Using Large Databases to Inform Decision Making: The Kaiser Permanente Experience

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Overview

- Description of KP Databases
- Use of KP Databases Case Study: COX-2 Inhibitors
- Advantages and Limitations
"Sorry, bub. You're not in the database."
KP Membership Data

- 6.1 Million members in California
- Unique Medical Record Number (MRN)
- Demographics
- Linked to US Census block group data
- Linked to State of California death data
KP Inpatient Data

- 90% of hospital discharges from 25 CA hospitals
- Remaining 10% in claims database
- Diagnoses and procedures (DRG, ICD-9, CPT-4)
- Many discharge diagnoses validated
KP Outpatient Data

- Multiple diagnoses for each clinic visit
- Procedures also captured
- Limited clinical measurements such as blood pressure and smoking status
KP Prescription Data

- 99% coverage from 180 pharmacies
- Captures prescriptions and refills
- NDC codes, therapeutic classes
- Quantity, strength, dose
- Clinic-infused medications not completely captured in past, but getting better
KP Lab Data

- Complete outpatient and inpatient lab data
- All lab testing processed in centralized lab
- Includes test results
- Includes pathology reports (SNOMED)
Additional KP Data

- Registries: Cancer, Diabetes, HIV/AIDs
- Paper Medical Records
- Surveys of KP physicians and patients
KP HealthConnect

- Program-wide system that integrates the clinical record with appointments, registration and billing

- Highly sophisticated information management and delivery system
  - Best practice alerts
  - Alternative medication alerts
KP HealthConnect

- **Enhances Research**
  - Data not previously available
  - Weight, blood pressure, race/ethnicity

- **Creates Research**
  - Impact on patient care, cost and outcomes
  - Physician/patient relationships
  - Effectiveness of alternative medication alerts
How Are KP Databases Used to Inform Decisions?

- Support Drug Use Management Initiatives.
- Evaluation of pharmacist-managed ambulatory care clinics.
- Investigate effects of patient cost-sharing.
- Evaluation of therapeutic interchange programs.
- Address questions about drug safety.
- Contribute to national policy regarding important public health issues.
Case Study: COX-2 Inhibitors

- **FDA/Kaiser Vioxx Study**
  

- **Impact of DTC advertising**
  

- **GI Score Tool**
  
  
FDA/Kaiser Vioxx Study

- Early concerns about cardiovascular safety
  - Many patients exposed
  - Heart attack is a fairly common event
  - Small increase in risk could mean thousands harmed

- Study objective: To determine if rofecoxib, celecoxib, ibuprofen, naproxen or other NSAID use increases the risk of AMI and SCD.
  - Nested case-control study
  - 1.4 million NSAID users in base population
  - Three years of data, 1999-2001
  - 8,199 cases and 32,796 controls
Higher-dose rofecoxib (> 25 mg/d) conferred a 3-fold increased risk of AMI and SCD compared with remote use of any NSAID.

Risk was also increased with lower-dose rofecoxib (≤ 25 mg/d) but not significantly so, compared with remote NSAID use.

Naproxen use did not confer a protective effect; rather it increased risk by 14%.
FDA/Kaiser Vioxx Study Impact

- Presented by lead author Dr. David Graham of FDA at ISPE, August 2004.

- APPROVe trial provides evidence of increased risk of cardiovascular events, leading to market withdrawal of Vioxx, September 2004.

- FDA initiatives to strengthen drug safety.
FDA/Kaiser Vioxx Study

Use of KP Databases

- **AMI and SCD**
  - Verification of AMIs via lab data
  - Linked to state death data to capture SCD

- **Inclusion/Exclusion criteria**
  - Use of continuous membership and drug benefit data
  - Use of registries, skilled nursing facility data

- **NSAID exposure**
  - Prescription dates, dose, quantity, days supply, sig
  - Current, recent, remote
FDA/Kaiser Vioxx Study
Use of KP Databases

- **Covariates**
  - Diagnosis and prescription history
  - Use of cardiovascular risk score

- **Telephone survey**
  - OTC use of low-dose aspirin and NSAIDs
  - Family history of AMI and smoking history
DTC Advertising of COX-2 Inhibitors

- **Research Aim:** to determine if patients who were aware of COX-2 DTC ads and asked their doctor about these drugs were appropriately prescribed a COX-2 according to guideline.

