The American College of Obstetricians and Gynecologists
Women's Health Care Physicians

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COMMITTEE OPINION

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(Reaffirmed 2016)

Committee on Obstetric Practice

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Prevention of Early-Onset Group B Streptococcal Disease in Newborns

ABSTRACT: In 2010, the Centers for Disease Control and Prevention revised its guidelines for the prevention of perinatal group B streptococcal disease. Although universal screening at 35–37 weeks of gestation and intrapartum antibiotic prophylaxis continue to be the basis of the prevention strategy, these new guidelines contain important changes for clinical practice. The Committee on Obstetric Practice endorses the new Centers for Disease Control and Prevention recommendations, and recognizes that even complete implementation of this complex strategy will not eliminate all cases of early-onset group B streptococcal disease.

Implementation of national guidelines for intrapartum antibiotic prophylaxis since the 1990s has resulted in an approximate 80% reduction in the incidence of early-onset neonatal sepsis due to group B streptococci (GBS). Yet, GBS remains the leading cause of infectious mortality and morbidity among newborns (1). In 2010, the Centers for Disease Control and Prevention (CDC), in collaboration with several professional groups, including the American College of Obstetricians and Gynecologists, issued its third set of GBS prevention guidelines (1). Although universal screening at 35–37 weeks of gestation and intrapartum antibiotic prophylaxis continue to be the basis of the prevention strategy, these new guidelines contain important changes for clinical practice (Table 1), including the following:

- Expanded recommendations on laboratory methods for identification of GBS
- Clarification of the inoculum required for reporting GBS detected in the urine of pregnant women
- Updated algorithms for GBS screening and intrapartum antibiotic prophylaxis for women with preterm labor or preterm premature rupture of membranes (PROM)
- A change in the recommended dosage of penicillin-G for intrapartum antibiotic prophylaxis
- Updated intrapartum antibiotic prophylaxis regimens for women with penicillin allergy
- A revised algorithm for management of newborns with respect to risk of early-onset group B streptococcal disease

The Committee on Obstetric Practice endorses the new CDC recommendations and recognizes that even complete implementation of this complex strategy will not eliminate all cases of early-onset group B streptococcal disease.

Background

Group B streptococci, also known as *Streptococcus agalactiae*, emerged as an important cause of perinatal morbidity and mortality in the 1970s (2, 3). Between 10% and 30% of pregnant women are colonized with GBS in the vagina or rectum (4–7). The organism may cause maternal urinary tract infection, amnionitis, endometritis, sepsis, or, rarely, meningitis (8–13). Invasive group B streptococcal disease in the newborn is characterized primarily by sepsis and pneumonia, or, less frequently, meningitis (1).

Vertical transmission of GBS during labor or delivery may result in invasive infection in the newborn during the first week of life, known as early-onset group B streptococcal infection. Since the early 1990s, national guidelines have resulted in an 80% decrease in the incidence of early-onset group B streptococcal sepsis, from 1.7 cases to less than 0.4 cases per 1,000 live births (1). As expected, the guidelines have had no effect on late-onset disease

Table 1. Comparison of Key Points in the 2002 and 2010 Centers for Disease Control and Prevention Guidelines for the Prevention of Perinatal Group B Streptococcal Disease

