SPS PREVENTION BUNDLES

To jump to a specific bundle, simply click on the title of the bundle below:

- Catheter-Associated Urinary Tract Infections (CAUTI)
- Central Line-Associated Blood Stream Infections (CLABSI)
- Falls
- Pressure Injuries
- Readmissions
- Surgical Site Infections
- Unplanned Extubations
- Ventilator-Associated Pneumonia (VAP)
- Venous Thromboembolism
Table of Contents
I. Background & Team
II. Prevention Bundle Elements – Overview
III. Prevention Bundle Elements – Evidence Reviewed
IV. Prevention Bundle Elements – Care Descriptions
V. Measurement – Prevention Bundle Reliability
VI. Spotlight Tools
VII. Spotlight Hospitals
VIII. References
IX. Revision History
I. Background & Team

CAUTI (Catheter – Associated Urinary Tract Infections) is the 6th largest contributor to harm caused across the SPS network. In 2011, approximately 19 children were harmed each month as a result of CAUTI across the Phase I SPS hospitals (n=33). The CAUTI team formed in May of 2012 to develop strategies consistent with high reliability concepts to reduce harm caused by CAUTI, and released the first recommended bundle to the network. In 2013, Phase II hospitals (n=55) joined the network and the number of children harmed per month increased to 38.

The network strategy has been successful with a 25% CAUTI reduction across the network as of May 2014. Using data obtained from the SPS network as well as external evidence in the medical literature, the CAUTI team has identified those bundle elements within the first recommended CAUTI bundle 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 CAUTI and the other 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.

**CAUTI Co-Leaders**

Rachel Bowes, Cook Children’s Medical Center
Vera Hupertz, Cleveland Clinic Children’s

**CAUTI Subject Matter Experts**

Kathy Ackerman, New York Presbyterian Morgan Stanley Children’s Hospital
Charles Foster, Cleveland Clinic Children’s
Cindy Guess, Cook Children’s Medical Center
Joann Sanders, Cook Children’s Medical Center
Lisa Schlaefli, Cook Children’s Medical Center

**SPS Staff**

Laurie Mustin, Senior Quality Outcomes Manager
Erin Goodman, Project Specialist
Carrie Hughes, Project Coordinator
Patsy Sisson, Data Analyst
II. Prevention Bundle Elements – Overview

Insertion
SPS Standard Elements
- Use aseptic technique for insertion
- Avoid unnecessary catheterization

SPS Recommended Elements
- Not applicable

Maintenance
SPS Standard Elements
- Maintain a closed drainage system
- Maintain hygiene
- Keep bag below level of bladder
- Maintain Unobstructed flow
- Remove catheter when no longer needed

SPS Recommended Elements
- Secure catheter

III. Prevention Bundle Elements – Evidence Reviewed

<table>
<thead>
<tr>
<th>Prevention Bundle Element - Insertion</th>
<th>Level of Evidence CDC*/SPS**</th>
<th>Evidence Cited (Numbers refer to Reference Section)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Elements</td>
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<tr>
<td>Use aseptic technique for insertion</td>
<td>*IB/**Scenario 4</td>
<td>2, 3, 4</td>
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<tr>
<td>Avoid unnecessary catheterization</td>
<td>*IB/**Scenario 4</td>
<td>2, 3, 4</td>
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<tr>
<td>Prevention Bundle Element - Maintenance</td>
<td>Level of Evidence SPS**</td>
<td>Evidence Cited (Numbers refer to Reference Section)</td>
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<tr>
<td>----------------------------------------</td>
<td>------------------------</td>
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<tr>
<td><strong>Standard Elements</strong></td>
<td></td>
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<tr>
<td>Maintain a closed drainage system</td>
<td>*IB/**Scenario 2</td>
<td>2, 3, 4</td>
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<tr>
<td>Maintain Hygiene</td>
<td>*IB/**Scenario 2</td>
<td>2, 3, 4</td>
</tr>
<tr>
<td>Keep bag below level of bladder</td>
<td>*IB/**Scenario 4</td>
<td>2, 3, 4</td>
</tr>
<tr>
<td>Maintain Unobstructed flow of urine</td>
<td>*IB/**Scenario 4</td>
<td>2, 3, 4</td>
</tr>
<tr>
<td>Remove catheter when no longer needed</td>
<td>*IB/**Scenario 4</td>
<td>2, 3, 4</td>
</tr>
<tr>
<td><strong>Recommended Elements</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Secure catheter</td>
<td>*IB/N/A</td>
<td>2, 3, 4</td>
</tr>
</tbody>
</table>

*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 trade off 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. Prevention Bundle Elements Care Descriptions

<table>
<thead>
<tr>
<th>Prevention Bundle Element - Insertion</th>
<th>Care Descriptions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Standard Elements</strong></td>
<td></td>
</tr>
</tbody>
</table>
| Use Aseptic Technique for Insertion   | • Perform hand hygiene immediately before and after insertion or any manipulation of the catheter device or site [CDC Reference]  
• Use sterile gloves, drape, sponges, and appropriate antiseptic or sterile solution for per urethral cleaning, and a single packet of lubricant jelly for insertion [CDC Reference] |
| Avoid unnecessary catheterization    | • Consider having written clinical indications [CDC Reference] |

<table>
<thead>
<tr>
<th>Prevention Bundle Element - Maintenance</th>
<th>Care Descriptions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Standard Elements</strong></td>
<td></td>
</tr>
<tr>
<td>Maintain closed drainage system</td>
<td>• If breaks in aseptic technique, disconnection, or leakage occur, replace the catheter and collecting system using aseptic technique and sterile equipment</td>
</tr>
<tr>
<td>Maintain Hygiene</td>
<td>• Perform perineal hygiene at minimum daily.</td>
</tr>
<tr>
<td>Keep bag below level of bladder</td>
<td>• Do not rest bag on floor [CDC Reference]</td>
</tr>
<tr>
<td>Maintain Unobstructed flow of urine</td>
<td>• Keep the catheter and collecting tube free from kinking</td>
</tr>
</tbody>
</table>
| Remove catheter when no longer needed   | • Review necessity daily  
• Document indication daily |
| **Recommended Elements**                 |                   |
| Secure catheter                         |                   |
V. Measurement – Prevention Bundle Reliability

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Formula</th>
<th>Standards</th>
<th>Reporting Period</th>
</tr>
</thead>
</table>
| CAUTI Prevention Bundle Insertion and Maintenance to be measured separately. | Number of audits totally compliant with SPS Prevention Bundle Elements/Number of audits completed* \( \times \frac{1}{100} \) | • Your bundle reliability data should include all the SPS Prevention Bundle 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. See Reference 5 for IHI description of All on None.  
• Minimum of 20 audits per month. If procedures are fewer than 20, then include all procedures. | Monthly |

VI. Spotlight Tools

We have asked hospitals to share their spotlight tools, and have highlighted a few in this SharePoint folder (note: this folder is password protected and can only be accessed by SPS network member hospitals). The highlighted categories are: Bundle Measure Methodology, PDSAs and Interventions, Risk Assessment, Training, Patient & Family Engagement and Failure Analysis.

VII. Spotlight Hospitals

Please click here to view the Sharing Hospitals' Innovation for Network Engagement (SHINE) report.
VIII. References

3. 2014 A Special. On the CUSP: Stop CAUTI, APIC
4. 2014 Update Author(s): Evelyn Lo, MD; Lindsay E. Nicolle, MD; Susan E. Coffin, MD, MPH; Carolyn Gould, MD, MS; Lisa L. Maragakis, MD, MPH; Jennifer Meddings, MD, MSc; David A. Pegues, MD; Ann Marie Pettis, RN, BSN, CIC; Sanjay Saint, MD, MPH; Deborah S. Yokoe, MD, MPH. (May 2014), Strategies to Prevent Catheter-Associated Urinary Tract Infections in Acute Care Hospitals: Source: Infection Control and Hospital Epidemiology, Vol. 35, No. 5, pp. 464-479

IX. Revision History

<table>
<thead>
<tr>
<th>Version</th>
<th>Primary Author(s)</th>
<th>Description of Version</th>
<th>Date Completed</th>
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<tbody>
<tr>
<td>Version 1</td>
<td>Sharyl Wooton &amp; Rachel Bowes</td>
<td>Initial Draft</td>
<td>October 2, 2012</td>
</tr>
<tr>
<td>Version 3</td>
<td>SPS Staff</td>
<td>Contact information updated</td>
<td>April 5, 2017</td>
</tr>
<tr>
<td>Version 4</td>
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</table>

Thank you to the following CAUTI Co-Leaders and Subject Matter Experts who contributed to this document:
Rachel Bowes, Cook Children’s Medical Center; Vera Hupertz, Cleveland Clinic Children’s; Lisa Schlaefli, Cook Children’s Medical Center; Joann Sanders, Cook Children’s Medical Center; Kathy Ackerman, New York Presbyterian Morgan Stanley Children’s Hospital; Charles Foster, Cleveland Clinic Children’s
SPS PREVENTION BUNDLE

Central Line-Associated Blood Stream Infections (CLABSI)

Table of Contents

I. Background & Team

II. Prevention Bundle Elements – Overview

III. Prevention Bundle Elements – Evidence Reviewed

IV. Prevention Bundle Elements – Care Descriptions

V. Measurement – Prevention Bundle Reliability

VI. Spotlight Tools

VII. Spotlight Hospitals

VIII. References

IX. Revision History
I. Background & Team

CLABSI (Central Line-Associated Blood Stream Infections) is the largest contributor to harm caused across the SPS network. In 2011, approximately 97 children were harmed each month as a result of CLABSI across the Phase I SPS hospitals (n=33). The CLABSI team formed in May of 2012 to develop strategies consistent with high reliability concepts to reduce harm caused by CLABSI, and released the first recommended bundle to the network. In 2013, Phase II hospitals (n=55) joined the network and the number of children harmed per month increased to 159.

