INTERIM UPDATE

ACOG COMMITTEE OPINION SUMMARY

Number 797

(Replaces Committee Opinion No. 782, June 2019)

For a comprehensive overview of these recommendations, the full-text version of this Committee Opinion is available at http://dx.doi.org/10.1097/AOG.0000000000003668.

Committee on Obstetric Practice

The American Academy of Pediatrics, the American College of Nurse-Midwives, the Association of Women’s Health, Obstetric and Neonatal Nurses, and the Society for Maternal-Fetal Medicine endorse this document. Although the American Society for Microbiology cannot endorse this document because the content is outside the organization’s scope, they have reviewed the document. This Committee Opinion was developed by the American College of Obstetricians and Gynecologists (ACOG) Committee on Obstetric Practice in collaboration with the American College of Nurse-Midwives liaison member Tekoa L. King, CNM, MPH; ACOG Committee on Obstetric Practice committee member Neil S. Silverman, MD; and ACOG Committee on Practice Bulletins-Obstetrics committee member Mark Turrentine, MD.

INTERIM UPDATE: The content in this Committee Opinion has been updated as highlighted (or removed as necessary) to reflect a limited, focused change in the language regarding penicillin allergy testing, categories for penicillin (ie, low-risk and high-risk of anaphylaxis or severe reaction) (Table 2), and penicillin dose (Figure 3).

Prevention of Group B Streptococcal Early-Onset Disease in Newborns

ABSTRACT: Group B streptococcus (GBS) is the leading cause of newborn infection. The primary risk factor for neonatal GBS early-onset disease (EOD) is maternal colonization of the genitourinary and gastrointestinal tracts. Approximately 50% of women who are colonized with GBS will transmit the bacteria to their newborns. Vertical transmission usually occurs during labor or after rupture of membranes. In the absence of intrapartum antibiotic prophylaxis, 1–2% of those newborns will develop GBS EOD. Other risk factors include gestational age of less than 37 weeks, very low birth weight, prolonged rupture of membranes, intraamniotic infection, young maternal age, and maternal black race. The key obstetric measures necessary for effective prevention of GBS EOD continue to include universal prenatal screening by vaginal–rectal culture, correct specimen collection and processing, appropriate implementation of intrapartum antibiotic prophylaxis, and coordination with pediatric care providers. The American College of Obstetricians and Gynecologists now recommends performing universal GBS screening between 36 0/7 and 37 6/7 weeks of gestation. All women whose vaginal–rectal cultures at 36 0/7–37 6/7 weeks of gestation are positive for GBS should receive appropriate intrapartum antibiotic prophylaxis unless a prelabor cesarean birth is performed in the setting of intact membranes. Although a shorter duration of recommended intrapartum antibiotics is less effective than 4 or more hours of prophylaxis, 2 hours of antibiotic exposure has been shown to reduce GBS vaginal colony counts and decrease the frequency of a clinical neonatal sepsis diagnosis. Obstetric interventions, when necessary, should not be delayed solely to provide 4 hours of antibiotic administration before birth. 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.”
Recommendations and Conclusions

Key components of screening and prophylaxis for Group B streptococcal (GBS) early-onset neonatal disease include:

- Targeted intravenous intrapartum antibiotic prophylaxis has demonstrated efficacy for prevention of GBS early-onset disease (EOD) in neonates born to women with positive antepartum GBS cultures and women who have other risk factors for intrapartum GBS colonization. Neither antepartum nor intrapartum oral or intramuscular regimens have been shown to be comparably effective in reducing GBS EOD.

- Regardless of planned mode of birth, all pregnant women should undergo antepartum screening for GBS at 36 0/7–37 6/7 weeks of gestation, unless intrapartum antibiotic prophylaxis for GBS is indicated because of GBS bacteriuria during the pregnancy or because of a history of a previous GBS-infected newborn. This new recommended timing for screening provides a 5-week window for valid culture results that includes births that occur up to a gestational age of at least 41 0/7 weeks.

- All women whose vaginal–rectal cultures at 36 0/7–37 6/7 weeks of gestation are positive for GBS should receive appropriate intrapartum antibiotic prophylaxis unless a prelabor cesarean birth is performed in the setting of intact membranes.

- Women with a positive prenatal GBS culture result who undergo a cesarean birth before the onset of labor and with intact membranes do not require GBS antibiotic prophylaxis.

- If the prenatal GBS culture result is unknown when labor starts, intrapartum antibiotic prophylaxis is indicated for women who have risk factors for GBS EOD. At-risk women include those who present in labor with a substantial risk of preterm birth, who have preterm prelabor rupture of membranes (PPROM) or rupture of membranes for 18 or more hours at term, or who present with intrapartum fever (temperature 100.4°F [38°C] or higher). If intra-amniotic infection is suspected, broad-spectrum antibiotic therapy that provides coverage for polymicrobial infections as well as GBS should replace the antibiotic that provides coverage for GBS prophylaxis specifically.

- If a woman presents in labor at term with unknown GBS colonization status and does not have risk factors that are an indication for intrapartum antibiotic prophylaxis but reports a known history of GBS colonization in a previous pregnancy, the risk of GBS EOD in the neonate is likely to be increased. With this increased risk, it is reasonable to offer intrapartum antibiotic prophylaxis based on the woman’s history of colonization. Health care providers also may consider discussing the option of empiric intrapartum antibiotic prophylaxis as a shared decision-making process in this clinical scenario.

