

The Mini-Sentinel Distributed Database Project

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Boston Area SAS Users Group

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Outline

1. Mini-Sentinel Project Overview
2. Mini-Sentinel Common Data Model and Distributed Database
3. Distributed Approach to Querying Data
4. Requirements for Maintenance

Mini-Sentinel Goals

- To develop a distributed database and supporting infrastructure to **enable an active surveillance system** for monitoring the safety of drugs, biologics and devices in the United States

“The Secretary shall...develop **validated methods** for the establishment of a postmarket risk identification and analysis system to **link and analyze safety data from multiple sources**, with the goals of including, in aggregate...at least 100,000,000 patients by July 1, 2012.”

– *Food and Drug Administration Amendments Act of 2007*

Mini-Sentinel Data Environments

(as of 12/31/2012)

- ❑ 19 Data Partner organizations
- ❑ **Over 130 million individuals**
 - 382 million person-years of observation time from 2000 into 2012
 - 41 million individuals currently enrolled, accumulating new data
 - 34 million individuals have over 3 years of data
- ❑ 3.7 billion drug dispensings
- ❑ Accumulating over 40 million drug dispensings per month
- ❑ 4.1 billion unique encounters, including 46 million acute inpatient stays
- ❑ Accumulating over 52 million encounters per month

Organizations

- **Aetna**
- America's Health Insurance Plans
- Brigham and Women's Hospital
 - Division of Pharmacoepidemiology and Pharmacoeconomics
 - Division of General Medicine
- Cincinnati Children's Hospital Medical Center
- Columbia University
- Critical Path Institute
- Duke U Clinical Research Institute
- **HMO Research Network:**
Group Health Research Institute,
Harvard Pilgrim Health Care Institute,
HealthPartners Inst for Education & Research,
Henry Ford Health System,
Lovelace Clinic Foundation,
Marshfield Clinic Research Foundation,
Meyers Primary Care Inst (UMass / Fallon)
- **HealthCore, Inc**
- **Humana – Competitive Health Analytics**
- **Kaiser Permanente:**
Colorado,
Georgia,
Hawaii,
Mid-Atlantic,
N. California, and
Northwest regions
- **OptumInsight**
- Outcome Sciences, Inc
- Rutgers University
- U of Alabama at Birmingham
- U of Illinois at Chicago
- U of Iowa College of Public Health
- U of Pennsylvania School of Medicine
- **Vanderbilt U School of Medicine**
- **Weill Cornell Medical College**

Distributed Network Approach

- ❑ Standardize data
- ❑ Data Partners maintain physical control of their data
- ❑ Data Partners control all uses of their data
- ❑ Data Partners control all transfer of data
- ❑ Computer programs should run at multiple sites without modification

Mini-Sentinel

Common Data Model and Distributed Database

Mini-Sentinel Common Data Model: Selected Guiding Principles

Mini-Sentinel Common Data Model should:

1. Accommodate all current requirements
2. Be appropriate for all Data Partners
3. Be appropriate for frequent extracts, updating, checking
4. Be transparent, intuitive, simple, well documented and easily understood
5. Allow distributed programs to execute without site-specific modification
6. Have flexibility: able to incorporate new data types and elements

Sample Data Dictionary

MSCDM: Diagnosis Table Structure

Description: The MSCDM Diagnosis Table contains one record per unique combination of DX and EncounterID (PatID, ADate, Provider and EncType). This table should capture all observed diagnoses for all encounters.

Variable Name	Variable Format (Bytes)	Values	Definition / Comments / Guideline	Example
PatID	Char (Site Specific length)	Unique member identifier	Arbitrary person-level identifier. Used to link across files.	123456789012345
EncounterID	Char (Site Specific length)	Char (Site Specific length)	Arbitrary encounter-level identifier. Used to link the Encounter, Diagnosis, and Procedure tables.	QMPZ019293
ADate	Numeric(4)	SAS Date	Admission Date	12/24/2005
Provider	Char (Site Specific length)	Numeric (4)	Provider Identifier	99218766
DX	Char(8)	Diagnosis Code	Note the decimal point. Clean up site introduced suffixes.	761.5

Mini-Sentinel Common Data Model v1.0

- ❑ Describes populations with administrative and claims data
 - Has well-defined person-time for which medically-attended events are known
- ❑ Data areas
 - Enrollment
 - Demographics
 - Outpatient pharmacy dispensing
 - Utilization – 3 tables
 - Encounters
 - Diagnoses
 - Procedures
 - Mortality – 2 tables
 - Death
 - Cause of Death

Enrollment

- ☐ Unique person identifier
- ☐ Start and end dates
- ☐ Medical coverage flag
- ☐ Drug coverage flag

1 record per unique period defined by:
 Person, dates, and each coverage flag

Demographics

- ☐ Unique person identifier
- ☐ Date of birth
- ☐ Sex
- ☐ Race
- ☐ Ethnicity

1 record per person

Outpatient Pharmacy Dispensings

- ☐ Unique person identifier
- ☐ Fill date
- ☐ National Drug Code (NDC -- links to details such as route of administration, dose, drug class)
- ☐ Days supplied
- ☐ Amount dispensed

1 record per person per NDC, per day

Encounter (Visits)

- ☐ Unique person identifier
 - ☐ Encounter identifier
 - ☐ Encounter type (e.g., inpatient, outpatient, ED)
 - ☐ Start and end date for encounter
 - ☐ Discharge status and disposition
 - ☐ Admitting source
 - ☐ DRG code and code type
 - ☐ Provider and facility identifiers
 - ☐ Provider location (3-digit zipcode)
- 1 record per:
Person, encounter type, start date, and provider