Topic in the Guidelines	Key Points Unchanged From 2002	Key Points Changed From 2002
Universal screening for GBS	Universal screening at 35–37 weeks of gestation remains the sole strategy for IAP.	Permissive statement for limited role of nucleic acid amplification tests for intrapartum testing for GBS
Preterm delivery		New and separate algorithms for preterm labor and for preterm PROM (see Fig. 1 and Fig. 2)
GBS specimen collection and processing	Rectovaginal swab specimens collected at 35–37 weeks of gestation remains the recommendation.	Transport options clarified Identification options expanded to include use of chromogenic media and nucleic acid amplification tests. Laboratories to report GBS in concentrations of greater than or equal to 104 CFU in urine culture specimens (previously, it was GBS "in any concentration")
Intrapartum antibiotic prophylaxis	Penicillin remains drug of choice, with ampicillin as an alternative. Cefazolin remains the drug of choice for penicillin allergy without anaphylaxis, angioedema, respiratory distress, or urticaria. GBS isolates from women at high risk of anaphylaxis should be tested for susceptibility to clindamycin and erythromycin. Vancomycin use is recommended if isolate is resistant to either clindamycin or erythromycin.	Definition of high risk for anaphylaxis is clarified. Minor change in penicillin dose permitted Erythromycin is no longer recommended under any circumstances. D-test recommended to detect inducible resistance in isolates tested for susceptibility to clindamycin and erythromycin
Other obstetric management issues		Data are not sufficient to make recommendations regarding the timing of procedures intended to facilitate progression of labor, such as amniotomy, in GBS-colonized women. Intrapartum antibiotic prophylaxis is optimal if administered at least 4 hours before delivery; therefore, such procedures should be timed accordingly, if possible. No medically necessary obstetric procedure should be delayed in order to achieve 4 hours of GBS prophylaxis before delivery.
Newborn management		Algorithm now applies to all newborns, whether or not from GBS-positive mothers. Clarification of "adequate" IAP. See full CDC guidelines for details.

Abbreviations: CDC, Centers for Disease Control and Prevention; CFU, colony-forming units; GBS, group B streptococci; IAP, intrapartum antibiotic prophylaxis; PROM, premature rupture of membranes.

Data 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.

(defined as occurring in infants older than 6 days). The 2010 CDC guidelines focus on the prevention of early-onset group B streptococcal disease.

Factors Associated With Early-Onset Disease

The primary risk factor for early-onset group B streptococcal infection is maternal intrapartum rectovaginal colonization with GBS (1). Other clinical risk factors include gestational age of less than 37 weeks, prolonged rupture of membranes, intra-amniotic infection, young maternal age, and black race (1). Neonates born to women who have previously given birth to a GBS-infected newborn (14–16) or who have heavy GBS colonization, such as that seen with group B streptococcal bacteriuria, are at increased risk of neonatal infection (1, 17–21).

Identifying Candidates for Intrapartum Antibiotic Prophylaxis

The 2010 CDC guidelines recommend a universal culture-based strategy for identifying candidates for GBS intrapartum antibiotic prophylaxis. Screening of all women at 35–37 weeks of gestation is conducted by obtaining a single swab specimen from the lower vagina (introitus) and rectum (through the anal sphincter), placing the swab in transport media, and using selective broth media (see Box 1). All women in whom cultures are positive for GBS are to be given intrapartum antibiotic prophylaxis in labor unless a cesarean delivery is performed before onset of labor in a woman with intact amniotic membranes. Cultures for GBS are not required in women who have group B streptococcal bacteriuria during the current pregnancy or who have previously given birth to a neonate with early-onset group B streptococcal disease because these women should receive intrapartum antibiotic prophylaxis. If at any time during pregnancy group B streptococcal bacteriuria is detected, antibiotics should be administered (1). Because women who had GBS colonization during a previous pregnancy are likely not to be colonized during subsequent pregnancies, they require culture evaluation for GBS with each pregnancy but not intrapartum antibiotic prophylaxis unless there is an indication for GBS prophylaxis during the current pregnancy.

The new guidelines provide updated algorithms for screening for GBS and intrapartum antibiotic prophylaxis for women with preterm labor or preterm premature rupture of membranes (PROM) (Fig. 1 and Fig. 2). Intrapartum antibiotic prophylaxis is to be administered to women with unknown culture status who are in preterm labor with significant risk of imminent delivery or who have preterm PROM, rupture of membranes for 18 or more hours, or intrapartum fever (temperature greater than or equal to 100.4°F or greater than or equal to 38°C) (Table 2).

