Guideline for Infection Prevention in NICU Patients: Workgroup Update

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Overview

• Public Comment Review and Draft Section Approval
  • *S. aureus*

• Draft Recommendations
  • CLABSI
    • PPE: Glove use
    • Skin Prep for Insertion and Maintenance
    • Chlorhexidine Bathing
    • Catheter Care Team
    • Catheter Hub Antisepsis
    • Catheter Hub Manipulation
    • Insertion and Maintenance Bundles

• Updates
  • Respiratory Illness

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Methods: GRADE

Confidence in the Evidence
• RCTs start high
• Non-randomized studies start low

• Factors lower the quality of evidence
  • Risk of Bias, Inconsistency, Indirectness, Imprecision, and Publication bias

• Factors can increase the quality of evidence
  • Large magnitude of effect, Dose-Response, and Confounding
Methods: Updated Recommendation Categories

Recommendation
• Benefits clearly exceed the harms (or vice versa)
• Confidence in supporting evidence:
  • High to moderate
  • Low, very low, or expert opinion if high-quality evidence is impossible to obtain
• Federal regulation

Conditional Recommendation
• Benefits likely to exceed the harms (or vice versa)
• Confidence in supporting evidence is low, moderate, or high when:
  • High quality evidence exists, but benefit/harm balance is not clearly in one direction
  • Weak evidence and the recommendation may not consistently lead to benefit
  • Indirect high quality evidence (e.g. benefit is seen in other populations & settings)
  • Evidence of benefit (or harm) is in the context of simultaneously implemented interventions
  • The evidence base is likely to change
  • Benefit is most likely if intervention is implemented as a supplemental measure

No Recommendation
• Lack of evidence
• Unclear balance of benefits and harms
Draft Recommendations

Statement (Recommendation; Conditional Recommendation; No Recommendation)

• Supporting Evidence:
• Level of confidence in evidence:
• Benefits:
• Harms:
• Resource use:
• Balance of benefits and harms:
• Value judgments:
• Intentional vagueness:
• Exceptions:
S. aureus

- Available for public comment on regulations.gov
  - Review period: September 2 – November 4, 2019
  - 4 comments received:
    - Health Watch USA
    - Cleveland Clinic Children’s Hospital
    - Children’s Hospital of Philadelphia
    - Private individual
- Presenting today for final approval

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S. aureus Draft Recommendation 2.1.A.1

Perform active surveillance testing for S. aureus colonization in neonatal intensive care unit patients when there is an increased incidence of S. aureus infection or in an outbreak setting. (Recommendation)

Summary of public comment:
• “Outbreak” should be defined

Response:
• CDC maintains outbreak definitions elsewhere
• They will not be repeated in this document

Proposed action:
• No change

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**S. aureus Draft Recommendation 2.1.A.2**

*Perform active surveillance testing for methicillin-resistant S. aureus (MRSA) colonization in neonatal intensive care unit patients when there is evidence of ongoing healthcare-associated transmission within the unit. (Recommendation)*

Summary of public comment:

- State that the guidance to perform active surveillance in neonatal units should be enacted if the pathogen is endemic to the community or institution

Response:

- “Ongoing healthcare associated transmission within the unit” is defined within the Intentional Vagueness section. Additional information on how facilities can determine when action is necessary can be found within the Introduction

Proposed action:

- No change

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"... Identification of some infants with methicillin-resistant S. aureus (MRSA) colonization may result in the implementation of Contact Precautions, which has inconsistently been associated with unintended consequences, such as decreased healthcare personnel-patient contact, in other populations ..."

Summary of public comment:

• The requirement for Contact Precautions with MRSA has been weakened with insertion of “may.” Recommend changing “may result in” to “requires.” (same general comment about need for Contact Precautions made by 2 additional reviewers)

• The implementation of Contact Precautions differs among NICUs. Request that the document address:
  • Whether the spread of S. aureus is influenced by environmental factors and whether the patient is in an incubator vs open crib, single room vs ward
  • Suggestion that universal gloving and removal of white coats are forms of Contact Precautions

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S. aureus Draft Recommendation 2.1.A.1 and 2.1.A.2, Justification Table, Risks and Harms

“... Identification of some infants with methicillin-resistant S. aureus (MRSA) colonization may result in the implementation of Contact Precautions, which has inconsistently been associated with unintended consequences, such as decreased healthcare personnel-patient contact, in other populations ...”

Response:

• Definition of and recommendations for Contact Precautions are provided in CDC’s Guideline for Isolation Precautions

• Literature search did not retrieve data to address environmental factors or variations in the implementation of Contact Precautions

• SHEA-sponsored companion document will address topics where evidence was insufficient to formulate evidence-based guidelines

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S. aureus Draft Recommendation 2.1.A.1 and 2.1.A.2, Justification Table, Risks and Harms

“... Identification of some infants with methicillin-resistant S. aureus (MRSA) colonization may result in the implementation of Contact Precautions, which has inconsistently been associated with unintended consequences, such as decreased healthcare personnel-patient contact, in other populations ...”

