



Complete Summary

GUIDELINE TITLE

Management of abnormal cervical cytology and histology.

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Management of abnormal cervical cytology and histology. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2008 Dec. 26 p. [169 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: American College of Obstetricians and Gynecologists (ACOG). Management of abnormal cervical cytology and histology. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2005 Sep. 20 p. (ACOG practice bulletin; no. 66). [214 references]

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SCOPE

DISEASE/CONDITION(S)

Abnormal cervical cytology and histology, including:

- Atypical squamous cells (ASC)
- Low-grade or high-grade squamous intraepithelial lesions (LSIL or HSIL)
- Squamous cell carcinoma
- Atypical glandular cells (AGC)
- Adenocarcinoma in situ (AIS)

- Cervical intraepithelial neoplasia (CIN)
- Adenocarcinoma

GUIDELINE CATEGORY

Diagnosis
Management
Risk Assessment
Screening
Treatment

CLINICAL SPECIALTY

Obstetrics and Gynecology
Oncology
Pathology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To define strategies for diagnosis and management of abnormal cervical cytology and histology results

TARGET POPULATION

Women with abnormal cervical cytology and histology test results, including pregnant women and adolescents

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Screening

1. Cervical cytology assessment (Pap smear)
2. Human papillomavirus (HPV) deoxyribonucleic acid (DNA) testing
3. Repeat cervical cytology testing
4. Diagnostic excisional procedure

Management/Treatment

1. Colposcopy
2. Endocervical sampling using a brush or curette
3. Loop electrosurgical excision procedure (LEEP)
4. Cryotherapy
5. Laser ablation
6. Laser or knife conization
7. Hysterectomy

8. Re-excision
9. Follow-up

MAJOR OUTCOMES CONSIDERED

- Sensitivity and specificity of cervical epithelial testing
- Predictive value of tissue sampling methods on progression to cervical cancer
- Incidence of progression to cervical cancer
- Risk of recurrence

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

The MEDLINE database, the Cochrane Library, and the American College of Obstetricians and Gynecologists' (ACOG's) own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1995 and November 2007. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document. Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles.

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

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force:

I: Evidence obtained from at least one properly designed randomized controlled trial.

II-1: Evidence obtained from well-designed controlled trials without randomization.

II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.

II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetrician-gynecologists were used. See also the "Rating Scheme for the Strength of Recommendations" field regarding Grade C recommendations.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A — Recommendations are based on good and consistent scientific evidence.

Level B — Recommendations are based on limited or inconsistent scientific evidence.

Level C — Recommendations are based primarily on consensus and expert opinion.

COST ANALYSIS

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

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and sub-specialists. The final guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The grades of evidence (I-III) and levels of recommendation (A-C) are defined at the end of the "Major Recommendations" field.

The following recommendations are based on good and consistent scientific evidence (Level A):

- Premenopausal women 21 years and older with atypical squamous cells of undetermined significance (ASC-US) cytology results may undergo immediate colposcopy or may undergo triage testing to determine which of them should be referred to colposcopy. Triage testing may be performed by a single test for high-risk (oncogenic) types of human papillomavirus (HPV) or by repeat cytology screening at 6 months and 12 months. When the index cytology test specimen was obtained by liquid-based cytology or when an HPV specimen was co-collected, "reflex" HPV testing is the preferred approach.
- Colposcopy is recommended in premenopausal women 21 years and older with ASC-US who are HPV positive, those with two consecutive ASC-US cytology results or with low grade squamous intraepithelial lesions (LSIL), or women of any age with atypical squamous cells, cannot exclude high grade squamous intraepithelial lesions (ASC-H).
- For premenopausal women 21 years and older with an HPV-positive ASC-US, or ASC-H or LSIL cytology result in whom cervical intraepithelial neoplasia (CIN) grades 2,3 is not identified, follow-up without treatment is recommended using either repeat cervical cytology tests at 6 months and 12 months or an HPV test at 12 month-intervals; a repeat colposcopy is indicated for a cytology result of ASC-US or higher-grade abnormality or a positive high-risk HPV test result. After two consecutive negative cytology results or one negative HPV result women can return to routine screening.
- In women 21 years and older with HSIL cytology results, immediate loop electrosurgical excision or colposcopy with endocervical assessment are both acceptable management options. In adolescents and pregnant women with HSIL cytology results, colposcopy is recommended. Immediate excision is not acceptable in adolescents and pregnant women. A diagnostic excisional procedure is recommended for all nonpregnant women with HSIL when

colposcopy is unsatisfactory or when CIN of any grade is identified on endocervical assessment.

