Complete Summary

GUIDELINE TITLE

Screening for bacterial vaginosis in pregnancy to prevent preterm delivery: U.S. Preventive Services Task Force Recommendation Statement.

BIBLIOGRAPHIC SOURCE(S)

U.S. Preventive Services Task Force. Screening for bacterial vaginosis in pregnancy to prevent preterm delivery: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med 2008 Feb 5;148(3):214-9. PubMed

GUIDELINE STATUS

This is the current release of the guideline.

This release updates a previously published guideline: Berg AO. Screening for bacterial vaginosis in pregnancy. Recommendations and rationale. Am J Prev Med 2001 Apr;20(3 Suppl):59-61. [5 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Bacterial vaginosis during pregnancy

GUIDELINE CATEGORY

Prevention
Screening

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Nursing
Obstetrics and Gynecology
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To summarize the U.S. Preventive Services Task Force (USPSTF) recommendations and supporting scientific evidence on screening for bacterial vaginosis in pregnancy to prevent preterm delivery
- To update the 2001 USPSTF recommendations on screening for bacterial vaginosis in pregnancy

TARGET POPULATION

Asymptomatic pregnant women

INTERVENTIONS AND PRACTICES CONSIDERED

Note: The following was considered but not recommended.

Routine screening for bacterial vaginosis during pregnancy using Amsel clinical criteria or Gram stain

MAJOR OUTCOMES CONSIDERED

Key Question 1: Does screening for bacterial vaginosis during pregnancy in asymptomatic women reduce adverse pregnancy outcomes for those at low-risk, average, or high-risk for preterm delivery?

Key Question 2: Does treatment of bacterial vaginosis during pregnancy in asymptomatic women reduce adverse pregnancy outcomes for those at low-, average-, or high-risk for preterm delivery?

Key Question 3: What adverse effects does the screening and/or treatment of bacterial vaginosis have on pregnancy outcomes?

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): A review of the literature was prepared by Oregon Evidence-based Practice Center (EPC) for use by the U.S. Preventive Services Task Force (USPSTF) (see the "Availability of Companion Documents" field).

Literature Search and Strategy

EPC staff conducted literature searches relevant to their critical key questions (see Appendix A in the Evidence Synthesis [see "Availability of Companion Documents" field] and "Major Outcomes Considered" field). All citations and articles were managed in an electronic database (Endnote®). Searches were conducted in the Cochrane Central Database of Controlled Trials, the Cochrane Database of Systematic Reviews, and the Database of Abstracts of Reviews of Effects through 2nd quarter 2006 to identify studies relevant to the critical key questions. The Ovid MEDLINE Database of In-Process and Other Non-Indexed Citations was searched from January 2000–July 2006 to identify otherwise non-indexed studies relevant to any critical key question. In addition, key question specific searches were conducted for key questions 1, 2, and 3 in Ovid MEDLINE from January 1996–July 2006.

EPC staff identified 8 systematic reviews and used those systematic reviews as sources of relevant randomized controlled trials for this review. Additional articles were obtained from comparing reference lists of reviews, studies, editorials, reports, websites, and by consulting experts to the list of articles obtained through searching.

Inclusion and Exclusion Criteria

Investigators dual reviewed abstracts identified by the searches and papers identified as described above for potential relevance to all critical key questions, and determined eligibility by applying inclusion and exclusion criteria (see Appendix B in the Evidence Synthesis [see "Availability of Companion Documents" field). Eligible studies for the screening and treatment key questions were conducted in settings where pregnant women went for prenatal and obstetric care. This included both University based and non-University based obstetric and hospital clinics. Systematic reviews and individual randomized controlled trials that evaluated screening and/or treatment pregnancy outcomes and/or adverse effects for asymptomatic women with bacterial vaginosis (BV) were reviewed. Participants included pregnant women at low, average, or high risk for preterm delivery. Eligible studies were in English-language and conducted in the U.S. or developed country. Studies of non-pregnant women, lacking pregnancy outcomes, of poor quality, or animal studies were excluded (see Appendix C in the Evidence Synthesis [see "Availability of Companion Documents" field). Studies were excluded if the focus of the study was multiple infections and data was not available for the BV group only. A "best evidence" approach was applied in which studies with the highest quality and most rigorous design are emphasized.

