



Complete Summary

GUIDELINE TITLE

Initial management of abnormal cervical cytology (Pap smear) and HPV testing.

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Initial management of abnormal cervical cytology (pap smear) and HPV testing. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2006 Oct. 32 p. [73 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Immunizations update. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2005 Jun. 61 p.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Abnormal cervical cytology (Pap smear)

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Nursing
Obstetrics and Gynecology
Oncology
Pathology
Pediatrics

INTENDED USERS

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

GUIDELINE OBJECTIVE(S)

- To provide recommendations for appropriate clinical follow-up for women who undergo cervical cytologic analysis (Pap smear) and receive an abnormal cervical cytology result
- To provide recommendations regarding colposcopic directed biopsy and/or loop electrosurgical excision procedure (LEEP) for women who are diagnosed with a high grade abnormal cervical cytology result
- To reduce the psychological distress and increase the knowledge of women who are notified of a cervical cytology abnormality

TARGET POPULATION

Any adolescent or adult woman who has undergone cervical cytologic analysis (Pap smear) and has received an abnormal result

INTERVENTIONS AND PRACTICES CONSIDERED

1. Patient education regarding cervical cytology (Pap smear) and abnormal results
2. Routine cervical cytology screening
3. Management based on classification of abnormal cytology results. Options include repeat Pap smear, treatment of infections, intravaginal estrogen creams, human papillomavirus (HPV) DNA testing, colposcopy, endocervical curettage (ECC), endometrial biopsy, loop electrocautery excision procedure (LEEP), dilation and curettage (D & C), and cone biopsy
4. Consultation with gynecology or gynecologic oncology, when necessary

MAJOR OUTCOMES CONSIDERED

- Incidence of abnormal cervical cytology findings
- Risk of cervical and endometrial cancer in women with abnormal cervical cytology

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

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

Not stated

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

Clinical Validation-Pilot Testing
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Institute Partners: System-Wide Review

The guideline annotation, discussion, and measurement specification documents undergo thorough review. Written comments are solicited from clinical, measurement, and management experts from within the member groups during an eight-week review period.

Each of the Institute's participating member groups determines its own process for distributing the guideline and obtaining feedback. Clinicians are asked to suggest modifications based on their understanding of the clinical literature coupled with their clinical expertise. Representatives from all departments involved in implementation and measurement review the guideline to determine its operational impact. Measurement specifications for selected measures are developed by the Institute for Clinical Systems Improvement (ICSI) in collaboration with participating member groups following implementation of the guideline. The specifications suggest approaches to operationalizing the measure.

Guideline Work Group

Following the completion of the review period, the guideline work group meets 1 to 2 times to review the input received. The original guideline is revised as necessary, and a written response is prepared to address each of the responses received from member groups. Two members of the Ob/Gyn Steering Committee carefully review the input, the work group responses, and the revised draft of the guideline. They report to the entire committee their assessment of four questions: (1) Is there consensus among all ICSI member groups and hospitals on the content of the guideline document? (2) Has the drafting work group answered all criticisms reasonably from the member groups? (3) Within the knowledge of the appointed reviewer, is the evidence cited in the document current and not out-of-date? (4) Is the document sufficiently similar to the prior edition that a more thorough review (critical review) is not needed by the member group? The committee then either approves the guideline for release as submitted or negotiates changes with the work group representative present at the meeting.

Pilot Test

Member groups may introduce the guideline at pilot sites, providing training to the clinical staff and incorporating it into the organization's scheduling, computer, and other practice systems. Evaluation and assessment occurs throughout the pilot test phase, which usually lasts for three-six months. At the end of the pilot test phase, ICSI staff and the leader of the work group conduct an interview with the member groups participating in the pilot test phase to review their experience and gather comments, suggestions, and implementation tools.

The guideline work group meets to review the pilot sites' experiences and makes the necessary revisions to the guideline, and the Ob/Gyn Steering Committee reviews the revised guideline and approves it for implementation.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC) and the Institute for Clinical Systems Improvement (ICSI): For a description of what has changed since the previous version of this guidance, refer to [Summary of Changes -- October 2005](#).

