Complete Summary

GUIDELINE TITLE

Screening for cervical cancer: recommendations and rationale.

BIBLIOGRAPHIC SOURCE(S)

Screening for cervical cancer: recommendations and rationale. Am Fam Physician 2003 Apr 15;67(8):1759-66. [32 references] PubMed

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Cervical cancer

GUIDELINE CATEGORY

Prevention
Screening

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Obstetrics and Gynecology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To summarize the current U.S. Preventive Services Task Force (USPSTF) recommendations on screening for cervical cancer and the supporting evidence
- To update the 1996 recommendations contained in the Guide to Clinical Preventive Services, Second Edition

TARGET POPULATION

- Women who have been sexually active and have a cervix
- Women older than age 65 years
- Women who have had a total hysterectomy for benign disease

INTERVENTIONS AND PRACTICES CONSIDERED

1. Screening for cervical cancer with cervical cytology (Papanicolaou [Pap] testing)
2. Routine use of new technologies to screen for cervical cancer
    - Thin layer cytology (ThinPrep®, AutoCyte PREP®)
    - Computerized rescreening (PapNet®)
    - Algorithm-based screening (AutoPap®)
3. Routine use of human papillomavirus (HPV) testing as a primary screening test for cervical cancer

MAJOR OUTCOMES CONSIDERED

- Morbidity and mortality associated with squamous cell carcinoma of the cervix
- Accuracy and reliability of screening tests for cervical cancer

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 systematic evidence review was prepared by the Research Triangle Institute-University of North Carolina Evidence-based Practice Center for the Agency for Healthcare Research and Quality (AHRQ) for use by the U.S. Preventive Services Task Force (USPSTF) (see the "Companion Documents" field).

Literature Search Strategy

Key questions guided the preliminary review of the literature. Emphasized was the identification of new research, existing syntheses of the literature, and opinions of leading medical and policy organizations, especially those reported since the completion of the second Guide to Clinical Preventive Services. As part of the

preliminary search, four steps were taken: (1) reviewed prior USPSTF findings; (2) obtained current recommendations and/or guidelines for cervical cancer screening from the American Academy of Family Physicians (AAFP), American Cancer Society (ACS), American College of Obstetricians and Gynecologists (ACOG), Australian Health Ministers´ Advisory Council, Canadian National Workshop on Screening for Cancer of the Cervix, the National Strategic Plan for Early Detection and Control of Breast and Cervical Cancer, and the UK National Health Service Cervical Cancer Screening Program; (3) identified recent relevant systematic reviews in the medical literature; and (4) consulted with USPSTF liaisons for this topic.

Inclusion/Exclusion Criteria

Overall inclusion and exclusion criteria were established a priori. Tables 3 and 4 in the Systematic Evidence Review (see "Companion Documents" field) present results of the search strategy with specific search terms.

The search strategy, developed with the assistance of the Research Triangle Institute-University of North Carolina Evidence-based Practice Center research librarian who specializes in evidence-based literature review is described in Table 4 of the Systematic Evidence Review. Using a selection of sentinel publications relevant to each key topic that were captured in the original broad search (see Table 3 in the Systematic Evidence Review), searches were specified that would provide focused identification of articles related to each key question. However, further specifying exhaustive searches for each question resulted in oversight of articles likely to be relevant as judged by missing sentinel articles. Key Question 1 about older age, older age and interval, and hysterectomy was the most difficult search to focus. As a result, an exhaustive approach was taken to categorize all articles obtained in the larger search. This process is described in detail in the Systematic Evidence Review.

NUMBER OF SOURCE DOCUMENTS

Key Question 1: Who should be screened for cervical cancer and how often?
1A. Among women age 65 and older?
1B. Among women who have had a hysterectomy?

In total, 118 full articles were screened to determine relevance. Of these, 42 were retained for Key Questions 1A and 1B: 14 for full abstraction and 28 for supplementary information.

Key Question 2: To what extent do new methods for preparing or evaluating cervical cytology improve diagnostic yield compared to conventional methods? At what cost (harms and economic)?