Proposed action:

- Workgroup recognizes that some hospitals do not use Contact Precautions for MRSA
- Does HICPAC believe we need to explicitly recommend Contact Precautions for NICU patients with MRSA colonization/infection?
**S. aureus Draft Recommendation 2.1.A.3**

The use of active surveillance testing for methicillin-sensitive S. aureus (MSSA) colonization in neonatal intensive care unit patients to detect ongoing healthcare-associated MSSA transmission is an unresolved issue. *(No Recommendation)*

Summary of public comment:

- “[Our facility] does not perform routine surveillance testing for MSSA colonization, as there is no apparent benefit from performing the additional testing. Implementing this in our 100+ bed unit would be a significant resource and cost burden with unclear benefit to the patient population, as it would require additional resources in materials, time, laboratory space, and personnel. Our facility would not do any additional interventions if patients were found to be colonized, as we do not institute contact precautions for MSSA, nor do we currently perform any decolonization protocol.”

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**S. aureus Draft Recommendation 2.1.A.3**

The use of active surveillance testing for methicillin-sensitive *S. aureus* (MSSA) colonization in neonatal intensive care unit patients to detect ongoing healthcare-associated MSSA transmission is an unresolved issue. **(No Recommendation)**

Response:

- Thank you for your comment.
- Recommendation 2.1.A.1. is not to perform *routine* active surveillance testing for MSSA, but only to perform active surveillance testing when there is an increased incidence of infection or in an outbreak setting. The use of active surveillance testing for MSSA colonization remains an unresolved issue (Rec 2.1.A.3)

Proposed action:

- No change

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**S. aureus Draft Recommendation 2.1.A.5., Risks and Harms, Resource Use**

*If active surveillance testing for S. aureus colonization in neonatal intensive care unit patients is implemented, consider testing outborn infants or infants transferred from other newborn care units on admission to promptly identify newly admitted colonized patients. (Conditional Recommendation)*

**Risks and Harms:** “... there could be minor patient discomfort from performing nasal swabs.”

**Resource Use:** “Performing testing for *S. aureus* colonization ... would result in increased material and human resource costs.”

**Summary of public comment:**

- “The ‘minor discomfort’ from a nasal swab in the newborn is negligible ... the cost of MRSA testing pales in comparison to that of an average NICU patient bill and should be also considered negligible.”

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S. aureus Draft Recommendation 2.1.A.5., Risks and Harms, Resource Use

If active surveillance testing for S. aureus colonization in neonatal intensive care unit patients is implemented, consider testing outborn infants or infants transferred from other newborn care units on admission to promptly identify newly admitted colonized patients. *(Conditional Recommendation)*

**Risks and Harms:** “... there could be minor patient discomfort from performing nasal swabs.”

**Resource Use:** “Performing testing for S. aureus colonization ... would result in increased material and human resource costs.”

**Response/ Proposed Action:**

- The Workgroup has been tasked with outlining risks, harms and costs in the Justification Table
- Balance of benefits and harms reworded to address benefits of prevention, as we did in other sections

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If active surveillance for S. aureus colonization in neonatal intensive care unit patients is performed, use culture-based or polymerase chain reaction detection methods. (Recommendation)

Summary of public comment:
• The reader is left not knowing which to choose, PCR or culture: request for additional guidance

Response/ Proposed Action:
• The evidence did not suggest a clear benefit to one method over the other. After weighing benefits and harms, as noted in the Justification Table, the choice of test is dependent on an individual facility’s needs. These factors are captured in 2.E.1.E.1.a. Implementation Considerations.
• No change

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**S. aureus Draft Recommendation 2.1.B.2., Risks and Harms**

*If active surveillance for S. aureus colonization of neonatal intensive care unit patients is performed, collect samples from at least the anterior nares of neonatal intensive care unit patients.* *(Recommendation)*

**Risks and Harms:** “… include minor patient discomfort from performing nasal swabs. Further, if neonates are not colonized in the anterior nares and only the nares are sampled, then colonization at another anatomic sites may be missed.”

**Summary of public comment:**
- Suggest to comment on care needed in sampling nares of VLBW infants, as the product can cause trauma (bleeding)
- Use of additional sites may be especially important in this size infant

**Response/ Proposed Action:**
- Additional clarification will be added, emphasizing potential harm (bleeding)
- Option to sample additional sites already included

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**S. aureus Draft Recommendation 2.1.C.1., Risks and Harms**

Consider targeted decolonization for *S. aureus*-colonized neonatal intensive care unit patients in addition to the implementation of, and adherence to, appropriate infection prevention and control measures in an outbreak setting, or when there is ongoing healthcare-associated transmission, or an increase in the incidence of infection. **(Conditional Recommendation).**

