Complete Summary

GUIDELINE TITLE

Cervical cancer screening guideline: October 2006.

BIBLIOGRAPHIC SOURCE(S)

Kaiser Permanente National Cervical Cancer Screening Guideline Development Team. Cervical cancer screening guideline. Oakland (CA): Kaiser Permanente Care Management Institute; 2006 Oct. 124 p. [199 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Cervical cancer

GUIDELINE CATEGORY

Prevention
Screening

CLINICAL SPECIALTY

Family Practice
Infectious Diseases
Internal Medicine
Obstetrics and Gynecology

Oncology
Pathology
Pediatrics
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To provide recommendations (evidence-based and consensus-based) on cervical cancer screening
- To assist primary care and specialist physicians and other health care professionals in counseling asymptomatic adolescents and adults about cervical cancer screening procedures

TARGET POPULATION

- Asymptomatic adult women 21 years of age and older and females under age 21 who are sexually active who have had none of the following:
    - Hysterectomy with total removal of the cervix for a benign condition
    - Hysterectomy with total removal of the cervix for a precancerous or cancerous condition of the uterus, cervix, or vagina
    - Human immunodeficiency virus (HIV) infection and/or immunosuppression (due to organ transplantation or other condition)
    - A single positive human papillomavirus (HPV) test
    - Persistently positive human papillomavirus tests
    - A recent abnormal cytologic result
    - Previous diagnosis of cervical cancer or cervical intraepithelial neoplasia, grade 2/3 (CIN2/3)
- Asymptomatic adolescent and adult females with a cytology smear of atypical squamous cells of unknown significance (ASC-US)
- Asymptomatic adult women who have had a hysterectomy with total removal of the cervix for a benign condition of the uterus, cervix, or vagina
- Women who are infected with human immunodeficiency virus (HIV), are immunosuppressed (e.g., due to organ transplantation or other condition), or who have been previously diagnosed with cervical cancer or cervical intraepithelial neoplasia, grade 2/3 (CIN2/3)

INTERVENTIONS AND PRACTICES CONSIDERED

Cervical Cancer Screening

1. Conventional cytology alone or with human papillomavirus (HPV) testing
2. Liquid-based cytology alone or with HPV testing
3. HPV testing as compared with repeat cytology or immediate colposcopy

MAJOR OUTCOMES CONSIDERED

Efficacy of cervical cancer screening

- Sensitivity and specificity of diagnostic tests
- Morbidity and mortality from cervical cancer
- Adverse effects of tests (e.g., inconvenience, anxiety, discomfort, pain, false-positive results, false-negative results)

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Guidelines are developed using an "evidence-based methodology" that involves a systematic literature search, critical appraisal of the research design and statistical results of relevant studies, and grading of the sufficiency (quantity, quality, consistency, and relevancy) of the evidence for drawing conclusions.

During the guideline development process, the Guideline Development Team reviews evidence published in peer-reviewed scientific journals, existing evidence-based guidelines and consensus statements from external professional societies and government health organizations, and clinical expert opinion of Kaiser Permanente regional specialty groups.

For details of the literature search, including databases searched and search terms for each clinical question, see the original guideline document.

NUMBER OF SOURCE DOCUMENTS

Not stated

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

Refer to Table 2 in Appendix B of the original guideline document for the system for grading the strength of a body of evidence.

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

The Guidelines Project Management Team performed systematic reviews of the medical literature on each of the clinical questions identified by the workgroup.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

For the Cervical Cancer Screening Guideline, the Project Management Team performed systematic reviews of the medical literature on each of the clinical questions identified by the workgroup, assembled the evidence, and developed draft recommendations for review by the Guidelines Workgroup. All of the recommendations and supporting evidence were reviewed by the Guidelines Workgroup in depth through a series of conference calls in 2004. The National Guideline Directors reviewed and sponsored the guidelines on January 27, 2005.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Recommendations are classified as either "evidence-based (A-D, I)" or "consensus-based."

