Complete Summary

GUIDELINE TITLE

American Cancer Society guideline for the early detection of cervical neoplasia and cancer.

BIBLIOGRAPHIC SOURCE(S)

Saslow D, Runowicz CD, Solomon D, Moscicki AB, Smith RA, Eyre HJ, Cohen C. American Cancer Society guideline for the early detection of cervical neoplasia and cancer. CA Cancer J Clin 2002 Nov-Dec;52(6):342-62. [88 references]

GUIDELINE STATUS

This is the current release of the guideline.

It updates a previously released version: American Cancer Society. Update January 1992: the American Cancer Society guidelines for the cancer-related checkup. CA Cancer J Clin 1992 Jan-Feb;42(1):44-5.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Cervical neoplasia and cancer

GUIDELINE CATEGORY

Diagnosis
Prevention
Screening

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Nursing
Obstetrics and Gynecology
Oncology
Pathology
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Nurses
Patients
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

- To update the 1988 American Cancer Society guideline pertaining to early detection of cervical neoplasia and cancer
- To offer new screening recommendations that address when to begin screening, when screening may be discontinued, whether to screen women who have had a hysterectomy, appropriate screening intervals, and new screening technologies, including liquid-based cytology and human papillomavirus (HPV) deoxyribonucleic acid (DNA) testing

TARGET POPULATION

Women and female adolescents beginning approximately three years after the onset of vaginal intercourse, no later than 21 years of age

INTERVENTIONS AND PRACTICES CONSIDERED

1. Cervical screening performed using conventional cervical cytology test, Papanicolaou (Pap) test
2. Cervical screening performed using liquid-based cytology
3. Human papillomavirus (HPV) deoxyribonucleic acid (DNA) testing with cytology (Food and Drug Administration [FDA]-approved 3/31/2003)
4. Education for teens and young women on regular health visits, gynecologic care and preventive care

MAJOR OUTCOMES CONSIDERED

- Incidence of cervical neoplasia and cancer
- Sensitivity and specificity of cervical cancer screening tests

- Morbidity and mortality related to cervical neoplasia and cancer

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

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

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

During the current guideline review, published articles related to cervical cancer screening, including new screening tests, were identified using MEDLINE (National Library of Medicine), bibliographies of identified articles, personal files of panel members, and unpublished manuscripts.

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

Criteria for Evidence Grading

1. Strong Evidence
    - Evidence is useful to the panel´s task (reviewer´s conclusion may be different from authors´).
    - Sample size is adequate to give statistical power.
    - Unbiased or biases addressed.
    - Endpoint defined as cervical intraepithelial neoplasia 2/3 (CIN2/3).
2. Limited Evidence
    - Conclusions/assumptions are not supported by data, but some useful data is provided.
    - Sample size insufficient to give statistical power to observe a true effect.
    - Flaws or biases that could negate conclusions.
    - Study design weakens conclusions (reviewer should provide explanation).
    - Review article with a new perspective.
3. No Evidence/Exclude
    - No relevant data (e.g., review article).
    - Symptomatic women.
    - Shortcomings negate conclusions.
    - Articles not in English.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Expert panel members reviewed articles using specified criteria (see Appendix A in the original guideline document). Key data abstracted from each article that met inclusion criteria included: country; sample size; sample description (age, risk, ethnicity, screening history); time period, biases (selection, verification, observer); issue addressed, endpoints, length of follow-up (e.g., average, individual, person-years); major flaws; major strengths; authors´ conclusions; and reviewer´s conclusions.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Each work group developed recommendations, rationale, and evidence summaries, and reviewed the summaries developed by the other work groups prior to an April 2002 workshop. When evidence was insufficient or lacking, the final recommendations incorporated the expert opinions of the panel members. Relevant unpublished manuscripts were distributed to workshop attendees prior to the meeting. During the conference calls and workshop, consensus was reached on the key issues within the guideline recommendations. Following the workshop, American Cancer Society (ACS) Gynecologic Cancer Advisory Group members deliberated over the guideline modifications. Each work group member and workshop attendee reviewed the draft of this manuscript.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

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

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Several organizations reviewed the guideline manuscript, provided comments, and indicated their support of the new recommendations. These organizations include the American College of Obstetricians and Gynecologists, the American Social Health Association, the American Society of Colposcopy and Cervical Pathology,

the Association of Reproductive Health Professionals, the Gynecologic Cancer Foundation, the National Association of Nurse Practitioners in Women´s Health, and the Society of Gynecologic Oncologists.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

When to Start Screening

Cervical cancer screening should begin approximately three years after the onset of vaginal intercourse. Screening should begin no later than 21 years of age. It is critical that adolescents who may not need a cervical cytology test obtain appropriate preventive health care, including assessment of health risks, contraception, and prevention counseling, screening and treatment of sexually transmitted diseases. The need for cervical cancer screening should not be the basis for the onset of gynecologic care.

