

SECTION 8 OTHER OUTCOMES

8.1 Thromboembolic Disease

Thromboembolic disease, as a WHI outcome, includes both deep vein thrombosis and pulmonary embolism. These conditions are adjudicated in WHI for HRT participants only. In all other WHI participants, outcomes information on thromboembolic disease is obtained by self-report only.

8.1.1 Deep Vein Thrombosis

The presence of thrombus within a deep vein of a lower extremity only and the accompanying inflammatory response in vessel wall is termed deep vein thrombosis.

The diagnosis can be made when the diagnosis is present in the discharge summary **and any** of the following are recorded:

- Positive findings on a venogram, defined as presence of a filling defect or absence of filling .
- Positive findings on impedance plethysmography, duplex scan, or ultrasound, defined as a report of a flow defect.
- Positive findings on doppler examination, defined as a demonstration of flow velocity disturbance.
- Positive findings on isotope scan (e.g., I¹²⁵ fibrinogen scan).

8.1.2 Pulmonary Embolism

Pulmonary embolism (PE) is defined as present if the following are present:

- Pulmonary embolism reported as a diagnosis in the discharge summary **AND**
- Report of a positive findings on appropriate diagnostic studies, including:
 - a) Pulmonary ventilation/perfusion (V/Q) report describing either “high” or “moderate” probability of deficit (“low” probability V/Q studies will not be considered evidence for presence of PE).
 - b) Pulmonary angiography report describing either “cut off” of a vessel or “filling defect.”
- Diagnosis of deep vein thrombosis (DVT) based on ≥ 1 DVT criteria (see *Section 8.1.1 – Deep Vein Thrombosis*) plus signs and symptoms of PE (i.e., acute chest pain, dyspnea, tachypnea, hypoxemia, tachycardia, or chest X-ray findings characteristic of PE).

8.2 Hysterectomy

Hysterectomy, as a WHI outcome, is adjudicated for HRT participants only. In all other WHI participants, outcomes information on hysterectomy is obtained by self-report only.

Adjudication of hysterectomy includes review of the adjudication case packet (containing face sheet, discharge summary or outpatient report and operative report) to identify:

- **Type of hysterectomy** – Abdominal or vaginal
- **Associated surgery** – Oophorectomies performed
- **Reason for the hysterectomy** – Abstraction of narrative information in medical records

Review of the case packet should include a determination of the possibility of a WHI cancer outcome. If a cancer is identified, request appropriate documents and/or adjudication of the cancer (if appropriate documents have already been obtained). Note that if the hysterectomy is hospitalized, review of the hospitalization for other WHI outcomes and completion of *Form 125 – Summary of Hospitalization Diagnosis* are required.

8.3 Other Outcomes Information

Information on other WHI outcomes, including age-related changes, will be obtained by self-report.

Section 8
Other Outcomes

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