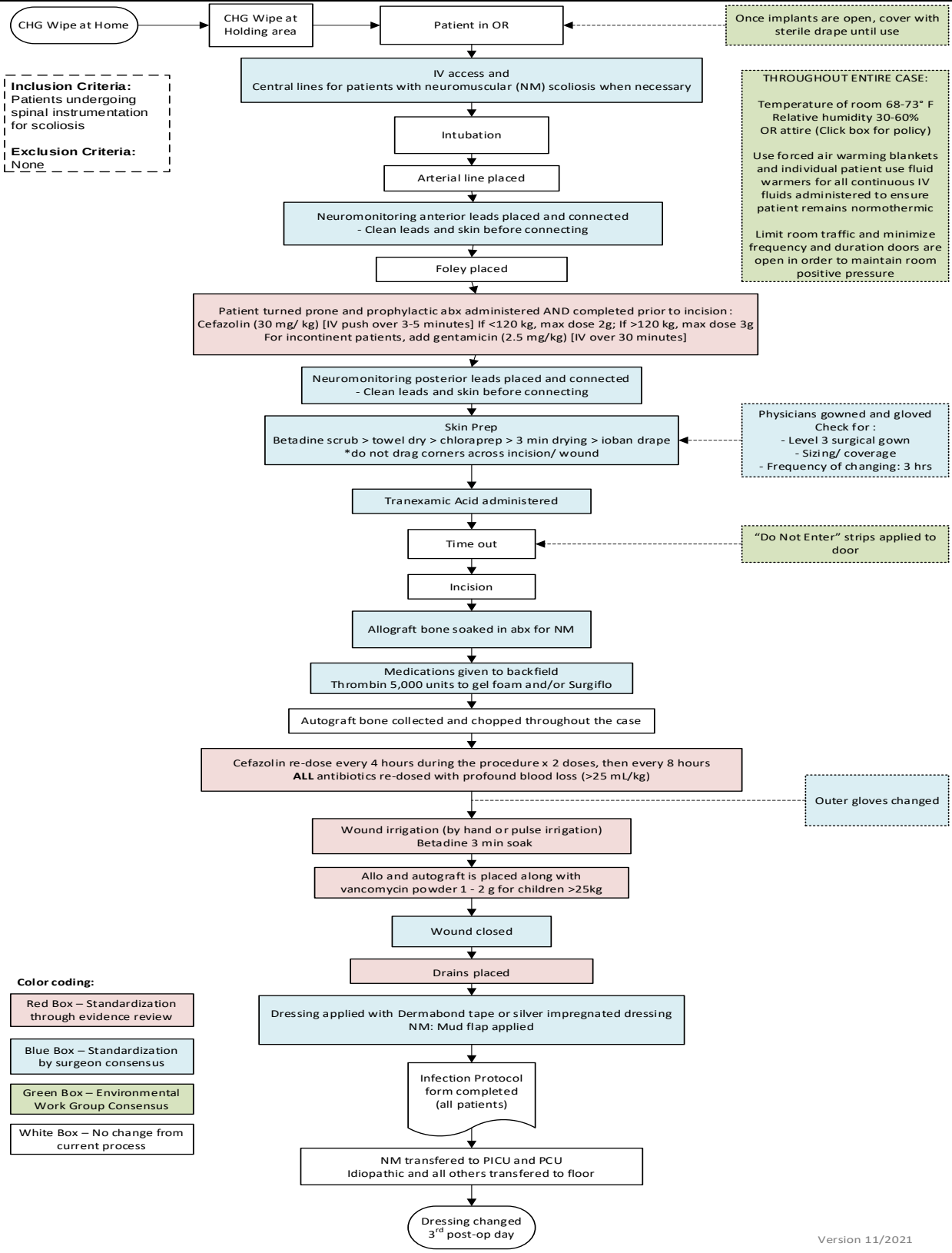
TEXAS CHILDREN'S HOSPITAL
EVIDENCE-BASED OUTCOMES CENTER
Intraoperative Spinal Instrumentation Prevention
Evidence-Informed Pathway



Version 11/2021

Clinical standards are developed for 80% of the patient population with a particular disease. Each practitioner must use his/her clinical judgment in the management of any specific patient.