NUMBER OF SOURCE DOCUMENTS

Key Question 1: 209 abstracts were reviewed to identify literature showing direct evidence of screening related to reduced adverse pregnancy outcomes, of which none met the inclusion criteria.

Key Question 2: 213 abstracts were reviewed to identify literature showing evidence that treatment reduces adverse pregnancy outcomes, of which 7 randomized controlled trials (and 8 systematic reviews that were used for source documents) met the inclusion criteria.

Key Question 3: 74 abstracts were reviewed to identify literature showing evidence whether there are adverse effects associated with screening and/or treatment of bacterial vaginosis on pregnancy outcomes, of which 9 met the inclusion criteria.

178 additional abstracts from keyword searches were reviewed for applicability to any of the questions, and then combined with the appropriate questions. (Seven treatment trials and 5 adverse effects studies from the 2001 report were synthesized with the new evidence).

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): A review of the literature was prepared by Oregon Evidence-based Practice Center (EPC) for use by the U.S. Preventive Services Task Force (USPSTF) (see the "Availability of Companion Documents" field).

Critical Appraisal

Two reviewers independently rated the quality of studies using design-specific criteria developed by the USPSTF and Jadad (see Appendix D in the Evidence Synthesis [see "Availability of Companion Documents" field]). Reviews were not excluded based on quality as searching for individual trials within these reviews was the priority. The overall rating for each individual study is a combination of internal and external validity scores. When reviewers disagreed, a final rating was

reached through consensus. Good or fair quality individual randomized controlled trials are emphasized in this report.

Data Synthesis

Data from the full text of the original articles and systematic reviews were abstracted to evidence tables. The data included study, year, setting, patient demographics, inclusion/exclusion criteria, and risk status. Pregnancy outcome data included completed weeks of gestation at delivery, preterm premature rupture of membranes (PPROM), neonatal death, and other pregnancy outcomes if provided. Abstracted treatment data included gestational age (in weeks) at screening/treatment, type of treatment, dose, regimen, administration route, number of treatment rounds, and adverse effects. Data on the percentage of adverse pregnancy outcomes in the bacterial vaginosis (BV) positive treatment group and percentage of adverse pregnancy outcomes in the BV positive placebo group were also abstracted. Summary tables with specific information were then developed for use of the team in evidence synthesis and by the statistician to provide further analysis of the data.

Statistical Analysis

EPC staff performed a series of meta-analyses that included trials located for this review and the previous review to estimate the effect of treatment on preterm delivery (<37 weeks, <34 weeks, or <32 weeks), on low birth weight (LBW), and on PPROM. The primary measure of effect of BV treatment was the difference in proportions of pregnancy outcomes between the control and treatment group, the absolute risk reduction (ARR) [Control – Treatment]. A zero would indicate no treatment effect, or no differences between the treatment and control groups for adverse pregnancy outcomes. A negative ARR favors placebo, where reduced adverse pregnancy outcomes are evident for those not being treated. A positive ARR favors treatment where those being given the treatment show less adverse pregnancy outcomes. For each study, the ARR and its standard error was calculated and used as the measure for the effect of treatment. Analysis was stratified by risk group (low, average, or high risk group) and studies were pooled when appropriate to provide a combined estimate of ARR and its 95% confidence intervals (CI). If there was evidence of heterogeneity among trials at a significance level of $P = .10$ based on the standard chi-square test for heterogeneity, a random effects model was used. To address the effect of quality of trials, a sensitivity analysis was performed by excluding poor quality trials with a Jadad score ≤ 2.

EPC staff also assessed publication bias by using funnel plots and Egger's linear regression method. No publication bias was detected by these methods; however, their interpretation is limited by the small numbers of trials for each therapy. All analyses were performed using Stata version 9.0 (StataCorp LP, College Station, Tex).

