Complete Summary

GUIDELINE TITLE

Human papillomavirus (HPV).

BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. Human papillomavirus (HPV). New York (NY): New York State Department of Health; 2007 Oct. 11 p. [19 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Human immunodeficiency virus (HIV) infection
- Human papillomavirus (HPV) infection

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Prevention
Screening
Treatment

CLINICAL SPECIALTY

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

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

To provide guidelines for prevention, diagnosis, and treatment of human papillomavirus (HPV) infection in human immunodeficiency virus (HIV)-infected patients

TARGET POPULATION

Human immunodeficiency virus (HIV)-infected patients with human papillomavirus (HPV) coinfection

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation/Screening

1. Screening for human papillomavirus (HPV) infection including visual inspection, cervical and anal cytology
2. High-resolution anoscopy, Pap test (for women)
3. Biopsy of abnormal findings
4. HPV deoxyribonucleic acid (DNA) testing (not recommended)

Management/Treatment

1. Patient-applied treatment (podophyllotoxin, imiquimod, cidofovir gel)
2. Provider-applied treatments (cryotherapy, podophyllin resin, trichloroacetic acid, bichloroacetic acid, interferon-alfa-2b, electrodessication, surgical excision, laser, loop electrosurgical excision procedure, infrared coagulation)
3. Management of sex partners (assistance with partner notification, management of human immunodeficiency virus [HIV] and HPV exposure)

Prevention

1. HPV vaccine in HIV-infected female patients aged 9 to 26 years
2. Pap tests in HIV-infected women

3. Counseling HIV-infected patients on safe sexual practices and reduction in number of sexual partners

MAJOR OUTCOMES CONSIDERED

- Prevalence of human papillomavirus (HPV) infection in human immunodeficiency virus (HIV)-infected patients
- Impact of HIV infection on the manifestation of HPV infection
- Usefulness of diagnostic procedures
- Effectiveness of treatment in terms of clearance rates

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

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review
Review of Published Meta-Analyses

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

AIDS Institute clinical guidelines are developed by distinguished committees of clinicians and others with extensive experience providing care to people with HIV infection. Committees* meet regularly to assess current recommendations and to write and update guidelines in accordance with newly emerging clinical and research developments.

The Committees* rely on evidence to the extent possible in formulating recommendations. When data from randomized clinical trials are not available, Committees rely on developing guidelines based on consensus, balancing the use of new information with sound clinical judgment that results in recommendations that are in the best interest of patients.

* Current committees include:

- Medical Care Criteria Committee
- Committee for the Care of Children and Adolescents with HIV Infection
- Dental Standards of Care Committee
- Mental Health Committee
- Women's Health Committee
- Substance Use Committee
- Physician's Prevention Advisory Committee
- Pharmacy Committee

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

The guideline developers reviewed published cost analyses.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

All guidelines developed by the Committee are externally peer reviewed by at least two experts in that particular area of patient care, which ensures depth and quality of the guidelines.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Diagnosis, treatment, and follow-up of human papillomavirus (HPV)-related lesions in human immunodeficiency virus (HIV)-infected patients should be

performed in consultation with a clinician experienced in the management of HPV and HIV.

Prevention of HPV

HPV Vaccine

Clinicians should offer the HPV vaccine to HIV-infected women between the ages of 9 and 26 years.

Clinicians should continue to obtain cervical Pap tests on the recommended schedule in HIV-infected women who have been vaccinated with HPV vaccine (see "Screening for HPV" section below). Vaginal and vulvar visual inspection should be continued at regularly scheduled pelvic examinations.

HPV typing prior to administering the vaccine is not recommended.

There currently are no recommendations to vaccinate males against HPV.

Other Strategies to Prevent HPV Infection

Clinicians should counsel HIV-infected patients on practices that may reduce the risk of acquiring HPV infection, including safe sexual practices and reduction in number of sexual partners.

Screening for HPV

Visual Inspection

Clinicians should examine the anogenital area, including the vulva and vagina in women, to assess for visible HPV lesions at baseline and as part of the annual comprehensive physical examination.