- Posttreatment management options for women 21 years and older who have CIN 2,3 include a single human papillomavirus deoxyribonucleic acid (HPV DNA) test at 6–12 months, cytology alone at 6-month intervals or a combination of cytology and colposcopy at 6-month intervals. For adolescents who have undergone treatment, cytology follow-up is preferred. Colposcopy with endocervical sampling is recommended for women who are HPV DNA positive or have a result of ASC-US or greater on repeat cytology. If the HPV DNA test is negative or if two consecutive repeat cytology test results are negative, routine screening commencing at 12 months is recommended for at least 20 years.

The following recommendations are based on limited and inconsistent scientific evidence (Level B):

- Women 21 years or older with ASC-US who test negative for HPV, or whose HPV status is unknown and who test negative for abnormalities using colposcopy, should have a repeat cytology test in 1 year. Women with ASC-US who have two negative results on repeat cytology at 6-month intervals can return to routine screening.
- In adolescents (before age 21 years) with ASC-US or LSIL cytology results, or CIN 1 histology results preceded by ASC-US or LSIL or atypical glandular cells not otherwise specified (AGC-NOS) cytology results, follow-up is recommended at 12-month intervals. At the first follow-up visit (at 12 months), only adolescents with HSIL or greater on the repeat cytology should be referred to colposcopy. At the 24-month follow-up, those with an ASC-US or greater result should be referred to colposcopy. Human papillomavirus DNA testing is unacceptable for adolescents. If HPV testing is inadvertently performed, a positive result should not influence management.
- In nonpregnant women with ASC and LSIL cytology results who are undergoing colposcopy, endocervical sampling using a brush or curette is preferred for women in whom no lesions are identified and those with an unsatisfactory colposcopy results. Endocervical sampling is acceptable for women with satisfactory colposcopy results and a lesion identified in the transformation zone. Endocervical assessment either with colposcopy or by sampling is recommended for all nonpregnant women with HSIL cytology results. Endocervical curettage is unacceptable in pregnant women.
- The recommended management of pregnant women with a histology diagnosis of CIN 1 is follow-up without treatment. Treatment of pregnant women for CIN 1 is unacceptable.
- In a woman 21 years and older with CIN 1 that has persisted for at least 2 years, either continued follow-up or treatment is acceptable. If treatment is selected and the colposcopy result is satisfactory, either excision or ablation is acceptable. If treatment is selected and the colposcopy examination is unsatisfactory, the ECC is positive, or the woman has been previously treated, excision is recommended and ablative procedures are unacceptable.
- Pregnant women with biopsy-proven CIN 2 or CIN 3 in whom there is no suspicion of invasive cancer may postpone re-evaluation with cytology and colposcopy to no sooner than 6 weeks postpartum. Treatment during pregnancy is unacceptable unless invasion is suspected. When invasion is suspected, a diagnostic excisional procedure is recommended.

- For women 21 years and older, the preferred management of CIN 2,3 identified at the margins of a diagnostic excisional procedure or in an endocervical sample obtained at the end of the procedure is reassessment using cytology with endocervical sampling at 4 to 6 months following treatment. Performing a repeat diagnostic excisional procedure is acceptable, as is a hysterectomy if a repeat diagnostic procedure is not feasible and for women with a histology diagnosis of recurrent or persistent CIN 2,3.
- In nonpregnant women 21 years and older, both excision and ablation are acceptable treatment modalities in the presence of histology diagnoses of CIN 2,3 and satisfactory colposcopy results. Ablation is unacceptable when colposcopy has not been performed, the endocervical sampling is positive for any grade of CIN, the colposcopy result is unsatisfactory, or a woman has recurrent CIN 2,3.
- Colposcopy with endocervical sampling is recommended and HPV DNA testing is preferred for women with all subcategories of AGC and adenocarcinoma in situ (AIS). In addition, endometrial sampling is recommended in women 35 years and older and in women younger than 35 years with clinical indications suggesting they may be at risk of neoplastic endometrial lesions (e.g., unexplained vaginal bleeding, chronic anovulation, or atypical endometrial cells). Colposcopy can be performed either at the initial evaluation or after the results are known. If no endometrial pathology is identified, colposcopy is recommended. Endometrial and endocervical sampling are unacceptable in pregnant women.
- Women 21 years and older with either atypical endocervical, endometrial, or glandular cells NOS who do not have CIN or glandular neoplasia identified histologically should receive repeat cytology testing combined with HPV DNA testing at 6 months if they are HPV DNA positive and at 12 months if they are HPV DNA negative. Referral to colposcopy is recommended for women who subsequently test positive for high-risk HPV DNA or who are found to have ASC-US or greater on their repeat cytology tests. If both tests are negative, women can return to routine cytology testing.
- Women with AGC, favors neoplasia or AIS cytology results should undergo a diagnostic excisional procedure unless invasive disease is identified during the initial colposcopy workup. The diagnostic excisional procedure used in this setting should provide an intact specimen with interpretable margins. Concomitant endocervical sampling is preferred, except in pregnant women.
- Hysterectomy is unacceptable as the primary therapy for CIN.
- Diagnostic ablation or excision is unacceptable as the initial management for ASC or LSIL.

