



Please check all areas that apply:	PATIENT CARE						
☐ UnityPoint Health-Meriter-hospital	CLINICAL GUIDELINE						
☐ UnityPoint Health-Meriter-clinics	CG #2						
☐ UnityPoint Health-Meriter-Medical Sta	Page 1 of 12						
→ Department/Unit-specific: Birthing Center/NICU							
TITLE: Prevention, Identification and Management of Early Onset Neonatal Sepsis (EONS)							
DATE CREATED (Initial approval):	January 2025						
APPROVED: Roberta Sonner  Director of Perinatal	<u> </u>						

#### I. GUIDELINE PREFACE

Guidelines are designed to assist clinicians by providing a framework for the evaluation and treatment of patients. This guideline outlines the preferred approach for most patients. It is not intended to replace a clinician's judgment or to establish a protocol for all patients. It is understood that some patients will not fit the clinical condition contemplated by a guideline and that a guideline will rarely establish the only appropriate approach to a problem.

#### II. DEFINITION OF POPULATION

Early onset neonatal sepsis (EONS) is defined as infection presenting in the first week of life. Rates of EONS in the United States are between 0.5 and 0.77 per 1,000 live births. The most common causes of EONS include Group B Strep (GBS), E. coli, Listeria and viruses, such as HSV. Despite a dramatic decline in cases of GBS disease in newborns, GBS remains the leading infectious cause of morbidity and mortality among newborns in the United States. Birthing person colonization with GBS is the primary risk factor for early onset GBS infection in newborns. Primary prevention of early onset GBS infection is accomplished by identifying pregnant persons who are colonized with GBS near the time of delivery and providing appropriate intrapartum antibiotic prophylaxis. Secondary prevention of early onset GBS disease consists of careful observation and evaluation of the neonate for signs and symptoms of infection. Effective communication among all healthcare providers is essential for prevention of GBS disease.

The Center for Disease Control and Prevention (CDC) published revised guidelines for the prevention of Perinatal Group B Streptococcal Disease in 2010. These guidelines were further revised by the American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics (AAP) in 2019. In accordance with ACOG, AAP and CDC recommendations, UnityPoint Health-Meriter Hospital will adopt the revised guidelines for prevention of perinatal GBS disease.

#### III. ASSESSMENT/DIAGNOSIS

#### **GUIDELINES FOR OBSTETRIC CARE TEAM**

#### Prenatal management recommendations:

- 1. Obtain vaginal and rectal GBS screening test between 36 0/7 weeks and 37 6/7 weeks gestation on all pregnant persons. Screening may be by bacterial culture or NAAT (nucleic acid amplification test).
- 2. If a pregnant person has GBS bacteriuria during current pregnancy or previous infant with invasive GBS disease, intrapartum prophylaxis is warranted, and screening culture is not necessary.
- 3. Lab reports, culture results and susceptibility testing results (if available), should be sent/faxed to the anticipated site of delivery and to the obstetrical provider.

