Complete Summary

GUIDELINE TITLE

Human papillomavirus.

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Human papillomavirus. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2005 Apr. 13 p. (ACOG practice bulletin; no. 61). [112 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Human papillomavirus (HPV) infection of the uterine cervix

GUIDELINE CATEGORY

Counseling
Prevention
Screening
Treatment

CLINICAL SPECIALTY

Family Practice
Infectious Diseases
Internal Medicine
Obstetrics and Gynecology
Pediatrics
Preventive Medicine

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To review the screening recommendations and treatment for human papillomavirus infection in sexually active women

TARGET POPULATION

Sexually active women and adolescent girls

INTERVENTIONS AND PRACTICES CONSIDERED

Screening

1. Cervical cytology (conventional or liquid based)
2. Colposcopy
3. Human papillomavirus (HPV) deoxyribonucleic acid (DNA) testing
4. Combined HPV DNA screening and cervical cytology
5. Age at screening
6. Frequency of screening

Prevention/Clearance

1. Abstention
2. Monogamy
3. Partner condom use
4. Prophylactic vaccine

Treatment

1. Patient-applied medication (podofilox solution or gel, imiquimod cream)
2. Provider-applied medication (trichloroacetic acid, bichloroacetic acid)
3. Provider procedures (cryosurgery; excision by scissor, scalpel or electrosurgical loop; electrocautery; laser vaporization or excision)
4. "Test of cure" using HPV DNA test

Counseling on the Following Topics

1. Mode of transmission

2. Risk reduction
3. Prevention of reinfection
4. Source of infection
5. Effect on pregnancy

MAJOR OUTCOMES CONSIDERED

- Cure rate
- Relapse rate
- Side effects
- Cost

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' own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1985 and December 2004. 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

In 2001, the National Cancer Institute completed a large multicenter randomized trial called the Atypical Squamous Cells of Undetermined Significance/Low Grade Squamous Intraepithelial Lesion Triage Study (ALTS). The study compared immediate colposcopy, human papilloma virus (HPV) deoxyribonucleic acid (DNA) testing by Hybrid Capture 2, and repeat cytology in the management of women with atypical squamous cells of undetermined significance (ASC-US) and low-grade squamous intraepithelial lesions (LSIL) cytology. The study showed that 83% of women with LSIL cytology tested positive for high-risk HPV DNA, limiting the usefulness and the cost-effectiveness of HPV testing in differentiating which women with LSIL cytology should undergo colposcopy.

In 2001, the American Society for Colposcopy and Cervical Pathology (ASCCP), in conjunction with the American College of Obstetricians and Gynecologists and 28 other participating professional and health organizations and federal agencies, hosted a consensus conference to develop comprehensive evidence-based guidelines for the management of women with cervical cytologic abnormalities and cervical cancer precursors. Among repeat cytology, immediate colposcopy, and HPV DNA testing, the consensus conference concluded that all three options were acceptable for managing women with ASC-US cytology. However, the preferred option was reflex HPV DNA testing for high-risk types when liquid-based cytology was used at the time of the initial visit. This approach eliminates the need for a repeat office visit, is the most sensitive of the triage tools, and results in the referral of fewer women to colposcopy than the other options at all age groups. Human papillomavirus testing was not recommended for triage of women with LSIL, atypical squamous cells that cannot exclude high-grade squamous intraepithelial lesions, or atypical glandular cells cytology. These women should undergo immediate colposcopy, and the use of HPV testing is not cost-effective in this population.

Although surgical treatment is relatively expensive, the ability to avoid multiple visits saves both the patient and the physician time and money and adds to the cost-effectiveness of the technique.

Because of the cost of the equipment and because laser surgery usually is performed in an operating room with general anesthesia, it is the most expensive modality for the treatment of genital warts.

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):

- Because human papillomavirus (HPV) deoxyribonucleic acid (DNA) testing is more sensitive than cervical cytology in detecting cervical intraepithelial neoplasia (CIN) 2 and CIN 3, women with negative concurrent test results can be reassured that their risk of unidentified CIN 2 and CIN 3 or cervical cancer is approximately 1 in 1,000.
- Studies using combined HPV testing with cervical cytology have reported a negative predictive value for CIN 2 and CIN 3 of 99 to 100%.
- HPV DNA testing is not recommended in women with low-grade squamous intraepithelial lesions (LSIL), atypical squamous cells (ASC) that cannot exclude high-grade squamous intraepithelial lesions, or atypical glandular cell cytology.
- The triage of women with ASC of undetermined significance (ASC-US) cytology using reflex HPV DNA testing for high-risk types when liquid-based cytology was used at the time of the initial visit eliminates the need for a repeat office visit and is a more sensitive triage tool than repeat cytology while referring fewer women to colposcopy.
- Women with high-risk HPV who have ASC-US or LSIL cytology but are not found to have CIN 2 or CIN 3 at their initial colposcopy have approximately a 10% risk of having CIN 2 or CIN 3 within 2 years.

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

- Although evidence is lacking that condoms offer complete protection from HPV infection, condom use may reduce the risk of HPV-related disease, such as genital warts and cervical neoplasia.
- Studies show that condoms may be effective in the clearance of HPV or HPV-associated lesions.
- Use of a combination of cervical cytology and HPV DNA screening is appropriate for women aged 30 years and older. If this combination is used, women who receive negative results on both tests should be rescreened no more frequently than every 3 years.
- Because of a similar risk of recurrence, no single treatment for external genital warts can be recommended over another.

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

- Women older than 30 years with a negative cytology result who have high-risk HPV DNA positive test results should have both tests repeated in 6 to 12 months. Those with persistent high-risk HPV (on repeat testing) should undergo colposcopy regardless of the cytology result.
- Human papillomavirus DNA testing could be used as a test of cure for women with CIN 2 or CIN 3 at 6–12 months following excision or ablation of the transformation zone. Those with high-risk HPV should be referred for colposcopy.

- Treatment for genital warts should be guided by the preference of the patient and the experience of the heath care provider.

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)

None provided

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 treatment of human papillomavirus (HPV) infection

POTENTIAL HARMS

- All treatment modalities for genital warts result in local inflammation or discomfort, and the patient should be warned that ablation modalities might be associated with persistent hypopigmentation or hyperpigmentation and rarely in disabling chronic pain syndromes, such as vulvodynia.
- Pain and necrosis and occasional blistering follow the application of liquid nitrogen to genital warts.
- Trichloroacetic acid and bichloroacetic acid solutions have a low viscosity and can run onto adjacent normal tissue if over-applied, causing damage.
- Pain following laser vaporization is dependent on the area being treated. Treatment of large areas can result in severe pain that peaks after 5–7 days and can last up to 3 weeks. Vitiligo and hyperpigmentation are possible, and scarring is a potential complication of laser vaporization that is very extensive or too deep.

CONTRAINDICATIONS

CONTRAINDICATIONS

- Neither podofilox nor imiquimod should be used during pregnancy.
- Although there are no real patient-related contraindications to cryotherapy, proper training is required to avoid overtreatment or undertreatment.

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.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

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
Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Human papillomavirus. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2005 Apr. 13 p. (ACOG practice bulletin; no. 61). [112 references]

ADAPTATION

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

DATE RELEASED

2005 Apr

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

Not stated

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 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 is available:

- Human papillomavirus infection. Atlanta (GA): American College of Obstetricians and Gynecologists (ACOG); 2006.

Electronic copies: Available from the American College of Obstetricians and Gynecologists (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

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