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OPERATIONAL DEFINITION

MEASUREMENT: Venous Thromboembolism (VTE)

I. Definition

VTE is a condition in which a blood clot forms within a deep vein and may compromise blood flow or embolize to the lungs (pulmonary embolism). In the specific case of pulmonary embolism, obstructed pulmonary arteries can result in life-threatening decreased oxygenation of the blood.

II. Description and Rationale

This measure answers the question: How many patients are harmed due to hospital-acquired VTE events?

III. Population Definition

Inpatient and observational stay patients of any age will be included in the measure.

Inclusion criteria

a. All acute VTE events deemed to be hospital-acquired including:
1. Any clot within a deep vein (see section **X. Attachments**)
2. Pulmonary embolism (PE)
3. Any intra-cardiac clot (all 4 chambers of the heart)
4. Any clot within the cerebral sinus veins
5. Clots related to fistula, graft, and other prosthetic materials

b. Any VTE event (meeting the above criteria) that occurs within one week of hospital discharge.

c. Multiple clots in any anatomic location identified within 3 days of each other should be considered as a single VTE event.

Exclusion criteria

a. VTEs that developed prior to hospital admission, based on clinical history and exam, **and** are identified within 48 hours of admission (i.e., community-acquired rather than hospital-acquired.)
   - *An exception to a. above is a VTE associated with the placement of a new central venous catheter (CVC) during the admission. These should be counted regardless of the time of VTE diagnosis.*

b. Fibrin sheath, or a thrombus limited to the catheter only, with no vascular component

c. Venous narrowing, stenosis, or scarring

d. Post-thrombotic syndrome

e. Chronic clot: either previously identified or based upon clinical judgement it is determined to be clot that developed prior to the current admission by taking into account the patient's clinical history, imaging characteristics and symptoms.

f. Extension of an acute VTE already reported for the current hospitalization

g. Arterial and superficial vein thrombosis (see section **X. Attachments**)
Note: if a patient has both a deep vein **and** an arterial thrombi or a deep vein and a superficial vein thrombi, the deep vein thrombosis should be counted.

h. Clots originating within externalized, mechanical cardiopulmonary circulation. (Examples: ECMO, Cardiopulmonary Bypass, LVAD circuit)

IV. Data Source(s)

A VTE diagnostic validation process is expected to include two or more of the following methods to identify potential VTE events:

Review of radiology reports, discharge ICD-10 codes, problem list, hematology/oncology consults, new anticoagulation order review, self-reporting, other, etc.

Then, review each chart for presence of a VTE event. Radiologic confirmation or direct surgical visualization of the VTE event is required.

V. Sampling and Data Collection Plan

VTE events are assigned to the month the event was diagnosed.

VI. Calculation

Numerator(s):

a. Number of central venous catheter (CVC) related VTEs (all ages)
b. Number of NON-CVC VTE events in children (≥) 12 years of age
c. All VTEs (CVC **all** ages + NON-CVC <12 y.o. + NON-CVC ≥ 12 y.o.)

Denominator:

a. CLABSI definition of line days
b. and c. Number of patient days

Formulas:

a. $CVC\ VTE\ Rate\ per\ 1{,}000\ CVC\ days = \frac{No.of\ CVC\ related\ VTE}{Number\ of\ CVC\ days} * 1{,}000$

b. $NON-CVC\ \geq 12\ y.o. VTE\ Rate\ per\ 1{,}000\ patient\ days = \frac{No.of\ Non\ CVC \geq 12\ y.o.}{Number\ of\ patient\ days} * 1{,}000$

c. $Total\ \ VTE\ Rate\ per\ 1{,}000\ patient\ days = \frac{(all\ VTE\ events.)}{Number\ of\ patient\ days} * 1{,}000$

VII. Data Quality Audit Procedures

Hospitals should develop their own procedures for auditing data quality, until quality auditing procedures are suggested by the network.