48 full articles were screened; in total, three high-quality and five other articles were abstracted for the evidence tables and 5 were retained for supplementary information.

Key Question 3: What is the role of human papillomavirus (HPV) testing in cervical cancer screening strategies?

3A. What are the benefits, harms, and costs of using HPV testing as a screening test, or of incorporating HPV testing at the time of the screening Pap test, compared with not testing for HPV?
3B. What are the benefits, harms, and costs of using HPV testing as part of a screening strategy to determine which women with an abnormal Pap test should receive further evaluation?

The search identified 64 abstracts. In total, 30 full articles were screened; 16 of these 30 articles were included: 13 for full abstraction and 3 for supplementary information.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

The U.S. Preventive Services Task Force (USPSTF) grades the quality of the overall evidence for a service on a 3-point scale (good, fair, or poor).

Good

Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes.

Fair

Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies; generalizability to routine practice; or indirect nature of evidence on health outcomes.

Poor

Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.

Note: See the companion document titled "Current Methods of the U.S. Preventive Services Task Force: a Review of the Process" (Am J Prev Med 2001 Apr;20[3S]:21-35) for a more detailed description of the methods used to assess the quality and strength of the evidence for the three strata at which the evidence was reviewed.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): A systematic evidence review was prepared by the Research Triangle Institute-University of North Carolina Evidence-based Practice Center for the Agency for Healthcare Research and Quality (AHRQ) for use by the U.S. Preventive Services Task Force (USPSTF) (see the "Companion Documents" field).

Screening of Articles

Two evidence-based practice center (EPC) staff independently reviewed the titles and abstracts of the articles identified and excluded those that did not meet eligibility criteria. If the reviewers disagreed, the article in question was carried forward to the next stage where the full article was reviewed and a final decision was made about inclusion or exclusion. At each step, the fate of the article was recorded in the ProCite database. See Table 5 in the Systematic Evidence Review for the disposition of articles identified as potentially relevant publications (for review of the full article), summarizing the number of publications at each step and their categorization.

In limiting the exhaustive search (refer to search 8, Table 4 in the Systematic Evidence Review) to identify only articles that reported on trials, 57 articles were identified. Of these, 25 are primary reports of randomized trials: 15 address methods to promote uptake and continuance of appropriate screening; 3 examine methods to improve follow-up of abnormal screening findings; 3 compare tools for collecting cytologic samples (i.e., type of spatula, brush or swab); 3 investigate patient education and satisfaction; and 1 compares cytology alone to cytology with cervicography as a primary screening modality. This exercise confirmed the assessment that few data would be available from randomized controlled clinical trials to inform this review.

Because final inclusion criteria were closely linked to the intent of the key question, greater detail was given about selection of articles for each of the key questions. Refer to Table 5 in the Systematic Evidence Review for a summary of the disposition of the articles identified in the literature search and the number of full articles on each topic retained for review.

Data Abstraction and Development of Evidence Tables

Information was abstracted about study objective, design, population, conduct, outcomes, and quality into designated sections and positions within evidence tables created in Microsoft Excel and Word. Two readers, a methodologist and a clinician-researcher, reviewed each article in an evidence table. The order of review by each pair of readers was not mandated, and both parties checked calculations of summary data, such as test sensitivity, that was generated for the tables.

To assess systematically comparable features of included articles and assure consistency, a checklist of potential indicators of study quality for the literature related to each key question was used. For Key Questions 2 and 3, scores were provided using the system designed for the Evaluation of Cervical Cytology evidence report, which fully documents development of the scoring system. For

Key Question 1, indicators more relevant to cohort research were incorporated, eliminating those items related purely to evaluation of diagnostic tests. Scores were assigned separately by two individuals and discussed as a group in the rare cases of substantial differences of opinion. These scores and a global categorization of the internal and external validity of the reviewed research contributed to grading of individual articles and the body of relevant literature consistent with USPSTF methods.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Balance Sheets
Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

When the overall quality of the evidence is judged to be good or fair, the U.S. Preventive Services Task Force (USPSTF) proceeds to consider the magnitude of net benefit to be expected from implementation of the preventive service. Determining net benefit requires assessing both the magnitude of benefits and the magnitude of harms and weighing the two.

