

Sentinel

MDEpiNet Registry Assessment of Peripheral
Interventional Devices (RAPID) Think Tank

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Ways Sentinel might assist device surveillance

- ❑ Data for largest national insurers can be linked to UDI
- ❑ Sentinel data model can be used for UDI registries
- ❑ Sophisticated analytic tools to analyze data in Sentinel data model format

Sentinel Data Partners



MASSACHUSETTS



Sentinel distributed database*

- ❑ Populations with well-defined person-time for which most medically-attended events are known
 - 193 million members**
 - 351 million person-years of observation time
 - 39 million people currently accruing new data
 - 4.8 billion dispensings
 - 5.5 billion unique encounters
 - 51 million acute inpatient stays
 - 33 million people with ≥ 1 laboratory test result

* As of August 2015, excludes HCA and BCBS of Massachusetts

** Double counting exists for individuals who change health plans

Sentinel distributed database*

- ❑ Intensive data checking and cleaning performed before data are approved for use

Sentinel Common Data Model (SCDM)

| Administrative | | | | | |
|------------------------------|-------------|--------------------------|---------------------------|-------------------------------|---------------------------|
| Enrollment | Demographic | Dispensing | Encounter | Diagnosis | Procedure |
| Person ID | Person ID | Person ID | Person ID | Person ID | Person ID |
| Enrollment start & end dates | Birth date | Dispensing date | Service date(s) | Service date(s) | Service date(s) |
| Drug coverage | Sex | National drug code (NDC) | Encounter ID | Encounter ID | Encounter ID |
| Medical coverage | ZIP code | Days supply | Encounter type & provider | Encounter type & provider | Encounter type & provider |
| Medical record availability | Etc. | Amount dispensed | Facility | Diagnosis code & type | Procedure code & type |
| | | | Etc. | Principal discharge diagnosis | Etc. |

| Clinical | | Registry | | |
|---|---------------------------|------------|----------------|---------------------|
| Lab Result | Vital Signs | Death | Cause of Death | State Vaccine |
| Person ID | Person ID | Person ID | Person ID | Person ID |
| Result and specimen collection dates | Measurement date and time | Death date | Cause of death | Vaccination date |
| Test type, immediacy & location | Height and weight | Source | Source | Admission Type |
| Logical Observation Identifiers Names and Codes (LOINC ®) | Diastolic & systolic BP | Confidence | Confidence | Vaccine code & type |
| Test result & unit | Tobacco use & type | Etc. | Etc. | Provider |
| Etc. | Etc. | | | Etc. |

Sentinel Common Data Model:

One patient

DEMOGRAPHIC

| PATID | BIRTH_DATE | SEX | HISPANIC | RACE | zip |
|--------|------------|-----|----------|------|-------|
| PatID1 | 2/2/1964 | F | N | 5 | 32818 |

ENCOUNTER

| PATID | ENCOUNTERID | ADATE | DDATE | ENCTYPE |
|--------|-------------|------------|------------|---------|
| PatID1 | EncID1 | 10/18/2005 | 10/20/2005 | IP |

ENROLLMENT

| PATID | ENR_START | ENR_END | MEDCOV | DRUGCOV |
|--------|-----------|------------|--------|---------|
| PatID1 | 7/1/2004 | 12/31/2006 | Y | Y |
| PatID1 | 9/1/2007 | 6/30/2009 | Y | Y |

DIAGNOSIS

| PATID | ENCOUNTERID | ADATE | PROVIDER | ENCTYPE | DX | DX_CODETYPE | PDX |
|--------|-------------|------------|-----------|---------|--------|-------------|-----|
| PatID1 | EncID1 | 10/18/2005 | Provider1 | IP | 296.2 | | 9P |
| PatID1 | EncID1 | 10/18/2005 | Provider1 | IP | 300.02 | | 9S |
| PatID1 | EncID1 | 10/18/2005 | Provider1 | IP | 305.6 | | 9S |
| PatID1 | EncID1 | 10/18/2005 | Provider1 | IP | 311 | | 9P |
| PatID1 | EncID1 | 10/18/2005 | Provider1 | IP | 401.9 | | 9S |
| PatID1 | EncID1 | 10/18/2005 | Provider1 | IP | 493.9 | | 9S |
| PatID1 | EncID1 | 10/18/2005 | Provider1 | IP | 715.9 | | 9S |