Diagnoses

- ☐ Unique person identifier
- ☐ Encounter identifier
- ☐ Encounter type (e.g., inpatient, outpatient, ED)
- ☐ Encounter date
- ☐ Clinical diagnosis code
- ☐ Type of code (e.g., ICD-9-CM, ICD-10-CM)
- ☐ Primary diagnosis flag
- ☐ Original diagnosis code (if different)
- ☐ Provider identifier

1 record per:

Person, encounter type, start date, provider *and diagnosis*

Procedures

- ☐ Unique person identifier
- ☐ Encounter identifier
- ☐ Encounter type (e.g., inpatient, outpatient, ED)
- ☐ Encounter date
- ☐ Clinical Procedure code
- ☐ Type of code (e.g., ICD-9-CM, CPT4, HCPCS)
- ☐ Original procedure code (if different)
- ☐ Provider identifier

1 record per:

Person, encounter type, start date, provider *and procedure*

Death

- ☐ Unique person identifier
- ☐ Date of death
- ☐ Imputation of date information
- ☐ Data source
- ☐ Matching confidence (excellent, fair, poor)

1 record per death

Sources vary by partner; state death registries, national death index, tumor registries

Cause of Death

- ☐ Unique person identifier
- ☐ Cause of death diagnosis code
- ☐ Code type
- ☐ Cause type (e.g., primary, underlying)
- ☐ Data source
- ☐ Confidence in cause of death match

1 record per cause of death

Sources vary by partner; state death registries, national death index, tumor registries

Data Quality and Checking

Level 1 Data Checking

- ❑ Data must meet the Common Data Model specifications and other industry standards
- ❑ Name, data type, length, justification, format, values
 - Industry Standard examples:
 - NDC: 11-digit codes, only digits (no space or letter)
 - HCPCS Levels I, II, III: 5-digit codes, Levels II and III start with a letter
 - ICD-9-CM diagnosis: 3- to 5- digit codes, may start with letter E or V
 - Recorded values consistent with Mini-Sentinel Common Data Model
 - Unique person identifier, service dates, services codes, and encounter types must be non-missing for all records to reconstitute medical history

Level 2 Data Checking

- ❑ Completeness and integrity between variables within and across Mini-Sentinel Common Data Model tables
 - Person, Provider, and Encounter Identifier variables must be consistently created to allow linkage across tables
 - Sanity/logic checks
 - Enrollment start < enrollment end, birth date < death date
 - Discharge status populated for institutional record types only
 - Any diagnosis or procedure codes can be linked to an Encounter record
 - Unique combination of key variables to define tables / No duplicates
 - One demographic record per person (date of birth, sex and race)
 - One prescription per person per day for a given drug is a unique combination of: person identifier, Rx date and NDC code
 - One record per enrollment period: - Unique combination of: unique person identifier, enrollment start date, enrollment stop date, medical coverage flag, and drug coverage flag

