The role of health data in the Learning Health System

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Which Treatment is Best for Whom?
High-Quality Evidence is Scarce: < 15% of guideline recommendations are supported by high quality evidence

ORIGINAL CONTRIBUTION

Scientific Evidence Underlying the ACC/AHA Clinical Practice Guidelines

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CLINICAL PRACTICE GUIDELINES are systematically developed statements to assist practitioners with decisions about appropriate health care for spe-

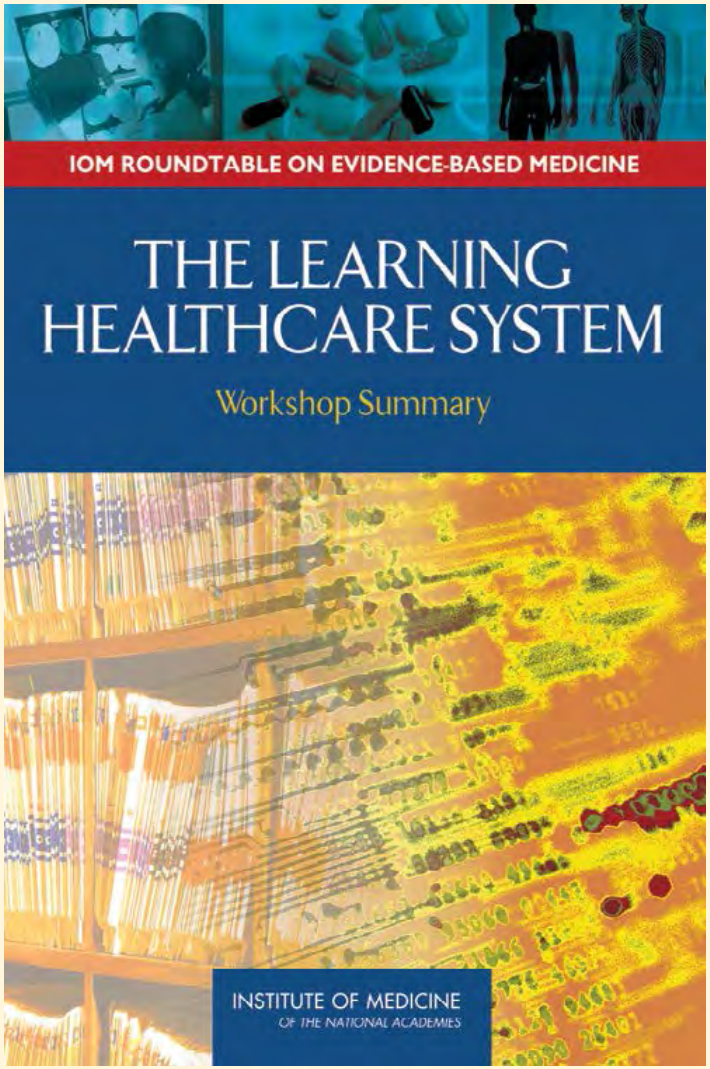
Context The joint cardiovascular practice guidelines of the American College of Cardiology (ACC) and the American Heart Association (AHA) have become important documents for guiding cardiology practice and establishing benchmarks for quality of care.

Objective To describe the evolution of recommendations in ACC/AHA cardiovascular guidelines and the distribution of recommendations across classes of recommendations and levels of evidence.

Data Sources and Study Selection Data from all ACC/AHA practice guidelines issued from 1984 to September 2008 were abstracted by personnel in the ACC Science and Quality Division. Fifty-three guidelines on 22 topics, including a total of 7196 recommendations, were abstracted.

Tricoci P et al. JAMA 2009;301:831-41

Learning Healthcare System



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Advising the nation / Improving health

"The increased complexity of health care requires a sustainable system that gets the right care to the right people when they need it, and then captures the results for improvement. **The nation needs a healthcare system that learns.**"

