

Using health plan data to improve post-marketing safety

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HMO Research Network

Centers for Education and Research on Therapeutics (CERTs)

First priorities

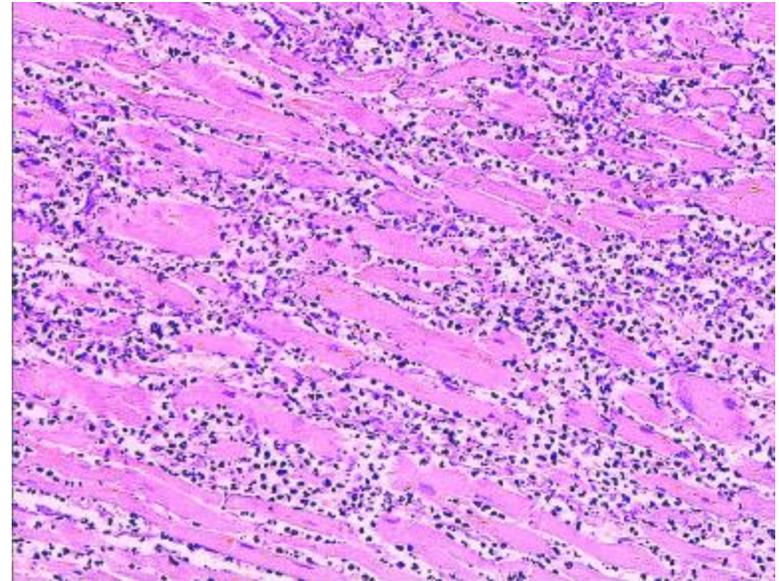
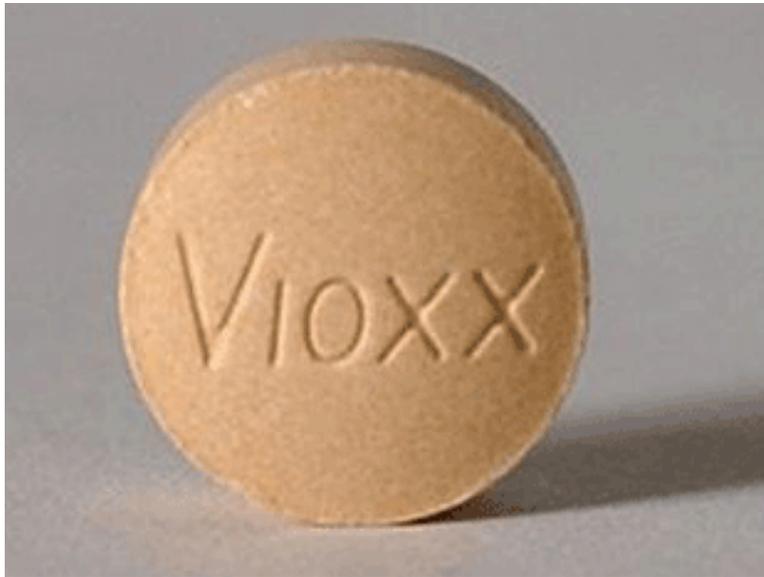
- Detect signals
- Allow followup of signals
- Assess appropriateness of use

- Estimate benefit (comparative effectiveness)

Active surveillance resources

- **Claims+ databases with medical record access**
- Electronic medical record data
- Phase 4 clinical trials
- Large simple trials
- Disease-specific networks
 - Liver (DILIN), kidney, SJS, myopathy, lupus, torsades de pointes
- Registries
- Specimen repositories for patients with rare adverse events

When could we have suspected a link?