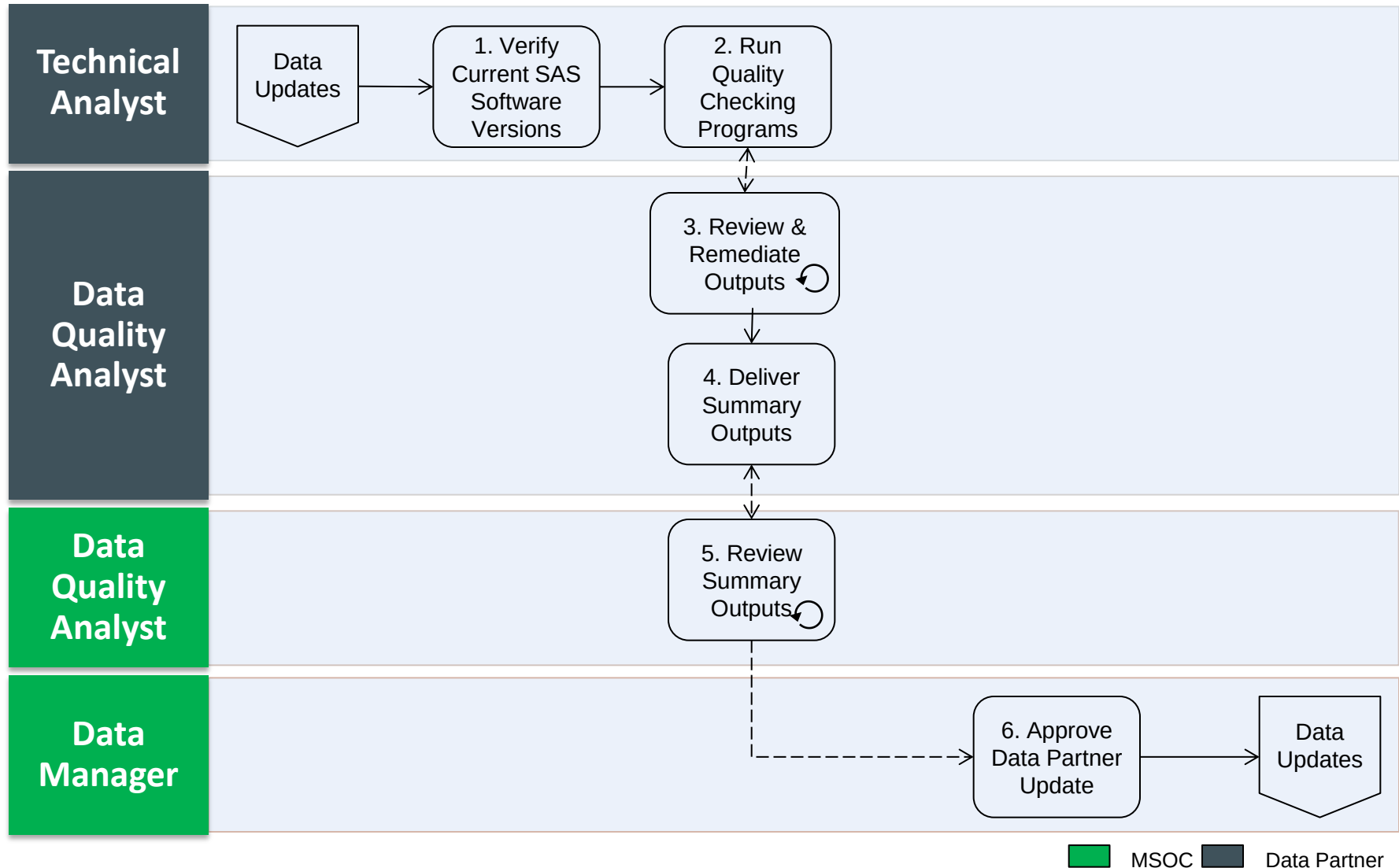
Level 3 Data Checking

- ❑ High-level data characterization to determine the range of values within each field
 - Summary statistics on key outcomes
 - Number of prescriptions or encounters per member per month/year
 - Number of different diagnoses per encounter per encounter type
 - Number of enrollment months per member
 - Identify outliers and obvious errors
 - Dispensing supply > 100 days
 - Date of birth < 1900
 - Daily, monthly and yearly counts of records to identify holes in the data
 - A whole month missing or drop in number of records for a specific period because a group of providers did not submit their claims or the Data Partner did not correctly assemble multiple data streams
 - Frequencies of key variables over time to identify trends

Level 4 Data Checking

- ❑ Clinically-specific examples to confirm data quality
 - Currently under development
 - Evaluate specific clinical scenarios for variability
 - Inconsistent data
 - Males with ovarian cancer, Females with prostate cancer
 - Number of ED visits that become inpatient visits
 - Frequency of specific procedures by age and sex over time
 - Hip replacement
 - Broken ankle

MS Data Standardization and Checking



Distributed Querying Approach

Distributed Querying Approach

Three ways to query data:

1) Summary Table queries

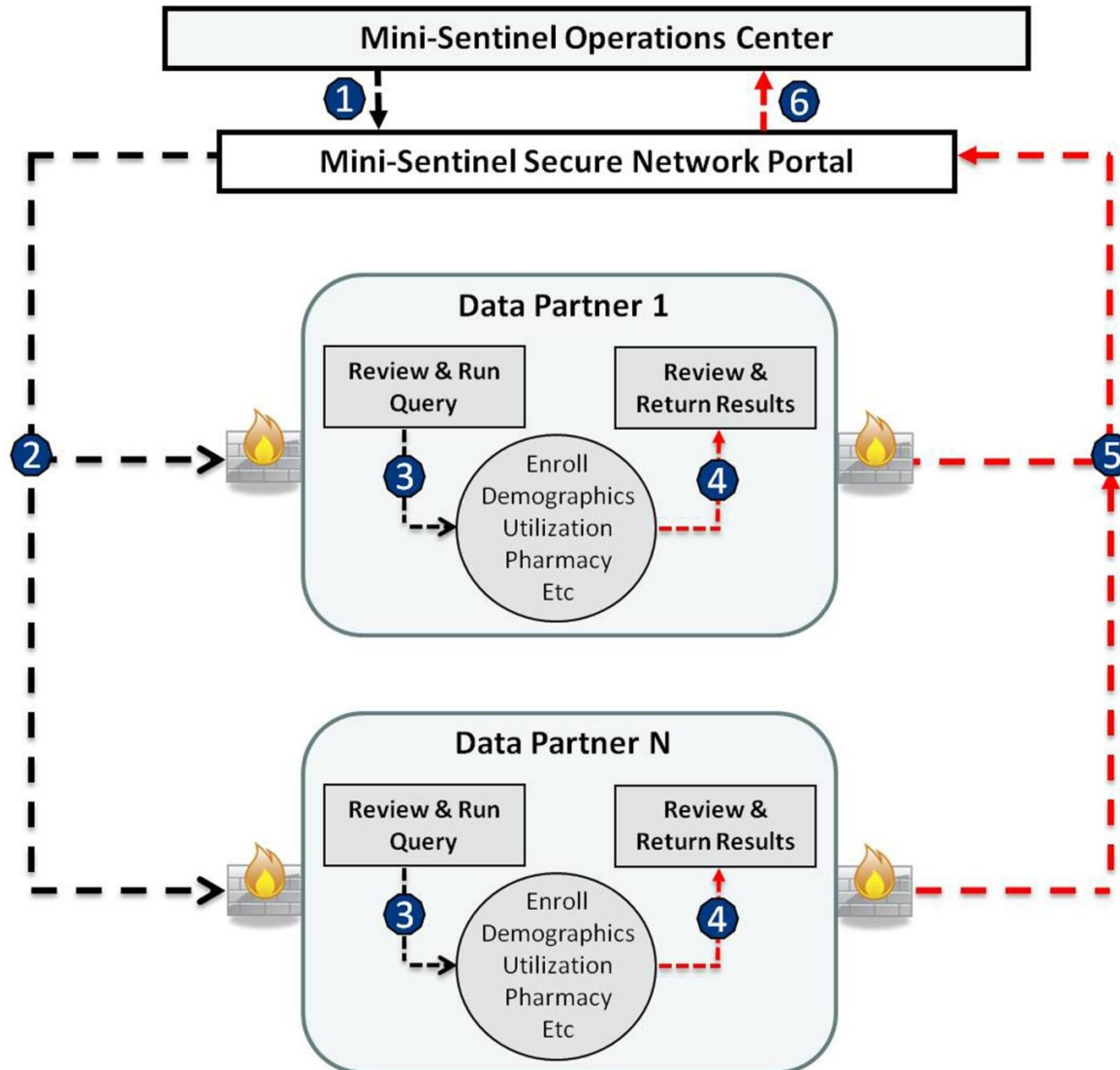
- Menu-driven querying via secure portal
- Crude prevalence and incident rates
 - *Example: How many people have been dispensed Drug X, by month, since it was licensed until the present time? What is the age distribution of these drug recipients?*

