



# INDIANA UNIVERSITY

DEPARTMENT OF EMERGENCY MEDICINE

School of Medicine

## MATH VTE Guidance Document

### Inclusion Criteria

Q: Can we include patients who are diagnosed with upper extremity or jugular vein DVTs?

A: Yes, these are perfectly fine to include as long as they meet all other inclusion and exclusion criteria.

Q: How should we determine creatinine clearance if there is not a standard of care lab done?

A: You may use the follow link which will calculate the creatinine clearance based on sex, age, weight, height, and creatinine.

<https://www.mdcalc.com/creatinine-clearance-cockcroft-gault-equation>

Q: What is the definition of “history of cancer” in PESI and sPESI?

A: Cancer means a patient is actively under care of an oncologist or palliative care physician.

Q: Once a patient is diagnosed with VTE and meets all inclusion criteria is there an enrollment window/time limit on when we can enroll them?

A: There is not a time limit. As long as the patient meets all inclusion criteria they can be enrolled even after they finish treatment as long as the 30 day outcomes are known.

Q: Can we enroll someone if they receive a dose of rivaroxaban in the ED?

A: Yes, as long as they are still discharged on apixaban.

Q: Can we enroll a patient diagnosed with a chronic DVT on ultrasound?

A: Yes, as long as they meet all other inclusion criteria.

Q: Can we enroll a patient who has an inconclusive ultrasound result?

A: Yes, as long as the patient is discharged on apixaban and the plan is to treat for at least 30 days.

Q: Can a patient with a VQ scan positive for PE be enrolled?

A: Yes, but you won't find many of them because these patients usually have kidney problems and this would be an exclusion criterion.

### Exclusion Criteria

Q: What should we do if a patient has a positive troponin, but is otherwise low risk?

A: Monitor in observations for 12-18 hours for hypoxemia or hypotension. If the patient is ultimately discharged within this timeline the patient is still eligible.

Q: What constitutes recent major bleeding?

A: Any bleeding within the past 6 weeks that meets the ISTH definition of major bleeding. The ISTH defines major bleeding as bleeding in non-surgical patients having a symptomatic presentation and



# INDIANA UNIVERSITY

## DEPARTMENT OF EMERGENCY MEDICINE

School of Medicine

- Bleeding in a critical area or organ, such as intracranial, intraspinal, intraocular, retroperitoneal, intra-articular or pericardial, or intramuscular with compartment syndrome, and/or
- Bleeding causing a fall in hemoglobin level of 20 g L<sup>-1</sup> (1.24 mmol L<sup>-1</sup>) or more, or leading to transfusion of two or more units of whole blood or red cells.”

Q: What is the definition of anemia?

A: Anemia means a hemoglobin (Hgb) < 8.0 grams/dL or hematocrit (Hct) < 28%, measured within the previous week. Values obtained more than a week ago should not be used to exclude the patient.

Q: What is the definition of cancer according to the Ruiz Gimenez method?

A: Cancer means a patient is actively under care of an oncologist or palliative care physician.

### Outcomes/Endpoint Variables

Q: What is the definition of clinically relevant non-major bleeding we should use to determine if the subject meets the qualification of treatment failure?

A: Clinically relevant non-major bleeding is any sign or symptom of hemorrhage (e.g., more bleeding than would be expected for a clinical circumstance, including bleeding found by imaging alone) that does not fit the criteria for the ISTH definition of major bleeding but does lead to the subject to seek the care of a physician. In order for the subject to be deemed a treatment failure, the bleeding must result in re-hospitalization > 24 hours.

### REDCap Data Entry

#### ED Data Fields

Q: Which set of labs should I record for the ED Data Fields CRF?

A: Closest to triage.

Q: Which set of vitals should I record for the ED Data Fields CRF?

A: Closest to triage.

Q: Can you provide a list of NSAIDs (other than aspirin) for the ED Data Fields Medication section?

A: celecoxib, diclofenac, ibuprofen, indomethacin, ketoprofen, naproxen, oxaprozin, piroxicam

#### Risk Factors and Comorbids

Q: How do I distinguish yes from no for the Charleston Comorbidities if I am unsure of the answer?

A: If a comorbidity is obviously/clearly noted in the EMR it should be marked as “yes”. If you are unsure or there is not enough information it should be marked as “no”.

#### 30 Day Phone Follow-Up



# INDIANA UNIVERSITY

DEPARTMENT OF EMERGENCY MEDICINE

School of Medicine

Q: Is there a time window for the 30 day follow-up call?

A: The phone call cannot be done before 30 days, but there is no upper limit on when the call must be done.

Q: How many attempts should we make to contact the subject before deeming them lost to follow-up?

A: A total of 10 calls should be made before the subject is lost to follow-up. They should be made at different times of the day (morning, afternoon, evening, night) and on different days.

Q: The 30 day follow-up CRF asks about unscheduled ED or clinic visits within 30 days of diagnosis. Does an urgent care visit count as unscheduled ED or clinic visit?

A: Yes

Q: If there are more than one set of labs done within the 30 day time period before follow-up which set should we record?

A: Labs closest to the 30 day follow-up time point.

Q: Is there a script for the 30 day follow-up phone call?

A: Yes: see below. You may also follow along with the 30 day follow-up CRF in REDCap.

*Hello,*

*My name is XXX and I am calling you because you enrolled about a month ago in a registry called the MATH VTE study related to your blood clot. I want to ask a few questions to see how you are doing.*

*Have you had any major changes to your health since you were diagnosed on XXX date?*

*Is your health better, worse or the same than it was when you were diagnosed a month ago?*

*What is your single biggest health problem?*

*Have you had to stop taking apixaban or hold a dose for more than one day?*

*If yes, what date did you stop?*

*If yes are you taking any anticoagulant?*

*If yes, what is the name of the anticoagulant you are taking now? What dose?*

*Have you had to visit the emergency department or had an unscheduled clinic visit in the last 30 days?*

*If yes can you tell me the name of the hospital(s)? How about the date(s)?*

*Were you admitted to the hospital?*

*What was your primary diagnosis?*

*Have you had any bleeding since your clot diagnosis on XXX date?*

*Where?*

*Did you have any bleeding complications with transfusion of PRBCs within 30 days?*

*What was the date?*



# INDIANA UNIVERSITY

DEPARTMENT OF EMERGENCY MEDICINE

School of Medicine

*How many units of PRBCs?*

*Have you been diagnosed with any new clots since your diagnosis on XXX date?*

*Where?*

*Was any diagnostic testing performed?*

*If yes, get results from ultrasound Doppler or CT scan.*

*Did you have any complications within 30 Days (renal failure, liver failure, stroke, MI)?*

*Is there anything else you would like to tell me about your health?*

*I thank you for your time and goodbye.*