Box 1. Procedures for Collecting Clinical Specimens for Culture of Group B Streptococci at 35–37 Weeks of Gestation

- Swab the lower vagina (vaginal introitus), followed by the rectum (ie, insert swab through the anal sphincter) using the same swab or two different swabs. Cultures should be collected in the outpatient setting by the health care provider or, with appropriate instruction, the patient herself. Cervical, perianal, perirectal, or perineal specimens are not acceptable, and a speculum should not be used for culture collection.
- Place the swab(s) into a nonnutritive transport medium. Appropriate transport systems (eg, Stuart or Amies media with or without charcoal) are commercially available. Group B streptococci isolates can remain viable in transport media for several days at room temperature; however, the recovery of isolates declines over 1–4 days, especially at elevated temperatures, which can lead to false-negative test results.
- Specimen requisitions should clearly indicate that specimens are for group B streptococci culture.
- Patients who state they are allergic to penicillin should be evaluated for risk of anaphylaxis. If a woman is determined to be at high-risk of anaphylaxis*, susceptibility testing for clindamycin and erythromycin should be ordered.

*Patients with a history of any of the following after receiving penicillin or a cephalosporin are considered to be at high risk of anaphylaxis: anaphylaxis, angioedema, respiratory distress, and urticaria.

Data 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.

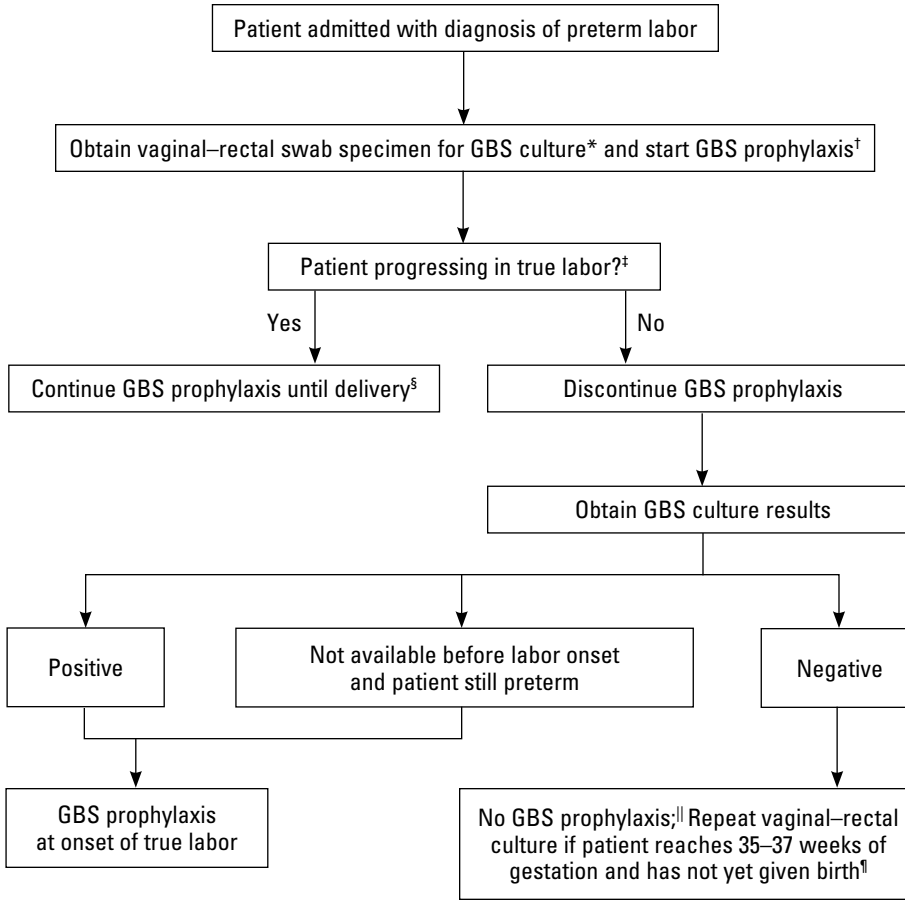
Intrapartum Antibiotic Prophylactic Agents

Penicillin remains the agent of choice for intrapartum prophylaxis, with ampicillin as an acceptable alternative (Fig. 3). In view of increasing rates of resistance of GBS to erythromycin (up to 32% or more for invasive isolates), erythromycin is no longer recommended. Group B streptococci may show either inducible or intrinsic resistance to clindamycin. Inducible resistance is detected by the D-test, which tests the isolate for resistance to both clindamycin and erythromycin. Clindamycin continues to be recommended only if the isolate is susceptible to both clindamycin and erythromycin, or if the isolate is sensitive to clindamycin and the D-zone test result for inducible resistance is negative (1). Intravenous administration is the route recommended for intrapartum GBS prophylaxis. No oral or intramuscular regimen has been shown to be effective (1).

