



POLICY STATEMENT

Recommendations for the Prevention of Perinatal Group B Streptococcal (GBS) Disease

COMMITTEE ON INFECTIOUS DISEASES AND COMMITTEE ON
FETUS AND NEWBORN**KEY WORDS**group B *Streptococcus*, early onset, diagnosis, prophylaxis,
penicillin allergy, treatment**ABBREVIATIONS**GBS—group B streptococcal/*Streptococcus*
IAP—intrapartum antibiotic prophylaxis
CDC—Centers for Disease Control and Prevention
CBC—complete blood cell

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www.pediatrics.org/cgi/doi/10.1542/peds.2011-1466

doi:10.1542/peds.2011-1466

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PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

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abstract

FREE

The Centers for Disease Control and Prevention (CDC) guidelines for the prevention of perinatal group B streptococcal (GBS) disease were initially published in 1996. The American Academy of Pediatrics (AAP) also published a policy statement on this topic in 1997. In 2002, the CDC published revised guidelines that recommended universal antenatal GBS screening; the AAP endorsed these guidelines and published recommendations based on them in the 2003 *Red Book*. Since then, the incidence of early-onset GBS disease in neonates has decreased by an estimated 80%. However, in 2010, GBS disease remained the leading cause of early-onset neonatal sepsis. The CDC issued revised guidelines in 2010 based on evaluation of data generated after 2002. These revised and comprehensive guidelines, which have been endorsed by the AAP, reaffirm the major prevention strategy—universal antenatal GBS screening and intrapartum antibiotic prophylaxis for culture-positive and high-risk women—and include new recommendations for laboratory methods for identification of GBS colonization during pregnancy, algorithms for screening and intrapartum prophylaxis for women with preterm labor and premature rupture of membranes, updated prophylaxis recommendations for women with a penicillin allergy, and a revised algorithm for the care of newborn infants. The purpose of this policy statement is to review and discuss the differences between the 2002 and 2010 CDC guidelines that are most relevant for the practice of pediatrics. *Pediatrics* 2011;128:000

INTRODUCTION

Group B streptococcal (GBS) disease has been a leading cause of neonatal morbidity and mortality since the 1970s.^{1,2} Maternal colonization with GBS in the genitourinary or gastrointestinal tract and transmission to the infant during the labor-and-delivery process is the principal risk factor for early-onset invasive GBS disease.³ Women who are identified as being GBS-colonized through culture-based screening are more than 25 times more likely to deliver an infant with early-onset infection than are women with negative prenatal cultures.⁴ Identification of maternal colonization through universal, culture-based screening with intrapartum antibiotic prophylaxis (IAP) for women with positive screening results has been recommended since 2002.⁵ This strategy, endorsed by the American Academy of Pediatrics, has been widely adopted in the United States and has resulted in an estimated 80% decrease in early-onset GBS infection.⁶

TABLE 1 Evidence-Based Rating System Used to Determine Strength of Recommendations

Category	Definition	Recommendation
Strength of recommendation		
A	Strong evidence for efficacy and substantial clinical benefit	Strongly recommended
B	Strong or moderate evidence for efficacy, but only limited clinical benefit	Generally recommended
C	Insufficient evidence for efficacy, or efficacy does not outweigh possible adverse consequences	Optional
D	Moderate evidence against efficacy or for adverse outcome	Generally not recommended
E	Strong evidence against efficacy or for adverse outcome	Never recommended
Quality of evidence supporting recommendation		
I	Evidence from at least 1 well-executed randomized, controlled trial or 1 rigorously designed laboratory-based experimental study that has been replicated by an independent investigator	
II	Evidence from at least 1 well-designed clinical trial without randomization; cohort or case-controlled analytic studies (preferably from more than 1 center); multiple time-series studies; dramatic results from uncontrolled studies; or some evidence from laboratory experiments	
III	Evidence from opinions of respected authorities based on clinical or laboratory experience, descriptive studies, or reports of expert committees	

Adapted with permission from Centers for Disease Control and Prevention. Guidelines for the prevention and treatment of opportunistic infections among HIV-exposed and HIV-infected children: recommendations from CDC, the National Institutes of Health, the HIV Medicine Association of the Infectious Diseases Society of America, the Pediatric Infectious Diseases Society, and the American Academy of Pediatrics. *MMWR Recomm Rep.* 2009;58(RR-11):1–166.