The following recommendations are based primarily on consensus and expert opinion (Level C):

- In nonpregnant women 21 years and older with HSIL in whom CIN 2,3 has not been identified, three management options are acceptable: diagnostic excisional procedure; review of the cytology, histology, and colposcopy findings and management of the patient according to the revised interpretation; or if the colposcopy is satisfactory and endocervical sampling is negative, observation with colposcopy and cytology at 6 month-intervals for 1 year. A diagnostic excisional procedure is recommended for women with repeat HSIL cytology results at either the 6-month or 12-month visit. Women

- with two consecutive negative cytology results can return to routine screening.
- In adolescents (before age 21 years) with HSIL cytology results, a satisfactory colposcopy result, negative endocervical sampling, and no CIN 2,3 identified on colposcopy biopsy, follow-up is recommended at 6-month intervals with Pap testing and colposcopy for up to 24 months. If during follow-up a high grade colposcopy lesion is identified or HSIL cytology results persist for 1 year, biopsy is recommended. If HSIL persists for 24 months without identification of CIN 2,3, or if the colposcopy result is unsatisfactory, a diagnostic excisional procedure is recommended. After two consecutive negative cytology results, women can return to routine cytology testing.
 - For adolescents and young women with a histology diagnosis of CIN 2,3 NOS and a satisfactory colposcopy result either treatment or observation for up to 24 months using both colposcopy and cytology at 6-month intervals is acceptable. When a histology diagnosis of CIN 2 is specified, observation is preferred. When a histology diagnosis of CIN 3 is specified or when the colposcopy result is unsatisfactory, treatment is recommended. If the colposcopy appearance of the lesion worsens or if an HSIL cytology result or a high-grade colposcopy lesion persists for 1 year, repeat biopsy is recommended. After two consecutive negative cytology results, women with normal colposcopy results can return to routine cytology screening. Treatment is recommended if CIN 3 is subsequently identified or if CIN 2,3 persists for 24 months.
 - In nonpregnant women 21 years and older with HSIL or AGC-NOS cytology results in whom CIN 1 has been identified on colposcopy three management options are acceptable: diagnostic excisional procedure; review of the cytology, histology, and colposcopy findings and management of the patient according to the revised interpretation; or if the colposcopy is satisfactory and endocervical sampling is negative, observation with colposcopy and cytology at 6-month intervals for 1 year. A diagnostic excisional procedure is recommended for women with repeat HSIL cytology results at either the 6-month or 12-month visit. Women with two consecutive negative cytology results can return to routine cytology screening.
 - In women 21 years and older with atypical endocervical, endometrial, or glandular cells NOS, HPV DNA testing is preferred at the time of colposcopy (if not already performed). For women of unknown HPV status who do not have CIN or glandular neoplasia identified histologically, the recommended postcolposcopy management is to repeat cytology testing at 6-month intervals. After four consecutive negative cytology results, women can return to routine cytology testing.
 - Women with a cervical biopsy diagnosis of AIS should undergo excision to exclude invasive cancer. A conization technique that preserves specimen orientation and permits optimal interpretation of histology and margin status is recommended. After conization, hysterectomy is preferred for women who have completed childbearing. Conservative management is acceptable if the margins of the specimen and the postprocedure endocervical curettage results are negative and future fertility is desired. If conservative management is planned and the margins of the specimen are involved or the postprocedure endocervical curettage specimen contains CIN or AIS, re-excision is preferred. Reevaluation at 6 months using a combination of cervical cytology, HPV DNA testing, and colposcopy with endocervical sampling is acceptable in this circumstance. Long-term follow-up after treatment is recommended for all women with AIS.

Definitions:

Grades of Evidence

I: Evidence obtained from at least one properly designed randomized controlled trial.

II-1: Evidence obtained from well-designed controlled trials without randomization.

II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.

II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Levels of Recommendations

Level A — Recommendations are based on good and consistent scientific evidence.