Cervical Cytology

Clinicians should obtain cervical Pap tests in HIV-infected women at baseline, 6 months after baseline, and then annually as long as results are normal. Colposcopy should be performed for women with abnormal Pap tests (atypical squamous cells of uncertain significance [ASC-US], atypical squamous cells: cannot exclude high grade squamous intraepithelial lesion ASC-H, low-grade squamous intraepithelial lesion [LSIL], or high-grade squamous intraepithelial lesion [HSIL], or the World Health Organization (WHO) or cervical intraepithelial neoplasia [CIN] equivalent); treatment would then vary according to individual colposcopy results. After treatment, Pap tests should be repeated every 3 to 6 months until there have been two successive normal Pap tests.

For Women Who Have Undergone Hysterectomy

Clinicians should obtain at least an annual cervical Pap test in HIV-infected women who have undergone a hysterectomy when:

- The hysterectomy was performed because of high-grade dysplasia, HPV-related anogenital dysplasia of the cervix, or carcinoma
- A supracervical hysterectomy (uterus removed and cervix left in place) was performed
- The reason for the hysterectomy cannot be determined by patient self-report or other means
- Any cervical tissue remains

Annual Pap tests are not recommended for HIV-infected women who have undergone a total hysterectomy for reasons not related to cervical abnormalities.

Anal Cytology

Clinicians should perform anal Pap tests at baseline and annually in the following populations:

- Men who have sex with men
- Any patient with a history of anogenital condylomas
- Women with abnormal cervical/vulvar histology

HPV Deoxyribonucleic Acid (DNA) Testing

HPV DNA testing in HIV-infected patients is *not* recommended at this time.

Presentation and Diagnosis

Clinicians should include HPV in the differential diagnosis of anogenital symptoms, such as itching, bleeding, pain, or spotting after sexual intercourse.

Patients with abnormal anogenital physical findings, such as warts, hypopigmented or hyperpigmented plaques/lesions, lesions that bleed, or any other lesions of uncertain etiology, should be referred for high-resolution anoscopy, a cervical Pap test (for women), and/or examination with biopsy of abnormal findings.

Treatment

Clinicians should use the same therapeutic modalities to treat HPV in HIV-infected patients as those used in non-HIV-infected patients (see Table 1 below). The following factors should be considered when choosing treatment:

- Patient preference
- Clinician experience and available resources
- Size of wart(s) and number of warts
- Anatomic site of wart(s)
- Adverse effects of treatment

Clinicians should switch treatment modalities if warts have not improved substantially within 3 months of therapy. For condyloma that have not responded to treatment, clinicians should obtain biopsy to exclude dysplasia or cancer.

Clinicians should not use podophyllotoxin or interferon in pregnant women.

Clinicians should refer patients with lesions that are resistant to simple therapies, lesions that change in appearance, and lesions with ulceration, irregular shape, or variegated coloration to clinicians experienced in the management of HPV and HIV.

Primary care clinicians should refer HIV-infected patients with cervical, vulvar, or anal cancer to an oncologist for treatment (see the New York State Department of Health (NYSDOH) guidelines "Neoplastic Complications" and "Anogenital Neoplasia" for further discussion regarding treatment of cancer).

Table 1. Available Treatment Options for Condyloma

Patient-Applied Treatments	Provider-Applied Treatments
• Podophyllotoxin* • Imiquimod** • Cidofovir gel	• Cryotherapy • Podophyllin resin* • Trichloroacetic acid (TCA) • Bichloroacetic acid (BCA) 80%-90% • Interferon alfa-2b* • Electrodesiccation • Surgical excision • Laser (carbon dioxide, pulsed-dye) • Loop electrosurgical excision procedure (LEEP) • Infrared coagulation

*Should not be used in pregnant women. TCA or BCA can be used to treat small external warts during pregnancy but may not be as effective.

** May decrease likelihood of recurrences.

Management of Sex Partners

Clinicians should consider both the HIV exposure and the sexually transmitted infection (STI) exposure to partners when HIV-infected patients present with a new STI. Clinicians should also assess for the presence of other STIs.