**Risks and Harms:** “... There could be minor patient discomfort from the application of intranasal ointment.”

Summary of public comment:
- Address technical difficulties related to using mupirocin in the nose of a VLBW: ointment can partially occlude small nares and can accumulate in the prongs of CPAP and cannulas

Response/Proposed Action:
- Additional details will be added to Harms section

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S. aureus Draft Recommendation 2.1.C.3

The optimal decolonization agent or combination of agents remains an unresolved issue. (No recommendation)

Summary of public comment:

• Suggest rewording to specify concerns with chlorhexidine use in preterm infants
• Concern that the phrase “is indicated for use” [Justification Table, Risks and Harms] could be misinterpreted
• Potential harms are mentioned later in document, but not first time CHG mentioned
• Suggest indicating whether data support restricting chlorhexidine use in very low birth weight infants or infants below a specific gestational age

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S. aureus Draft Recommendation 2.1.C.3

The optimal decolonization agent or combination of agents remains an unresolved issue. **(No recommendation)**

Response/ Proposed Action, Justification Table text:

- The phrase “topical chlorhexidine is indicated for use ‘with care’” will be re-worded
- The FDA indication for topical chlorhexidine specifies to use “with care” in premature infants or infants under 2 months of age
- The FDA does not specify restrict use based on age or gestational age
- Literature review did not retrieve evidence that would allow specific recommendation
- Current statement about harms of CHG can be reworded to include more specific language

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**S. aureus Draft Section 2.E.1.A. Multi-intervention Strategies**

Summary of public comment:
- Suggest addressing strategies of “universal gloving, removing lab coats, and perhaps unit or ward design features such as private rooms and location of sinks”

Response:
- The literature search did not retrieve data to individually address the efficacy of these strategies

Proposed action:
- No change
S. aureus Appendix

Summary of public comment:
• Mention of culturing HCP hands in the Appendix may be confusing and lead readers to suggest that this is an important intervention

Response/ Proposed Action:
• The information in the Appendix summarizes what was found in the literature
• We make no recommendation regarding culturing of HCP hands
• CDC Core Practices are emphasized as key interventions
• Text will be reviewed to ensure clarity
S. aureus General Comments

Summary of public comment:

• State that surveillance includes both neonates and HCP

Response/ Proposed Action:

• HCP interventions are outside the scope of this document and are addressed in the HCP Guideline

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**S. aureus General Comments**

**Summary of public comment:**

- Suggest additional detail regarding infection control strategies such as Contact Precautions, cohorting, hand hygiene, environmental cleaning, adherence monitoring
- “Those involved in limiting outbreaks in the NICU would benefit from specific guidance as to ‘when to do what.’ It seems that a tiered approach as described in the HICPAC 2006 MDRO document may be helpful.”

**Response:**

- HICPAC Guidelines do not repeat recommendations provided in other HICPAC or CDC resources
- References will be added to the 2006 MDRO Guideline and other applicable documents to direct readers to additional resources for limiting outbreaks
- SHEA-sponsored companion document will address topics where evidence was insufficient to formulate evidence-based guidelines

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**S. aureus General Comments**

**Summary of public comment:**

- Suggest addressing kangaroo care, cohorting patients, cohorting staff, staffing ratios, keeping new admissions in a separate area, whole genome sequencing, cleaning, training environmental services staff, and design of NICUs

**Response:**

- Kangaroo care is recognized as having many benefits
  - One study was retrieved that addressed kangaroo care as a risk factor for MRSA acquisition
  - Did not retrieve literature about how to mitigate risk
- Cohorting
  - Described as an element of multi-intervention bundles described in the retrieved articles
  - Recommended in the Isolation Guidelines and MDRO Guidelines

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S. aureus General Comments

Summary of public comment:

• Suggest addressing kangaroo care, cohorting patients, cohorting staff, staffing ratios, keeping new admissions in a separate area, whole genome sequencing, cleaning, training environmental services staff, and design of NICUs.

Response:

• Other Prevention Strategies
  • Evidence not retrieved to formulate specific recommendations about whole genome sequencing
  • Work group acknowledges this may be important tool for investigating outbreaks
  • Evidence not retrieved to formulate a NICU-specific recommendation

Proposed Action

• Paragraph added to narrative about whole genome sequencing
• SHEA-sponsored companion document will address topics where evidence was insufficient to formulate evidence-based guidelines

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S. aureus General Comments

Summary of public comment:

• Add a section addressing precautions for surgical infants. “Might screening and decolonizing infants before surgeries be advisable under certain conditions?”

