SPS PREVENTION BUNDLES

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

- Catheter-Associated Urinary Tract Infections (CAUTI)
- Central Line-Associated Blood Stream Infections (CLABSI)
- Falls
- Peripheral IV Infiltrations and Extravasations (PIVIE)
- Pressure Injuries
- Readmissions
- Surgical Site Infections
- Unplanned Extubations
- Ventilator-Associated Pneumonia (VAP)
- Venous Thromboembolism
SPS PREVENTION BUNDLE
Catheter – Associated Urinary Tract Infections (CAUTI)

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**
OCHSPS@cchmc.org

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><strong>Standard Elements</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Use aseptic technique for insertion</td>
<td>*IB/**Scenario 4</td>
<td>2, 3, 4</td>
</tr>
<tr>
<td>Avoid unnecessary catheterization</td>
<td>*IB/**Scenario 4</td>
<td>2, 3, 4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prevention Bundle Element - Maintenance</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>Prevention Bundle Element - Maintenance</td>
<td>Level of Evidence SPS**</td>
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</tr>
<tr>
<td>----------------------------------------</td>
<td>-------------------------</td>
<td>---------------------------------------------------</td>
</tr>
<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>
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<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>
</tbody>
</table>

**Recommended Elements**

| Secure catheter                      | *IB/N/A                | 2, 3, 4                                           |

**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>
<tr>
<td>Use Aseptic Technique for Insertion</td>
<td>• Perform hand hygiene immediately before and after insertion or any manipulation of the catheter device or site [CDC Reference]</td>
</tr>
<tr>
<td></td>
<td>• 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]</td>
</tr>
<tr>
<td>Avoid unnecessary catheterization</td>
<td>• Consider having written clinical indications [CDC Reference]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prevention Bundle Element - Maintenance</th>
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</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>
<tr>
<td>Remove catheter when no longer needed</td>
<td>• Review necessity daily</td>
</tr>
<tr>
<td></td>
<td>• Document indication daily</td>
</tr>
<tr>
<td><strong>Recommended Elements</strong></td>
<td></td>
</tr>
<tr>
<td>Secure catheter</td>
<td></td>
</tr>
</tbody>
</table>

### V. Measurement – Prevention Bundle Reliability
### 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.

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### Measurement

<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* x 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 |

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### 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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<tr>
<td>Version 1</td>
<td>Sharyl Wooton &amp; Rachel Bowes</td>
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<td>Version 3</td>
<td>SPS Staff</td>
<td>Contact information updated</td>
<td>April 5, 2017</td>
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<td>Version 4</td>
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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 Schlafli, 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. References
VIII. 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. As we move into 2019, we have 135+ hospitals aimed at reducing harm to hospitalized children as a result of CLABSI. Using data obtained from the SPS network as well as external evidence in the medical literature, the CLABSI team has identified 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 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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Elizabeth Mack, MUSC Children’s Hospital
Eugenia Pallotto, Children’s Mercy, Kansas City
W. Charles Huskins, Mayo Clinic Children’s Center

**SPS Staff**
Maitreyya Coffey, Associate Clinical Director
OCHSPS@cchmc.org
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
- Daily CHG treatments for all patients > 2 months adjusted age with central venous catheters (SPS strongly recommends the use of 2% CHG wipes)

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

<table>
<thead>
<tr>
<th>Prevention Bundle Element - Insertion</th>
<th>Level of Evidence CDC*/SPS**</th>
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</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>
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<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>
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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>
<td>3,4,5</td>
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<tr>
<td>Daily CHG treatments with 2% wipes</td>
<td>*1A</td>
<td>1,2,6,7,8,9,10,13,15,16</td>
</tr>
</tbody>
</table>

### Recommended Elements

| An in-depth review of all identified CLABSI with multidisciplinary involvement AND the intent to change the process if needed. | N/A/N/A | 5 |

| Daily linen changes                   |                                               |                                              |

**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.
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**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>
<tr>
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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 .05% 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>
</tr>
</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 |
Daily CHG treatments

- CHG treatment performed daily on all patients >2 months adjusted age with central venous catheters
  - Those patients <2 months adjusted age* should be cared for based on institutional protocol.
*Adjusted age is <48 weeks for premature infants or <2 months of age for full-term infants. For example, if a patient is born at 28 weeks, they would receive their first CHG treatment at 20 weeks chronological age (48 weeks adjusted).

Note: SPS CLABSI Leaders have determined that the strongest available evidence suggests that the implementation specifically of 2% CHG wipe treatments are associated with a significant decrease in patient harm. However, there is some evidence supporting equivalent efficacy of other products, and therefore hospitals using other forms of CHG for daily CHG treatments will be considered compliant to this element in the process bundle.

