Critically Analyze the Evidence

The GRADE criteria were used to evaluate the quality of evidence presented in research articles reviewed during the development of this guideline. The table below defines how the quality of evidence is rated and how a strong versus a weak recommendation is established.

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Type of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>STRONG</td>
<td>Desirable effects clearly outweigh undesirable effects or vice versa</td>
</tr>
<tr>
<td>WEAK</td>
<td>Desirable effects closely balanced with undesirable effects</td>
</tr>
<tr>
<td>High</td>
<td>Consistent evidence from well-performed RCTs or exceptionally strong evidence from unbiased observational studies</td>
</tr>
<tr>
<td>Moderate</td>
<td>Evidence from RCTs with important limitations (e.g., inconsistent results, methodological flaws, indirect evidence, or imprecise results) or unusually strong evidence from unbiased observational studies</td>
</tr>
<tr>
<td>Low</td>
<td>Evidence for at least 1 critical outcome from observational studies, from RCTs with serious flaws or indirect evidence</td>
</tr>
<tr>
<td>Very Low</td>
<td>Evidence for at least 1 critical outcome from unsystematic clinical observations or very indirect evidence</td>
</tr>
</tbody>
</table>

PICO Question 1: In children, does a PICC line compared to a CVL or port increase the risk of adverse events?

Recommendation(s): No recommendation can be made due to inconclusive literature and the vast quantity of variables that influence the decision of the type of central catheter to utilize in patients. Data from the TCH population exhibited an increased trend in thrombosis with PICC lines in a subset of immunocompromised patients.

A review of the literature revealed six observational studies and two systematic reviews with meta-analysis that compared PICC lines, ports, or non-tunneled/tunneled lines to determine which type of catheter was associated with a higher risk of CLABSI. A 2013 meta-analysis of 23 studies with 57,250 patients found that the risk of CLABSI was similar for patients who received PICCs compared to those who received central catheters inserted in the internal jugular, subclavian, or femoral vein. The results of an earlier meta-analysis that compared PICCs, ports and non-tunneled/ tunneled central catheters, Maki 2006, illustrated that central and peripheral ports had a lower rate of infection (0.1 1000/catheter days) than PICCs (1.1 1000/catheter days), non-tunneled (2.7 1000/catheter days) and tunneled line (1.7 1000/catheter days). The researchers noted that outpatient PICC lines have a lower rate of infection (1.0 [95% CI: 0.8-1.2] 1000/catheter days) than inpatient PICC lines (2.1 [95% CI: 1.0-3.2] 1000/catheter days). Two studies compared ports to tunneled/non-tunneled external lines in children to determine the association with CLABSI. Both studies found that children with tunneled/ non-tunneled lines had higher odds of infection; however there were differences noted in the maintenance of the different types of lines (e.g. frequency of flush).

The CLABSI rates from a cohort of TCH oncology patients are listed below stratified by temporary lines (PICC and non-tunneled catheters) and permanent lines (tunneled catheters and port). CLABSI rates displayed below do not contain any outliers; however there is a gradual trending increase for all line types. There were no findings noted within the data to support a recommendation to favor the use of either line type.
Five observational studies and a meta-analysis evaluated the outcome of deep vein thrombosis relative to central line type. Chopra 2013 found that PICCs were associated with an increased odds of deep vein thrombosis than other central venous catheters (OR 2.55; 95% CI: 1.54-4.23, p<0.0001). The literature review revealed an additional two pediatric studies that found that PICC lines had an increased association with deep vein thrombosis than tunneled and non-tunneled lines. A retrospective review of over 5000 PICCs and 900 tunneled lines found that the odds ratio of developing a DVT with a PICC as compared to a tunneled line, with tunneled line as the reference, was 0.83 (95% CI: 0.55-1.29), p=0.38.

PICO Question 2: In children, does a dedicated team (for central line dressing and tubing change) decrease the risk of catheter related events?

Recommendation(s): Weak recommendation with low quality evidence. Hospitals should consider the use of two people for central line dressing and tubing changes in patients whose movement inhibits the sterility of these procedures.

There is a paucity of literature that evaluates the effect of a dedicated team to change central line dressings and/or tubing on the rate of catheter related events. In a 2012 observational study, a PICC team consisting of 20 trained nurses that dedicated 4 hours per day to catheter maintenance was implemented along with a central line bundle. The study found that the monthly CLABSI rate was directly related to the number of days in the month that the PICC team did not provide care (r=0.84, p<0.0001) with a co-efficient of determination (r2) of 0.70. Holzmann-Pazgal 2012 evaluated the use of a PICC team that was responsible for all tubing changes, accessing the central line for blood draws, all dressing changes, and medication administration via central lines. The study found that the overall CLABSI rate before the line team was 12.9/1000 and 4.0/1000 post-line team (p<0.001).

There were no studies found that evaluated the effect of dedicated teams to change central line dressings and/or tubing on the outcomes of catheter displacement, dislodgement, or accidental suture removal.

PICO Question 3: In children, what are the indications for central line placement and insertion of a central catheter with multiple lumens?

Recommendation(s): Weak recommendation with low quality evidence. The decision to place a central line should be based upon the length of intended IV therapy, type of IV therapy needed, the patient’s ability to care for the catheter, and assessment of peripheral veins.