2) Modular SAS Program queries

- 7 SAS programs (macros) that address common questions
 - *Example: Rate of a specific outcome during exposure to a medical product*

3) Custom SAS Programs for in-depth analysis

Data Flow: Distributed Querying



- 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 and returned

Querying:

Pre-tabulated Summary Table Overview

- ❑ Summarize utilization information using pre-defined concepts (disease, age groups, exposure)
- ❑ Created via distributed programs
- ❑ Summary tables held by the Data Partners
- ❑ Benefits:
 - Potential for blanket data sharing approval
 - Rapid access to information
 - No protected information shared
- ❑ Limitations:
 - No linkage across tables
 - Cannot add individuals across periods (double-count)
 - No temporal relationships

Querying:

Pre-tabulated Summary Tables

- ❑ Enrollment and demographics
- ❑ ICD-9-CM diagnoses, 3, 4, and 5 digit
- ❑ HCPCS procedures, 5 digit
- ❑ ICD-9-CM procedures, 3 and 4 digit
- ❑ Outpatient pharmacy dispensings
 - Generic name
 - Drug class

All stratified by age group, sex, year/quarter, and care setting

Enrollment and Demographics

Pre-tabulated Summary Table

☐ Stratified by:

- Age group (pre-specified)
- Sex
- Period (year)
- Enrollment coverage type

Enrollment and Demographics

Example of Enrollment and Demographics Summary Table*

Age_Group	Sex	DrugCov	MedCov	Members	Year
0- 4	F	Y	Y	21917	2007
0- 4	M	Y	Y	22897	2007
5- 9	F	Y	Y	23479	2007
5- 9	M	Y	Y	24644	2007
10-14	F	Y	Y	25188	2007
10-14	M	Y	Y	26829	2007
15-19	F	Y	Y	22477	2007
15-19	M	Y	Y	23447	2007
20-44	F	Y	Y	141567	2007
20-44	M	Y	Y	121718	2007
45-64	F	Y	Y	103322	2007
45-64	M	Y	Y	92848	2007
65-74	F	Y	Y	16972	2007
65-74	M	Y	Y	15410	2007
75+	F	Y	Y	12126	2007
75+	M	Y	Y	8323	2007

*Year 1 age groups

Outpatient Pharmacy Dispensings:

Pre-tabulated Summary Table Overview

- ❑ Dispensings grouped by generic name and drug class
- ❑ Stratified by:
 - Age group (pre-specified)
 - Sex
 - Period (annual and quarterly)

Outpatient Pharmacy Dispensings:

Example of Pharmacy Dispensings by Generic Name*

Age_Group	Sex	Period	GenericName	Dispensings	Members	Days
0- 4	M	2007	CARVEDILOL	68	63	3100
20-44	F	2007	CARVEDILOL	138	95	6540
20-44	M	2007	CARVEDILOL	119	25	8525
45-64	F	2007	CARVEDILOL	230	48	17250
45-64	M	2007	CARVEDILOL	777	28	73500
65-74	F	2007	CARVEDILOL	133	102	9200
65-74	M	2007	CARVEDILOL	371	62	26450
75+	F	2007	CARVEDILOL	117	24	16275
75+	M	2007	CARVEDILOL	208	35	27550

*Year 1 age groups

ICD-9-CM Diagnosis:

Pre-tabulated Summary Table

- ❑ Encounters grouped by 3/4/5-digit ICD-9-CM diagnosis code
- ❑ Stratified by:
 - Age group (pre-specified)
 - Sex
 - Period (year)
 - Care setting (inpatient, outpatient, ED)

ICD-9-CM Diagnosis:

Example of 3-digit ICD-9-CM Diagnosis Code Outpatient Setting*

Age_Group	Sex	Period	Dx	DxName	EncType	Encounters	Members
0- 4	F	2007	402	HYPERTENSIVE HEART DISEASE	OUTP	60	50
0- 4	M	2007	402	HYPERTENSIVE HEART DISEASE	OUTP	120	80
5- 9	M	2007	402	HYPERTENSIVE HEART DISEASE	OUTP	131	88
10-14	F	2007	402	HYPERTENSIVE HEART DISEASE	OUTP	60	50
10-14	M	2007	402	HYPERTENSIVE HEART DISEASE	OUTP	162	100
15-19	F	2007	402	HYPERTENSIVE HEART DISEASE	OUTP	60	50
15-19	M	2007	402	HYPERTENSIVE HEART DISEASE	OUTP	145	80
20-44	F	2007	402	HYPERTENSIVE HEART DISEASE	OUTP	1750	730
20-44	M	2007	402	HYPERTENSIVE HEART DISEASE	OUTP	3470	1840