<table>
<thead>
<tr>
<th>Recommended Elements</th>
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<tbody>
<tr>
<td>An in-depth review of all identified CLABSI with multidisciplinary involvement AND the intent to change the process if needed.</td>
</tr>
<tr>
<td>Utilize a systematic approach to review all hospital acquired CLABSI</td>
</tr>
</tbody>
</table>

Daily linen changes

V. Measurement – Prevention Bundle Reliability

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Formula</th>
<th>Standards</th>
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| 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. | Monthly |
VI. Spotlight Tools

We have asked hospitals to share their 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).

VII. References

1. Aaron M Milstone, 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 Daily chlorhexidine bathing to reduce bacteraemia in critically ill children: a multicentre, cluster-randomised, crossover trial http://dx.doi.org/10.1016/S0140-6736(12)61687-0


VIII. Revision History

<table>
<thead>
<tr>
<th>Version</th>
<th>Primary Author(s)</th>
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<tr>
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<td>Sharyl Wooton</td>
<td>Initial Draft</td>
<td>October 2, 2012</td>
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<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>
</tr>
<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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<tr>
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<td>Description of Version</td>
<td>Date Completed</td>
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<tr>
<td>Version 6</td>
<td>CLABSI Co-leaders</td>
<td>Changed CHG bathing from a recommended bundle element to a standard bundle element (added level of evidence and references)</td>
<td>January 11, 2019</td>
</tr>
</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; Michele Saysana, Riley Hospital for Children at Indiana University Health; Jeff Hord, Akron Children’s Hospital; Charlie Huskins, Mayo Clinic Children’s Center; Elizabeth Mack, MUSC Children’s Hospital; and Jean Pallotto, Children’s Mercy Kansas City.
# SPS PREVENTION BUNDLE

## Falls

## Table of Contents

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VII. Spotlight Hospitals  
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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
ochps@cchmc.org
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 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>
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<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><strong>Recommended Elements</strong></td>
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<td></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>
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</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

<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:  
  - At shift change (nurse to nurse)  
  - At time of transfer in care (unit to unit)  
  - 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-skid 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>
</thead>
</table>
| Falls 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 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>
<th>Date Completed</th>
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<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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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 fifth largest contributor to harm across the SPS network. The PI team formed in May 2012 to develop strategies consistent with high reliability concepts to reduce harm caused by PI. Using data obtained from the SPS network as well as external evidence in the medical literature, the PI team identified those bundle elements that when reliably implemented are highly likely to result in decreased harm to hospitalized children, and in 2014 released the first PI prevention bundle to the network. In 2019, subject matter experts convened to revise the bundle, incorporating new evidence, clarifying language, and aligning with external organizations.

SPS stratifies bundle elements based on their level of evidence to assist hospitals in prioritizing their efforts in preventing PI and other 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.

The network strategy has been successful, resulting in a 37% decrease in PI across the network as of August 2018. The network has been challenged to sustain these results, seeing a shift up of 16% in September 2018, for a net reduction of 27% since initiating the work. We estimate that as of early 2020, 438 serious harm PIs have been prevented across the network.

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Cindy Henderson, Children’s Healthcare of Atlanta
Pam Paige, Children’s Healthcare of Atlanta
Brenda Ruth, Nationwide Children’s Hospital
Stephanie Stafford, Nationwide Children’s Hospital

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Sandy Quigley, Boston Children’s
Jennifer Werner, Texas Children’s Hospital

**SPS Staff**
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Nikki Rotundo, Project Coordinator
Patsy Sisson, Data Analyst
Trey Coffey, Associate Clinical Director
II. Prevention Bundle Elements* – Overview

SPS Standard Elements
- Skin Assessment
- Medical Device Rotation/Reposition
- Patient Positioning
- Appropriate Surface
- Moisture Management

SPS Recommended Elements
- Regular frequency of offloading pressure of respiratory device, straps, tubing, etc.
- Padding (non-device)
- Padding under devices
- Assessment for proper fit of respiratory device

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

SPS recommends that hospitals review their PI data and consider applying the prevention bundle to any units/populations/scenarios where PI are occurring, even when patients are not screening as high risk. A particular vulnerability related to screening is that, while SPS data suggests 44% of serious harm PI are device-related, traditional scoring tools may not identify these patients as at-risk. We recommend reviewing recent literature on PI risk identification and consider updating to newer screening tools including Braden QD\textsuperscript{10}.