- Intravenous penicillin remains the agent of choice for intrapartum prophylaxis, with intravenous ampicillin as an acceptable alternative. First-generation cephalosporins (i.e., cefazolin) are recommended for women whose reported penicillin allergy indicates a low risk of anaphylaxis or is of uncertain severity. For women with a high risk of anaphylaxis, clindamycin is the recommended alternative to penicillin only if the GBS isolate is known to be susceptible to clindamycin.

- Alternatively, penicillin allergy testing, if available, is safe during pregnancy and can be beneficial for all women who report a penicillin allergy, particularly those that are suggestive of being IgE mediated, or of unknown severity, or both. Ascertaining the absence of a type I hypersensitivity reaction will eliminate the need to use alternatives to penicillin for GBS EOD prophylaxis and provide long-term benefit if treatment with beta-lactam antibiotics is indicated in their future health care management. Because most women who have a reported penicillin allergy are, in fact, penicillin tolerant, use of penicillin allergy testing is increasingly being used in all areas of health care as part of antibiotic stewardship initiatives, and expansion of its use is encouraged in obstetric patients.

- For women who are at high risk of anaphylaxis after exposure to penicillin, the laboratory requisitions for ordering antepartum GBS screening cultures (whether on paper or online in electronic medical records) should indicate clearly the presence of penicillin allergy. This step is intended to ensure that the need to test GBS isolates for clindamycin susceptibility is recognized and performed by laboratory personnel, and that the health care provider understands the importance of reviewing such a test result.

- Intravenous vancomycin remains the only pharmacokinetically and microbiologically validated option for intrapartum antibiotic prophylaxis in women who report a high-risk penicillin allergy and whose GBS isolate is not susceptible to clindamycin. The vancomycin dosage for intrapartum GBS prophylaxis should be based on weight and baseline renal function (20 mg/kg intravenously every 8 hours, with a maximum of 2 g per single dose.)

- Obstetric interventions, when necessary, should not be delayed solely to provide 4 hours of antibiotic administration before birth. Such interventions include but are not limited to administration of oxytocin, artificial rupture of membranes, or planned cesarean birth, with or without precesarean rupture of membranes. However, some variation in practice may be warranted based on the needs of individual patients to enhance intrapartum antibiotic exposure.
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 severe 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.)

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[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 severe 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.)
### Table 2  Penicillin Allergy: Low Risk or High Risk of Anaphylaxis or Severe Non-IgE Mediated Reaction

<table>
<thead>
<tr>
<th>Risk</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Low Risk</td>
<td>• Nonspecific symptoms unlikely to be allergic (gastrointestinal distress, headaches, yeast vaginitis)</td>
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<tr>
<td></td>
<td>• Nonurticarial maculopapular (morbilliform) rash without systemic symptoms*</td>
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<td></td>
<td>• Pruritis without rash</td>
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<td>• Family history of penicillin allergy but no personal history</td>
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<td></td>
<td>• Patient reports history but has no recollection of symptoms or treatment</td>
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<tr>
<td>High Risk</td>
<td>• High risk for anaphylaxis: A history suggestive of an IgE-mediated event: pruritic rash, urticaria (hives), immediate flushing, hypotension, angioedema, respiratory distress or anaphylaxis(^1)</td>
</tr>
<tr>
<td></td>
<td>• Recurrent reactions, reactions to multiple beta-lactam antibiotics, or positive penicillin allergy test</td>
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<td></td>
<td>• High risk for severe non IgE-mediated reaction: 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(^2)</td>
</tr>
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</table>

*This rash typically occurs several days after initial exposure and is limited to the skin (mucous membranes, palms and soles are not involved). May be mildly pruritic but not urticarial.

\(^1\)Anaphylactic reactions are IgE mediated and typically occur within 1–6 hours after exposure to a penicillin.

\(^2\)Some institutions have performed penicillin allergy testing in pregnant women with a history suggestive of an IgE-mediated event (classified by some experts as a moderate risk of anaphylaxis): urticaria (hives), isolated urticaria occurring greater than 10 years prior, or intense pruritic rash. Penicillin allergy testing can be achieved in these situations through referral to an allergy and immunology specialist.

\(^3\)Severe rare delayed-onset reactions, such as eosinophilia and systemic symptoms/drug-induced hypersensitivity syndrome, Stevens-Johnson syndrome, or toxic epidermal necrolysis are T-cell mediated and typically occur days to weeks after initiation of antibiotic treatment. Some experts consider these a contraindication to standard penicillin allergy testing.

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This information is designed as an educational resource to aid clinicians in providing obstetric and gynecologic care, and use of this information is voluntary. This information should not be considered as inclusive of all proper treatments or methods of care or as a statement of the standard of care. It is not intended to substitute for the independent professional judgment of the treating clinician. Variations in practice may be warranted when, in the reasonable judgment of the treating clinician, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology. The American College of Obstetricians and Gynecologists reviews its publications regularly; however, its publications may not reflect the most recent evidence. Any updates to this document can be found on acog.org or by calling the ACOG Resource Center.

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