

Sentinel Initiative Public Workshop

The Brookings Institution

Marriott at Metro Center • Washington, DC

Tuesday, January 14, 2014



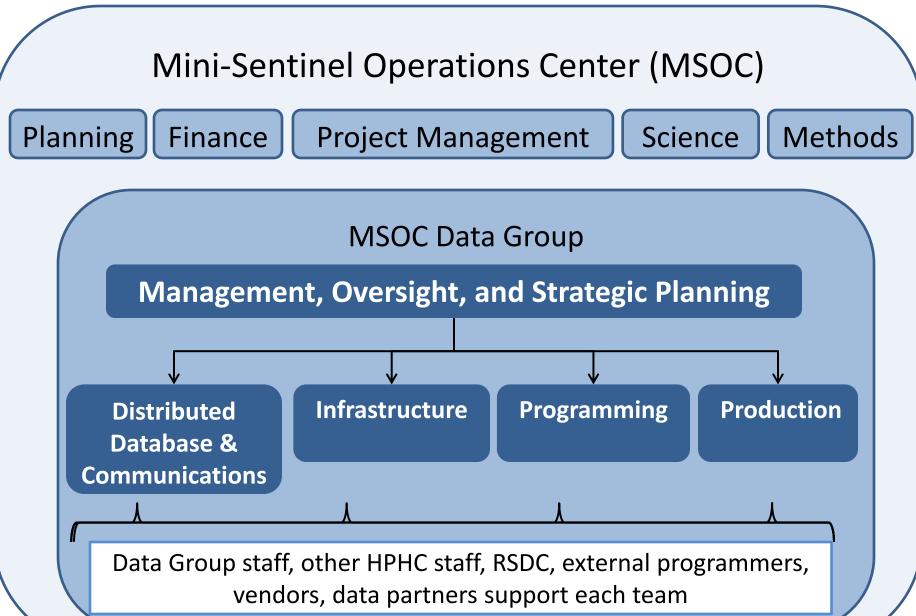
Sentinel Initiative Public Workshop Panel: Overview of Enhancements Underway to Mini-Sentinel

Overview of changes in Mini-Sentinel data querying capacity, tools, systems and data

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for the Mini-Sentinel Data Core

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Growing demands require ongoing system upgrades and expansion of capabilities

- Increased use of rapid response querying
- New types of surveillance (eg, PROMPT)
- More workgroups expanding into new areas
 - Laboratory results
 - Inpatient data
 - External linkages



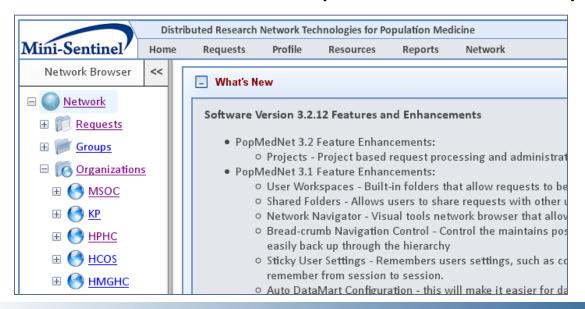
System Upgrades (selected)

- Standard operating procedures
- Standardization to improve throughput and support reporting tools
- Secure infrastructure
- Query tracking and query metadata tracking
- Mechanisms to bring lessons learned and network information closer to the investigators



Distributed query tool

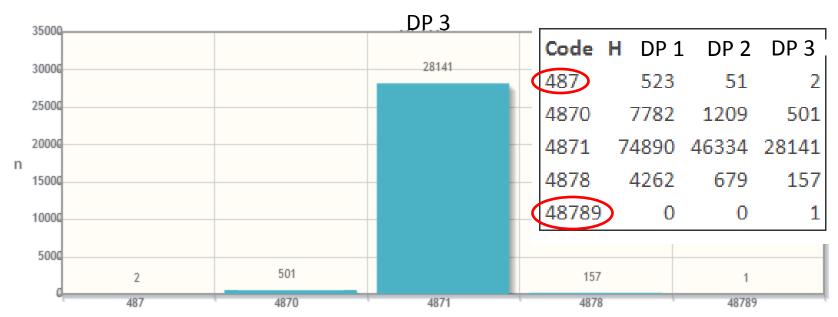
- Software to enable secure distributed querying
- Now used by NIH, PCORI, and others to build networks
- New features
 - Improve query tracking and reporting functions
 - Query metadata searching (who has queried what)
 - Rapid data characterization queries across data partners





Data checking query: Diagnosis code review

Quickly investigate codes by partner



Sample data (influenza)



Expansion of Modular Program Capabilities (selected)

- Attrition tables in standard output
- Availability of laboratory results
- Incidence risk ratio from Modular Program results
- Event rate during concomitant medication use
- ☐ Highly-flexible exposure and outcome definitions (Combo Tool)