Intrapartum Antibiotic Prophylaxis

The benefit of prevention of group B streptococcal early-onset infection in the newborn greatly outweighs the risk to the woman and her fetus of maternal allergic reactions to antibiotics during labor. Allergic reactions occur in an estimated 0.7–4% of all treatment courses with penicillin, with the risk of anaphylaxis estimated at 4/10,000–4/100,000 recipients (1). The Committee agrees with the CDC that local health agencies should establish surveillance systems to monitor the incidence of early-onset neonatal group B streptococcal disease, the emergence of infection in women and their newborns that is caused by resistant organisms, and other complications of widespread maternal antibiotic administration, such as severe allergic reactions.

The Committee believes that when culture results are not available, intrapartum antibiotic prophylaxis should be offered only on the basis of the presence of intrapartum



*If patient has undergone vaginal–rectal GBS culture within the preceding 5 weeks, the results of that culture should guide management. GBS-colonized women should receive intrapartum antibiotic prophylaxis. No antibiotics are indicated for GBS prophylaxis if the result of a vaginal–rectal screen within 5 weeks was negative.

†See Figure 3 for recommended antibiotic regimens.

‡Patient should be regularly assessed for progression to true labor; if the patient is considered not to be in true labor, discontinue GBS prophylaxis.

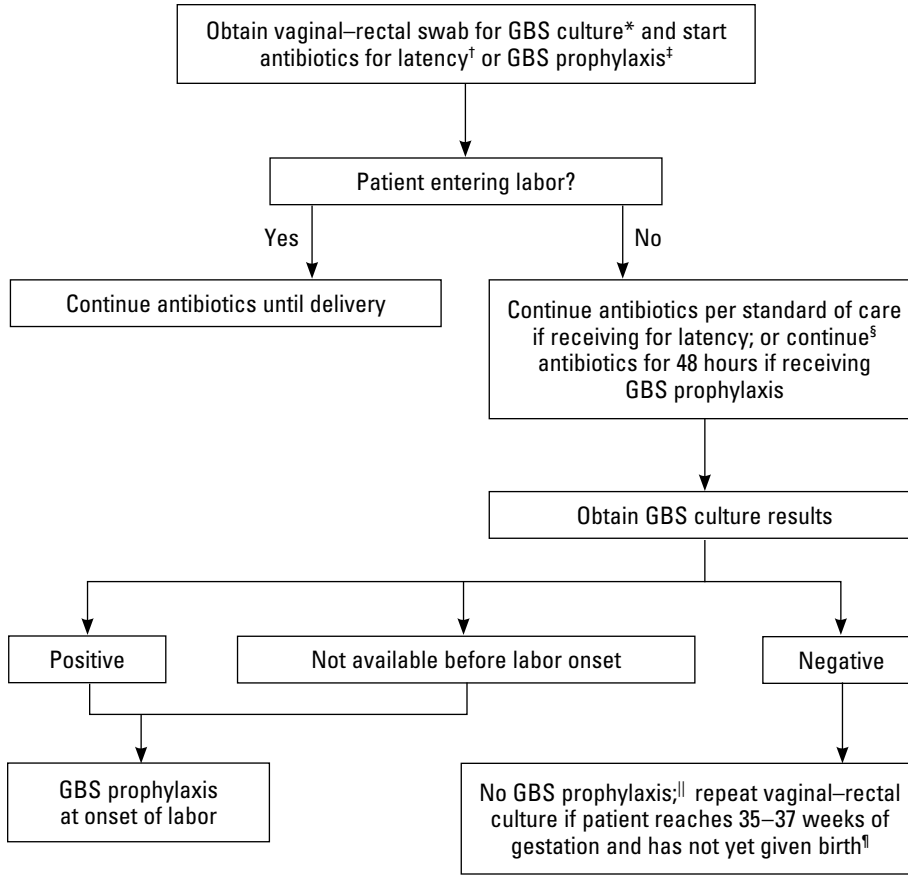
§If GBS culture results become available before delivery and are negative, then discontinue GBS prophylaxis.

