



SPS RECOMMENDED BUNDLES

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SPS Recommended Bundle

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I. Background

ADE (Adverse Drug Events) is the 8th largest contributor to harm caused across the SPS network. These events include levels 6-9 or F-I. In 2011, approximately 15 children were harmed each month across the Phase I SPS hospitals. The team formed in May of 2012 to develop strategies consistent with high reliability concepts to reduce harm caused by ADEs.

II. Bundle Strategies - Overview

Develop Delivery System Intervention Bundle

1. Identifying High Harm Events
2. Review and catalog last 20 F & higher / 6-9 (NCC MERP Scale) ADE Events
3. Identify which medication delivery system the failure occurred
 - a. Ordering
 - b. Pharmacy
 - c. Administration
 - d. Monitoring
4. Determine top 1-2 factors that are common across those events (ie. Phase, Drug, Location, Failure mode, etc.)
5. Develop & Report 2-3 interventions (Hospital Specific Bundle)
6. Track impact on Hospital's 6-9 events

III. Bundle Elements – Evidence

Grade of body evidence: LOW

IV. Bundle Elements – Standards of Care
To be developed at future data

Bundle Element	Standards of Care
Identifying High Harm Events	
Review and catalog last 20 F & higher / 6-9 (NCC MERP Scale) ADE Events	
Identify which medication delivery system the failure occurred	
Determine top 1-2 factors that are common across those events	
Develop & Report 2-3 interventions (Hospital Specific Bundle)	
Track impact on Hospital's 6-9 events	

V. Measurement- Bundle Reliability

Measurement	Formula	Recommendations	Reporting Period
Delivery System Intervention Bundle	Number of audits totally compliant with system failure bundle / Number of audits completed* x 100	*Apply formula to your hospital bundle elements.	Monthly

VI. Tools

We have asked hospitals for some of their spotlight tools, and have highlighted a few in this [folder](#). The highlighted categories are: Bundle Measure Methodology, PDSAs and Interventions, Risk Assessment, Training, and Failure Analysis.

Please click [here](#) to view the SHINE report.

VII. References

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6. Unpublished, non-peer-reviewed consensus documents – CHCA, CDC

VII. Revision History

I. Version	Primary Author(s)	Description of Version	Date Completed
Version 1	Katie Hilbert	Initial Draft	7-Nov-2012
Version 2.0	Jason Bailey	Addition of sections III, IV & V	5 Feb 2013

SPS Recommended Bundle

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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

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

VTE Prevention Intervention for Patients Undergoing General Anesthesia

- Age >12 AND
- Anesthesia duration >1 hour

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 $< 50,000/\text{mcl}$
- 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]

Screening Bundle Element	Level of Evidence CDC*/SPS**	Evidence Cited (Numbers refer to Reference Section)
Cyanotic heart disease or low-flow states	CDC Modified: IB	[14, 21]
Family history of VTE in a 1 st 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 procedure if the procedure is anticipated to last >1 hour.	CDC Modified: IB	[44]
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	CDC Modified II	[1, 41, 45]

Prevention Bundle Element	Level of Evidence CDC*/SPS**	Evidence Cited (Numbers refer to Reference Section)
elements), unless anticoagulation is contraindicated.		

***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	<ul style="list-style-type: none"> • 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 [46]. 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
Version 1	Katie Hilbert	Initial Draft	9 Nov 2012
V2.0	Jason Bailey	Addition of section III, IV & V	4 Feb 2013
V3.0	Char Witmer, Daniela Davis, Brian Branchford, Julie Jaffray, Darcy Doellman, Leslie Raffini, Sheila Hanson, Neil Goldenberg, Chadi Zeinati, Lisa Battista	Revised entire document to match SPS VTE rework 2016	24 Oct 2016