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Balance Sheets
Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The U.S. Preventive Services Task Force (USPSTF) systematically reviews the evidence concerning both the benefits and harms of widespread implementation of a preventive service. It then assesses the certainty of the evidence and the magnitude of the benefits and harms. On the basis of this assessment, the USPSTF assigns a letter grade to each preventive service signifying its recommendation about provision of the service (see Table below). An important, but often challenging, step is determining the balance between benefits and harms to estimate "net benefit" (that is, benefits minus harms).

Table 1. U.S. Preventive Services Task Force Recommendation Grid*

Certainty of Net Benefit	Magnitude of Net Benefit			
	Substantial	**Moderate**	**Small**	**Zero/Negative**
High	A	B	C	D
Moderate	B	B	C	D
Low	Insufficient			

**A, B, C, D*, and *Insufficient* represent the letter grades of recommendation or statement of insufficient evidence assigned by the U.S. Preventive Services Task Force after assessing certainty and magnitude of net benefit of the service (see the "Rating Scheme for the Strength of the Recommendations" field.

The overarching question that the Task Force seeks to answer for every preventive service is whether evidence suggests that provision of the service would improve health outcomes if implemented in a general primary care population. For screening topics, this standard could be met by a large randomized, controlled trial (RCT) in a representative asymptomatic population with follow-up of all members of both the group "invited for screening" and the group "not invited for screening."

Direct RCT evidence about screening is often unavailable, so the Task Force considers indirect evidence. To guide its selection of indirect evidence, the Task Force constructs a "chain of evidence" within an analytic framework. Each arrow in the framework defines a key question, and each key question represents a link in the chain of evidence. Rectangles in the framework represent the intermediate outcomes (rounded corners) or the health outcomes (square corners); ovals represent harms. To form an unbroken chain, evidence must support each link in the chain, thereby connecting the target population (far left side of the framework) to the improved health outcome (far right side of the framework). For each key question, the body of pertinent literature is critically appraised, focusing on the following 6 questions:

1. Do the studies have the appropriate research design to answer the key question(s)?
2. To what extent are the existing studies of high quality? (i.e., what is the internal validity?)
3. To what extent are the results of the studies generalizable to the general U.S. primary care population and situation? (i.e., what is the external validity?)

4. How many studies have been conducted that address the key question(s)? How large are the studies? (i.e., what is the precision of the evidence?)
5. How consistent are the results of the studies?
6. Are there additional factors that assist us in drawing conclusions (e.g., presence or absence of dose-response effects, fit within a biologic model)?

The next step in the Task Force process is to use the evidence from the key questions to assess whether there would be net benefit if the service were implemented. In 2001, the USPSTF published an article that documented its systematic processes of evidence evaluation and recommendation development. At that time, the Task Force's overall assessment of evidence was described as good, fair, or poor. The Task Force realized that this rating seemed to apply only to how well studies were conducted and did not fully capture all of the issues that go into an overall assessment of the evidence about net benefit. To avoid confusion, the USPSTF has changed its terminology. Whereas individual study quality will continue to be characterized as good, fair, or poor, the term *certainty* will now be used to describe the Task Force's assessment of the overall body of evidence about net benefit of a preventive service and the likelihood that the assessment is correct. Certainty will be determined by considering all 6 questions listed above; the judgment about certainty will be described as high, moderate, or low.

In making its assessment of certainty about net benefit, the evaluation of the evidence from each key question plays a primary role. It is important to note that the Task Force makes recommendations for real-world medical practice in the United States and must determine to what extent the evidence for each key question-even evidence from screening RCTs or treatment RCTs--can be applied to the general primary care population. Frequently, studies are conducted in highly selected populations under special conditions. The Task Force must consider differences between the general primary care population and the populations studied in RCTs and make judgments about the likelihood of observing the same effect in actual practice.

It is also important to note that 1 of the key questions in the analytic framework refers to the potential harms of the preventive service. The Task Force considers the evidence about the benefits and harms of preventive services separately and equally. Data about harms are often obtained from observational studies because harms observed in RCTs may not be representative of those found in usual practice and because some harms are not completely measured and reported in RCTs.