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>
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</thead>
<tbody>
<tr>
<td><strong>Standard Elements</strong></td>
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<td>Skin Assessment</td>
<td>*Level 2/**Scenario 1</td>
<td>4, 5, 10, 11, 14</td>
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<tr>
<td>Medical Device Rotation/Reposition</td>
<td>*Level 5 /**Scenario 1</td>
<td>2, 5, 13, 14, 17</td>
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<tr>
<td>Patient Positioning</td>
<td>*Level 5/**Scenario 1</td>
<td>5, 12, 13</td>
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<tr>
<td>Appropriate Surface</td>
<td>*Level 1/**Scenario 1</td>
<td>5, 7, 13</td>
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<td>Moisture Management</td>
<td>*Level 5/**Scenario 1</td>
<td>5, 8, 14</td>
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<tr>
<td>Non-device padding</td>
<td>*Level 5/**Scenario 6</td>
<td>13, 18</td>
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<tr>
<td>Assessment for proper fit of respiratory device</td>
<td>*Level 5/**Scenario 5</td>
<td>11, 13, 15</td>
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<tr>
<td>Device padding</td>
<td>*Level 5/**Scenario 6</td>
<td>11, 13, 15, 16, 18</td>
</tr>
<tr>
<td>Regular frequency of offloading pressure of respiratory device, straps, tubing, etc.</td>
<td>*Level 5/**Scenario 6</td>
<td>14, 15, 19</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
- **Scenario 5**: Hospitals that implement element with less than 80% reliability had a higher rate
- **Scenario 6**: SPS subject matter expert opinion
IV. Prevention Bundle Elements† Care Descriptions

†All bundle elements are applied to patients who, score as high risk with a pressure injury risk assessment scale or have clinical “risk factors” for pressure injury development

<table>
<thead>
<tr>
<th>Prevention Bundle Element - Maintenance</th>
<th>Care Descriptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Elements</td>
<td></td>
</tr>
</tbody>
</table>
| Skin Assessment‡                       | • Perform full skin assessment AND PI risk assessment within 24 hours of admission (consensus best practice is within 8 hours)  
• Repeat:  
  • At least every 24 hours (as per NDNQI, consensus best practice is every shift change particularly for high risk units and high-risk patients)  
  • In operating room at end of cases lasting 4 hours or more, and/or upon arrival to post-operative inpatient unit  
  • Change in patient condition e.g. decreased level of consciousness or casting |
| Medical Device Rotation/Reposition      | • Assess skin in contact with medical devices at minimum each shift  
• Medical devices known to cause PI include: Respiratory devices (masks, cannula, securement devices, ETT), immobilizers, orthotics, nasal and enteral feeding tubes, peripheral and central venous access devices and related securement devices, external monitoring devices (EEG leads, pulse oximetry probes), VTE prevention equipment (stockings and compression devices), and miscellaneous equipment unintentionally in contact with patient (cords, tubes)§.  
• Reposition/rotate medical devices per manufacturer recommendations  
• For respiratory devices see recommended element below  
• Rotate pulse -ox probe at least every 8 hours or more often if able  
• C-collars: skin care and assessment daily, remove collar at least twice daily (unless it’s medically contraindicated), change the collar padding if soiled §Defer to manufacturer recommendation when more frequent |

Note: NDNQI supports inspecting skin under or around removable devices at least twice a day
<table>
<thead>
<tr>
<th>Prevention Bundle Element - Maintenance</th>
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</thead>
</table>
| **Patient Positioning**                | ● Reposition or turn immobile patients or those with limited mobility at least every 2 hours (or timed with care in NICU)  
● Maintain HOB less than or equal 30 degrees (unless medically contraindicated)  
● Patients in chairs or upright in bed greater than 2 hours must still be repositioned to redistribute pressure (consider appropriate surface and consider time limit)  

Note: "Do Not Turn" instructions should require a provider order and be re-evaluated every 24 hours. |
| **Appropriate Surface**                | ● Utilize the support surface that meets the individual’s needs for pressure redistribution  
● Evaluate need for specialty surface based on PI Risk Assessment.  
● Use gel pads, fluidized positioners, and/or other pressure redistribution positioning aids to cushion bony prominences. |
| **Moisture Management**               | ● Keep all skin clean, dry and appropriately hydrated (including perineum, skin near devices such as tracheostomies, tubes, drains and casts).  
● Apply moisture barrier and/or wicking product to keep skin dry |

## Recommended Elements

- **Non-device padding**  
  ● Consider use on bony prominences: assess the skin under the prophylactic dressing **at least daily**

- **Assessment for proper fit of respiratory device**  
  Assessment for proper fit of respiratory device (Preferred every 4 hours; minimum every 6 hours):  
  ● CPAP/BIPAP (assessment of proper fit per your institutional practice)  
  ● Tracheostomy (assessment that trach ties/collar is not too tight by being able to fit one finger between neck and ties/collar)  
  ● Endotracheal tube (ETT) (assessment that the tension from ventilator circuit to the ETT is minimized); best practice with every position change  
  ● Nasal cannula (assessment that the tubing is not too tight where in contact with the skin)