However, even in the era of universal screening, cases of GBS disease continue to occur.^{7–11} To evaluate data published after the Centers for Disease Control and Prevention (CDC) issued guidelines for the prevention of GBS perinatal disease in 2002, the CDC called a meeting of clinical and public health representatives in June 2009. The goal of the meeting was to identify potentially modifiable reasons for continued GBS disease and to address these issues. The American Academy of Pediatrics was represented by members of its Committee on Infectious Diseases and Committee on Fetus and Newborn. The purpose of this policy statement is to review and discuss the differences between the 2002 and 2010 CDC guidelines that are most relevant for the practice of pediatrics. Table 1 outlines the evidence-based rating system that supports each recommendation; strength (indicated by a letter) and quality (indicated by a roman numeral) of evidence are shown in parentheses. The 2010 CDC guidelines can be accessed online (www.cdc.gov/groupbstrep/guidelines/guidelines.html).

LABORATORY DIAGNOSIS OF GBS COLONIZATION

The 2002 guidelines from the CDC recommended universal culture-based screening for GBS at 35 to 37 weeks of gestation. In the intervening years, new diagnostic technologies have been developed, including pigmented enrichment broths, chromogenic agars, DNA probes, and nucleic acid amplification tests (NAATs). These methods have been validated for antenatal testing for GBS colonization and are used in many clinical laboratories, which enables more rapid identification of GBS. A positive test result for GBS by culture, DNA probe, or NAAT performed during antenatal screening indicates colonization, and the woman should receive IAP. However, infants with early-onset GBS can be born to women with negative antenatal screening results, because all laboratory-screening methods are imperfect. Culture-based screening, especially if processing in the laboratory does not always follow the CDC guidelines, may not identify all colonized women.^{7,11} Infants with signs and symptoms of sepsis should be managed according to the neonatal algorithm (Fig 1) and receive an initial antibiotic reg-

imen that includes ampicillin regardless of maternal screening results.

Recommendations

- Options for GBS identification from culture of maternal vaginal/rectal swabs have been expanded to include a positive identification from chromogenic agar media. Identification of GBS directly by nucleic acid amplification tests (NAATs), such as commercially available polymerase chain reaction assays, can also be used after broth enrichment if laboratories have validated their NAAT performance and instituted appropriate quality controls (CII).

INTRAPARTUM ANTIBIOTIC PROPHYLAXIS

Penicillin and ampicillin have each been demonstrated in controlled clinical trials to be effective in preventing early-onset GBS disease when administered during labor.^{12,13} Penicillin and ampicillin at the recommended dosages for IAP rapidly achieve therapeutic concentrations in the fetal circulation and then amniotic fluid. Cefazolin has similar pharmacokinetics when compared with penicillin, and IAP dos-