‖Unless subsequent GBS culture result before delivery is positive

¶A negative GBS screen result is considered valid for 5 weeks. If a patient with a history of preterm labor is readmitted with signs and symptoms of preterm labor and had a negative GBS screen result more than 5 weeks prior, she should be rescreened and managed according to this algorithm at that time.

Data 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.

Figure 1. Algorithm for group B streptococci intrapartum prophylaxis for women with preterm labor. Abbreviation: GBS, group B streptococci.



*If patient has undergone vaginal–rectal GBS culture within the preceding 5 weeks, the results of that culture should guide management. GBS-colonized women should receive intrapartum antibiotic prophylaxis. No antibiotics are indicated for GBS prophylaxis if the result of a vaginal–rectal screen within 5 weeks was negative.

†Antibiotics given for latency in the setting of preterm premature rupture of membranes that include ampicillin, 2 g intravenously once, followed by 1 g intravenously every 6 hours for at least 48 hours are adequate for GBS prophylaxis. If other regimens are used, GBS prophylaxis should be initiated in addition.

‡See Figure 3 for recommended antibiotic regimens.

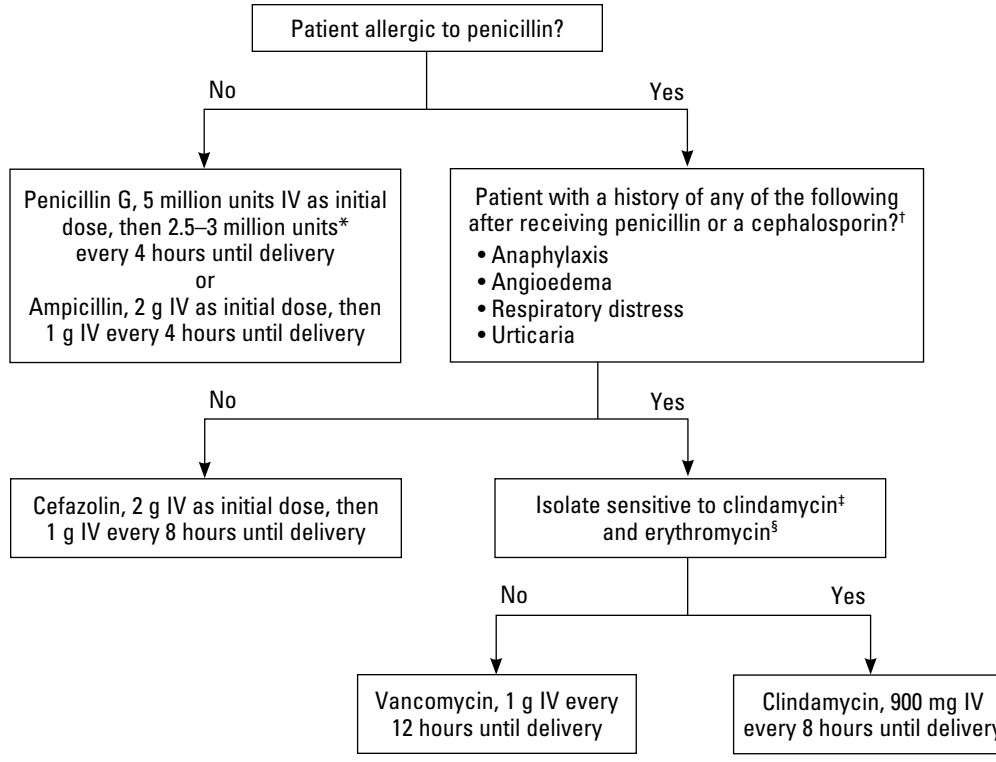
§GBS prophylaxis should be discontinued at 48 hours for women with preterm premature rupture of membranes who are not in labor. If results from a GBS screen performed on admission become available during the 48-hour period and are negative, GBS prophylaxis should be discontinued at that time.