The USPSTF classifies benefits, harms, and net benefits on a 4-point scale: "substantial," "moderate," "small," and "zero/negative."

"Outcomes tables" (similar to 'balance sheets') are the USPSTF's standard resource for estimating the magnitude of benefit. These tables, prepared by the topic teams for use at USPSTF meetings, compare the condition specific outcomes expected for a hypothetical primary care population with and without use of the preventive service. These comparisons may be extended to consider only people of specified age or risk groups or other aspects of implementation. Thus, outcomes tables allow the USPSTF to examine directly how the preventive services affects benefits for various groups.

When evidence on harms is available, the topic teams assess its quality in a manner like that for benefits and include adverse events in the outcomes tables. When few harms data are available, the USPSTF does not assume that harms are small or nonexistent. It recognizes a responsibility to consider which harms are likely and judge their potential frequency and the severity that might ensue from implementing the service. It uses whatever evidence exists to construct a general confidence interval on the 4-point scale (e.g., substantial, moderate, small, and zero/negative).

Value judgments are involved in using the information in an outcomes table to rate either benefits or harms on the USPSTF's 4-point scale. Value judgments are also needed to weigh benefits against harms to arrive a rating of net benefit.

In making its determinations of net benefit, the USPSTF strives to consider what it believes are the general values of most people. It does this with greater confidence for certain outcomes (e.g., death) about which there is little disagreement about undesirability, but it recognizes that the degree of risk people

are willing to accept to avert other outcomes (e.g., cataracts) can vary considerably. When the USPSTF perceives that preferences among individuals vary greatly, and that these variations are sufficient to make trade-off of benefits and harms a 'close-call', then it will often assign a C recommendation (see the "Recommendation Rating Scheme" field). This recommendation indicates the decision is likely to be sensitive to individual patient preferences.

The USPSTF uses its assessment of the evidence and magnitude of net benefit to make recommendations. The general principles the USPSTF follows in making recommendations are outlined in Table 5 of the companion document cited below. The USPSTF liaisons on the topic team compose the first drafts of the recommendations and rationale statements, which the full panel then reviews and edits. Recommendations are based on formal voting procedures that include explicit rules for determining the views of the majority.

From: Harris RP, Helfand M, Woolf SH, Lohr KN, Mulrow, CD, Teutsch SM, Atkins D. Current methods of the U.S. Preventive Services Task Force: a review of the process. Methods Work Group, Third U.S. Preventive Services Task Force. Am J Prev Med 2001 Apr;20(3S):21-35.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The U.S. Preventive Services Task Force (USPSTF) grades its recommendations according to one of five classifications (A, B, C, D, or I), reflecting the strength of evidence and magnitude of net benefit (benefits minus harms).

A

The U.S. Preventive Services Task Force (USPSTF) strongly recommends that clinicians provide [the service] to eligible patients. (The USPSTF found good evidence that [the service] improves important health outcomes and concludes that benefits substantially outweigh harms.)

B

The U.S. Preventive Services Task Force (USPSTF) recommends that clinicians provide [the service] to eligible patients. (The USPSTF found at least fair evidence that [the service] improves health outcomes and concludes that benefits outweigh harms.)

C

The U.S. Preventive Services Task Force (USPSTF) makes no recommendation for or against routine provision of [the service]. (The USPSTF found at least fair evidence that [the service] can improve health outcomes but concludes that the balance of benefits and harms it too close to justify a general recommendation.)

D

The U.S. Preventive Services Task Force (USPSTF) recommends against routinely providing [the service] to asymptomatic patients. (The USPSTF found at least fair evidence that [the service] is ineffective or that harms outweigh benefits.)

I

The U.S. Preventive Services Task Force (USPSTF) concludes that the evidence is insufficient to recommend for or against routinely providing [the service]. (Evidence that [the service] is effective is lacking, of poor quality, or conflicting and the balance of benefits and harms cannot be determined.)