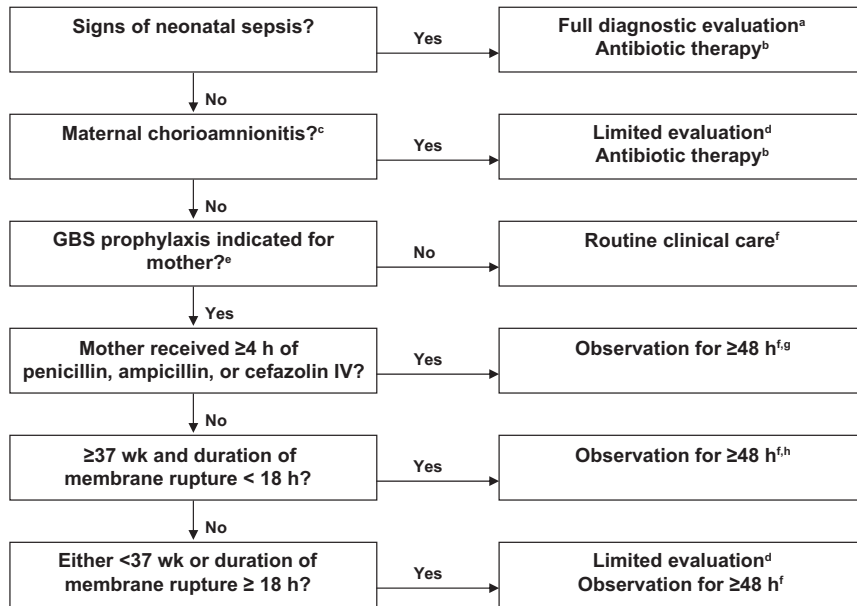


FIGURE 1

Algorithm for the prevention of early-onset GBS infection in the newborn. (Adapted with permission from Centers for Disease Control and Prevention. Prevention of perinatal group B streptococcal disease: prevention of perinatal group B streptococcal disease from CDC, 2010. *MMWR Recomm Rep*. 2010;59[RR-10]:1–32.) ^a Full diagnostic evaluation includes a blood culture; CBC count, including white blood cell differential and platelet counts; chest radiograph (if respiratory abnormalities are present); and lumbar puncture (if the patient is stable enough to tolerate procedure and sepsis is suspected). ^b Antibiotic therapy should be directed toward the most common causes of neonatal sepsis, including intravenous ampicillin for GBS and coverage for other organisms (including *Escherichia coli* and other Gram-negative pathogens) and should take into account local antibiotic-resistance patterns. ^c Consultation with obstetric providers is important in determining the level of clinical suspicion for chorioamnionitis. Chorioamnionitis is diagnosed clinically, and some of the signs are nonspecific. ^d Limited evaluation includes blood culture (at birth) and CBC count with differential and platelets (at birth and/or at 6–12 hours of life). ^e GBS prophylaxis is indicated if 1 or more of the following is true: (1) mother is GBS-positive within the preceding 5 weeks; (2) GBS status is unknown and there are 1 or more intrapartum risk factors, including <37 weeks' gestation, rupture of membranes for ≥18 hours, or temperature of ≥100.4°F (38.0°C); (3) GBS bacteriuria during current pregnancy; or (4) history of a previous infant with GBS disease. ^f If signs of sepsis develop, a full diagnostic evaluation should be performed, and antibiotic therapy should be initiated. ^g If at ≥37 weeks' gestation, observation may occur at home after 24 hours if other discharge criteria have been met, there is ready access to medical care, and a person who is able to comply fully with instructions for home observation will be present. If any of these conditions is not met, the infant should be observed in the hospital for at least 48 hours and until discharge criteria have been achieved. ^h Some experts recommend a CBC count with differential and platelets at 6 to 12 hours of age.²⁴ IV indicates intravenously.

ing achieves high intra-amniotic concentrations.^{14–16} Cefazolin has been the preferred alternative for IAP for penicillin-allergic women at low risk of anaphylaxis since 2002, although it has been used uncommonly for this indication. At least 4 hours of IAP with one of these β -lactam antibiotics is effective in preventing early-onset GBS disease in neonates. The definition of adequate IAP has been clarified to include penicillin, ampicillin, or cefazolin for at least 4 hours before delivery. Duration

of IAP shorter than 4 hours and all other regimens, including clindamycin and vancomycin, are considered to be inadequate prophylaxis for infants because of lack of data regarding efficacy and limited data regarding favorable pharmacokinetics. No clinical trials have evaluated the efficacy of non- β -lactam regimens for IAP in women with serious penicillin allergy. Although clindamycin is the most commonly chosen IAP regimen in the United States for penicillin-allergic

women at low risk of anaphylaxis, current data indicate that approximately 20% of GBS isolates are resistant to clindamycin. Clindamycin should never be used for IAP if susceptibility testing of the mother's GBS isolate has not been performed. Several recent studies have revealed that susceptibility testing is rarely performed on GBS isolates,^{5,6,17} and early-onset GBS disease has been reported in infants born to mothers who have received clindamycin IAP.^{11,17}

Recommendations

- Penicillin remains the agent of choice for IAP, and ampicillin is an acceptable alternative (AI).
- Penicillin-allergic women who do not have a history of anaphylaxis, angioedema, respiratory distress, or urticaria after administration of penicillin or a cephalosporin should receive cefazolin (BII).
- Penicillin-allergic women at high risk of anaphylaxis should receive clindamycin if their GBS isolate is susceptible or vancomycin if their GBS isolate is intrinsically resistant to clindamycin (CIII).
- The definition of adequate IAP has been clarified to be at least 4 hours of penicillin, ampicillin, or cefazolin. The initial intravenous dose of penicillin is 5 million units; for ampicillin and cefazolin, the initial dose is 2 g (AIII).
- All other antibiotics, doses, or durations are considered inadequate for the purposes of neonatal management (AIII).

PREVENTION OF EARLY-ONSET GBS DISEASE

The revised 2010 GBS American Academy of Pediatrics guidelines for neonatal management were designed to broaden the scope to include all neonates, to increase the clarity of the recommendations, and to decrease un-

necessary laboratory evaluations and empirical antibiotics for infants at low risk. Although this strategy will never prevent all infections, the revised guidelines should result in a further decrease in cases of perinatal GBS disease. The management of neonates continues to be based on clinical signs, the presence of maternal risk factors for GBS neonatal disease, and the likely efficacy of IAP (or maternal antimicrobial treatment in the case of clinical or occult chorioamnionitis) in preventing early-onset disease. The revised infant management algorithm (Fig 1) is derived from recent data summarized in the published CDC document regarding the epidemiology of GBS disease and the usefulness of a “limited evaluation” of well-appearing neonates.

