

## Complete Summary

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### GUIDELINE TITLE

Medical care for menopausal and older women with HIV infection.

### BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. Medical care for menopausal and older women with HIV infection. New York (NY): New York State Department of Health; 2008 Mar. 10 p. [22 references]

### GUIDELINE STATUS

This is the current release of the guideline.

## COMPLETE SUMMARY CONTENT

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## SCOPE

### DISEASE/CONDITION(S)

- Human immunodeficiency virus (HIV) infection
- Menopause
- Mental health disorders and substance use
- Sexual dysfunction

### GUIDELINE CATEGORY

Counseling  
 Diagnosis  
 Evaluation  
 Management  
 Prevention

Risk Assessment  
Screening

## **CLINICAL SPECIALTY**

Allergy and Immunology  
Family Practice  
Geriatrics  
Infectious Diseases  
Internal Medicine  
Obstetrics and Gynecology  
Psychiatry

## **INTENDED USERS**

Advanced Practice Nurses  
Health Care Providers  
Nurses  
Physician Assistants  
Physicians  
Psychologists/Non-physician Behavioral Health Clinicians  
Substance Use Disorders Treatment Providers

## **GUIDELINE OBJECTIVE(S)**

To discuss prevalence and identification of human immunodeficiency virus (HIV) in women over the age of 50, primary health care for HIV-infected older women, the implications of initiating highly active antiretroviral therapy (HAART) and/or hormone replacement therapy, and the psychosocial issues that may affect older women living with HIV infection

## **TARGET POPULATION**

Menopausal and older women with human immunodeficiency virus (HIV) infection

## **INTERVENTIONS AND PRACTICES CONSIDERED**

### **Evaluation/Diagnosis/Screening**

1. Including human immunodeficiency virus (HIV) infection in the differential diagnosis for flu-like illnesses
2. Routine primary healthcare including gynecological evaluation, cytologic screening, post-hysterectomy cervical screening, screening for sexually transmitted infections, mammography, and bone mineral density measurement
3. Mental health assessment using brief screening instruments and including the following components: cognitive impairment, depression, anxiety, alcohol and substance use, psychiatric history, psychotropic medications, psychosocial assessment and others
4. Assessment for sexual dysfunction

## **Management/Prevention**

1. Risk reduction counseling for prevention of sexually transmitted infections and human immunodeficiency virus (HIV) transmission
2. Use of highly active antiretroviral therapy (HAART)
3. Hormone replacement therapy (HRT)
4. Patient education about risks and benefits of HAART and HRT, possible side effects and drug-drug interactions, weight control, improved nutrition, and smoking cessation
5. Use of alternatives to HRT
6. Referrals to mental health and substance use specialists if indicated

## **MAJOR OUTCOMES CONSIDERED**

Effectiveness of highly active antiretroviral therapy (HAART) and hormone replacement therapy

## **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

### **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 human immunodeficiency virus (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**

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

### **METHOD OF GUIDELINE VALIDATION**

External Peer Review

### **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

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

#### Identification and Prevention of Human Immunodeficiency Virus (HIV) in Older Women

##### Risk Assessment and Risk-Reduction Counseling

Clinicians should discuss sexual and other risk behaviors and HIV prevention education at routine clinical visits for all HIV-infected women, regardless of age.

##### Key Point:

Use of water-based lubricants and treatment with vaginal estrogen preparations, which are considered safe and effective, can decrease the discomfort that some older women may experience with condom use.

#### Identification of Acute Retroviral Syndrome and New Diagnoses in Older Women

Clinicians should consider acute retroviral syndrome in the differential diagnosis for older women who present with flu-like illnesses.

#### Routine Primary Healthcare Recommendations for Older HIV-Infected Women

**Table. Routine Primary Healthcare Recommendations for Older HIV-Infected Women<sup>1</sup>**

Procedure	Frequency
Gynecological evaluation	At baseline and annually and as indicated for ongoing problems. This examination should include direct visualization of the vulva, vagina, and cervix, and a bimanual pelvic examination that includes a digital rectal examination.
Cytologic screening	<ul style="list-style-type: none"> <li>Cervical Pap tests <ul style="list-style-type: none"> <li>Baseline and then 6 months after baseline; repeat annually, as long as results are normal</li> <li>Abnormal Pap tests results should be repeated every 3 to 6 months until two successive normal Pap tests are reported<sup>2</sup></li> </ul> </li> <li>Anal Pap tests <ul style="list-style-type: none"> <li>Baseline and annually for women with a history of anogenital condyloma or abnormal cervical/vulvar histology</li> </ul> </li> </ul>
Post-hysterectomy cervical	Annual cervical Pap test when: <ul style="list-style-type: none"> <li>Hysterectomy was performed because of high-grade</li> </ul>