*Year 1 age groups

ICD-9-CM Procedures:

Pre-tabulated Summary Table

- ❑ Encounters grouped by 3 and 4-digit ICD-9-CM procedure code
- ❑ Stratified by:
 - Age group (pre-specified)
 - Sex
 - Period (year)
 - Care setting (inpatient, outpatient, ED)

ICD-9-CM Procedures:

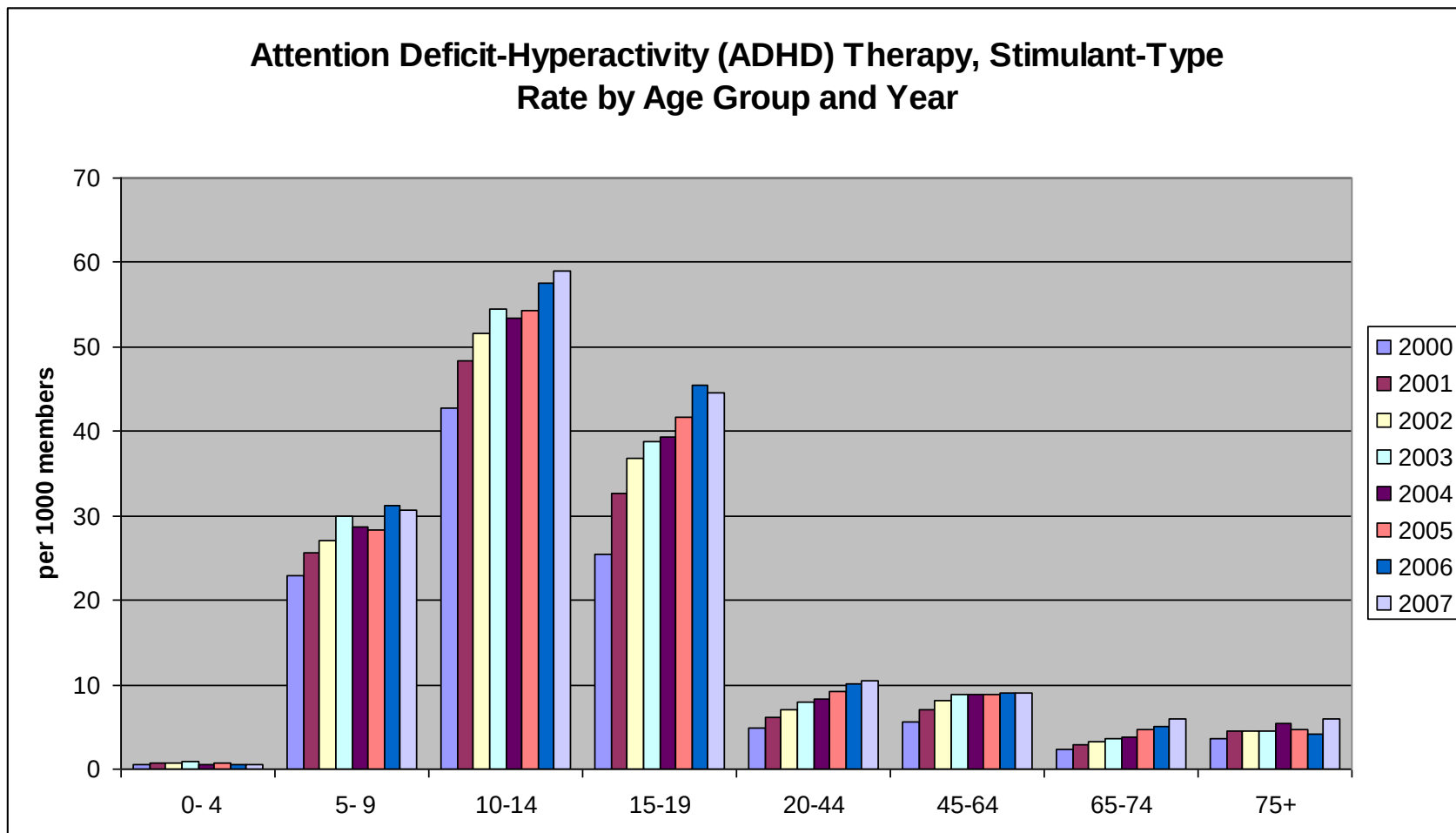
Example of Three-digit ICD-9-CM Procedure Code Summary Table – Inpatient Setting*

Age_Group	Sex	Period	PxName	EncType	Px	Encounters	Members
45-64	F	2007	BYPASS ANASTOMOSIS FOR HEART REVASCULARIZATION	INP	36.1	80	33
45-64	M	2007	BYPASS ANASTOMOSIS FOR HEART REVASCULARIZATION	INP	36.1	377	132
65-74	F	2007	BYPASS ANASTOMOSIS FOR HEART REVASCULARIZATION	INP	36.1	26	15
65-74	M	2007	BYPASS ANASTOMOSIS FOR HEART REVASCULARIZATION	INP	36.1	103	49
75+	F	2007	BYPASS ANASTOMOSIS FOR HEART REVASCULARIZATION	INP	36.1	18	13