VIII. Notes

IX. Experts/Resources

N/A

X. Attachments

A Central Venous Catheter (CVC) is defined as:

1. A catheter that has an access/insertion site in a deep vein, regardless of tip location.
2. Non central catheters (midlines) are counted as catheter associated events if their access point or tip location is a deep vein.
3. All types of catheters should be counted including implanted ports, tunneled catheters (i.e. Hickman or Broviac), non-tunneled central venous catheters (i.e. subclavian, jugular or femoral catheters, apheresis catheters, hemodialysis catheters, ECMO catheters, etc), Peripherally Inserted Central Catheters (PICC) with the tip location in a deep vein and procedures that require temporary placement of a catheter (i.e. cardiac catheterization, interventional radiology procedures requiring catheterization, etc).

A deep vein is defined as:

In the upper and lower extremities veins are classified as either deep or superficial. **Only patients with DEEP vein thrombosis are reportable events**, descriptions and figures are provided below. All other veins outside of the extremities are considered deep veins (i.e. cerebral sinus veins, jugular vein, superior vena cava, inferior vena cava, renal veins, hepatic vein, portal vein etc.)

References:

1. Moll, Stephan. "Arm and Leg Veins – Anatomy + Terminology." *Clot Connect.* University of Carolina at Chapel Hill. 24 Jan. 2011. Web. 3 March 2016.
2. "THE CHAT REGISTRY: Extremity Deep Vein Reference Guide for Subject Identification." Print.

Reference #1

Arm and Leg Veins – Anatomy + Terminology

Confusion as to which veins of arms and legs are superficial and which are deep can lead to misclassification superficial thrombophlebitis and DVT and, thus, to incorrect treatment decisions.

A. Arm Veins

Graph of Arm Vein Terminology

- Basilic and cephalic veins are superficial veins;
- Brachial veins are deep veins;
- Brachial veins drain into the axillary vein, followed by the subclavian vein, brachiocephalic vein, and then the SVC (superior vena cava).

B. Leg Veins

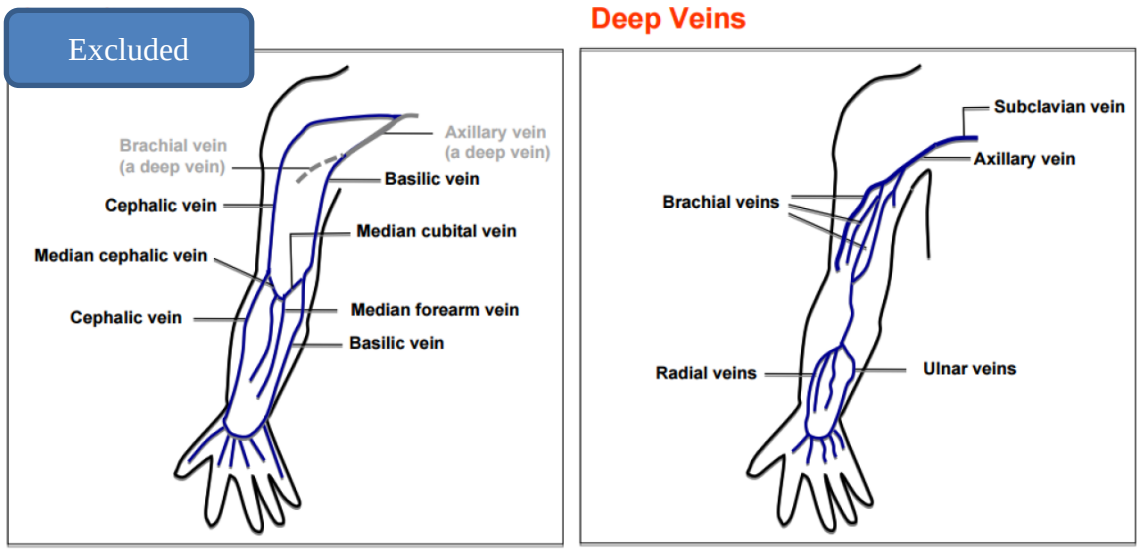
Graph of Leg Vein Terminology

- Greater and lesser saphenous veins are superficial veins;
- popliteal vein and anything proximal to it are considered a proximal veins;
- gastrocnemius and soleal veins are intramuscular calf veins and part of the deep venous system. Together with the peroneal and tibial veins they make up the deep veins of the distal leg.
- The "superficial femoral vein" is an outdated term. It is now called the "femoral vein". It is the major deep vein of the thigh.