The recommendations for the initial management of abnormal cervical cytology and human papilloma virus (HPV) testing are presented in the form of five algorithms with a total of 53 components, accompanied by detailed annotations. Algorithms are provided for: [Initial Abnormal Cytology Result](#); [Benign Endometrial Cells \(BEC\)](#); [Atypical Squamous Cells of Undetermined Significance \(ASCUS\)](#); [Atypical Glandular Cells \(AGC\)](#); and [Abnormal Cervical Cytology in Adolescents \(Less than 21 years\)](#). Clinical highlights and selected annotations (numbered to correspond with the appropriate algorithm) follow.

Class of evidence (A-D, M, R, X) ratings are defined at the end of the "Major Recommendations" field.

Clinical Highlights

- Atypical squamous cells of undetermined significance (ASCUS) as an initial cytology result in women necessitates human papilloma virus (HPV) testing. If HPV testing is unavailable, a repeat Pap smear in six months is recommended. (*ASCUS Algorithm; Annotations # 7, 14*)
- Atypical glandular cells (AGC) as an initial cytology result requires a colposcopy and endocervical curettage (ECC) and possible endometrial biopsy. AGC cytology results can, in some cases, be indicative of extracervical malignancy. Follow-up is highly recommended. (*AGC Algorithm; Annotations #27, 28*)
- Low-grade squamous intraepithelial lesion (LSIL) as an initial cytology result in an adult generally warrants a colposcopy. Special considerations may be made for adolescent and postmenopausal women. (*LSIL Annotations #40, 41 and Abnormal Cervical Cytology in Adolescents Algorithm Annotation #47*)
- High-grade squamous intraepithelial lesion (HSIL) as an initial cytology result requires colposcopy with biopsy and/or loop electrosurgical excision (LEEP). (*Annotations #42*)
- In adolescents, for ASCUS and LSIL cytologic screening results, the HPV regression rate is so high that conservative management without colposcopy is recommended. (*Abnormal Cervical Cytology in Adolescent Algorithm annotation #47*)

Introduction

The guideline group recognizes the difficulties faced by clinicians who must respond to abnormal cervical cancer screening test results. The group also recognizes this is an area of changing technology. Mindful of these concerns, the work group strives to present a framework based on objective evidence that will provide guidance to the clinician and patient in the management of abnormal cervical cancer screening test results.

Health Education

Receiving the diagnosis of an abnormal cervical cytology is a traumatic occurrence for many women. The work group was made aware of this fact repeatedly and felt that education attempts need to be improved if patient anxiety is to be successfully reduced. It was felt that written general information provided at the time of the initial cervical cancer screening test could serve to educate patients about the role of cervical cytology, as well as to provide basic information about some of the potential results, and to emphasize the fact that most such findings may require nothing further than repeating the cytology or undergoing relatively simple evaluations such as colposcopy. It was felt to be imperative that physicians or health care personnel who provide the initial diagnosis of an abnormal result to a patient have sufficient training to allay most fears and answer basic questions. Finally, it was felt that mailing written material specific to the diagnosis and recommended procedures and follow-up would help prepare the patient for the next phase of evaluation. With a commitment to such education and continued sensitivity to the anxiety produced by the finding of an abnormal cervical cytology result, physicians and other health care workers can provide effective and compassionate evaluation and treatment as needed.

Evidence supporting this recommendation is of classes: A, C

Benign Endometrial Cells Algorithm Annotations

2-6. Benign Endometrial Cells (BEC) Present

Key Points:

- The Bethesda System 2001 reports the presence of normal, cytologically benign-appearing exfoliated endometrial glandular cells only in women age 40 or greater.
- Benign-appearing endometrial cells are noted in up to 12% of cervical cancer screenings performed over one year, more commonly in premenopausal than in postmenopausal women.

The presence of benign endometrial glandular cells on cervical screening tests may reflect physiologic shedding or shedding in response to a pathological process. In women over age 40, the presence of benign-appearing endometrial cells on cervical cytology has been found to be less than 2%. Benign-appearing endometrial cells are more likely to be identified on cervical cytology in the first 10 to 12 days of the menstrual cycle (prevalence 21% to 24%) than in the remainder of the cycle (prevalence 2%). The presence of benign endometrial cells on cervical cytology are reported so that a clinician can determine the significance of the finding in an individual woman.

Eighty-four percent (84%) of pre- and postmenopausal women who underwent endometrial sampling due to findings of benign endometrial cells on cervical pathology had no pathology, benign pathology or nondiagnostic pathology. Sixteen percent (16%) of these women were found to have significant pathology (simple or complex hyperplasia with or without atypia or carcinoma) at the time of their endometrial sampling.