- **Device padding**  
  ● Use prophylactic padding to protect skin under medical devices to reduce pressure injuries, follow manufacturer instructions for use if available (NPIAP), unless contraindicated
Prevention Bundle Element - Maintenance

| Regular frequency of offloading pressure of respiratory device, straps, tubing, etc. | Regular frequency of offloading pressure of respiratory device, straps, tubing, etc. (Preferred every 4 hours; minimum every 6 hours):
|---|---|
| Recommend capturing compliance thru observation or discussion with staff (can capture alternating of CPAP/BiPAP mask through documentation if hospitals have that available) | • CPAP/BiPAP mask (alternate between 2 different types of mask if possible, to redistribute pressure - if not possible, ensure that mask is clean and dry)
| | • Tracheostomy (reposition head/neck as needed to minimize pressure)
| | • Endotracheal tube (secure without creating additional pressure)
| | • Off load pressure of ventilatory circuit, tubing and connections
| | • Nasal cannulas can be excluded from this element – please refer to Assessment for proper fit of respiratory device element.

*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>
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| 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


IX. Revision History

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<th>Primary Author(s)</th>
<th>Description of Version</th>
<th>Date Completed</th>
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<td>Version 1</td>
<td>SPS Staff</td>
<td>Initial Draft</td>
<td>Nov 9, 2012</td>
</tr>
<tr>
<td>Version 3</td>
<td>HAC Co-Leader Team</td>
<td>Release of new SPS Prevention Bundle content</td>
<td>June 10, 2014</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>
</tr>
<tr>
<td>Version 6</td>
<td>PI Co-Leaders and SMEs</td>
<td>Major revision: Language throughout; clarified all “Standard” elements particularly medical device rotation/reposition; added all four “Recommended” elements focused on padding and respiratory devices</td>
<td>March 2020</td>
</tr>
</tbody>
</table>

June 2014: 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

March 2020: Thank you to the following PI Co-Leaders, Subject Matter Experts, and Taskforce Experts who contributed to revising this document:
Trish Burdett, Children’s Healthcare of Atlanta; Gary Frank, Children’s Healthcare of Atlanta; Ginny Fowler, Advocate Children’s; Cindy Henderson, Children’s Healthcare of Atlanta; Denise Lauderbaugh, Rady Children’s Hospital – San Diego; Pam Paige, Children’s Healthcare of Atlanta; Michelle Miller, Nationwide Children’s Hospital; Shelly Morning, Cincinnati Children’s; Sandy Quigley, Boston Children’s; Brenda Ruth, Nationwide Children’s Hospital; Stephanie Stafford, Nationwide Children’s Hospital; Jennifer Werner, Texas Children’s Hospital
# Peripheral IV Infiltrations and Extravasations (PIVIE) Prevention Bundle 1.0

## Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. Background &amp; Team</td>
<td>2</td>
</tr>
<tr>
<td>II. Prevention Bundle Elements - Overview</td>
<td>3</td>
</tr>
<tr>
<td>III. Prevention Bundle Elements – Evidence Reviewed</td>
<td>3</td>
</tr>
<tr>
<td>IV. Prevention Bundle Elements Descriptions</td>
<td>5</td>
</tr>
<tr>
<td>V. Measurement – Outcome Data</td>
<td>5</td>
</tr>
<tr>
<td>VI. Measurement – Prevention Bundle Reliability</td>
<td>6</td>
</tr>
<tr>
<td>VII. References</td>
<td>7</td>
</tr>
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<td>VIII. Revision History</td>
<td>7</td>
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</table>
I. Background & Team

Intravenous catheter placement and management is commonly regarded as a routine clinical practice. Approximately 74% of hospitalized pediatric patients have vascular access catheters inserted either peripherally or centrally. However, potential complications from a peripheral IV infiltrate range from trivial irritation and discomfort to serious harm, such as permanent skin and soft tissue loss, impaired limb function, compartment syndrome, distal vascular compromise, and even loss of fingers or other parts of a limb.

In 2015, a cohort of 27 hospitals came together to test various factors thought likely to reduce incidents of peripheral IV infiltrations and extravasations. The original cohort hospitals each chose 1-2 factors out of a list of 19 to test. In early 2017, a statistical analysis was conducted to determine which factors were correlated to improved outcomes, but it was determined that the factors were too loosely defined which made the analysis inconclusive. In late 2017, after identifying and interviewing eight hospitals achieving good results, the factors were consolidated from 19 to 5 and very clearly defined for consistency in implementation across the cohort hospitals. After re-establishing baselines beginning in 2018, the cohort, then consisting of 33 hospitals, began testing the five new factors.

In early 2019, the cohort had a 17.5% reduction in the centerline of serious PIVIE rate. A second analysis was conducted to identify the combination of interventions statistically correlated with the reduction of PIVIEs. Multiple analytical methods were utilized, including ANCOVA, response plots, LS Means, and Tukey-Kramer. For analysis purposes, hospitals were divided into three groups based on level of reliability to factor adherence, and each factor along with combinations of factors were compared based on PIVIE rates for hospitals in each group.