Putting the body of evidence for all key questions together as a chain, the Task Force assesses the certainty of net benefit of a preventive service by asking the 6 major questions listed above. The Task Force would rate a body of convincing evidence about the benefits of a service that, for example, derives from several RCTs of screening in which the estimate of benefits can be generalized to the general primary care population as "high" certainty (see the "Rating Scheme for the Strength of Recommendations" field). The Task Force would rate a body of evidence that was not clearly applicable to general practice or has other defects in quality, research design, or consistency of studies as "moderate" certainty. Certainty is "low" when, for example, there are gaps in the evidence linking parts of the analytic framework, when evidence to determine the harms of treatment is

unavailable, or when evidence about the benefits of treatment is insufficient. Table 4 in the methodology document listed below (see "Availability of Companion Documents" field) summarizes the current terminology used by the Task Force to describe the critical assessment of evidence at all 3 levels: individual studies, key questions, and overall certainty of net benefit of the preventive service.

Sawaya GF et al. Update on the methods of the U.S. Preventive Services Task Force: estimating certainty and magnitude of net benefit. Ann Intern Med. 2007;147:871-875.[5 references].

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

What the United States Preventive Services Task Force (USPSTF) Grades Mean and Suggestions for Practice

Grade	Grade Definitions	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or 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 or 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 or provide this service only if there are other considerations in support of the offering/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 "Clinical Considerations" section of USPSTF Recommendation Statement (see "Major Recommendations" field). If offered, patients should understand the uncertainty about the balance of benefits and harms.

USPSTF Levels of Certainty Regarding Net Benefit

Definition: The U.S. Preventive Services Task Force 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.

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 factors such as: • the number, size, or quality of individual studies; • inconsistency of findings across individual studies; • limited generalizability of findings to routine primary care practice; or • 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 not generalizable to routine primary care practice; or • a lack of information on important health outcomes. More information may allow an estimation of effects on health outcomes.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups
External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Peer Review. Before the U.S. Preventive Services Task Force makes its final determinations about recommendations on a given preventive service, the

Evidence-Based Practice Center and the Agency for Healthcare Research and Quality send a draft evidence review to 4 to 6 external experts and to federal agencies and professional and disease-based health organizations with interests in the topic. They ask the experts to examine the review critically for accuracy and completeness and to respond to a series of specific questions about the document. After assembling these external review comments and documenting the proposed response to key comments, the topic team presents this information to the Task Force in memo form. In this way, the Task Force can consider these external comments and a final version of the systematic review before it votes on its recommendations about the service. Draft recommendation statements are then circulated for comment from reviewers representing professional societies, voluntary organizations and Federal agencies. These comments are discussed before the final recommendations are confirmed.

Comparison with Guidelines from Other Groups. Recommendations for screening from the following groups were discussed: the Centers for Disease Control and Prevention, the American College of Obstetricians and Gynecologists, the Cochrane Pregnancy and Childbirth Group, the British Association for Sexual Health and HIV/Clinical Effectiveness Group, and the American Academy of Family Physicians.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The US Preventive Services Task Force (USPSTF) grades its recommendations (A, B, C, D, or I) and identifies the Levels of Certainty regarding Net Benefit (High, Moderate, and Low). The definitions of these grades can be found at the end of the "Major Recommendations" field.

Summary of Recommendations 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.**

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 of 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 birth weight 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 out 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).

Definitions:

What the United States Preventive Services Task Force (USPSTF) Grades Mean and Suggestions for Practice

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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 or provide this service.
C	The USPSTF recommends against	Offer or provide this service only if

Grade	Grade Definitions	Suggestions for Practice
	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.	there are other considerations in support of the offering/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 "Clinical Considerations" section of USPSTF Recommendation Statement (see "Major Recommendations" field). If offered, patients should understand the uncertainty about the balance of benefits and harms.

USPSTF Levels of Certainty Regarding Net Benefit

Definition: The U.S. Preventive Services Task Force 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.