The network strategy has been successful with a 11% CLABSI reduction across the network as of May 2014. Using data obtained from the SPS network as well as external evidence in the medical literature, the CLABSI team has identified those bundle elements within the first recommended CLABSI bundle 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 CLABSI and the other 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.

**CLABSI Co-Leaders**
Marjorie McCaskey, Children’s of Alabama
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Patsy Sisson, Associate Data Analyst
II. Prevention Bundle Elements – Overview

Insertion
SPS Standard Elements
- Hand Hygiene
- CHG Scrub
- No iodine ointment
- Prepackaged or filled insertion cart, tray or box
- Insertion checklist with staff empowerment to stop non-emergent procedure
- Full sterile barrier for providers and patients
- Insertion training for all providers

SPS Recommended Elements
- Not applicable

Maintenance
SPS Standard Elements
- Daily discussion of line necessity, functionality and utilization including bedside and medical care team members
- Regular assessment of dressing to assure clean/dry/occlusive
- Standardized access procedure
- Standardized dressing, cap and tubing change procedures/timing

SPS Recommended Elements
- An in-depth review of all identified CLABSI with multidisciplinary involvement AND the intent to change the process if needed.
- Daily CHG bathing and linen changes
### III. Prevention Bundle Elements – Evidence Reviewed

<table>
<thead>
<tr>
<th>Prevention Bundle Element - Insertion</th>
<th>Level of Evidence CDC*/SPS**</th>
<th>Evidence Cited (Numbers refer to Reference Section)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Standard Elements</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hand Hygiene</td>
<td>*IB/**Scenario 4</td>
<td>3,4,5</td>
</tr>
<tr>
<td>CHG Scrub</td>
<td>*IA/**Scenario 4</td>
<td>3,4,5</td>
</tr>
<tr>
<td>No iodine ointment</td>
<td>*IB/**Scenario 4</td>
<td>3,4,5</td>
</tr>
<tr>
<td>Prepackaged or filled insertion cart, tray or box</td>
<td>NA/**Scenario 4</td>
<td>3,4,5</td>
</tr>
<tr>
<td>Insertion checklist with staff empowerment to stop non-emergent procedure</td>
<td>NA/**Scenario 4</td>
<td>3,4,5</td>
</tr>
<tr>
<td>Full sterile barrier for providers and patients</td>
<td>*IB/**Scenario 4</td>
<td>3,4,5</td>
</tr>
<tr>
<td>Insertion training for all providers</td>
<td>*IA/**Scenario 4</td>
<td>3,4,5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>Prevention Bundle Element - Maintenance</strong></td>
<td><em><em>Level of Evidence CDC</em>/SPS</em>*</td>
<td><strong>Evidence Cited (Numbers refer to Reference Section)</strong></td>
</tr>
<tr>
<td><strong>Standard Elements</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Daily discussion of line necessity, functionality and utilization including bedside and medical care team members</td>
<td>*IB/**Scenario 4</td>
<td>3,4,5</td>
</tr>
<tr>
<td>Regular assessment of dressing to assure clean/dry/occlusive</td>
<td>*IB/**Scenario 4</td>
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<tr>
<td>----------------------------------------</td>
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</tr>
<tr>
<td>Standardized access procedure</td>
<td>*IB/**Scenario 4</td>
<td>3,4,5</td>
</tr>
<tr>
<td>Standardized dressing, cap and tubing change procedures/timing</td>
<td>*IB/**Scenario 4 &amp; 2</td>
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<tr>
<td><strong>Recommended Elements</strong></td>
<td></td>
<td></td>
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<tr>
<td>An in-depth review of all identified CLABSI with multidisciplinary involvement AND the intent to change the process if needed.</td>
<td>N/A/N/A</td>
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</tr>
<tr>
<td>Daily CHG bathing and linen changes</td>
<td></td>
<td>6</td>
</tr>
</tbody>
</table>

*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 trade off 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. Prevention Bundle Elements Care Descriptions

<table>
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<th>Care Descriptions</th>
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</thead>
<tbody>
<tr>
<td><strong>Standard Elements</strong></td>
<td></td>
</tr>
<tr>
<td>Hand Hygiene</td>
<td>• Perform hand hygiene procedures, either by washing hands with conventional soap and water or with alcohol-based hand rubs (ABHR). Hand hygiene should be performed before and after palpating catheter insertion sites as well as before and after inserting, replacing, accessing, repairing, or dressing an intravascular catheter. Palpation of the insertion site should not be performed after the application of antiseptic, unless aseptic technique is maintained [CDC Reference]</td>
</tr>
</tbody>
</table>
| CHG Scrub                            | • Prepare clean skin with an antiseptic (70% alcohol, tincture of iodine, an iodophor or chlorhexidine gluconate) before peripheral venous catheter insertion [CDC Reference]  
  • Prepare clean skin with a .0.5% chlorhexidine preparation with alcohol before central venous catheter and peripheral arterial catheter insertion and during dressing changes. If there is a contraindication to chlorhexidine, tincture of iodine, an iodophor, or 70% alcohol can be used as alternatives [CDC Reference] |
| No iodine ointment                   | • Do not use topical antibiotic ointment or creams on insertion sites, except for dialysis catheters, because of their potential to promote fungal infections and antimicrobial resistance [CDC reference] |
| Prepackaged or filled insertion cart, tray or box | • Catheter cart that contains all the necessary supplies (CDC reference) |
| Insertion checklist with staff empowerment to stop non-emergent procedure | • Include a checklist to ensure adherence to proper practices; [CDC Reference]  
  • Stoppage of procedures in non-emergent situations, if evidence-based practices were not being followed [CDC Reference] |
<p>| Full sterile barrier for providers and patients | • Use maximal sterile barrier precautions, including the use of a cap, mask, sterile gown, sterile gloves, and a sterile full body drape, for the insertion of CVCs, PICCs, or guidewire exchange 2. Use a sterile sleeve to protect pulmonary artery catheters during insertion [CDC reference] |
| Insertion training for all providers | • Refer to CDC reference on education &amp; training details (page e169) |</p>
<table>
<thead>
<tr>
<th>Prevention Bundle Element - Maintenance</th>
<th>Care Descriptions</th>
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</thead>
<tbody>
<tr>
<td><strong>Standard Elements</strong></td>
<td></td>
</tr>
</tbody>
</table>
| Daily discussion of line necessity, functionality and utilization including bedside and medical care team members | • Discuss with the medical team continued necessity of line
• Discuss with the medical team the function of the line and any problems
• Discuss with the medical team the frequency of access and utilization of line. Consider bundling labs and line entries.
• Consider best practice is documentation that the discussion occurred in the medical record. |
| Regular assessment of dressing to assure clean/dry/occlusive | • Replace catheter site dressing if the dressing becomes damp, loosened, or visibly soiled (CDC Reference)
• Replace dressings used on short-term central venous catheters sites every 2 days for gauze dressings and at least every 7 days for transparent dressings [CDC Reference] |
| Standardized access procedure | • Refer to Hand Hygiene details in CLABSI insertion Bundle
• Disinfect cap before all line entries by scrubbing with an appropriate antiseptic and accessing the port only with sterile devices [CDC Reference]
• Alcohol (15 second scrub and allowed to dry) or an alcohol/CHG containing product per manufacturers’ recommendations [CDC Reference]
• Sterile gloves used for needle access for all implanted permanent central lines (example: Portacath) |
| Standardized dressing, cap and tubing change procedures/timing | • Scrub skin around site with CHG for 30 seconds (2 minute for femoral site), followed by complete drying. (Note: institutional preference for CHG use for infant < 2 months of age) [CDC Reference]
• Change crystalloid tubing no more frequently than every 96 hours [CDC Reference]
• Change tubing used to administer blood products every 24 hours or more frequently per institutional standard [CDC Reference]
• Change tubing used for lipid infusions every 24 hours [CDC Reference]
• Document date dressing/cap/tubing was changed or is due for change [CDC Reference & SPS Data]
• Consider when hub of catheter or insertion site are exposed, wear a mask (all providers and assistants)—shield patient’s face, ETT or trach with mask or drape
• Sterile gloves used for dressing/tubing/cap changes |

**Recommended Elements**
An in-depth review of all identified CLABSI with multidisciplinary involvement AND the intent to change the process if needed.

