

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

Susan E. Andrade, Sc.D.

Meyers Primary Care Institute/ University of
Massachusetts Medical School

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Stillbirth Validation Project Workgroup



- **Meyers Primary Care Institute:** Susan Andrade, ScD; Tiffany Moore-Simas, MD, MPH, Med, FACOG; Cassandra Saphirak, MA; Christopher Delude, BA
- **Sentinel Operations Center:** Justin Bohn, ScD; Sandra DeLuccia, MPH; Elnara Fazio-Eynullayeva, MA; Tancy Zhang, MPH; Autumn Gertz
- **U.S. Food and Drug Administration (FDA):** Danijela Stojanovic, PhD, PharmD; Lockwood Taylor, PhD; Steven Bird, PhD, PharmD
- **Adjudicators:** Julianne Loring, MD (University of Massachusetts Medical School); Erin Longley, MD (Community Health Care)

- This project is one of a series being launched to support FDA's use of the active postmarket risk identification and analysis system (ARIA) for select medical products, including recent new drug applications
- 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 (continued)

- 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%)
 - No published U.S. or Canadian studies have validated algorithms to identify stillbirths based upon ICD-10-CM codes

Objectives

- Develop an ICD-10-CM based algorithm to identify stillbirth
- Assess the positive predictive value (PPV) of the ICD-10-CM based algorithm and Patient Episode Profile Retrieval (PEPR) results through medical chart review

Design of Stillbirth Validation Project

- **Determination of the population in whom to identify stillbirth, development of an ICD-10-CM-based algorithm, formulation of the clinical case definition, and formulation of a strategy to evaluate the accuracy of PEPR results to identify patients who had a stillbirth event**
- Execution of PEPR and retrieval of patient profiles and medical records for review
- Abstraction and adjudication
- Calculation of PPV

Sentinel Tools for Identification and Retrieval of Cohorts/Data of Interest

■ Cohort Identification and Descriptive Analysis (CIDA) Tool

- Main purpose of the CIDA tool is to identify and extract cohorts of interest from the Sentinel Distributed Database (SDD) based on the specification of requester-defined options (e.g., exposures, outcomes, continuous enrollment requirements, incidence criteria, inclusion/exclusion criteria, relevant age groups and demographic criteria such as sex and race)

■ Patient Episode Profile Retrieval (PEPR) Tool

- Retrieves patient-level electronic data drawn from Data Partners' SDDs
- A “patient episode profile” is a summary of information (e.g., encounters, diagnosis codes, procedure codes, etc.) pertaining to a particular patient during a particular time period

Identification of Stillbirth Events: Algorithm Development

- Algorithm based upon information from published studies and results of trend and code distribution analyses using Truven Health MarketScan[®] Commercial and Medicare Supplemental Databases
 - Identified ICD-10-CM diagnosis for potential stillbirths by conducting forward-backward mapping of ICD-9-CM codes validated in the VSD study by Naleway et al. using the General Equivalence Mappings (GEMs) tool
 - Additional search of ICD-10-CM diagnosis codes to ensure complete capture of potentially relevant codes
 - Trend analysis: found an almost two-fold increase in the rate of stillbirth in the ICD-10 era compared to ICD-9 era using the initial code list determined by the workgroup
 - More pronounced in outpatient setting vs. inpatient setting

Algorithm Development (continued)

ICD-10-CM Diagnosis Codes	
O31.00XX	Papyraceous fetus, unspecified trimester
O31.02XX	Papyraceous fetus, second trimester
O31.03XX	Papyraceous fetus, third trimester
O36.4XXX	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

