

# Sentinel Pregnancy Tool and Transition to ICD-10

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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

# 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

- 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

**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

More in: Andrade, S. E., et al. (2015). "Surveillance of Medication Use During Pregnancy in the Mini-Sentinel Program." [Matern Child Health J.](#)

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

More in: Andrade, S. E., et al. (2015). "Surveillance of Medication Use During Pregnancy in the Mini-Sentinel Program." [Matern Child Health J.](#)

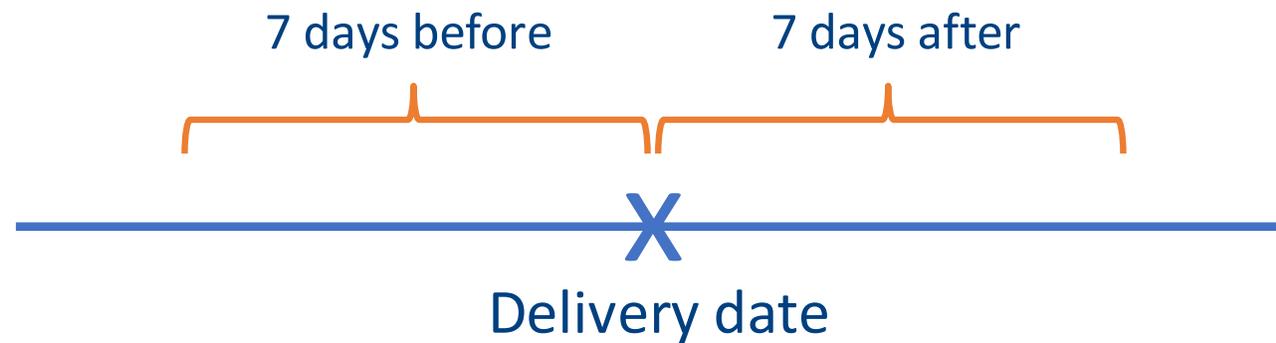
# Gestational Age (GA) Algorithm

Delivery date is identified



# 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

<b>Code</b>	<b>Description</b>	<b>Weeks</b>
644.21	Onset of delivery before 37 completed weeks of gestation	35
765.24	27-28 completed weeks of gestation	28
645.10-645.13	Post-term pregnancy	41

# Examples of ICD-9-CM GA Codes

Code	Description	Weeks
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765.24	27-28 completed weeks of gestation	28
645.10-645.13	Post-term pregnancy	41

## Medication Exposure in Pregnancy Risk Evaluation Program (MEPREP):

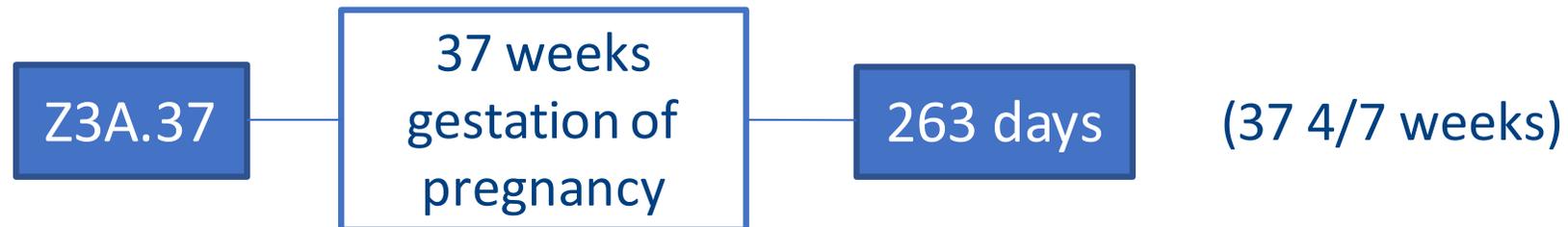
- High sensitivity but low specificity for identifying term births
- High sensitivity and specificity for identifying trimester specific antidepressant use

More in: Li, Q., et al. (2013). "Validation of an algorithm to estimate gestational age in electronic health plan databases." Pharmacoepidemiol Drug Saf **22**(5): 524-532.

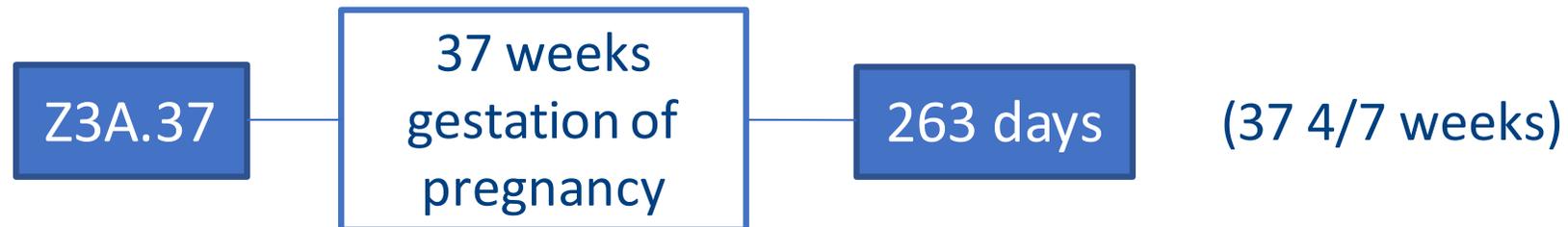
# New in ICD-10-CM: Z3A Codes

- 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)

**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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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**

Code	Description	Weeks	Days
O60.12XX	Preterm labor 2 <sup>nd</sup> trimester with preterm delivery 2 <sup>nd</sup> trimester	24	168
O60.13XX	Preterm labor 2 <sup>nd</sup> trimester with preterm delivery 3 <sup>rd</sup> trimester	35	245
O60.14XX	Preterm labor 3 <sup>rd</sup> trimester with preterm delivery 3 <sup>rd</sup> trimester	35	245
O48.0	Post-term pregnancy	41	287
O48.1	Prolonged pregnancy	42	294
P07.20	Extreme immaturity of newborn, unspecified weeks of gestation	28	196
P07.30	Preterm newborn, unspecified weeks of gestation	35	245

# 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:**

<b>Code</b>	<b>Description</b>	<b>Duration</b>	<b>Specific?</b>	<b>Preterm?</b>	<b>Priority</b>
Z3A.34	34 weeks gestation	242	Yes	Yes	
Z3A.35	35 weeks gestation	249	Yes	Yes	
O60.14X1	3 <sup>rd</sup> trimester preterm labor and delivery	245	No	Yes	

# Example: Classifying Gestational Age

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

Code	Description	Duration	Specific?	Preterm?	Priority
Z3A.34	34 weeks gestation	242	Yes	Yes	2
<b>Z3A.35</b>	<b>35 weeks gestation</b>	<b>249</b>	<b>Yes</b>	<b>Yes</b>	<b>1</b>
O60.14X1	3 <sup>rd</sup> trimester preterm labor and delivery	245	No	Yes	3

# 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