- Utilize a systematic approach to review all hospital acquired CLABSI

Daily CHG bathing and linen changes

- Follow manufacturer recommendations for usage

V. Measurement – Prevention Bundle Reliability

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Formula</th>
<th>Standards</th>
<th>Reporting Period</th>
</tr>
</thead>
</table>
| CLABSI Prevention Bundle Insertion and Maintenance to be measured separately. | 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. See Reference 7 for IHI description of All on None.
- Minimum of 20 audits per month. If procedures are fewer than 20, then include all procedures. | Monthly |

VI. Spotlight Tools

We have asked hospitals to share their spotlight tools, and have highlighted a few in this SharePoint folder (note: this folder is password protected and can only be accessed by SPS network member hospitals). The highlighted categories are: Bundle Measure Methodology, PDSAs and Interventions, Risk Assessment, Training, Patient & Family Engagement, and Failure Analysis.
VII. Spotlight Hospitals

Please click here to view the Sharing Hospitals' Innovation for Network Engagement (SHINE) report.

VIII. References

6. Aaron M Millstone, Alexis Elward, Xiaoyan Song, Danielle M Zerr, Rachel Orscheln, Kathleen Speck, Daniel Obeng. Nicholas G Reich, Susan E Coffin,Trish M Perl, Published online January 28, 2013 for the Pediatric SCRUB Trial Study Group; www.thelancet.com http://dx.doi.org/10.1016/S0140-6736(12)61687-0
Daily chlorhexidine bathing to reduce bacteraemia in critically ill children: a multicentre, cluster-randomised, crossover trial

IX. Revision History

<table>
<thead>
<tr>
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<th>Primary Author(s)</th>
<th>Description of Version</th>
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<tr>
<td>Version 1</td>
<td>Sharyl Wooton</td>
<td>Initial Draft</td>
<td>October 2, 2012</td>
</tr>
<tr>
<td>Version 3</td>
<td>CLABSI Co-leaders</td>
<td>Added use of sterile gloves to maintenance bundle elements: 1) assessment of dressing, 2) access procedure, 3) dressing, cap, tubing changes</td>
<td>12/30/2015</td>
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<tr>
<td>Version 4</td>
<td>SPS Staff</td>
<td>Contact information updated</td>
<td>April 5, 2017</td>
</tr>
<tr>
<td>Version 5</td>
<td>CLABSI Co-leaders</td>
<td>Changed recommendation of crystalloid tubing from every 72 hours to every 96 hours</td>
<td>July 26th, 2017</td>
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</tbody>
</table>
Thank you to the following CLABSI Co-Leaders and Subject Matter Experts who contributed to this document: Mike Gutzeit, Children’s Hospital of Wisconsin; Marjorie McCaskey, Children’s of Alabama; Holly O’Brien, Children’s Hospital of Wisconsin; and Michele Saysana, Riley Hospital for Children at Indiana University Health.
SPS PREVENTION BUNDLE

Falls

Table of Contents

I. Background & Team
II. Prevention Bundle Elements – Overview
III. Prevention Bundle Elements – Evidence Reviewed
IV. Prevention Bundle Elements – Care Descriptions
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VI. Spotlight Tools
VII. Spotlight Hospitals
VIII. References
IX. Revision History
I. Background & Team

Falls is the 9th largest contributor to harm caused across the SPS network. In 2011, approximately 20 children were harmed each month as a result of Falls across the Phase I SPS hospitals (n=33). The Falls team formed in May of 2012 to develop strategies consistent with high reliability concepts to reduce harm caused by Falls, and released the first recommended bundle to the network. In 2013, Phase II hospitals (n=55) joined the network and the number of children harmed per month decrease to 12.

The network strategy has been successful with an 81% Falls reduction across the network as of May 2014. Using data obtained from the SPS network as well as external evidence in the medical literature, the Falls team has identified those bundle elements within the first recommended Falls bundle 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 Falls and the other 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.

**Falls Co-Leaders**
Hila Collins, Dayton Children’s Hospital
Heidi Fields, St. Louis Children's Hospital

**SPS Staff**
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Erin Goodman, Project Specialist
Carrie Hughes, Project Coordinator
Patsy Sisson, Data Analyst
II. Prevention Bundle Elements – Overview

SPS Standard Elements
- Screen patients for risk of fall
- Identify and communicate patients at risk for falls & injury
- Ensure a safe environment
- Review of safety protocols with parents/guardians/family

SPS Recommended Elements
- Implement specific mitigation strategies for patients at risk of falls with injury.

III. Prevention Bundle Elements – Evidence Reviewed

<table>
<thead>
<tr>
<th>Prevention Bundle Element</th>
<th>Level of Evidence</th>
<th>Evidence Cited (Numbers refer to Reference Section)</th>
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<tbody>
<tr>
<td>Standard Elements</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screen patients for risk of fall</td>
<td>*Level 3/**Scenario 4</td>
<td>2, 3, 4, 5, 9</td>
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<tr>
<td>Identify and communicate patients at risk for falls &amp; injury</td>
<td>*Level 3/**Scenario 2/4</td>
<td>1, 4, 10</td>
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<tr>
<td>Ensure a safe environment</td>
<td>*Level 4/**Scenario 4</td>
<td>6, 9</td>
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<tr>
<td>Review of safety protocols with parents/guardians/family</td>
<td>*Level 3/**Scenario 2</td>
<td>1, 7, 9, 10, 11</td>
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<tr>
<td>Recommended Elements</td>
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<tr>
<td>Implement specific mitigation strategies for patients at risk of falls with injury.</td>
<td>*Level 5/N/A</td>
<td>6, 8, 9</td>
</tr>
</tbody>
</table>

*Muir Gray Classification Levels
- **Level 1** – meta-analysis of a series of randomized controlled trials
- **Level 2** – at least one well designed randomized controlled trial
- **Level 3** – at least one controlled study without randomization
- **Level 4** – non-experimental descriptive studies
- Level 5 – reports or opinions from respected authorities

**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
## Prevention Bundle Elements Care Descriptions

<table>
<thead>
<tr>
<th>Prevention Bundle Element - Maintenance</th>
<th>Care Descriptions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Standard Elements</strong></td>
<td></td>
</tr>
</tbody>
</table>
| Screen patients for risk of fall       | • Screen on admission and at interval(s) defined by the selected fall risk assessment tool.  
• Consider using a fall risk assessment tool that includes variables specific to the pediatric population. |
| Identify and communicate patients at risk for falls & injury | • Identify patients are risk for falls by signage, armbands, or other identifiers  
• Communicate fall risk at handoff:  
  o At shift change (nurse to nurse)  
  o At time of transfer in care (unit to unit)  
  o Nurse to other (Child Life specialist, Radiology Technician, etc.) |
| Ensure a safe environment              | • Ensure unused equipment is removed and pathways to door and bathroom are clear  
• Clutter in room is minimized  
• Non-slip footwear for ambulating patients  
• Call light is within reach; orient to use periodically  
• Use of appropriate sized clothing to prevent tripping  
• Bed in low position with brakes on  
• Appropriate sized bed is used (no co-bedding)  
• Evaluate for gaps in the bed railings that may allow the child to slip between the rails  
• Wheelchair and commode brakes are locked during transfers |
| Review of safety protocols with parents/guardians/family | • Parents/guardian/family members have an integral role in a falls risk prevention program  
• Parent/guardian/family education regarding fall risks of hospitalized children is important.  
• Educate parents/guardians/family on safe environment |
| **Recommended Elements**               |                   |
| Implement specific mitigation strategies for patients at risk of falls with injury | • Hourly rounds that include risk identification and prioritizing individualized risk reduction strategies helps to keep patients safe and comfortable by proactively meeting their needs.  
• Assisting when up and out of bed  
• 1:1 observation (only when appropriate) |
V. Measurement – Prevention Bundle Reliability

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Formula</th>
<th>Standards</th>
<th>Reporting Period</th>
</tr>
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</table>
| Falls Prevention Bundle          | Number of audits totally compliant with SPS Prevention Bundle Elements/ Number of audits completed* × 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. See Reference 12 for IHI description of All on None.  
• Minimum of 20 audits per month. If procedures are fewer than 20, then include all procedures. | Monthly          |

VI. Spotlight Tools

We have asked hospitals to share their spotlight tools, and have highlighted a few in this SharePoint [folder](note: this folder is password protected and can only be accessed by SPS network member hospitals). The highlighted categories are: Bundle Measure Methodology, PDSAs and Interventions, Risk Assessment, Training, Patient & Family Engagement and Failure Analysis.