The role of electronic health information

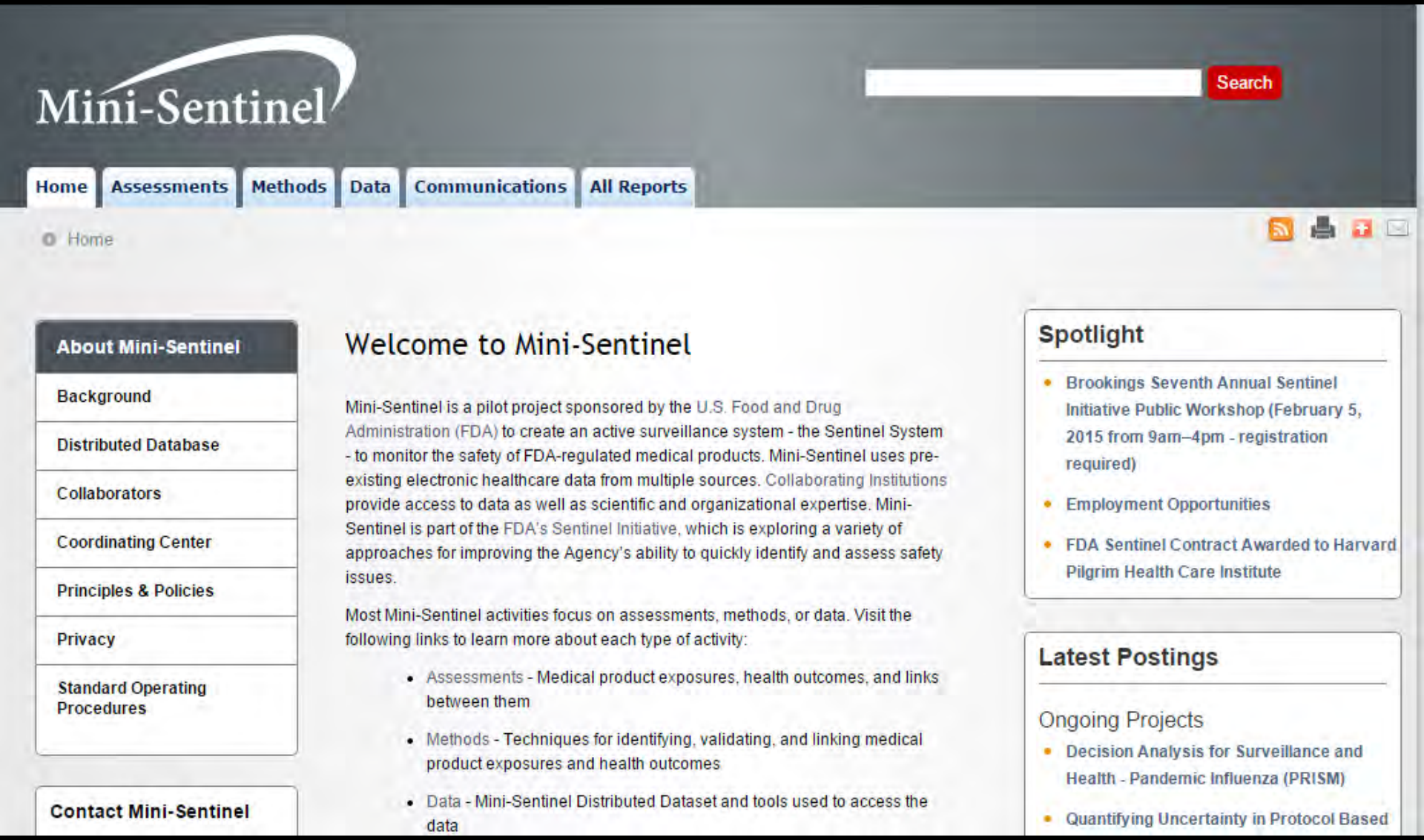
- Electronic health records and billing data are irreplaceable for
- Answering many clinical questions
  - Effectiveness and safety of medical practices
  - Understanding which treatments work best for specific groups like children, the elderly, pregnant women, etc.
  - Quality of care, overall and in specific health systems
  - Assessing health status of communities
  - Guiding public health interventions and measuring impact
- Identifying patients who might want to participate in clinical trials

Base conditions

- Some questions require use of fully identified information, e.g., linking to the National Death Index
- Not possible to obtain individual consent for all uses of individuals' data
- Not possible to notify all individuals personally about all uses of their data
- Opt out provisions can make answers unreliable