Critical Points of Evidence*

Evidence Supports

- Administer cefazolin at a dose of 30 mg/kg up to a maximum dose of 2 grams for patients under 120 kg, and 30 mg/kg up to a maximum dose of 3 grams for patients over 120 kg. Re-dose cefazolin every 4 hours times 2 doses, then every 8 hours (1-3) – Strong recommendation, very low quality evidence
- Use 1-2 grams of vancomycin powder sprinkled in the surgical wound prior to closure to prevent surgical site infection in children that weigh >25kg. (4-10) – Strong recommendation, very low quality evidence
- To provide coverage for gram negative pathogens for incontinent pediatric patients by administering gentamicin at a dosing of 2.5 mg/kg with a maximum dose of 120 mg. (2, 11-14) – Strong recommendation, very low quality evidence
- To use drains in pediatric patients undergoing spinal instrumentation surgery for scoliosis. (3, 15-17) – Strong recommendation, very low quality evidence

Evidence Lacking/Inconclusive

- Irrigation by hand compared to pulse irrigation to decrease surgical site infection. (13, 18-20) – Unable to make a recommendation
- Use a three-minute povidone-iodine soak decrease the risk of surgical site infection. (21-22) – Unable to make a recommendation
- To re-dose cefazolin every four hours or with profound blood loss (>25 mL/kg), whichever comes first. – Consensus recommendation
- To administer vancomycin as the prophylactic pre-incision antibiotic in patients with severe penicillin allergy (defined by anaphylaxis) or known cephalosporin allergy. – Consensus recommendation

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

Measures

Process

- Timely prophylactic antibiotic administration
- Maintenance of normothermia
- Appropriate prophylactic antibiotic re-dosing

Outcome

- Mortality
- Morbidity
- Instrumented spine surgical site infections
- Length of stay

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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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No relevant financial or intellectual conflicts to report.

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
   - Clinical Practice Guidelines for Antimicrobial Prophylaxis in Surgery, 2013
   - National Institute for Clinical Excellence, Surgical Site Infection: Prevention and Treatment of Surgical Site Infection, 2020
   - Children's Hospital of Philadelphia, Spine Deformity "Best Practice" Guidelines, 2013
   - Seattle Children's Spine Pathway, 2019
   - Children's Hospital Colorado, High-Risk Spinal Fusion Clinical Care Guideline, 2018
   - Children's Hospital of Orange County, Spinal Fusion for Adolescent Idiopathic Scoliosis Care Guideline, 2018
   - Cincinnati Children's Hospital, Spine Surgical Site Infection Prevention Protocol, 2014
3. Literature Review of Relevant Evidence
   - Searched: PubMed, Cochrane Collaboration, Google
4. Critically Analyze the Evidence
   - 2 meta-analyses, 6 randomized **controlled** trials, and 21 nonrandomized studies
5. Summarize the Evidence
   - Materials used in the development of the clinical standard, literature appraisal, and any order sets are maintained in an Intraoperative Spinal Instrumentation Infection evidence-informed 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.

Recommendation	
STRONG	Desirable effects clearly outweigh undesirable effects or vice versa
WEAK	Desirable effects closely balanced with undesirable effects
Quality	**Type of Evidence**
High	Consistent evidence from well-performed RCTs or exceptionally strong evidence from unbiased observational studies
Moderate	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
Low	Evidence for at least 1 critical outcome from observational studies, RCTs with serious flaws or indirect evidence
Very Low	Evidence for at least 1 critical outcome from unsystematic clinical observations or very indirect evidence

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 diagnosis/management of children undergoing spinal instrumentation surgery for scoliosis. 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 should 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.

Permission of Use

Version History

Date	Comments
Jun 2016	Originally completed
Nov 2021	recommendation & algorithm update