

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.](#)

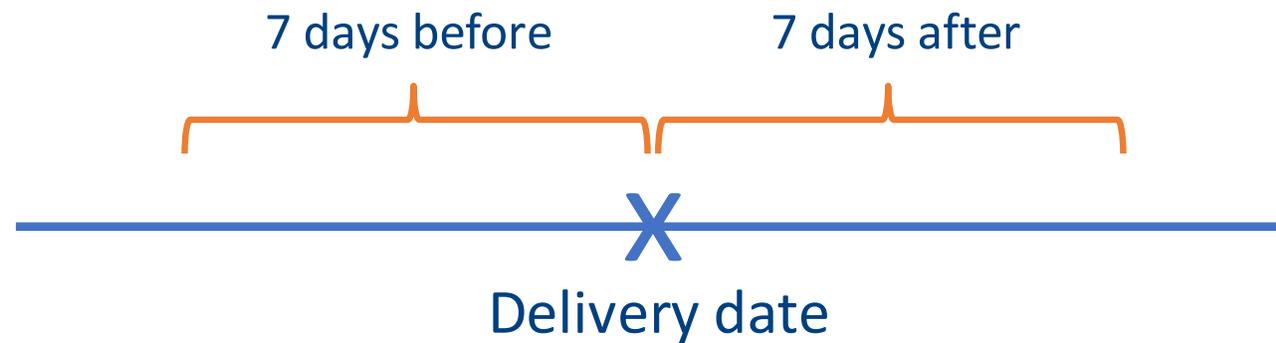
Gestational Age (GA) Algorithm

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

Code	Description	Weeks
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

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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

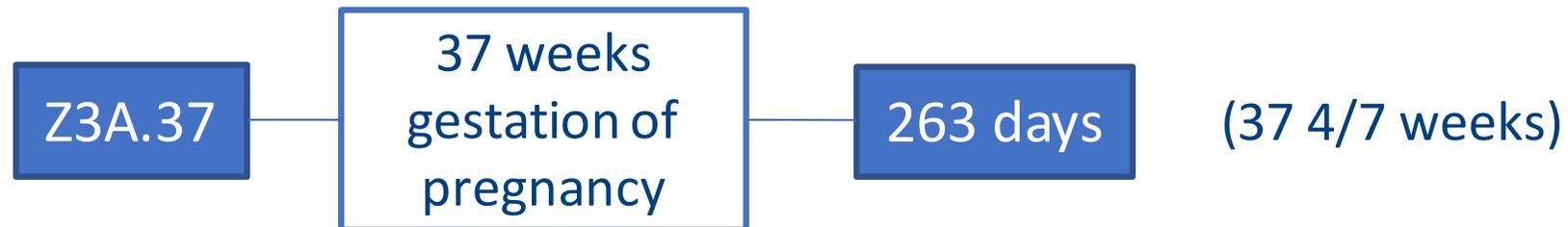
More in: Li, Q., et al. (2013). "Validation of an algorithm to estimate gestational age in electronic health plan databases." Pharmacoepidemiol Drug Saf **22**(5): 524-532.

New in ICD-10-CM: Z3A Codes

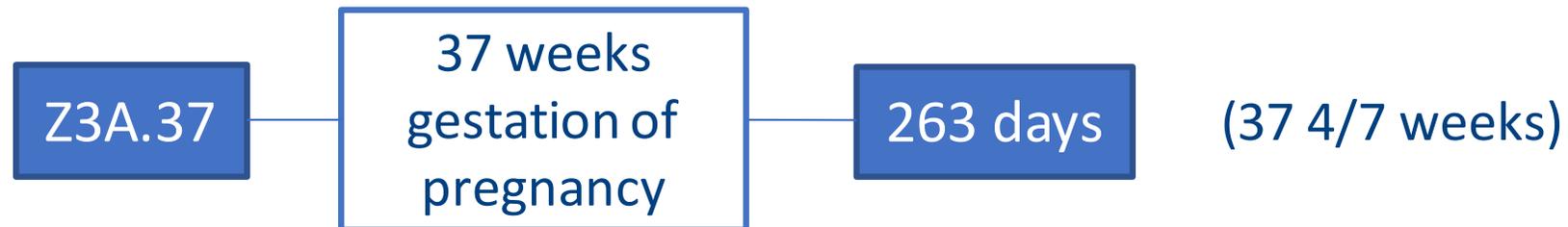
- Z3A codes document gestational age in weeks
 - One code per week from <8 to >42 weeks

- 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)

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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 nd trimester with preterm delivery 2 nd trimester	24	168
O60.13XX	Preterm labor 2 nd trimester with preterm delivery 3 rd trimester	35	245
O60.14XX	Preterm labor 3 rd trimester with preterm delivery 3 rd 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:

Code	Description	Duration	Specific?	Preterm?	Priority
Z3A.34	34 weeks gestation	242	Yes	Yes	
Z3A.35	35 weeks gestation	249	Yes	Yes	
O60.14X1	3 rd 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
Z3A.35	35 weeks gestation	249	Yes	Yes	1
O60.14X1	3 rd 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