

## 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

<b>Title</b>	Venous Thromboembolism Algorithm Defined in "Gardasil Vaccination and Venous Thromboembolism (PRISM)"
<b>Description</b>	<p>This report lists International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis codes and algorithms used to define venous thromboembolism (VTE) 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:  <a href="https://www.sentinelinitiative.org/vaccines-blood-biologics/assessments/gardasil-vaccination-and-venous-thromboembolism-prism">https://www.sentinelinitiative.org/vaccines-blood-biologics/assessments/gardasil-vaccination-and-venous-thromboembolism-prism</a>.</p>
<b>Outcome</b>	Venous thromboembolism
<b>Algorithm to Define Outcome</b>	Evidence of an ICD-9-CM code used to define VTE in the Inpatient, Emergency Department, or Ambulatory Visit care setting in any diagnosis position.
<b>Query Period</b>	2006 - 2011

## 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 Revision, Clinical Modification (ICD-9-CM) Diagnosis Codes Used to Define Venous Thromboembolism in this Request**

<b>Code</b>	<b>Description</b>	<b>Code Type</b>	<b>Code Category</b>
415.1	Pulmonary embolism and infarction	ICD-9-CM	Diagnosis
415.11	Iatrogenic pulmonary embolism and infarction	ICD-9-CM	Diagnosis
415.12	Septic pulmonary embolism	ICD-9-CM	Diagnosis
415.19	Other pulmonary embolism and infarction	ICD-9-CM	Diagnosis
451	Phlebitis and thrombophlebitis	ICD-9-CM	Diagnosis
451.1	Phlebitis and thrombophlebitis of deep veins of lower extremities	ICD-9-CM	Diagnosis
451.11	Phlebitis and thrombophlebitis of femoral vein (deep) (superficial)	ICD-9-CM	Diagnosis
451.19	Phlebitis and thrombophlebitis of other deep vessels of lower extremities	ICD-9-CM	Diagnosis
451.2	Phlebitis and thrombophlebitis of lower extremities, unspecified	ICD-9-CM	Diagnosis
451.8	Phlebitis and thrombophlebitis of other sites	ICD-9-CM	Diagnosis
451.81	Phlebitis and thrombophlebitis of iliac vein	ICD-9-CM	Diagnosis
451.82	Phlebitis and thrombophlebitis of superficial veins of upper extremities	ICD-9-CM	Diagnosis
451.83	Phlebitis and thrombophlebitis of deep veins of upper extremities	ICD-9-CM	Diagnosis
451.84	Phlebitis and thrombophlebitis of upper extremities, unspecified	ICD-9-CM	Diagnosis
451.89	Phlebitis and thrombophlebitis of other site	ICD-9-CM	Diagnosis
451.9	Phlebitis and thrombophlebitis of unspecified site	ICD-9-CM	Diagnosis
453	Other venous embolism and thrombosis	ICD-9-CM	Diagnosis
453.1	Thrombophlebitis migrans	ICD-9-CM	Diagnosis
453.2	Other venous embolism and thrombosis, of inferior vena cava	ICD-9-CM	Diagnosis
453.3	Embolism and thrombosis of renal vein	ICD-9-CM	Diagnosis
453.4	Acute venous embolism and thrombosis of deep vessels of lower extremity	ICD-9-CM	Diagnosis
453.41	Acute venous embolism and thrombosis of deep vessels of proximal lower extremity	ICD-9-CM	Diagnosis
453.42	Acute venous embolism and thrombosis of deep vessels of distal lower extremity	ICD-9-CM	Diagnosis
453.5	Chronic venous embolism and thrombosis of deep vessels of lower extremity	ICD-9-CM	Diagnosis
453.51	Chronic venous embolism and thrombosis of deep vessels of proximal lower extremity	ICD-9-CM	Diagnosis
453.52	Chronic venous embolism and thrombosis of deep vessels of distal lower extremity	ICD-9-CM	Diagnosis
453.6	Venous embolism and thrombosis of superficial vessels of lower extremity	ICD-9-CM	Diagnosis
453.7	Chronic venous embolism and thrombosis of other specified vessels	ICD-9-CM	Diagnosis
453.71	Chronic venous embolism and thrombosis of superficial veins of upper extremity	ICD-9-CM	Diagnosis
453.72	Chronic venous embolism and thrombosis of deep veins of upper extremity	ICD-9-CM	Diagnosis
453.73	Chronic venous embolism and thrombosis of upper extremity, unspecified	ICD-9-CM	Diagnosis
453.74	Chronic venous embolism and thrombosis of axillary veins	ICD-9-CM	Diagnosis
453.75	Chronic venous embolism and thrombosis of subclavian veins	ICD-9-CM	Diagnosis
453.76	Chronic venous embolism and thrombosis of internal jugular veins	ICD-9-CM	Diagnosis
453.77	Chronic venous embolism and thrombosis of other thoracic veins	ICD-9-CM	Diagnosis
453.79	Chronic venous embolism and thrombosis of other specified veins	ICD-9-CM	Diagnosis
453.8	Acute venous embolism and thrombosis of other specified veins	ICD-9-CM	Diagnosis
453.81	Acute venous embolism and thrombosis of superficial veins of upper extremity	ICD-9-CM	Diagnosis
453.82	Acute venous embolism and thrombosis of deep veins of upper extremity	ICD-9-CM	Diagnosis
453.83	Acute venous embolism and thrombosis of upper extremity, unspecified	ICD-9-CM	Diagnosis
453.84	Acute venous embolism and thrombosis of axillary veins	ICD-9-CM	Diagnosis
453.85	Acute venous embolism and thrombosis of subclavian veins	ICD-9-CM	Diagnosis
453.86	Acute venous embolism and thrombosis of internal jugular veins	ICD-9-CM	Diagnosis
453.87	Acute venous embolism and thrombosis of other thoracic veins	ICD-9-CM	Diagnosis
453.89	Acute venous embolism and thrombosis of other specified veins	ICD-9-CM	Diagnosis
453.9	Embolism and thrombosis of unspecified site	ICD-9-CM	Diagnosis