Two studies were found that listed common indications for central line placement in their cohort of patients. Chopra 2014 reported the most common indications for central line placement were long-term antibiotic administration (52%), venous access (21%), TPN (16%), and delivery of chemotherapy (11%) in an adult population. The study found that patients that received a PICC line due to the need for venous access or TPN had higher odds of infection than patients that received a PICC line for long-term antibiotic use; however the results were not significantly different. Migita 2009 found that the most common indications for PICC placement were TPN, antibiotics, chemotherapy, and patients with venous access needs due to critical care status. Contraindications for PICCs were TPN if patient could be fed enterally, antibiotics if PO options were available, potential hemodialysis patients due to risk of thrombosis, and patients with recent bacteremia. The CDC guideline recommends the use of a midline catheter or PICC line, instead of a peripheral IV, when the duration of IV therapy will likely exceed six days.

The search for literature evaluating when to use central catheters with multiple lumens resulted in one quality improvement report. The study set criteria for when to place single and double lumen lines; however the authors did not compare before and after CLABSI rates with this initiative. Many national guidelines recommend using the minimum number of lumens on a central line that is essential to manage the patient.
Critical Points of Evidence*

Evidence Supports
- Hospitals should consider the use of two people for central line dressing and tubing changes in patients whose movement inhibits the sterility of these procedures. (14-15) – Weak recommendation, low quality evidence
- The decision to place a central line should be based upon the length of intended IV therapy, type of IV therapy needed, the patient’s ability to care for the catheter, and assessment of peripheral veins. (16-21) – Weak recommendation, low quality evidence

Evidence Lacking/Inconclusive
- No recommendation can be made due to inconclusive literature and the vast quantity of variables that influence the decision of the type of central catheter to utilize in patients. Data from the TCH population exhibited an increased trend in thrombosis with PICC lines in a subset of immunocompromised patients. (1-13)

*NOTE: The references cited represent the entire body of evidence reviewed to make each recommendation.
References


Clinical Standards Preparation
This clinical standard was prepared by the Evidence-Based Outcomes Center (EBOC) team in collaboration with content experts at Texas Children’s Hospital. Development of this clinical standard supports the TCH Quality and Patient Safety Program initiative to promote clinical standards and outcomes that build a culture of quality and safety within the organization.

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Development Process
This clinical standard was developed using the process outlined in the EBOC Manual. The literature appraisal documents the following steps:

1. Review Preparation
   - PICO questions established
   - Evidence search confirmed with content experts

2. Review of Existing External Guidelines
   - Central Venous Catheter Care for the Patient with Cancer: American Society of Clinical Oncology Clinical Practice Guideline 2013

3. Literature Review of Relevant Evidence
   - Searched: Pubmed, Cochrane Library, EMBASE, CINAHL

4. Critically Analyze the Evidence
   - 5 prospective observational study, 2 systematic reviews and meta-analysis, 1 case-control study, 1 systematic review, 1 retrospective analysis, 1 retrospective study, 1 retrospective review, 1 prospective study, 3 retrospective cohort, 2 quality improvement project

5. Summarize the Evidence
   - Materials used in the development of the clinical standard, literature appraisal, and any order sets are maintained in a Central Line Complications evidence-based review manual within EBOC.

Evaluating the Quality of the Evidence
Published clinical guidelines were evaluated for this review using the AGREE II criteria. The summary of these guidelines are included in the literature appraisal. AGREE II criteria evaluate Guideline Scope and Purpose, Stakeholder Involvement, Rigor of Development, Clarity and Presentation, Applicability, and Editorial Independence using a 4-point Likert scale. The higher the score, the more comprehensive the guideline.

This clinical standard specifically summarizes the evidence in support of or against specific interventions and identifies where evidence is lacking/inconclusive. The following categories describe how research findings provide support for treatment interventions. “Evidence Supports” provides evidence to support an intervention
“Evidence Against” provides evidence against an intervention.
“Evidence Lacking/Inconclusive” indicates there is insufficient evidence to support or refute an intervention and no conclusion can be drawn from the evidence.

The GRADE criteria were utilized to evaluate the body of evidence used to make practice recommendations. The table below defines how the quality of the evidence is rated and how a strong versus weak recommendation is established. The literature appraisal reflects the critical points of evidence.

<table>
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Recommendations
Practice recommendations were directed by the existing evidence and consensus amongst the content experts. Patient and family preferences were included when possible. The Content Expert Team and EBOC team remain aware of the controversies in the management of Central Line Complications in children. When evidence is lacking, options in care are provided in the clinical standard and the accompanying order sets (if applicable).

Approval Process
Clinical standards are reviewed and approved by hospital committees as deemed appropriate for its intended use. Clinical standards are reviewed as necessary within EBOC at Texas Children’s Hospital. Content Expert Teams are involved with every review and update.

Disclaimer
Practice recommendations are based upon the evidence available at the time the clinical standard was developed. Clinical standards (guidelines, summaries, or pathways) do not set out the standard of care and are not intended to be used to dictate a course of care. Each physician/practitioner must use his or her independent judgment in the management of any specific patient and is responsible, in consultation with the patient and/or the patient’s family, to make the ultimate judgment regarding care.

Version History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Comments</th>
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<tbody>
<tr>
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