Response:

• Literature search focused on the general NICU patient population
• It is understood that this question is important and that the strategy has been successful in other populations, but the literature search did not retrieve evidence regarding decolonization as a prevention strategy for SSIs in the NICU population

Proposed Action

• SHEA-sponsored companion document will address topics where evidence was insufficient to formulate evidence-based guidelines

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S. aureus General Comments

Summary of public comment:
• Comments and suggestions regarding layout, formatting, organization of the document
• Suggestions for additional references for the Introduction: MDRO Guideline, MMWR
• Request to add section to guide future research

Response/ Proposed Action:
• Final editing and review will be conducted
• When the document is published on the Infection Control Guidelines website, the “landing page” provides a matrix of the recommendations
• References will be updated prior to publication
• Guidance for future research is beyond the scope of this document
  • Consider brief paragraph on ”research gaps”
  • Similar section included in C. difficile review

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S. aureus Literature Search Update

KQ1: 3 new studies identified in literature search, 1 suggested by Workgroup - no changes to recommendations suggested


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S. aureus Literature Search Update

Rana 2012: Descriptive study (N=4304)
• Implemented admission screening for S. aureus for NICU patients
• Also addressed decolonization and implementation of Contact Precautions
• Does not differentiate between inborn and outborn patients
• Results do not suggest that finding positive cultures was linked to infections
• No harms/adverse events reported
• No change in draft recommendations

Huang 2011: Retrospective Pre-Post Study (N=1233)
• Decolonization of umbilicus and nares as part of a multimodal intervention strategy
• Extension of Taiwanese study: 2 papers already retrieved and reviewed, study population is the same
• No harms/adverse events reported
• No change in draft recommendations

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S. aureus Literature Search Update

Bozzella 2019: Retrospective Study (N=151)
- Retrospective review after addition of decolonization protocol as part of a multi-intervention approach, including dedicated technician to clean shared medical equipment, to reduce MRSA transmission in a NICU
- Concluded that enhancing cleaning of reusable equipment, not decolonization, led to significant reduction of MRSA transmission
- No harms/adverse events reported
- No change in draft recommendations

Lyles 2016: Diagnostic Study (N=2101)
- Multi-unit and multi-center study examined sensitivity of umbilicus and nares using PCR or culture (with or without broth enrichment)
- Nares more sensitive than umbilicus for detecting presence of MRSA colonization
- No change in draft recommendations

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S. aureus Literature Search Update

KQ2A: What are the risk factors for S. aureus infection in NICU patients? Do these factors differ between MRSA and MSSA or in the setting of an outbreak?

KQ2B: What are the risk factors for S. aureus colonization in NICU patients? Do these factors differ between MRSA and MSSA or in the setting of an outbreak?

7 new studies identified:
- Azarian 2016
- Denkel 2014
- Garcia 2014
- Geva 2011
- Sakaki 2009
- Schultz 2009
- Huang 2005

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S. aureus Literature Search Update

1. Azarian 2016: Retrospective Cohort Study (N=1940)
   • Weekly MRSA screening of infants’ nares
   • Risk factors associated with MRSA acquisition (univariate analysis):
     o Infant characteristics: birthweight, born off-site, gestational age, white race, birth by caesarean section
     o Clinical characteristics: length of stay

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S. aureus Literature Search Update

2. Denkel 2014: Prospective Cohort Study (N=221)
   • MRSA screening via nasal swabs of mothers and infants
   • Associated with MRSA acquisition (univariate analysis):
     o Clinical characteristics: patient days

3. Garcia 2014: Prospective Cohort Study (N=403)
   • MRSA screening of multiple anatomical sites of mothers and infants
   • Associated with MRSA acquisition (multivariate analysis of all newborns):
     o Maternal characteristics: mother with <4 years of formal education, maternal rhinosinusitis
   • Associated with MRSA acquisition (multivariate analysis of newborns hospitalized >72 hours) (n=80):
     o Infant characteristics: breastfeeding

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**S. aureus Literature Search Update**

4. Geva 2011: Prospective Cohort Study (N=2620)
   - Universal weekly MRSA screening of multiple anatomical sites of infants
   - Associated with MRSA acquisition (multivariate analysis):
     - Hospital characteristics: normalized group degree centrality (the proportion of possible connections that actually exist between MRSA- non-colonized infants and ≥1 colonized infant)

5. Sakaki 2009: Prospective Cohort Study (N=923)
   - MRSA surveillance culture of anterior nares of infants on admission and weekly
   - Associated with MRSA acquisition (multivariate analysis):
     - Infant characteristics: birthweight, eye mucous
     - Clinical characteristics: kangaroo care
     - Hospital characteristics: MRSA colonization rate

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S. aureus Literature Search Update

6. Schultz 2009: Prospective Cohort Study (N=1760)
   • Weekly MRSA surveillance via nasopharyngeal swab of all infants using PCR or culture
   • Associated with MRSA acquisition (univariate analysis):
     o Infant characteristics: gestational age, inborn birth

7. Huang 2005: Case-Control Study (N=42)
   • Blood cultures of infants with nosocomial MRSA bacteremia and matched controls
   • Associated with MRSA acquisition (multivariate analysis):
     o Clinical characteristics: presence of skin infection at onset

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CLABSI: What are effective strategies to prevent CLABSI in neonatal intensive care unit patients?

