

Mother-Infant Linkage in Sentinel

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Disclosures



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- This presentation reflects the views of the authors and not necessarily those of the U.S. FDA



Outline

- The Sentinel Distributed Database
- Mother-Infant Linkage
 - Background
 - Process
 - Mothers/deliveries/infant identification
 - Results
 - Propensity Score Tool
 - Innovation in Medical Evidence and Development Surveillance (IMEDS)

The Sentinel Distributed Database



- 66.9 million members with medical and drug coverage currently accruing new data
- 292.5 million cumulative patient identifiers between 2000 and 2017
- 14.4 billion pharmacy dispensings
- 13.3 billion unique medical encounters
- 45.6 million members with at least one laboratory test result



Network of Collaborators

Sentinel brings together public, academic and private organizations that provide access to healthcare data and expertise.



Data at a Glance

The Sentinel Distributed Database is comprised of quality-checked electronic data held by 18 partner organizations.



Statistical Methods

Sentinel explores the application of a wide range of methods to enhance medical product safety assessment.

Mother-Infant Linkage Background

- Pregnancy episodes with live births were previously identified in the Sentinel Distributed Database (SDD) without any linkage to infants claims
- Inability to evaluate the effect of exposures during pregnancy on outcomes in infants
 - Necessary to link mothers/deliveries with infants
- Mother-infant linkage (MIL) data expansion project
 - Deliverables from two rounds of linkages
 - October 31, 2018 and January 31, 2019



Participating Data Partners*

- Aetna
 - Harvard Pilgrim Health Care
 - HealthCore, Inc.
 - Humana/CHI
 - OptumInsight
 - Vanderbilt University Medical Center/Tennessee Medicaid
- Account for approximately 73% of all distinct PatIDs (members) in SDD

*Data will be refreshed approximately every 12 months, depending on the Data Partner

Mother-Infant Linkage Process



- Sentinel Operations Center (SOC) does not have access to patient-level data
 - DPs have total responsibility for the linkage
- The SOC identified mothers/deliveries and infants via a standardized, distributed package
- Matching on subscriber numbers is implemented by all DPs, but there are variations within each DP
- Linking methods for those not initially matched on subscriber ID will vary depending on the identifying information each DP has in their source data

Mothers/Deliveries Identification

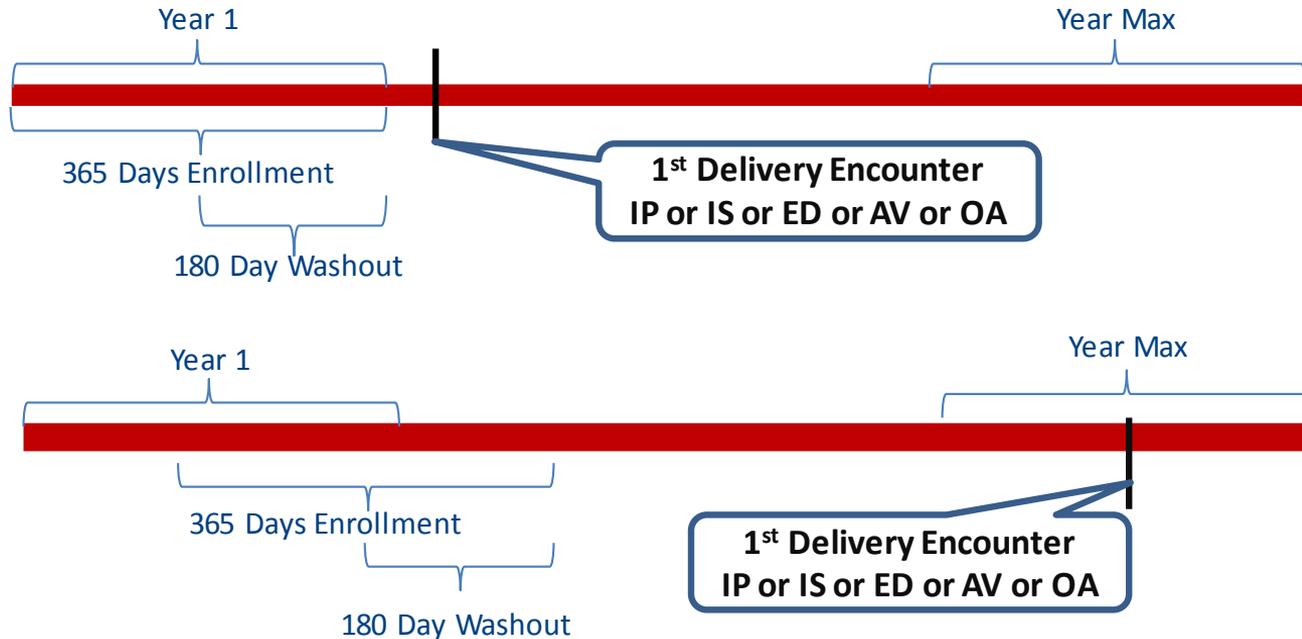


- Mothers must:
 - Be 10-54 years of age inclusive at the time of delivery
 - Have 1 year of medical and drug enrollment coverage at the time of delivery
 - Therefore, no deliveries identified in 1st year of SDD
- Uses over 700 Diagnosis and Procedure codes to identify live birth delivery
 - A validated algorithm developed by the Medication Exposure in Pregnancy Risk Evaluation Program (MEPREP) and other Sentinel and non-Sentinel related pregnancy projects
- 180-day washout period of no evidence of delivery