COST ANALYSIS

A central goal of the Evaluation of Cervical Cytology evidence report was modeling the effects on total health care costs, morbidity, and mortality of regular cervical cytologic screening using newer screening technologies compared with conventional Pap smear in women participating in screening. Using a Markov model of a cohort of women ages 15 to 85, incorporating estimates about the natural history of HPV, and investigating one-, two-, and three-year screening intervals, they reached the following conclusions:

- The cost-effectiveness of either a technology that improves primary screening sensitivity (e.g., thin-layer cytology) or one that improves rescreening sensitivity (e.g., computerized rescreening) is directly related to the frequency of screening-longer intervals result in lower estimates of cost per life year saved.
- Findings were relatively insensitive to assumptions about cervical cancer incidence, cost of technologies, diagnostic strategies for abnormal screening results, age at onset of screening, or most of the other variables tested.
- Substantial uncertainty surrounds the estimates of sensitivity and specificity of thin-layer cytology and computerized rescreening technologies compared with each other and with conventional Pap testing. This uncertainty is not reflected in the point estimates of cost-effectiveness. Although both thin-layer cytology and computerized rescreening technologies clearly improve effectiveness at higher cost, the imprecision in estimates of effectiveness makes drawing conclusions about the relative cost-effectiveness of thin-layer cytology and computerized rescreening technologies problematic.
- Given the uncertainty surrounding these estimates, all three technologies may well fall within accepted ranges of cost-effectiveness at 3-year screening intervals. No strategy or technology used for screening more often than every 3 years results in estimates of less than $50,000 per life-year.

This model substantially improves on prior work; it includes global costs of downstream care resulting from screening and cancers, more accurate estimates of the performance of conventional cytology then previously available, and sophisticated sensitivity analyses. However, important parameters of this model deserve note. Base assumptions include the following: (1) all women receive screening at the appropriate interval; (2) new technologies increase sensitivity without any decrement in specificity; (3) all patients receive appropriate follow-up; and (4) diagnostic evaluation of abnormal cytology detects all true abnormalities (i.e., no colposcopy or pathology errors are made). Adjusting each of these assumptions closer to actual clinical scenarios has the effect of increasing

the cost-effectiveness ratio. If, as the SER update and the full Cervical Cytology report suggest, new technologies do have lower specificity than conventional cytology, then costs and harms of false positives have important system and individual implications.

The Cervical Cytology report also includes systematic review of prior literature on the cost-effectiveness of cervical cytology. In summary:

- Published models examining the cost and effectiveness of Pap smear screening have consistently found Pap screening to have a significant impact on the incidence and mortality of cervical cancer and to have an acceptable range of cost-effectiveness ratios when compared with no screening.
- Estimates of Pap test accuracy used in these models generally overestimated Pap test performance, as determined by recent unbiased studies, the findings of the report itself [Cervical Cytology], and a previously published meta-analysis. Best estimates of Pap test performance fall outside the range used in sensitivity analyses of some models.

Many of these models have results that are consistent when important parameters of the models are varied across of broad spectrum of assumptions. Ultimately, however, all current models are tied to the limitations in this literature and must be considered temporary substitutes for prospective research.

From: Hartmann KE, Hall SA, Nanda K, Boggess JF, Zolnoun D. Screening for cervical cancer. Systematic evidence review. Rockville (MD); Agency for Healthcare Research and Quality; 2003 Jan. (Systematic evidence review; No. 25) (see the "Companion Documents" field).

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 (USPSTF) 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 systematic 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 recommendations are then circulated for comment from reviewers representing professional societies, voluntary organizations and Federal agencies. These comments are discussed before the whole U.S. Preventive Services Task Force before final recommendations are confirmed.

Recommendations of Others. Recommendations regarding the initiation of screening and discontinuation of screening for cervical cancer were discussed from the following groups: American Cancer Society (ACS), American Academy of Family Physicians (AAFP), American College of Obstetricians and Gynecologists (ACOG), American College of Preventive Medicine (ACPM), American Medical Association (AMA), the Canadian Task Force on Preventive Health Care (CTFPHC), and the American Academy of Pediatrics (AAP).