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 factors such as: • the number, size, or quality of individual studies; • inconsistency of findings across individual studies; • limited generalizability of findings to routine primary care practice; or • 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

Level of Certainty	Description
	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 not generalizable to routine primary care practice; or • a lack of information on important health outcomes. More information may allow an estimation of effects on health outcomes.

CLINICAL ALGORITHM(S)

None available

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

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 symptomatic, pregnant women at high risk for preterm delivery. Evidence from good-quality studies is conflicting with respect to the benefits of treating bacterial vaginosis.

POTENTIAL HARMS

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.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- 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.
- Recommendations are based 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 policy-makers should understand the evidence but individualize decision making to the specific patient or situation.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The experiences of the first and second U.S. Preventive Services Task Force (USPSTF), as well as that of other evidence-based guideline efforts, have highlighted the importance of identifying effective ways to implement clinical recommendations. Practice guidelines are relatively weak tools for changing clinical practice when used in isolation. To effect change, guidelines must be coupled with strategies to improve their acceptance and feasibility. Such strategies include enlisting the support of local opinion leaders, using reminder systems for clinicians and patients, adopting standing orders, and audit and feedback of information to clinicians about their compliance with recommended practice.

In the case of preventive services guidelines, implementation needs to go beyond traditional dissemination and promotion efforts to recognize the added patient and clinician barriers that affect preventive care. These include clinicians' ambivalence about whether preventive medicine is part of their job, the psychological and practical challenges that patients face in changing behaviors, lack of access to health care or of insurance coverage for preventive services for some patients, competing pressures within the context of shorter office visits, and the lack of organized systems in most practices to ensure the delivery of recommended preventive care.

Dissemination strategies have changed dramatically in this age of electronic information. While recognizing the continuing value of journals and other print formats for dissemination, the Agency for Healthcare Research and Quality will make all U.S. Preventive Services Task Force (USPSTF) products available through its Web site. The combination of electronic access and extensive material in the public domain should make it easier for a broad audience of users to access U.S. Preventive Services Task Force materials and adapt them for their local needs. Online access to U.S. Preventive Services Task Force products also opens up new possibilities for the appearance of the annual, pocket-size *Guide to Clinical Preventive Services*.

To be successful, approaches for implementing prevention have to be tailored to the local level and deal with the specific barriers at a given site, typically requiring the redesign of systems of care. Such a systems approach to prevention has had notable success in established staff-model health maintenance organizations, by addressing organization of care, emphasizing a philosophy of prevention, and altering the training and incentives for clinicians. Staff-model plans also benefit from integrated information systems that can track the use of needed services and generate automatic reminders aimed at patients and clinicians, some of the most consistently successful interventions. Information systems remain a major challenge for individual clinicians' offices, however, as well as for looser affiliations of practices in network-model managed care and independent practice associations, where data on patient visits, referrals, and test results are not always centralized.

IMPLEMENTATION TOOLS

Foreign Language Translations
Patient Resources
Personal Digital Assistant (PDA) Downloads
Pocket Guide/Reference Cards
Tool Kits

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

U.S. Preventive Services Task Force. Screening for bacterial vaginosis in pregnancy to prevent preterm delivery: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med 2008 Feb 5;148(3):214-9. PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1996 (revised 2008)

GUIDELINE DEVELOPER(S)

United States Preventive Services Task Force - Independent Expert Panel

GUIDELINE DEVELOPER COMMENT

The U.S. Preventive Services Task Force (USPSTF) is a federally-appointed panel of independent experts. Conclusions of the U.S. Preventive Services Task Force do not necessarily reflect policy of the U.S. Department of Health and Human Services (DHHS) or its agencies.

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

U.S. Preventive Services Task Force (USPSTF)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

*Task Force Members**: 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); George J. Isham, MD, MS, Medical Director and Chief Health Officer, Health Partners, Inc. Minneapolis, MN; 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)

**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*.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The U.S. Preventive Services Task Force has an explicit policy concerning conflict of interest. All members disclose at each meeting if they have a significant financial, professional/business, or intellectual conflict for each topic being discussed. Task Force members with conflicts may be recused from discussing or voting on recommendations about the topic in question.

