

Sentinel Using Prenatal Tests to Estimate Pregnancy Start in Health Insurance Claims Data

Lyons JG¹, Bird ST², Stojanovic D², Maro JC¹, Toh D¹, Fazio-Eynullayeva E¹, Petrone AB¹, Rajbhandari R¹, Taylor LG²

¹Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute, Boston, MA;
²U.S. Food and Drug Administration Center for Drug Evaluation and Research, Division of Epidemiology, Silver Spring, MD

BACKGROUND

- Claims-based studies evaluating medical product safety during pregnancy are typically limited to pregnancies ending in a live-birth delivery.
- Identifying pregnancy start in administrative claims can be difficult in the absence of gestational age codes and for non-live birth deliveries.
- Our study aimed to develop a claims-based algorithm using diagnosis and procedure codes for routine prenatal tests and fertility procedures to classify the timing of pregnancy start in a live-birth delivery cohort.
- We evaluated the prevalence of the individual prenatal tests and fertility procedures in a cohort of stillbirths and reported the proportion of stillbirths captured by the algorithm.

METHODS

Sentinel is an active surveillance system that uses routine querying tools and pre-existing electronic healthcare data from multiple sources, including health insurance claims data, to monitor the safety of regulated medical products. In the Sentinel Distributed Database, we identified pregnancies ending in a live birth delivery from 1/1/06-1/31/18 among women aged 15-45 years and assigned an estimated pregnancy start date using a previously validated claims-based algorithm¹ that calculates gestational age at delivery based on International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis codes indicative of weeks of gestation, and International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and ICD-10-CM diagnosis codes for preterm and postterm deliveries in the mother's health insurance claims record. This claims-based validated algorithm was shown to classify 77% of pregnancies within two weeks of the clinical estimate of last menstrual period, and we considered it to be the gold standard reference for comparing our prenatal test and fertility procedures algorithms.

IDENTIFYING PRENATAL TEST AND PROCEDURES AND ESTIMATING PERFORMANCE

Using Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) procedure codes, we identified 16 potential prenatal tests and fertility procedures for inclusion in the algorithms. We used clinically recommended timing of these tests and procedures to assign a single gestational day for each test and estimated pregnancy start based on this gestational day within the cohort of live birth deliveries. We quantified the days difference between the reference start date from the gold standard claims-based algorithm and each estimated start date, then defined performance as the proportion of estimated (prenatal test and procedure) start dates that occurred within two weeks of the reference (gold standard) start date.

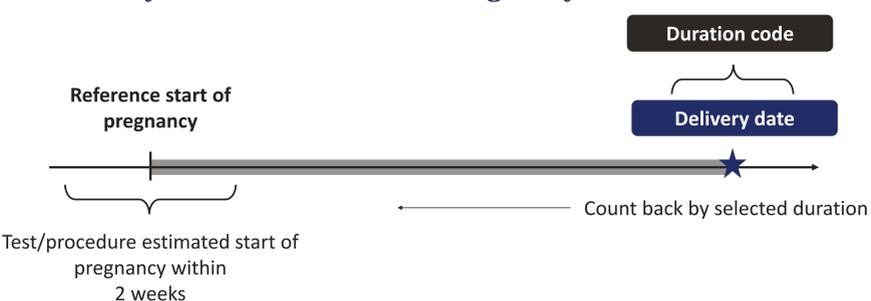
PRENATAL TEST AND PROCEDURE ALGORITHM

We developed three algorithms by adding the 12 highest-performing prenatal tests and fertility procedures in order of this measure of performance and assigned an algorithm-identified pregnancy start date based on the highest performing test that was observed in the mother's health insurance claims record. We calculated the proportion of live birth pregnancies captured by each algorithm and the median difference in days between the reference and algorithm-identified start dates.

EVALUATING STILLBIRTH COHORT

We identified a cohort of pregnancies among women aged 15-45 years with probable stillbirth using a validated claims-based algorithm² and reported the percent of probable stillbirths with each prenatal test or fertility procedure of interest in the 224, 280 and 301 days prior to the observed stillbirth code. We then calculated the proportion of stillbirths assigned a gestational age at stillbirth by each of the three algorithms for each evaluation period.

Figure 1: Calculating Reference Pregnancy Start and Prenatal Test/Fertility Procedure Estimated Pregnancy Start



ACKNOWLEDGEMENTS

- Many thanks are due to Data Partners who provided data used in the analysis.
- The authors have no conflicts of interests to disclose.
- The opinions expressed in this poster are those of the authors and not necessarily of the U.S. FDA.
- This work was supported by the FDA through the Department of Health and Human Services (HHS) Contract number HHSF223201400030I.