When to Discontinue Screening

Women who are age 70 and older with an intact cervix and who have had three or more documented, consecutive, technically satisfactory normal/negative cervical cytology tests, and no abnormal/positive cytology tests within the 10-year period prior to age 70 may elect to cease cervical cancer screening. Screening is recommended for women who have not been previously screened, women for whom information about previous screening is unavailable, and for whom past screening is unlikely. Women who have a history of cervical cancer, in utero exposure to diethylstilbestrol (DES), and/or who are immunocompromised (including human immunodeficiency virus [HIV+]) should continue cervical cancer screening for as long as they are in reasonably good health and do not have a life-limiting chronic condition. Until more data are available, women aged 70 and older who have tested positive for human papillomavirus (HPV) deoxyribonucleic acid (DNA) should continue screening at the discretion of their health care provider. Women over the age of 70 should discuss their need for cervical cancer screening with their health care provider based on their individual circumstances (including the potential benefits, harms, and limitations of screening) and make informed decisions about whether to continue screening. Women with severe comorbid or life-threatening illnesses may forego cervical cancer screening.

Screening After Hysterectomy

Screening with vaginal cytology tests following total hysterectomy (with removal of the cervix) for benign gynecologic disease is not indicated. Efforts should be made to confirm and/or document via physical exam and review of the pathology report (when available) that the hysterectomy was performed for benign reasons (the presence of cervical intraepithelial neoplasia (CIN) 2/3 is not considered benign) and that the cervix was completely removed. Women who have had a subtotal hysterectomy should continue cervical cancer screening as per current guidelines. Women with a history of CIN2/3 or for whom it is not possible to document the absence of CIN2/3 prior to/or as the indication for the hysterectomy should be screened until three documented, consecutive, technically satisfactory

normal/negative cervical cytology tests and no abnormal/positive cytology tests within a 10-year period are achieved. Women with a history of in utero DES exposure and/or with a history of cervical carcinoma should continue screening after hysterectomy for as long as they are in reasonably good health and do not have a life-limiting chronic condition.

Screening Interval

After initiation of screening, cervical screening should be performed annually with conventional cervical cytology smears OR every two years using liquid-based cytology; at or after age 30, women who have had three consecutive, technically satisfactory normal/negative cytology results may be screened every two to three years (unless they have a history of in utero DES exposure, are HIV+, or are immunocompromised by organ transplantation, chemotherapy, or chronic corticosteroid treatment).

Liquid-based Pap Technology

As an alternative to conventional cervical cytology smears, cervical screening may be performed every two years using liquid-based cytology; at or after age 30, women who have had three consecutive, technically satisfactory normal/negative cytology results may be screened every two to three years (unless they have a history of in utero DES exposure, are HIV+, or are immunocompromised).

Preliminary Recommendation for HPV DNA Testing With Cytology for the Screening of Cervical Cancer and Its Precursor Lesions

HPV DNA testing with cytology for primary cervical cancer screening has not been approved by the Food and Drug Administration (FDA). Based on the available data, both published and unpublished, the American Cancer Society (ACS) guideline review panel found this technology to be promising. Should the FDA approve HPV DNA testing for this purpose, it would be reasonable to consider that for women aged 30 and over, as an alternative to cervical cytology testing alone, cervical screening may be performed every three years using conventional or liquid-based cytology combined with a test for DNA from high-risk HPV types. Frequency of combined cytology and HPV DNA testing should NOT be more often than every three years. Counseling and education related to HPV infection is a critical need. Consensus guidelines for the management of women with a technically satisfactory normal/negative cytology result and a HPV DNA test result that is positive for high-risk HPV types would need to be developed.

Additional Recommendations

The expert panel made several additional recommendations:

1. The ACS and others should educate women, particularly teens and young women, that a pelvic exam does not equate with a cytology (Pap) test, and that women who may not need a cytology test still need regular health care visits, including gynecologic care and sexually transmitted disease (STD) screening and prevention.

2. The current guideline review did not address the potential usefulness of pelvic and/or rectal examinations. Pelvic exams are not effective in detecting cervical cancer, however both pelvic and rectal exams may facilitate identification of other types of cancer and of other gynecologic conditions. Women should discuss the need for these exams with their provider.
3. Referrals of women with low-grade lesions for colposcopy may be less necessary for adolescents given the self-limited nature of many low-grade squamous intraepithelial lesions (LSILs) in this age group. Detection and treatment of high-grade squamous intraepithelial lesion (HSIL) should be the goal of adolescent screening and referral.
4. Health insurance payers should not exclude adolescents or women of any age from coverage for cervical health on the basis of false-positive cytology results and/or mild abnormalities on cervical cytology.
5. Health insurance coverage for new cervical screening technologies is not uniform. Providers should confirm coverage before ordering tests such as liquid-based pap (LBP) and HPV DNA testing, including use for triage of patients with atypical squamous cells- uncertain significance (ASC-US).