As a result of this evidence, three out of five factors were adopted as standard bundle elements that are highly likely to result in decreased harm to hospitalized children when reliably implemented:

- Assess PIV every 60 minutes using Touch/Look/Compare (TLC) or Assess/Compare/Touch (ACT)
- Notify hospital-acquired condition (HAC) champion / Unit leader / Vascular Access Team (VAT) member and provider for ongoing injury assessment and adequate treatment
- Use standardized percentage measurement-based assessment tool

Of the above factors, assessing the PIV every 60 minutes was linked to statistically significant rate reduction. The other two had statistical support when used in combination with the practice of assessing the PIV. A fourth factor, “Educating patients/families on Touch/Look/Compare or Assess/Compare/Touch,” was not statistically significant and was thus not included as a standard element. However, this factor has strong support from clinical experts and is therefore included as a recommended bundle element. The fifth factor did not show statistical significance or have strong enough support to include in this bundle.

Section IV of this document lists the standard and recommended bundle elements along with descriptions of each.

Originally, PIVIEs were separated into three categories based on level of harm. However, based on the experience of the participating cohort hospitals, the PIVIE leadership team recommended the consolidation of the three PIVIE categories to two, Moderate and Serious, and reclassified some of the swelling definitions to better match the definition of serious harm across other hospital acquired condition (HAC) workstreams within SPS. Because of these changes, all baselines will be re-established, even for the cohort hospitals.
PIVIE Leadership Team
Jillian Rojas, Ann & Robert H. Lurie Children’s Hospital of Chicago (Co-Leader)
Vicki Jones, Monroe Carell Jr. Children’s Hospital at Vanderbilt (Subject Matter Expert)
Sara Gravelle, Wolfson Children’s Hospital (Subject Matter Expert)
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Melissa Chambers, Children’s Health Children’s Medical Center Dallas (former Subject Matter Expert)
Dort Foglia, Children’s Health Children’s Medical Center Dallas (former Co-Leader)
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Neil D. Johnson, Cincinnati Children’s Hospital (former Subject Matter Expert)
Sylvia Rineair, Cincinnati Children’s Hospital (former Subject Matter Expert)

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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
Children’s Hospital Colorado
Children’s Hospital of Philadelphia
Children’s Hospital of Wisconsin
Children’s National Medical Center
Cohen Children’s Medical Center of New York
Cook Children's Medical Center
Dayton Children’s
Dell Children’s Medical Center of Central Texas
Gillette Children’s Specialty Healthcare
Hasbro Children’s Hospital at Rhode Island
Intermountain Primary Children’s Hospital
Le Bonheur Children’s Hospital
Lehigh Valley Children’s Hospital
Miller Children’s & Women's Hospital Long Beach
Monroe Carell Jr. Children’s Hospital at Vanderbilt
MUSC Children’s Hospital
Prisma Health Children’s Hospital
Penn State Hershey Children’s Hospital
Phoenix Children’s Hospital
ProMedica Toledo Children’s Hospital
Riley Hospital for Children at Indiana University Health
Seattle Children’s
Texas Children’s Hospital
Valley Children’s Hospital
Wolfson Children’s Hospital

II. Prevention Bundle Elements - Overview

SPS Standard Element
- Assess PIV every 60 minutes using Touch/Look/Compare (TLC) or Assess/Compare/Touch (ACT)

SPS Recommended Elements
- Educate patient and families on Touch / Look / Compare or Assess / Compare / Touch once per day
- Notify HAC champion / Unit leader / Vascular Access Team (VAT) member and provider for ongoing injury assessment and adequate treatment
- Use standardized percentage measurement-based assessment tool

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 PIVIEs and the other aviator HACs:

- **Standard Element:** Strong evidence suggests that implementation of this element is associated with significant decrease in serious 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>Standard Bundle Element</th>
<th>Level of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assess PIV every 60 minutes using Touch/Look/Compare (TLC) or Assess/Compare/Touch (ACT)</td>
<td>Scenario 1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Recommended Bundle Element</th>
<th>Level of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Educate patient and families on Touch / Look / Compare or Assess / Compare / Touch once per day</td>
<td>Scenario 5</td>
</tr>
<tr>
<td>Notify HAC champion / Unit leader / Vascular Access Team (VAT) member and provider for ongoing injury assessment and adequate treatment</td>
<td>Scenario 5 When combined with assessing PIV element, this recommended element bundle evidence demonstrated statistically significant improvement</td>
</tr>
<tr>
<td>Use standardized percentage measurement-based assessment tool</td>
<td>Scenario 5 When combined with assessing PIV element, this recommended element bundle evidence demonstrated statistically significant improvement</td>
</tr>
</tbody>
</table>

