of Interest (sample, confounders/effect mod)

- Elements:
  1. Denominator
  2. Numerator
  3. Who is the patient?
  4. When/where is the procedure occurring?

Device Information (exposure)

- Elements:
  1. Reference numbers
  2. Descriptions/names
  3. Device attributes

Performance (outcome)

- Elements:
  1. Failure (when)
  2. Death
  3. Competing risks events
  4. Attrition
Medical Device Epidemiology Data Sources

- **Primary**
  - Device registries - hybrid data collection
  - Studies
  - Implant retrieval databases

- **Secondary**
  - Electronic medical records (EMR)
  - Claims data (medical and pharmacy)
  - Death records
  - ‘Boutique’ databases: specific disease registries
  - Device manufacturers
Medical Device Epidemiology Data Sources

Population of Interest
Device Information
Performance

Registries and studies capture all domains.
Medical Device Epidemiology Data Sources

**Population of Interest**
- Data Sources:
  1. Claims
  2. EMR
  3. Patient registries

**Device Information**
- Data Sources:
  1. EMR
  2. Device manufacturers

**Performance**
- Data Sources:
  1. Claims
  2. EMR
  3. Death records
  4. Implant retrieval databases
I. Primary Data Sources

a. Device Registries
Device Registries

- What is a registry?
  - “…an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes.”
Example: Kaiser Permanente (KP) Anterior Cruciate Ligament Reconstruction (ACLR) Registry

- **Goal:** Monitor devices used to reconstruct an ACL
- **Sampling Frame:** KP membership, 9.5 million patients, 7 US regions
- **Coverage:** 1 integrated healthcare system, 52 hospitals, 330 surgeons
- **Outcomes:** revisions, re-operations, infections, thromboembolic events
- **Available to:** registry participants
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KP ACLR Registry Data Sources

Extracted from EMR & Registry Forms

- **Implant Components**
  - Company Name
  - Catalog #
  - Lot/Serial #
  - Quantity

- **Patient Demographics**
  - Medical Record #
  - DOB
  - Gender
  - Race

- **Implant Reference Table**
  - Company Name
  - Catalog #
  - Description*
  - Name*
  - Attributes

- **Registry Forms**
  - Electronic SmartForm/Paper
    - Procedures
    - Diagnoses
    - Surgical Characteristics
    - Fixation Types

- **Outcomes**
  - Revisions
  - Re-operations
  - Infections
  - VTE

- **Other Data Sources**
  - Claims
  - Diabetes Registries
  - Membership
  - Mortality
  - GEMS

*Obtained from device manufacturer catalogs.
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I. Primary Data Sources

b. Studies
Example: US FDA 522 Postmarket Surveillance Study

- **Goal:** evaluate specific device after introduction to the market because of:
  - Possible serious adverse health consequences
  - Pediatric use
  - Intended to be implanted >1 year or be a life-sustaining/supporting device used outside a facility

- **Sampling Frame:** limited

- **Coverage:** limited

- **Outcomes:** study design/focus varies and information obtained from it varies

- **Available to:** investigators
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Example: Postmarket study of Acell’s MatriStem® Pelvic Floor Matrix

- **Goal:** measure pain, quality of life, adverse events, long term need for retreatment
- **Sampling Frame:** 8 recruiting location’s patient population
- **Coverage:** 162 women
- **Timeframe:** June 2014-2020
- **Available to:** investigators
I. Primary Data Sources

c. Implant retrieval databases
Implant Retrieval Databases

- Repositories of explanted implants and electronic information regarding implants
- Typically several institutions collaborating
- Typically smaller scale
- Biomechanical experts involved
- Passive surveillance
- Availability: institutions only
- Examples:
  - London Implant Retrieval Centre
  - Drextel University Implant Retrieval Research
  - HSS Dept of Biomechanical Implant Retrieval
II. Secondary Data Sources

a. EMR
EMR

- Computerized records of clinical information for providers and patients
- Can cover several areas, including:
  - Medical history
  - Encounter information (inpatient, outpatient, emergency)
  - Laboratory data
  - Imaging services
  - Pharmacy data
  - Operating room information
  - Scheduling/reminder
  - Billing
  - Membership monitoring
Example: KP HealthConnect Structure
KP HealthConnect