If a woman has symptoms of endometrial cancer (abnormal uterine bleeding/spotting) or she is at increased risk of endometrial cancer (i.e., postmenopausal; family or personal history of ovarian, breast, colon or endometrial cancer; tamoxifen use; chronic anovulation; obesity; or prior endometrial hyperplasia), a sampling of the endometrium with endometrial biopsy or dilation and curettage (D & C) is suggested to rule out endometrial cancer. If the above symptoms or risk factors are not present, routine gynecological care should be continued, as women have not been proven to be at increased risk of endometrial cancer based on the presence of benign endometrial cells on cytology alone.

Evidence supporting this recommendation is of classes: B, C, D, R

Atypical Squamous Cells of Undetermined Significance (ASCUS) Algorithm Annotations

7, 12, 13. Atypical Squamous Cells of Undetermined Significance (ASCUS) Present

Key Points:

- Atypical squamous cells of undetermined significance (ASCUS) is used by pathologists to denote cellular changes that are more marked than those attributable to reactive changes, but that are quantitatively or qualitatively short of a definitive diagnosis of squamous intraepithelial lesion (SIL).
- Exceptions may apply to special circumstances.

The new Bethesda System has identified criteria for ASCUS on cervical cytology screening. Atypical squamous cells of undetermined significance (ASCUS) is used by pathologists to denote cellular changes that are more marked than those attributable to reactive changes, but that are quantitatively or qualitatively short of a definitive diagnosis of squamous intraepithelial lesion (SIL).

Despite the evidence that supports a conservative approach, some clinicians favor immediate colposcopy for all ASCUS smears. The presence of these high-risk factors may influence the decision toward a more aggressive approach: teenage sexual activity, multiple sexual partners, intercourse with a male who has HPV, history of sexually transmitted disease or genital warts, tobacco use or history of tobacco use, intrauterine exposure to diethylstilbestrol (DES), poor compliance for follow-up, lack of normal immune response, no history of regular Pap smears, and age less than 30.

Advantages of immediate colposcopy for all ASCUS Pap smear results include:

- Reduced risk of missing a significant lesion
- Reduced risk of being lost to follow-up
- Faster reassurance to patient of normalcy or avoidance of multiple follow-up Pap smears, resulting poor compliance, and potentially overburdened clinics
- Avoidance of delay in diagnosis of cancer or high-grade cervical intraepithelial neoplasia (CIN)

Options for evaluation include triage to colposcopy by HPV DNA testing, immediate colposcopy, or repeat cytology tests at 6 and 12 months.

Special circumstances exist when infection or atrophy are present. Atrophy-associated benign changes in the cervical epithelium is the most common cause of squamous atypia in cytologic testing of postmenopausal patients. Therefore in the postmenopausal patient with ASCUS cytology and atrophy, it is reasonable to treat that condition, then retest (though no published studies address this situation directly).

A few studies have demonstrated that 4 to 12 weeks of intravaginal estrogen therapy (conjugated equine estrogen [CEE] 0.5 to 1 gram twice a week or 25 micrograms of estradiol twice a week) are sufficient to reverse the atrophy. Repeat the cytology one week posttreatment.

For ASCUS in the menopausal patient without atrophy, the evaluation should be the same as the premenopausal patient.

When evidence of infection is present, it is reasonable to treat it and repeat cytology in four to six months.

Evidence supporting this recommendation is of classes: B, C, D, M, R, X

14. Repeat Cytology at 6 and 12 Months or Colposcopy

Key Points:

- Two consecutive negative cytology results at 6 and 12 months approach the sensitivity of a single HPV test for the detection of CIN 2/3 or greater.
- Immediate colposcopy may be an option for some women who have an initial cytology result of ASCUS.

One option for the low-risk reliable patient with an ASCUS result would be to have a follow-up cytology test at 6 and 12 months. Two consecutive negative follow-up tests will approach the sensitivity of a single HPV test for the detection of CIN 2/3+. Routine testing can be resumed after normal results at 6 and 12 months. If either is ASCUS or higher, colposcopy is recommended.

