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	Clostridium difficile Algorithm Defined in "Testing Routine Querying Tools with Known Positive Exposure-Outcome Associations: Clostridium difficile Events After Use of Oral Clindamycin versus Penicillins"
Request ID	to16_cap_mpl2r_wp002
Description	This report lists International Classification of Diseases, Ninth Edition, Clinical Modification (ICD-9-CM) diagnosis codes and algorithms used to define clostridium difficile 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 Modular Program report here: https://www.sentinelinitiative.org/sentinel/methods/clostridium-difficile-events-after-use-of-oral-clindamycin-vs-penicillins.
Outcome	Clostridium difficile
Algorithm to Define Outcome	Algorithm A: Evidence of an ICD-9-CM code used to define Clostridium difficile in the Inpatient care setting in any diagnosis position. Algorithm B: Evidence of an ICD-9-CM code used to define Clostridium difficile in either the Inpatient care setting in any diagnosis position or in an outpatient (Emergency Department or Ambulatory Visit) care setting as long as that outpatient encounter was accompanied by evidence of a dispensing of a Clostridium difficile medication treatment within 7 days before or after the encounter. (Clostridium difficile treatments included oral vancomycin, nitazoxanide, fidaxomicin, and oral or intravenous metronidazole.)
Query Period	January 1, 2006 - December 31, 2013
Request Send Date	April 2, 2015

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

International Classification of Diseases, Ninth Edition, Clinical Modification (ICD-9-CM) Diagnosis Codes, Generic Names, and Healthcare Common Procedure Coding System (HCPCS) Codes Used to Define Clostridium Difficile in this Request

Clostridium difficile Event Definition 1

Code	Description	Code Type	Caresetting
008.45	Clostridium difficile	ICD-9-CM	Inpatient

Clostridium difficile Event Definition 2

Code	Description	Code Type	Caresetting
008.45	Clostridium difficile	ICD-9-CM	Inpatient

OR

Code	Description	CodeType	Caresetting
008.45	Clostridium difficile	ICD-9-CM	Ambulatory Visit, Emergency Department

AND

Code	Generic Name	Code Type	Caresetting

Clostridium difficile treatment dispensing within 7 days of encounter

Code	Generic Name	Code Type	Caresetting
	FIDAXOMICIN	National Drug Code	ANY
	METRONIDAZOLE	National Drug Code	ANY
	NITAZOXANIDE	National Drug Code	ANY
	VANCOMYCIN HCL	National Drug Code	ANY
	METRONIDAZOLE HCL	National Drug Code	ANY
	METRONIDAZOLE/SODIUM CHLORIDE	National Drug Code	ANY
	COLLOIDAL BISMUTH SUBCITRATE/METRONIDAZOLE/TETRACYCLINE HCL	National Drug Code	ANY
	BISMUTH SUBSALICYLATE/METRONIDAZOLE/TETRACYCLINE HCL	National Drug Code	ANY
S0030	INJECTION METRONIDAZOLE 500 MG	HCPCS Procedure Code	ANY