Distributed Research Networks: Lessons from the Field

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Selected Federally-funded Distributed Networks

- CDC
  - Vaccine Safety Datalink
- NIH
  - NCI Cancer Research Network
  - NHLBI Cardiovascular Research Network
  - NIMH Mental Health Research Network
- AHRQ
  - Center for Education and Research in Therapeutics
  - Developing Evidence to Improve Decisions about Effectiveness
  - Scalable PArtnering Network for Comparative Effectiveness Research
- FDA
  - Medication Exposure in Pregnancy Risk Evaluation Program
  - FDA Mini-Sentinel
- ONC
  - MDPHnet
Distributed Model Principles

• **Send questions to the data**
  – *What are responsibilities for ensuring a valid answer?*

• Data is kept in the hands of the original data holders
  – Decrease proprietary and liability concerns
  – Decrease risk and severity of data breaches
  – Data holders know their data; improve value and better interpretation of findings

• Minimize data transfer; minimum necessary

• Voluntary – data partner autonomy

• Reciprocity – value for participation

• Partnership

• Well-defined purpose
Guillain Barre Syndrome in Pregnancy?

http://www.unilim.fr/neurolim/Images/GuillainBarre01.jpg
There’s more than one kind of GBS

Guillain Barre – GBS

Group B Streptococcus – GBS

http://www.unilim.fr/neurolim/Images/GuillainBarre01.jpg
Implementing Distributed Networks

• Establish clear purpose and governance
• Develop policies
  – Coordinating center
• Define necessary data elements
  – Common data model
• Adopt a query approach
The Evolution of Distributed Networks

• Initial networks supported a single study. Each required large start up time, effort, and cost.
  – Works but not scalable

• 2\textsuperscript{nd} generation networks focus more on data infrastructure and efficiency
  – Improved throughput and efficiency, not scalable

• New networks use software tools and standardized querying approaches
  – Greatly improved efficiency (days not months)
  – Software-enabled querying and governance
  – Scalable
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  - **FDA Mini-Sentinel**
- ONC
  - MDPHnet
Welcome to Mini-Sentinel

Mini-Sentinel is a pilot project sponsored by the U.S. Food and Drug Administration (FDA) to inform and facilitate development of a fully operational active surveillance system, the Sentinel System, for monitoring the safety of FDA-regulated medical products.

Mini-Sentinel is one piece of the Sentinel Initiative, a multi-faceted effort by the FDA to develop a national electronic system that will complement existing methods of safety surveillance.

Mini-Sentinel Collaborators include Data and Academic Partners that provide access to health care data and ongoing scientific, technical, methodological, and organizational expertise.
Mini-Sentinel Partner Organizations

Contact: Jeff_brown@hphc.org
MSDD at a Glance

- Populations with well-defined person-time for which medically-attended events are known
  - 126 million individuals*
    - 345 million person-years of observation time (2000-2011)
    - 44 million individuals currently enrolled, accumulating new data
    - 27 million individuals have over 3 years of data

*As of 12 December 2011. The potential for double-counting exists if individuals moved between data partner health plans.
MSDD at a Glance* (cont.)

• 3 billion dispensings
  – Accumulating 37 million dispensings per month
• 2.4 billion unique encounters
  – 40 million acute inpatient stays
  – Accumulating 41 million encounters per month including over 400,000 hospitalizations
• 12.6 million people with ≥1 laboratory test result**

*As of 12 December 2011
**Laboratory results from 9 sites include: alkaline phosphatase (ALP), alanine aminotransferase (ALT), total bilirubin, glucose (fasting and randomized), glycosylated hemoglobin (HbA1c), creatinine, hemoglobin, international normalized ratio (INR), fibrin d-dimer, absolute neutrophil count (ANC), and lipase
Query Distribution/Response

1- User creates and submits query (a computer program)
2- Data partners retrieve query
3- Data partners review and run query against their local data
4- Data partners review results
5- Data partners return results via secure network
6 Results are aggregated
Secure architecture
Applies governance policies
Role-based access control

www.popmednet.org
Welcome: Mini-Sentinel Operations Center 1

Mini-Sentinel Query Tool

What's New

Software Version: 2.3.14 Features and Enhancements
- Summary Emails: Go to the Notifications Tab to enable emails at daily, weekly, or monthly intervals.
- Code Search Page: Located under the Query Tab; search for codes within each query type. Export a code list to an Excel file, CSV file, or a new query.
- New Query Type: Under the Query Tab, the summary query Most Frequent Utilization captures the top XX users or events for each query type.
- For more features, see the Full release notes.

Your login credentials (password) will expire in 5 day(s). Please change your password from the Administration > Users menu option.

Notifications

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<tr>
<th>Priority</th>
<th>Notification</th>
<th>Sent</th>
<th>Message</th>
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<td>High</td>
<td>New Results</td>
<td>5/8/2012 1:05:02 AM</td>
<td>[MSY3_68_HCPCS(447)] from HealthCore was uploaded by HealthCore-DM Admin 6 on 5/7/2012 11:27 AM for your query.</td>
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Smoking Cessation Drugs and Cardiac Outcomes

FDA indicates intent to query Mini-Sentinel

Smoking Cessation Drugs and Cardiac Outcomes

FDA indicates intent to query

4PM FDA provides final specs

Smoking Cessation Drugs and Cardiac Outcomes

- FDA indicates intent to query
- 4PM FDA provides final specs
- 6PM Programs distributed to 17 data partners


Confidential. Do no distribute.  Contact: Jeff_brown@hphc.org
Smoking Cessation Drugs and Cardiac Outcomes

* High level summary with data from 13 data partners; complete report on 7/12

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Multiple Networks Sharing Infrastructure

- FDA Mini-Sentinel
- CDC
- Prof Societies
- NIH
- PhRMA

Health Plan 1
- Health Plan 4
- Health Plan 7
- Hospital 1

Health Plan 2
- Health Plan 5
- Health Plan 8
- Hospital 2

Health Plan 3
- Health Plan 6
- Health Plan 9
- Hospital 3

Hospital 4

Hospital 5

Outpatient clinic 1

Outpatient clinic 2

Outpatient clinic 3

Outpatient clinic 4

Outpatient clinic 5

Outpatient clinic 6
Multiple Networks Sharing Infrastructure

- Each organization can choose to participate in multiple networks
- Each network controls its governance and coordination
- Networks share infrastructure, data curation, analytics, lessons, security, software development
Thank You