KAISER PERMANENTE

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
  - Graham DJ, Campen D, Hui R, Spence M, Cheetham C, Levy G, Shoor S, Ray WA. Risk of acute myocardial infarction and sudden cardiac death in patients treated with cyclo-oxygenase 2 selective and non-selective non-steroidal anti-inflammatory drugs: nested case-control study. The Lancet 2005;365:475-481.
- Impact of DTC advertising
  - Spence MM, Teleki SS, Cheetham TC, Schweitzer SO, Millares M. Direct-to-consumer advertising of COX-2 inhibitors: effect on appropriateness of prescribing. Medical Care Research and Review 2005;62(5):544-59.
- GI Score Tool
  - Cheetham TC, Levy G, Spence M. Predicting the risk of gastrointestinal bleeding due to nonsteroidal anti-inflammatory drugs. J. Rheumatol 2003;30:2241-4.
  - Spence M, Cheetham C, Teleki S. Comparison of electronic versus survey assessment of a patient's risk for NSAID-induced GI hospitalization. Pharmacotherapy 2002;22:420.

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

FDA/Kaiser Vioxx Study Results

- 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 "*e*Score " Tool.
- *e*Score used to proactively identify patients who can be appropriately treated with a COX-2.

GI Score Tool: Survey

SCORE© Tool

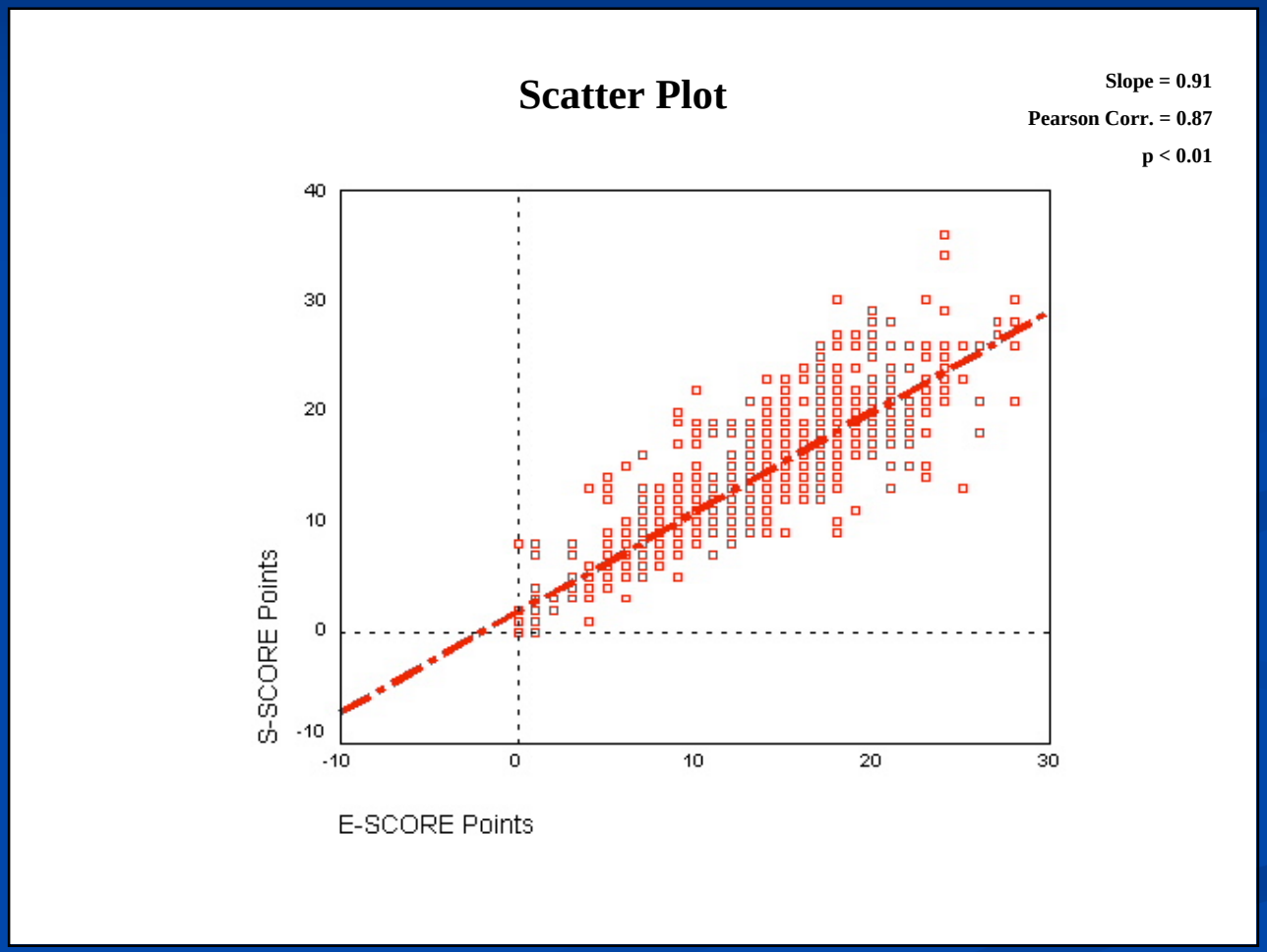
1.	Patient's age in years? **46 – 50** ..... 8 points **51 – 55** ..... 9 points **56 – 60** ..... 10 points **61 – 65** ..... 12 points	**66 – 70** ..... 13 points **71 – 75** ..... 14 points **76 – 80** ..... 16 points **81 – 85** ..... 17 points **>85** ..... 18 points	
2.	Current health status as 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 ..... 3 points	**7-10** mo ..... 4 points **11-12** mo ..... 5 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):* →	