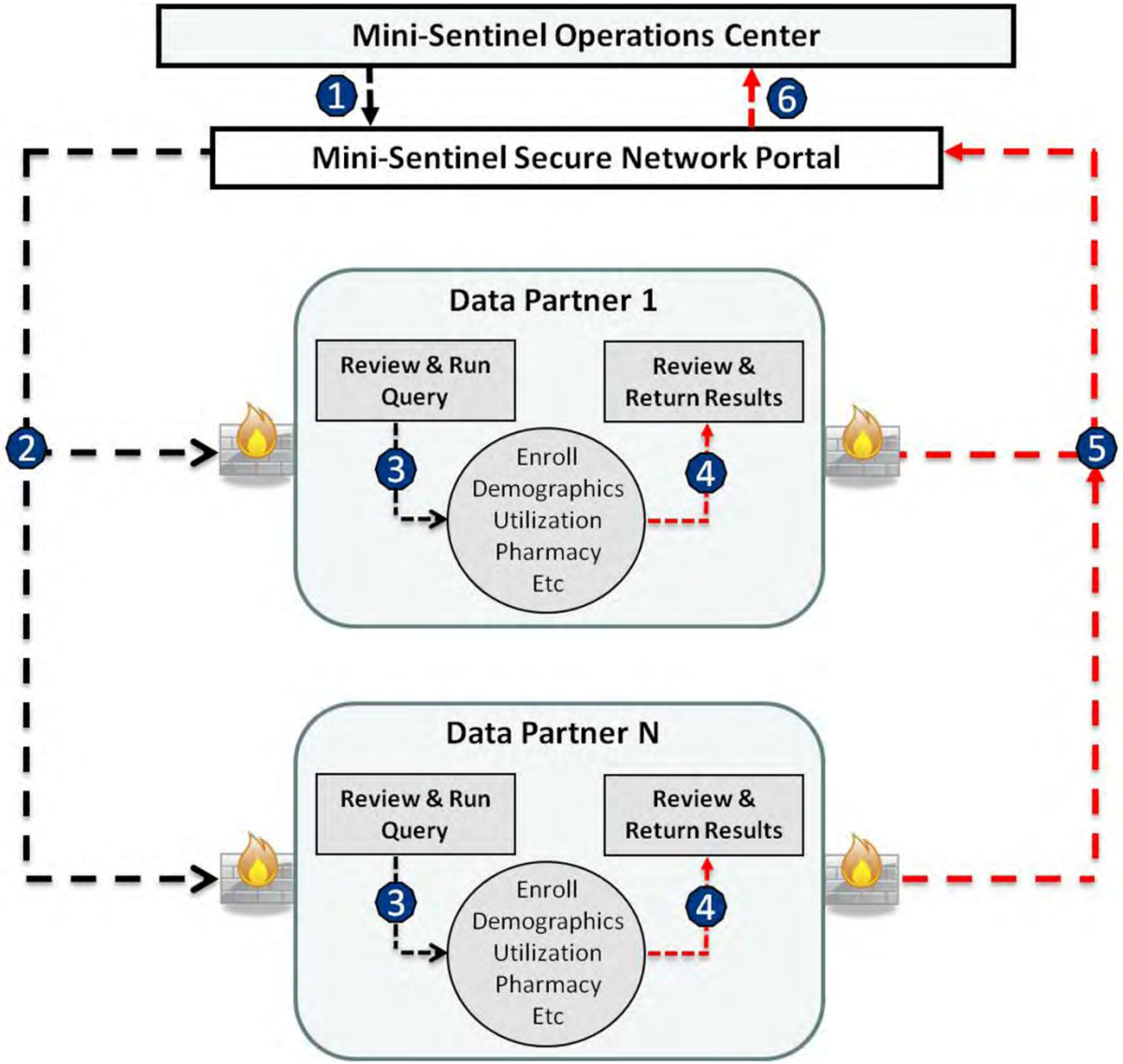
Suggested conditions for use

- The minimum necessary amount of identifiable data should be used
- Approval and oversight should always be required
- Specific uses of data should be stated publicly
- The number of individuals with access to personal medical information should be minimized



www.mini-sentinel.org

Mini-Sentinel Distributed Analysis



1- User creates and submits query (a computer program)

2- Data partners retrieve query

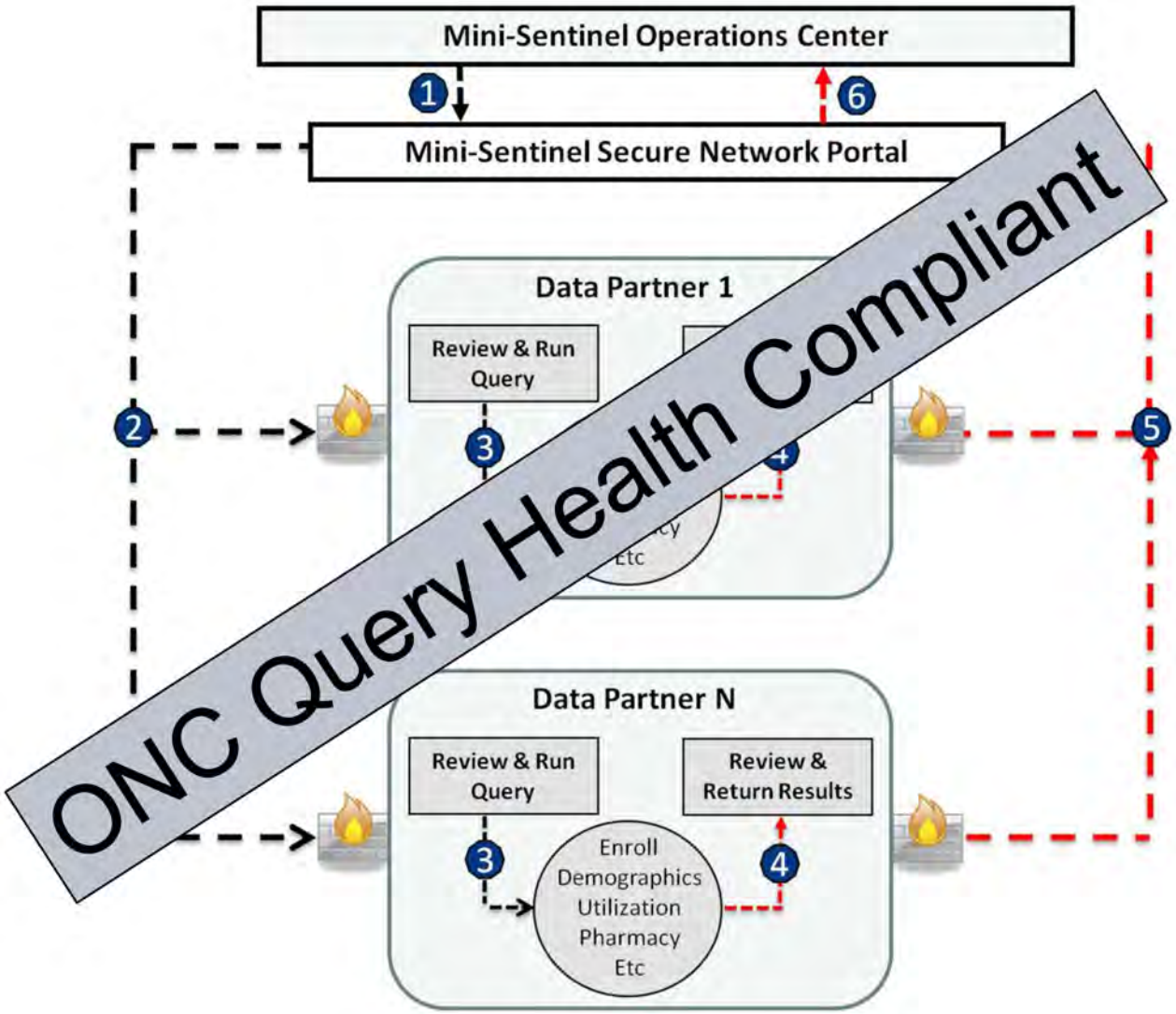
3- Data partners review and run query against their local data