17. ASCUS with High-Risk HPV DNA Positive?

Key Points:

- It is now scientifically well established that Human Papillomavirus (and more specifically, certain DNA subtypes like #16 and #18) has an important role in the progress of cervical dysplasia and development of squamous cervical cancer in almost all cases.
- Some experts advocate follow-up HPV DNA testing for ASCUS Pap smears. It is the consensus of the work group that this is an excellent option.

The work group is advocating the use of HPV testing to help triage patients with ASCUS. It can be cost-effective when done in a setting that includes liquid-based cytology collection methods, since the residual fluid can be saved for HPV analysis rather than calling the patient back for sampling. Since HPV testing is another viable option for evaluation of the ASCUS cytology result, colposcopy could be deferred and performed only for those women who have tested positive for high-risk HPV types.

Clinicians ordering HPV tests should be aware of the strengths and limitations of the assay. The report that clinicians will receive from the high risk assay will often state that the patient tested positive or negative for "one or more of the following high-risk types" followed by a list of the HPV types. The careful wording is intended to convey to clinicians that the assay does not test for all HPV types known to associate with cervical cancer. A positive test for high-risk HPV types should indicate a need to educate the patient about HPV infection. A colposcopic examination should be scheduled. A negative HPV test result tells the clinician that the patient does not have a detectable burden of the high-risk virus types included in the test. The patient may, however, have a high-risk type at a lower titer than that which is reliably tested for or the patient may have an infection with a high-risk HPV type that is not part of the HPV assay.

Evidence supporting this recommendation is of classes: D, R

18. Repeat Cytology at 12 Months

Women who test negative for high-risk HPV can be reassured that their risk of having CIN 2/3+ is less than 2%. They can be scheduled for repeat cytology in 12 months.

19. Colposcopy

Women who test positive for high-risk HPV have a 15 to 27% chance of having CIN 2/3 or worse. They should be scheduled for colposcopy. The exception to this recommendation is the adolescent, for whom the risk of invasive cancer approaches zero and the likelihood of HPV clearance is very high.

20, 21. Atypical Squamous Cells: Cannot Exclude High-Grade Squamous Intraepithelial Lesion (ASC-H) Present

The Bethesda System 2001 recognizes a new category of atypical squamous cells -- high grade dysplasia (ASC-H) cannot be ruled out. In the 1988 system,

emphasis was placed on identifying all squamous intraepithelial lesion (SIL) Paps, including LSIL and HSIL. Currently, the emphasis of the Bethesda System 2001 is to identify HSIL and cytology associated with histologically proven high-grade disease.

ASC-H is thought to include 5 to 10% of all ASC cases and includes mixtures of true HSIL and mimics. The positive predictive value of ASC-H in detecting CIN 2 and CIN 3 lies somewhere between 48 and 56%.

Colposcopic examination is the established appropriate evaluation of women with ASC-H Pap smear reports. ECC should be performed if no lesion can be visualized. Initial evaluation of the ASC-H Pap smear should not routinely include the use of LEEP.

Evidence supporting this recommendation is of classes: D, R

Atypical Glandular Cells (AGC) Algorithm Annotations

22-26. Atypical Glandular Cells (AGC) Present

Key Points:

- A cytologic interpretation of atypical glandular cells could be caused by inflammation, hyperplasia, dysplasia, endometrial or cervical adenocarcinoma and rarely signals the presence of distant cancer (e.g., pancreatic).

Atypical glandular cells (which can be either uterine or cervical in origin) have enlarged nuclei, decreased cytoplasmic volume, and a variety of other unusual characteristics. In the new Bethesda system, "favor reactive change" has been dropped. Cells become AGC (atypical glandular cells) with one of the following subheadings: NOS (not otherwise specified), FN (favor neoplasia) and favor either endocervical or endometrial origin.

Evidence supporting this recommendation is of classes: C, D

27, 28. Perform Colposcopy and Endocervical Curettage/Perform Endometrial Biopsy if: Age 35 or Older, Abnormal Bleeding, Morbid Obesity, Oligomenorrhea, or Clinical Evaluation Suggests

Key Points:

- Women age 35 and older or women who have abnormal bleeding should have an endometrial biopsy performed if AGC is present.

