Complete Summary

GUIDELINE TITLE

Care for the HIV-infected female adolescent.

BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. Care for the HIV-infected female adolescent. New York (NY): New York State Department of Health; 2007 Mar. 12 p. [7 references]

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

- June 10, 2005, Sustiva (efavirenz): Revisions to the WARNINGS, PRECAUTIONS/Pregnancy and Information for Patients, and PATIENT INFORMATION sections of the prescribing information, indicated in the treatment of HIV-1 infection.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

- Human immunodeficiency virus (HIV) infection
- Pregnancy
- Unintended pregnancy
- Reproductive health
- Sexually transmitted diseases

GUIDELINE CATEGORY

Counseling
Evaluation
Management
Prevention
Risk Assessment

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
Nurses
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

To provide guidelines for the care of the human immunodeficiency virus (HIV)-infected female adolescents

TARGET POPULATION

Human immunodeficiency virus (HIV)-infected female adolescents

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation/Risk Assessment

1. Sexual risk assessment and risk-reduction counseling including discussion of birth control, safe sex, partner disclosure, sexual abuse, drug or alcohol use
2. Gynecologic examination including menstrual, gynecologic, and sexual history; examination of anogenital area, breasts, and axilla; patient education

about importance of periodic pelvic examinations, screening for sexually transmitted diseases (STDs), and Pap tests
3. Laboratory tests for sexually active human immunodeficiency virus (HIV)-infected adolescents including cervical Pap test, deoxyribonucleic acid (DNA) amplification test or urine test for gonorrhea, tests for chlamydia, herpes simplex virus serology, and pregnancy test

Counseling/Management/Prevention

1. Human papilloma virus (HPV) vaccine
2. Patient counseling about contraceptive options and importance of using dual contraceptive methods, drug interactions between antiretroviral (ARV) therapy and oral contraceptives
3. Reproductive health counseling about effect of HIV on pregnancy and pregnancy on HIV, emergency contraception, potential for maternal and fetal toxicity from ARV, importance of adherence to the ARV regimen, vitamin and folic acid supplementation, risks of HIV transmission and risk prevention
4. Providing care for pregnant adolescents including patient education about the role of ARV therapy, three-part zidovudine regimen, consultation with HIV Specialist, referral to supportive services at prenatal clinics

MAJOR OUTCOMES CONSIDERED

Not stated

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

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 of a Supportive Adult

Clinicians should identify a supportive adult to whom the adolescent can safely disclose human immunodeficiency virus (HIV)-related information and discuss reproductive health issues.

Human Papillomavirus Vaccine (HPV)

Clinicians should offer the HPV vaccine to HIV-infected females 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 the Table below). Vaginal and vulvar visual inspection should be continued at regularly scheduled pelvic examinations.

HPV typing prior to administering the vaccine is not recommended.

Sexual Risk Assessment and Risk-Reduction Counseling

Clinicians should obtain a sexual risk assessment during the baseline examination and during routine visits (see Table 1 in the original guideline document).

The clinician should routinely discuss sexuality, personal relationships, birth control, safe sex, and partner disclosure with patients. Clinicians should discuss partner disclosure prior to the onset of the adolescent's sexual activity.

Clinicians should inquire about physical and sexual abuse and sexual assault and should refer patients for counseling when indicated.

Clinicians should recommend consistent and correct use of latex condoms to prevent pregnancy, acquisition of sexually transmitted diseases (STDs), transmission of HIV/STDs, and superinfection. For patients with a latex allergy, clinicians should recommend polyurethane condoms. Clinicians should advise HIV-infected adolescents to avoid using lambskin condoms or condoms that are lubricated with nonoxynol-9. For adolescents with same-sex partners, the use of dental dams during oral sex and safe use of sex toys should be discussed to prevent disease transmission.

Clinicians should use a model to demonstrate to adolescents the correct way to use a condom.

Clinicians who are not comfortable discussing sexual practices with adolescents should consult with clinicians who have experience in risk-reduction counseling for adolescents or seek training to enhance their comfort level.

Performing Gynecologic Examinations

At baseline and as part of the annual comprehensive physical examination, clinicians should obtain a menstrual, gynecologic, and sexual history as well as examine the external genitalia, anus, perineal area, breasts, and axilla using the Tanner rating scale for sexual maturity.

The clinician should educate the patient about the importance of periodic pelvic examinations, STD screening, and Pap tests.

Clinicians should perform the first gynecologic examination when any of the following occur:

- The patient reports sexual activity
- The patient requests a pelvic examination
- The patient presents with any gynecologic symptom for which a pelvic examination would assist in a differential diagnosis (e.g., pelvic pain or new onset menstrual irregularity)
- The patient presents with symptoms of an STD or sexual activity
- The patient reaches age 14 -- however, if the inspection reveals an intact hymen or no likely sexual activity, the speculum examination and the Pap test should be deferred until age 18 or until the patient is sexually active, whichever occurs first

Before performing a first-time pelvic examination in a patient, the clinician should explain the various steps and components involved in the examination, including a review of basic genital anatomy, the instruments used for the examination, and the purpose of the examination.

Clinicians should use the smallest speculum available for a first-time examination, even in sexually active adolescents.

Patients should be asked if they would prefer having a female provider perform the examination. During the examination, an additional female member of the medical staff should be present as a chaperone.

Primary care clinicians who do not directly provide gynecologic care should obtain a menstrual, gynecologic, and sexual history and then refer the patients to gynecologic providers with experience providing examinations to adolescents.