All newborn infants with signs suggestive of sepsis should have a full diagnostic evaluation, including a lumbar puncture if the infant is stable enough to undergo the procedure; 15% to 38% of infants with early-onset meningitis have sterile blood cultures, so evaluating the cerebrospinal fluid is required for optimal diagnostic sensitivity.^{18–21} If the care provider believes that a non-infectious condition is responsible for the infant’s signs (eg, transient tachypnea of the newborn) and there are no maternal risk factors for sepsis in an otherwise well-appearing infant, the lumbar puncture can be deferred or eliminated. Empirical antimicrobial therapy, typically intravenous ampicillin and gentamicin (unless local antibiotic-resistance patterns suggest the need for another combination), then should be initiated promptly. Chorioamnionitis continues to be a significant risk factor for early-onset GBS sepsis in infants born to GBS-colonized women. All well-appearing newborn infants born to women who have a clinical diagnosis of chorioamnionitis from their obstetric provider should un-

dergo a “limited evaluation,” which includes a complete blood cell (CBC) count and differential and a blood culture before initiation of empirical antimicrobial therapy. The sensitivity of the CBC count is improved if delayed for 6 to 12 hours after birth. Empirical therapy should be discontinued as soon as the clinical course and laboratory evaluation exclude sepsis.

The indications for maternal IAP remain unchanged and include 1 of more of the following: (1) GBS culture–positive within preceding 5 weeks; (2) GBS status unknown with 1 or more intrapartum risk factors including less than 37 weeks’ gestation, prolonged rupture of membranes for ≥ 18 hours, or temperature of $\geq 100.4^{\circ}\text{F}$ (38.0°C); (3) GBS bacteriuria during current pregnancy; and (4) history of a previous infant with GBS disease. When a cesarean delivery is performed before onset of labor with intact amniotic membranes, the risk of early-onset GBS disease among infants is extremely low^{22,23}; therefore, IAP is not recommended as a routine practice for cesarean deliveries performed under these circumstances, regardless of the GBS colonization status of the woman or the gestational age of the infant.

In well-appearing newborn infants born to women without an indication for IAP, routine clinical care is indicated unless signs of sepsis develop. For well-appearing term newborn infants born to mothers with an indication for IAP to prevent GBS disease and receipt of 4 or more hours of penicillin, ampicillin or cefazolin at the appropriate doses before delivery, routine care, and 48 hours of observation continue to be recommended. However, if these infants meet other discharge criteria, including term birth and ready access to medical care, discharge can occur as early as 24 hours after birth. In

this latter circumstance, follow-up care by a care provider within 48 to 72 hours is recommended.

In well-appearing term newborn infants whose mothers had an indication for GBS prophylaxis and rupture of membranes for < 18 hours but who received inadequate IAP—either by duration before delivery or by inappropriate agent or dose—observation in the hospital for at least 48 hours is recommended. These infants would include infants born to women with a serious penicillin allergy who received either clindamycin or vancomycin. This revised recommendation is based on the poor sensitivity of the “limited-evaluation” assessments in this circumstance and also data indicating that signs of early-onset GBS sepsis appear in more than 98% of neonates within this interval of hospitalization. The authors of several studies have reported the sensitivity of an abnormal CBC count in predicting GBS sepsis to range from 41% to 68%, whereas the presence of clinical signs has a sensitivity of 92%.^{24–27} The yield of blood culture can be low among newborn infants exposed to intrapartum antibiotics.²⁸ Finally, for all preterm neonates (< 37 weeks of gestation) or for term newborn infants born in the setting of rupture of membranes 18 hours or more before delivery without adequate maternal IAP, a limited evaluation and observation for at least 48 hours is recommended.

Recommendations for Management of Newborn Infants

- All newborn infants with signs of sepsis should undergo a full diagnostic evaluation (including a lumbar puncture) and receive empirical antimicrobial therapy (AII).
- All well-appearing newborn infants born to women given a diagnosis of chorioamnionitis by their obstetrical provider should undergo a

limited diagnostic evaluation (no lumbar puncture) and receive empirical antimicrobial therapy (AII).

- For all women who received adequate IAP defined as penicillin (preferred), ampicillin, or cefazolin (penicillin-allergic women at low risk of anaphylaxis) for 4 or more hours before delivery, their newborn infants require only routine care and observation in the hospital for 48 hours (BIII). If these infants meet other discharge criteria, including term birth and ready access to medical care, discharge can occur as early as 24 hours after birth with follow-up care by a care provider within 48 to 72 hours (CII).
- Well-appearing term newborn infants whose mothers received no or inadequate IAP (including clindamycin or vancomycin) and had rupture of membranes for less than 18 hours require only observation for 48 hours (BIII).
- Well-appearing term infants born to women with no or inadequate IAP and rupture of membranes for 18 or more hours before delivery should undergo a “limited evaluation” (ie, blood culture and CBC count with differential and platelets at birth) and observation for at least 48 hours (BIII).

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- All preterm infants born to women with no or inadequate IAP should undergo a limited evaluation and observation for at least 48 hours (BIII).

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Pediatrics originally published online August 1, 2011;

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Pediatrics originally published online August 1, 2011;

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