

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

Overview

Title	Thromboembolic Stroke Algorithm Defined in "Stroke, Intracranial Hemorrhage, and Bleeding following Dabigatran, Rivaroxaban, and Apixaban Use in Patients Aged 65 or Older: A Propensity Score Matched Analysis"
Request ID	cder_mpl2p_wp017
Description	<p>This report lists International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis codes and algorithms used to define thromboembolic stroke in this request.</p> <p>For additional information about the algorithm and how it was defined relative to the cohort and exposures of interest in the inferential analysis, see the analysis page here: https://www.sentinelinitiative.org/assessments/drugs/stroke-intracranial-hemorrhage-bleeding-following-dabigatran-rivaroxaban-apixaban-use-patients-65-older</p>
Outcome	Thromboembolic stroke
Algorithm to Define Outcome	The thromboembolic stroke outcome is defined as evidence of an ICD-9-CM diagnosis code from the specified code list that is the primary diagnosis from an inpatient encounter.
Query Period	October 19, 2010 - September 30, 2015
Request Send Date	December 20, 2019

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

List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Diagnosis Codes Used to Define Thromboembolic Stroke in this Request

Code	Description	Code Type
433.01	Occlusion and stenosis of basilar artery with cerebral infarction	ICD-9-CM
433.11	Occlusion and stenosis of carotid artery with cerebral infarction	ICD-9-CM
433.21	Occlusion and stenosis of vertebral artery with cerebral infarction	ICD-9-CM
433.31	Occlusion and stenosis of multiple and bilateral precerebral arteries with cerebral infarction	ICD-9-CM
433.81	Occlusion and stenosis of other specified precerebral artery with cerebral infarction	ICD-9-CM
433.91	Occlusion and stenosis of unspecified precerebral artery with cerebral infarction	ICD-9-CM
434.01	Cerebral thrombosis with cerebral infarction	ICD-9-CM
434.11	Cerebral embolism with cerebral infarction	ICD-9-CM
434.91	Unspecified cerebral artery occlusion with cerebral infarction	ICD-9-CM
436	Acute, but ill-defined, cerebrovascular disease	ICD-9-CM