



Validation of an ICD-10-based Algorithm to Identify Stillbirth in the Sentinel System

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Disclosures

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Background

- Fetal deaths include stillbirths and spontaneous abortions, which are generally differentiated by gestational age and/or birth weight
- Stillbirth data in the U.S. are commonly reported as fetal deaths at ≥ 20 weeks gestation
- Approximately 24,000 stillbirths occur in the U.S. annually, representing about 1% of all pregnancies*

Background

- Few studies have developed and validated algorithms to identify stillbirths using administrative or claims data in U.S. populations
 - Vaccine Safety Datalink (VSD) developed and validated an International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) based algorithm for identifying pregnancy episodes, outcomes, and mother-infant pairs*
 - 12 pregnancies identified with ICD-9-CM codes for stillbirth, 11 were confirmed through medical record review (PPV=92%)

Objectives

- To develop and validate an ICD-10-CM-based algorithm to identify cases of stillbirth using electronic healthcare data

Study Design

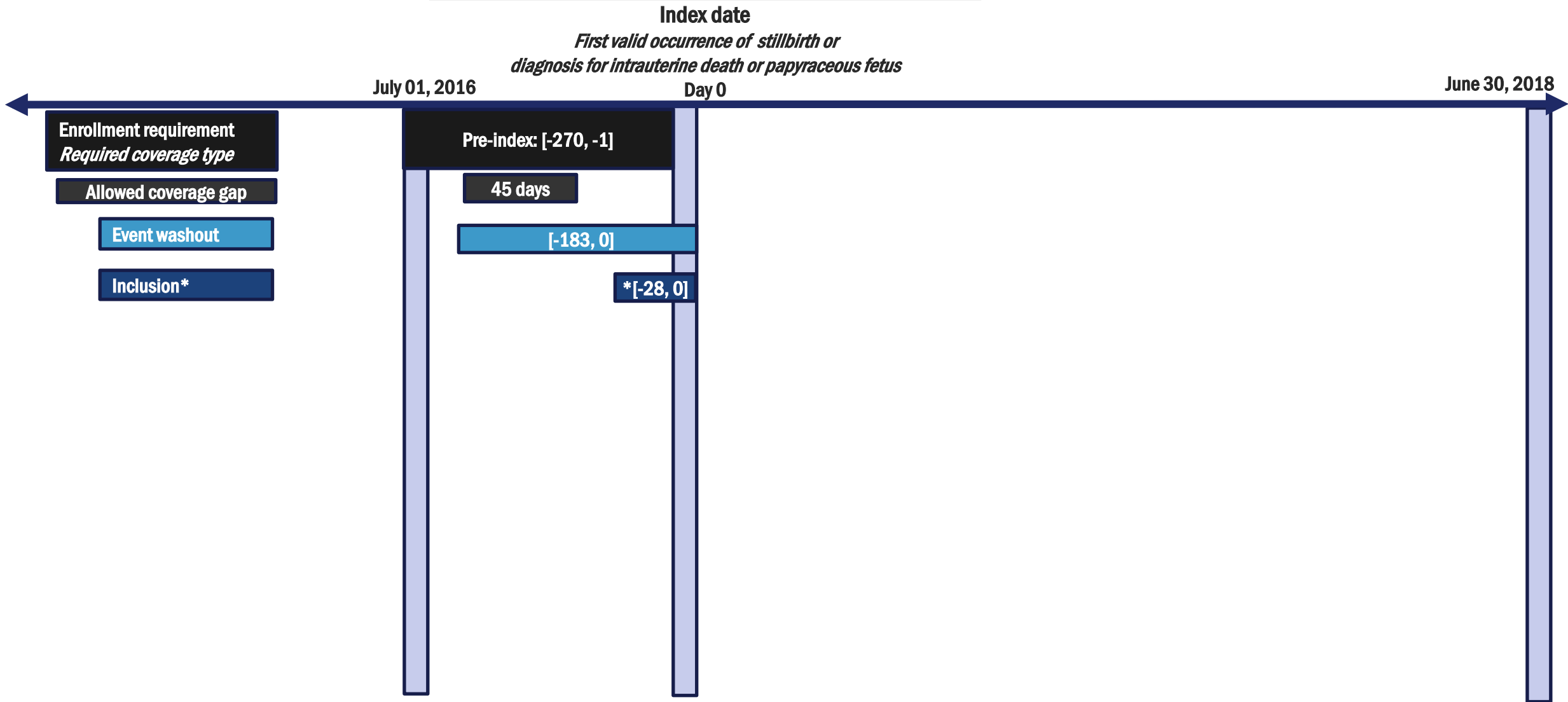
- Development of an ICD-10-CM based algorithm to identify cases of stillbirth using electronic health data
 - Based upon information from published studies and results of trend and code distribution analyses using IBM® MarketScan® Research Databases
 - Algorithm included diagnosis codes for stillbirth or a combination of intrauterine death or papyraceous fetus and a gestational age code ≥ 20 weeks