An AGC cytology may be indicative of a precancerous change or a frank malignancy. Approximately one half of the patients will have a normal exam, including colposcopy and ECC; however, 21%–57% will have a clinically significant lesion. Results of two recent studies showed that 57% of patients had histological diagnoses, 37% had a significant lesion, and that the closer a practitioner looked for an abnormality, the more likely one would be found. Further, those patients having a previous diagnosis of CIN had an almost three-

fold increase in findings of significant lesions in the current study. These numbers warrant a vigorous approach to evaluating these Pap smears. Some laboratories qualify AGC abnormalities as favor reactive or favor neoplasm. Perform an endometrial biopsy to rule out endometrial cancer or hyperplasia in patients with abnormal bleeding or if 35 years of age and older. (A recent study showed correlation with significant lesions [60%] in postmenopausal women with only a 6% chance of significant lesions in premenopausal women.) Referral is appropriate for the portions of the evaluation the primary practitioner cannot complete.

Evidence supporting this recommendation is of classes: C, D

33. Diagnostic Excisional Procedure

Because of the increased chance of HSIL or a glandular endocervical neoplasia, the practitioner should perform a procedure to obtain a specimen from the transformation zone **and** endocervical canal. Although cold-knife cone has historically been preferred, laser conization, LEEP, and loop electrosurgical conization are acceptable sampling procedures.

37. D & C or Endometrial Biopsy if Not Already Performed

Endometrial sampling should be done to obtain a specimen for histologic evaluation. This should be correlated with the abnormal endometrial cells on the cytology specimen so as to explain the original abnormality. Sampling can be done as an office endometrial biopsy or fractional D&C; either of which can be preceded by hysteroscopy to enhance the evaluation. Referral to GYN or GYN Oncology should be made if the sampling does not explain the original abnormality or if the sampling identifies an endometrial abnormality. Follow-up will be dependent on the findings of this evaluation.

40. Low-Grade Squamous Intraepithelial Lesion (LSIL) Present

The LSIL category includes changes consistent with human papillomavirus (HPV), mild dysplasia or CIN 1 (grade 1 cervical intraepithelial neoplasia). Eighty percent will be high-risk HPV positive and 15% to 30% have moderate or severe dysplasia at initial colposcopy. The ALTS group could not identify a useful triage strategy for this category that could spare colposcopic evaluation. Therefore colposcopy is recommended for initial evaluation of LSIL.

There is consensus and expert opinion that follow-up without immediate colposcopy may be appropriate in the postmenopausal patient. HPV prevalence is low, allowing for triage with HPV testing. If negative, patients can return to routine surveillance. If clinical or cytologic evidence of atrophy is present, and there are no contraindications for it, women may be treated with vaginal estrogen for four to twelve weeks. Repeat cytology should then be performed within one week of discontinuance. **Any** abnormalities on repeat testing require colposcopy.

Evidence supporting this recommendation is of class: D, R

41. Colposcopy

The most common management option is to perform a colposcopy. One must be cautious about over-aggressive biopsy and treatment. Specifically, routine LEEP of the transformation zone as a method for evaluating a LSIL Pap smear is not recommended.

Rate of regression has been quoted as high as 62% to 80% on follow-up. (Some investigators believe this reported regression rate is falsely high because prior biopsy, in effect, "treated" the original lesion. Under this assumption, regression rates of unbiopsied low grade lesions may be as low as 25%).

Evidence supporting this recommendation is of classes: C, R

42. High-Grade Squamous Intraepithelial Lesion (HSIL) Present

The 2001 Bethesda System combines moderate dysplasia with severe dysplasia and carcinoma-in-situ (CIS) into a single category of high-grade intraepithelial lesion (HSIL). Up to 95% of patients with high-grade cervical cytology results have been found to have high-grade lesions.

Of all the categories in current nomenclature for cervical cytology results, perhaps the least ambiguity and the least controversy in management is with HSIL. Histologic evaluation of directed cervical biopsies from women with HSIL will commonly show moderate or severe dysplasia or even carcinoma in situ. Thus the standard of practice for management is clearly to perform colposcopy and directed biopsy.

Further management of the patient will then be guided by the biopsy results.

43. Colposcopy with Biopsy and/or LEEP

Colposcopic examination with directed biopsies or LEEP is the appropriate management for women with HSIL cytology results. If follow-up for the patient is unreliable or in a "see and treat" circumstance, LEEP may be performed immediately. When a LEEP is performed immediately it is not necessary to automatically do an ECC. But if endocervical disease is suspected as a result of the colposcopy and LEEP is not done, an ECC should still be performed.