VII. Spotlight Hospitals

Please click [here](note: this folder is password protected and can only be accessed by SPS network member hospitals) to view the Sharing Hospitals' Innovation for Network Engagement (SHINE) report.
VIII. References

10. Krauss, Tutlam, Costantinou, Johnson, Jackson, Fraser, 2008
11. Ryu, Roche, Brunton, 2009

IX. Revision History

<table>
<thead>
<tr>
<th>Version</th>
<th>Primary Author(s)</th>
<th>Description of Version</th>
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<tr>
<td>Version 1</td>
<td>Katie Hilbert</td>
<td>Initial Draft</td>
<td>Oct 2012</td>
</tr>
<tr>
<td>Version 2</td>
<td>Heidi Fields, Amy Hester</td>
<td>Addition of evidence levels, reliability, and references</td>
<td>Jan 2013</td>
</tr>
<tr>
<td>Version 4</td>
<td>SPS Staff</td>
<td>Contact information updated</td>
<td>April 5, 2017</td>
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</table>

Thank you to the following Falls Co-Leaders who contributed to this document:
Hila Collins, Dayton Children’s Hospital; Heidi Fields, St. Louis Children’s Hospital
# SPS PREVENTION BUNDLE

Pressure Injuries (PI)

## Table of Contents

I. Background & Team

II. Prevention Bundle Elements – Overview

III. Prevention Bundle Elements – Evidence Reviewed

IV. Prevention Bundle Elements – Care Description

V. Measurement – Prevention Bundle Reliability

VI. Spotlight Tools

VII. Spotlight Hospitals

VIII. References

IX. Revision History
I. Background & Team

PI (Pressure Injuries) is the 2nd largest contributor to harm caused across the SPS network. In 2011, approximately 43 children were harmed each month as a result of PI across the Phase I SPS hospitals (n=33). The PI team formed in May of 2012 to develop strategies consistent with high reliability concepts to reduce harm caused by PI, and released the first recommended bundle to the network. In 2013, Phase II hospitals (n=55) joined the network and the number of children harmed per month increased to 65.

The network strategy has been successful with a 30% PI increase across the network as of May 2014. Using data obtained from the SPS network as well as external evidence in the medical literature, the PI team has identified those bundle elements within the first recommended PI bundle 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 PI and the other 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.**

**PI Co-Leaders**
Gary Frank, Children’s Healthcare of Atlanta
Rich Brilli, Nationwide Children’s Hospital

**PI Subject Matter Experts**
Trish Burdett, Children’s Healthcare of Atlanta
Cindy Henderson, Children’s Healthcare of Atlanta
Pam Paige, Children’s Healthcare of Atlanta
Michelle Miller, Nationwide Children’s Hospital
Brenda Ruth, Nationwide Children’s Hospital
Stephanie Stafford, Nationwide Children’s Hospital

**SPS Staff**
Laurie Mustin, Senior Quality Outcomes Manager
Erin Goodman, Project Specialist
Carrie Hughes, Project Coordinator
Patsy Sisson, Data Analyst
II. Prevention Bundle Elements* – Overview

SPS Standard Elements
- Skin Assessment
- Device Rotation
- Patient Positioning
- Appropriate Bed Surface
- Moisture Management

SPS Recommended Elements
- Not applicable

* All bundle elements are applied to patients who score as a high risk for Pressure Injuries
III. Prevention Bundle Elements* – Evidence Reviewed

* All bundle elements are applied to patients who score as a high risk for Pressure Injuries

<table>
<thead>
<tr>
<th>Prevention Bundle Element</th>
<th>Level of Evidence SPS**</th>
<th>Evidence Cited (Numbers refer to Reference Section)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Standard Elements</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin Assessment</td>
<td>*Level 2/**Scenario 1</td>
<td>3</td>
</tr>
<tr>
<td>Device Rotation</td>
<td>*Level 5/**Scenario 1</td>
<td>1, 4, 9</td>
</tr>
<tr>
<td>Patient Positioning</td>
<td>*Level 5/**Scenario 1</td>
<td>4</td>
</tr>
<tr>
<td>Appropriate Bed Surface</td>
<td>*Level 1/**Scenario 1</td>
<td>4, 7</td>
</tr>
<tr>
<td>Moisture Management</td>
<td>*Level 5/**Scenario 1</td>
<td>8</td>
</tr>
</tbody>
</table>

*Muir Gray Classification Levels
- Level 1 – meta-analysis of a series of randomized controlled trials
- Level 2 – at least one well designed randomized controlled trial
- Level 3 – at least one controlled study without randomization
- Level 4 – non-experimental descriptive studies
- Level 5 – reports or opinions from respected authorities

**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. Prevention Bundle Elements* Care Descriptions

* All bundle elements are applied to patients who score as a high risk for Pressure Injuries

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<th>Prevention Bundle Element - Maintenance</th>
<th>Care Descriptions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Standard Elements</strong></td>
<td></td>
</tr>
<tr>
<td>Skin Assessment *</td>
<td>• At least every 24 hours but consensus best practice - recommend every shift change (Q4H in perfusion compromised patients), Operating Room (OR) at end of cases lasting 4 hours or more and/or on arrival PACU/ICU's</td>
</tr>
<tr>
<td>Device Rotation</td>
<td>• Assess skin in contact with medical devices each shift or more frequently with other care, Rotate pulse-ox probe at least every 8 hours or more often if able</td>
</tr>
<tr>
<td>Patient Positioning</td>
<td>• Turn all immobile patients at least every 2 hours or timed with care in NICU (e.g. standardized turning schedule, clock at bedside); • Maintain HOB less than or equal 30 degrees (unless medically contraindicated) Note: Patients who are mobile and/or able to get out of bed may sit in a chair or upright in bed if physically able to do so. Patient position must still be shifted regularly to reduce pressure.</td>
</tr>
<tr>
<td>Appropriate Bed Surface</td>
<td>• Evaluate need for specialty bed based on Skin Risk Assessment. • Use gel pads, pillows and/or pressure reduction device to cushion bony prominences.</td>
</tr>
<tr>
<td>Moisture Management</td>
<td>• Barrier cream applied to create a moisture barrier for all diapered patients; • Keep skin clean and dry</td>
</tr>
</tbody>
</table>

* Skin Assessment for high risk patients is in addition to Active Surveillance for all patients.
V. **Measurement – Prevention Bundle Reliability**

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Formula</th>
<th>Standards</th>
<th>Reporting Period</th>
</tr>
</thead>
</table>
| PI Prevention Bundle | 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  
• 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. See Reference 10 for IHI description of All on None.  
• Minimum of 20 audits per month. If procedures are fewer than 20, then include all procedures. | Monthly |

VI. **Spotlight Tools**

We have asked hospitals to share their spotlight tools, and have highlighted a few in this SharePoint folder (note: this folder is password protected and can only be accessed by SPS network member hospitals). The highlighted categories are: Bundle Measure Methodology, PDSAs and Interventions, Risk Assessment, Training, Patient & Family Engagement and Failure Analysis.
VII. Spotlight Hospitals

Please click here to view the Sharing Hospitals’ Innovation for Network Engagement (SHINE) report.

VIII. References

9. Manufacturing Recommendations → Nellcor recommends inspection of the pulse oximeter probe site every 8 hours.

IX. Revision History

<table>
<thead>
<tr>
<th>Version</th>
<th>Primary Author(s)</th>
<th>Description of Version</th>
<th>Date Completed</th>
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<tbody>
<tr>
<td>Version 1</td>
<td>Katie Hilbert</td>
<td>Initial Draft</td>
<td>Nov 9, 2012</td>
</tr>
<tr>
<td>Version 4</td>
<td>Matt Short &amp; Erin Goodman</td>
<td>Format &amp; Update of HAC name and minor changes to numbering of stages</td>
<td>June 21, 2016</td>
</tr>
<tr>
<td>Version 5</td>
<td>SPS Staff</td>
<td>Contact information updated</td>
<td>April 5, 2017</td>
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</table>
Thank you to the following PI Co-Leaders and Subject Matter Experts who contributed to this document:
Gary Frank, Children’s Healthcare of Atlanta; Rich Brilli, Nationwide Children’s Hospital; Trish Burdett, Children’s Healthcare of Atlanta; Brenda Ruth, Nationwide Children’s Hospital
SPS PREVENTION BUNDLE

Readmissions

Table of Contents

I. Background & Team

II. Prevention Bundle Elements - Overview

III. Prevention Bundle Elements – Evidence

IV. Prevention Bundle Elements Care Descriptions

V. Measurement- Prevention Bundle Reliability

VI. References

VII. Revision History
I. Background & Team

The Readmissions Reduction team was formed in May, 2012 to determine key strategies for reducing readmissions. Readmissions have become the focus of quality improvement efforts in both adult and pediatric medicine. Payers, regulatory bodies and government all are encouraging hospitals to reduce readmissions. Typically, pediatric readmission rates have been much lower than those in adults. It is also not clear the extent to which readmissions are preventable in pediatric patients. One recent study using a 15-day readmission standard suggested that about 20% of pediatric readmissions were preventable. Our preliminary analysis of the hospital data in preparation for this quality improvement effort to reduce readmissions found that at least that many readmissions (using a 7-day readmission standard) were potentially preventable (unpublished data). Therefore, we set our goal for the Collaborative at a 20% reduction in readmissions at 7 days after the initial discharge.

Using data obtained from the Readmissions Cohort and data analysis, the Readmissions 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 Readmissions and the other aviator HACs:

- **Standard Element:** Strong evidence suggest 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.