REVIEWED					
REVISED					

Page

- 4, Obstetrical provider should inform the patient of their GBS status and the recommended interventions.
- 5. Antibiotics should not be used before the intrapartum period to treat asymptomatic GBS colonization. **Intrapartum management recommendations:**
- 1. If there is concern for chorioamnionitis or sepsis in the birthing person:
  - a. Administer broad spectrum antibiotics
  - b. Alert pediatric provider to evaluate infant for risk of neonatal infection
- 2. Intrapartum prophylaxis is indicated if there is:
  - a. Positive (+) GBS vaginal and/or rectal culture at 36 0/7 week to 37 6/7 weeks gestation;
  - b. GBS bacteriuria in any concentration during current pregnancy;
  - c. History of previous infant with invasive GBS disease, or
  - d. Unknown GBS status and presence of one of the following risk factors:
    - i. Delivery <37 weeks gestation
    - ii. Rupture of Membranes (ROM) 18 hours or greater
    - iii. Maternal temperature 100.4' F (38'C) or more
    - iv. Positive NAAT
- 3. Intrapartum prophylaxis is not indicated if:
  - a. The birthing person had a previous pregnancy with positive (+) GBS screening culture and has a negative (-) screening culture this pregnancy.
  - b. Delivery is via cesarean section without rupture of membranes (ROM) or onset of labor, (regardless of GBS status and gestational age of the pregnancy).
  - c. There were negative (-) vaginal and rectal GBS screening cultures at 36 0/7 and 36 6/7 weeks gestation during current pregnancy, regardless of intrapartum risk factors unless chorioamnionitis is suspected.
- 4. Intrapartum antibiotic prophylaxis recommendations (see Appendix 1):
  - a. Penicillin G 5 million units IV, then 2.5 to 3 million units IV every 4 hours until delivery or;
  - b. If Penicillin is not available, Ampicillin 2 grams IV, then 1 gram IV every 4 hours until delivery.
  - c. If birthing person is penicillin-allergic with no history of anaphylaxis, angioedema, respiratory distress or urticaria following administration of a penicillin or cephalosporin: Cefazolin 2 grams IV, then 1 gram IV every 8 hours until delivery.
  - d. If birthing person is penicillin-allergic with a history of anaphylaxis, angioedema, respiratory distress or urticaria following administration of a penicillin or cephalosporin:
    - i. Clindamycin 900 mg IV every 8 hours until delivery if GBS isolate is susceptible to Clindamycin and erythromycin or if GBS isolate is susceptible to clindamycin, resistant to erythromycin and inducible clindamycin resistance is negative
    - ii. Vancomycin if GBS isolate is resistant to clindamycin, has inducible resistance to clindamycin, or if susceptibility to both agents is unknown.
    - iii. Erythromycin is no longer an acceptable alternative for intrapartum GBS prophylaxis

# Threatened preterm delivery recommendations: Spontaneous Preterm Labor (see Appendix 2):

- 1. If no GBS culture has been performed within last 5 weeks or results are not available:
  - a. Obtain vaginal and rectal GBS culture at hospital admission.
  - b. Initiate prophylaxis for GBS. GBS prophylaxis may be discontinued immediately if GBS screen is negative after 48 hours or if the birthing person is determined not to be in true labor.
  - c. Persons with threatened preterm delivery who have a negative GBS screen but do not deliver at that time should have repeat screening at 35-37 weeks gestation
- 2. If positive GBS culture:
  - a. IV penicillin for 48 hours (during tocolysis).
  - b. Reinitiate antibiotics when labor is likely to proceed to delivery.
- 3. If negative GBS culture:
  - a. Prophylaxis for GBS is not indicated.
  - b. Repeat culture if delivery has not occurred within 4 weeks.

#### **Preterm Premature Rupture of Membranes (see Appendix 3):**

1. If no GBS culture has been performed within last 5 weeks or results are not available:

Page

a. Obtain vaginal and rectal GBS culture at hospital admission.

b. Initiate prophylaxis for latency or GBS prophylaxis. If the birthing person is determined not to be in labor, continue antibiotics per standard of care if receiving for latency or continue antibiotics for 48 hours if receiving for GBS prophylaxis. Initiate antibiotic prophylaxis at onset of true labor if GBS positive or results unknown. No GBS prophylaxis indicated if GBS negative. Repeat GBS screen if birthing person reaches 35-37 weeks and has not yet delivered.