4- Data partners review results

5- Data partners return results via secure network

6 Results are aggregated

Mini-Sentinel Distributed Analysis



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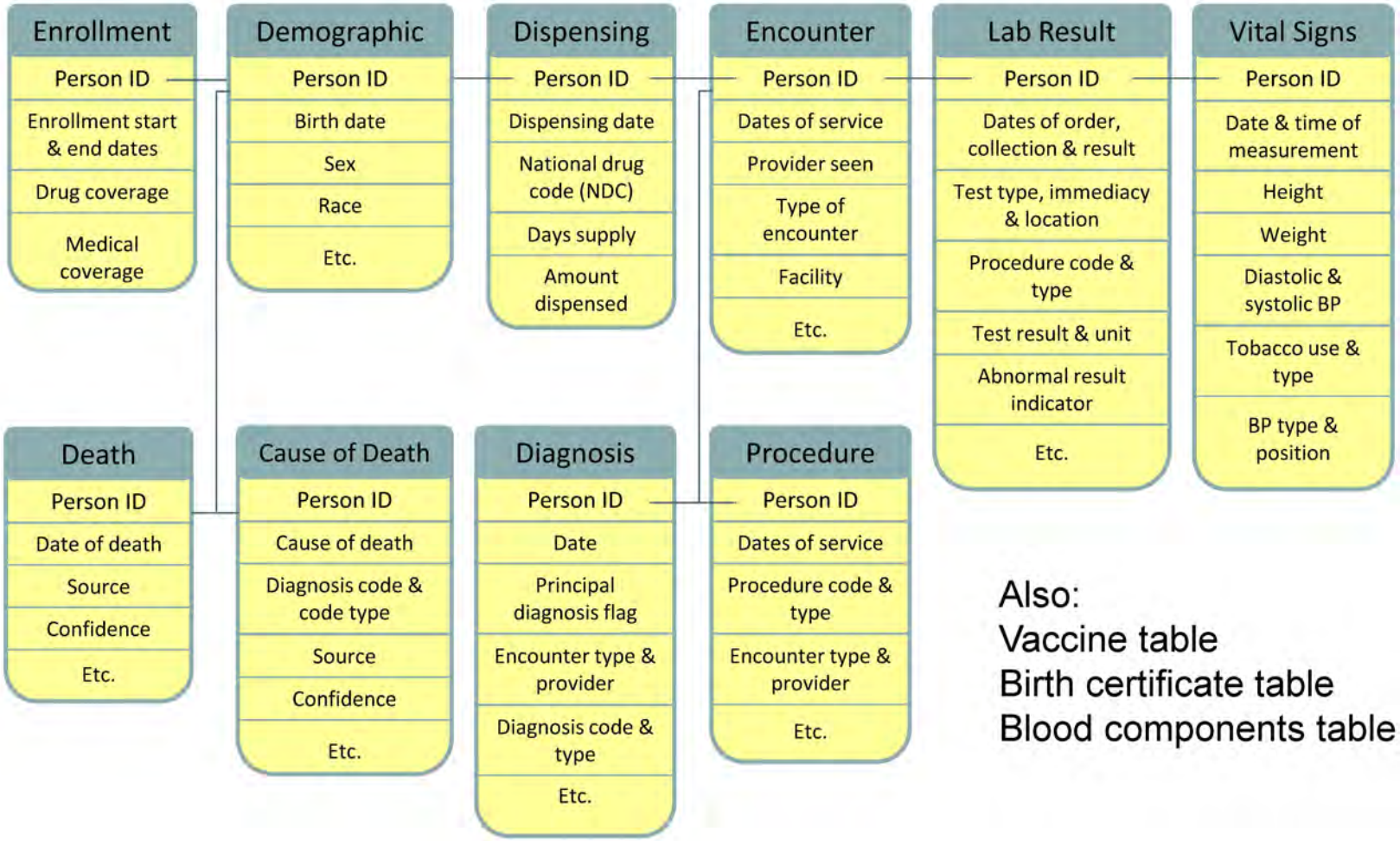
Mini-Sentinel's Common Data Model