Readmissions Co-Leaders
Herminia Shermont, Boston Children’s Hospital
Robyn Strosaker, UH/Rainbow Babies & Children’s Hospital

SPS Staff
Laurie Mustin, Senior Quality Outcomes Manager
Erin Goodman, Project Specialist
Carrie Hughes, Project Coordinator
Patsy Sisson, Data Analyst
II. Prevention Bundle Elements - Overview

SPS Standard Elements

- Schedule follow-up medical and post discharge tests/labs appointments prior to discharge
- Identify high risk populations of patients, and develop specialized care coordination plans (e.g. sickle cell, asthma, seizures, etc.)
- Post-discharge follow-up call to reinforce discharge instructions with a standardize script
- Discharge instructions contain a plan on potential problems and what to do if they arise (as in who to call)
- Provide feedback to clinicians on any readmission

III. Prevention Bundle Elements – Evidence Reviewed

<table>
<thead>
<tr>
<th>Prevention Bundle Element</th>
<th>Level of Evidence SPS</th>
<th>Evidence Cited (Author(s), Publication, Year, Pages)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Schedule follow-up medical and post discharge tests/labs appointments prior to discharge</td>
<td>Scenario 1</td>
<td>8, 9</td>
</tr>
<tr>
<td>2. Identify high risk populations of patients, and develop specialized care coordination plans (e.g. sickle cell, asthma, seizures, etc.)</td>
<td>Scenario 1</td>
<td>5, 10, 11, 12</td>
</tr>
<tr>
<td>3. Post-discharge follow-up call to reinforce discharge instructions with a standardize script</td>
<td>Scenario 1</td>
<td>9</td>
</tr>
<tr>
<td>4. Discharge instructions contain a plan on potential problems and what to do if they arise (as in who to call)</td>
<td>Scenario 1</td>
<td>8</td>
</tr>
<tr>
<td>5. Provide feedback to clinicians on any readmission</td>
<td>Scenario 1</td>
<td></td>
</tr>
</tbody>
</table>
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. Prevention Bundle Elements Care Descriptions

<table>
<thead>
<tr>
<th>Bundle Element</th>
<th>Care Descriptions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Standard Elements</strong></td>
<td></td>
</tr>
</tbody>
</table>
| Schedule follow-up medical and post discharge tests/labs appointments prior to discharge | - *For weekday discharges:* Patient’s 1st follow up appointment scheduled prior to discharge including an exact time, date, location, and care provider.  
- *For weekend and holiday discharges:* The patient’s discharge instruction to list the follow up appointment provider, their phone number, and the time frame for the appointment. |
| Identify high risk populations | - Each hospital will identify a population at high risk for readmission.  
- Develop and implement readmission risk mitigation plan for the identified patient population.  
- Measure adherence to the plan at the time of discharge. |
| Post-discharge follow-up call to reinforce discharge instructions with a standardize script | - A follow up phone call within 72 hours of discharge using a standard script and providing direct access to a medical professional, if needed.  
- A second attempts on a different day should be made if the first call is unsuccessful.  
- Parents not wanting to talk is considered a successful call. |
| Discharge instructions contain a plan on potential problems and what to do if they arise (as in who to call) | - Discharge instructions contain a plan including:  
  - Accurate medication list and instructions  
  - How to recognize and respond to the patient’s clinical changes  
  - Escalation contact relevant to the situation  
  - Use “teach-back” method to convey discharge instructions to family  
- Measurement of “teach-back” is not required |
<table>
<thead>
<tr>
<th>Bundle Element</th>
<th>Care Descriptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Elements</td>
<td></td>
</tr>
<tr>
<td>Provide feedback to clinicians on any readmission</td>
<td>• Timely notification to discharging physicians of the readmission</td>
</tr>
<tr>
<td></td>
<td>• In a non-judgmental fashion, invite the discharging physician to review the case and make recommendations, if appropriate, as to how this readmission might have been prevented.</td>
</tr>
</tbody>
</table>

V. Measurement- Prevention Bundle Reliability

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Formula</th>
<th>Standards</th>
<th>Reporting Period</th>
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</table>
| Readmissions Prevention Bundle | 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 Prevention Bundle Standard Elements  
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• Minimum of 20 audits per month. If procedures are fewer than 20, then include all procedures | Monthly          |
VI. References


VII. Revision History

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<th>Description of Version</th>
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<tr>
<td>Version 1</td>
<td>Katie Hilbert</td>
<td>Initial Draft</td>
<td>9- Nov - 2012</td>
</tr>
<tr>
<td>Version 2</td>
<td>Rob Payne, MD</td>
<td>Added in additional bundle details, references, and recommended approaches.</td>
<td>29- Jan - 2012</td>
</tr>
<tr>
<td></td>
<td>Sharyl Wooton, MS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Version 3</td>
<td>Rob Payne, MD</td>
<td>Updated bundle elements, references and analysis</td>
<td>24-Feb-2016</td>
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<tr>
<td></td>
<td>Robyn Strosaker, MD</td>
<td></td>
<td></td>
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<tr>
<td>Version 4</td>
<td>SPS Staff</td>
<td>Contact information updated</td>
<td>5-April-2017</td>
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Thank you to the following Readmissions Co-Leaders and Subject Matter Experts who contributed to this document: Rob Payne, Children's Hospitals and Clinics of Minnesota; Robyn Strosaker, UH/Rainbow Babies and Children's Hospital.
# Table of Contents

I. Background & Team  
II. Prevention Bundle Elements – Overview  
III. Prevention Bundle Elements – Evidence Reviewed  
IV. Prevention Bundle Elements – Care Descriptions  
V. Measurement – Prevention Bundle Reliability  
VI. Spotlight Tools  
VII. Spotlight Hospitals  
VIII. References  
IX. Revision History
I. Background & Team

SSI (surgical site infection) is the 4th largest contributor to harm caused across the SPS network. In 2011, approximately 33 children were harmed each month as a result of SSI across the Phase I SPS hospitals (n=33). The SSI team formed in May of 2012 to develop strategies consistent with high reliability concepts to reduce harm caused by SSI, and released the first recommended bundle to the network. In 2013, Phase II hospitals (n=55) joined the network and the number of children harmed per month increased to 46.

The network strategy has been successful with a 19% SSI reduction across the network as of May 2014. Using data obtained from the SPS network as well as external evidence in the medical literature, the SSI team has identified those bundle elements within the first recommended SSI bundle 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 SSI and the other 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**.

SSI Co-Leaders
Lory Harte, Children’s Mercy Kansas City
Josh Schaffzin, Cincinnati Children’s
Jason Newland, St. Louis Children’s Hospital
Jen Lavin, Ann & Robert H. Lurie Children’s Hospital of Chicago

SPS Staff
Chris Kramer, Quality Outcomes Manager
Chelsea Volpenhein, Project Specialist
Sydney Bogardus, Project Coordinator
Patsy Sisson, Associate Data Analyst
II. Prevention Bundle Elements – Overview

SPS Standard Elements
- Preoperative Bath
- No razor
- Appropriate antibiotic timing

SPS Recommended Elements
- Appropriate skin antisepsis (‘Skin Prep’ IntraOp’)
- Appropriate antibiotic redosing

III. Prevention Bundle Elements – Evidence Reviewed

<table>
<thead>
<tr>
<th>Prevention Bundle Element</th>
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<tbody>
<tr>
<td><strong>SPS Standard Elements</strong></td>
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<td></td>
</tr>
<tr>
<td>Preoperative Bath</td>
<td>GRADE/Scenario 1</td>
<td>3, Plus GRADE*</td>
</tr>
<tr>
<td>No Razor</td>
<td>GRADE/Scenario 1</td>
<td>4, 7, Plus GRADE*</td>
</tr>
<tr>
<td>Appropriate antibiotic timing</td>
<td>GRADE/Scenario 1</td>
<td>1, 5, 6, 10, 11 Plus GRADE*</td>
</tr>
<tr>
<td><strong>SPS Recommended Elements</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appropriate skin antisepsis</td>
<td>GRADE/N/A</td>
<td>7, Plus GRADE*</td>
</tr>
<tr>
<td>Appropriate antibiotic redosing</td>
<td>GRADE/N/A</td>
<td>7, 12, 13 Plus GRADE*</td>
</tr>
</tbody>
</table>

*GRADE

- See Appendix A for GRADED Evidence.

**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,
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</thead>
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<tr>
<td><strong>Standard Elements</strong></td>
<td></td>
</tr>
<tr>
<td>Preoperative Bath</td>
<td>• Preoperative bath should take place. Options include; bathing with soap and water, bathing with chlorhexidine-containing solution, or wiping with a chlorhexidine-impregnated cloth, the night before and/or the morning of surgery.</td>
</tr>
<tr>
<td>No Razor</td>
<td>• Do not use razor for hair removal, use clipper or other non-traumatic method</td>
</tr>
<tr>
<td>Appropriate antibiotic timing</td>
<td>• All antibiotics except vancomycin and fluoroquinolones 0-60 minutes prior to incision • Vancomycin and fluoroquinolones 0-120 minutes prior to incision</td>
</tr>
<tr>
<td><strong>Recommended Elements</strong></td>
<td></td>
</tr>
<tr>
<td>Appropriate skin antisepsis</td>
<td>• Use of alcohol containing agent if no contraindication</td>
</tr>
</tbody>
</table>
| Appropriate antibiotic redosing | Redosing intervals:  
  • Cefazolin- every 3 or 4 hours*  
  • Clindamycin- every 4 or 6 hours*  
  • Vancomycin- no redosing or every 6 hours  |

*The ASHP national guideline recommends cefazolin to be given every 4 hours, clindamycin every 6 hours and recommends no redosing for vancomycin. These national guidelines do have pediatric recommendations and the authors state these guidelines are mainly extrapolated data from adults and are largely expert opinion based.
V. Measurement – Prevention Bundle Reliability

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Formula</th>
<th>Standards</th>
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</table>
| SSI Prevention Bundle | 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. See Reference 8 for IHI description of All on None.  
• Minimum of 20 audits per month. If procedures are fewer than 20, then include all procedures. | Monthly |

VI. Spotlight Tools

We have asked hospitals to share their spotlight tools, and have highlighted a few in this SharePoint folder (note: this folder is password protected and can only be accessed by SPS network member hospitals). The highlighted categories are: Bundle Measure Methodology, PDSAs and Interventions, Risk Assessment, Training, Patient & Family Engagement, and Failure Analysis.
VII. **Spotlight Hospitals**

Please click [here](#) to view the Sharing Hospitals' Innovation for Network Engagement (SHINE) report.