Literature Search

• 134 studies selected for inclusion
  • 71 studies included from 2012
  • 63 studies included from 2012-2018

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CLABSI Topics

• HICPAC Approved
  • Central Line Antimicrobial Locks (May 2019)
  • Central Line Type and Insertion Site (Aug 2019)
  • Dwell Time, Umbilical Catheters (Aug 2019)
  • Dwell Time, PICCs (Aug 2019)
  • Number of Catheter Lumens (Aug 2019)
  • Systemic Anticoagulant Prophylaxis (Aug 2019)
  • Systemic Antibiotic Prophylaxis (Aug 2019)

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CLABSI Topics for Review and Approval

- PPE: Universal glove use
- Skin Prep for Insertion and Maintenance
- Chlorhexidine Bathing
- Catheter Care Team
- Catheter Hub Antisepsis
- Catheter Hub Manipulation
- Insertion & Maintenance Bundles
Draft CLABSI Recommendation:  
**PPE: Universal Glove Use**

**Evidence:** 1 RCT (N=120)

Kaufman, 2014

- Examined efficacy of non-sterile glove use after hand hygiene, compared with hand hygiene alone, in NICU patients
- No difference reported in outcomes of CLABSI, BSI, and gram-negative BSI
- Reduction reported in possible CLABSI, gram-positive BSI
Draft CLABSI Recommendation:  
**PPE: Universal Glove Use**

2019 Draft Recommendation: The use of non-sterile gloves after hand hygiene but before all patient contact, compared with hand hygiene alone, to reduce CLABSI in neonatal intensive care unit patients, remains an unresolved issue. *(No Recommendation)*

- **Supporting Evidence:** One randomized, non-blinded, controlled trial (Kaufman)
- **Level of confidence in evidence:** The level of confidence in this evidence is moderate. There was a loss of confidence due to imprecision in the data.
- **Benefits:** The evidence suggested a benefit to using non-sterile gloves after hand hygiene prior all patient contact to decrease possible CLABSI and gram-positive BSIs in a subset of preterm infants (for infants <1000 g or <29 weeks GA and <8 days old) admitted into a single facility.
- **Harms:** Harms were not assessed in this study.
- **Balance of benefits and harms:** Although harms were not assessed, the evidence suggested a benefit to implementing glove use after hand hygiene practices as a part of infection prevention and control practices with the potential to decrease possible CLABSI and gram-positive BSI in preterm infants.

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Draft CLABSI Recommendation:  
**PPE: Universal Glove Use**

2019 Draft Recommendation: The use of non-sterile gloves after hand hygiene but before all patient contact, compared with hand hygiene alone, to reduce CLABSI in neonatal intensive care unit patients, remains an unresolved issue. (No Recommendation)

- **Resource use:** Theoretically, compared to standard of care, implementing glove use after hand hygiene could result in an increase in material cost, although this cost could be offset by the decrease in costs associated with CLABSI.
- **Value judgments:** Value judgments considered in the formulation of this recommendation include the age of the studies compared to the current standard of care, and patient safety.
- **Intentional vagueness:** The standard of care for hand hygiene in a given NICU may be different than what was used as the control in this study (alcohol hand rub or use of an antimicrobial soap, eg, 2% chlorhexidine gluconate).
- **Exceptions:** There are no exceptions to this recommendation.

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Questions?

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Draft CLABSI Recommendation:
Skin Antisepsis: Skin Preparation for Insertion and Maintenance

In NICU patients requiring skin antisepsis for catheter insertion and maintenance, does alcoholic chlorhexidine, compared with alcoholic povidone-iodine, prevent CLABSI?

Evidence: 1 RCT (n=48 patients)

Garland, 2009
• 2% alcoholic chlorhexidine gluconate (CHG) compared with 10% povidone iodine (PI) to prepare skin for catheter insertion and maintenance
• No difference in CRBSI, CABSI, presumed BSI, or septicemia
Draft CLABSI Recommendation: Skin Antisepsis: Skin Preparation for Insertion and Maintenance

2019 Draft Recommendation: The efficacy of alcoholic chlorhexidine, compared with povidone-iodine, for the prevention of CLABSI in NICU patients remains an unresolved issue. (No Recommendation)

• Supporting Evidence: 1 randomized controlled trial (Garland)
• Level of confidence in evidence: The level of confidence in this evidence is very low due to indirectness and imprecision. This study was published prior to 2011 before the widespread implementation of insertion and maintenance bundles.
• Benefits: One study (Garland) reported there was no reduction in infections found to using either alcoholic chlorhexidine or povidone iodine with an unclear base for catheter insertion or maintenance (1/24 in CHG and 1/24 PI had CRBSI).
• Harms: The evidence (Garland) detected an increase in CHG absorption after single use for skin preparation, and no significant systemic side effects were observed. It is unclear what the impact of this level of systemic chlorhexidine absorption is on neonates. This study reported no increased risk of contact dermatitis, although the the trial enrolled a select group of NICU infants (those weighing >1500 gm and >7 days of age). Harms were not assessed in younger or smaller infants).
Draft CLABSI Recommendation:  
Skin Antisepsis: Skin Preparation for Insertion and Maintenance  

