Disclaimer

The FDA chose a specific outcome algorithm that met its need for a given medical product-outcome assessment. The use of a specific outcome algorithm in a Sentinel assessment should not be interpreted as an endorsement from FDA to use the algorithm for all safety assessments. Investigators should always consider the objective, study design, analytic approach, and data source of a given medical product safety assessment when choosing the outcome algorithm. The suitability of an outcome algorithm may change when applied to different scenarios. For additional information, please refer to the

Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data guidance document provided by the FDA.

Overview

Title	Preterm Birth Algorithm Defined in "Risk of Adverse Maternal Health Outcomes Among Pregnant Patients With and Without COVID-19: A Propensity Score Matched Analysis"
Request ID	cder_mpl2p_wp048
Description	This report lists International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes and algorithms used to define preterm birth in this request. For additional information about the algorithm and how it was defined relative to the cohort and exposure(s) of interest in the analysis, refer to the analysis webpage here: https://www.sentinelinitiative.org/studies/drugs/individual-drug-analyses/risk-adverse-maternal-health-outcomes-among-pregnant
Outcome	Preterm birth
Algorithm to Define Outcome	The preterm birth outcome is defined as one ICD-10-CM diagnosis code for preterm birth (Code List 1) in the 22 weeks 0/7 days to 36 weeks 6/7 days (154 to 258 days from estimated pregnancy start date).
Query Period	January 1, 2020 - November 30, 2023
Request Send Date	February 8, 2024

Glossary

Care Setting - type of medical encounter or facility where the exposure, event, or condition code was recorded. Possible care settings include: Inpatient Hospital Stay (IP), Non-Acute Institutional Stay (IS), Emergency Department (ED), Ambulatory Visit (AV), and Other Ambulatory Visit (OA). For laboratory results, possible care settings include: Emergency department (E), Home (H), Inpatient (I), Outpatient (O), or Unknown or missing (U)

Outcome - outcome of interest (either primary or secondary)

Principal Diagnosis (PDX) - diagnosis or condition established to be chiefly responsible for admission of the patient to the hospital. 'P' = principal diagnosis, 'S' = secondary diagnosis, 'X' = unspecified diagnosis, '.' = blank. Along with the Care Setting values, forms the Caresetting/PDX parameter.

Query Period - period in which the modular program looks for exposures and outcomes of interest

Request Send Date - date the request was sent to Sentinel Data Partners

Code List 1. List of International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Codes Used to Define Preterm Birth in this Request