#### **GUIDELINES FOR NEONATAL CARE TEAM**

#### Management of infants at risk for early-onset GBS Disease: (see Appendices 4, 5, 6 & 7)

- 1. All newborns, regardless of the birthing person's GBS status, will have their early onset neonatal sepsis (EONS) risk score calculated and documented in the electronic health record (EHR).
- 2. At any time during the birth hospitalization, a neonatal provider should be notified with any of the following vital sign abnormalities:
  - a. Tachycardia (Heart rate 160 or greater)
  - b. Tachypnea (Respiratory rate 60 or greater)
  - c. Temperature instability (100.4°F or greater or 97.4°F or less)
- 3. Any newborn with clinical illness or EONS risk in the red zone should receive a full diagnostic evaluation and receive antibiotic therapy pending the results of the evaluation. This requires transfer to the Neonatal Intensive Care Unit (NICU) for treatment (refer to Appendix 8, Neonatal Sepsis Reference Guide, Order Set: Neonatal ICU Admission (Katherine F Hirsch, APNP MHM NICU Admission v09-2022).
- 4. Any newborn who has a baseline EONS risk in the yellow zone should be evaluated by a neonatal provider when risk is identified and with any change in clinical condition. A blood culture, either from the umbilical cord or from a peripheral vein, should be considered based on EONS risk calculator guidance.
- 5. Newborns born to a person with suspected chorioamnionitis as diagnosed by the obstetric provider (T>100.4 and/or sustained fetal tachycardia, foul-smelling amniotic fluid, uterine tenderness) should be evaluated by a neonatal provider at the time of delivery and with any change in clinical condition.
  - a. Delivery should be paged as a C2 delivery
  - b. Newborn care provider attending the delivery is responsible for:
    - i. Initial resuscitation
    - ii. Performing a physical exam
    - iii. Verifying EONS risk in the EHR
    - iv. Communicating risk zone and plan of care to the nursing staff
    - v. Ordering blood culture if indicated
    - vi. Repeat evaluation of newborn with any change in clinical condition
    - vii. Transferring newborn to NICU if clinically ill or based on EONS risk calculator recommendations
- 6. Well-appearing infants whose birthing parent received ADEQUATE GBS prophylaxis (GBS positive or unknown and received 4 or more hours of penicillin, ampicillin, or cefazolin) should receive the following monitoring:
  - a. Monitor vital signs (VS) every hour x 3. If these are within normal limits, monitor VS per EONS calculator recommendations for the remainder of the birth hospitalization.
  - b. RN to perform a full head-to-toe assessment approximately every eight hours per *Birthing Center Infant Recovery and Care (35 weeks gestation or more)* Standard of Care #4
  - c. Notify neonatal provider if infant develops signs of infection (e.g., temperature instability, lethargy, irritability, poor feeding, hypoglycemia, signs of poor perfusion, etc.) at any time.
  - d. Infants can be discharged as early as 24 hours after delivery assuming other discharge criteria have been met, ready access to medical care exists, and that a person able to comply fully with instructions for home observation will be present.

Page

#### 4 of 14

- 7. Infants whose birthing parent received INADEQUATE GBS prophylaxis (any antibiotic <4 hours prior to delivery or any antibiotic other than penicillin, ampicillin, or cefazolin) should receive the following monitoring:
  - a. Monitor VS every hour x 3. If these are within normal limits, monitor VS per EONS calculator recommendations.
  - b. RN to perform a full head-to-toe assessment approximately every eight hours per *Birthing Center Infant Recovery and Care (35 weeks gestation or more)* Standard of Care #4.
  - c. Notify neonatal provider if infant develops signs of infection (e.g., temperature instability, lethargy, irritability, poor feeding, hypoglycemia, signs of poor perfusion, etc.) at any time.
  - d. Observe in hospital for minimum of 36 hours

#### IV. DOCUMENTATION

- 1. To facilitate an accurate EONS Risk score generated by the EONS calculator, OB providers/LD RNs document the following information in the EHR:
  - a. Gestational age of the neonate
  - b. Highest birthing person antepartum temperature
  - c. Duration of rupture of membranes (ROM)
  - d. Birthing person GBS status (should flow into the EHR automatically)
  - e. Administration of intrapartum antibiotics (chart as infused)
- 2. The EONS calculator can be found in the following locations:
  - a. LD grease boards
  - b. Patient Lists report
  - c. Sidebar Summary report (RNs)
  - d. Sidebar Summary (link in Physician Index)
  - e. Summary Activity reports:
    - i. Neonatal Sepsis Risk
    - ii. Kardex (OB, NB, NICU overview RNs)
    - iii. Physician Overview
    - iv. Index NICU MD and Index MD: link in Pediatric section
- 3. Enter any missing documentation (e.g., GBS status) into the newborn's chart using the Neonatal Sepsis Risk flowsheet (RNs) or the Admission navigator (providers)