DISPENSING

| PATID | RXDATE | NDC | RXSUP | RXAMT |
|--------|------------|-------------|-------|-------|
| PatID1 | 10/14/2005 | 00006074031 | 30 | 30 |
| PatID1 | 10/14/2005 | 00185094098 | 30 | 30 |
| PatID1 | 10/17/2005 | 00378015210 | 30 | 45 |
| PatID1 | 10/17/2005 | 54092039101 | 30 | 30 |
| PatID1 | 10/21/2005 | 00173073001 | 30 | 30 |
| PatID1 | 10/21/2005 | 49884074311 | 30 | 30 |
| PatID1 | 10/21/2005 | 58177026408 | 30 | 60 |
| PatID1 | 10/22/2005 | 00093720656 | 30 | 30 |
| PatID1 | 10/23/2005 | 00310027510 | 30 | 15 |

PROCEDURE

| PATID | ENCOUNTERID | ADATE | PROVIDER | ENCTYPE | PX | PX_CODETYPE |
|--------|-------------|------------|-----------|---------|-------|-------------|
| PatID1 | EncID1 | 10/18/2005 | Provider1 | IP | 84443 | C4 |
| PatID1 | EncID1 | 10/18/2005 | Provider1 | IP | 99222 | C4 |
| PatID1 | EncID1 | 10/18/2005 | Provider1 | IP | 99238 | C4 |
| PatID1 | EncID1 | 10/18/2005 | Provider2 | IP | 27445 | C4 |

Sentinel Common Data Model: Device table?

ENCOUNTER

| PATID | ENCOUNTERID | ADATE | DDATE | ENCTYPE |
|--------|-------------|------------|------------|---------|
| PatID1 | EncID1 | 10/18/2005 | 10/20/2005 | IP |

PROCEDURE

| PATID | ENCOUNTERID | ADATE | PROVIDER | ENCTYPE | PX | PX_CODETYPE |
|--------|-------------|------------|-----------|---------|-------|-------------|
| PatID1 | EncID1 | 10/18/2005 | Provider1 | IP | 84443 | C4 |
| PatID1 | EncID1 | 10/18/2005 | Provider1 | IP | 99222 | C4 |
| PatID1 | EncID1 | 10/18/2005 | Provider1 | IP | 99238 | C4 |
| PatID1 | EncID1 | 10/18/2005 | Provider2 | IP | 27445 | C4 |

DEVICES

| PATID | ENCOUNTERID | ADATE | PROVIDER | ENCTYPE | PX | PX_CODETYPE | UDI |
|--------|-------------|------------|-----------|---------|-------|-------------|----------------|
| PatID1 | EncID1 | 10/18/2005 | Provider2 | IP | 27445 | C4 | 00814703010668 |
| PatID1 | EncID1 | 10/18/2005 | Provider2 | IP | 27445 | C4 | 00814703010682 |

Routine Query Capabilities

| Capability |
|--|
| Descriptive Analyses |
| Calculate prevalence and incidence rates |
| Evaluate drug use during pregnancies resulting in live birth |
| Assess exposure to a medical product and define exposed time |
| Allow optional cohort inclusion and/or exclusion criteria |
| Define clinical concepts using complex algorithms |
| Define clinical concepts using laboratory result values |

| Capability |
|---|
| Adjusted Analyses that Control for Confounding |
| Covariate identification and extraction |
| Propensity score estimation and matching |
| Self-controlled risk interval (SCRI) design |
| Sequential Adjusted Analyses |
| Binomial maximized sequential probability ratio testing |

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Thank you!