GI *e*Score Tool: Databases

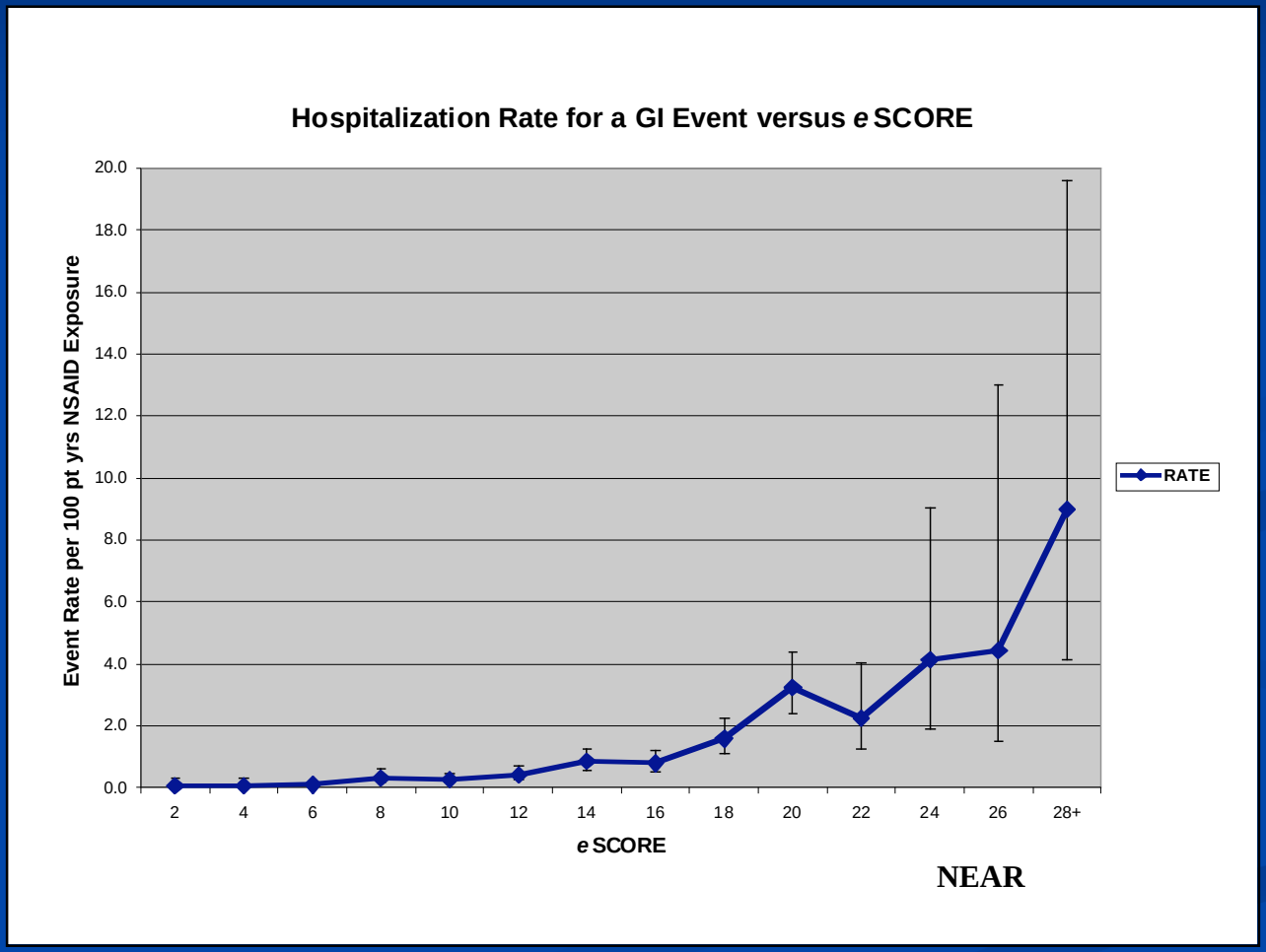
eSCORE Marker

Risk Factor	*e*SCORE	Points Awarded
1. AGE	Membership Data Sets	0 to 18
2. Health Status	Chronic Disease Score (Automated Pharmacy Data)	0 to 4
3. Rheumatoid Arthritis	Diagnosis Codes and Automated Pharmacy Data	0 or 2
4. Corticosteroid Use	Automated Pharmacy Data	0 to 5
5. Prior GI Bleed	Hospital Records (DRG and ICD-9 Codes)	0 or 8
6. NSAID Dyspepsia	Automated Pharmacy Data (GI Medication Use)	0 or 2

Correlation between Survey Score and *e*Score



Predictability of *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