How Can Addition of the UDI to Claims Inform Device Active Surveillance?

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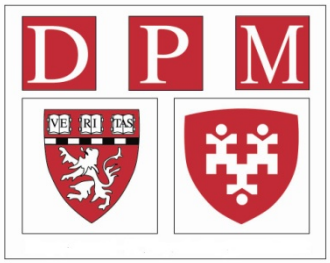
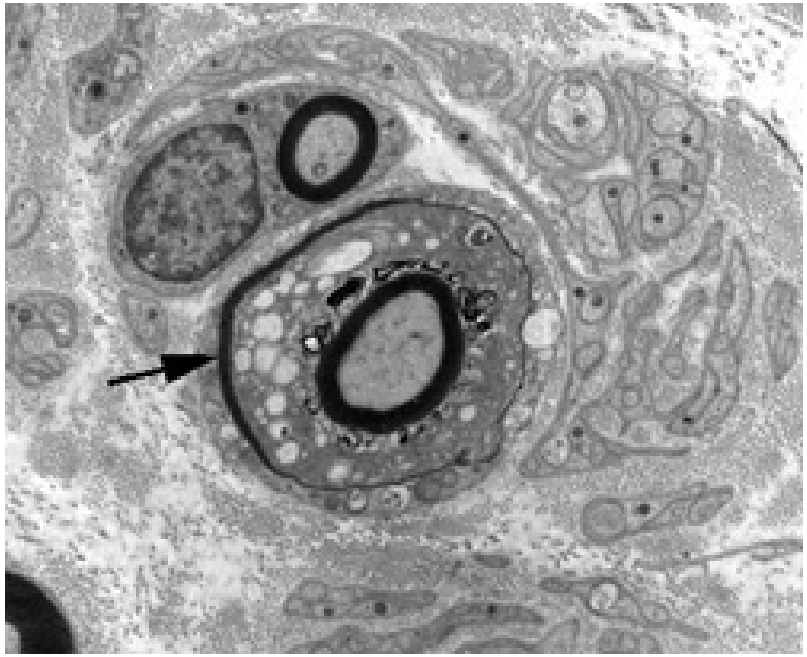


Does this?

Cause this?



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http://neuro.pathology.pitt.edu/webstuff/NeuromuscularPathology.html

Meningococcal Vaccine & Guillain-Barré Syndrome

- **Problem:** New meningococcal vaccine might increase GBS risk
- **Methods:**
  - Retrospective study of 12.6 million 11- to 21-y.o. members of five US health plans
  - Enrollment and claims identified the eligible population, vaccinations, and possible cases of GBS
  - Cases confirmed by medical record review
- **Results:**
  - 99 confirmed GBS cases during 18.3 million person-years (5.4/1,000,000 person-years)
  - 1.4 million meningococcal vaccinations
  - No confirmed case of GBS within 6 weeks after vaccination
  - Maximum potential excess risk <1.5 cases per million doses.
- **Conclusion:** <u>No increased risk</u>

Velentgas Pharmacoepi Drug Saf. 2012 Jul 16. doi: 10.1002/pds.3321

GBS Study Takeaways

- Administrative data provided “free” exposure information and preliminary outcome data
  - Population base was meaningful fraction of U.S. population
  - Many exposures captured via unique claims code
  - Outcomes could be confirmed by review of small number of medical records
- One-off approach doesn’t scale
  - Study required years to design and implement
  - Expensive
- New methods/capabilities needed to study many other products

Mini-Sentinel Partner Organizations



Mini-Sentinel Distributed Database

- 126 million individuals*
  - 345 million person-years of observation time
  - Most medically-attended events are known
  - 13 million people have laboratory test results
- 2.4 billion encounters
  - 40 million hospitalizations
- 3 billion dispensings

*As of 12 December 2011. The potential for double-counting exists if individuals moved between data partner health plans.

Data types under development

- State birth registries
- Electronic Health Records

Full text records

- 90% are available
- Uses
  - Confirm critical exposures / outcomes
  - Obtain historical / clinical detail not in electronic data