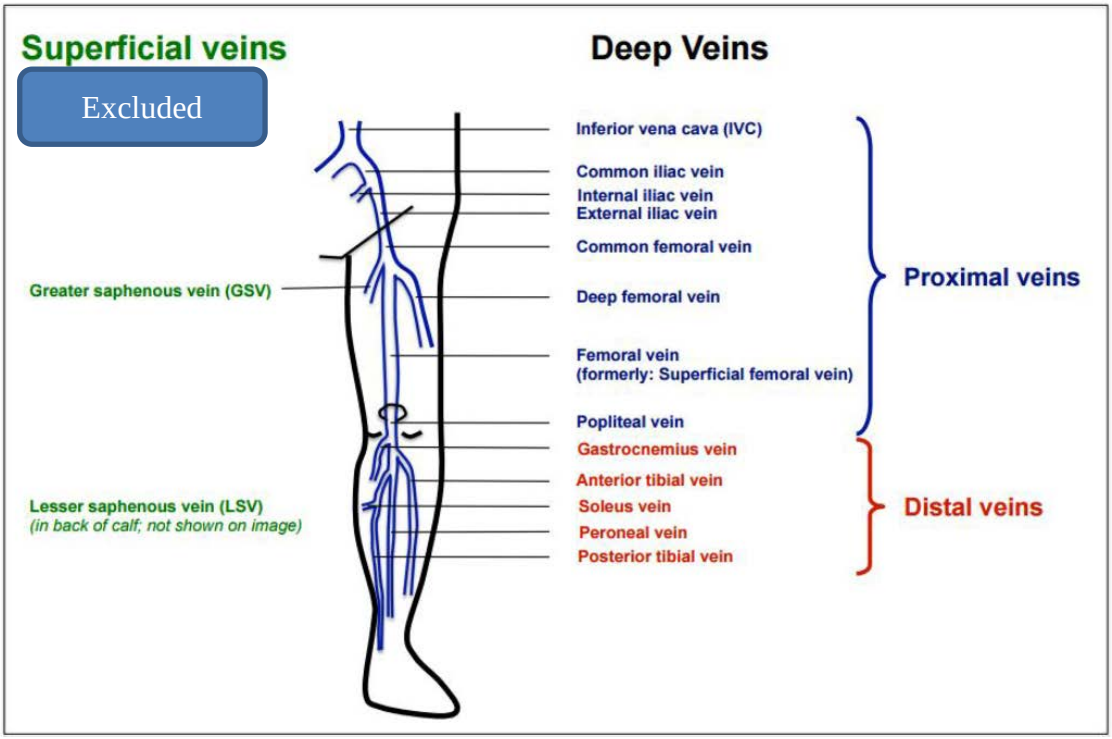
Finally, Doppler ultrasound of the legs can only visualize the veins distal to the inguinal ligament, i.e. the common femoral vein and below. For assessment of iliac vein (i.e. pelvic vein) thrombosis or narrowing (such as detection of May-Thurner syndrome), pelvic CT venogram or MRI venogram need to be performed.

Reference #2:

Arm Vein Terminology



Leg Vein Terminology



A central line associated VTE is defined as:

1. A deep vein thrombosis that is found in the path of a central venous catheter
    i. Including branching veins (i.e. left portal vein thrombosis from an umbilical catheter.)
    ii. A DVT may not be identified until after a CVC is removed but should be considered CVC related if identified within 4 weeks of catheter removal.
    iii. A DVT at a site of multiple venous puncture "attempts" to place a CVC.
2. A pulmonary embolism in the setting of a central venous catheter without a non-line associated source.