*Year 1 age groups

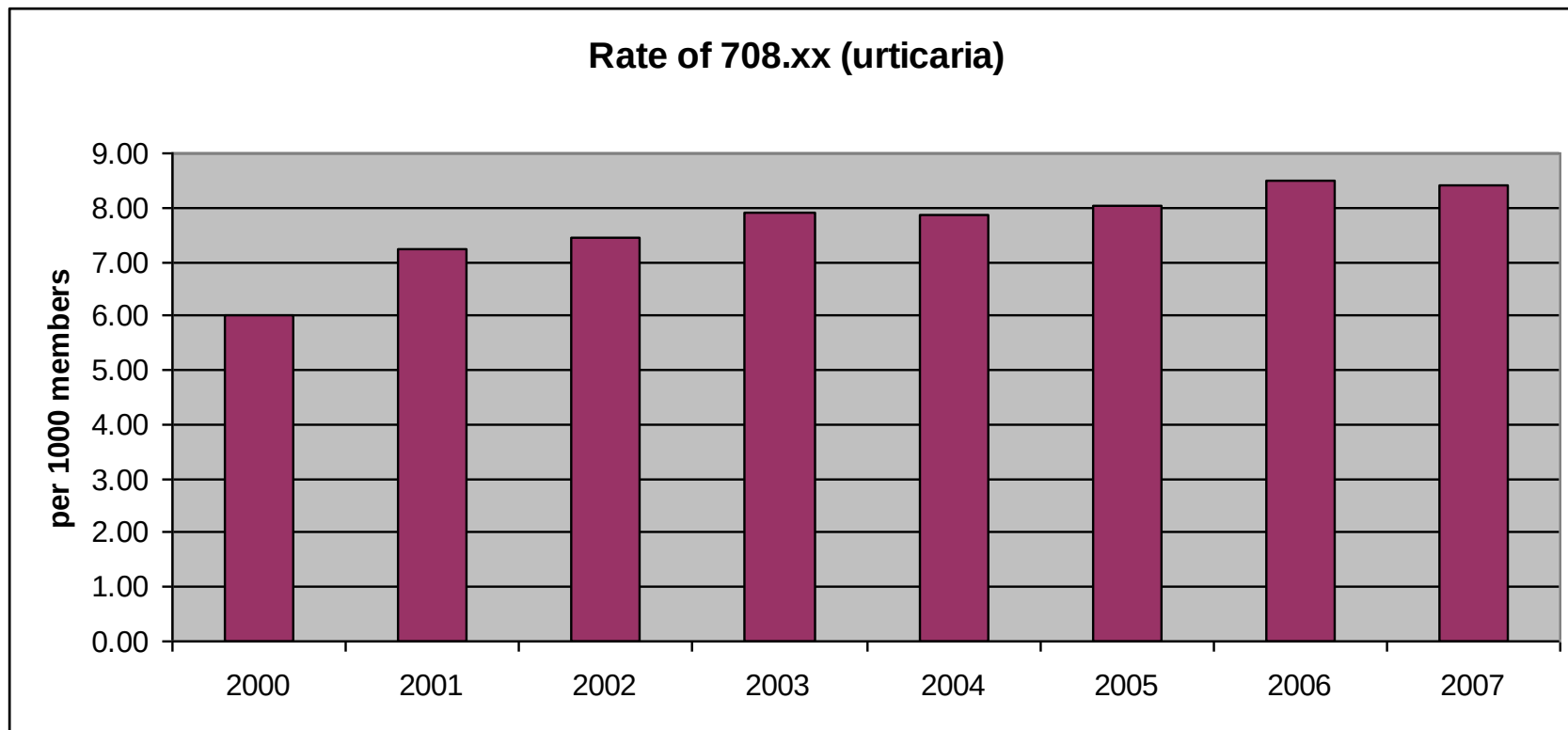
Example Based on Summary Tables:

Drug Use by Age and Year



Example Based on Summary Tables:

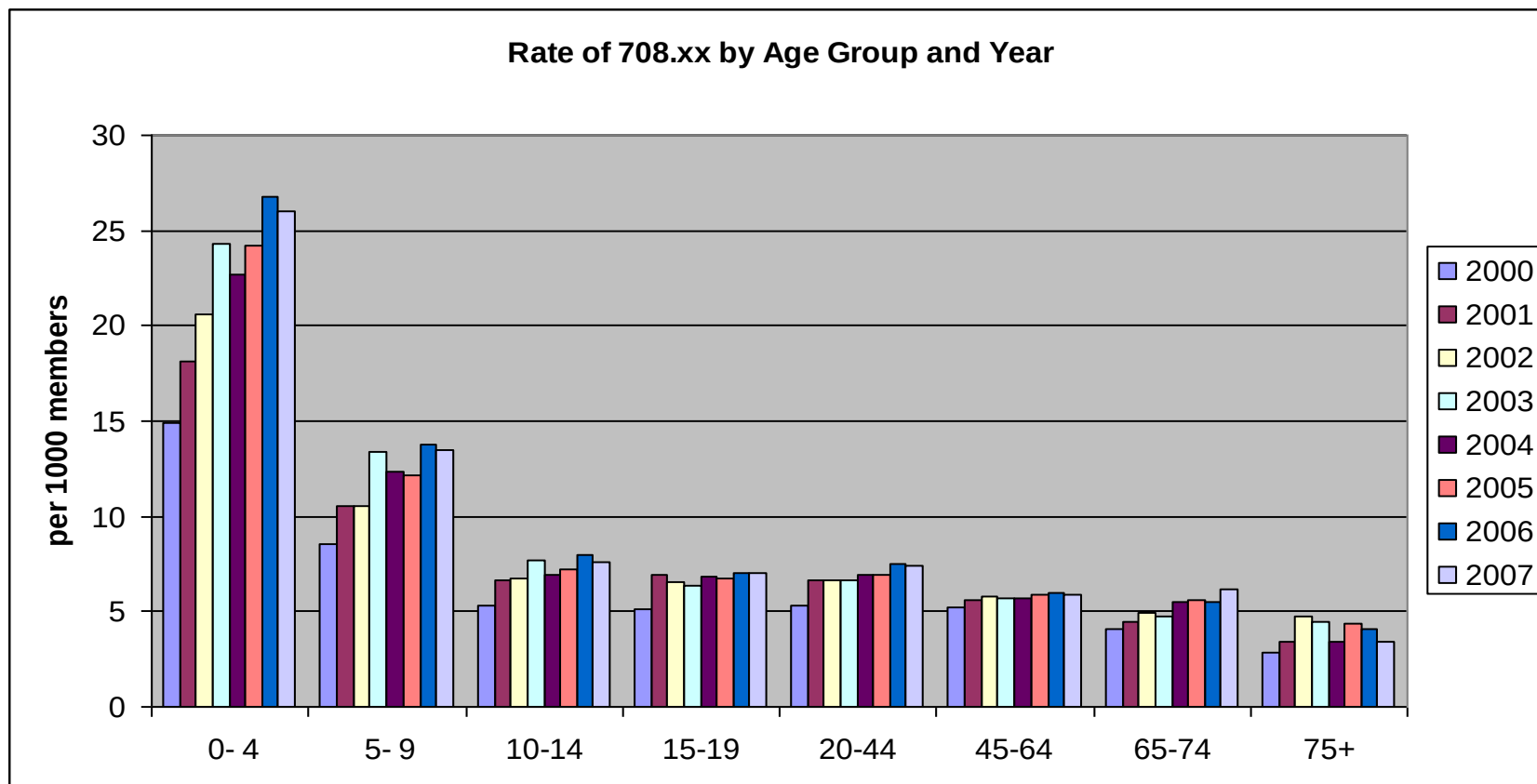
Diagnoses by Year



39.5% increase 2000 - 2007

Example Based on Summary Tables:

Urticaria (hives) Diagnoses by Age and Year



74% increase 2000 – 2007 in 0-4 age group, 58% in 5-9 age group

Querying: SAS Modular Programs

- ❑ Modular programs target common queries
- ❑ Modular programs reduce programming time to respond to questions
- ❑ Programs have been pre-tested and validated
- ❑ They reduce review effort by Data Partners
- ❑ Consistent and predictable output

Structure of Modular Programs

- ❑ Each modular program includes:
 - Required inputs (e.g., medical product, outcomes)
 - Optional inputs (e.g., period increments, age groups)
- ❑ Outputs vary, but will typically contain counts data, e.g.:
 - Number of members exposed to a drug
 - Number of members with specific diagnosis/procedure
 - Stratified by the optional parameters, e.g., age group, sex, year
- ❑ Timeline once MP request is distributed to DPs
 - Data Partners: Required response time is ≤ 5 business days
 - Operations Center: Report to FDA in 5-10 business days after Data Partners' responses

Current Modular Programs

1. Characterization of Use of Medical Product Exposures
2. Characterization of Use of Medical Product Exposures among Individuals with a Pre-existing Condition
3. Frequency of Select Events During Exposure to a Drug/Procedure Group of Interest
4. Concomitant Drug and/or Procedure Use
5. Background Rates for Health Outcomes of Interest
6. Frequency and Duration of Treatment Following an Event of Interest
7. Drug Use, Medical Diagnoses, and Medical Procedures Before and After an Exposure or Event of Interest

Modular Programs are *Big* Macros

```
%ModularProgram3 (  
    RequestID = rtest,  
    DRUGFROM = 01/01/2009,  
    DRUGTO = 12/31/2009,  
    DRUGWASHPER = ,  
    FOLLOWPER = 30,  
    BLACKOUTPER = ,  
    EPISODEGAP = ,  
    EXPEXTPER = ,  
    MINEPISDUR = ,  
    MINDAYSUPP = ,  
    ...  
    NDCLENGTH = 11,  
    STUDYNDCFILE = studyndc.sas7bdat,  
    INCNDCFILE = ,  
    STUDYEVENTFILE = cardiac_death.sas7bdat,  
    AGERANGE = 0-99,  
    AGESTRAT = 00-12 13-17 18-44 45-64 65-74 75+  
);
```

Modular Programs Macro Parameter Descriptions

Macro Variable Name	Short Description	Long Description
DRUGFROM	Start date of study drug identification period	Input type: Required (cannot be left blank) Format: mm/dd/yyyy Example: DRUGFROM = 03/01/2008
DRUGWASHPER	Duration in days of the drug washout period	Input type: Optional (default value is 0) Format: Integer from 0 to infinity Example: WASHPER = 180
FOLLOWPER	Minimum follow-up period	Input type: Optional (default value is 0) Format: Integer 0 to infinity Example: FOLLOWPER = 180

Custom Programs for Other Analyses

- ❑ Users can develop SAS programs to run against the Mini-Sentinel Distributed Dataset
 - Modular programs and summary tables will not address all questions
 - Project-specific code will become part of the Mini-Sentinel library
 - Time consuming to develop, QC, and document
- ❑ The Mini-Sentinel Operations Center will
 - Distribute programs to the Data Partners
 - Receive/collate the output
 - Provide it to the requestor

Structure of SAS Programs

❑ Top area for Data Partner editing

***1) Edit DPID according to the table above;**

```
%let DPID=MS;
```

***2) Edit this section to reflect your name for each Table/File (or View);**

```
%let ENRTABLE=Enrollment;
```

```
%let DEMTABLE=Demographic;
```

...Etc.

