Screening for Bacterial Vaginosis in Pregnancy to Prevent Preterm Delivery: U.S. Preventive Services Task Force Recommendation Statement

U.S. Preventive Services Task Force*

Description: Update of the 2001 U.S. Preventive Services Task Force (USPSTF) recommendation on screening for bacterial vaginosis in pregnancy.

Methods: The USPSTF weighed the benefits and harms of screening for bacterial vaginosis in pregnancy by identifying new evidence addressing previously identified gaps from the 2001 USPSTF recommendation. Published literature on this topic was identified by using MEDLINE, Cochrane Library databases, the Database of Abstracts of Reviews of Effects, reference lists, and consultation with experts and was systematically reviewed. When data allowed, a series of meta-analyses (using new and 2001 report data) was done to estimate the pooled effect of treatment on preterm delivery (<37 weeks, <34 weeks, or <32 weeks) and on low birthweight and preterm, premature rupture of membranes.

Recommendation: Do not screen for bacterial vaginosis in pregnant women at low risk for preterm delivery. (D recommendation)

Current evidence is insufficient to assess the balance of benefits and harms of screening for bacterial vaginosis in pregnant women at high risk for preterm delivery. (I statement)

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*For a list of members of the U.S. Preventive Services Task Force, see the **Appendix** (available at www.annals.org).

The U.S. Preventive Services Task Force (USPSTF) makes recommendations about preventive care services for patients without recognized signs or symptoms of the target condition.

It bases its recommendations on a systematic review of the evidence of the benefits and harms and an assessment of the net benefit of the service.

The USPSTF recognizes that clinical or policy decisions involve more considerations than this body of evidence alone. Clinicians and policymakers should understand the evidence but individualize decision making to the specific patient or situation.

Summary of Recommendation and Evidence

The USPSTF recommends against screening for bacterial vaginosis in asymptomatic pregnant women at low risk for preterm delivery. This is a grade D recommendation.

The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for bacterial vaginosis in asymptomatic pregnant women at high risk for preterm delivery. This is an I statement.

See the Clinical Considerations section for a discussion of risk assessment and suggestions for practice.

See the **Figure** for a summary of this recommendation and its impact on clinical practice. See **Table 1** for a description of the USPSTF grades and **Table 2** for a description of the USPSTF classification of levels of certainty about net benefit. Both are also available at www.annals.org.

See also:

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Rationale

Importance

The associations between bacterial vaginosis and adverse pregnancy outcomes, such as preterm delivery, are well documented.

Detection

Good-quality evidence indicates that screening tests (the Amsel clinical criteria or Gram stain) can detect bacterial vaginosis.

Benefits of Detection and Early Intervention

Asymptomatic Pregnant Women at Low Risk for Preterm

Delivery. No direct evidence indicates that screening for bacterial vaginosis reduces adverse health outcomes in asymptomatic pregnant women at low risk for preterm delivery. Good evidence indicates that treatment of bacterial vaginosis in these women lacks benefit.

Asymptomatic Pregnant Women at High Risk for Preterm Delivery. No direct evidence indicates that screening for bacterial vaginosis reduces adverse health outcomes in asymptomatic pregnant women at high risk for preterm delivery. Evidence from good-quality studies is conflicting with respect to the benefits of treating bacterial vaginosis.

Harms of Detection and Early Treatment

Asymptomatic Pregnant Women at Low Risk for Preterm Delivery. Evidence is poor (because studies are lacking) for harms of screening for bacterial vaginosis in asymptomatic pregnant women at low risk for preterm delivery. Evidence is fair that false-positive results from screening lead to harms due to treatment.

Asymptomatic Pregnant Women at High Risk for Preterm Delivery. Evidence is poor (because studies are lacking) for harms of screening for bacterial vaginosis in asymptomatic pregnant women at high risk for preterm delivery. Studies on the harms of treatment have conflicting results.

USPSTF Assessment. The USPSTF concludes that for asymptomatic pregnant women at low risk for preterm delivery, there is moderate certainty that screening for bacterial vaginosis has no net benefit.

The USPSTF concludes that for asymptomatic pregnant women at high risk for preterm delivery, the evidence is conflicting and the balance of benefits and harms cannot be determined.

Clinical Considerations

Patient Population

This recommendation addresses screening for bacterial vaginosis in asymptomatic pregnant women.

