

Results of Topic Selection Process & Next Steps

- D-dimer testing for venous thromboembolism (VTE) is addressed by an in-process evidence review that will be used to update existing guidelines from the American College of Chest Physicians. Given that the in-process review will cover the VTE portion of this nomination, no further activity will be undertaken on this topic.
- D-dimer testing for disseminated intravascular coagulation (DIC) is not feasible for a full systematic review due to the limited data available for a review at this time.

Topic Description

Nominator: Health care professional association

NominationThe nominator is interested in the ability of the D-dimer assay to rule out VTE disease,
as an aid for diagnosing DIC, in the performance characteristics of D-dimer,
standardization of those characteristics, and in the relative role of fibrin soluble
degradation products (FSP) in diagnosing DIC.

Staff-Generated PICO - VTE

Population(s): Patients who present to the emergency department, hospital, or clinic with signs and symptoms suggestive of deep vein thrombosis and/or pulmonary emboli Intervention(s): Clinical prediction rule with D-dimer test Comparator(s): Clinical prediction rule without D-dimer test Outcome(s): Added clinical utility to rule out VTE; faster and more appropriate diagnosis and management of patients with suspected VTE; avoidance of unnecessary diagnostic tests and associated radiation; reduction of DVT and PE; avoidance of hospitalization; improved quality of life; reduced costs of care (via reduced need for additional more expensive tests)

Staff-Generated PICO - DIC

Population(s): Hospitalized patients suspected of having DIC Intervention(s): Clinical prediction rule with D-dimer or FSP test Comparator(s): Clinical prediction rule without D-dimer or FSP test Outcome(s): Added clinical utility of test to aid in diagnosis of DIC; reduced bleedingrelated events; reduced mortality and morbidity associated with DIC; improved quality of life; improved outcomes associated with hospitalization

Key Questions from Nominator:

- 1. What are the analytical performance requirements for an assay for D-dimer? Are they different for thromboembolic disease vs. disseminated intravascular coagulation (DIC)?
- **2.** Are there separate cutoff concentrations for use of the D-dimer test for rule out of VTE vs. diagnosis of DIC?
- **3.** Are there technological performance advantages and limitations of the latex agglutination test vs. immunoassay?
- 4. What are the appropriate patient populations for the D-dimer test for VTE and DIC?
- 5. Is there standardization of the units used for measuring D-dimer?
- 6. Is there a role of the fibrin split/degradation products test (FSP)? Should it be available in addition to or instead of D-dimer?

Considerations

- The topic meets EHC Program appropriateness and importance criteria. (For more information, see http://effectivehealthcare.ahrq.gov/index.cfm/submit-a-suggestion-for-research/how-are-research-topics-chosen/.)
- This nomination includes two discreet areas, VTE and DIC, which were considered separately.
 - VTE: D-dimer testing for VTE was found to be addressed by an in-process AHRQ evidence review that will be used to update the 8th edition of "Antithrombotic and Thrombolytic Therapy: American College of Chest Physicians (ACCP) Evidence-Based Clinical Guidelines."
 - DIC: DIC is a serious illness associated with a large number of critical underlying conditions and has been reported to be an independent predictor for mortality. Existing guidelines indicate that the wide discordance of cutoff values for current assays make diagnosis of DIC challenging. While this topic has clear clinical significance, a literature scan revealed a limited, heterogeneous literature on d-dimer testing for DIC. Moreover, determining the independent value of the d-dimer test in the diagnosis of DIC is not feasible from the existing literature. Therefore, the topic of d-dimer testing for diagnosis of DIC is not feasible for a full systematic review due to the limited data available at this time.