#### V. REFERENCE/RESOURCES

- a. ACOG Committee Opinion #797: "Prevention of Group Be Streptococcal Early Onset Disease in Newborns," February 2020.
- b. Karen M. Puopolo, MD, PhD, FAAP,, Ruth Lynfield, MD, FAAP, James J. Cummings, MD, MS, FAAP, COMMITTEE ON FETUS AND NEWBORN, COMMITTEE ON INFECTIOUS DISEASES, "Management of Infants at Risk for Group B Streptococcal Disease," Pediatrics: Volume 144 Number 2, August 2019.
- c. Karen M. Puopolo, Md and Carol Baker, MD, "Group B Streptococcal Infection in Neonates and Young Infants," UpToDate, content current through June 2020, retrieved July 22, 2020.
- d. Laura Filkins, PhD, D(ABMM), Jocelyn Hauser PhD, MLS(ASCP)CM,
- e. Barbara Robinson-Dunn, PhD, D(ABMM), FAAM, Robert Tibbetts, PhD, D(ABMM), F(CCM),
- f. Bobby Boyanton, MD, Paula Revell PhD, D(ABMM) on behalf of the American Society for Microbiology Clinical and Public Health Microbiology Committee, Subcommittee on Laboratory Practices Guidelines for the Detection and Identification of Group B Streptococcus, "Guidelines for the Detection and Identification of Group B Streptococcus," American Society for Microbiology, March 10, 2020.
- g. <u>UPH Neonatal Sepsis Reference Guide (042424)</u> Order Set: Neonatal ICU Admission (Katherine F Hirsch, APNP MHM NICU Admission v09-2022).

#### VI. REVIEWED/APPROVED BY

- a. Department of OB/GYN
- b. Department of Pediatrics
- c. Department of Family Medicine

CG #2

5 of 14

d. Nursery Committee

#### VII. LINKS TO OTHER MERITER POLICIES/STANDARDS/PROTOCOLS/GUIDELINES

A. Birthing Center Infant Recovery and Care (35 weeks gestation or more) - Standard of Care #4

#### VIII. FORMERLY KNOWN AS

- A. Perinatal Group B Streptococcal Disease Perinatal Medical Practice Guideline
- B. Chorioamnionitis Birthing Center Patient Care Policy/Procedure #26

#### IX. APPENDICES

- A. Appendix 1: Determination of Antibiotic Regimen for GBS Prophylaxis in Labor
- B. Appendix 2: Management of Women with Preterm Labor <37-0/7 Weeks Gestation
- C. Appendix 3: Management of Women with Preterm Prelabor ROM
- D. Appendix 4: EONS Calculator/Risk Score Summary
- E. Appendix 5: EONS Treatment Algorithm
- F. Appendix 6: EONS Lumbar Puncture Guidelines
- G. Appendix 7: RN SBAR Script when calling Provider for Sepsis evaluation
- H. Appendix 8: Neonatal Sepsis Reference Guide, Order Set

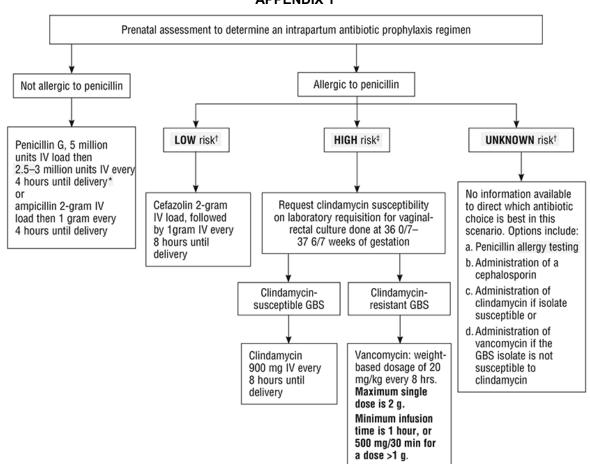


Figure 3. Determination of Antibiotic Regimen for Group B Streptococcus Prophylaxis in Labor. Abbreviations: GBS, group B streptococcus; IV, intravenous. \*Doses ranging from 2.5 to 3.0 million units are acceptable for the doses administered every 4 hours following the initial dose. The choice of dose within that range should be guided by which formulations of penicillin G are readily available in order to reduce the need for pharmacies to specially prepare doses. Individuals with a history of any of the following: nonspecific symptoms unlikely to be allergic (gastrointestinal distress, headaches, yeast vaginitis), nonurticarial maculopapular (morbilliform) rash without systemic symptoms, pruritis without rash, family history of penicillin allergy but no personal history, or patient reports history but has no recollection of symptoms or treatment. Individuals with a history of any of the following after administration of a penicillin: a history suggestive of an IgE-mediated event: pruritic rash, urticaria (hives), immediate flushing, hypotension, angioedema, respiratory distress or anaphylaxis; recurrent reactions, reactions to multiple beta-lactam antibiotics, or positive penicillin allergy test; or severe rare delayed-onset cutaneous or systemic reactions, such as eosinophilia and systemic symptoms/drug-induced hypersensitivity syndrome, Stevens-Johnson syndrome, or toxic epidermal necrolysis. (Modified from Verani JR, McGee L, Schrag SJ. Prevention of perinatal group B streptococcal disease: revised guidelines from CDC, 2010. Division of Bacterial Diseases, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention [CDC]. MMWR Recomm Rep 2010;59(RR-10):1-36.) (This Committee Opinion, including Table 1, Box 2, and Figures 1-3, updates and replaces the obstetric components of the CDC 2010 guidelines, "Prevention of Perinatal Group B Streptococcal Disease: Revised Guidelines From CDC, 2010.")