**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 not statistically associated with improvement; however, preliminary data and clinical expert opinion support the implementation of this element
IV. Prevention Bundle Elements Descriptions

<table>
<thead>
<tr>
<th>Prevention Bundle Element</th>
<th>Care Descriptions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Standard Elements</strong></td>
<td></td>
</tr>
</tbody>
</table>
| Assess PIV every 60 minutes using Touch/Look/Compare (TLC) or Assess/Compare/Touch (ACT) | • PIV site must be touched and validated as soft, warm, and dry.  
• PIV site must be seen as uncovered, dry, and visible.  
• PIV site must be the same size as the other extremity. |
| **Recommended Element**   |                   |
| Educate patients/families on Touch/Look/Compare (TLC) or Assess/Compare/Touch (ACT) | • Patients / families are educated on the importance of TLC or ACT and taught symptoms to watch for  
• Education completed every day the PIV is present |
| Notify HAC champion / Unit leader / Vascular Access Team (VAT) member and provider for ongoing injury assessment and adequate treatment | • Designated person notified within the institution  
• Notified party comes to bedside real time for bedside assessment  
• Appropriate treatment started |
| Use Standardized Measurement Based Assessment Tool | • Percentage based assessment tool used on every PIVIE |

V. Measurement – Outcome Data

Outcome measures are the number of events as defined in the PIVIE Operational Definition. Outcomes are submitted monthly. The definition of serious and moderate PIVIE injuries is included in the PIVIE Operational Definition, Appendix A.

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Formula</th>
<th>Reporting Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serious PIVIE injuries</td>
<td>Number of serious PIVIE injuries / Total number patient days x 1000</td>
<td>Monthly</td>
</tr>
<tr>
<td>Moderate PIVIE injuries</td>
<td>Number of moderate PIVIE injuries / Total number patient days x 1000</td>
<td>Monthly</td>
</tr>
<tr>
<td>All PIVIE injuries</td>
<td>(Number of serious + moderate PIVIE injuries) / Total number patient days x 1000</td>
<td>Monthly</td>
</tr>
</tbody>
</table>

Example Outcomes Webform for PIVIE:

**Outcomes Data (New Definition! please refer to Op Def in SPS Share Point)**

- Reporting outcomes data this month: Yes/No
- Number of MODERATE PIVIES
- Number of SERIOUS PIVIES
VI. Measurement – Prevention Bundle Reliability

Process reliability is measured by looking at 20 monthly house-wide observations of patients with PIV to see if the factors were implemented reliably to the observed patient.

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Formula</th>
<th>Number of Observations</th>
<th>Reporting Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>% reliability to the standard PIVIE Standard Bundle element*</td>
<td>Number of audits totally compliant with SPS Standard Bundle Element / Number of audits completed x 100</td>
<td>• Minimum of 20 house-wide audits per month for assessment of PIV every 60 minutes</td>
<td>Monthly</td>
</tr>
</tbody>
</table>

Example Process Reliability Webform for PIVIE:

<table>
<thead>
<tr>
<th>Bundle Reliability (please refer to PIV Bundle in SPS SharePoint)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reporting bundle reliability data</td>
</tr>
<tr>
<td>Number of bundles observed that were successfully completed</td>
</tr>
<tr>
<td>Number of bundles observed</td>
</tr>
</tbody>
</table>

How to Complete Monthly Audits for Bundle Process Reliability:

- Audits should occur in units house-wide (i.e., all inpatient areas where patients have peripheral IVs). See inclusion and exclusion criteria in PIVIE operational definition for further details.
- Success or failure for each bundle audit is determined by evaluating one (single) hourly assessment. The bundle standard is that every PIV be assessed every 60 minutes, with a 15 minute grace period; if >75 minutes have passed since the last assessment, the audit would not pass.
- Audits should follow random sampling practices; should staff identify a PIVIE during assessment, they are encouraged to complete an apparent cause analysis.
- Audits can be completed via direct observation OR chart review, following the recommendations below:

<table>
<thead>
<tr>
<th>If Auditing by Observation</th>
<th>If Auditing by Chart Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Identify a patient, date and time to observe</td>
<td>• Identify a patient, date and time to sample; recommendation is to pick a sample time from the previous day or shift</td>
</tr>
<tr>
<td>• Ensure the patient has at least one IV fluid running during the sample time</td>
<td>• Ensure the patient has at least one IV fluid running during the sample time</td>
</tr>
<tr>
<td>• Identify when last hourly assessment was completed</td>
<td>• Review the chart and look at the previous hour’s documentation from the sample date and time</td>
</tr>
<tr>
<td>• Evaluate whether staff’s assessment using TLC or ACT meets bundle criteria</td>
<td>• Documentation should be 60-75 minutes from the previous assessment</td>
</tr>
<tr>
<td>• If the assessment meets bundle criteria, the audit is compliant</td>
<td>• If the documentation is in the chart for PIVIE prevention (TLC or ACT), this audit is compliant</td>
</tr>
<tr>
<td>• If the assessment does NOT meet bundle criteria, the audit is non-compliant</td>
<td>• If the documentation is missing from the chart, this audit is non-compliant</td>
</tr>
<tr>
<td>• If necessary, prompt staff to enter assessment documentation into the patient’s chart</td>
<td></td>
</tr>
</tbody>
</table>
VII. References

- NDNQI Staff, "Guidelines for Data Collection And Submission on Peripheral Intravenous (PIV) Infiltration Indicator," NDNQI, pp. 5-6, June 2014.

