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	Gastrointestinal Hemorrhage Algorithm Defined in "Stroke 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 gastrointestinal 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	Gastrointestinal hemorrhage
Algorithm to Define Outcome	The gastrointestinal hemorrhage outcome is defined as either 1) evidence of one ICD-9-CM diagnosis code from Code List 1 that is the primary diagnosis from an inpatient encounter OR 2) one ICD-9-CM code from Code List 2 that is the primary diagnosis from an inpatient encounter AND one code from Code List 1 that is the secondary or unspecified diagnosis from an inpatient encounter on the same day.
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

Code List 1. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Diagnosis Codes Used to Define Gastrointestinal Hemorrhage in this Request

Code	Description	Code Type
455.2	Internal hemorrhoids with other complication	ICD-9-CM
455.5	External hemorrhoids with other complication	ICD-9-CM
455.8	Unspecified hemorrhoids with other complication	ICD-9-CM
456.0	Esophageal varices with bleeding	ICD-9-CM
456.20	Esophageal varices with bleeding in diseases classified elsewhere	ICD-9-CM
459.0	Unspecified hemorrhage	ICD-9-CM
530.7	Gastroesophageal laceration-hemorrhage syndrome	ICD-9-CM
530.82	Esophageal hemorrhage	ICD-9-CM
531.00	Acute gastric ulcer with hemorrhage, without mention of obstruction	ICD-9-CM
531.01	Acute gastric ulcer with hemorrhage and obstruction	ICD-9-CM
531.20	Acute gastric ulcer with hemorrhage and perforation, without mention of obstruction	ICD-9-CM
531.21	Acute gastric ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM
531.40	Chronic or unspecified gastric ulcer with hemorrhage, without mention of obstruction	ICD-9-CM
531.41	Chronic or unspecified gastric ulcer with hemorrhage and obstruction	ICD-9-CM
531.60	Chronic or unspecified gastric ulcer with hemorrhage and perforation	ICD-9-CM
531.61	Chronic or unspecified gastric ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM
532.00	Acute duodenal ulcer with hemorrhage, without mention of obstruction	ICD-9-CM
532.01	Acute duodenal ulcer with hemorrhage and obstruction	ICD-9-CM
532.20	Acute duodenal ulcer with hemorrhage and perforation, without mention of obstruction	ICD-9-CM
532.21	Acute duodenal ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM
532.40	Duodenal ulcer, chronic or unspecified, with hemorrhage, without mention of obstruction	ICD-9-CM
532.41	Chronic or unspecified duodenal ulcer with hemorrhage and obstruction	ICD-9-CM
532.60	Chronic or unspecified duodenal ulcer with hemorrhage and perforation, without mention of obstruction	ICD-9-CM
532.61	Chronic or unspecified duodenal ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM
533.00	Acute peptic ulcer, unspecified site, with hemorrhage, without mention of obstruction	ICD-9-CM
533.01	Acute peptic ulcer, unspecified site, with hemorrhage and obstruction	ICD-9-CM
533.20	Acute peptic ulcer, unspecified site, with hemorrhage and perforation, without mention of obstruction	ICD-9-CM
533.21	Acute peptic ulcer, unspecified site, with hemorrhage, perforation, and obstruction	ICD-9-CM
533.40	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage, without mention of obstruction	ICD-9-CM
533.41	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage and obstruction	ICD-9-CM
533.60	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage and perforation, without mention of obstruction	ICD-9-CM
533.61	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage, perforation, and obstruction	ICD-9-CM
534.00	Acute gastrojejunal ulcer with hemorrhage, without mention of obstruction	ICD-9-CM
534.01	Acute gastrojejunal ulcer, with hemorrhage and obstruction	ICD-9-CM
534.20	Acute gastrojejunal ulcer with hemorrhage and perforation, without mention of obstruction	ICD-9-CM
534.21	Acute gastrojejunal ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM
534.40	Chronic or unspecified gastrojejunal ulcer with hemorrhage, without mention of obstruction	ICD-9-CM
534.41	Chronic or unspecified gastrojejunal ulcer, with hemorrhage and obstruction	ICD-9-CM
534.60	Chronic or unspecified gastrojejunal ulcer with hemorrhage and perforation, without mention of	ICD-9-CM
534.61	Chronic or unspecified gastrojejunal ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM
535.01	Acute gastritis with hemorrhage	ICD-9-CM
535.11	Atrophic gastritis with hemorrhage	ICD-9-CM
535.21	Gastric mucosal hypertrophy with hemorrhage	ICD-9-CM

Code List 1. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Diagnosis Codes Used to Define Gastrointestinal Hemorrhage in this Request