REFERENCES

- Li Q, Andrade SE, Cooper WO, Davis RL, Dublin S, Hammad TA, et al. Validation of an algorithm to estimate gestational age in electronic health plan databases. *Pharmacoepidemiol Drug Saf.* 2013;22(5):524-32.
- Likis FE, Sathe NA, Carnahan R, McPheeters ML. A systematic review of validated methods to capture stillbirth and spontaneous abortion using administrative or claims data. *Vaccine.* 2013 Dec 30;31(Suppl 10(31 Suppl 10)):K74-82.

RESULTS

- Among 4,727,266 live birth pregnancies, 97.9% had at least one prenatal test or fertility procedure of interest.
- Performance ranged from 90.6% (nuchal translucency) to 20.1% (first trimester ultrasound; data not shown).
- Algorithm 1 included the six highest performing tests ($\geq 80\%$), captured 81.9% of live birth pregnancies, and had a median difference of 5 days compared to the reference start date.
- Algorithms 2 and 3 had lower cut offs for test performance ($\geq 70\%$ and $\geq 60\%$) and included 87.6% and 97.9% of live birth pregnancies with median differences of 6 days and 6 days, respectively, compared to the reference start date.
- Among 40,484 probable stillbirth pregnancies, 92.7% had at least one prenatal test or fertility procedure of interest.
- Two-thirds of stillbirth pregnancies were captured by at least one algorithm.

Table 1. Prenatal Tests and Fertility Procedures Selected for Inclusion in the Algorithm

Test or Procedure	Codes	Gestational Age at Start (days)	Performance (%)
Nuchal Translucency Measurement	76813, 76814	88	90.6%
Chorionic villus sampling	59015	84	84.4%
PAPP-A serum test	84163	85	82.6%
Group B streptococcus screening	87081	252	82.2%
Assay of estriol	82677	119	79.6%
IFV/IUI	58321, 58322, 58974, 58976, S4011, S4013, S4014, S4015, S4016, S4035, S4037	14	78.3%
Inhibin A	86336	119	78.1%
Fetal aneuploidy genomic sequence analysis, cell-free fetal DNA	81420	85	72.6%
Detailed fetal anatomic examination	76811, 76812	138	70.4%
Alpha-fetoprotein, amniotic	82106	120	68.4%
Glucose	82950, 82951	190	66.4%
Complete Ultrasounds, Second and Third Trimesters	76805, 76810	128	63.8%

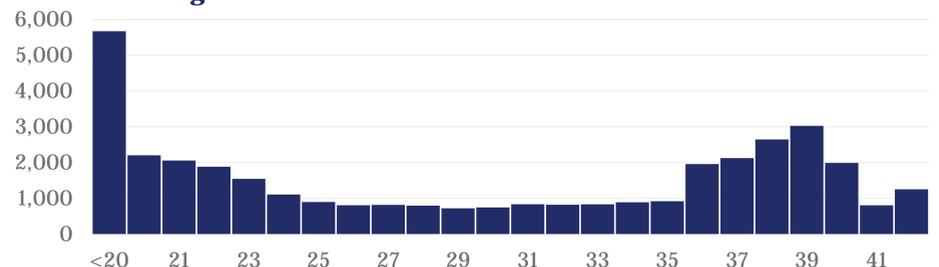
Table 2. Live Born Pregnancies Captured by Three Prenatal Tests and Fertility Procedures Algorithms

Algorithm	Pregnancies captured by algorithm, n (%)	Median, days	IQR, days	Mean (SD), days
Algorithm 1	3,872,826 (81.9%)	5	7	13.6 (36.5)
Algorithm 2	4,139,920 (87.6%)	6	7	14.2 (36.1)
Algorithm 3	4,630,050 (97.9%)	6	8	14.8 (35.6)

Table 3. Stillbirth Pregnancies Captured by Prenatal Tests and Fertility Procedures Algorithms

Algorithm	Pregnancies captured by algorithm, n (%)		
	224 Days	280 Days	301 Days
Algorithm 1	25,448 (62.9%)	25,666 (63.4%)	25,729 (63.6%)
Algorithm 2	31,562 (78.0%)	31,691 (78.3%)	31,734 (78.4%)
Algorithm 3	37,433 (92.5%)	37,498 (92.6%)	37,525 (92.7%)

Figure 2: Count of Probable Stillbirths by Algorithm-Estimated Gestational Age at Stillbirth



DISCUSSION

- Our algorithms used routine prenatal tests and fertility procedures to define pregnancy start in a population of commercially- and Medicaid-insured pregnant women with live birth deliveries.
- A large proportion of pregnancies ending in stillbirth were observed to have codes for these routine tests and procedures.
- With no gold standard for estimating pregnancy start for non-live birth pregnancies using health insurance claims data, the ability of the algorithms to estimate pregnancy start could not be quantified.
- Future research will assess the accuracy of these algorithms in non-live birth deliveries.