Level B — Recommendations are based on limited or inconsistent scientific evidence.

Level C — Recommendations are based primarily on consensus and expert opinion.

CLINICAL ALGORITHM(S)

The following clinical algorithms are provided in the original guideline:

- Use of human papillomavirus deoxyribonucleic acid (HPV DNA) testing as an adjunct to cytology for cervical cancer screening in women 30 years and older (Figure 1)
- Management of women with atypical squamous cells of undetermined significance (ASC-US) (Figure 2)
- Management of adolescent women with either ASC-US or low-grade squamous intraepithelial lesion (LSIL) (Figure 3)
- Management of women with atypical squamous cells: cannot exclude high-grade squamous intraepithelial lesions (ASC-H) (Figure 4)
- Management of women with LSIL (Figure 5)
- Management of women with HSIL (Figure 6)
- Management of adolescent women (20 years and younger) with HSIL (Figure 7)
- Initial workup of women with atypical glandular cells (AGC) (Figure 8)
- Subsequent management of women with AGC (Figure 9)
- Management of pregnant women with LSIL (Figure 10)

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate screening and management of abnormal cervical cytology and histology

POTENTIAL HARMS

- Newer data show that cervical treatments, such as ablation or excisional procedures, may have adverse effects on pregnancy, including preterm delivery and low birth weight; thus, risk-benefit assessment sometimes favors observation of CIN 2, especially among younger women.
- There is increasing recognition that colposcopy is less sensitive than previously thought. A single colposcopy examination in women with positive low-grade cytology results identified only 60% of women with CIN 2,3 lesions and 54% of women with CIN 3 lesions who received their diagnoses within 2 years of study enrollment. Recent studies suggest that the correlation between colposcopy impression and biopsy grade is poor.

CONTRAINDICATIONS

CONTRAINDICATIONS

- Endocervical curettage is contraindicated during pregnancy.
- Unless cancer is identified or suspected, treatment of cervical intraepithelial neoplasia is contraindicated during pregnancy.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.
- The guidelines discussed in this document follow the 2006 consensus guidelines published by the American Society for Colposcopy and Cervical Pathology. These guidelines recognized that a small risk of failing to detect high-grade cervical intraepithelial neoplasia (CIN) and even cancer must be accepted. It is unreasonable for patients or clinicians to expect that the risk can be reduced to zero, and attempts to achieve zero risk will result in

greater harm than good in the form of overtreatment. When providing care for an individual patient, guidelines define the evidence base for most cases but are not a substitute for clinical judgment because it is impossible to develop guidelines that would apply to all situations.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Clinical Algorithm
Foreign Language Translations
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

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Management of abnormal cervical cytology and histology. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2008 Dec. 26 p. [169 references]

ADAPTATION

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

DATE RELEASED

2005 Sep (revised 2008 Dec)

GUIDELINE DEVELOPER(S)

American College of Obstetricians and Gynecologists - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Obstetricians and Gynecologists (ACOG)

GUIDELINE COMMITTEE

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins-Gynecology

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

American College of Obstetricians and Gynecologists (ACOG) committees are created or abolished and their overall function defined by the Executive Board. Appointments are made for one year, with the understanding that such appointment may be continued for a total of three years. The majority of committee members are Fellows, but Junior Fellows also are eligible for appointment. Some committees may have representatives from other organizations when this is particularly appropriate to committee activities. The president elect appoints committee members annually.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: American College of Obstetricians and Gynecologists (ACOG). Management of abnormal cervical cytology and histology. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2005 Sep. 20 p. (ACOG practice bulletin; no. 66). [214 references]

GUIDELINE AVAILABILITY

Electronic copies: None available

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the [ACOG Web site](#).

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

The following are available:

- The Pap test. American College of Obstetricians and Gynecologists (ACOG); 2003. Available from the [American College of Obstetricians and Gynecologists \(ACOG\) Web site](#). Copies are also available in Spanish.
- Colposcopy. American College of Obstetricians and Gynecologists (ACOG); 2009. Available from the [ACOG Web site](#). Copies are also available in Spanish.
- Loop electrosurgical excision procedure. American College of Obstetricians and Gynecologists (ACOG); 2009. Available from the [ACOG Web site](#). Copies are also available in Spanish.

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the ACOG Web site.

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NGC STATUS

This NGC summary was completed by ECRI Institute on October 8, 2007. The information was verified by the guideline developer on December 3, 2007. This NGC summary was updated by ECRI Institute on June 18, 2009. The updated information was verified by the guideline developer on June 29, 2009.

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Date Modified: 7/27/2009