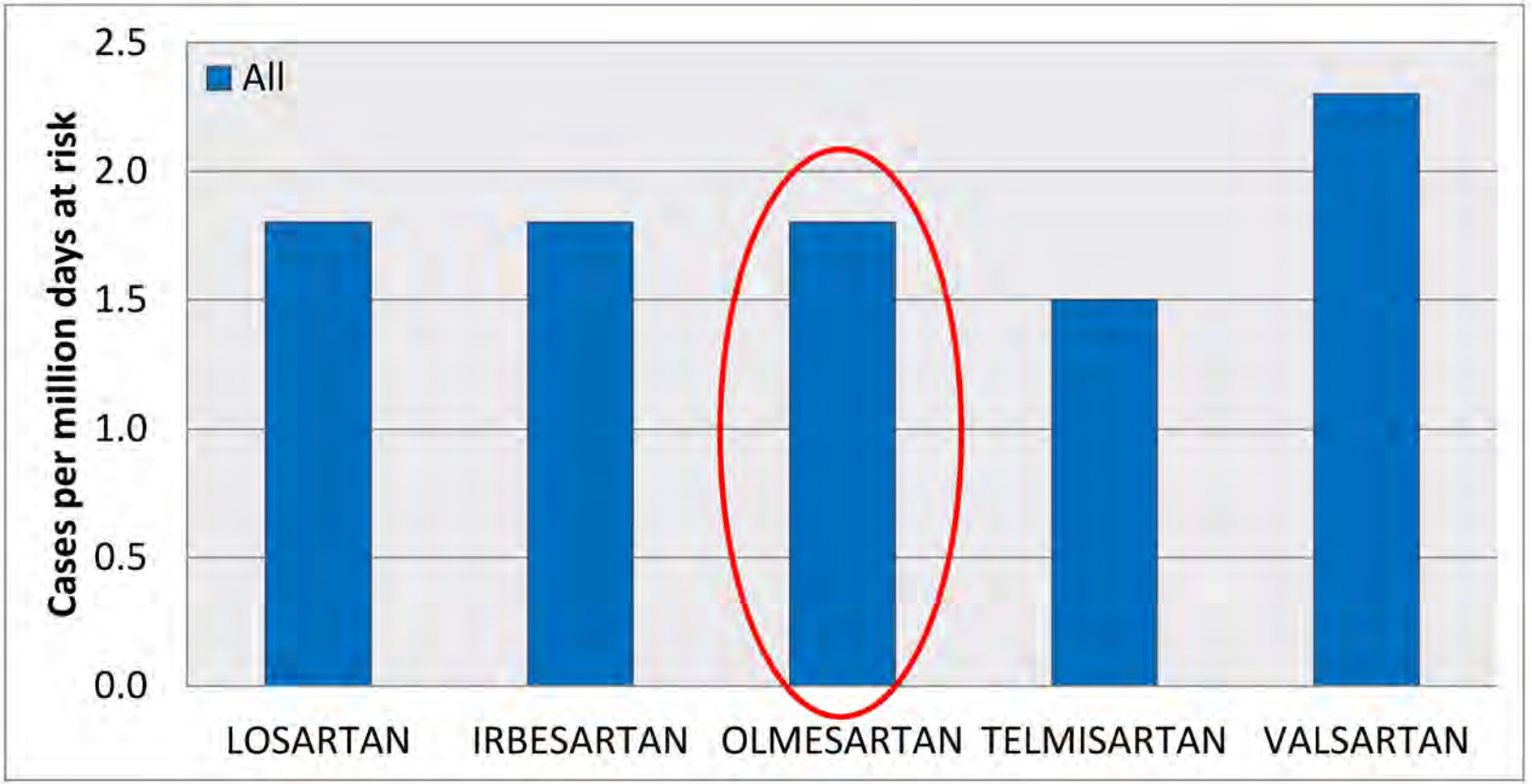
www.minisentinel.org/data_activities/distributed_db_and_data/details.aspx?ID=105