Risk Assessment

Several factors have been associated with increased risk for preterm delivery. All of these associations are small to moderate. These factors include, but are not limited to, African-American race or ethnicity, body mass index less than 20 kg/m^2, previous preterm delivery, vaginal bleeding, a short cervix (<2.5 cm), pelvic infection, and bacterial vaginosis. These factors can act in isolation or in combination. Furthermore, bacterial vaginosis in pregnancy is more common among African-American women, women of low socioeconomic status, and those who have previously delivered low-birthweight infants. For the purpose of the current recommendation, women were considered to be at low risk if they had no previous preterm delivery or other risk factors for preterm delivery (often these were nulliparous women). Women were considered to be at high risk if they had a previous preterm delivery.

Screening Tests

Bacterial vaginosis is diagnosed by using the Amsel clinical criteria or Gram stain. With the Amsel criteria, the clinical diagnosis is made by fulfilling 3 of 4 criteria: vaginal pH greater than 4.7, the presence of clue cells on wet mount, thin homogeneous discharge, and amine "fishy odor" when potassium hydroxide is added to the discharge.

Suggestions for Practice

This recommendation statement addresses screening for bacterial vaginosis in asymptomatic women. Treatment of symptomatic cases should be based on the clinical situation.

Treatment

Oral metronidazole and oral clindamycin, as well as vaginal metronidazole gel or clindamycin cream, are used to treat bacterial vaginosis. The optimal treatment regimen for pregnant women with bacterial vaginosis is unclear. Refer to the Centers for Disease Control and Prevention Web site for current treatment recommendations (www.cdc.gov/std/treatment/2006/vaginal-discharge.htm#vagdis2).

Other Considerations

Research Needs

There are several evidence gaps in the literature on screening and treating bacterial vaginosis in asymptomatic pregnant women. A critical gap in the evidence exists in demonstrating a benefit of treatment in asymptomatic pregnant women at increased risk for preterm delivery. Available evidence on treatment benefit is conflicting. Additional research is needed to evaluate the benefit of screening and treating asymptomatic bacterial vaginosis in women at highest risk for preterm delivery. Research is also needed to assess which screening tests providers use to diagnose bacterial vaginosis in clinical practice and the accuracy of these tests. Finally, continued research is needed to determine the optimal treatment regimen for bacterial vaginosis.

Discussion

Burden of Disease

Bacterial vaginosis is the most common lower genital tract syndrome among women of reproductive age. It involves an imbalance in the vaginal bacterial ecosystem, with a decrease in hydrogen peroxide–producing lactobacilli and an increase in *Gardnerella vaginalis*, anaerobes, and mycoplasmas. Studies have documented an association between bacterial vaginosis and the adverse pregnancy outcome of preterm delivery. This epidemiologic evidence has been used as a rationale for screening asymptomatic pregnant women for bacterial vaginosis.

The literature demonstrates a prevalence of bacterial vaginosis ranging from 9% to 23% in studies conducted in academic medical centers or public hospitals. The prevalence of bacterial vaginosis in pregnant women in community clinical settings is not well studied. Bacterial vaginosis in pregnancy is more common among African-American women, women of

low socioeconomic status, and women who have previously delivered low-birthweight infants.

The natural history of bacterial vaginosis in pregnant women has shown that up to 50% of cases resolve spontaneously during pregnancy. Because bacterial vaginosis may not continue throughout pregnancy, whether to screen and treat multiple times, and optimal screening intervals, are not known (1).

Scope of Review

The USPSTF updated its 2001 recommendation on bacterial vaginosis. The goal was to review the literature and to identify new evidence addressing previously identified gaps, such as the characterization of patients most likely to benefit from screening and the optimal timing of screening and treatment on pregnancy outcomes.

Accuracy of Screening Tests

Bacterial vaginosis is diagnosed by using the Amsel clinical criteria or Gram stain. The reliability of the Amsel clinical criteria in community practice is unknown. Gram stain of vaginal discharge may be a more reliable means of diagnosing bacterial vaginosis and offers the added ability to quantify and classify bacterial load. As a result, Gram stain has been the primary means used to diagnose bacterial vaginosis in research studies. However, Gram stain is less commonly used in clinical practice because of the need for laboratory facilities and the delay in receiving diagnostic results (1).