***3) Edit this section to reflect locations for the Libraries and Folders for Mini-Sentinel;**

```
%let indata=K:\FDA_Sentinel\MSCDM\;
```

```
%let lookup=K:\FDA_Sentinel\LookupTables\;
```

```
%let DPLocal=K:\FDA_Sentinel\DPLocal_Request201304\;
```

```
%let MSCO=K:\FDA_Sentinel\MSOC_Request201304\;
```

...Etc.

```
***** END OF USER INPUT *****;
```

```
***** PLEASE DO NOT EDIT CODE BELOW THIS LINE *****;
```

Structure of SAS Programs

❑ Management Features of All Programs

- **Log file sent to MSOC directory:** Contains only relevant information on program execution; no directory paths

```
proc printto log="&MSOC.&DPID.&SITEID._log" new;  
run;
```

- **“Signature” file sent to MSOC:** contains program execution data

Variable	VALUE
DpID	MS
Start_Time	18JUL2011:10:22:10.10
Stop_Time	18JUL2011:13:25:20.70
Execution_time	3 h 3 m 10 s
REQUESTID	dysrhythmias_cs1
DRUGFROM	3/1/2008
DRUGTO	3/31/2009
AGERANGE	00-99
etc....	

Security and Privacy:

Behind the Data Partner "Firewall"

- ❑ Data Partners have complete control over all uses of their data
- ❑ Data Partners ensure their own data sharing procedures are followed
- ❑ Data Partners approve all data transmissions
- ❑ All transmissions are secure (http/SSL) and auditable
- ❑ All data transmission systems are FISMA* compliant

*Federal Information Security Management Act

Project Challenges

- ❑ Development for datasets which you cannot touch
- ❑ Quality control
- ❑ Heterogeneity of Data Partner understanding
- ❑ Heterogeneity of Data Partner data
- ❑ Managing results from Data Partners
- ❑ Heterogeneity of Environments
 - SAS versions and platforms
 - SAS is not perfectly compatible from platform to platform
 - Hardware limitations
 - Technical platforms can require workarounds

Project Challenges

Development for datasets which you cannot touch

- ❑ Use synthetic data in development environment
 - Develop program-specific datasets ($\approx$ 50K patients)
 - Use Medicaid data from single state ($\approx$ 5.4mil patients)
- ❑ Beta test with Data Partner
 - Enables further test in a real environment
 - Identifies issues in:
 - Performance
 - Data robustness & logic flaws
 - SAS platforms

Project Challenges

Heterogeneity of Data Partner understanding

- Numerous meetings to discuss project
- Voluminous documentation
 - ☐ Epidemiological protocols
 - ☐ Specifications for SAS program development
 - ☐ Specifications for SAS program execution
- Data Partner Surveys
 - ☐ What is *your* definition for populating the variable that records a Principal Diagnosis?
 - ☐ How do you interpret your data streams that contain seemingly contradictory data?

Project Challenges

Heterogeneity of Environments

- ☐ Beta-test in multiple SAS environments
- ☐ Recode when needed to earliest SAS version
- ☐ Work with Data Partners to tune their SAS environments

Project Challenges

Heterogeneity of Data Partner data and
Managing results from Data Partners

- ❑ Mini-Sentinel as a pilot, resolves Data Partner variability of data
- ❑ Increased streamlining for aggregating Data Partner results
 - MSOC programs and systems
- ❑ Improved reporting of Data Partner results

Ongoing Needs: SAS Programming Help

- ❑ Looking for MSOC programming expertise
- ❑ Looking for DP support for programming activities
- ❑ Range of effort is flexible
 - New programming: workgroups, base infrastructure
 - Quality check: modular programs, summary tables, workgroup
 - Program specification and coding (e.g., Data checks, Modular Programs, ad hoc programs)
 - Development of new tools/infrastructure

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Job Listings

[Epidemiologist \(290770-561\)](#)

Boston, MA, United States

[Manager of Administration \(290827-561\)](#)

Boston, MA, United States

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Welcome to Mini-Sentinel

Mini-Sentinel is a pilot project sponsored by the U.S. Food and Drug Administration (FDA) to create an active surveillance system - the Sentinel System - to monitor the safety of FDA-regulated medical products. Mini-Sentinel uses pre-existing electronic healthcare data from multiple sources. [Collaborating Institutions](#) provide access to data as well as scientific and organizational expertise.

Mini-Sentinel is part of the [FDA's Sentinel Initiative](#), which is exploring a variety of approaches for improving the Agency's ability to quickly identify and assess safety issues.

The Mini-Sentinel pilot provides FDA the ability to:

- Work through the “nuts and bolts” of designing safety assessments using multiple existing electronic healthcare data systems
- Develop and evaluate scientific methods to increase the precision of active safety surveillance efforts
- Identify and address barriers and challenges to building a practical, accurate, and timely system for active safety surveillance

NEW POSTINGS

[Assessment Protocol: Influenza Vaccines and Febrile Seizures \(PRISM\)](#)

[Modular Program Report: Dabigatran \(Pradaxa\), Warfarin & GI Bleed, Intracerebral Hemorrhage](#)

[Protocol posted for public comment: Influenza Vaccines and Birth Outcomes \(PRISM\)](#)

[Projected Timelines for CBER Protocol-Based Mini-Sentinel Medical Product Assessments](#)

[Influenza vaccines and pregnancy outcomes \(PRISM\)](#)

[Influenza vaccine safety sequential analysis \(PRISM\)](#)

[Prevnam 13 vaccine and Kawasaki disease](#)

Questions & Answers



Email