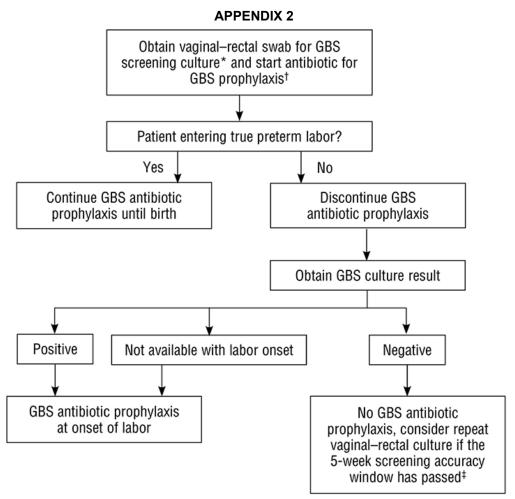


Figure 1. Management of Women With Preterm Labor <37 0/7 Weeks of Gestation. Abbreviation: GBS, group B streptococcus. \*If a patient has undergone vaginal-rectal GBS screening culture within the preceding 5 weeks, the results of that culture should guide management. Women colonized with GBS should receive intrapartum antibiotic prophylaxis. Although a negative GBS culture is considered valid for 5 weeks, the number of weeks is based on early-term screening and data in preterm gestations is lacking. † See Figure 3 for recommended antibiotic regimens. ‡A negative GBS culture is considered valid for 5 weeks. However, the number of weeks is based on early-term screening and data in preterm gestations is lacking. If a patient with preterm labor is entering true labor and had a negative GBS culture more than 5 weeks previously, she should be rescreened and treated according to this algorithm at that time. (Modified from Verani JR, McGee L, Schrag SJ. Prevention of perinatal group B streptococcal disease: revised guidelines from CDC, 2010. Division of Bacterial Diseases, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention [CDC]. MMWR Recomm Rep 2010;59(RR-10):1–36.) (This Committee Opinion, including Table 1, Box 2, and Figures 1–3, updates and replaces the obstetric components of the CDC 2010 guidelines, "Prevention of Perinatal Group B Streptococcal Disease: Revised Guidelines From CDC, 2010.")

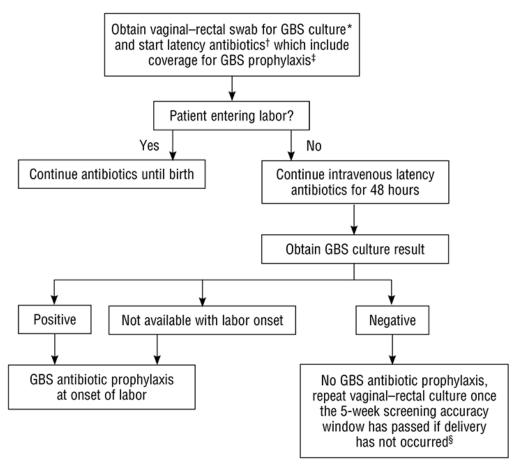
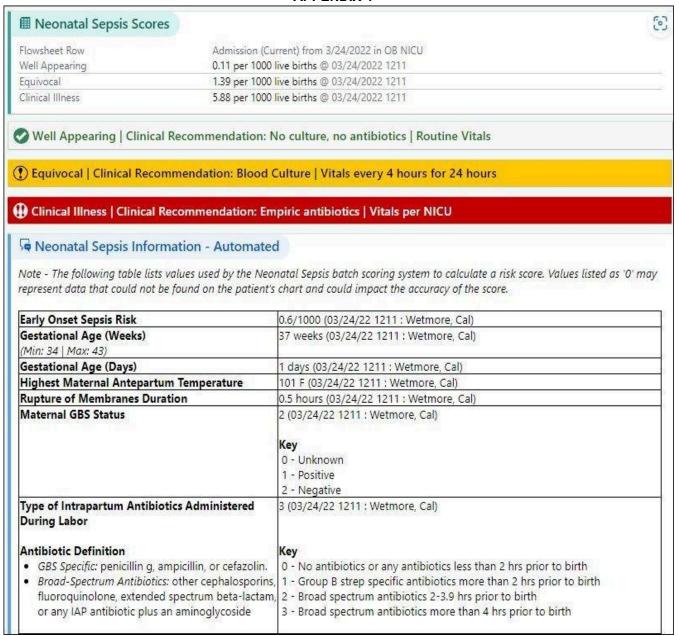