2019 Draft Recommendation: The efficacy of alcoholic chlorhexidine, compared with povidone-iodine, for the prevention of CLABSI in NICU patients remains an unresolved issue. (No Recommendation)

- **Balance of Benefits and Harms**: Neither benefits nor harms were identified in this study.
- **Resource use**: The evidence retrieved did not report any differences in resource use whether chlorhexidine or povidone-iodine was used. Theoretically, there would be minimal difference in human, education, and material costs.
- **Value judgments**: Value judgments considered in the formulation of this recommendation include the age of the study and the applicability of the evidence base, the current standard of care, and patient safety.
- **Intentional vagueness**: There is no intentional vagueness.
- **Exceptions**: There are no exceptions to this recommendation.
2019 Draft Recommendation: The efficacy of alcoholic chlorhexidine, compared with povidone-iodine, for the prevention of CLABSI in NICU patients remains an unresolved issue. (No Recommendation)

- Additional studies assessed only harms
  - 3 observational studies (Brown, Smerdley, Chapman)
  - 1 case series (Neri)
  - 3 case reports (Kutsch, Lashkari, Mannan)
- Variety of harms or potential harms reported
  - Burns and skin injuries (Chapman, Kutsch, Lashkari, Neri, Mannan)
  - CHG absorption (Garland, Chapman)
  - Iodine absorption and urinary iodine excretion (Brown, Smerdley)
- Diversity of CHG products
  - 1% and 2% aqueous CHG
  - 0.5% alcoholic CHG

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Questions?

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Draft CLABSI Recommendation: 
**Skin Antisepsis: Chlorhexidine Bathing**

Does chlorhexidine bathing, compared with no bathing or bathing with placebo, prevent CLABSI in NICU patients?

**Evidence:**
1 RCT: Sankar (n=60)
   - Examined safety and efficacy of a single bath using 0.25% chlorhexidine impregnated washcloths compared with saline impregnated washcloths or no bath
   - Reported outcomes of culture positive sepsis and clinical sepsis
   - Suggested no difference in incidence of culture-positive sepsis or clinical sepsis at one week between groups
2 OBS: Cleves (n=4243), Quach (n=790)
   - Examined safety and efficacy of using 2% CHG washcloths compared with using soap (Quach) or no baths (Cleves)
   - Reported outcomes of CLABSI
   - Suggested clinically meaningful (Quach) or significant (Cleves) decrease in CLABSI rate in NICU patients
   - Both conducted in facilities with high baseline rates
   - Unclear if study conducted in an international setting (Cleves) implemented insertion and maintenance bundles for the prevention of CLABSI

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Draft CLABSI Recommendation:
**Skin Antisepsis: Chlorhexidine Bathing**

**2019 Draft Recommendation:** The efficacy of chlorhexidine bathing to prevent CLABSI in NICU patients remains an unresolved issue. *(No Recommendation)*

- **Supporting Evidence:** One randomized controlled trial (Sankar, and 2 observational studies (Cleves, Quach)
- **Level of confidence in evidence:** The level of confidence in this evidence is low because observational studies start at low quality evidence. There was a loss of confidence due imprecision in the data. One of the studies was published prior to 2011 and the widespread implementation of insertion and maintenance bundles.
- **Benefits:** The evidence suggested a benefit to routine CHG bathing in facilities with high baseline rates despite implementation of and adherence to insertion and maintenance bundles and infection prevention and control practices (Quach, Cleves). The evidence suggested no benefit to using a single CHG bath (Sankar).
- **Harms:** The evidence (Sankar) suggested no incidences of hypothermia were associated with using CHG washcloths for single bath. All three studies reported no skin reaction associated with chlorhexidine skin bathing with washcloths or solutions. Chlorhexidine resistance was not assessed in any of the studies.
2019 Draft Recommendation: The efficacy of chlorhexidine bathing to prevent CLABSI in NICU patients remains an unresolved issue. (No Recommendation)

- **Balance of benefits and harms**: The evidence suggested a benefit to routine CHG bathing in facilities with high baseline rates despite implementation of and adherence to insertion and maintenance bundles and infection prevention and control practices. Other adverse events were not reported in association with CHG bathing. The long-term impact of CHG bathing on the development of resistance and cross-resistance was not adequately assessed in the evidence.

- **Resource use**: Theoretically, compared to standard of care, implementing chlorhexidine bathing could result in an increase in human, education, and material cost, but it is anticipated that this cost will be offset by the decrease in costs associated with CLABSI.

- **Value judgments**: Value judgments considered in the formulation of this recommendation include the age of the studies compared to the current standard of care, and patient safety.