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is specifically stated following each recommendation in the original guideline.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Decreased Mortality

Cervical cancer mortality in the United States has decreased over the last five decades by over 70 percent in large part attributable to the introduction of the Papanicolaou (Pap) test. Cervical cancer, once the number one cancer killer of women, now ranks 13th in cancer deaths for women in the United States. Women with preinvasive lesions have a five-year survival rate of nearly 100 percent. When cervical cancers are detected at an early stage, the five-year survival rate is approximately 92 percent.

Subgroups of Patients Most Likely to Benefit:

- Women with a history of cervical intraepithelial neoplasia (CIN) 2/3 or for whom it is not possible to document the absence of CIN2/3 prior to/or as the indication for the hysterectomy
- Women with a history of in utero diethylstilbestrol (DES) exposure and/or with a history of cervical carcinoma

- Women who have not been screened or who have not been screened regularly

POTENTIAL HARMS

- False-negative results occur even in optimized screening programs and cannot be entirely eliminated.
- False-positive results can lead to unnecessary patient discomfort and anxiety and higher health care costs

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- Changes to the screening recommendations are unlikely to have a significant impact on the relatively low incidence and mortality associated with cervical cancer in the United States.
- The guideline continues to emphasize the importance of flexibility for women and their providers in the context of informed decision-making. Individual patients will have different perceptions of risk and risk tolerance that may affect their choice of screening interval, screening test, and whether to discontinue screening after a certain age. Ideally these decisions should be based on discussions of the benefits, risks, and limitations of cervical cancer screening between women and their providers.
- Screening interval remains a controversial issue in the United States. While the evidence supports the conclusion that conventional cytology can be safely performed at two- to three-year intervals, many women and providers in the United States may be more comfortable with annual screening. A key factor is the limited sensitivity of the conventional Papanicolaou (Pap) test.
- It is important to reiterate that the biggest gain in reducing cervical cancer incidence and mortality would be achieved by increasing screening rates among women who have not been screened or who have not been screened regularly.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Patient Resources

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)

Saslow D, Runowicz CD, Solomon D, Moscicki AB, Smith RA, Eyre HJ, Cohen C. American Cancer Society guideline for the early detection of cervical neoplasia and cancer. CA Cancer J Clin 2002 Nov-Dec;52(6):342-62. [88 references]

ADAPTATION

Not applicable: Guideline was not adapted from another source.

DATE RELEASED

2002 Nov-Dec

GUIDELINE DEVELOPER(S)

American Cancer Society - Disease Specific Society

SOURCE(S) OF FUNDING

American Cancer Society

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

R. Marshall Austin, MD, PhD, has served as a consultant and/or speaker without accepting personal compensation for AutoCyte Inc., Cytyc Corporation, Digene Corporation, Morphometrix Technologies Inc., NeoPath, Inc., Neuromedical Sciences Inc., and Veracel Inc. J. Thomas Cox, MD, has consulted for Cytyc Corporation, Digene Corporation, 3M Pharmaceuticals, Inc., and Merck & Co., Inc., and is on the speaker´s bureau of Cytyc Corporation, and 3M Pharmaceuticals, Inc. Jack Cuzick, PhD, is a consultant to Digene Corporation. Eduardo Franco, MPH, DrPH, has occasionally been invited by 3M Pharmaceuticals, Inc., GlaxoSmithKline, Digene Corporation, and F. Hoffmann-La Roche Ltd. to serve as a temporary consultant or visiting speaker. Walter Kinney, MD, has received research support from 3M Pharmaceuticals and serves on the speaker´s bureau for Cytyc Corporation and Digene Corporation. Evan Myers, MD, MPH, has received research support from and is a consultant to Merck Research Laboratories. Ellen Sheets, MD, was appointed as a vice president of Cytyc Corporation in May 2002, following the ACS guideline workshop. Thomas C. Wright, Jr., MD, has received research support from Digene Corporation and Cytyc Corporation and is on the speaker´s bureau of Cytyc Corporation and TriPath Imaging, Inc.

GUIDELINE STATUS

This is the current release of the guideline.

It updates a previously released version: American Cancer Society. Update January 1992: the American Cancer Society guidelines for the cancer-related checkup. CA Cancer J Clin 1992 Jan-Feb;42(1):44-5.

GUIDELINE AVAILABILITY

Electronic copies: Available from CA online, A Cancer Journal for Clinicians, a publication of the American Cancer Society:

- HTML Format
- Portable Document Format (PDF)

Print copies: Available from the American Cancer Society, 1599 Clifton Rd. NE, Atlanta, GA 30329; Web site: www.cancer.org.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

The following is available:

- Patient pages. Early detection of cervical cancer. CA Cancer J Clin 2002 Nov-Dec;52(6):375-6.

Electronic copies: Available from the American Cancer Society Web site:

- HTML Format
- Portable Document Format (PDF)

Print Copies: Available from the American Cancer Society, 1599 Clifton Rd. NE, Atlanta, GA 30329.

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 NGC summary was completed by ECRI on March 25, 2003. The information was verified by the guideline developer on August 13, 2003.

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