VIII. **References**

## IX. Revision History

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<th>Description of Version</th>
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<tr>
<td>Version 1</td>
<td>Katie Hilbert</td>
<td>Initial Draft</td>
<td>9- Nov - 2012</td>
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<tr>
<td>Version 2</td>
<td>Jason Newland, Kathy Ball, Lory Harte</td>
<td>Updating evidence, recommended approaches, measuring reliability, and references.</td>
<td>4- Feb -2013</td>
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<tr>
<td>Version 3</td>
<td>Sharyl Wooton, Erin Goodman on behalf of HAC Team</td>
<td>SPS Prevention Bundles – Standards and Recommendations</td>
<td>15-June -2014</td>
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<tr>
<td>Version 4</td>
<td>Sharyl Wooton, Erin Goodman on behalf of HAC Team</td>
<td>Updating redosing element with changes and evidence to support.</td>
<td>28-August -2014</td>
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<tr>
<td>Version 5</td>
<td>SPS Staff</td>
<td>Contact information updated</td>
<td>5-April-2017</td>
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</table>
Thank you to the following SSI Co-Leaders and Subject Matter Experts who contributed to this document: Suanne Davies, Monroe Carell Children’s Hospital at Vanderbilt; Jason Newland, St. Louis Children’s Hospital; Duha Al Zubeidi, Children’s Mercy Kansas City; Lory Harte, Children’s Mercy Kansas City, Scott Marquette, C.S. Mott Children’s Hospital
Unplanned Extubations Prevention Bundle 1.0

Table of Contents

I. Background & Team..................................................................................................................2
II. UE Pioneer Cohort Data Analysis 1.0 Summary.....................................................................4
III. Prevention Bundle Elements – Evidence Reviewed..............................................................5
IV. Measurement- Prevention Bundle Reliability ......................................................................7
V. References ..........................................................................................................................7
VI. Revision History .................................................................................................................8
I. Background & Team

A pediatric unplanned extubation (UE) is the inadvertent dislodgement of an endotracheal tube in a pediatric patient setting. Historically, many providers have considered unplanned extubations an expected consequence of care delivery in children’s hospitals because of various difficult challenges, including sedation of a child, length of the neonatal/pediatric airway and inability to predict extubation readiness.

Multiple single-center studies have shown that quality improvement initiatives can reduce unplanned extubations. Summarized below are three studies that highlight quality improvement efforts that reduced unplanned extubation rates and showed that certain aspects of care, such as sedation practices, may impact unplanned extubation rates:

- “Unplanned extubation in a paediatric intensive care unit: impact of a quality improvement programme” (2008) – A five year quality improvement effort reduced unplanned extubations from 2.9/100 ventilator days to 0.6/100 ventilator days in the last year of the study[4].
- “An interdisciplinary initiative to reduce unplanned extubations in pediatric critical care units.” (2012) – Coordinated inter-disciplinary efforts to standardize taping, sedation, hand-offs and review of unplanned extubations leads to reduction in events over time in pediatric and cardiac intensive care units [5].
- “Decreasing unplanned extubations: utilization of the Penn State Children’s Hospital Sedation Algorithm.” (2004) – Following the implementation of a standardized sedation algorithm and without altering any additional care delivery models or practice, unplanned extubations were reduced without increasing length of stay [6].

To further quantify prevention methods, the SPS UE Pioneer Cohort was launched in January, 2016. They have since achieved significant improvement and identified prevention bundle elements using data and analysis obtained from the UE Pioneer Cohort. The UE Pioneer Cohort has identified the initial bundle elements that are highly likely to result in decreased harm to hospitalized children when reliably implemented. The mechanism to spread this new knowledge is through the use of this bundle at individual SPS hospitals.

Unplanned Extubations Co-Leaders and Subject Matter Experts
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Kristin Melton, Cincinnati Children’s

UE Subject Matter Experts
Anthony Lee, Nationwide Children’s Hospital
Vicki Montgomery, Norton Children’s Hospital
Mary Nock, UH/Rainbow Babies & Children’s Hospital
Christina Sperling, The Hospital for Sick Children

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Akron Children’s Hospital
Arkansas Children’s Hospital
Baystate Children’s Hospital
Boston Children’s Hospital
Children’s Health Children’s Medical Center Dallas
Children’s Healthcare of Atlanta
Hasbro Children’s Hospital at Rhode Island
Hassenfeld Children’s Hospital at NYU Langone
Helen DeVos Children’s Hospital
Kravis Children’s Hospital at Mount Sinai
Lehigh Valley Children’s Hospital
Mary Bridge Children’s Hospital and Health Network
Memorial Health, an affiliate of University of Colorado Health

Email: OCHSPS@echmc.org
Children's Hospital and Medical Center (Omaha)
Children's Hospital at Dartmouth Hitchcock
Children's Hospital New Orleans
Children's Hospital of Michigan
Children's Hospital of Pittsburgh of UPMC
Children's Hospital of the King's Daughters
Children's Hospital of Wisconsin
Children's Hospital Orange County
Children's Mercy Hospital and Clinics
Children’s National Medical Center
Cincinnati Children’s
Cleveland Clinic Children’s
Cohen Children’s Medical Center of New York
Connecticut Children’s Medical Center
Cook Children’s Medical Center
Covenant Children’s
CS Mott Children’s Hospital
Dayton Children’s
East Tennessee Children’s Hospital
Florida Hospital for Children

Monroe Carell Jr. Children’s Hospital at Vanderbilt
MUSC Children’s Hospital
Nationwide Children’s Hospital
Norton Children’s Hospital
Palmetto Health Children’s Hospital
Penn State Hershey Children’s Hospital
Phoenix Children’s Hospital
Riley Hospital for Children at Indiana University Health
SSM Health Cardinal Glennon Children’s Hospital
St. Jude Children’s Research Hospital
Texas Children’s Hospital
The Hospital for Sick Children
UCSF Benioff Children’s Hospital Oakland
UF Health Shands Children’s Hospital
UH/Rainbow Babies & Children’s Hospital
UW Health American Family Children’s Hospital
Winthrop Children’s Hospital
Wolfson Children’s Hospital
Yale-New Haven Children’s Hospital

SPS Staff
Aaron Dawson, Sr. Quality Improvement Consultant
Gowri Madhavan, Sr. Data Analyst
Shamon Gharst, Project Specialist
Michelle Vonderhaar, Project Coordinator
II. UE Pioneer Cohort Data Analysis 1.0 Summary

**UE Pioneer Cohort Results**
The UE Pioneer Cohort consisted of 53 network hospitals that tested various factors in an attempt to identify those most closely related to an UE rate reduction. Since the cohort began, the UE Pioneer Cohort had a reduction of 17%.

**Data Collection and Preparation**
The testing requires reliable house-wide implementation of factors and relating those factors to a change in outcomes. For our purposes, a ‘factor’ is a measured change to your hospital’s system. The theory is that if the factor is effective, increasing the reliability of the factor will improve the outcomes measure.

- Each participating hospital has a start month in the cohort and time series for their baseline and post baseline. The total time for this period was 19 months.
- The baseline period was defined as March 2016 to October 2016
- The post baseline period was defined as November 2016 to September 2017
- Criteria to be included in the data required a hospital to have submitted outcomes data for at least 80% of the time in the baseline period (6 months or more). Once that was taken into account, there were 43 left from the cohort to be included in the data.

**Factor Analysis**
Analysis was completed using the ANCOVA model to statistically control for the initial rate of each group, and a p-value was determined. ANCOVA combines the feature of both regression and analysis of variance. ANCOVA is a generalized linear model that evaluates if the means of a DV (post baseline) are equal across levels of a categorical variable IV (buckets), while statistically controlling for the effects of other continuous variables know as a co-variate (baseline). This analysis placed hospitals into four groups: Reliable at baseline, Implementing and Measuring, Implementing but Not Reliable, and Not Implementing.