Mini-Sentinel Distributed Database*

- Populations with well-defined person-time for which most medically-attended events are known
- 358 million person-years of observation time
- 48 million people currently accruing new data
- 4 billion dispensings
- 4.1 billion unique encounters
  - 42 million acute inpatient stays
- 30 million people with ≥1 laboratory test result

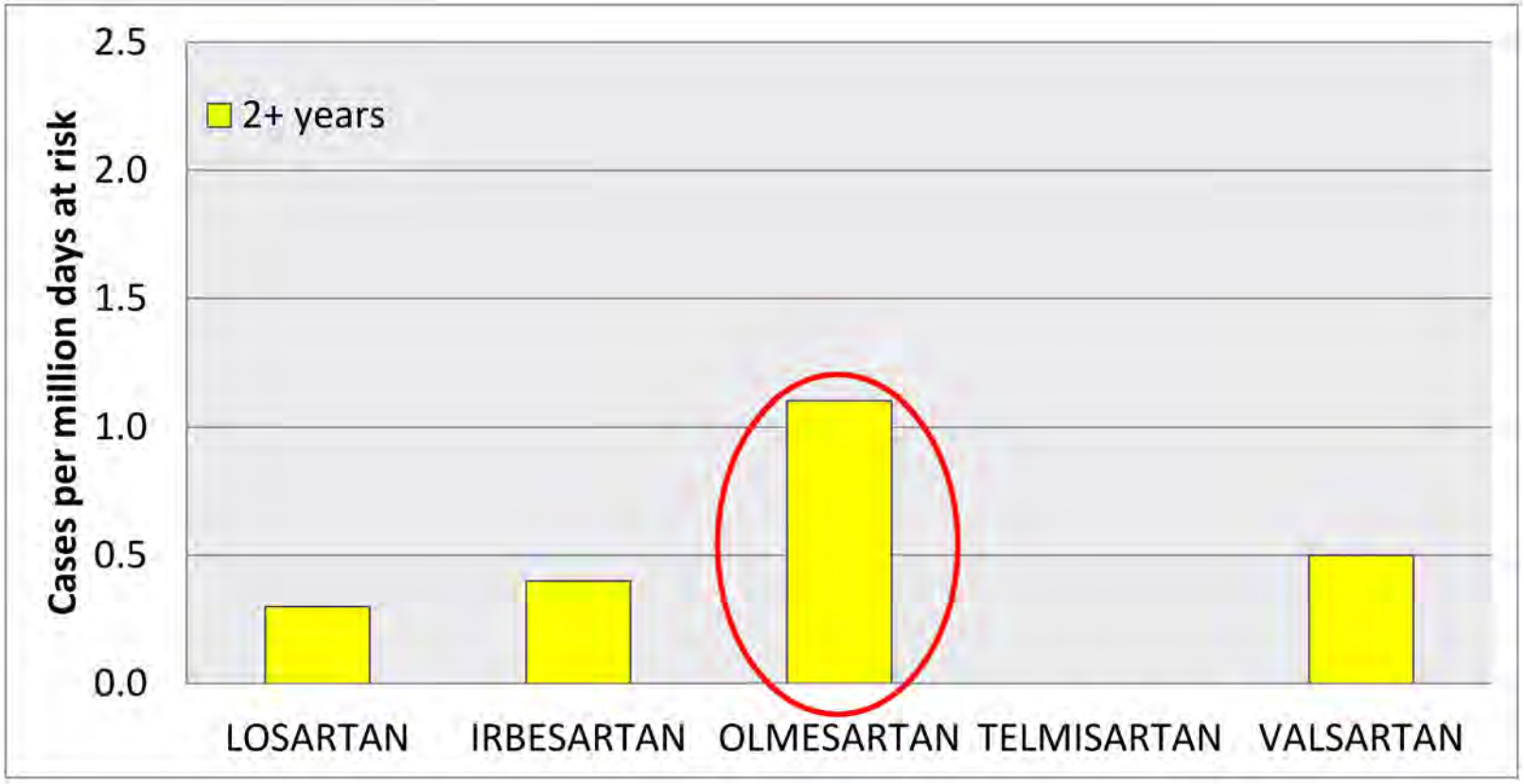
*As of July 2014

ARBs and celiac disease: all users



Cases	213	28	55	10	150
New users	535,045	69,868	171,630	44,770	346,618

ARBs and celiac disease: 2+ years



Cases	9	1	5	0	7
New users	25,045	2,721	4,419	1,124	13,925

Drugs

Drug Safety and Availability
- Drug Alerts and Statements
- Importing Prescription Drugs
- Medication Guides
- Drug Safety Communications

Drug Shortages

Postmarket Drug Safety Information for Patients and Providers

Information by Drug Class

Medication Errors

FDA Drug Safety Newsletter

Drug Safety Podcasts

Safe Use Initiative

Drug Recalls

Drug Integrity and Supply Chain Security

Multistate outbreak of fungal meningitis and other infections

FDA Drug Safety Communication: FDA approves label changes to include intestinal problems (sprue-like enteropathy) linked to blood pressure medicine olmesartan medoxomil

View and print full Drug Safety Communication (PDF - 54KB)

en Español

Safety Announcement | Facts about Olmesartan | Additional Information for Patients | Additional Information for Health Care Professionals | Data Summary | References

Safety Announcement

[7-3-2013] The U.S. Food and Drug Administration (FDA) is warning that the blood pressure drug olmesartan medoxomil (marketed as Benicar, Benicar HCT, Azor, Tribenzor, and generics) can cause ... to the labels of these ...