- *Evidence-based*: sufficient number of high-quality studies from which to draw a conclusion, and the recommended practice is consistent with the findings of the evidence. A recommendation can also be considered "evidence-based" if there is insufficient evidence and no practice is recommended.
- *Consensus-based*: insufficient evidence and a practice is recommended based on the consensus or expert opinion of the Guideline Development Team.

Label and Language of Recommendations*

Label	Evidence-Based Recommendations
Evidence-based (A)	**Language**: [a] The intervention is strongly recommended for eligible patients. **Evidence**: The intervention improves important health outcomes, based on good evidence, and the Guideline Development Team (GDT) concludes that benefits substantially outweigh harms and costs. **Evidence Grade**: Good.
Evidence-based (B)	**Language**: [a] The intervention is recommended for eligible patients. **Evidence**: The intervention improves important health outcomes, based on 1) good evidence that benefits outweigh harms and costs; or 2) fair evidence that benefits substantially outweigh harms and costs. **Evidence Grade**: Good or Fair.
Evidence-	**Language**: [a] No recommendation for or against routine provision of

Label	Evidence-Based Recommendations
based (C)	the intervention. (At the discretion of the GDT, the recommendation may use the language "option," but must list all the equivalent options.) **Evidence**: Evidence is sufficient to determine the benefits, harms, and costs of an intervention, and there is at least fair evidence that the intervention improves important health outcomes. But the GDT concludes that the balance of the benefits, harms, and costs is too close to justify a general recommendation. **Evidence Grade**: Good or Fair.
Evidence-based (D)	**Language**: [a] Recommendation against routinely providing the intervention to eligible patients. **Evidence**: The GDT found at least fair evidence that the intervention is ineffective, or that harms or costs outweigh benefits. **Evidence Grade**: Good or Fair.
Evidence-based (I)	**Language**: [a] The evidence is insufficient to recommend for or against routinely providing the intervention. (At the discretion of the GDT, the recommendation may use the language "option," but must list all the equivalent options.) **Evidence**: Evidence that the intervention is effective is lacking, of poor quality, or conflicting and the balance of benefits, harms, and costs cannot be determined. **Evidence Grade**: Insufficient.
Consensus-based	**Language**: [a] The language of the recommendation is at the discretion of the GDT, subject to approval by the National Guideline Directors. **Evidence**: The level of evidence is assumed to be "Insufficient" unless otherwise stated. However, do not use the A, B, C, D, or I labels which are only intended to be used for evidence-based recommendations. **Evidence Grade**: Insufficient, unless otherwise stated.
For the rare consensus-based recommendations which have "Good" or "Fair" evidence, the evidence must support a different recommendation, because if the evidence were good or fair, the recommendation would usually be evidence-based. In this kind of consensus-based recommendation, the evidence grade should point this out (e.g., "Evidence Grade: Good, supporting a different recommendation").	

[a] All statements specify the population for which the recommendation is intended.

*Recommendations should be labeled and given an evidence grade. The evidence grade should appear in the rationale. Evidence is graded with respect to the degree it supports the specific clinical recommendation. For example, there may be good evidence that Drugs 1 and 2 are effective for Condition A, but no evidence that Drug 1 is more effective than Drug 2. If the recommendation is to

use either Drug 1 or 2, the evidence is good. If the recommendation is to use Drug 1 in preference to Drug 2, the evidence is insufficient.

COST ANALYSIS

Published cost analyses were reviewed that evaluated the cost-effectiveness of the different screening strategies. Additional details are contained in the original guideline document.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The National Guideline Directors reviewed and sponsored the guidelines on January 27, 2005. The updated evidence review was sponsored and approved on October 12, 2006.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Recommendations are identified as either "evidence-based (A-D, I)" or "consensus-based." For definitions of the levels of recommendations see the end of the "Major Recommendations" field.