**Level of SPS Evidence Scenario Key:**

- **Scenario 1:** Hospitals that reliably implement an element show improvement
- **Scenario 2:** Hospitals that do not implement an element fail to improve when the system improves
- **Scenario 3:** When all hospitals implement an element, hospitals that implement an element without measuring reliability fail to improve when the system improves
- **Scenario 4:** Hospitals that reliably implement an element do not show improvement; however, relevant research literature supports adoption
- **Scenario 5:** Implementing an element is associated with improvement; however, the impact of reliability cannot be determined due to data or design factors
**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

**III. Prevention Bundle Elements – Evidence Reviewed**

SPS stratified bundle elements based on their level of evidence to assist hospitals in prioritizing their efforts at designing and implementing evidence-based bundles for Unplanned Extubations and the other 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.**

<table>
<thead>
<tr>
<th>Prevention Bundle Element</th>
<th>Description</th>
<th>Level of Evidence SPS Pioneer Analysis</th>
<th>Level of Evidence: Medical Literature, CDC **</th>
<th>Evidence Cited</th>
</tr>
</thead>
</table>
| Standardized anatomic reference points and securement methods | Two licensed clinicians are present for securing, repositioning, and/or manipulating endotracheal tubes  
Hospitals will select one of the following as an anatomic landmark: gums, teeth, or nare. When unable, use lips (reference NRP guidelines)  
Each unit selects one standard securement method (or one house-wide standard securement method) | Scenario 1 | | 1, 5 |
<table>
<thead>
<tr>
<th>Prevention Bundle Element</th>
<th>Description</th>
<th>Level of Evidence SPS Pioneer Analysis</th>
<th>Level of Evidence: Medical Literature, CDC **</th>
<th>Evidence Cited</th>
</tr>
</thead>
</table>
| Protocol for high risk situations | **High Risk Situations include at least:**  
- Repositioning with 2 licensed clinicians (having 1 dedicated to hold the tube during movement and repositioning)  
- Repositioning for the following (**use local ACA data to append list**):  
  a. Bedside imaging procedures  
  b. Bedside invasive procedures  
  c. Kangaroo care/parent holding  
  d. Routine repositioning  
  e. Switching beds  
  f. Early mobility | Scenario 1 | | 4, 7 |

### Recommended Elements

| Multidisciplinary Apparent Cause Analysis | A multidisciplinary ACA event form should be completed for each event on the current shift by all clinical witnesses  
ACA should be used to pareto institutional-specific causes of UE to identify areas for improvement | Scenario 5 | | |
IV. Measurement- Prevention Bundle Reliability

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Formula</th>
<th>Number of observations</th>
<th>Reporting Period</th>
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<td>Standardized anatomic reference points and securement methods</td>
<td>Number of audits totally compliant with SPS Prevention Bundle Elements/Number of audits completed x 100</td>
<td>• Minimum of 20 house-wide audits per month.</td>
<td>Monthly</td>
</tr>
<tr>
<td>Protocol for high risk situations</td>
<td>Number of audits totally compliant with SPS Prevention Bundle Elements/Number of audits completed x 100</td>
<td>• Minimum of 20 house-wide audits per month.</td>
<td>Monthly</td>
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V. References


VI. Revision History

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<th>Description of Version</th>
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<td>Version 1</td>
<td>Klugman D., Maynord P., Melton, K.</td>
<td>Bundle 1.0</td>
<td>03/07/18</td>
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</table>

Thank you to the following UE Co-Leaders and Subject Matter Experts who contributed to this document: Kathy Deakins, UH/Rainbow Babies & Children’s Hospital, Darren Klugman, Children’s National Medical Center, Anthony Lee, Nationwide Children’s Hospital, Patrick O’Neal Maynord, Monroe Carell Jr. Children’s Hospital at Vanderbilt, Kristin Melton, Cincinnati Children’s, Vicki Montgomery, Norton Children’s Hospital, Mary Nock, UH/Rainbow Babies & Children’s Hospital, and Christina Sperling, The Hospital for Sick Children
# SPS PREVENTION BUNDLE

Ventilator-Associated Pneumonia (VAP)

## Table of Contents

I. Background & Team

II. Prevention Bundle Elements - Overview

III. Prevention Bundle Elements – Evidence Reviewed

IV. Prevention Bundle Elements – Recommended Approaches

V. Measurement- Prevention Bundle Reliability

VI. Spotlight Tools

VII. Spotlight Hospitals

VIII. References

IX. Revision History
I. Background & Team

VAP (Ventilator-Associated Pneumonia) is the 7th largest contributor to harm caused across the SPS network. In 2011, approximately 16 children were harmed each month as a result of VAP across the Phase I SPS hospitals (n=33). The VAP team formed in May of 2012 to develop strategies consistent with high reliability concepts to reduce harm caused by VAP, and released the first recommended bundle to the network. In 2013, Phase II hospitals (n=55) joined the network and the number of children harmed per month increased to 25, using their 2012 baseline data.

The network strategy has been successful with a 48% VAP rate reduction across the network as of July 2014. Using data obtained from the SPS network as well as external evidence in the medical literature, the VAP team has identified those bundle elements within the first recommended VAP bundle 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 VAP and the other 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**.

Subject Matter Expert
Grace Lee, Boston Children's Hospital

SPS Staff
Laurie Mustin, Senior Quality Outcomes Manager
Erin Goodman, Project Specialist
Carrie Hughes, Project Coordinator
Gowri Madhavan, Data Analyst
II. Prevention Bundle Elements - Overview

SPS Standard Elements
- Not applicable

SPS Recommended Elements
- Readiness to Extubate
- Head of Bed Elevation
- Minimize Disruption of the Circuit
- Oral Hygiene
III. Prevention Bundle Elements – Evidence Reviewed

<table>
<thead>
<tr>
<th>Bundle Element</th>
<th>SHEA (2014) – Grading of the Quality of Evidence</th>
<th>Evidence Cited (Numbers refer to Reference Section)</th>
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<tbody>
<tr>
<td>Readiness to Extubate - Assess readiness to extubate daily* *Performed minimally once per day</td>
<td>Grade II - Pediatric Grade III - Neonates</td>
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<tr>
<td>Head of Bed Elevation - Elevate head of bed to 30–45 degrees (non-neonates)* *Performed minimally once per day</td>
<td>Grade III - Pediatric Grade III - Neonates</td>
<td>1, 2, 8</td>
</tr>
<tr>
<td>Minimize Disruption of the Circuit – Inspect ventilator circuit for gross contamination daily, and if present change circuit.* *Performed minimally once per day</td>
<td>Grade II - Pediatric Grade III – Neonates Grade 1 - Adults</td>
<td>1, 2, 6, 7</td>
</tr>
<tr>
<td>Oral Hygiene -Perform oral hygiene minimally every 12 hours*</td>
<td>Grade III–Pediatrics No Grade Available – Neonates</td>
<td>1, 2, 5</td>
</tr>
</tbody>
</table>

SHEA (2014) – Grading of the Quality of Evidence

- **I. High** - Highly confident that the true effect lies close to that of the estimated size and direction of the effect. Evidence is rated as high quality when there is a wide range of studies with no major limitations, there is little variation between studies, and the summary estimate has a narrow confidence interval.
- **II. Moderate** - The true effect is likely to be close to the estimated size and direction of the effect, but there is a possibility that it is substantially different. Evidence is rated as moderate quality when there are only a few studies and some have limitations but not major flaws, there is some variation between studies, or the confidence interval of the summary estimate is wide.
- **III. Low** - The true effect may be substantially different from the estimated size and direction of the effect. Evidence is rated as low quality when supporting studies have major flaws, there is important variation between studies, the confidence interval of the summary estimate is very wide, or there are no rigorous studies, only expert consensus.
### IV. Prevention Bundle Elements – Recommended Approaches

<table>
<thead>
<tr>
<th>Prevention Bundle Element</th>
<th>Recommended Approaches</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>Recommended Elements</strong></th>
<th><strong>Recommended Approaches</strong></th>
</tr>
</thead>
</table>
| **Readiness to Extubate** - Assess readiness to extubate daily * | • Ongoing assessment of readiness to extubate with minimum documentation at least every 24 hours.  
• Every day the care team should actively discuss whether the patient still needs to be intubated and what steps are necessary to move towards extubation. |
| **Head of Bed Elevation** - Elevate head of bed to 30-45 degrees (non-neonates)* | • Keep the head of the bed elevated to 30-45 degrees for all ventilated patients beyond infancy.  
• Consider the use of a visual measuring device (e.g. protractor painted on bedside) to ensure the angle is correct. |
| **Minimize Disruption of the Circuit** – Inspect ventilator circuit for gross contamination daily, and if present change circuit.* | • Perform inspection of circuit at least every 8 hours for condensation and/or gross contamination. Drain condensation. Only change circuit for gross contamination.  
• Visually inspect ventilator for condensation or contamination.  
• Change ventilator circuit when visibly soiled.  
• Drain ventilator circuit if fluid has accumulated.  
• Avoid changing of the ventilator circuit on a routine basis. |
| **Oral Hygiene** - Perform oral hygiene minimally every 12 hours* | • Brushing teeth and gums with a soft bristle toothbrush and product for plaque removal, or use a gauze and sterile water for patients without teeth.  
• Consider Perform oral care (moistening mouth and lips, removal of oropharyngeal secretions) before repositioning patient. |
## V. Measurement- Prevention Bundle Reliability

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Formula</th>
<th>Recommendations</th>
<th>Reporting Period</th>
</tr>
</thead>
</table>
| Reliability of VAP Bundle    | Number of audits totally compliant with bundle / 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. See Reference 8 for IHI description of All on None.  
• Minimum of 20 audits per month. If procedures are fewer than 20, then include all procedures. | Monthly          |

## VI. Spotlight 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.

## VII. Spotlight Hospitals

Please click [here](#) to view the Sharing Hospitals’ Innovation for Network Engagement (SHINE) report.