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The U.S. Preventive Services Task Force (USPSTF) grades its recommendations (A, B, C, D, or I) and the quality of the overall evidence for a service (good, fair, poor). The definitions of these grades can be found at the end of the "Major Recommendations" field.

- The U.S. Preventive Services Task Force (USPSTF) strongly recommends screening for cervical cancer in women who have been sexually active and have a cervix. A recommendation.

  The USPSTF found good evidence from multiple observational studies that screening with cervical cytology (Papanicolaou [Pap] smears) reduces incidence of and mortality from cervical cancer. Direct evidence to determine the optimal starting and stopping age and interval for screening is limited. Indirect evidence suggests most of the benefit can be obtained by beginning screening within 3 years of onset of sexual activity or age 21 (whichever comes first) and screening at least every 3 years (see Clinical Considerations below). The USPSTF concludes that the benefits of screening substantially outweigh potential harms.

- The USPSTF recommends against routinely screening women older than age 65 for cervical cancer if they have had adequate recent screening with normal Pap smears and are not otherwise at high risk for cervical cancer (see Clinical Considerations below). D recommendation.

  The USPSTF found limited evidence to determine the benefits of continued screening in women older than 65. The yield of screening is low in previously screened women older than 65 due to the declining incidence of high-grade cervical lesions after middle age. There is fair evidence that screening women older than 65 is associated with an increased risk for potential harms, including false-positive results and invasive procedures. The USPSTF concludes that the potential harms of screening are likely to exceed benefits among older women who have had normal results previously and who are not otherwise at high risk for cervical cancer.

- The USPSTF recommends against routine Pap smear screening in women who have had a total hysterectomy for benign disease. D recommendation.

  The USPSTF found fair evidence that the yield of cytologic screening is very low in women after hysterectomy and poor evidence that screening to detect

vaginal cancer improves health outcomes. The USPSTF concludes that potential harms of continued screening after hysterectomy are likely to exceed benefits.

- The USPSTF concludes that the evidence is insufficient to recommend for or against the routine use of new technologies to screen for cervical cancer. I recommendation.

  The USPSTF found poor evidence to determine whether new technologies, such as liquid-based cytology, computerized rescreening, and algorithm based screening, are more effective than conventional Pap smear screening in reducing incidence of or mortality from invasive cervical cancer. Evidence to determine both sensitivity and specificity of new screening technologies is limited. As a result, the USPSTF concludes that it cannot determine whether the potential benefits of new screening devices relative to conventional Pap tests are sufficient to justify a possible increase in potential harms or costs.

- The USPSTF concludes that the evidence is insufficient to recommend for or against the routine use of human papillomavirus (HPV) testing as a primary screening test for cervical cancer. I recommendation.

  The USPSTF found poor evidence to determine the benefits and potential harms of HPV screening as an adjunct or alternative to regular Pap smear screening. Trials are underway that should soon clarify the role of HPV testing in cervical cancer screening.

Clinical Considerations

- The goal of cytologic screening is to sample the transformation zone, the area where physiologic transformation from columnar endocervical epithelium to squamous (ectocervical) epithelium takes place and where dysplasia and cancer arise. A meta-analysis of randomized trials supports the combined use of an extended tip spatula to sample the ectocervix and a cytobrush to sample the endocervix.
- The optimal age to begin screening is unknown. Data on natural history of human papillomavirus (HPV) infection and the incidence of high-grade lesions and cervical cancer suggest that screening can safely be delayed until 3 years after onset of sexual activity or until age 21, whichever comes first. Although there is little value in screening women who have never been sexually active, many U.S. organizations recommend routine screening by age 18 or 21 for all women, based on the generally high prevalence of sexual activity by that age in the U.S. and concerns that clinicians may not always obtain accurate sexual histories.
- Discontinuation of cervical cancer screening in older women is appropriate, provided women have had adequate recent screening with normal Pap results. The optimal age to discontinue screening is not clear, but risk of cervical cancer and yield of screening decline steadily through middle age. The USPSTF found evidence that yield of screening was low in previously screened women after age 65. New American Cancer Society (ACS) recommendations suggest stopping cervical cancer screening at age 70. Screening is recommended in older women who have not been previously screened, when information about previous screening is unavailable, or when