Recommendations 1A-D: Effectiveness of Cervical Cancer Primary Screening Tests in Asymptomatic, Average-Risk Women

1A: Routine cervical cancer screening is recommended for all asymptomatic, average-risk women. ***(Evidence-based: B)***

1B: Either of the following tests are options for cervical cancer screening in asymptomatic, average-risk women <u>under age 30</u>.

- Conventional cytology ***(Evidence-based: B)***
- Liquid-based cytology ***(Consensus-based)***

1C: All of the following tests are acceptable options for cervical cancer screening in asymptomatic, average-risk women <u>age 30 and older</u>.

- Conventional cytology ***(Evidence-based: B)***
- Conventional cytology and human papillomavirus (HPV) testing*‡** cytology ***(Consensus-based)***
- Liquid-based cytology ***(Consensus-based)***
- Liquid-based cytology and HPV testing*‡** cytology ***(Consensus-based)***

**HPV testing has not been Food and Drug Administration (FDA) approved as a stand alone test for primary screening.*

‡ Combined cytology and HPV testing provides useful risk-stratification

*** Hybrid Capture 2 (HC2) Testing Device.*

1D: No recommendation for or against routine use of computer-assisted slide evaluation or automated rescreening of cytology slides. ***(Evidence-based: I)***

Recommendations 2A-B: Cervical Cancer Screening Intervals in Asymptomatic, Average-risk Women

2A: The following screening intervals are recommended:

- Cytology alone: every 3 years* ***(Consensus-based)***
- Cytology + HPV (age 30 and older): every 3 years*‡ ***(Consensus-based)***

**Screen if more than 30 months has elapsed.*

‡ Hybrid Capture 2 (HC2) Testing Device.

2B: No recommendation for or against routinely providing annual screening tests prior to beginning a triennial screening program. ***(Evidence-based: I)***

Recommendations 3A-B: Optimal Age to Begin and End Screening in Asymptomatic, Average-risk Women

3A: Initiation of cervical cancer screening is recommended approximately 3 years after first sexual intercourse or by the age of 21, whichever comes first.*‡ ***(Consensus-based)***

3B: Routine screening for cervical cancer for women older than age 65 is not recommended if they have had adequate recent screening** with normal results on their last cytology (and HPV test if applicable). ***(Evidence-based: D)***

> **The Guideline Development Team (GDT) recognizes that the age to begin screening may not adequately reflect the current The Health Plan Employer Data and Information Set (HEDIS) measures. Some regions may choose to offer screening at a younger age. The HEDIS® cervical cancer screening rate estimates the percentage of women aged 21 to 64 that were enrolled in the health plan and who had one cytology test during measurement year or the two years prior.*
>
> *‡Routine cervical cancer screening continues to be recommended for women who have received the HPV vaccine.*
>
> ***The Guideline Development Team defined adequate recent screening as 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.*

Recommendations 4A-B: Triage for Atypical Squamous Cells of Undetermined Significance (ASC-US) Results Using HPV Testing in Asymptomatic, Average-risk Women

4A: HPV testing is recommended in women of all ages for triage of cytology results indicating atypical squamous cells of undetermined significance. ***(Evidence-based: B)***

4B: No recommendation for or against the use of HPV testing to triage women with cytologic results higher than ASC-US. ***(Evidence-based: I)***

Recommendations 5A-5B: Optimal Cervical Cancer Screening Strategy for Women Who Have Had a Total Hysterectomy for a Benign Condition

5A: Routine cytology screening is not recommended for women who have had a total hysterectomy for a benign condition unless there was a history of cervical intraepithelial neoplasia grade 2/3 (CIN2/3). ***(Evidence-based: D)***

5B: Three consecutive negative cytology results with or without HPV testing are recommended prior to discontinuation of screening in women who have a history of cervical intraepithelial neoplasia grade 2/3 and a subsequent hysterectomy for a benign condition. ***(Consensus-based)***