Figure 2. Management of Women With Preterm Prelabor Rupture of Membranes. Abbreviation: GBS, group B streptococcus. \*If a patient has undergone vaginal–rectal GBS culture within the preceding 5 weeks, the results of that culture should guide management. Women colonized with GBS should receive intrapartum antibiotic prophylaxis. Although a negative GBS culture is considered valid for 5 weeks, the number of weeks is based on early-term screening and data in preterm gestations is lacking. Latency antibiotics that include ampicillin given in the setting of preterm prelabor rupture of membranes are adequate for GBS prophylaxis. The optimal latency antibiotic regimen is unclear but one of the published protocols should be used (See ACOG Practice Bulletin No. 188, Prelabor Rupture of Membranes [Obstet Gynecol 2018;131:e1-14.]). If other regimens are used that do not provide appropriate GBS coverage, GBS prophylaxis should be initiated in addition. \$See Figure 3 for recommended antibiotic regimens. §A negative GBS culture is considered valid for 5 weeks. However, the number of weeks is based on early-term screening and data in preterm gestations is lacking. If a patient with preterm prelabor rupture of membranes is entering labor and had a negative GBS culture more than 5 weeks previously, she should be rescreened and managed according to this algorithm at that time. (Modified from Verani JR, McGee L, Schrag SJ. Prevention of perinatal group B streptococcal disease: revised guidelines from CDC, 2010. Division of Bacterial Diseases, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention [CDC]. MMWR Recomm Rep 2010;59(RR-10):1-36.) (This Committee Opinion, including Table 1, Box 2, and Figures 1-3, updates and replaces the obstetric components of the CDC 2010 guidelines, "Prevention of Perinatal Group B Streptococcal Disease: Revised Guidelines From CDC, 2010.").