screening is unlikely to have occurred in the past (e.g., among women from countries without screening programs). Evidence is limited to define "adequate recent screening." The ACS guidelines recommend that older women who have had three or more documented, consecutive, technically satisfactory normal/negative cervical cytology tests, and who have had no abnormal/positive cytology tests within the last 10 years, can safely stop screening.

- The USPSTF found no direct evidence that annual screening achieves better outcomes than screening every 3 years. Modeling studies suggest little added benefit of more frequent screening for most women. The majority of cervical cancers in the U.S. occur in women who have never been screened or who have not been screened within the past 5 years; additional cases occur in women who do not receive appropriate follow-up after an abnormal Pap smear. Because sensitivity of a single Pap test for high-grade lesions may only be 60% to 80%, however, most organizations in the U.S. recommend that annual Pap smears be performed until a specified number (usually 2 or 3) are cytologically normal before lengthening the screening interval. The ACS guidelines suggest waiting until age 30 before lengthening the screening interval; the American College of Obstetricians and Gynecologists (ACOG) identifies additional risk factors that might justify annual screening, including a history of cervical neoplasia, infection with HPV or other sexually transmitted diseases (STDs), or high-risk sexual behavior, but data are limited to determine the benefits of these strategies.
- Discontinuation of cytological screening after total hysterectomy for benign disease (e.g., no evidence of cervical neoplasia or cancer) is appropriate given the low yield of screening and the potential harms from false-positive results in this population. Clinicians should confirm that a total hysterectomy was performed (through surgical records or inspecting for absence of a cervix); screening may be appropriate when the indications for hysterectomy are uncertain. ACS and ACOG recommend continuing cytologic screening after hysterectomy for women with a history of invasive cervical cancer or diethylstilbestrol (DES) exposure due to increased risk for vaginal neoplasms, but data on the yield of such screening are sparse.
- A majority of cases of invasive cervical cancer occur in women who are not adequately screened. Clinicians, hospitals, and health plans should develop systems to identify and screen the subgroup of women who have had no screening or who have had inadequate past screening.
- Newer Food and Drug Administration (FDA)-approved technologies, such as liquid-based cytology (e.g., ThinPrep®), may have improved sensitivity over conventional Pap smear screening, but at a considerably higher cost and possibly with lower specificity. Even if sensitivity is improved, modeling studies suggest these methods are not likely to be cost-effective unless used with screening intervals of 3 years or longer. Liquid-based cytology permits testing of specimens for HPV, which may be useful in guiding management of women whose Pap smear reveals atypical squamous cells. HPV DNA testing for primary cervical cancer screening has not been approved by the FDA and its role in screening remains uncertain.

USPSTF grades its recommendations according to one of 5 classifications (A, B, C, D, I) reflecting the strength of evidence and magnitude of net benefit (benefits minus harms).

A

The USPSTF strongly recommends that clinicians provide [the service] to eligible patients. The USPSTF found good evidence that [the service] improves important health outcomes and concludes that benefits substantially outweigh harms.

B

The USPSTF recommends that clinicians provide [this service] to eligible patients. The USPSTF found at least fair evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms.

C

The USPSTF makes no recommendation for or against routine provision of [the service]. The USPSTF found at least fair evidence that [the service] can improve health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation.

D

The USPSTF recommends against routinely providing [the service] to asymptomatic patients. The USPSTF found at least fair evidence that [the service] is ineffective or that harms outweigh benefits.

I

The USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing [the service]. Evidence that [the service] is effective is lacking, of poor quality, or conflicting and the balance of benefits and harms cannot be determined.

The U.S. Preventive Services Task Force (USPSTF) grades the quality of the overall evidence for a service on a 3-point scale (good, fair, poor).

Good

Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes.