No studies of diagnostic assessment in the clinical practice setting were found in the literature. Most studies compared the application of all Amsel clinical criteria with Gram stain in a research setting. In the 2001 USPSTF review, comparisons of the Amsel clinical criteria with Gram stain yielded sensitivities from 62% to 97% and specificities from 66% to 95%, with Gram stain as the criterion standard in diagnosing bacterial vaginosis (2).

The 2001 USPSTF evidence review stated that the preferred screening test would predict pregnancy outcomes with the most accuracy. The current update identified studies that evaluated diagnostic tests in predicting preterm birth (1). A poor-quality meta-analysis (11 studies) showed no difference in accuracy between clinical criteria and Gram stain in preterm delivery (3).

Effectiveness of Early Detection and Treatment

Because the evidence is poor, there is no known benefit of early detection in either low-risk or high-risk, asymptomatic pregnant women.

The USPSTF found good evidence of a lack of benefit from treatment in low-risk, asymptomatic pregnant women. Randomized clinical trials of good quality pooled with 2001 report data showed no treatment effects for asymptomatic women at low risk for preterm delivery at less than 37 weeks (1).

Randomized, controlled trials of good quality had conflicting results about treatment benefit in high-risk, asymptomatic pregnant women. There was statistically significant heterogeneity among the trials ($P < 0.001$). Three of the 5 trials reported a statistically significant benefit from treatment, 1 showed a statistically significant harm from treatment, and 1 showed no benefit (4–8).

Potential Harms of Screening and Treatment

No studies directly addressed the harms of screening (for example, increased risk for preterm delivery). The effects of treatment in women with a misdiagnosis of bacterial vaginosis have been indirectly studied and were documented in the 2001 review (2). Two studies of women who tested negative for bacterial vaginosis and received treatment compared with women who tested negative and were not treated found an increase in preterm delivery at less than 34 weeks in the group who tested negative and were treated (7, 9). A recent study also confirmed the potential harm of misdiagnosis (greater spontaneous preterm delivery at <37 weeks) in women who tested negative for bacterial vaginosis and were treated versus the placebo group, but this finding did not reach statistical significance (10).

Estimate of Magnitude of Net Benefit

In low-risk, asymptomatic pregnant women, the USPSTF found no known benefits of detection and early treatment and concluded with moderate certainty that screening has no net benefit. Given the lack of net benefit, the USPSTF recommends against routine screening for bacterial vaginosis in low-risk, pregnant women. The results of studies assessing bacterial vaginosis treatment in high-risk, asymptomatic pregnant women are conflicting. As a result of this significant evidence gap, the USPSTF concluded that the evidence is insufficient to make a recommendation about screening for bacterial vaginosis in high-risk pregnant women.

RECOMMENDATIONS OF OTHER GROUPS

The Centers for Disease Control and Prevention (11), the American College of Obstetricians and Gynecologists (12), the Cochrane Pregnancy and Childbirth Group (13), the British Association for Sexual Health and HIV/Clinical Effectiveness Group (14), and the American Academy of Family Physicians make similar recommendations about screening and treatment of pregnant women with bacterial vaginosis (15). All recommend against routine screening for bacterial vaginosis in asymptomatic pregnant women. With respect to women at high risk for preterm delivery, the Centers for Disease Control and Prevention, American College of Obstetricians and Gynecologists, the American Academy of Family Physicians, and British Association for Sexual Health and HIV state that there may be high-risk women for whom screening and treatment may be beneficial. The Centers for Disease Control and Prevention does not recommend the use of clindamycin vaginal cream in the second half of pregnancy.

From the U.S. Preventive Services Task Force, Agency for Healthcare Research and Quality, Rockville, Maryland.

