

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 |