Evidence supporting this recommendation is of classes: C, M, R

Abnormal Cervical Cytology in Adolescents (Less than 21 Years) Algorithm Annotations

47-52. Abnormal Cytology Results in Adolescents Present

Key Point:

- In adolescents, the HPV regression rate is so high that conservative management without colposcopy is recommended.

Management of ASCUS Cervical Cancer Screening Test Results in Adolescents

A report of ASCUS on a cervical cytological screening test often indicates a woman is harboring an HPV infection. In the adolescent population, the prevalence of HPV in that subset with an ASCUS report will be much higher than in an older population. As noted, the risk of invasive cancer in adolescents approaches zero, and the likelihood of HPV clearance is very high.

The preferred method of triage for adolescent patients with ASCUS is monitoring with cytology twice at six-month intervals or a single high-risk HPV test at 12 months. If the repeat cytology test results are abnormal, or there is evidence of persistent HPV, colposcopy should be performed. These alternatives are equally sensitive for the detection of CIN-2/3+; they avoid the expense of colposcopy and biopsy, and they allow for the high likelihood of clearance of CIN-1 and HPV in this population.

Immediate colposcopy is an acceptable alternative for the management of the adolescent who tests positive for ASCUS and HPV, particularly if follow-up is problematic. Adolescents with ASCUS cervical cytology who test negative for high-risk HPV DNA and whose follow-up is problematic should have cervical cytological screening in 12 months and not undergo immediate colposcopy.

Evidence supporting this recommendation is of classes: B, R

Management of LSIL Cervical Cancer Screening Test Results in Adolescents

The ALTS trial showed that patients with cytological report of LSIL and ASCUS behave in a similar manner regarding clearance of HPV and the risk of developing CIN-2/3+. Due to the similarities in the natural history of these cervical cancer screening findings, management for adolescents is the same as for ASCUS.

Management of All Cervical Cancer Screening Test Results with High Probability of CIN-2/3+ in Adolescents

Screening test results of ASC-H, HSIL and AGC all indicate a higher probability for a CIN-2/3+ lesion and should be managed by immediate colposcopy and endocervical assessment as for older women. The management algorithm is identical to the main algorithm for these cervical cancer screening test results.

In pregnancy, the only diagnosis that may alter clinical management is invasive cancer. The presence of cancer may change treatment goals for the route and timing of delivery. Cervical cancer screening test results that are not likely to be associated with cancer may undergo colposcopic evaluation either during pregnancy or 6 to 12 weeks postpartum. Pregnant women whose screening test results indicate a high risk for CIN-2/3+ should undergo colposcopy without

endocervical sampling, reserving biopsy for visible cervical lesions consistent with CIN-3, AIS or cancer.

Definitions:

Classes of Research Reports:

A. Primary Reports of New Data Collection:

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Non-randomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

CLINICAL ALGORITHM(S)

Detailed and annotated clinical algorithms are provided for:

- [Initial Abnormal Cytology Result](#)
- [Benign Endometrial Cells \(BEC\)](#)
- [Atypical Squamous Cells of Undetermined Significance \(ASCUS\)](#)
- [Atypical Glandular Cells \(AGC\)](#)
- [Abnormal Cervical Cytology in Adolescents \(Less than 21 years\)](#)

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is classified for selected recommendations (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Improved clinical follow-up of women who undergo cervical cytologic analysis and receive an abnormal result

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These clinical guidelines are designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and are not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.
- This health care guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients are urged to consult a health care professional regarding their own situation and any specific medical questions they may have.
- The work group recognizes that circumstances may arise during routine screening in which a patient has a positive high-risk human papillomavirus (HPV) DNA result without concomitant cervical cytology results. There is currently no consensus or evidence on the management strategy in these circumstances. The work group is aware that there are ongoing studies that may help clarify these management strategies in the future.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Once a guideline is approved for general implementation, a medical group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they may form an action group.

In the action group, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment, and tobacco cessation.

Detailed measurement strategies are presented in the original guideline document to help close the gap between clinical practice and the guideline recommendations. Summaries of the measures are provided in the National Quality Measures Clearinghouse (NQMC).

Key Implementation Recommendations

The following system changes were identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline.