- **Intentional vagueness**: The delivery method for chlorhexidine bathing and the frequency of bathing are left intentionally vague in this recommendation.

- **Exceptions**: There are no exceptions to this recommendation.
Questions?

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Draft CLABSI Recommendation: 
**Catheter Care Team**

**Evidence:** 1 observational study (n=200)

Taylor, 2011

- Evaluated effect of a dedicated percutaneously-inserted central catheter (PICC) team to reduce catheter-related bloodstream infections (CRBSIs) in extremely low birth weight NICU patients
- Implementation of the PICC team was compared to previous standard of care
- Reported no difference in CRBSI incidence

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Draft CLABSI Recommendation:
Catheter Care Team

2019 Draft Recommendation: The efficacy of having a dedicated percutaneously-inserted central catheter care team to prevent CLABSI in NICU patients remains an unresolved issue. (No Recommendation)

• Supporting Evidence: One observational study (Taylor)
• Level of confidence in evidence: The level of confidence in this evidence is very low. There was a loss of confidence due to imprecision in the data.
• Benefits: The evidence suggested no benefit to using a PICC care team to decrease catheter-related BSI incidence in NICU patients. However, having an indwelling central line ≥30 days showed benefit in reducing CRBSIs, no difference if line duration <30 days.
• Harms: Harms attributable to the PICC care team were not reported in this study.
• Balance of benefits and harms: Even though no harms or benefits were reported from implementing a PICC Care Team, the evidence suggested indwelling central lines placed ≥30 days reduced CRBSIs in neonates.
Draft CLABSI Recommendation:

Catheter Care Team

2019 Draft Recommendation: The efficacy of having a dedicated percutaneously-inserted central catheter care team to prevent CLABSI in NICU patients remains an unresolved issue. (No Recommendation)

• Balance of benefits and harms: Even though no harms or benefits were reported from implementing a PICC Care Team, the evidence suggested indwelling central lines placed ≥30 days reduced CRBSIs in neonates.

• Resource use: Theoretically, compared to standard of care, implementing a PICC Care Team could result in an increase in material cost, but it is anticipated that this cost will be offset by the decrease in costs associated with CLABSI.

• Value judgments: Value judgments considered in the formulation of this recommendation include the age of the studies compared to the current standard of care, and patient safety.

• Intentional vagueness: The composition of the catheter care team is left intentionally vague.

• Exceptions: There are no exceptions to this recommendation.

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Draft CLABSI Recommendation:
*Catheter Hub Antisepsis*

**Evidence:** 1 observational study (n=860)

Bjorkman, 2015

- Compared HCP scrubbing the hub of central catheters with an alcohol-5% chlorhexidine wipe for an unspecified time prior to accessing intravenous tubing to administer drugs or collect blood samples, to HCP scrubbing the hub for 15 seconds prior to catheter use
- Non-significant decease in coagulase-negative staphylococcal sepsis (1.5% to 0)

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Draft CLABSI Recommendation: Catheter Hub Antisepsis

2019 Draft Recommendation: Scrubbing central venous catheter hubs for 15 seconds with an alcohol wipe (chlorhexidine 5%) before use, compared to an unspecified scrub duration, for the prevention of CLABSI in NICU patients remains an unresolved issue. (No Recommendation)

- **Supporting Evidence**: One observational study (Bjorkman)
- **Level of confidence in evidence**: The level of confidence in this evidence is very low. There was a loss of confidence due to imprecision in the data.
- **Benefits**: The evidence suggests that “scrubbing the hub” of central venous catheters with an alcohol-5% chlorhexidine wipe for 15 seconds prior to catheter use may reduce coagulase-negative staphylococci (CoNS) in NICU patients; the results were not statistically significant but may be clinically significant.
- **Harms**: Harms and adverse events attributable to the intervention were not reported in this study.

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Draft CLABSI Recommendation: 
_Catheter Hub Antisepsis_

2019 Draft Recommendation: Scrubbing central venous catheter hubs for 15 seconds with an alcohol wipe (chlorhexidine 5%) before use, compared to an unspecified scrub duration, for the prevention of CLABSI in NICU patients remains an unresolved issue. **(No Recommendation)**

- **Balance of benefits and harms:** Potential clinical benefit is weighed against the lack of harm; however, the level of confidence in the evidence is very low.
- **Resource use:** No increase in material or human cost was reported in association with implementing the intervention.
- **Value judgments:** No value judgments were applied to this recommendation.
- **Intentional vagueness:** There is no intentional vagueness in this recommendation.
- **Exceptions:** There are no exceptions to this recommendation.