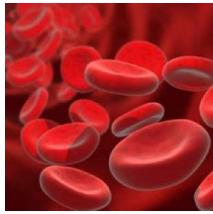


Planned Enhancements

- Testing environment and processes
- Query creation and report processing
- Add new data elements into existing tools
- Query metadata capture and reporting
- Streamline request execution
- Report automation
- ☐ Training material (videos, documentation)



Blood Safety Continuous Active Surveillance Network (BloodSCAN)



http://www.newsrx.com/images/sizeduploads/topics/blood1-300x300.ipg

- Develop an active surveillance system for regulated blood component and bloodderived product use
- Identify and verify potential safety concerns
 - Recipient safety
 - Non-infectious complications



Feasibility/Test Case Evaluation

- Identify data sources
 - Inpatient electronic health data with blood components & blood-derived products
- Evaluate the granularity and completeness of the inpatient data
- Transform relevant data elements into a Common Data Model
- Test this data source using an exposure outcome pair that would occur during a single hospitalization





Hospital Corporation of America Test Case

- □ Goal: Evaluate rates of transfusion-related acute lung injury (TRALI) after transfusion of red blood cells, platelets and plasma, using inpatient EHR data
- Exposure: red blood cells, platelets, plasma
- Outcome: TRALI
 - TRALI occurs within first 6 hours after a transfusion
- Chart confirm exposure and outcome



Ongoing Work

- □ Create and populate new inpatient data tables in the Mini-Sentinel Common Data Model
 - These will apply to other potential sources of inpatient EHR data
 - Capture inpatient blood component and blood-derived product data
- □ Test case: assess incidence of TRALI after blood component transfusion
- Assess utility of new inpatient data



Post-licensure Rapid Immunization Safety Monitoring system (PRISM)

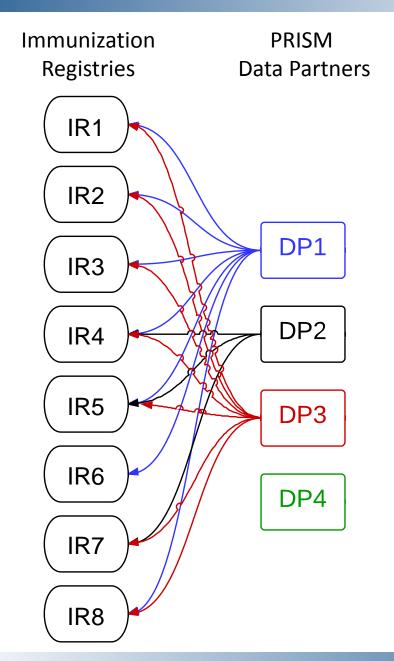
- Establish a national system for active vaccine safety surveillance within Mini-Sentinel
- Address key gaps in existing vaccine safety monitoring capabilities
 - Building capacity to study the safety of vaccines in pregnant populations



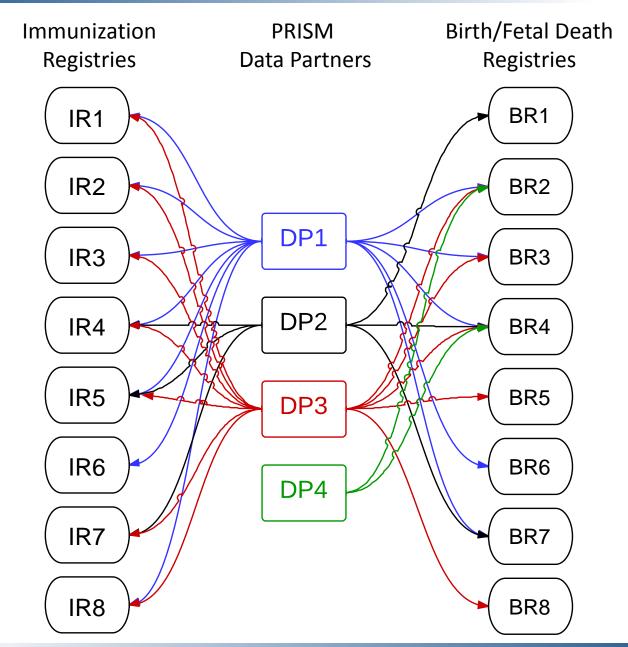
Vaccine Safety in Pregnancy

- Our knowledge of the safety of medication and vaccine use during pregnancy is limited
- Birth certificate and fetal death report data provide information on factors that may affect adverse pregnancy outcomes and birth outcomes











Current Progress and Ongoing Work

- Developed standard file structures for birth and fetal death data
- Linkage accomplished for 2 states
 - Assessment of matching underway
- Linkage with 8 immunization registries completed
 - Assessment of contribution of immunization registries underway



Thank you