# **CMS COMMENTS (Spring 2023 MUC cycle): PLEASE CONSIDER THE FOLLOWING FEEDBACK.**

1. **Include a narrowed list of symptoms more specific to lower limb venous thromboembolism (VTE) or possibly in combination with one of the more broad cardiopulmonary symptoms (syncope, tachycardia, shortness of breath, hemoptysis).**

All of the symptoms included in our final list relate to either lower extremity venous thromboembolism (LE DVT) or PE; however, most patients included in the eCQM calculation presented to primary care with a combination of signs/symptoms. Along with these signs/symptoms, the DOVE eCQM requires an ICD10 diagnosis code, CPT imaging code and RxNorm treatment code to accurately identify a patient with VTE. Response to feedback on lower extremity VTE signs/symptoms: We selected the list of VTE-related signs/symptoms using a combination of literature review and qualitative methods (interviews with physicians with experience in treating VTE patients). As a first step, we conducted a comprehensive literature review of previous VTE studies and generated an initial list of signs and symptoms. Then, we conducted 1-hour semi-structured interviews with five physicians with experience treating VTE patients to provide additional insight into signs and symptoms based on clinical experience. Signs and symptoms were also reviewed by a technical expert panel (TEP) over the course of development and their feedback was used to finalize the symptom list.

Response to feedback on narrowed list of symptoms: Narrowing the list to include only known and established symptoms or combinations of symptoms highly indicative of LE DVT or PE would significantly lower the ability of the eCQM to detect cases of delayed/missed VTE diagnoses, and artificially lower the rates of delay reported (see details of our empirical testing on this point below). This lowered sensitivity would result in persistence of the problem of delayed diagnosis, which leads to morbidity and mortality in VTE patients. It would also result in missed opportunities for education of physicians who may not include VTE in their differential diagnosis on first presentation. Additionally, failure to include unusual or less common symptoms of VTE further lowers the index of suspicion for this morbid disease.

None of the symptoms we include is specific to upper extremity VTE. We elected to not include upper extremity DVT (UE DVT) in this eCQM. Although 4 to 10% of all DVTs occur in the upper extremities, the etiologies (e.g., catheter-related) are quite different from LE DVTs, there are far fewer studies on detection of UE DVT, and there is less consensus on the optimal management of UE DVT. Pulmonary embolism is less likely with UE DVT, and if it occurs, is typically small and not life-threatening.1 Since routine anticoagulation is not recommended for all patients with UE DVT, the eCQM would not pick up these patients.2

One key challenge is that VTE symptoms are nonspecific. We completed a series of interviews with primary care providers and VTE survivors. One point that we heard frequently through the interviews was that primary care providers may not consider acute VTE during a visit. Additionally, based on chart reviews, we found that healthcare providers often attribute VTE symptoms to patients’ existing diagnoses such as heart failure, COPD, or lung cancer. Therefore, they focus on the patient’s main diagnosis and miss the VTE. Also, most of the patients that we interviewed (all VTE survivors) reported that they had presented to primary care and reported symptoms of VTE which were not fully considered or investigated at the time, thus resulting in a delayed diagnosis.

Empirical testing that supports the current measure specification: The DOVE eCQM uses signs/symptoms documented in primary care clinical notes or problem lists and when present along with the structured codes (e.g., ICD, CPT and RxNorm) indicate the presence of an incident VTE. This design allows us to link symptoms with well-defined VTE events. We found that the rule-based sign/symptom extraction algorithm performed very well across both cases (i.e., notes of patients with confirmed VTE) and control patients (i.e., notes of patients without documented VTE):

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Positive Predictive Value | Recall (Sensitivity) | Specificity | Negative Predictive Value |
| Patient with VTE diagnosis (329 notes) | 1.00 | 1.00 | 1.00 | 1.00 |
| Patients with no VTE diagnosis (50 notes) | 0.850 | 0.895 | 0.997 | 0.998 |

The excellent performance of the rule-based sign/symptom extraction algorithm suggests that documented signs/symptoms were accurately identified and extracted to calculate the DOVE eCQM rate.

After testing the NLP algorithm at Mass General Brigham (MGB), we also tested at the University of Kentucky (rural system) and Penn State Health (mix of urban, metro, rural) where we performed beta testing of the DOVE eCQM. On a random sample of 30 notes in each of these external healthcare systems, we found that the NLP algorithm was accurate in identifying VTE symptoms in notes across systems. MGB, University of Kentucky, and Penn State Health use three different EHR vendor systems demonstrating that this approach translates to multiple geographically distant settings using different EHRs.

1. **Refine the 24-hour timeframe to account for weekends/holidays and the testing that would be required to diagnose a VTE.**

Response: Based on literature and clinical guidelines summarized below, the >24-hour definition for delayed diagnosis was recommended by our TEP and in interviews with primary care providers. These stakeholders believe that 24 hours is sufficient time for patients to get the recommended follow-up after presenting to primary care with signs/symptoms.

The rationale for the 24-hour timeframe relies on clinical guidelines which specify that VTE can be fatal if untreated; once a patient presents with symptoms, the provider should initiate prompt detection and follow-up.3 There is a stark contrast in mortality between patients who receive immediate diagnosis and treatment of VTE and those who are left undiagnosed.4 VTE events are associated with a high 30-day mortality rate and delays in VTE diagnosis are associated with higher rates of complications and an increased risk of mortality.5,6 Earlier diagnosis of VTE may reduce the morbidity as well as the mortality associated with this dangerous condition, meaning that more prompt diagnosis promotes patient safety.7,8 Untreated pulmonary embolisms have a mortality rate of approximately 30%, and nearly 30% of untreated DVTs will result in severe swelling or ulceration of the leg, including chronic venous stasis disease which can result in lifelong disability. With prompt diagnosis and treatment, PE or treatment-related mortality is less than 1%.9-11

To address the CMS request to refine the 24-hour timeframe to account for weekends and holidays, our team conducted additional testing across MGB and Penn State Health to identify the impact of expanding the >24-hour delayed diagnosis timeframe to >72 hours. We found that by expanding the delayed diagnosis time frame, the DOVE rate remained unacceptably high across organizations (69-70%). We also conducted preliminary analyses to understand where delays occurred in the diagnostic process. We found that most of the delay was accounted for by time to scan order, and that once a scan was ordered, the diagnostic process was generally completed within 24 hours. We presented these findings to VTE and primary care experts and we were advised to keep the definition of delayed VTE diagnosis at >24 hours. **All experts agreed that when a provider suspects that a patient has a VTE, they are able to send the patient to the emergency department to get the necessary testing completed within 24 hours. The stakeholders further expressed that time of day, day of the week, or holidays should not impact access to high-quality medical care; in this case, timely diagnostic evaluation and treatment to prevent potentially fatal events.**

## **References**

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