A non-line associated VTE is defined as:

1. A DVT in an area with no prior CVC or attempts to place a CVC.

XI. Revision History

Version	Primary Author(s)	Description of Version	Date Completed
V 1.0	Karen Zieker	Initial Draft	30-Mar-2012
V 2.0	Jason Olivea/Neil Goldenberg	Draft #2	6-Nov- 2012
V 3.0	Jason Bailey/Brian Branchford	Added exclusion of NICU patients	27-Feb-13
V 4.0	Brian Branchford	Added more information location of DVT.	05-Nov-2013
V 5.0	Karen Zieker, Jason Olivea, Brian Branchford	Further clarity with Notes	14-Nov- 2013
V 6.0	Karen Zieker	Added exclusion F (excluding clots) and added notes regarding multiple VTE events	17-Mar-2015
V 7.0	VTE Leaders and SMEs	Completely re-written to refocus group efforts	3-Mar-2016
V 8.0	VTE Leaders	Definition of a CVC clot and a Non-CVC clot	7-Oct-2016

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SPS PREVENTION BUNDLE

Venous Thromboembolism (VTE), Non-CVC Bundle

Table of Contents

I. Background & Team

Venous thromboembolism (VTE) is the 2nd largest contributor to harm caused across the SPS network. In 2015, there were 951 VTE events comprising 16% of all Serious Harm Events within the network. The VTE team formed in May of 2012 to develop strategies consistent with high reliability concepts to reduce harm caused by VTEs. Participating hospitals created methods for screening patients at risk and developed systems for event detection. This raised situational awareness and created scaffolding upon which to build a risk reduction strategy. In 2016 the VTE operational definition was revised based on feedback received from engaged stakeholders and content specific experts. The revised 2016 SPS VTE operational definition works toward recording all events of harm from hospital-acquired venous thromboembolism classified as either central venous catheter (CVC) related or non-CVC related, and correlating metrics were established. In addition patients who experienced harm from hospital acquired VTE were included regardless of age.

Process bundles target the pathophysiology of thrombus formation. Virchow described the risk factors for thrombosis as stasis of venous blood flow, hypercoagulability and endothelial injury. We believe reduction of these risk factors for both catheter and non-catheter related bundles are the keystone of the bundles aimed at harm prevention. Using data obtained from the SPS network as well as external evidence in the medical literature the VTE team has identified those bundle elements that when reliably implemented are highly likely to result in decreased harm to hospitalized children.

As a result, SPS is stratifying bundle elements based on their level of evidence to assist hospitals in prioritizing their efforts at designing and implementing evidence-based bundles for for all aviator HACs:

- *Standard Element:* Strong evidence suggests that implementation of this element is associated with significant decrease in patient harm; **all SPS hospitals should implement and measure reliability of this element.**
- *Recommended Element*: Preliminary data and clinical expert opinion support the implementation of this element; **SPS hospitals should strongly consider implementing this element.**

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II. Bundle Elements-Overview

1. **Non-CVC VTE**
    a. **Non-CVC VTE: general anesthesia for > 1 hour**
2. *CVC-VTE : To be determined*

Screening for Non-CVC VTE Risk

Screen all patients ≥ 12 years for VTE risk. *For patients ≥18 years please follow adult guidelines either ACCP 2012 thrombosis guidelines [1] or affiliated adult institution VTE guidelines.)*

Screening should be performed (minimally): on admission, pre- and post-operatively, and upon transfer to a different level of care.

SPS Standard Elements for Screening: VTE Risk Factors

- Mobility status
    - Baseline: Usual state of ambulation
    - Altered: A temporary inability to ambulate freely: bathroom privileges, pivot to chair, etc. (Corresponds to Braden Q Scale, Mobility 1-3, Activity 1-2)
- Personal history of thrombosis
- Thrombophilia
    - Inherited deficiency of protein S, C or antithrombin, factor V Leiden or prothrombin gene mutation.
- Critically ill (currently in an intensive care unit)
- Active cancer/malignancy
- Recent Surgery within the past 30 days
- Estrogen therapy: currently taking or within the past 2 weeks

SPS Recommended Elements for Screening: VTE Risk Factors

- Acute systemic inflammation/infection

- Major trauma requiring admission to an intensive care unit
- Obesity
    - BMI > 95th percentile in patients < 18 years of age
    - BMI >30 in patients > 18 years of age
- Burns:
    - Increased VTE risk has been associated with total body surface area burns >50-65% in adults.
- Severe Dehydration
- Protein-losing disorder
    - Examples: nephrotic syndrome, protein losing enteropathy (PLE), draining chylous effusion etc.
- Cyanotic heart disease or low-flow states
- Family history of VTE in a 1st degree relative