- **Goal**: monitor clinical activity
- **Sampling Frame**: US population in 8 geographical regions
- Modules that **could contribute** to device epidemiology:
  - **Patient information**: demographics, characteristics, history of encounters for co-morbidity assessment, death information
  - **Optime**: operating room module—devices (bar codes), surgical characteristics (*operative time, blood loss, etc*)
  - **Encounters**: inpatient, outpatient, and emergency/urgent encounters to identify reoperations, complications
- **Available to**: KP researchers and associated institutions
Example: KP HealthConnect Structure

Web Access Portal

Ancillaries
- Outpatient Pharmacy
- Lab
- Radiology/Imaging
- Others (immunizations, EKG, dictation)

Care Delivery Core
- Outpatient
  - Scheduling
  - Registration
  - Clinicals
  - Billing
- Inpatient
  - Scheduling
  - Admission, Discharge, and Transfer
  - Clinicals
  - Pharmacy
  - Emergency Department
  - Operating Room
  - Billing

Health Plan
- Membership/Benefits
- Claims Processing
- Benefits Accumulation
- Pricing System

Finance
- General Ledger
- Capital Planning
- Financial Reporting

Data Warehouse / EDR Enterprise Data Repository
KP HealthConnect

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II. Secondary Data Sources

b. Claims
Claims

- Health encounter (any) collected for administrative purposes
- Contains major reasons for encounter (diagnoses, procedures) or dispensing information
- Several available files:
  - US Medicare claims
  - US DVA claims
  - Australia DVA Medicare claims
  - US DHHS AHRQ
    - Healthcare Cost and Utilization Project (ambulatory surgery, emergency dept visits, hospitalizations)
    - Medical Expenditure Panel Survey (accessibility of care)
  - Etc.
Example Medical Claims: AHRQ Healthcare Cost and Utilization Project, National Inpatient Sample (NIS)

- **Goal:** National estimates of hospital inpatient stays
- **Sampling Frame:** US
- **Files/variables that could contribute** to device epidemiology:
  - **Patient:** basic demographics, history of encounters for co-morbidity assessment, inpatient death information
  - **Encounters:** diagnoses for procedure, procedure type, and re-operations and/or complications
- **Available to:** Anyone
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Example Pharmacy Claims: Australian DVA dispensing records

- **Goal:** monitor all medication dispensed to eligible veterans
- **Sampling Frame:** Australian Veteran population and spouses
- Files/variables that **could contribute** to device epidemiology:
  - **Patient:** history of medication for co-morbidity assessment
  - **Outcome:** medications used to treat conditions (e.g. antibiotic prescription for infection monitoring)
- **Available to:** UniSA researchers
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II. Secondary Data Sources

c. Others
Death Records

- Vital records, national registries, state records recording death of individuals and reasons for death
- Important to understand limitations and coverage of source
- Availability: mostly easily available, but will cost
- Examples in the US:
  - National Archives: state specific death archives.
  - Social Security Administration: Death Master File
  - CDC/NCHS: National Death Index
Infection Prevention and Control Surveillance

- Different organizations in several countries track hospital acquired (nosocomial) infections for the purpose of monitoring infection, assess effect of prophylactic interventions, and examine infection variation.

- Nosocomial infection include surgical site infections.

- Several procedures with medical devices are included in these data; in the US over 40 procedures are monitored.

- Availability: limited upon request.

- Examples:
  - ECDC- Hospitals in Europe Link for Infection Control through Surveillance (HELICS)
  - CDC/NHSN- Healthcare associated infection tracking system
Implant Manufacturer Catalogs

- Descriptive information on devices:
  - Implant name
  - Short description
  - Long description
  - Attributes- sometimes not standard, usually company specific

- Central repositories are difficult to find

- Some effort from certain groups to harmonize this information into one reference system-
  - ICOR for orthopedics
  - FDA UDI for all devices

- Availability: upon request from manufacturers, larger repositories must be requested from owners
Thank you

- Questions