VIII. 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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<tr>
<td>Version 1</td>
<td>Mike Adamson, Melissa Chambers, Debbie Haddon, Vicki Jones, Sylvia Rineair</td>
<td>Initial version</td>
<td>9/10/2019</td>
</tr>
<tr>
<td>Version 2</td>
<td>Melissa Chambers, Debbie Haddon, Vicki Jones, Aaron Dawson</td>
<td>Added clarification to the measurement of reliability</td>
<td>2/11/2020</td>
</tr>
<tr>
<td>Version 3</td>
<td>Aaron Dawson; Co-Leaders</td>
<td>Moving two standard elements to recommended</td>
<td>2/26/2021</td>
</tr>
<tr>
<td>Version 4</td>
<td>Katie Staubach; Sarah Gomez; Patsy Sisson, Emily Gehring, PIVIE Co-Leaders &amp; SMEs</td>
<td>Added clarification to the measurement of reliability</td>
<td>4/29/2021</td>
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</tbody>
</table>

Thank you to the following PIVIE Co-Leaders and Subject Matter Experts who contributed to this document: Jillian Rojas, Ann & Robert H. Lurie Children’s Hospital of Chicago, Vicki Jones, Monroe Carrell Jr. Children’s Hospital at Vanderbilt, Sara Gravelle, Wolfson Children’s Hospital, Rick Lanham, Ann & Robert H. Lurie Children’s Hospital of Chicago, Melissa Chambers, Children’s Health Children’s Medical Center Dallas, Dort Foglia, Texas Children’s Hospital, Debbie Haddon, Children’s National Medical Center, Neil D. Johnson, Cincinnati Children’s Hospital, and Sylvia Rineair, Cincinnati 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.\(^1\)\(^-\)\(^7\) Payers, regulatory bodies and government all are encouraging hospitals to reduce readmissions. Typically, pediatric readmission rates have been much lower than those in adults.\(^1\)\(^,\)\(^6\)\(^,\)\(^7\) 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.\(^7\) 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
Hermina Shermont, Boston Children’s Hospital
Robyn Strosaker, UH/Rainbow Babies & Children’s Hospital

SPS Staff
ochspscchmc.org
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><strong>Standard Elements</strong></td>
<td></td>
<td></td>
</tr>
<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><strong>Standard Elements</strong></td>
<td></td>
</tr>
</tbody>
</table>
| Provide feedback to clinicians on any readmission | • Timely notification to discharging physicians of the readmission  
• 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. |

V. **Measurement- Prevention Bundle Reliability**

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Formula</th>
<th>Standards</th>
<th>Reporting Period</th>
</tr>
</thead>
</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  
• 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  
• 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>
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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>
</tr>
<tr>
<td></td>
<td>Robyn Strosaker, MD</td>
<td></td>
<td></td>
</tr>
<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.
SPS PREVENTION BUNDLE

Surgical Site Infections (SSI)

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>
<th>Level of Evidence</th>
<th>Evidence Cited (Numbers refer to Reference Section)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><em>GRADE/SPS</em>*</td>
<td></td>
</tr>
<tr>
<td><strong>Standard Elements</strong></td>
<td></td>
<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</td>
<td>GRADE/Scenario 1</td>
<td>1, 5, 6, 10, 11 Plus GRADE*</td>
</tr>
<tr>
<td>antibiotic timing</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Recommended Elements</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appropriate skin</td>
<td>GRADE/N/A</td>
<td>7, Plus GRADE*</td>
</tr>
<tr>
<td>antisepsis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appropriate</td>
<td>GRADE/N/A</td>
<td>7, 12,13 Plus GRADE*</td>
</tr>
<tr>
<td>antibiotic redosing</td>
<td></td>
<td></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,
- 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</th>
<th>Care Descriptions</th>
</tr>
</thead>
<tbody>
<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 antiseptic</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>
<th>Reporting Period</th>
</tr>
</thead>
</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