‖Unless subsequent GBS culture result before delivery is positive

¶A negative GBS screen result is considered valid for 5 weeks. If a patient with preterm premature rupture of membranes is entering labor and had a negative GBS screen result more than 5 weeks prior, she should be rescreened and managed according to this algorithm at that time.

Data 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.

Figure 2. Algorithm for group B streptococci intrapartum prophylaxis for women with preterm premature rupture of membranes. Abbreviation: GBS, group B streptococci.



*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.

†Penicillin-allergic patients with a history of anaphylaxis, angioedema, respiratory distress, or urticaria following administration of penicillin or a cephalosporin are considered to be at high risk of anaphylaxis and should not receive penicillin, ampicillin, or cefazolin for group B streptococci (GBS) intrapartum prophylaxis. For penicillin-allergic patients who do not have a history of those reactions, cefazolin is the preferred agent because pharmacologic data suggest it achieves effective intra-amniotic concentrations. Vancomycin and clindamycin should be reserved for penicillin-allergic women at high risk of anaphylaxis.

‡If laboratory facilities are adequate, clindamycin and erythromycin susceptibility testing should be performed on prenatal GBS isolates from penicillin-allergic women at high risk of anaphylaxis. If no susceptibility testing is performed, or the results are not available at the time of labor, vancomycin is the preferred agent for GBS intrapartum prophylaxis for penicillin-allergic women at high risk of anaphylaxis.

§Resistance to erythromycin is often but not always associated with clindamycin resistance. If an isolate is resistant to erythromycin, it may have inducible resistance to clindamycin, even if it appears susceptible to clindamycin. If a GBS isolate is susceptible to clindamycin, resistant to erythromycin, and D-zone testing for inducible resistance has been performed and the result is negative (no inducible resistance), then clindamycin can be used for GBS intrapartum prophylaxis instead of vancomycin.

Data 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.

Figure 3. Recommended regimens for intrapartum antibiotic prophylaxis for prevention of early-onset group B streptococcal disease (broader spectrum agents, including an agent active against group B streptococci, may be necessary for treatment of chorioamnionitis). Abbreviation: IV, intravenously.

Table 2. Indications and Nonindications for Intrapartum Antibiotic Prophylaxis to Prevent Early-Onset Group B Streptococcal Disease

Intrapartum GBS Prophylaxis Indicated	Intrapartum GBS Prophylaxis not Indicated
Previous infant with invasive GBS disease	Colonization with GBS during a previous pregnancy (unless an indication for GBS prophylaxis is present for current pregnancy)
GBS bacteriuria during any trimester of the current pregnancy	GBS bacteriuria during previous pregnancy (unless another indication for GBS prophylaxis is present for current pregnancy)
Positive GBS screening culture during current pregnancy* (unless a cesarean delivery, is performed before onset of labor on a woman with intact amniotic membranes)	Cesarean delivery performed before onset of labor on a woman with intact amniotic membranes, regardless of GBS colonization status or gestational age
Unknown GBS status at the onset of labor (culture not done, incomplete, or results unknown) and any of the following: • Delivery at less than 37 weeks of gestation† • Amniotic membrane rupture greater than or equal to 18 hours • Intrapartum temperature greater than or equal to 100.4°F (greater than or equal to 38.0°C)‡ • Intrapartum NAAT§ positive for GBS	Negative vaginal and rectal GBS screening culture result in late gestation* during the current pregnancy, regardless of intrapartum risk factors

Abbreviations: GBS, group B streptococci; NAAT, nucleic acid amplification test.

*Optimal timing for prenatal GBS screening is at 35–37 weeks of gestation.