**Table. Routine Primary Healthcare Recommendations for Older HIV-Infected Women<sup>1</sup>**

Procedure	Frequency
screening <sup>3</sup>	<p>dysplasia, HPV-related anogenital dysplasia of the cervix, or carcinoma</p> <ul style="list-style-type: none"> <li>• A supracervical hysterectomy (uterus removed and cervix left in place) was performed</li> <li>• The reason for the hysterectomy cannot be determined by patient self-report or other means</li> <li>• Any cervical tissue remains</li> </ul>
STI screening	<ul style="list-style-type: none"> <li>• RPR or VDRL for syphilis with verification of positive test by confirmatory FTA-Abs or TP-PA <ul style="list-style-type: none"> <li>• Baseline and at least annually; every 3 months for patients with ongoing high-risk behavior</li> </ul> </li> <li>• Gonorrhea and chlamydia<sup>4,5</sup> <ul style="list-style-type: none"> <li>• Baseline and at least annually</li> </ul> </li> </ul>
Mammography	Annually, starting at age 40 <sup>6</sup>
Bone mineral densities	Baseline at menopause and after 50. The frequency thereafter has not been determined <sup>7</sup>

FTA-Abs, fluorescent treponemal antibody absorbance; HPV, human papilloma virus; RPR, rapid plasma reagin; STI, sexually transmitted infection; TP-PA, *Treponema pallidum* particle agglutination; VDRL, Venereal Disease Research Laboratory.

- <sup>1</sup>Routine immunizations can be found in the National Guideline Clearinghouse (NGC) summary of the New York State Department of Health (NYSDoH) guideline [Prevention of Secondary Disease: Immunizations](#); routine diagnostic screening tests can be found in the NGC summary of the NYSDoH guideline, [Primary Care Approach to the HIV-Infected Patient](#).
- <sup>2</sup>Colposcopy should be performed for women with abnormal Pap tests. Follow-up would then vary on a case-by-case basis. Women with cervical high-grade intraepithelial lesion (HSIL) should be referred for high-resolution anoscopy.
- <sup>3</sup>Annual Pap tests are not recommended for HIV-infected women who have undergone a total hysterectomy for reasons not related to cervical abnormalities.
- <sup>4</sup>All sites of exposure are screened. For specific recommendations regarding the types of assays used, refer to the NGC summary of the NYSDoH guideline [Gonococcal and Chlamydial Infections in Management of STIs in HIV-Infected Patients](#).
- <sup>5</sup>For women with one of the following: recent STI, multiple sexual partners, a new sexual partner, or a sexual partner with symptoms of an STI.
- <sup>6</sup>American Cancer Society (ACS), available at: <http://caonline.amcancersoc.org/cgi/reprint/53/3/141>. However, the optimal age of initiation for breast screening and the intervals for mammography are still being studied.
- <sup>7</sup>National Osteoporosis Foundation, available at: <http://www.nof.org>.

## Use of HAART in the Older HIV-Infected Woman

Clinicians should follow standard guidelines for initiation of HAART in older women (see the NGC summary of the NYSDoH guideline [Antiretroviral Therapy](#)).

## Adverse Drug Reactions and Drug-Drug Interactions

Clinicians should assess for signs or symptoms of adverse reactions, drug-drug interactions, and cumulative side effects when patients are receiving multiple types or classes of medications for comorbidities and/or HIV.

### **Hormone Replacement Therapy (HRT) in HIV-Infected Women**

Clinicians should refer HIV-infected women experiencing severe symptoms of menopause to a clinician experienced in the most current management of menopausal symptoms. An individualized risk/benefit analysis of the use of HRT should be performed regardless of whether or not the woman is receiving HAART.

Clinicians should discuss with HIV-infected women the benefits of exercise, weight control, improved nutrition, including calcium supplementation, and smoking cessation for the prevention of osteoporosis and coronary heart disease.

### **Guidelines for HRT**

<b>Table. Guidelines for Prescribing Hormone Replacement Therapy</b>	
<ul style="list-style-type: none"> <li>• Provide HRT for the shortest possible time at the lowest effective doses</li> <li>• Consult with the patient at least once a year about HRT therapy, working toward successfully discontinuing the use of HRT</li> <li>• Recommend regular breast cancer screening               <ul style="list-style-type: none"> <li>• Annual clinical breast examinations</li> <li>• Annual mammograms for women <math>\geq 40^*</math></li> </ul> </li> </ul>	

\*The optimal age of initiation for breast screening and the intervals for mammography are still being studied.