1. Disseminate recommendations for appropriate follow-up for each of the Bethesda classifications for abnormal cervical cytology results.
2. Implement a program or process to ensure complete follow-up of all abnormal results obtained by cervical cytology.

IMPLEMENTATION TOOLS

Clinical Algorithm
Pocket Guide/Reference Cards
Quality Measures

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

RELATED NQMC MEASURES

- [Initial management of abnormal cervical cytology \(Pap smear\) and human papillomavirus \(HPV\) testing: percentage of adult women diagnosed with initial abnormal cervical cytology of atypical squamous cells of undetermined significance \(ASCUS\) with high-risk HPV type who have follow-up colposcopy within six months of abnormality identified.](#)

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)

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ADAPTATION

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

DATE RELEASED

1999 May (revised 2006 Oct)

GUIDELINE DEVELOPER(S)

Institute for Clinical Systems Improvement - Private Nonprofit Organization

GUIDELINE DEVELOPER COMMENT

Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Community Medical Centers, Allina Medical Clinic, Altru Health System, Aspen Medical Group, Avera Health, CentraCare, Columbia Park Medical Group, Community-University Health Care Center, Dakota Clinic, ENT Specialty Care, Fairview Health Services, Family HealthServices Minnesota, Family Practice Medical Center, Gateway Family Health Clinic, Gillette Children's Specialty Healthcare, Grand Itasca Clinic and Hospital, HealthEast Care System, HealthPartners Central Minnesota Clinics, HealthPartners Medical Group and Clinics, Hutchinson Area Health Care, Hutchinson Medical Center, Lakeview Clinic, Mayo Clinic, Mercy Hospital and Health Care Center, MeritCare, Mille Lacs Health System, Minnesota Gastroenterology, Montevideo Clinic, North Clinic, North Memorial Care System, North Suburban Family Physicians, Northwest Family Physicians, Olmsted Medical Center, Park Nicollet Health Services, Pilot City Health Center, Quello Clinic, Ridgeview Medical Center, River Falls Medical Clinic, Saint

Mary's/Duluth Clinic Health System, St. Paul Heart Clinic, Sioux Valley Hospitals and Health System, Southside Community Health Services, Stillwater Medical Group, SuperiorHealth Medical Group, University of Minnesota Physicians, Winona Clinic, Ltd., Winona Health

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GUIDELINE COMMITTEE

Ob/Gyn Steering Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Work Group Members: Brendon Cullinan, MD (Work Group Leader) (Montevideo Hospital and Clinic) (Family Medicine); Jeanne M. Anderson, MD (Family HealthServices Minnesota) (Family Medicine); Lynne Lillie, MD (HealthEast Clinics) (Family Medicine); Amy Nelson, MD (Sioux Valley Hospitals and Health System) (Family Medicine); Melissa A. Geller, MD (University of MN) (Gynecology/Oncology); Dale Akkerman, MD (Park Nicollet Health Services) (Ob/Gyn); Brigitte Barrette, MD (Mayo Clinic) (Ob/Gyn); Ashley Briggs, MD (Sioux Valley Hospitals and Health System) (Ob/Gyn); Jeff Raines, MD (Columbia Park Medical Group) (Ob/Gyn); Lachlan Smith, MD (Affiliated Community Medical Center) (Ob/Gyn); Jane Suska, CNP (CentraCare) (Ob/Gyn); Corrine Esch, RN (HealthPartners Medical Group) (Nursing); R. Paul Weatherby, MD (Park Nicollet Health Services) (Pathology); Sylvia Robinson, BSN, MBA (Institute for Clinical Systems Improvement) (Measurement/Implementation Advisor); Linda Setterlund, MA, CPHQ (Institute for Clinical Systems Improvement) (Facilitator)

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GUIDELINE AVAILABILITY

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AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Initial management of abnormal cervical cytology (Pap smear) and HPV testing. Executive summary. Bloomington (MN): Institute for Clinical Systems Improvement, 2006 Oct. 1 p. Electronic copies: Available in Portable Document Format (PDF) from the [Institute for Clinical Systems Improvement \(ICSI\) Web site](#).
- ICSI pocket guidelines. April 2006 edition. Bloomington (MN): Institute for Clinical Systems Improvement, 2006. 298 p.

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PATIENT RESOURCES

None available

NGC STATUS

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