† Recommendations for the use of intrapartum antibiotics for prevention of early-onset GBS disease in the setting of preterm delivery are presented in Figure 3.

‡ If amnionitis is suspected, broad-spectrum antibiotic therapy that includes an agent known to be active against GBS should replace GBS prophylaxis.

§ NAAT testing for GBS is optional and may not be available in all settings. If intrapartum NAAT result is negative for GBS but any other intrapartum risk factor (delivery at less than 37 weeks of gestation, amniotic membrane rupture at 18 hours or more, or temperature greater than or equal to 100.4°F [greater than or equal to 38.0°C]) is present, then intrapartum antibiotic prophylaxis is indicated.

Data 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.

risk factors for early-onset group B streptococcal disease (Table 2). The Committee strongly recommends against administering intrapartum antibiotic prophylaxis to a woman with rupture of membranes for 18 hours or more with a culture negative for GBS at 35–37 weeks of gestation; antibiotics should be administered after 18 hours of ruptured membranes only when GBS culture results are not known. In these clinical scenarios, antibiotics should be administered only if there is chorioamnionitis or other indications, such as pyelonephritis.

Preterm Labor and Preterm Premature Rupture of Membranes

The Committee supports the revised algorithms for management of women with preterm labor and for preterm PROM (Fig. 1 and Fig. 2). The Committee concurs with the CDC that intrapartum prophylaxis for GBS is not recommended for women undergoing a planned cesarean delivery in the absence of labor and rupture of membranes, regardless of the gestational age, even among GBS-positive women. All patients undergoing cesarean delivery should have prophylactic antibiotics administered before the incision to reduce the risk of postoperative infections (23). Patients expected to have planned cesarean deliveries should nonetheless undergo culture screening at 35–37 weeks of gestation because onset of labor or rupture of membranes may occur before the planned cesarean delivery.

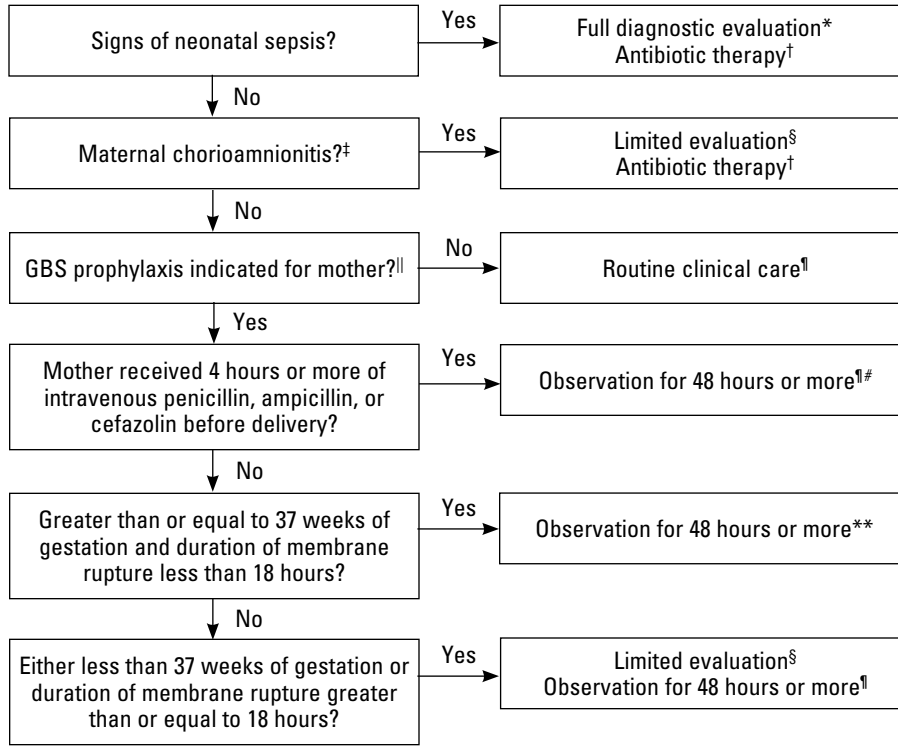
Obstetric Management

The Committee has insufficient data to support or discourage the use of scalp electrodes or fetal scalp and blood pH determinations in women known to be GBS colonized. Furthermore, the risks of membrane stripping in GBS-colonized women have not been investigated; therefore, data are insufficient to encourage or discourage this practice in these women.