Recommendations 6A-C: Screening in Women at Increased Risk of Cervical Cancer

6A: Cytology and HPV testing are recommended at 6 months following treatment for CIN2/3, and again at 24 months, with colposcopy for any positive result. Routine screening every 3 years can then be resumed indefinitely. ***(Consensus-based)***

6B: If HPV testing is not done, two cytology tests at 6 and 12 months after treatment are recommended, with colposcopy for a positive result, then annual cytologic screening indefinitely. ***(Consensus-based)***

6C: At least annual cytology with or without HPV testing is recommended for women who are immunosuppressed or human immunodeficiency virus (HIV)-positive. ***(Consensus-based)***

Recommendation 7A: Optimal Initial Management of Concurrent HPV-Positive and Cytology-Negative Cervical Screening Results

7A: HPV and cytology retesting is recommended in 12 months, rather than immediate colposcopy, for management of women with initial concurrent HPV-positive and cytology-negative screening results. ***(Consensus-based)***

Definitions:

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- *Consensus-based*: insufficient evidence and a practice is recommended based on the consensus or expert opinion of the Guideline Development Team (GDT).

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Evidence-based (C)	**Language**: [a] No recommendation for or against routine provision of the intervention. (At the discretion of the GDT, the recommendation may use the language "option," but must list all the equivalent options.) **Evidence**: Evidence is sufficient to determine the benefits, harms, and costs of an intervention, and there is at least fair evidence that the intervention improves important health outcomes. But the GDT concludes that the balance of the benefits, harms, and costs is too close to justify a general recommendation. **Evidence Grade**: Good or Fair.
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Label	Evidence-Based Recommendations
	costs cannot be determined. **Evidence Grade**: Insufficient.
Consensus-based	**Language**: [a] The language of the recommendation is at the discretion of the GDT, subject to approval by the National Guideline Directors. **Evidence**: The level of evidence is assumed to be "Insufficient" unless otherwise stated. However, do not use the A, B, C, D, or I labels which are only intended to be used for evidence-based recommendations. **Evidence Grade**: Insufficient, unless otherwise stated.
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[a] All statements specify the population for which the recommendation is intended.

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CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation, but the evidence underlying the recommendations are drawn from randomized controlled trials, meta-analyses, and existing systematic reviews. In cases where the data was inconclusive, inconsistent, or non-existent, recommendations were based on the consensus opinion of the group.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate cervical cancer screening
- Reduced morbidity and mortality from cervical cancer

POTENTIAL HARMS

- Inconvenience, anxiety, and adverse effects of tests (e.g., discomfort, pain, etc.)
- Unnecessary tests due to false-positive test results
- False reassurance from false-negative test results, neglect to follow-up, progression of cancer

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These guidelines are informational only. They are not intended or designed as a substitute for the reasonable exercise of independent clinical judgment by practitioners, considering each patient's needs on an individual basis. Guideline recommendations apply to populations of patients. Clinical judgment is necessary to design treatment plans for individual patients.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness
Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Kaiser Permanente National Cervical Cancer Screening Guideline Development Team. Cervical cancer screening guideline. Oakland (CA): Kaiser Permanente Care Management Institute; 2006 Oct. 124 p. [199 references]

ADAPTATION

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

DATE RELEASED

2006 Oct

GUIDELINE DEVELOPER(S)

Kaiser Permanente Care Management Institute - Managed Care Organization

SOURCE(S) OF FUNDING

Kaiser Permanente Care Management Institute

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: None available

Print copies: Available from the Kaiser Permanente Care Management Institute, One Kaiser Plaza, 16th Floor, Oakland, CA 94612

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Cervical cancer screening guideline. Oakland (CA): Kaiser Permanente Care Management Institute; 2006 Oct. 2 p.

Electronic copies: Not available at this time.

Print copies: Available from the Kaiser Permanente Care Management Institute, One Kaiser Plaza, 16th Floor, Oakland, CA 94612

PATIENT RESOURCES

None available

NGC STATUS

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