Page 9 of 14

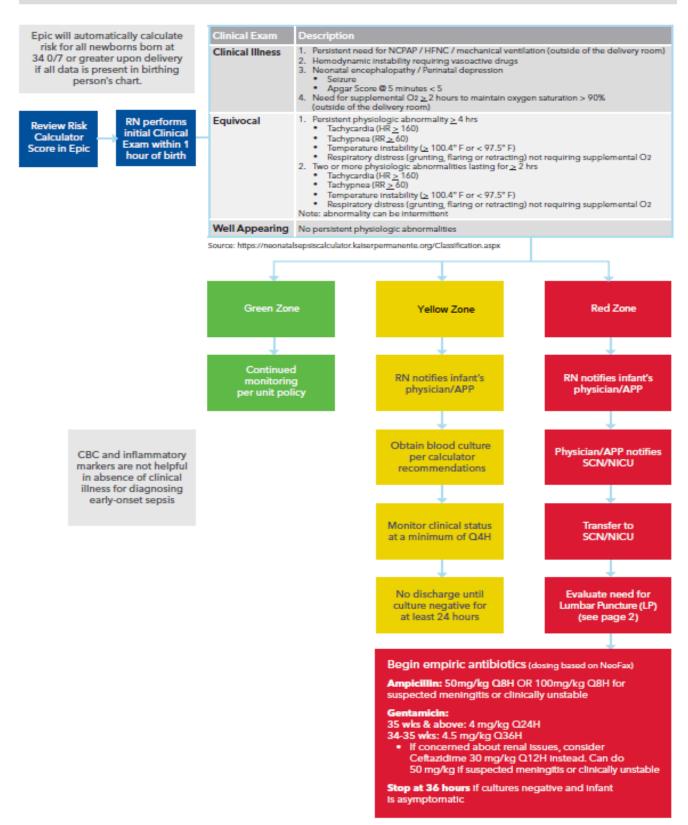


Page

Page

#### **APPENDIX 5**

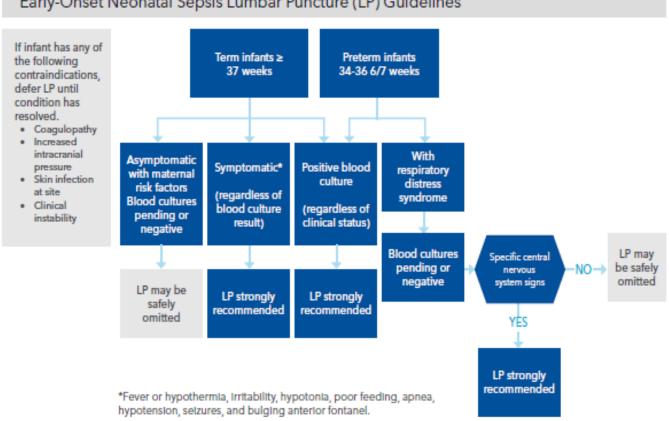
### Early-Onset Neonatal Sepsis Treatment Algorithm



**Page** 12 of 14

#### **APPENDIX 6**

# Early-Onset Neonatal Sepsis Lumbar Puncture (LP) Guidelines



From: Herrera T, Greenberg RG. When to perform lumbar in infants at risk for meningitis in the neonatal intensive care unit. In: Benitz WE, Smith PB, eds. Neonatology Questions and Controversies: Infectious Disease and Pharmacology. Philadelphia, PA: Elsevier; 2018.97

## **APPENDIX 7**

# RN SBAR Script when calling provider for Sepsis evaluation:

S: This is, the nurse caring for the newborn in Room
<b>B:</b> Infant was born at weeks and is now (minutes/hours) old.
Risk factors for infection include (inadequate GBS prophylaxis/ROM 18 hours or greater/maternal fever/IAI).
A: Sepsis calculator results show (baseline infection risk and risk zone color
Vital signs are currently normal/abnormal (specify what is abnormal, if applicable).
R: Per the guideline, this infant requires evaluation. Please come to Room .

Page 14 of 14

▼ Antibiotics
Early-Onset Sepsis Algorithm
✓ (1) Ampicillin IV
<ul> <li>ampicillin IV - post menstrual age greater than 34 weeks (\$\$)</li> <li>mg/kg, Intravenous, EVERY 8 HOURS, for 36 hours</li> </ul>
<ul> <li>ampicillin IV - post menstrual age 34 weeks or less (\$\$)</li> <li>mg/kg, Intravenous, EVERY 12 HOURS, for 36 hours</li> </ul>
<ul> <li>ampicillin IV - for suspected meningitits or clinically unstable (\$\$)</li> <li>100 mg/kg, Intravenous, EVERY 8 HOURS, for 36 hours</li> </ul>
Gentamicin or Ceftazidime
<ul> <li>gentamicin (GARAMYCIN) IV - post menstrual age 35 weeks or greater (\$\$)</li> <li>4 mg/kg, Intravenous, EVERY 24 HOURS, for 36 hours</li> </ul>
<ul> <li>gentamicin (GARAMYCIN) IV - post menstrual age 30-34 weeks (\$\$)</li> <li>4.5 mg/kg, Intravenous, EVERY 36 HOURS, for 36 hours</li> </ul>
<ul> <li>gentamicin (GARAMYCIN) IV - post menstrual age 29 weeks or less (\$\$)</li> <li>5 mg/kg, Intravenous, EVERY 48 HOURS, for 36 hours</li> </ul>
<ul> <li>ceftazidime IV - if suspected renal dysfunction (\$\$)</li> <li>mg/kg, Intravenous, EVERY 12 HOURS, for 36 hours</li> </ul>
Gentamicin labs & pharmacy consult