<table>
<thead>
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<td>Initial Draft</td>
<td>9- Nov - 2012</td>
</tr>
<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>
</tr>
<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>
</tr>
<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>
</tr>
<tr>
<td>Version 5</td>
<td>SPS Staff</td>
<td>Contact information updated</td>
<td>5-April-2017</td>
</tr>
</tbody>
</table>
APPENDIX A
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
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Christina Sperling, The Hospital for Sick Children

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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
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
Laurie Stevens, Project Specialist
Haley Richardson, 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>
<tbody>
<tr>
<td><strong>Standard Elements</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</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 | Repositioning occurs with 2 licensed clinicians (having 1 dedicated to hold the tube during movement and repositioning) during high risk situations. **High Risk Situations include at least (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

**Active discussion on Extubation Readiness**
- Conduct a multidisciplinary active discussion to evaluate for planned extubation
  - Conduct on all individual patients weaning toward extubation
  - Discussion to include:
    - Necessity for the ET tube
    - Discuss target extubation time
      - Post-extubation respiratory support plan
      - Pre-extubation sedation/analgesic/restraint s plan
      - Post-extubation analgesic plan
  - Scheduled re-evaluation time
  - Attended by at least: RN, RT, MD or NP, PA
  - Conduct discussion a minimum of once a day

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>
</tr>
</thead>
</table>
| UE Prevention Bundle Standard Bundle Elements:        | 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 Bundle Elements  
  • Minimum of 20 house-wide audits per month           | Monthly                                                                   |
| • Standardized anatomic reference points and securement methods |                                                                        |                                                                                        |                  |
| • Protocol for high risk situations                   |                                                                        |                                                                                        |                  |

V. References


### VI. Revision History

<table>
<thead>
<tr>
<th>I. Version</th>
<th>Primary Author(s)</th>
<th>Description of Version</th>
<th>Date Completed</th>
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<tr>
<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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<tr>
<td>Version 2</td>
<td>Klugman D., Maynord P., Melton, K., Mustin, L.</td>
<td>Updated section IV (Measurement – Prevention Bundle Reliability) to reflect measurement of the 2 standard aviator bundle elements “all or none” compliance</td>
<td>3/13/19</td>
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<td>Version 3</td>
<td>Klugman D., Maynord P., Melton, K.</td>
<td>Added recommended bundle element “Active discussion on Extubation Readiness” in section III</td>
<td>10/14/20</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
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
[ochsps@cchmc.org](mailto:ochsps@cchmc.org)
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>
</tr>
</thead>
<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>
<td>1</td>
</tr>
<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>
<tbody>
<tr>
<td><strong>Recommended Elements</strong></td>
<td></td>
</tr>
</tbody>
</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; 5 Michael D. Howell, MD, MPH; 6 Grace Lee, MD; Shelley S. Magill, MD, PhD; Lisa L. Maragakis, MD, MPH; Gregory P. Priebe, MD; Kathleen Speck, MP; 11 Deborah S. Yokoe, MD, MPH; 2 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>
<thead>
<tr>
<th>I. 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>9- Nov - 2012</td>
</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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</table>

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
  o Baseline: Usual state of ambulation
  o 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
  o Inherited deficiency of protein S, C or antithrombin, factor V Leiden or prothrombin gene mutation.
- Critically ill (currently in an intensive care unit)
- Active cancer/malignancy
- Recent Surgery within the past 30 days
- Estrogen therapy: currently taking or within the past 2 weeks

SPS Recommended Elements for Screening: VTE Risk Factors

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

**VTE Prevention Intervention Based on VTE Risk Assessment**

<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>
<thead>
<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>
</tr>
</thead>
</table>

**Interventions: with no contraindications present**

- Encourage highest degree of mobility
- SCD
- Anticoagulation

**VTE Prevention Intervention for Patients Undergoing Surgical Procedures with General Anesthesia**

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

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

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

  **Contraindications:**

  o Distal/Peripheral IV Access: i.e. IV in foot
  o Suspected or existing acute deep vein thrombosis
  o Skin conditions affecting extremity (e.g., dermatitis, burn)
  o Acute fracture- okay to use device on unaffected extremity
  o No appropriate SCD size available
  o 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:**

  o Intracranial hemorrhage
  o Acute stroke/ brain ischemia
  o Ongoing and uncontrolled bleeding
  o Uncorrected coagulopathy
  o Incomplete spinal cord injury with suspected or known para-spinal hematoma
  o Allergy to UFH or enoxaparin (i.e. heparin induced thrombocytopenia)
  o Platelet count < 50,000/mcl
  o Epidural anesthesia
  o The patient is likely to require an invasive procedure within 24 hours of starting anticoagulation
  o Congenital bleeding disorder
  o Uncontrolled severe hypertension
  o 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>
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</tr>
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<tr>
<td>Mobility status</td>
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<td>Personal history of thrombosis</td>
<td>CDC Modified: IB</td>
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<td>Thrombophilia</td>
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</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\* × 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 2016</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