Mother-Infant Linkage in Sentinel

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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

https://www.sentinelinitiative.org/sentinel/data/snapshot-database-statistics
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

IP=inpatient hospital stay; IS=non-acute institutional stay; ED=emergency department; AV=ambulatory visit; OA=other ambulatory visit
Mothers/Deliveries Identification

- Round 2

- Initial Delivery Encounter: ED, AV, or OA

- 365 Days Enrollment
- 180 Day Washout
- 90 Day Look Forward

Last Delivery Encounter: IP or IS
Becomes the Selected Delivery Encounter

IP = inpatient hospital stay; IS = non-acute institutional stay; ED = emergency department; AV = ambulatory visit; OA = other ambulatory visit
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

IP=inpatient hospital stay; IS=non-acute institutional stay; ED=emergency department; AV=ambulatory visit; OA=other ambulatory visit
## Linkage Statistics (Provisional)

### Table 1. Linkage Results by Mother’s Age Group

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

### Table 2. Linkage Results by Healthcare Encounter Type

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

INNOVATION IN MEDICAL EVIDENCE DEVELOPMENT AND SURVEILLANCE

http://reaganudall.org/innovation-medical-evidence-development-and-surveillance
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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