Fair

Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies, generalizability to routine practice, or indirect nature of the evidence on health outcomes.

Poor

Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting each recommendation is identified in the "Major Recommendations" field.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Effectiveness of Early Detection

Detection of cervical cancer in its earliest stages is lifesaving, as survival of cancer of the cervix uteri depends heavily on stage at diagnosis. Although 91.5% of women will survive 5 years when the cancer is localized, only 12.6% will survive distant disease. Introduction of screening programs to populations naïve to screening reduces cervical cancer rates by 60% to 90% within 3 years of implementation. This reduction of mortality and morbidity with introduction of the Papanicolaou (Pap) test is consistent and dramatic across populations. Although no prospective trial of Pap screening has ever been conducted, correlational studies of cervical cancer trends in countries in North America and Europe demonstrate dramatic reductions in incidence of invasive cervical cancer and a 20% to 60% reduction in cervical cancer mortality.

No prospective studies have directly compared the outcomes of screening at different intervals in a given population. Data from eight cervical cancer screening programs involving 1.8 million women compared the effects of different intervals among the programs: screening at intervals of 5, 3, 2 years or 1 year was estimated to reduce incidence of invasive disease by 84%, 91%, 93%, and 94%, respectively, among women aged 35 to 64, assuming perfect compliance. Data from a large screening program in the U.S. indicate that a longer interval (3 years vs. 1 or 2 years) between Pap tests is not associated with a higher risk for developing high-grade lesions.

Subgroups Most Likely to Benefit:

- Women with early onset of sexual intercourse
- Women with multiple sexual partners
- Women infected with high-risk strains of human papillomavirus (HPV)
- Women who smoke cigarettes

POTENTIAL HARMS

Potential Harms of Screening and Treatment

The U.S. Preventive Services Task Force (USPSTF) did not identify studies that specifically addressed harms of new technologies for cervical cancer screening. Better data on the performance characteristics (sensitivity, specificity, and predictive values) of the new screening technologies are needed to determine the risk for harm to an individual patient. Although the data are limited, on average these tools improve sensitivity and reduce specificity. This finding suggests that increased detection of low-grade lesions and false positives are the primary potential sources of harm; i.e., harm may take the form of increased evaluations, including repeated Papanicolaou (Pap) tests and biopsies; possible unnecessary treatment for low-grade lesions; and psychological distress for the women diagnosed with low grade lesions that may not have been clinically important. These harms are poorly documented for conventional Pap testing and have not yet been assessed for new technologies.

With regard to human papillomavirus (HPV) testing, the USPSTF did not identify any studies that quantified harms. Potential harms commented upon in the literature include stigma, partner discord, adverse effects of labeling some women as being at high risk for cervical cancer, and the potential undermining of routine cytologic screening known to be effective.

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.

Neither the resources nor the composition of the U.S. Preventive Services Task Force equip it to address these numerous implementation challenges, but a

number of related efforts seek to increase the impact of future U.S. Preventive Services Task Force reports. The U.S. Preventive Services Task Force convened representatives from the various audiences for the Guide "Put Prevention Into Practice. A Step-by-Step Guide to Delivering Clinical Preventive Services: A Systems Approach" - clinicians, consumers and policy makers from health plans, national organizations and Congressional staff - about how to modify the content and format of its products to address their needs. With funding from the Robert Wood Johnson Foundation, the U.S. Preventive Services Task Force and Community Guide effort have conducted an audience analysis to further explore implementation needs. The Put Prevention into Practice initiative at the Agency for Healthcare Research and Quality (AHRQ) has developed office tools such as patient booklets, posters, and handheld patient mini-records, and a new implementation guide for state health departments.

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 third edition of the Guide to Clinical Preventive Services. Freed from having to serve as primary repository for all of U.S. Preventive Services Task Force work, the next Guide may be much slimmer than the almost 1000 pages of the second edition.

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.

RELATED NQMC MEASURES

- Prenatal testing: percentage of patients who have a cervical cytology smear performed during the preceding year or by the second prenatal care visit.

