

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



Overview

Title	Intracranial Hemorrhage 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	This report lists International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis codes and algorithms used to define intracranial hemorrhage in this request. 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
Outcome	Intracranial hemorrhage
Algorithm to Define Outcome	The intracranial hemorrhage 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 Intracranial Hemorrhage in this Request

Code	Description	Code Type
430	Subarachnoid hemorrhage	ICD-9-CM
31	Intracerebral hemorrhage	ICD-9-CM
32	Other and unspecified intracranial hemorrhage	ICD-9-CM
32.0	Nontraumatic extradural hemorrhage	ICD-9-CM
32.1	Subdural hemorrhage	ICD-9-CM
32.9	Unspecified intracranial hemorrhage	ICD-9-CM
52.0	Subarachnoid hemorrhage following injury without mention of open intracranial wound	ICD-9-CM
52.00	Subarachnoid hemorrhage following injury, without mention of open intracranial wound, unspecified state of consciousness	ICD-9-CM
52.01	Subarachnoid hemorrhage following injury, without mention of open intracranial wound, no loss of consciousness	ICD-9-CM
52.02	Subarachnoid hemorrhage following injury, without mention of open intracranial wound, brief (less than 1 hour) loss of consciousness	
52.03	Subarachnoid hemorrhage following injury, without mention of open intracranial wound, moderate (1- 24 hours) loss of consciousness	ICD-9-CM
52.04	Subarachnoid hemorrhage following injury, without mention of open intracranial wound, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM
52.05	Subarachnoid hemorrhage following injury, without mention of open intracranial wound, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM
52.06	Subarachnoid hemorrhage following injury, without mention of open intracranial wound, loss of consciousness of unspecified duration	ICD-9-CM
52.09	Subarachnoid hemorrhage following injury, without mention of open intracranial wound, unspecified concussion	ICD-9-CM
52.2	Subdural hemorrhage following injury without mention of open intracranial wound	ICD-9-CM
52.20	Subdural hemorrhage following injury, without mention of open intracranial wound, unspecified state of consciousness	ICD-9-CM
52.21	Subdural hemorrhage following injury, without mention of open intracranial wound, no loss of consciousness	ICD-9-CM
52.22	Subdural hemorrhage following injury, without mention of open intracranial wound, brief (less than one hour) loss of consciousness	
52.23	Subdural hemorrhage following injury, without mention of open intracranial wound, moderate (1-24 hours) loss of consciousness	ICD-9-CM
52.24	Subdural hemorrhage following injury, without mention of open intracranial wound, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM
52.25	Subdural hemorrhage following injury, without mention of open intracranial wound, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM
52.26	Subdural hemorrhage following injury, without mention of open intracranial wound, loss of consciousness of unspecified duration	ICD-9-CM
52.29	Subdural hemorrhage following injury, without mention of open intracranial wound, unspecified concussion	ICD-9-CM
52.4	Extradural hemorrhage following injury without mention of open intracranial wound	ICD-9-CM
52.40	Extradural hemorrhage following injury, without mention of open intracranial wound, unspecified state of consciousness	ICD-9-CM
52.41	Extradural hemorrhage following injury, without mention of open intracranial wound, no loss of consciousness	ICD-9-CM



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

Code	Description	Code Type
852.42	Extradural hemorrhage following injury, without mention of open intracranial wound, brief (less than 1 hour) loss of consciousness	ICD-9-CM
852.43	Extradural hemorrhage following injury, without mention of open intracranial wound, moderate (1-24 hours) loss of consciousness	ICD-9-CM
852.44	Extradural hemorrhage following injury, without mention of open intracranial wound, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM
852.45	Extradural hemorrhage following injury, without mention of open intracranial wound, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM
852.46	Extradural hemorrhage following injury, without mention of open intracranial wound, loss of consciousness of unspecified duration	ICD-9-CM
852.49	Extradural hemorrhage following injury, without mention of open intracranial wound, unspecified concussion	ICD-9-CM
853.0	Other and unspecified intracranial hemorrhage following injury, without mention of open intracranial wound	ICD-9-CM
853.00	Other and unspecified intracranial hemorrhage following injury, without mention of open intracranial wound, unspecified state of consciousness	ICD-9-CM
853.01	Other and unspecified intracranial hemorrhage following injury, without mention of open intracranial wound, no loss of consciousness	ICD-9-CM
853.02	Other and unspecified intracranial hemorrhage following injury, without mention of open intracranial wound, brief (less than 1 hour) loss of consciousness	ICD-9-CM
853.03	Other and unspecified intracranial hemorrhage following injury, without mention of open intracranial wound, moderate (1-24 hours) loss of consciousness	ICD-9-CM
853.04	Other and unspecified intracranial hemorrhage following injury, without mention of open intracranial wound, prolonged (more than 24 hours) loss of consciousness and return to preexisting conscious level	ICD-9-CM
853.05	Other and unspecified intracranial hemorrhage following injury. Without mention of open intracranial wound, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM
853.06	Other and unspecified intracranial hemorrhage following injury, without mention of open intracranial wound, loss of consciousness of unspecified duration	ICD-9-CM
853.09	Other and unspecified intracranial hemorrhage following injury, without mention of open intracranial wound, unspecified concussion	ICD-9-CM