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	Maternal Death 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 maternal death 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	Maternal death
Algorithm to Define Outcome	The maternal death outcome is defined as one ICD-10-CM diagnosis code (Code List 1) or evidence of an encounter from the death table in the 42 days after and including live birth delivery 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 Maternal Death in this Request

Code	Description	Code Category	Code Type
	Maternal death		
P01.6	Newborn affected by maternal death	Diagnosis	ICD-10-CM