Figure. **Screening for bacterial vaginosis in pregnancy to prevent preterm delivery: clinical summary of a U.S. Preventive Services Task Force Recommendation.**

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Screening for Bacterial Vaginosis: Clinical Summary of U.S. Preventive Services Task Force Recommendation

Population	Asymptomatic Pregnant Women without Risk Factors for Preterm Delivery	Asymptomatic Pregnant Women with Risk Factors for Preterm Delivery
Recommendation	**Do not screen Grade: D**	**No recommendation Grade: I [Insufficient Evidence]**

Risk assessment	**Risk factors for preterm delivery include:** • African-American women • Pelvic infection • Previous preterm delivery Bacterial vaginosis is more common among African-American women, women of low socioeconomic status, and women who have previously delivered low-birthweight infants.
Screening tests	Bacterial vaginosis is diagnosed by using the Amsel clinical criteria or Gram stain. When using the Amsel criteria, 3 of 4 criteria must be met to make a clinical diagnosis: 1. Vaginal pH >4.7 2. The presence of clue cells on wet mount 3. Thin homogeneous discharge 4. Amine "fishy odor" when potassium hydroxide is added to the discharge
Screening intervals	Not applicable.
Treatment	Treatment is appropriate for pregnant women with symptomatic bacterial vaginosis infection. Oral metronidazole and oral clindamycin, as well as vaginal metronidazole gel or clindamycin cream, are used to treat bacterial vaginosis. The optimal treatment regimen is unclear.*

For a summary of the evidence systematically reviewed in making these recommendations, the full recommendation statement, and supporting documents, go to www.preventiveservices.ahrq.gov. *The Centers for Disease Control and Prevention recommends 250 mg oral metronidazole 3 times daily for 7 days as the treatment of bacterial vaginosis in pregnancy.

Table 1. **What the U.S. Preventive Services Task Force Grades Mean and Suggestions for Practice***

Grade	Definition	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer/provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer/provide this service.
C	The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is moderate or high certainty that the net benefit is small.	Offer/provide this service only if other considerations support offering or providing the service in an individual patient.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the clinical considerations section of the USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

* USPSTF = U.S. Preventive Services Task Force.

Table 2. **U.S. Preventive Services Task Force Levels of Certainty Regarding Net Benefit**

Level of Certainty*	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by such factors as: the number, size, or quality of individual studies inconsistency of findings across individual studies limited generalizability of findings to routine primary care practice lack of coherence in the chain of evidence. As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: the limited number or size of studies important flaws in study design or methods inconsistency of findings across individual studies gaps in the chain of evidence findings that are not generalizable to routine primary care practice a lack of information on important health outcomes. More information may allow an estimation of effects on health outcomes.

* The U.S. Preventive Services Task Force (USPSTF) defines *certainty* as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

tion of the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.

Financial Support: The USPSTF is an independent, voluntary body. The U.S. Congress mandates that the Agency for Healthcare Research and Quality support the operations of the USPSTF.

Requests for Single Reprints: Reprints are available from the USPSTF Web site (www.preventiveservices.ahrq.gov).

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Appendix: U.S. Preventive Services Task Force

Members of the U.S. Preventive Services Task Force† are Ned Calonge, MD, MPH, *Chair* (Colorado Department of Public Health and Environment, Denver, Colorado); Diana B. Petitti, MD, MPH, *Vice Chair* (Keck School of Medicine, University of Southern California, Sierra Madre, California); Thomas G. DeWitt, MD (Children's Hospital Medical Center, Cincinnati, Ohio); Leon Gordis, MD, MPH, DrPH (Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland); Kimberly D. Gregory, MD, MPH (Cedars-Sinai Medical Center, Los Angeles, California); Russell Harris, MD, MPH (University of North Carolina School of Medicine, Chapel Hill, North Carolina); Kenneth W. Kizer, MD, MPH (National Quality Forum, Washington, DC); Michael L. LeFevre, MD, MSPH (University of Missouri School of Medicine, Columbia, Missouri); Carol Loveland-Cherry, PhD, RN (University of Michigan School of Nursing, Ann Arbor, Michigan); Lucy N. Marion, PhD, RN (Medical College of Georgia, Augusta, Georgia); Virginia A. Moyer, MD, MPH (University of Texas Health Science Center, Houston, Texas); Judith K. Ockene, PhD (University of Massachusetts Medical School, Worcester, Massachusetts); George F. Sawaya, MD (University of California, San Francisco, San Francisco, California); Albert L. Siu, MD, MSPH (Mount Sinai Medical Center, New York, New York); Steven M. Teutsch, MD, MPH (Merck & Company, West Point, Pennsylvania); and Barbara P. Yawn, MD, MSPH, MSc (Olmsted Medical Center, Rochester, Minnesota).

†This list includes members of the Task Force at the time this recommendation was finalized. For a list of current Task Force members, go to www.ahrq.gov/clinic/uspstfab.htm.