Olmesartan label change: sprue-like enteropathy

... weight loss. The ... requires ... symptoms and no other ... hypertensive started. Discontinuation of olmesartan has resulted in clinical improvement of sprue-like enteropathy symptoms in all patients.

Olmesartan medoxomil is an angiotensin II receptor blocker (ARB) approved for the treatment of high blood pressure, alone or with other antihypertensive agents, and is one of eight marketed ARB drugs. Sprue-like enteropathy has not been detected with ARB drugs other than olmesartan.

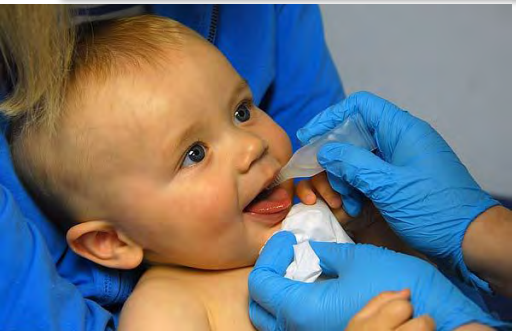
FDA will continue to evaluate the safety of olmesartan-containing products and will communicate again if additional information becomes available.

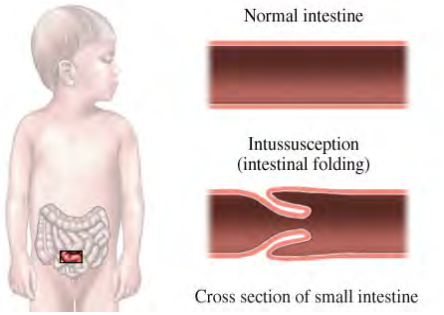
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

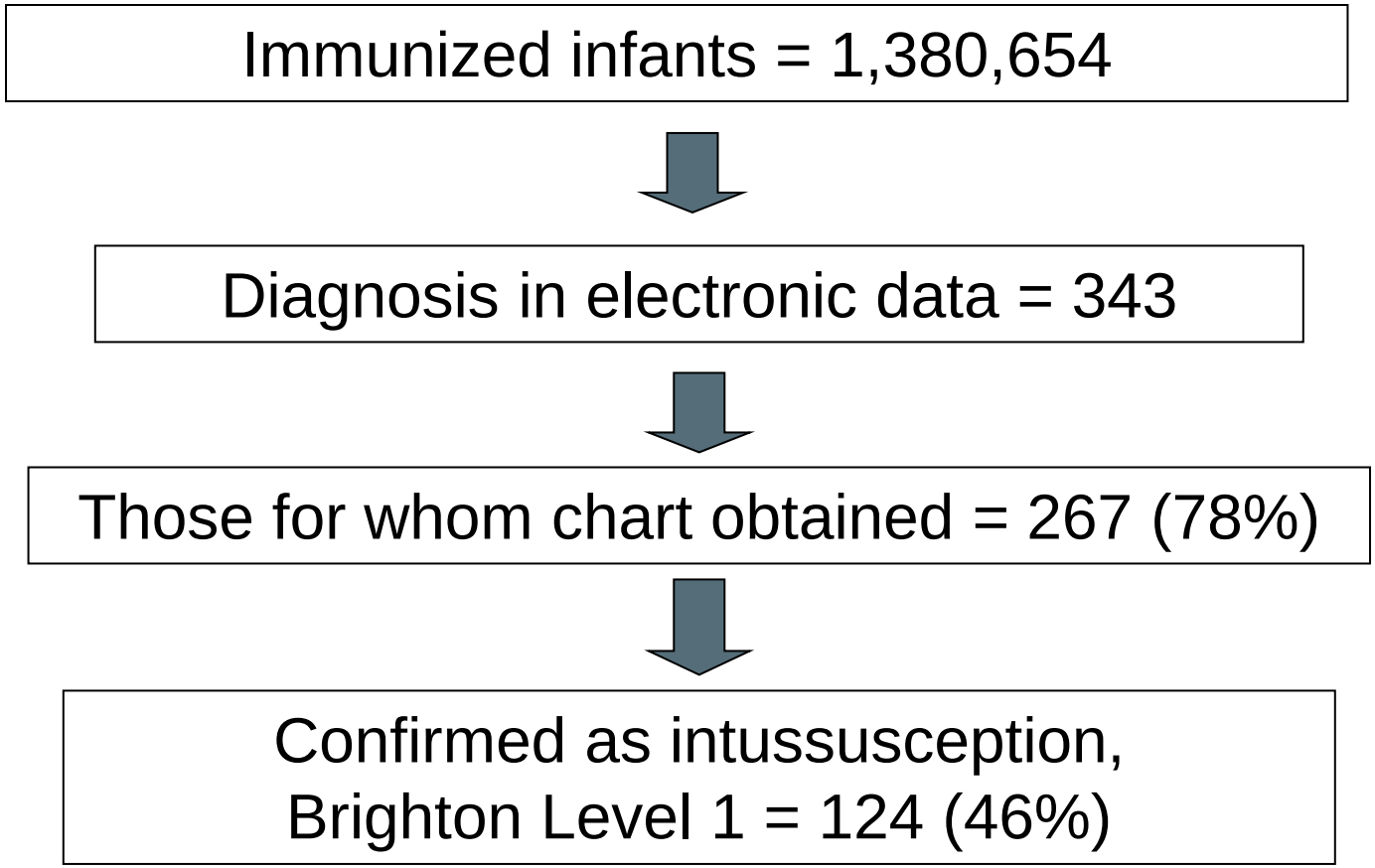
Intussusception Risk after Rotavirus Vaccination in U.S. Infants