Specimen Collection and Processing

Laboratories must process GBS cultures correctly using the recommended selective broth media for results to be accurate. Culture specimens should be collected by swabbing the lower vagina (not by speculum examination) and rectum (ie, through the anal sphincter), to maximize the likelihood of GBS recovery (see Box 1). The new guidelines provide expanded recommendations for lab-

oratory methods for the identification of GBS, with the options of using pigmented broth or DNA probe, latex agglutination, or nucleic acid amplification test (NAAT) after incubation for 18–24 hours. However, use of NAAT to detect GBS directly from rectovaginal specimens (ie, without incubation of the specimen for 18–24 hours) has a very limited role. In settings where NAAT is available for GBS detection, obstetric providers can choose to perform intrapartum testing on rectovaginal specimens when the GBS culture status is unknown and when there are no intrapartum risk factors (temperature greater than or equal to 100.4°F [greater than or equal to 38.0°C] or duration of rupture of membranes for 18 hours or more) at the time of testing and when the patient is at term. Women with a positive intrapartum NAAT result for GBS should receive intrapartum antibiotic prophylaxis. If an intrapartum risk factor develops subsequent to the test, intrapartum antibiotic prophylaxis should be given regardless of the NAAT results (ie, even if the NAAT result was negative) (1).



*Full diagnostic evaluation includes a blood culture, a complete blood count, including white blood cell differential, platelet counts, chest radiograph (if respiratory abnormalities are present), and lumbar puncture (if patient is stable enough to tolerate procedure and sepsis is suspected).

†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.

‡Consultation with obstetric providers is important to determine the level of clinical suspicion for chorioamnionitis. Chorioamnionitis is diagnosed clinically and some of the signs are nonspecific.

§Limited evaluation includes blood culture (at birth), and complete blood count with differential and platelets (at birth or at 6–12 hours of life or both).

‖GBS prophylaxis is indicated if one or more of the following is present: 1) mother is GBS positive within preceding 5 weeks; 2) GBS status unknown, with one or more intrapartum risk factors, including less than 37 weeks of gestation, duration of rupture of membranes for 18 hours or more, or temperature greater than or equal to 100.4°F (greater than or equal to 38.0°C); 3) group B streptococcal bacteriuria during current pregnancy; 4) history of a previous infant with group B streptococcal disease.

¶If signs of sepsis develop, a full diagnostic evaluation should be conducted and antibiotic therapy initiated.

#If greater than or equal to 37 weeks of gestation, observation may occur at home after 24 hours if other discharge criteria have been met, access to medical care is readily available, 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 are achieved.

**Some experts recommend a complete blood count with differential and platelets at 6–12 hours of age.

Data 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.

Figure 4. Algorithm for secondary prevention of early-onset group B streptococcal disease among newborns. Abbreviation: GBS, group B streptococci.

Management of Neonates

The new guidelines provide a revised algorithm for the prevention of early-onset group B streptococcal disease among neonates (Fig. 4). These may be accessed in the full CDC guidelines, which are available at http://www.cdc.gov/groupbstrep/guidelines/provisional-recs.htm.

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In "Committee Opinion No. 485: Prevention of Early-Onset Group B Streptococcal Disease in Newborns" from the American College of Obstetricians and Gynecologists, there is an error on page 2 in Table 1. In the "Key Points Changed From 2002" column, the last sentence in the "GBS specimen collection and processing" category incorrectly reads, "Laboratories to report GBS in concentrations of greater than or equal to 104 CFU" and should instead read, "Laboratories to report GBS in concentrations of greater than or equal to 10^4 CFU." The full, corrected sentence is as follows: "Laboratories to report GBS in concentrations of greater than or equal to 10^4 CFU in urine culture specimens (previously, it was GBS 'in any concentration')."