Mothers/Deliveries Identification



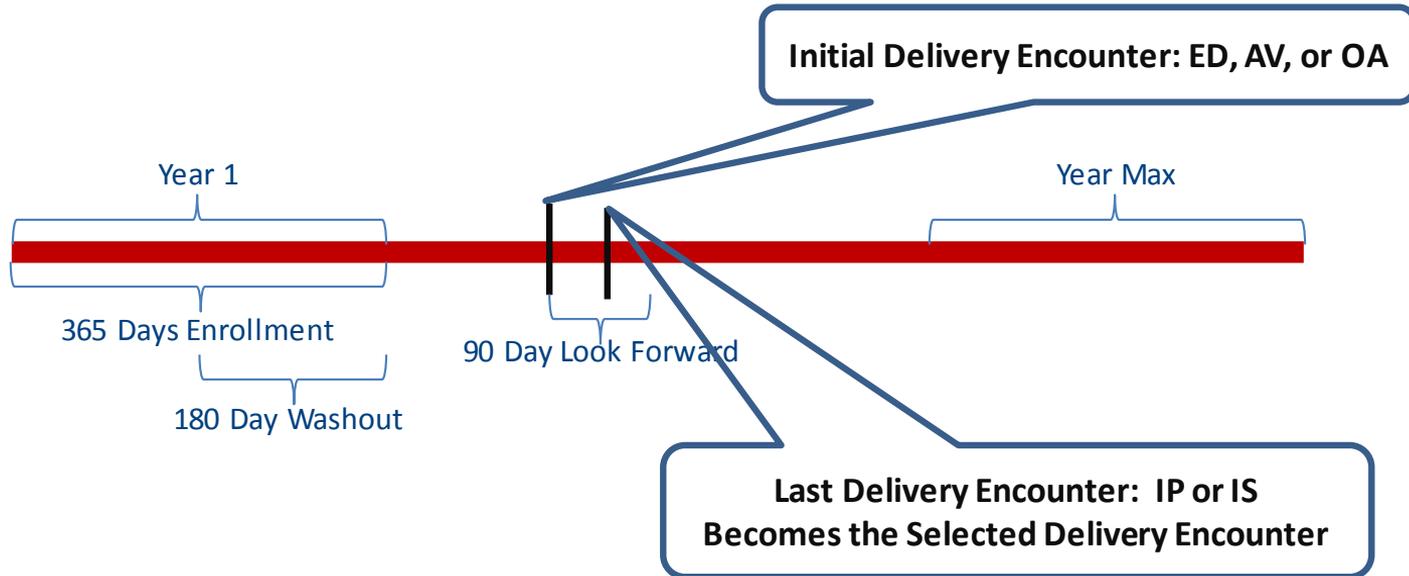
- Round 1



Mothers/Deliveries Identification

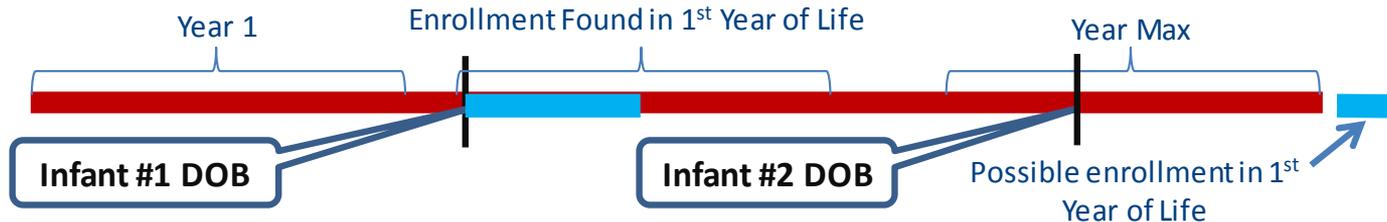


- Round 2



Infants Identification

- Born within dates of SDD
- Starting after 1st year of a SDD
 - Mirrors identification of deliveries
- Requires at least one day of enrollment during 1st year of life
 - Reduces the number of infants identified in the last year of a DP's SDD, as we can't look past the DP's end of data



Linkage Statistics (Provisional)



Table 1. Linkage Results by Mother's Age Group

Age Group	10-19	20-44	45-54	Total
Deliveries	248,880	5,074,881	40,497	5,364,258
Linked Deliveries	115,261	3,820,278	10,693	3,946,232
Linkage Rate	46.3%	75.3%	26.4%	73.6%

Table 2. Linkage Results by Healthcare Encounter Type

Encounter Type	Inpatient	Emergency Department	Institutional	Ambulatory	Other Ambulatory	Total
Deliveries	4,813,135	10,375	4,052	375,367	161,329	5,364,258
Linked Deliveries	3,826,784	1,082	2,773	61,958	53,635	3,946,232
Linkage Rate	79.5%	10.4%	68.4%	16.5%	33.2%	73.6%

Propensity Score Pregnancy Tool



- Before MIL
 - Comparator cohort was non-pregnant episodes matched by age/date to pregnancy episodes; Capability is retained
- Post MIL
 - Inclusion of a non-exposed pregnant cohort
 - Exposed to comparator drug of interest
 - Unexposed
- Propensity Score Tool will use exposed pregnant and non-exposed pregnant cohort as groups to evaluate risk of birth outcomes between the two groups



Access to the Mother-Infant Linkage Table



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Summary

- MIL data expansion project
 - Two rounds of linkages
- Mothers/deliveries/infants identified via a standardized, distributed package
- Matching on subscriber numbers is implemented by all DPs
- 3,946,232 overall linked deliveries (73.6% linkage rate)
- Propensity Score Tool
 - Inclusion of a non-exposed or active comparator pregnant cohort

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