Code	Description	Code Type
535.31	Alcoholic gastritis with hemorrhage	ICD-9-CM
535.41	Other specified gastritis with hemorrhage	ICD-9-CM
535.51	Unspecified gastritis and gastroduodenitis with hemorrhage	ICD-9-CM
535.61	Duodenitis with hemorrhage	ICD-9-CM
537.83	Angiodysplasia of stomach and duodenum with hemorrhage	ICD-9-CM
562.02	Diverticulosis of small intestine with hemorrhage	ICD-9-CM
562.03	Diverticulitis of small intestine with hemorrhage	ICD-9-CM
562.12	Diverticulosis of colon with hemorrhage	ICD-9-CM
562.13	Diverticulitis of colon with hemorrhage	ICD-9-CM
568.81	Hemoperitoneum (nontraumatic)	ICD-9-CM
569.3	Hemorrhage of rectum and anus	ICD-9-CM
569.85	Angiodysplasia of intestine with hemorrhage	ICD-9-CM
578.0	Hematemesis	ICD-9-CM
578.1	Blood in stool	ICD-9-CM
578.9	Hemorrhage of gastrointestinal tract, unspecified	ICD-9-CM

Code List 2. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Diagnosis Codes Used to Define Gastrointestinal Hemorrhage in this Request

Code	Description	Code Type
455.0	Internal hemorrhoids without mention of complication	ICD-9-CM
455.1	Internal thrombosed hemorrhoids	ICD-9-CM
455.3	External hemorrhoids without mention of complication	ICD-9-CM
455.4	External thrombosed hemorrhoids	ICD-9-CM
455.6	Unspecified hemorrhoids without mention of complication	ICD-9-CM
455.7	Unspecified thrombosed hemorrhoids	ICD-9-CM
531.1	Acute gastric ulcer with perforation	ICD-9-CM
531.3	Acute gastric ulcer without mention of hemorrhage or perforation	ICD-9-CM
531.5	Chronic or unspecified gastric ulcer with perforation	ICD-9-CM
531.7	Chronic gastric ulcer without mention of hemorrhage or perforation	ICD-9-CM
531.9	Gastric ulcer, unspecified as acute or chronic, without mention of hemorrhage or perforation	ICD-9-CM
532.1	Acute duodenal ulcer with perforation	ICD-9-CM
532.3	Acute duodenal ulcer without mention of hemorrhage or perforation	ICD-9-CM
532.5	Chronic or unspecified duodenal ulcer with perforation	ICD-9-CM
532.7	Chronic duodenal ulcer without mention of hemorrhage or perforation	ICD-9-CM
532.9	Duodenal ulcer, unspecified as acute or chronic, without mention of hemorrhage or perforation	ICD-9-CM
533.1	Acute peptic ulcer, unspecified site, with perforation	ICD-9-CM
533.3	Acute peptic ulcer, unspecified site, without mention of hemorrhage and perforation	ICD-9-CM
533.5	Chronic or unspecified peptic ulcer, unspecified site, with perforation	ICD-9-CM
533.7	Chronic peptic ulcer, unspecified site, without mention of hemorrhage or perforation	ICD-9-CM
533.9	Peptic ulcer, unspecified site, unspecified as acute or chronic, without mention of hemorrhage or perforation	ICD-9-CM
534.1	Acute gastrojejunal ulcer with perforation	ICD-9-CM
534.3	Acute gastrojejunal ulcer without mention of hemorrhage or perforation	ICD-9-CM
534.5	Chronic or unspecified gastrojejunal ulcer with perforation	ICD-9-CM
534.7	Chronic gastrojejunal ulcer without mention of hemorrhage or perforation	ICD-9-CM
534.9	Gastrojejunal ulcer, unspecified as acute or chronic, without mention of hemorrhage or perforation	ICD-9-CM
535.00	Acute gastritis without mention of hemorrhage	ICD-9-CM
535.10	Atrophic gastritis without mention of hemorrhage	ICD-9-CM
535.20	Gastric mucosal hypertrophy without mention of hemorrhage	ICD-9-CM
535.30	Alcoholic gastritis without mention of hemorrhage	ICD-9-CM
535.40	Other specified gastritis without mention of hemorrhage	ICD-9-CM
535.50	Unspecified gastritis and gastroduodenitis without mention of hemorrhage	ICD-9-CM
535.60	Duodenitis without mention of hemorrhage	ICD-9-CM
562.00	Diverticulosis of small intestine (without mention of hemorrhage)	ICD-9-CM
562.01	Diverticulitis of small intestine (without mention of hemorrhage)	ICD-9-CM
562.10	Diverticulosis of colon (without mention of hemorrhage)	ICD-9-CM
562.11	Diverticulitis of colon (without mention of hemorrhage)	ICD-9-CM
530.1	Esophagitis	ICD-9-CM