### **Alternatives to HRT**

<b>Table. Alternatives to Hormone Replacement Therapy</b>	
<b>Signs or Symptoms</b>	<b>Alternative Treatment</b>
Hot flashes/menopause symptom alleviation	<ul style="list-style-type: none"> <li>• Paroxetine</li> <li>• Gabapentin</li> <li>• Clonidine</li> </ul>
Vaginal dryness/atrophy	<ul style="list-style-type: none"> <li>• Water-based lubricants and vaginal estrogen preparations</li> </ul>
Prevention or treatment of osteoporosis	<ul style="list-style-type: none"> <li>• Alendronate sodium, risedronate, raloxifene, calcitonin</li> <li>• Smoking cessation</li> <li>• Decreased alcohol consumption</li> <li>• Increased physical activity</li> <li>• Calcium and vitamin D supplementation and</li> </ul>

<b>Table. Alternatives to Hormone Replacement Therapy</b>	
<b>Signs or Symptoms</b>	<b>Alternative Treatment</b>
	correction of malnutrition

### **HRT Interactions with HAART**

Because amprenavir and fosamprenavir levels are reduced with ethinyl estradiol and norethindrone use, they should not be used with hormone replacement therapy.

### **Mental Health and Substance Use**

Clinicians should perform a mental health assessment at baseline and at least annually. The assessment should include the following components:

- Cognitive impairment, depression, anxiety, posttraumatic stress disorder, suicidal/violent ideation, and alcohol and substance use
- Sleep habits and appetite assessment
- Psychiatric history, including psychotropic medications
- Psychosocial assessment, including domestic violence, housing status, and presence of social support

Clinicians should refer patients to appropriate mental health and substance use treatment providers when indicated.

Clinicians should incorporate selected brief screening instruments in the patient assessment. These instruments should be tailored for optimal use at initial, annual, and interim visits. The chosen screening instruments should be adjusted for the patient's mental health or substance use history.

### **Key Point**

Depressive symptoms and negative life events have been associated with symptoms of menopause in HIV-infected women.

### **Sexual Dysfunction**

Clinicians should assess older HIV-infected women for sexual dysfunction and/or decreased libido; testosterone supplementation should not be used for treating these conditions.

### **CLINICAL ALGORITHM(S)**

None provided



## EVIDENCE SUPPORTING THE RECOMMENDATIONS

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting is not specifically stated.

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

Appropriate medical care for menopausal and older women with human immunodeficiency virus (HIV)-infection

### POTENTIAL HARMS

#### Adverse Effects and Drug-Drug Interactions

- Risks of initiating *highly active antiretroviral therapy (HAART)* include metabolic complications, such as lipid disorders, insulin resistance and diabetes, altered body fat distribution, and, consequently, a higher risk of cardiovascular disease. These antiretroviral (ARV)-related complications can be difficult to diagnose and manage in older patients who may have the same, age-related, pre-existent metabolic abnormalities. Another potential risk of HAART includes bone loss, although the relationship among HIV infection, ARV therapy, and bone loss in women remains unclear. Components of HAART, in particular nucleoside reverse transcriptase inhibitors (NRTIs) and protease inhibitors (PIs), have been associated with a decrease in bone density. However, some evidence does exist for higher bone density in women exposed to nevirapine.
- HAART medications are known to interact with major classes of drugs that are commonly used to treat older patients, such as antidepressants, anticonvulsants, lipid-lowering agents, and many antibiotics and antifungals.
- Potential adverse effects of *hormone replacement therapy*

## CONTRAINDICATIONS

### CONTRAINDICATIONS

Because *amprenavir* and *fosamprenavir* levels are reduced with ethinyl estradiol and norethindrone use, they should not be used with hormone replacement therapy.

## 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 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

Getting Better  
Living with Illness  
Staying Healthy

### IOM DOMAIN

Effectiveness  
Patient-centeredness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. Medical care for menopausal and older women with HIV infection. New York (NY): New York State Department of Health; 2008 Mar. 10 p. [22 references]

### ADAPTATION

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

### DATE RELEASED

2008 Mar

### 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

Women's Health Committee

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## **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**

This NGC summary was completed by ECRI Institute on July 3, 2008.

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