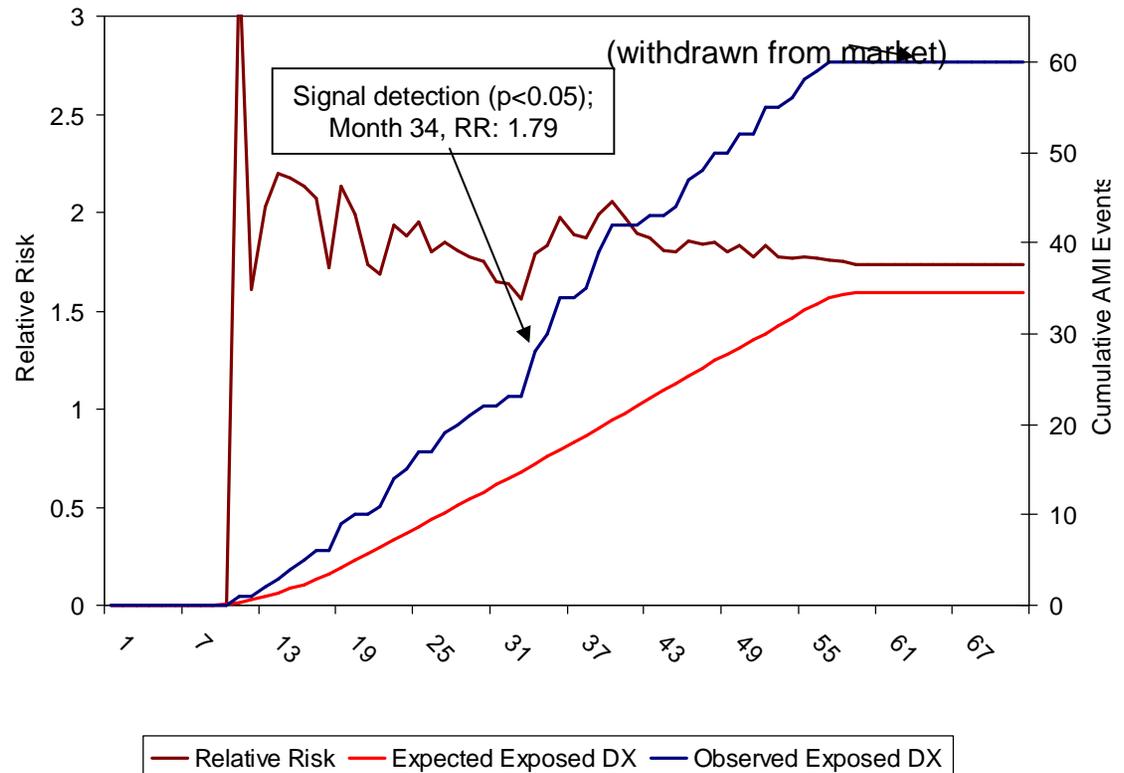


en.wikipedia.org/wiki/Heart_attack

Rofecoxib and myocardial infarction

HMO Research Network CERT – 7 million

- Relative risk rapidly stabilized between 1.5 and 2.
- Signal occurred after 28 heart attacks among new users of drug.
- Would have occurred by 2nd or 3rd month if 100 million people had been observed.

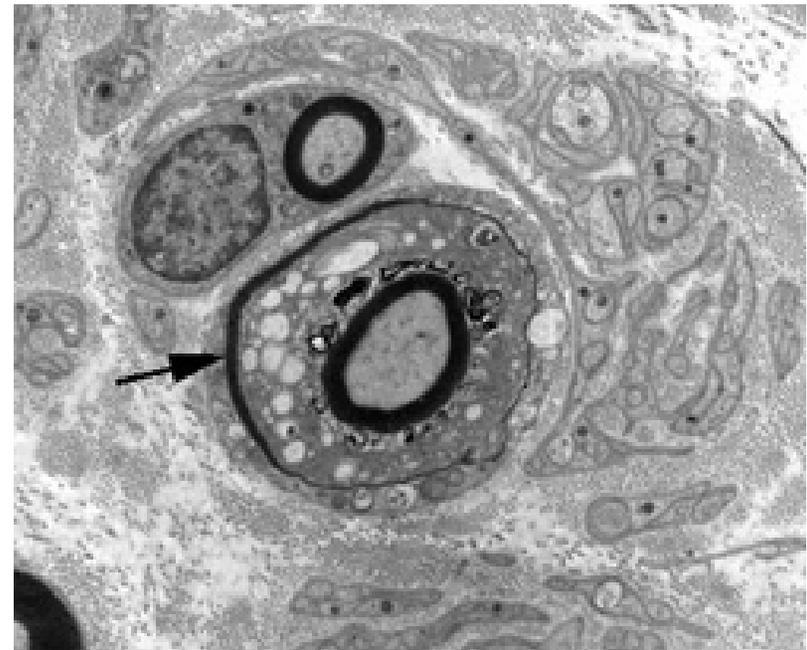


Comparator: naproxen. Adjusted for age, sex, health plan.

Does this?