Management of HIV Exposure

When HIV-infected patients present with a new STI, clinicians should encourage their partner(s) to undergo HIV testing at baseline, 1, 3, and 6 months. In New York State, if the test result is positive, a Western blot assay must be performed to confirm diagnosis of HIV infection.

Clinicians should be vigilant for any post-exposure acute febrile illness accompanied by rash, lymphadenopathy, myalgias, and/or sore throat. If the partner presents with signs or symptoms of acute HIV seroconversion, a quantitative ribonucleic acid polymerase chain reaction (RNA PCR) should be obtained, and consultation with an HIV Specialist should be sought. Positive RNA

tests should be confirmed with HIV antibody testing performed within 6 weeks of the RNA test.

Clinicians should offer assistance with partner notification if needed.

Management of HPV Exposure

For sex partners of patients with genital warts, clinicians should:

- Examine sex partners for the presence of genital warts and other STIs
- Counsel female sex partners about the importance of cervical cytologic screening

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate prevention, diagnosis, and treatment of human papillomavirus (HPV) infection in human immunodeficiency virus (HIV)-infected patients

Subgroups Most Likely to Benefit

Current studies demonstrate that the preventive efficacy of the HPV vaccine is greatest in women who are not yet sexually active and thus have not been exposed to HPV.

POTENTIAL HARMS

Podophyllotoxin and interferon should not be used in pregnant women.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The AIDS Institute's Office of the Medical Director directly oversees the development, publication, dissemination and implementation of clinical practice guidelines, in collaboration with The Johns Hopkins University, Division of Infectious Diseases. These guidelines address the medical management of adults,

adolescents and children with HIV infection; primary and secondary prevention in medical settings; and include informational brochures for care providers and the public.

Guidelines Dissemination

Guidelines are disseminated to clinicians, support service providers and consumers through mass mailings and numerous AIDS Institute-sponsored educational programs. Distribution methods include the HIV Clinical Resource website, the Clinical Education Initiative, the AIDS Educational Training Centers (AETC) and the HIV/AIDS Materials Initiative. Printed copies of clinical guidelines are available for order from the New York State Department of Health (NYSDOH) Distribution Center for providers who lack internet access.

Guidelines Implementation

The HIV Clinical Guidelines Program works with other programs in the AIDS Institute to promote adoption of guidelines. Clinicians, for example, are targeted through the Clinical Education Initiative (CEI) and the AIDS Education and Training Centers (AETC). The CEI provides tailored educational programming on site for health care providers on important topics in HIV care, including those addressed by the HIV Clinical Guidelines Program. The AETC provides conferences, grand rounds and other programs that cover topics contained in AIDS Institute guidelines.

Support service providers are targeted through the HIV Education and Training initiative which provides training on important HIV topics to non-physician health and human services providers. Education is carried out across the State as well as through video conferencing and audio conferencing.

The HIV Clinical Guidelines Program also works in a coordinated manner with the HIV Quality of Care Program to promote implementation of HIV guidelines in New York State. By developing quality indicators based on the guidelines, the AIDS Institute has created a mechanism for measurement of performance that allows providers and consumers to know to what extent specific guidelines have been implemented.

Finally, best practices booklets are developed through the HIV Clinical Guidelines Program. These contain practical solutions to common problems related to access, delivery or coordination of care, in an effort to ensure that HIV guidelines are implemented and that patients receive the highest level of HIV care possible.

IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads

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

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. Human papillomavirus (HPV). New York (NY): New York State Department of Health; 2007 Oct. 11 p. [19 references]

ADAPTATION

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

DATE RELEASED

2007 Oct

GUIDELINE DEVELOPER(S)

New York State Department of Health - State/Local Government Agency [U.S.]

SOURCE(S) OF FUNDING

New York State Department of Health

GUIDELINE COMMITTEE

Not stated

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: Available from the New York State Department of Health AIDS Institute Web site.

AVAILABILITY OF COMPANION DOCUMENTS

This guideline is available as a Personal Digital Assistant (PDA) download from the New York State Department of Health AIDS Institute Web site.

PATIENT RESOURCES

None available

NGC STATUS

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