- **Final Algorithm**

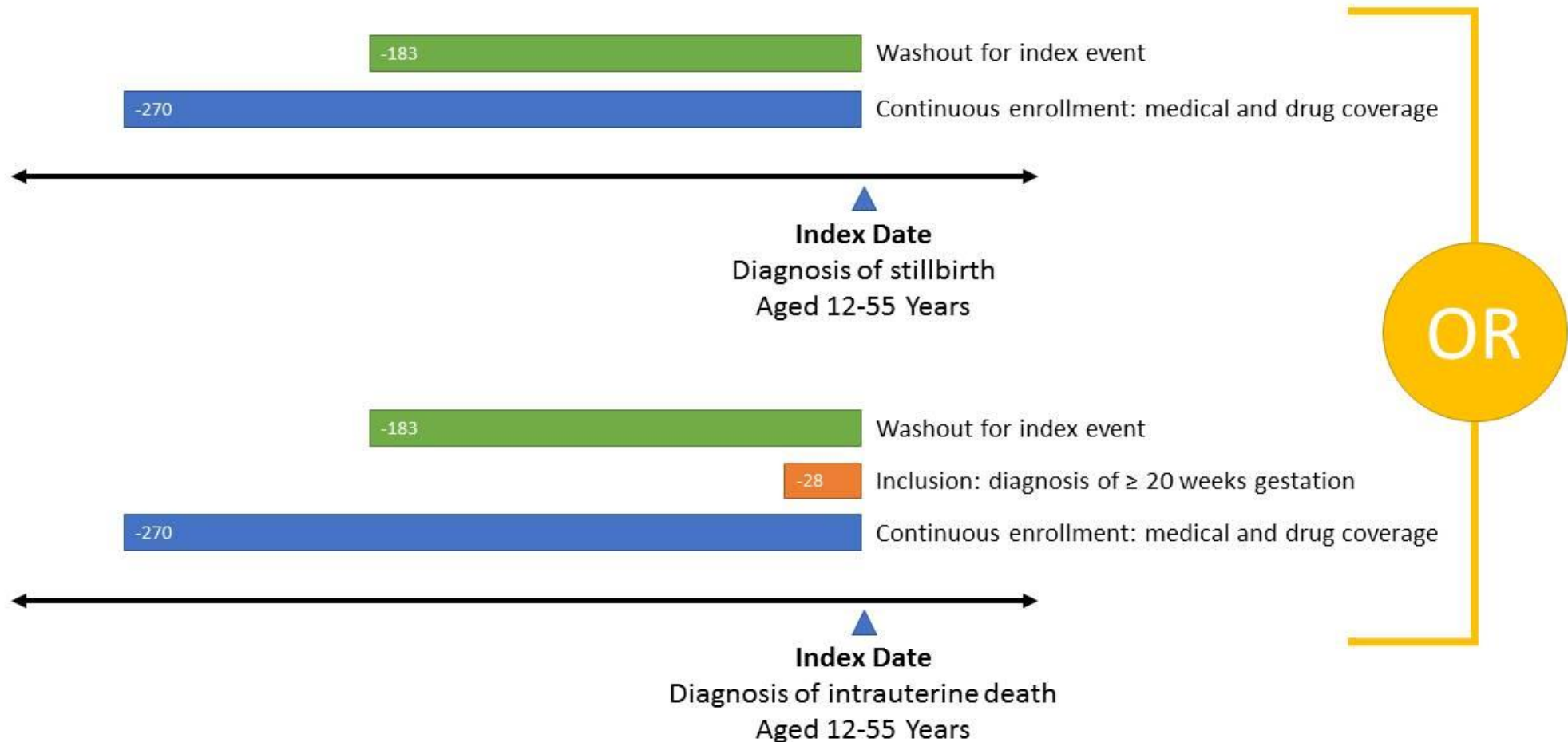
At least one ICD-10-CM code specifically describing **stillbirth/stillborn outcome of delivery** (Z37.1, Z37.3, Z37.4, Z37.6X, Z37.7, P95)

OR

At least one ICD-10 –CM code for **intrauterine death or papyraceous fetus** (O36.4XXX and O31.0XXX) **PLUS** an **ICD-10-CM code indicating a gestational age greater than or equal to 20 weeks** (ICD-10-CM codes Z3A20-Z3A49) was recorded within the period 28 days before the code for intrauterine death or papyraceous fetus

Final ICD-10-CM Based Algorithm for Stillbirth

Study Period: July 1 2016 – end of available data



Clinical Case Definition

- Clinical definition for stillbirth based upon case definition of Brighton Collaboration Stillbirth Working Group
- Death of the fetus could have been diagnosed before the onset of labor or at the time of delivery
- Information documented and procedures performed could differ for events diagnosed at the time of delivery (or post-delivery) and events diagnosed before the onset of labor (pre-delivery)

*Tavares Da Silva F, et al. Vaccine. 2016;34(49):6057-6068

Clinical Case Definition (continued)

- If the event was diagnosed post- delivery:
 - Determination of the absence of signs of life at time of delivery (no spontaneous movements, no heartbeat, no respirations, and Apgar score of 0 at 1 and 5 min) is made by physical examination after attended delivery by obstetric care provider
 - AND
 - Gestational age \geq 20 weeks
 - AND
 - No procedure performed to intentionally stop fetal cardiac activity (e.g. KCL injection for termination)

Clinical Case Definition (continued)

- If the event was diagnosed pre-delivery:
 - Prenatal ultrasound examination documenting lack of fetal cardiac activity or movement before the onset of labor
 - OR
 - Auscultation for fetal heart tones (using electronic devices or non-electronic devices) documenting lack of fetal heartbeat
 - AND
 - Gestational age \geq 20 weeks
 - AND
 - No procedure performed to intentionally stop fetal cardiac activity (e.g. KCL injection for termination)

Project Status

- ICD-10-CM based algorithm developed and tested on Truven Health MarketScan[®] data
- Clinical definition determined
- Draft abstraction and adjudication forms developed

Next Steps

- Identification and sampling of potential cases for chart and PEPR results review: will pursue retrieval of 200 and aim to retrieve up to 150 charts
- Retrieval and redaction of medical records
 - Standard Operation Procedures (SOP) document being developed for Data Partners
- Chart abstraction
- Adjudication of potential cases
 - PEPR results
 - to determine whether using PEPR data alone is sufficient to identify stillbirth among patients
 - Medical charts
 - Calculation of PPV

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