Study Design (continued)

ICD-10-CM Diagnosis Codes

031.00XX	Papyraceous fetus, unspecified trimester
031.02XX	Papyraceous fetus, second trimester
031.03XX	Papyraceous fetus, third trimester
036.4XXX	Maternal care for intrauterine death
Z37.1	Single stillbirth
Z37.3	Twins, one liveborn and one stillborn
Z37.4	Twins, both stillborn
Z37.60	Multiple births, unspecified, some liveborn
Z37.61	Triplets, some liveborn
Z37.62	Quadruplets, some liveborn
Z37.63	Quintuplets, some liveborn
Z37.64	Sextuplets, some liveborn
Z37.69	Other multiple births, some liveborn
Z37.7	Other multiple births, all stillborn
P95	Stillbirth

Stillbirth potential cases identification



<p>*Inclusion Diagnosis code ≥ 20-Week Gestation was required within 28 days of code for intrauterine death or papyraceous fetus</p>	<p>**Cohort Restrictions 12-55 years of age on index date Females</p>
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Study Design (continued)

- Retrospective study using data from three Data Partners (U.S. health systems) included in FDA's Sentinel System
 - A random sample of medical charts (N=169) was identified for chart abstraction and adjudication; 110 had obtainable chart
 - Two physician adjudicators reviewed potential cases to determine whether a stillbirth event was definite/probable, the date of the event, and the gestational age at delivery
 - Clinical definition based upon the Brighton Collaboration Stillbirth Working Group guidelines*

Analysis

- Positive predictive value (PPV) was calculated for the algorithm
 - Secondary analyses: PPV estimates stratified by demographic and encounter characteristics
 - Post hoc sensitivity analyses
- Among confirmed cases, agreement between the claims data and medical charts was determined for both the event date and gestational age (GA) at stillbirth

Results

- 54/110 confirmed stillbirth events (PPV= 49.1%; 95% CI, 39.4%-58.8%)
 - Majority were identified in the inpatient setting (90.7%; 49/54 confirmed cases)
 - All 54 confirmed cases had an ICD-10-CM diagnosis code indicating a GA \geq 20 weeks

Results (continued)

Validation of diagnosis and procedure codes in health plan administrative databases for identification of stillbirth - all woman for whom charts were obtained

Population	Number of charts reviewed	Number of cases confirmed	Positive predictive value (95% confidence interval)
Overall	110	54	49.1% (39.4%-58.8%)
Encounter type			
Inpatient	87	49	56.3% (45.3%-66.9%)
Emergency department	1	0	0.0% (0.0%-97.5%)
Ambulatory visit	17	4	23.5% (6.8%-49.9%)
Other ambulatory encounter type	5	1	20.0% (0.5%-71.6%)
Code for other pregnancy outcome on index date			
Livebirth only	24	8	33.3% (15.6%-55.3%)
Spontaneous abortion only	21	3	14.3% (3.0%-36.3%)
Induced abortion only	3	1	33.3% (0.8%-90.6%)
More than one other pregnancy outcome	6	1	16.7% (0.4%-64.1%)
No other pregnancy outcome code	56	41	73.2% (59.7%-84.2%)