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Draft CLABSI Recommendation:
*Catheter Hub Manipulation*

**Evidence:** 1 observational study (Patient n=223; Catheter n=357)

Mahieu, 2001

- Catheter hub manipulations that required disinfection, disconnection, or drawing blood through central line were associated with an increased risk of infection
Draft CLABSI Recommendation:
Catheter Hub Manipulation

2019 Draft Recommendation: Minimize the number of times central line hubs are accessed and minimize blood sampling through central lines to decrease the risk for CLABSI. (Recommendation)

- **Supporting Evidence**: One observational study (Mahieu)
- **Level of confidence in evidence**: The level of confidence in this evidence is very low because observational studies are at a higher risk of bias than RCTs, and there was a loss of precision because the evidence retrieved only one study.
- **Benefits**: The evidence suggested catheter manipulations were associated with an increase in infections.
- **Harms**: Potential harms associated with reduced catheter manipulation were not reported.
Draft CLABSI Recommendation: Catheter Hub Manipulation

2019 Draft Recommendation: Minimize the number of times central line hubs are accessed and minimize blood sampling through central lines to decrease the risk for CLABSI. (Recommendation)

- **Resource use:** Theoretically, reducing the number of times catheters are physically accessed would reduce human and material costs because supplies are needed every time the line is accessed. However, this reduction would be balanced by the need for thoughtful planning and coordination of multiple access needs to achieve this reduction.

- **Balance of benefits and harms:** The evidence suggests benefit to reducing catheter hub manipulations. Reducing the number of times central line hubs are accessed and minimized is considered standard of care and it is unlikely that future research will be conducted.

- **Value judgments:** The values considered in the formulation of this recommendation include patient safety and economic and human resource costs.

- **Intentional vagueness:** Central line hub access is left intentionally vague to capture the range of possible manipulations to the hub (eg, disinfection, access). Strategies to decrease catheter hub manipulation were not assessed.

- **Exceptions:** There are no exceptions to this recommendation.
Questions?

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Draft CLABSI Recommendation: 
*Insertion and Maintenance Bundles*

**Evidence:** Effect of CVC Insertion and Maintenance Bundles vs. Standard of Care

![Graph showing CLABSI Rate Difference](image)

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Draft CLABSI Recommendation: 
*Insertion and Maintenance Bundles*

2019 Draft Recommendation: Insertion and Maintenance

Use “bundled” interventions for central line insertion and maintenance as part of a single or multiple facility quality improvement effort to reduce rates of CLABSI. Elements of insertion and maintenance bundles for all patients have been recommended by the Centers for Disease Control and Prevention. *(Recommendation)*

- **Level of confidence in evidence:** The level of confidence in this evidence is very low. There was a loss of confidence due to imprecision.
- **Benefits:** The evidence suggested a benefit to using insertion and maintenance bundles to decrease CLABSI, BSI, and early bacterial sepsis in NICU patients.
- **Harms:** Neither harms of specific or bundled interventions were systematically assessed in the studies.
Draft CLABSI Recommendation: 
Insertion and Maintenance Bundles 

2019 Draft Recommendation: Insertion and Maintenance 
Use “bundled” interventions for central line insertion and maintenance as part of a single or multiple facility quality improvement effort to reduce rates of CLABSIs. Elements of insertion and maintenance bundles for all patients have been recommended by the Centers for Disease Control and Prevention. (Recommendation)

• **Balance of benefits and harms:** Even though harms were not assessed, the evidence suggested a benefit to implementing insertion and maintenance bundles as part of infection prevention and control practices with the potential to decrease CLABSIs, BSIs, and early bacterial sepsis in NICU patients.

• **Resource use:** Theoretically, compared to standard of care, Implementing insertion and maintenance checklists bundles could result in an increase in material cost and personnel, but it is anticipated that this cost will be offset by the decrease in costs associated with CLABSIs, BSIs, and early bacterial sepsis.
Draft CLABSI Recommendation: 
*Insertion and Maintenance Bundles*

2019 Draft Recommendation: Insertion and Maintenance

Use “bundled” interventions for central line insertion and maintenance as part of a single or multiple facility quality improvement effort to reduce rates of CLABSIs. Elements of insertion and maintenance bundles for all patients have been recommended by the Centers for Disease Control and Prevention. *(Recommendation)*

- **Value judgments:** Value judgments considered in the formulation of this recommendation include the age of the studies compared to the current standard of care, and patient safety. Use of insertion and maintenance bundles have become the standard of care in patients with central lines, including NICU infants.
- **Intentional vagueness:** The components of insertion and maintenance bundles studied in NICU patients vary and no study has compared the effectiveness of one bundle vs another in this population. The optimal components of NICU specific bundles, above and beyond the standard measures recommended by the CDC, cannot be determined from the available evidence.
- **Exceptions:** There are no exceptions to this recommendation.

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Respiratory Illness: What are effective strategies to prevent respiratory illness in NICU patients?

Progress

• 2012 extraction tables updated
  • 23 studies included

• Literature search update:
  • 557 studies retrieved for title and abstract screening
  • 112 studies selected for full text review
  • 18 studies included

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Respiratory Illness: What are effective strategies to prevent respiratory illness in NICU patients?

Next Steps
• Draft Systematic Review

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Thank you!

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.