Code	Description	Code Category	Code Type
	Preterm birth		
P0739	Preterm newborn, gestational age 36 completed weeks	Diagnosis	ICD-10-CM
P0738	Preterm newborn, gestational age 35 completed weeks	Diagnosis	ICD-10-CM
P0737	Preterm newborn, gestational age 34 completed weeks	Diagnosis	ICD-10-CM
P0736	Preterm newborn, gestational age 33 completed weeks	Diagnosis	ICD-10-CM
P0735	Preterm newborn, gestational age 32 completed weeks	Diagnosis	ICD-10-CM
P0734	Preterm newborn, gestational age 31 completed weeks	Diagnosis	ICD-10-CM
P0733	Preterm newborn, gestational age 30 completed weeks	Diagnosis	ICD-10-CM
P0732	Preterm newborn, gestational age 29 completed weeks	Diagnosis	ICD-10-CM
P0731	Preterm newborn, gestational age 28 completed weeks	Diagnosis	ICD-10-CM
P0726	Extreme immaturity of newborn, gestational age 27 completed weeks	Diagnosis	ICD-10-CM
P0725	Extreme immaturity of newborn, gestational age 26 completed weeks	Diagnosis	ICD-10-CM
P0724	Extreme immaturity of newborn, gestational age 25 completed weeks	Diagnosis	ICD-10-CM
P0723	Extreme immaturity of newborn, gestational age 24 completed weeks	Diagnosis	ICD-10-CM
P0722	Extreme immaturity of newborn, gestational age 23 completed weeks	Diagnosis	ICD-10-CM
P0721	Extreme immaturity of newborn, gestational age less than 23 completed weeks	Diagnosis	ICD-10-CM
P0720	Extreme immaturity of newborn, unspecified weeks of gestation	Diagnosis	ICD-10-CM
O6013X0	Preterm labor second trimester with preterm delivery third trimester	Diagnosis	ICD-10-CM
O6013X1	Preterm labor second trimester with preterm delivery third trimester	Diagnosis	ICD-10-CM
O6013X2	Preterm labor second trimester with preterm delivery third trimester	Diagnosis	ICD-10-CM
O6013X3	Preterm labor second trimester with preterm delivery third trimester	Diagnosis	ICD-10-CM
O6013X4	Preterm labor second trimester with preterm delivery third trimester	Diagnosis	ICD-10-CM
O6013X5	Preterm labor second trimester with preterm delivery third trimester	Diagnosis	ICD-10-CM
O6013X9	Preterm labor second trimester with preterm delivery third trimester	Diagnosis	ICD-10-CM
O6014X0	Preterm labor third trimester with preterm delivery third trimester	Diagnosis	ICD-10-CM
O6014X1	Preterm labor third trimester with preterm delivery third trimester	Diagnosis	ICD-10-CM
O6014X2	Preterm labor third trimester with preterm delivery third trimester	Diagnosis	ICD-10-CM
O6014X3	Preterm labor third trimester with preterm delivery third trimester	Diagnosis	ICD-10-CM
O6014X4	Preterm labor third trimester with preterm delivery third trimester	Diagnosis	ICD-10-CM
O6014X5	Preterm labor third trimester with preterm delivery third trimester	Diagnosis	ICD-10-CM
O6014X9	Preterm labor third trimester with preterm delivery third trimester	Diagnosis	ICD-10-CM
P0730	Preterm newborn, unspecified weeks of gestation	Diagnosis	ICD-10-CM
O6012X0	Preterm labor second trimester with preterm delivery second trimester	Diagnosis	ICD-10-CM
O6012X1	Preterm labor second trimester with preterm delivery second trimester	Diagnosis	ICD-10-CM
O6012X2	Preterm labor second trimester with preterm delivery second trimester	Diagnosis	ICD-10-CM
O6012X3	Preterm labor second trimester with preterm delivery second trimester	Diagnosis	ICD-10-CM
O6012X4	Preterm labor second trimester with preterm delivery second trimester	Diagnosis	ICD-10-CM
O6012X5	Preterm labor second trimester with preterm delivery second trimester	Diagnosis	ICD-10-CM
O6012X9	Preterm labor second trimester with preterm delivery second trimester	Diagnosis	ICD-10-CM
O6010X0	Preterm labor with preterm delivery, unspecified trimester, not applicable or unspecified	Diagnosis	ICD-10-CM
O6010X1	Preterm labor with preterm delivery, unspecified trimester, fetus 1	Diagnosis	ICD-10-CM
O6010X2	Preterm labor with preterm delivery, unspecified trimester, fetus 2	Diagnosis	ICD-10-CM

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Code	Description	Code Category	Code Type
O6010X3	Preterm labor with preterm delivery, unspecified trimester, fetus 3	Diagnosis	ICD-10-CM
O6010X4	Preterm labor with preterm delivery, unspecified trimester, fetus 4	Diagnosis	ICD-10-CM
O6010X5	Preterm labor with preterm delivery, unspecified trimester, fetus 5	Diagnosis	ICD-10-CM
O6010X9	Preterm labor with preterm delivery, unspecified trimester, other fetus	Diagnosis	ICD-10-CM
P0710	Other low birth weight newborn, unspecified weight	Diagnosis	ICD-10-CM
P0714	Other low birth weight newborn, 1000-1249 grams	Diagnosis	ICD-10-CM
P0715	Other low birth weight newborn, 1250-1499 grams	Diagnosis	ICD-10-CM
P0716	Other low birth weight newborn, 1500-1749 grams	Diagnosis	ICD-10-CM
P0717	Other low birth weight newborn, 1750-1999 grams	Diagnosis	ICD-10-CM
P0718	Other low birth weight newborn, 2000-2499 grams	Diagnosis	ICD-10-CM
P59.0	Neonatal jaundice associated with preterm delivery	Diagnosis	ICD-10-CM
P61.2	Anaemia of prematurity	Diagnosis	ICD-10-CM