Cause this?



http://www.sanofipasteur.us/sanofi-pasteur/front/index.jsp?siteCode=AVP_US&lang=EN&codeRubrique=115&codePage=00013 used with permission
<http://neuro.pathology.pitt.edu/webstuff/NeuromuscularPathology.html>

IOM Drug Safety Meeting March 12, 2007

Menactra and Guillain-Barré Syndrome

- Meningococcal conjugate vaccine (Menactra) approved in 2005.
- ACIP recommended immunization of all adolescents.
- 15 spontaneous reports of Guillain-Barré Syndrome (GBS) within 42 days of immunization through September 2006.
- Estimated 5.7 million doses distributed by then.
- Questions:
 - Is there excess risk? If yes,
 - How much?
 - Is there a high risk subgroup?

Menactra and GBS – current resources

- CDC's Vaccine Safety Datalink (~7M lives) is evaluating this
- After one year and 98,514 vaccine doses (11,000 person-years), no cases of GBS among vaccinees
- Background rate: 1-2 cases per 100,000 person-years
- Conclusion: Need larger population!

Existing linked claims databases

- CDC Vaccine Safety Datalink
 - 8 HMO Research Network Health Plans (includes 4 Kaiser Permanente plans)
 - ~7 million lives
- FDA post-marketing surveillance contracts
 - HMORN (13 plans including 4 Kaisers, plus separate California Kaiser contract), United, TN/WA Medicaid.
 - ~ 20 million lives.
- VA system ~6 million lives.

All combine data on eligibility / diagnoses /
procedures / pharmacy dispensing.

All are able to review full text medical records.

Current linked claims databases

- CDC Vaccine Safety Datalink
 - 8 HMO Research Network Health Plans (includes 4 Kaiser Permanente plans)
 - ~7 million lives. Emphasis on pediatric vaccines.
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Linked claims databases

What else we should have

- Medicare. Parts A, B, D
- Medicaid. Most large states
- Private health plans

- For all, need ability to review full text medical records

Menactra and Guillain Barré Syndrome – health plan study

- Cohort study in 4 health plans with 40+ million members. Intended to complement VSD study
- Use claims to identify:
 - Demographic information
 - Eligible person-time
 - Immunizations
 - Potential cases of GBS
- Review medical records of potential cases
 - adjudication by expert panel
- Report to FDA, CDC, manufacturer, public

Coming soon: CERTs Health Plan Consortium for Public Health

- Goal: Improve the safety and safe use of marketed vaccines and prescription drugs by studying their use in large populations of health plan members
- Target population: 100 million
- A planned activity of the Centers for Education and Research on Therapeutics (CERTs)
 - Created under Congressional mandate to be a trusted national resource in therapeutics
 - Administered by AHRQ in consultation with FDA
 - Accepted processes for administering public-private partnerships

CERTs Health Plan Consortium for Public Health – Aims

- Timely risk identification and quantification
 - Prospective evaluation of new therapeutics captured by health plan data
 - focus on pre-defined list of potential problems
 - Detailed followup of selected problems
- Identification of potentially unsafe use of preventive therapeutic agents
- Other topics, subject to Board approval

CERTs Health Plan Consortium for Public Health – Structure and governance

- Public-private partnership
 - health plans, federal agencies, industry, foundations, academic community
- Broadly representative governing board
- Research limited to public health priorities, as determined by Board with input from Council of Stakeholders
- Specific research topics can be proposed by any agency, group or individual
 - Must have agreement of at least one federal agency

CERTs Health Plan Consortium for Public Health – Data sources

- Health plans' claims data
 - Standard format files: eligibility, demographics, diagnoses, procedures, drug dispensing
 - Pre-processed to allow rapid queries via re-usable data tools
 - Updated at regular intervals
 - Ongoing quality checking
- Access to full text medical records as needed
- Other data increasingly available
 - Laboratory test results
 - Electronic medical record information

Any health plan can opt in/out of specific uses.

CERTs Health Plan Consortium for Public Health – Transparency

- Study protocols available for public comment before they are finalized
- Protocols available to public when study commences
- Results placed in public domain

CERTs Health Plan Consortium for Public Health – Confidentiality / Privacy

- Protection for individuals via HIPAA privacy regulations and federal human research rules
- Protection of health plans' identities and proprietary data

CERTs Health Plan Consortium for Public Health – Funding

- Infrastructure requires core funding
- Individual projects will require separate funding

CERTs Health Plan Consortium for Public Health

- Existing health plan data allow substantial enhancement of timeliness, power, and efficiency of post-marketing studies of therapeutics
- This information can/should complement other sources – Medicare/Medicaid, VA, Vaccine Safety Datalink