VTE Prevention Intervention Based on VTE Risk Assessment

	Low Risk	At risk		High Risk
Mobility Status	Baseline	Baseline	Altered	Altered
Number of VTE Risk Factors	0	1 or more	0-1	2 or more
Interventions: *with no contraindications present*				
o Encourage highest degree of mobility	Yes	Yes	Yes	Yes
o SCD	-	Yes	Yes	Yes
o Anticoagulation	-	-	-	Yes

VTE Prevention Intervention for Patients Undergoing Surgical Procedures with General Anesthesia

- Age ≥12 **AND**
- Anesthesia duration >1 hour **AND**
- Surgical procedure: including laparoscopic procedures, interventional radiology or interventional cardiology procedures
    - ***Excludes noninvasive procedures that may require general anesthesia***: i.e. dental, endoscopy, colonoscopy, radiographic imaging (i.e. MRI, CT etc)

SCDs should be placed prior to the induction of general anesthesia and for the duration of a procedure/surgery anticipated to be greater than 1 hour.

SPS Standard Interventions

- **Mobility**: encourage highest degree of mobility, ideally ambulation, for patients >/= 3 times a day
- **Sequential Compression Devices (SCD)** unless contraindicated
    1. While in bed
    2. Prior to the induction of general anesthesia and for the duration of a procedure/surgery if anticipated to be greater than 1 hour.

Contraindications:

- Distal/Peripheral IV Access: i.e. IV in foot
- Suspected or existing acute deep vein thrombosis
- Skin conditions affecting extremity (e.g., dermatitis, burn)
- Acute fracture- okay to use device on unaffected extremity
- No appropriate SCD size available
- Lower extremity conditions which result in significant pain with compression (ex. Solid tumor, veno-occlusive episode in sickle cell disease)

SPS Recommended Interventions

- **Anticoagulation**: Strongly consider prophylactic anticoagulation of high risk patients if the patient has altered mobility and 2 or more VTE risk factors present (see VTE intervention based on risk assessment unless contraindicated).

Prophylactic anticoagulation: utilize a form of low molecular weight heparin or subcutaneous unfractionated heparin. If a patient is already on other forms of anticoagulation (i.e. warfarin or direct oral anticoagulants) no additional prophylactic anticoagulation is needed. Aspirin or other antiplatelet therapy is not considered VTE prophylaxis.

Contraindications:

- Intracranial hemorrhage
- Acute stroke/ brain ischemia
- Ongoing and uncontrolled bleeding
- Uncorrected coagulopathy
- Incomplete spinal cord injury with suspected or known para-spinal hematoma
- Allergy to UFH or enoxaparin (i.e. heparin induced thrombocytopenia)
- Platelet count < 50,000/mcl
- Epidural anesthesia
- The patient is likely to require an invasive procedure within 24 hours of starting anticoagulation
- Congenital bleeding disorder
- Uncontrolled severe hypertension
- Intracranial mass

III. Bundle Elements – Evidence Reviewed

Screening Bundle Element	Level of Evidence CDC*/SPS**	Evidence Cited (Numbers refer to Reference Section)
Standard Elements		
Screen for VTE Risk	CDC Modified: IB	[2, 3]
Elements for Screening		
Mobility status	CDC Modified: IB	[4, 5]
Personal history of thrombosis	CDC Modified: IB	[6, 7]
Thrombophilia	CDC Modified: IB	[8-10]
Critically ill (in the intensive care unit)	CDC Modified: IB	[5, 6, 11]
Active cancer/malignancy	CDC Modified: IB	[6, 8, 12-19]
Recent surgery within the past 30 days.	CDC Modified: IB	[8, 17, 20, 21]
Estrogen therapy	CDC Modified: IB	[4, 22]
Recommended Elements		
Acute systemic inflammation/infection	CDC Modified: IB	[4, 6, 8, 11-13, 23]
Major trauma	CDC Modified: IB	[7, 8, 17, 24, 25]
Obesity	CDC Modified: IB	[22, 26-28]
Burns (>50-65% total body surface area)	CDC Modified: II	[29, 30]
Severe dehydration	CDC Modified: II	
Protein-losing disorder	CDC Modified: IB	[14, 17, 31]
Cyanotic heart disease or low-flow states	CDC Modified: IB	[14, 21]
Family history of VTE in a 1st degree relative	CDC Modified: IB	[14]