RELATED QUALITY TOOLS

- Pocket Guide to Good Health for Adults

- A Step-by-Step Guide to Delivering Clinical Preventive Services: A Systems Approach

- Screening for Cervical Cancer. What's New from the USPSTF.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Screening for cervical cancer: recommendations and rationale. Am Fam Physician 2003 Apr 15;67(8):1759-66. [32 references] PubMed

ADAPTATION

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

DATE RELEASED

1996 (revised 2003 Jan 22)

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 USPSTF do not necessarily reflect policy of the U.S. Department of Health and Human Services (DHHS) or DHHS agencies.

SOURCE(S) OF FUNDING

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GUIDELINE COMMITTEE

U.S. Preventive Services Task Force (USPSTF)

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The U.S. Preventive Services Task force has an explicit policy concerning conflict of interest. All members and evidence-based practice center (EPC) staff disclose at each meeting if they have an important financial conflict for each topic being discussed. Task Force members and EPC staff with conflicts can participate in discussions about evidence, but members abstain from voting on recommendations about the topic in question.

From: Harris RP, Helfand M, Woolf SH, Lohr KN, Mulrow, CD, Teutsch SM, Atkins D. Current methods of the U.S. Preventive Services Task Force: a review of the process. Methods Work Group, Third U.S. Preventive Services Task Force. Am J Prev Med 2001 Apr;20(3S):21-35.

GUIDELINE STATUS

This is the current release of the guideline.

This release updates a previously published guideline: U.S. Preventive Services Task Force. Screening for cervical cancer. In: Guide to clinical preventive services. 2nd ed; Baltimore (MD): Williams & Wilkins; 1996. p. 105-17.

GUIDELINE AVAILABILITY

Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site and the National Library of Medicine's Health Services/Technology Assessment Text (HSTAT) Web site.

Print copies: Available from the Agency for Healthcare Research and Quality (AHRQ) Publications Clearinghouse. For more information, go to 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:

- Hartmann KE, Hall SA, Nanda K, Boggess JF, Zolnoun D. Screening for cervical cancer. Systematic evidence review. Rockville (MD); Agency for Healthcare Research and Quality; 2003 Jan. (Systematic evidence review; No. 25).

Background Articles:

- Woolf SH, Atkins D. The evolving role of prevention in health care: contributions of the U.S. Preventive Services Task Force. Am J Prev Med 2001 Apr;20(3S):13-20.
- Harris RP, Helfand M, Woolf SH, Lohr KN, Mulrow, CD, Teutsch SM, Atkins D. Current methods of the U.S. Preventive Services Task Force: a review of the process. Methods Work Group, Third U.S. Preventive Services Task Force. Am J Prev Med 2001 Apr;20(3S):21-35.
- Saha S, Hoerger TJ, Pignone MP, Teutsch SM, Helfand M, Mandelblatt JS. The art and science of incorporating cost effectiveness into evidence-based recommendations for clinical preventive services. Cost Work Group of the Third U.S. Preventive Services Task Force. Am J Prev Med 2001 Apr;20(3S):36-43.

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

Additional Implementation Tools:

- A step-by-step guide to delivering clinical preventive services: a systems approach. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ), 2001. 189 p. (Pub. No. APPIP01-0001). Electronic copies available from the AHRQ 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 Preventive Services Selector, an application for Palm Pilots and other PDA's, is also available from the AHRQ Web site.
- Screening for cervical cancer. What's new from the third USPSTF. Rockville (MD): Agency for Healthcare Research and Quality; 2003 Jan. Electronic copies: Available from USPSTF Web site.

PATIENT RESOURCES

The following is available:

- The Pocket Guide to Good Health for Adults. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2003.

Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site. Copies also available in Spanish from the USPSTF Web site.

Print copies: Available from the Agency for Healthcare Research and Quality (AHRQ) Publications Clearinghouse. For more information, go to 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.

NGC STATUS

This summary was completed by ECRI on June 30, 1998. The information was verified by the guideline developer on December 1, 1998. This summary was updated by ECRI on January 17, 2003. The updated information was verified by the guideline developer on January 20, 2003.

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