GUIDELINE STATUS

This is the current release of the guideline.

This release updates a previously published guideline: Berg AO. Screening for bacterial vaginosis in pregnancy. Recommendations and rationale. Am J Prev Med 2001 Apr;20(3 Suppl):59-61. [5 references]

GUIDELINE AVAILABILITY

Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site and the Annals of Internal Medicine Web site.

Print copies: Available from the Agency for Healthcare Research and Quality (AHRQ) Publications Clearinghouse. For more information, go to http://www.ahrq.gov/news/pubsix.htm or call 1-800-358-9295 (U.S. only).

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

Evidence Reviews:

- Nygren P, Fu R, Freeman M, Bougatsos C, Guise JM. Screening and treatment for bacterial vaginosis in pregnancy: systematic review to update the 2001 U.S. Preventive Services Task Force recommendations. Evidence synthesis no. 57. AHRQ Publication No. 08-05106-EF-1. Rockville (MD): Agency for Healthcare Research and Quality, 2008 Jan. Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site.
- Nygren P, Fu R, Freeman M, Bougatsos C, Klebanoff M, Guise JM. Evidence on the benefits and harms of screening and treating pregnant women who are asymptomatic for bacterial vaginosis: an update review for the U.S. Preventive Services Task Force. Ann Intern Med 2008;148:220-233. Electronic copies: Available from the Annals of Internal Medicine Web site.
- Screening for bacterial vaginosis: clinical summary of U.S. Preventive Services Task Force recommendations. 2008. Electronic copies: Available in

Portable Document Format (PDF) from the U.S. Preventive Services Task Force (USPSTF) Web site.

Background Articles:

- Barton M et al. How to read the new recommendation statement: methods update from the U.S. Preventive Services Task Force. Ann Intern Med. 2007;147:123-127.
- Guirguis-Blake J et al. Current processes of the U.S. Preventive Services Task Force: refining evidence-based recommendation development. Ann Intern Med. 2007;147:117-122. [2 references]
- Sawaya GF et al. Update on the methods of the U.S. Preventive Services Task Force: estimating certainty and magnitude of net benefit. Rockville (MD): Agency for Healthcare Research and Quality, 2007 Dec.

Electronic copies: Available from U.S. Preventive Services Task Force (USPSTF) Web site.

The following are also available:

- The guide to clinical preventive services, 2007. Recommendations of the U.S. Preventive Services Task Force. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ), 2007. 228 p. Electronic copies available from the AHRQ Web site.
- A step-by-step guide to delivering clinical preventive services: a systems approach. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ), 2002 May. 189 p. Electronic copies available from the AHRQ Web site. See the related QualityTool summary on the Health Care Innovations Exchange Web site.

Print copies: Available from the Agency for Healthcare Research and Quality Publications Clearinghouse. For more information, go to http://www.ahrq.gov/news/pubsix.htm or call 1-800-358-9295 (U.S. only).

The Electronic Preventive Services Selector (ePSS), available as a PDA application and a web-based tool, is a quick hands-on tool designed to help primary care clinicians identify the screening, counseling, and preventive medication services that are appropriate for their patients. It is based on current recommendations of the USPSTF and can be searched by specific patient characteristics such as age, sex, and selected behavioral risk factors.

PATIENT RESOURCES

The following are available:

- Men: Stay Healthy at Any Age – Checklist for Your Next Checkup. Rockville (MD): Agency for Healthcare Research and Quality. AHRQ Pub. No. 07-IP006-A. 2007 Feb. Electronic copies: Available from the USPSTF Web site.
- Women: Stay Healthy at Any Age – Checklist for Your Net Checkup. Rockville (MD): Agency for Healthcare Research and Quality. AHRQ Pub. No. 07-IP005-A. 2007 Feb. Electronic copies: Available from the USPSTF Web site.

Print copies: Available from the Agency for Healthcare Research and Quality (AHRQ) Publications Clearinghouse. For more information, go to http://www.ahrq.gov/news/pubsix.htm or call 1-800-358-9295 (U.S. only).

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

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