Prevention Bundle Element	Level of Evidence CDC*/SPS**	Evidence Cited (Numbers refer to Reference Section)
Standard Elements		
Encourage highest degree of ambulation/mobility for patients (≥3 times a day)	CDC Modified: IB	[4, 5]
If altered mobility use sequential compression devices while in bed unless contraindicated.	CDC Modified: IB	[32-43]
Use sequential devices prior to the induction of anesthesia and the duration of the surgical procedure is anticipated to last >1 hour.	CDC Modified: IB	[44-49]
Recommended Elements		
Strongly consider, in addition to sequential compression devices, using anticoagulation for very high risk patients based on risk stratification if the patient has altered mobility and 2 or more VTE risk factors present (see VTE screening elements), unless anticoagulation is contraindicated.	CDC Modified II	[1, 41, 50]

*CDC Modified Recommendation Category

- IA - A strong recommendation supported by high to moderate quality† evidence suggesting net clinical benefits or harms.
- IB - A strong recommendation supported by low quality evidence suggesting net clinical benefits or harms or an accepted practice (e.g., aseptic technique) supported by low to very low quality evidence.
- IC - A strong recommendation required by state or federal regulation.

- II - A weak recommendation supported by any quality evidence suggesting a tradeoff between clinical benefits and harms.

**SPS Evidence

- Scenario 1: Reliably implementing element is associated with statistically significant improvement.
- Scenario 2: Failing to implement element is associated with statistically significant failure to improve along with the system.
- Scenario 3: In cases where all hospitals implement, implementing an element without measuring reliability of the element is associated with statistically significant failure to improve along with the system.

Scenario 4: Reliably implementing element is not associated with statistically significant improvement; however, literature supports adoption of element as an SPS Standard.

IV. VTE detection – must use at least two methods

Method	Comments
Pharmacy Records	This system would be highly sensitive for identifying patients but not specific, i.e. lots of patients on anticoagulants who do not have a VTE or are on it for VTE prophylaxis. In addition, a patient with an acute VTE with a contraindication to anticoagulation would be missed. Challenges include identifying who would sift through all that data to decide which patients were on anticoagulation for VTE and an alternative method to identify those patients with VTE who are not anticoagulated.
ICD-10 Codes	Highly insensitive and not time sensitive. Should not be used in isolation.
Hem/Onc Consult	Very sensitive and specific but only if a Hematology consult was mandated by the institution. In those institution's that do mandate a consult and that have a good method for collecting this data, it is an excellent method. It would not be applicable to institutions that do not require a consult from hematology for VTE patients.
EMR Trigger	An EMR trigger linked to an element in the EMR (a note, the MAR, a radiological test) would be an outstanding way to identify patients, however only if such a trigger can be developed and only if the trigger would then link to a database or to someone who would collect the data.
Radiological Records	This method could be highly specific and sensitive if the VTE diagnosis could be flagged and then go to a database or to notify a data manager to enter the data in a database.

V. Measurement – Bundle Reliability

Measurement	Formula	Standards	Reporting Period
VTE risk screening and prevention interventions.	Number of audits totally compliant with SPS Prevention Bundle Elements/ Number of audits completed* x 100	• Your bundle reliability data should include **all** the SPS Standard elements • SPS strongly encourages hospitals to also include the SPS Recommended Elements. • Hospitals can choose to include additional elements. Please note that including too many (>5) elements may confuse and overwhelm care providers so proceed with caution. • Measure your bundle as ALL or None [51]. See Reference #43 for IHI description of All on None. • Minimum of 20 audits per month. If procedures are fewer than 20, then include all procedures.	Monthly

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VII. Revision History

I. Version	Primary Author(s)	Description of Version	Date Completed
V1.0	Katie Hilbert	Initial Draft	9 Nov 2012
V2.0	Jason Bailey	Addition of section III, IV & V	4 Feb 2013
V3.0	VTE Leaders & SMEs	Revised entire document to match SPS VTE rework 2016	24 Oct 2016

V4.0	VTE Leaders	Clarified inclusion/exclusions of surgeries >1 hour	9 Feb 2017
V5.0	SPS Staff	Contact information updated	5 April 2017

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