## VIII. References

1. SHEA (2014) - Strategies to Prevent Ventilator-Associated Pneumonia in Acute Care Hospitals: 2014 Update. Michael Klompas, MD, MPH; Richard Branson, MSc, RRT; Eric C. Eichenwald, MD; Linda R. Greene, RN, MPS, CIC; Michael D. Howell, MD, MPH; Shelley S. Magill, MD, PhD; Lisa L. Maragakis, MD, MPH; Gregory P. Priebe, MD; Kathleen Speck, MPH; Deborah S. Yokoe, MD, MPH; Sean M. Berenholtz, MD, MHS
6. Long MN et al. Prospective, randomized study of ventilator-associated pneumonia in patients with one versus three ventilator circuit changes per week. Infect Control Hosp Epi (1996);17:14--19

IX. Revision History

<table>
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</tr>
<tr>
<td>Version 3</td>
<td>Erin Goodman &amp; Sharyl Wooton (on behalf of the HAC Co-Leader Team)</td>
<td>Format &amp; Release of the new SPS Prevention Bundle content</td>
<td>12 – 12 - 2014</td>
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<tr>
<td>Version 4</td>
<td>SPS Staff</td>
<td>Contact information updated</td>
<td>4-5-17</td>
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Thank you to the following VAP Co-Leaders and Subject Matter Experts who contributed to this document:
Nina Rauscher, Boston Children’s Hospital; Ethan Leonard, UH/Rainbow Babies & Children’s Hospital; Grace Lee, Boston Children’s Hospital
SPS PREVENTION BUNDLE

Venous Thromboembolism (VTE), Non-CVC Bundle

Table of Contents

I. Background & Team
II. Bundle Elements – Overview
III. Bundle Elements – Evidence
IV. VTE Detection
V. Measurement – Bundle Reliability
VI. References
VII. Revision History
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 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.

VTE Quality Improvement Co-Leaders
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Char Witmer, The Children’s Hospital of Philadelphia

VTE Research Co-Leaders
Brian Branchford, Children’s Hospital Colorado
Julie Jaffray, Children’s Hospital Los Angeles

VTE Subject Matter Experts
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
  o BMI > 95th percentile in patients < 18 years of age
  o BMI >30 in patients > 18 years of age
• Burns:
  o Increased VTE risk has been associated with total body surface area burns >50-65% in adults.
• Severe Dehydration
• Protein-losing disorder
  o 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**

<table>
<thead>
<tr>
<th>Mobility Status</th>
<th>Low Risk</th>
<th>At risk</th>
<th>High Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>Baseline</td>
<td>Altered</td>
<td>Altered</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>Number of VTE Risk Factors</th>
<th>0</th>
<th>1 or more</th>
<th>0-1</th>
<th>2 or more</th>
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</table>

**Interventions: with no contraindications present**

<table>
<thead>
<tr>
<th>Mobility Status</th>
<th>Low Risk</th>
<th>At risk</th>
<th>High Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Encourage highest degree of mobility</td>
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<td>Yes</td>
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<tr>
<td>SCD</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Anticoagulation</td>
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<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**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
  o **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 anesthelia
  - 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**
<table>
<thead>
<tr>
<th>Screening Bundle Element</th>
<th>Level of Evidence CDC*SPS**</th>
<th>Evidence Cited (Numbers refer to Reference Section)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Standard Elements</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screen for VTE Risk</td>
<td>CDC Modified: IB</td>
<td>[2, 3]</td>
</tr>
<tr>
<td><strong>Elements for Screening</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mobility status</td>
<td>CDC Modified: IB</td>
<td>[4, 5]</td>
</tr>
<tr>
<td>Personal history of thrombosis</td>
<td>CDC Modified: IB</td>
<td>[6, 7]</td>
</tr>
<tr>
<td>Thrombophilia</td>
<td>CDC Modified: IB</td>
<td>[8-10]</td>
</tr>
<tr>
<td>Critically ill (in the intensive care unit)</td>
<td>CDC Modified: IB</td>
<td>[5, 6, 11]</td>
</tr>
<tr>
<td>Active cancer/malignancy</td>
<td>CDC Modified: IB</td>
<td>[6, 8, 12-19]</td>
</tr>
<tr>
<td>Recent surgery within the past 30 days.</td>
<td>CDC Modified: IB</td>
<td>[8, 17, 20, 21]</td>
</tr>
<tr>
<td>Estrogen therapy</td>
<td>CDC Modified: IB</td>
<td>[4, 22]</td>
</tr>
<tr>
<td><strong>Recommended Elements</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute systemic inflammation/infection</td>
<td>CDC Modified: IB</td>
<td>[4, 6, 8, 11-13, 23]</td>
</tr>
<tr>
<td>Major trauma</td>
<td>CDC Modified: IB</td>
<td>[7, 8, 17, 24, 25]</td>
</tr>
<tr>
<td>Obesity</td>
<td>CDC Modified: IB</td>
<td>[22, 26-28]</td>
</tr>
<tr>
<td>Burns (&gt;50-65% total body surface area)</td>
<td>CDC Modified: II</td>
<td>[29, 30]</td>
</tr>
<tr>
<td>Severe dehydration</td>
<td>CDC Modified: II</td>
<td></td>
</tr>
<tr>
<td>Protein-losing disorder</td>
<td>CDC Modified: IB</td>
<td>[14, 17, 31]</td>
</tr>
<tr>
<td>Cyanotic heart disease or low-flow states</td>
<td>CDC Modified: IB</td>
<td>[14, 21]</td>
</tr>
<tr>
<td>Family history of VTE in a 1st degree relative</td>
<td>CDC Modified: IB</td>
<td>[14]</td>
</tr>
<tr>
<td>Prevention Bundle Element</td>
<td>Level of Evidence CDC*/SPS**</td>
<td>Evidence Cited (Numbers refer to Reference Section)</td>
</tr>
<tr>
<td>------------------------------------------------------------------------------------------</td>
<td>------------------------------</td>
<td>---------------------------------------------------</td>
</tr>
<tr>
<td><strong>Standard Elements</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Encourage highest degree of ambulation/mobility for patients (≥3 times a day)</td>
<td>CDC Modified: IB</td>
<td>[4, 5]</td>
</tr>
<tr>
<td>If altered mobility use sequential compression devices while in bed unless contraindicated.</td>
<td>CDC Modified: IB</td>
<td>[32-43]</td>
</tr>
<tr>
<td>Use sequential devices prior to the induction of anesthesia and the duration of the surgical procedure is anticipated to last &gt;1 hour.</td>
<td>CDC Modified: IB</td>
<td>[44-49]</td>
</tr>
<tr>
<td><strong>Recommended Elements</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td>CDC Modified II</td>
<td>[1, 41, 50]</td>
</tr>
</tbody>
</table>

*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

<table>
<thead>
<tr>
<th>Method</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy Records</td>
<td>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.</td>
</tr>
<tr>
<td>ICD-10 Codes</td>
<td>Highly insensitive and not time sensitive. Should not be used in isolation.</td>
</tr>
<tr>
<td>Hem/Onc Consult</td>
<td>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.</td>
</tr>
<tr>
<td>EMR Trigger</td>
<td>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.</td>
</tr>
<tr>
<td>Radiological Records</td>
<td>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.</td>
</tr>
</tbody>
</table>
V. Measurement – Bundle Reliability

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Formula</th>
<th>Standards</th>
<th>Reporting Period</th>
</tr>
</thead>
</table>
| 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          |
VI. References


VII. Revision History

<table>
<thead>
<tr>
<th>I. Version</th>
<th>Primary Author(s)</th>
<th>Description of Version</th>
<th>Date Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>V1.0</td>
<td>Katie Hilbert</td>
<td>Initial Draft</td>
<td>9 Nov 2012</td>
</tr>
<tr>
<td>V2.0</td>
<td>Jason Bailey</td>
<td>Addition of section III, IV &amp; V</td>
<td>4 Feb 2013</td>
</tr>
<tr>
<td>V3.0</td>
<td>VTE Leaders &amp; SMEs</td>
<td>Revised entire document to match SPS VTE rework</td>
<td>24 Oct 2016</td>
</tr>
</tbody>
</table>
Thank you to the following VTE Co-Leaders and Subject Matter Experts who contributed to this document: Lisa Battista, Cincinnati Children’s; Brian Branchford, Children’s Hospital Colorado; Daniela Davis, The Children’s Hospital of Philadelphia; Darcy Doellman, Cincinnati Children’s; Neil Goldenberg, All Children’s Hospital; Sheila Hanson, Children’s Hospital of Wisconsin; Julie Jaffray, Children’s Hospital Los Angeles; Leslie Raffini, The Children’s Hospital of Philadelphia; Char Witmer, The Children’s Hospital of Philadelphia; Chadi Zeinati, Children’s Hospital Los Angeles