- **Guideline:** treatment with either a COX-2 or traditional NSAID defined as appropriate using GI Score Tool. Patients at highest risk for GI bleeding can be appropriately treated with a COX-2.

- **Results:** Patients who saw COX-2 ads and asked their doctor were 4 times more likely to be inappropriately prescribed a COX-2 instead of a traditional NSAID according to guidelines.
DTC Advertising of COX-2 Inhibitors: Use of KP Databases

- Use of both patient survey and databases.
- Data about physicians also included (tenure, age, gender).
- GI Score Tool from survey used to develop and validate “eScore“ Tool.
- eScore used to proactively identify patients who can be appropriately treated with a COX-2.
**GI Score Tool: Survey**

1. **Patient's age in years?**
   - **66 – 70**
     - 8 points
   - **71 – 75**
     - 9 points
   - **76 – 80**
     - 10 points
   - **81 – 85**
     - 12 points
   - **86 – 90**
     - 14 points
   - **>90**
     - 16 points

2. **Current health status as rated by the patient?**
   - **Very Well**
     - 0 points
   - **Well**
     - 1 point
   - **Fair**
     - 2 points
   - **Poor**
     - 3 points
   - **Very Poor**
     - 4 points

3. **Does patient have rheumatoid arthritis?**
   - **No**
     - 0 points
   - **Yes**
     - 2 points

4. **Use of oral prednisone or other oral steroids in past year?**
   - **0 mo**
     - 0 points
   - **1-3 mo**
     - 1 point
   - **4-6 mo**
     - 2 points
   - **7-10 mo**
     - 3 points
   - **11-12 mo**
     - 4 points

5. **Hospitalized for a GI bleed or an ulcer? (If “Yes”, skip #6)**
   - **No**
     - 0 points
   - **Yes**
     - 8 points

6. **Has patient had GI side effects when taking NSAIDS?**
   - **No**
     - 0 points
   - **Yes**
     - 2 points

**Total SCORE (add all points):**

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## GI eScore Tool: Databases

### eSCORE Marker

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>eSCORE</th>
<th>Points Awarded</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. AGE</td>
<td>Membership Data Sets</td>
<td>0 to 18</td>
</tr>
<tr>
<td>2. Health Status</td>
<td>Chronic Disease Score (Automated Pharmacy Data)</td>
<td>0 to 4</td>
</tr>
<tr>
<td>3. Rheumatoid Arthritis</td>
<td>Diagnosis Codes and Automated Pharmacy Data</td>
<td>0 or 2</td>
</tr>
<tr>
<td>4. Corticosteroid Use</td>
<td>Automated Pharmacy Data</td>
<td>0 to 5</td>
</tr>
<tr>
<td>5. Prior GI Bleed</td>
<td>Hospital Records (DRG and ICD-9 Codes)</td>
<td>0 or 8</td>
</tr>
<tr>
<td>6. NSAID Dyspepsia</td>
<td>Automated Pharmacy Data (GI Medication Use)</td>
<td>0 or 2</td>
</tr>
</tbody>
</table>
Correlation between Survey Score and eScore

Scatter Plot

Slope = 0.91
Pearson Corr. = 0.87
p < 0.01
Predictability of $e$Score

Hospitalization Rate for a GI Event versus $e$SCORE

Event Rate per 100 pt yrs NSAID Exposure vs $e$SCORE
Advantages of Large Databases

- Large samples, many years of data
- Stable, diversified population
- Variety of data to capture comorbidities
- Residential information as socioeconomic proxy
- Large number of covariates: propensity scores
“Place under your tongue and swallow. Then spit it out when no one’s looking.”
Limitations of Large Databases

- May be necessary to validate outcomes
- Potential confounding by indication and self-selection
- Incomplete data
- Regional differences
- Lack of data on important variables
- KP not fully representative of U.S. population
Questions/Discussion