W. Katherine Yih, Ph.D., M.P.H., Tracy A. Lieu, M.D., M.P.H., Martin Kulldorff, Ph.D., David Martin, M.D., M.P.H., Cheryl N. McMahill-Walraven, M.S.W., Ph.D., Richard Platt, M.D., Nandini Selvam, Ph.D., M.P.H., Mano Selvan, Ph.D., Grace M. Lee, M.D., M.P.H., and Michael Nguyen, M.D.





Intussusception confirmation



Potential cases are from whole population aged 5-36 weeks and include unexposed

Vaccines, Blood & Biologics

Safety & Availability (Biologics)
- Biologics Product Shortages Q&A
- Recalls (Biologics)
- Biologic Product Shortages
- Report a Problem to the Center for Biologics Evaluation & Research
- Biologic Product Security
- Pandemics
- Blood Safety & Availability
- Tissue Safety & Availability
- Vaccine Safety & Availability
- HIV Home Test Kits

Resources for You

- 2013 Safety and Availability Communications

FDA Releases Final Study Results of a Mini-Sentinel Postlicensure Observational Study of Rotavirus Vaccines and Intussusception

FDA Safety Communication — June 13, 2013

FDA Releases Final Study Results of a Mini-Sentinel Postlicensure Observational Study of Rotavirus Vaccines and Intussusception

FDA Approves Required Revised Labeling for RotaTeq Based on the Study Results

Purpose: To inform the public and healthcare providers that FDA is releasing final study results from a Mini-Sentinel postlicensure observational study of intussusception (a form of bowel obstruction) after vaccination with RotaTeq (Merck and Co., Inc.) and Rotarix (GlaxoSmithKline Biologicals).

RotaTeq and Rotarix are vaccines for the prevention of rotavirus gastroenteritis in infants 6 weeks to 32 weeks of age (RotaTeq) and infants 6 weeks to 24 weeks of age (Rotarix). The study was conducted in Mini-Sentinel's Postlicensure Rapid Immunization Safety Monitoring (PRISM) program, the largest vaccine safety surveillance program in the United States.

FDA has approved required revisions to the Prescribing Information and Patient Information for RotaTeq as a result of the new safety data from this Mini-Sentinel PRISM study. New information was added to the Highlights, the existing intussusce[p]tions section, and the Post-Marketing Experience section of the Full Pr[e]nt Information. The Mini-Sentinel PRISM study is the largest study [t]o date and identified an increased risk of intussusception in the 21 day time period after the first dose of RotaTeq, with most cases occurring in the first 7 days after vaccination. No increased risk was found after the second or third doses. These findings translate into 1 to 1.5 additional cases of intussusception per 100,000 first doses of RotaTeq.

Label change

The data from the Mini-Sentinel PRISM study regarding the risk of intussusception following the use of Rotarix were inconclusive. Based on this study, no changes were made to the Prescribing Information or to the Patient Information for Rotarix. However, based on data from an observational study previously conducted in Mexico, it is estimated that 1 to 3 additional cases of intussusception would occur per 100,000 vaccinated infants in the United States within 7 days following the first dose of Rotarix. In September 2012, FDA announced that it had approved revisions to the Prescribing Information and to the Patient Information for Rotarix to include these results from the study in Mexico.

Sharing identifiable information

- Distributed data analysis can eliminate or greatly reduce the need to transfer personally identifiable data
- Personally identifiable information is required in some circumstances, e.g., linking an individual's data across two sources
- Identifiable information should be stored in protected locations. Data enclaves are one solution.

Notifying patients of data sharing practice

- Notification at time of care
- Public notice to the community via multiple means

Thank you!