Sentinel Pregnancy Tool and Transition to ICD-10

Elizabeth Suarez, MPH
UNC Chapel Hill
Disclosures

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

- Insurance claims data do not include pregnancy-specific parameters
- The tool enables surveillance of prescription medication use during pregnancy in the Sentinel Distributed Database by:
  - Identifying live births and estimating the length of the pregnancy period
  - Characterizing medical product use by trimester
  - Comparing drug utilization patterns to non-pregnant women by selecting eligible comparators
Pregnancy Tool

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  - **Identifying live births and estimating the length of the pregnancy period**
  - Characterizing medical product use by trimester
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Modify the tool to incorporate new (and more detailed) ICD-10 codes introduced October 1, 2015
Identification of Live Birth Events

- Diagnosis and procedure codes are used to identify a live birth event
  - The ICD-9-CM list was mapped to ICD-10-CM/ICD-10-PCS and reviewed for appropriate code inclusion

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- Users can specify:
  - Continuous enrollment criteria
  - Washout period for deliveries
  - Length of pre-pregnancy period to include for assessment of medication fills

Gestational Age (GA) Algorithm

Delivery date is identified

Delivery date
Gestational Age (GA) Algorithm

Window around delivery date for identifying gestational age codes is user-defined, i.e. 7 days before or after the delivery date

If multiple codes are found, the priority ranking determines the final code
## Examples of ICD-9-CM GA Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>644.21</td>
<td>Onset of delivery before 37 completed weeks of gestation</td>
<td>35</td>
</tr>
<tr>
<td>765.24</td>
<td>27-28 completed weeks of gestation</td>
<td>28</td>
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<tr>
<td>645.10-645.13</td>
<td>Post-term pregnancy</td>
<td>41</td>
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Medication Exposure in Pregnancy Risk Evaluation Program (MEPREP):
- High sensitivity but low specificity for identifying term births
- High sensitivity and specificity for identifying trimester specific antidepressant use

New in ICD-10-CM: Z3A Codes

- Z3A codes document gestational age in weeks
  - One code per week from <8 to >42 weeks

- General guidelines for use:
  - Required when an O code is applied (complications in pregnancy, childbirth, and the puerperium)
  - Optional for routine prenatal care visits and services (using Z34 code for supervision of normal pregnancy)
ICD-10-CM Z3A Codes

37 weeks of gestation: “37 completed weeks” or “less than 38 weeks”
Therefore, we applied the approximate mid-point: 37 weeks and 4 days
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Z3A.37

37 weeks gestation of pregnancy

263 days
(37 4/7 weeks)

Infant codes for extreme immaturity and pre-term newborns were assigned the same durations, weeks <23 through 36
P07.21-P07.26 and P07.31-P07.39


## Additional “Vague” ICD-10-CM Codes

Non-specific codes were assigned the same gestational age as their approximate matches in ICD-9 to maintain consistency across the algorithm.

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<th>Days</th>
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<tr>
<td>O60.12XX</td>
<td>Preterm labor 2\textsuperscript{nd} trimester with preterm delivery 2\textsuperscript{nd} trimester</td>
<td>24</td>
<td>168</td>
</tr>
<tr>
<td>O60.13XX</td>
<td>Preterm labor 2\textsuperscript{nd} trimester with preterm delivery 3\textsuperscript{rd} trimester</td>
<td>35</td>
<td>245</td>
</tr>
<tr>
<td>O60.14XX</td>
<td>Preterm labor 3\textsuperscript{rd} trimester with preterm delivery 3\textsuperscript{rd} trimester</td>
<td>35</td>
<td>245</td>
</tr>
<tr>
<td>O48.0</td>
<td>Post-term pregnancy</td>
<td>41</td>
<td>287</td>
</tr>
<tr>
<td>O48.1</td>
<td>Prolonged pregnancy</td>
<td>42</td>
<td>294</td>
</tr>
<tr>
<td>P07.20</td>
<td>Extreme immaturity of newborn, unspecified weeks of gestation</td>
<td>28</td>
<td>196</td>
</tr>
<tr>
<td>P07.30</td>
<td>Preterm newborn, unspecified weeks of gestation</td>
<td>35</td>
<td>245</td>
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Priority of Gestational Age Codes

1. Gestational week specific codes: Z3A codes and P07 codes
2. “Vague” pre-term codes, that do not specify gestational age but suggest pre-term status
3. “Vague” post-term codes, that do not specify gestational age but suggest post-term status

Within each category, the longest duration is selected

If no code is found, a user-defined default gestational age is defined: i.e. 273 days
Example: Classifying Gestational Age

Gestational age codes identified within 7 days before or after delivery date:

<table>
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<th>Description</th>
<th>Duration</th>
<th>Specific?</th>
<th>Preterm?</th>
<th>Priority</th>
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<tr>
<td>Z3A.34</td>
<td>34 weeks gestation</td>
<td>242</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Z3A.35</td>
<td>35 weeks gestation</td>
<td>249</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>O60.14X1</td>
<td>3rd trimester preterm labor and delivery</td>
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Validation

- Validation with medical records was not done, however the prevalence of pre-term and post-term live births was compared to ICD-9-CM era
- Due to the expansion of ICD-10-CM codes, we would not expect prevalence to map exactly, but major changes were not observed
Conclusions

- Accurately estimating gestational age is an essential part of monitoring drug utilization and safety in pregnancy.
- The number of obstetric codes in ICD-10-CM nearly doubled from what was available in ICD-9-CM, including the addition of specific gestational age codes.
- These codes have been integrated into the original gestational age algorithm in the pregnancy tool, and allow for continued surveillance and safety activities in the ICD-10-CM era.