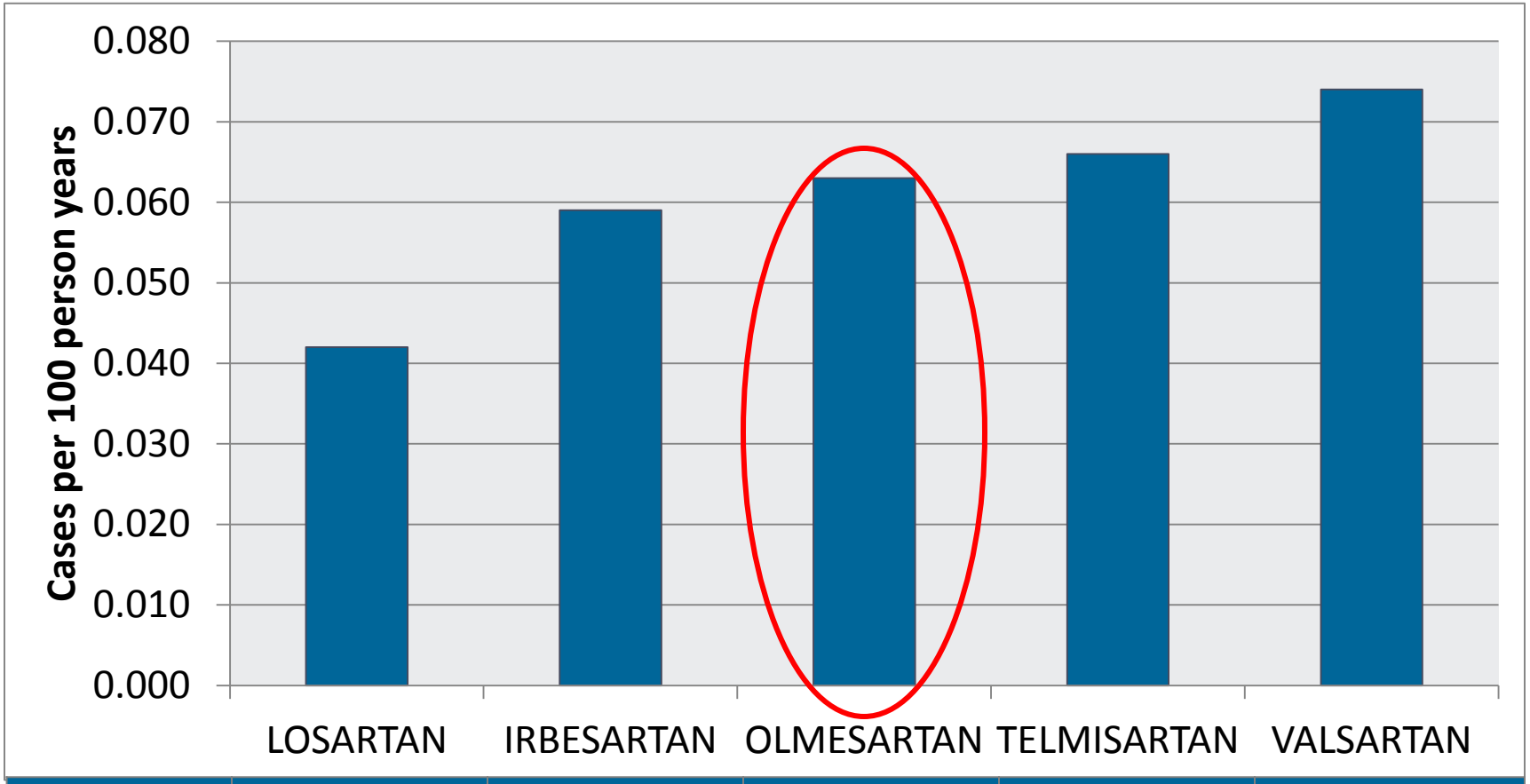
Kinds of active surveillance

- Older products
  - Standard
  - Custom
- New products
  - Prospective sequential

ARBs and celiac disease

- Potential signal identified in spontaneous reports
- Review of cases inconclusive

ARBs and celiac disease



Cases	63	10	17	5	50
New users	235,630	40,071	81,560	24,596	153,159

ARBs: New users after ≥365 day washout; Celiac Disease: 1st dx code after >365 day without diagnosis.

One-Time Protocol-based Assessments

- Rotavirus Vaccines and Intussusception
- Influenza Vaccine and Febrile Seizures
- Influenza Vaccine and Pregnancy Outcomes
- HPV4 vaccine and Venous thromboembolism
- ACEIs/ARBs/aliskiren and Angioedema

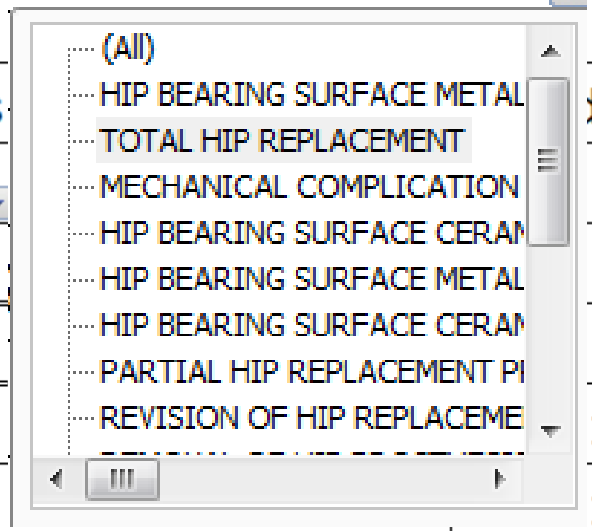
Common Data Model – Dispensing Table

Variable Name	Variable Format (Bytes)	Values
PatID	Char (Site Specific length)	Unique member identifier
RxDate	Numeric (4)	SAS Date
NDC	Char (11)	National Drug Code
RxSup	Num (4)	Days supply
RxAmt	Num (4)	Amount dispensed

One record per person per NDC per day

Total hip replacement procedures

Procedure/Diagnosis Name	TOTAL HIP REPLACEMENT	Selecting year here will update table below and



Sum of Events			
Age Group	2008	2009	2010
0-21	47	48	47
22-44	1,559	1,412	1,172
45-64	14,932	15,024	12,402
65+	17,374	17,566	15,019

http://minisentinel.org/assessments/diagnoses_and_medical_procedures/details.aspx?ID=134

How can claims-based systems inform device surveillance NOW?

- Complement to existing registries
  - Linkage can avoid need to collect some outcome data
- A “poor man’s” registry
  - For selected devices when there is no stand alone registry

How COULD claims-based systems with UDIs inform device surveillance?

- Obviate need for registries to collect exposure data
- Assess a wide range of device use and outcomes topics
  - Safety, Utilization, Effectiveness, Quality of care, etc.
- Multiple types of assessments
  - Rapid, using pre-planned analyses
  - Protocol-driven
  - Prospective
- Modest extra cost to add to existing assessment systems

Thank you!