Results (continued)

- Of the 56 potential cases not confirmed to be stillbirth events
 - 22 (39.3%) spontaneous abortions
 - 19 (33.9%) liveborn infants or continuing pregnancies
 - 11 (19.6%) were terminations of pregnancy, including inductions of labor for pregnancy complications
 - 1 neonatal death shortly after birth
 - 3 cases were unable to determine diagnosis (insufficient/conflicting information in the chart)
- $\geq 90\%$ agreement within 7 days between claims data and medical charts for both the outcome date and GA at stillbirth

Results – Post Hoc Sensitivity Analysis

- Sensitivity analyses conducted restricting to cohort with an ICD-10-CM diagnosis code indicating a GA \geq 20 weeks improved PPV (66.7%; 95% CI, 55.3%-76.8%)
- PPV = 83.7% (95% CI, 70.3%-92.7%) among women with a code indicating a GA \geq 20 weeks for whom no other pregnancy outcome code (i.e. livebirth, spontaneous abortion, induced abortion) was recorded on the index date

Results – Post Hoc Sensitivity Analysis

Validation of diagnosis and procedure codes in health plan administrative databases for identification of stillbirth - restricting to adjudicated potential cases with an ICD-10-CM diagnosis code indicating a gestational age \geq 20 weeks

Population	Number of charts reviewed	Number of cases confirmed	Positive predictive value (95% confidence interval)
Overall	81	54	66.7% (55.3%-76.8%)
Encounter type			
Inpatient	68	49	72.1% (59.9%-82.3%)
Emergency department	1	0	0.0% (0.0%-97.5%)
Ambulatory visit	10	4	40.0% (12.2%-73.8%)
Other ambulatory encounter type	2	1	50.0% (1.3%-98.7%)
Code for other pregnancy outcome on index date			
Livebirth only	23	8	34.8% (16.4%-57.3%)
Spontaneous abortion only	5	3	60.0% (14.7%-94.7%)
Induced abortion only	3	1	33.3% (0.8%-90.6%)
More than one other pregnancy outcome	1	1	100.0% (2.5%-100.0%)
No other pregnancy outcome code	49	41	83.7% (70.3%-92.7%)

Strengths

- Size and diversity of the study population
 - Mostly commercial healthcare systems
- Validation of cases was performed by clinical adjudicators with expertise in obstetrics and gynecology using established guidelines for the clinical definition of stillbirth

Limitations

- Evaluated only women meeting our specified criteria which included codes suggestive of stillbirth
 - could not evaluate the sensitivity and specificity of the algorithm
- 72% of medical records requested were obtained for chart review (62% of overall potential cases identified)
 - distributions of characteristics were generally similar among potential cases for whom charts were available versus those for whom charts were not obtained

Conclusions

- Electronic healthcare data may be useful for signal detection of medical product exposures potentially associated with stillbirth
- Further work is ongoing to refine the algorithm to maximize the PPV and sensitivity

Workgroup Members

- **Meyers Primary Care Institute:** Susan Andrade, ScD; Tiffany Moore-Simas, MD, MPH, Med, FACOG; Cassandra Saphirak, MA; Christopher Delude, BA
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- **U.S. Food and Drug Administration (FDA):** Danijela Stojanovic, PhD, PharmD; Steven Bird, PhD, PharmD; Lockwood Taylor, PhD
- **Adjudicators:** Julianne Luring, MD (University of Massachusetts Medical School); Erin Longley, MD (Community Health Care)



Thank You