Key Point:

Adolescents may require additional time during clinical visits to become comfortable with the idea of receiving a pelvic examination. Additional time may be needed when scheduling these appointments.

Evaluation for Sexually Active HIV-Infected Female Adolescents

At baseline and as part of the annual comprehensive physical examination, clinicians should examine the anogenital area, including the vulva and vagina, to assess for visible ulcerative lesions.

Clinicians should perform the laboratory tests listed in the Table below for HIV-infected females who are sexually active.

Table
Laboratory Tests for Sexually Active HIV-Infected Adolescent Females

Test	Frequency
Cervical Pap test	Baseline, repeated at 6 months, and then annually, if the results are normal[1,2]
Culture, deoxyribonucleic acid (DNA) amplification test, or urine test for gonorrhea[3,4]	Baseline and every 6 months
Rapid plasma regain (RPR) or Venereal Disease Research Laboratory (VDRL) for syphilis[5]	Baseline and at least annually
Immunofluorescence or DNA amplification test for chlamydia	Baseline and every 6 months
Urine test for chlamydia	At 6-month evaluation when a pelvic examination is not performed
Herpes simplex virus serology	Baseline
Herpes cultures	When symptoms are present
Pregnancy test	Baseline and when: 1) the adolescent requests one, 2) menses change in pattern or flow, 3) timing of unprotected sex concerns the patient or provider, or 4) prior to starting teratogenic medications (e.g., efavirenz)

[1]Women with abnormal Pap tests should be referred for colposcopy. Follow-up would then vary on a case-by-case basis. Abnormal Pap tests should be repeated every 3 to 6 months until there have been two successive normal cervical Pap tests. Women with cervical high-grade intraepithelial lesion (HSIL) should be referred for high-resolution anoscopy.

[2]Patients with a history of anogenital condyloma or abnormal cervical/vulvar histology should receive an annual anal Pap test.

[3]Urine screening should not preclude performing a pelvic examination because other visible STD lesions may be missed (HPV, herpes simplex virus [HSV], etc.)

[4]Depending on the sexual behaviors reported or suspected, oral and anal cultures may be indicated as well as cervical or urethral cultures.

[5]Positive test verified by confirmatory fluorescent treponemal antibody absorption test (FTA-Abs) or microhemagglutination-treponema pallidum (MHA-TP)

Contraception

Clinicians should counsel patients about contraceptive options. If necessary, patients should be referred to a family planning provider for contraceptive counseling.

Clinicians should recommend the simultaneous use of a condom and an additional method of contraception (dual method use) in the event of condom breakage or slippage.

When prescribing hormonal contraceptives, clinicians should consider, on a case-by-case basis, drug interactions between HIV-related medications and hormonal contraceptives, the patient's adherence patterns to medications, and the side effect profile of the hormonal contraceptives. Clinicians should also reinforce the importance of using condoms in addition to hormonal contraception.

Clinicians should counsel HIV-infected adolescents about the interactions between antiretroviral (ARV) medications and oral contraceptives, specifically lopinavir/ritonavir, nelfinavir, nevirapine, ritonavir, saquinavir, and tipranavir, because contraception protection may be reduced.

Clinicians should strongly recommend the use of contraception for HIV-infected adolescent females of childbearing age who are receiving efavirenz or combination pills containing efavirenz.

Key Point:

Correct and consistent use of routine contraception may be challenging for adolescents. A reliable contraceptive method that does not require daily use may be more successful in this population.

Reproductive Health Counseling

Clinicians should provide reproductive health counseling to HIV-infected female adolescents (see table below). As part of reproductive health counseling, clinicians should educate female adolescents about the importance of maintaining their own health should they wish to become pregnant in the future.

Clinicians should recommend prenatal vitamins and folic acid for adolescents who wish to become pregnant or who are not taking action to prevent pregnancy.

For adolescents considering pregnancy, likely to become pregnant, or not actively using a method of contraception, clinicians should discuss the following concerning ARV medications:

- Efavirenz (including combination pills containing efavirenz)
    - Efavirenz should be avoided because of teratogenicity concerns.
    - If there are no alternatives for efavirenz, clinicians should strongly advise the use of effective contraception and should obtain a pregnancy test before initiation.

    - For adolescents receiving efavirenz and expressing a desire to have children, efavirenz should be discontinued 2 months before stopping contraception.
- Hydroxyurea should be avoided.
- Liquid amprenavir and didanosine/stavudine in combination should be used with caution.

Key Point:

Clinicians providing HIV care to adolescents may be the only source of medical information for these patients. Female adolescents may not be as successful as older women in navigating the healthcare system to obtain reproductive health care and information.

Table **Elements of Reproductive Health Counseling for HIV-Infected Adolescent Females**	
General Concerns	• Effect of HIV on pregnancy • Effect of pregnancy on HIV • Future reproductive concerns and options
Contraception	• Routine contraception • Use of dual contraceptive methods • Emergency contraception • Effect of ARV drugs on oral contraceptive pills
ARV Medications	• Potential for maternal and fetal/neonatal toxicity • Effect on pregnancy outcome • Role in preventing perinatal transmission • Importance of adherence to the ARV regimen, especially for patients already receiving ARV medications
Routine Prenatal Care	• Vitamin and folic acid supplementation • Smoking cessation • Healthy nutrition
Perinatal HIV Transmission	• Risk of transmission and risk-prevention • Mode of delivery (cesarean vs vaginal) • Avoiding breastfeeding
Parenting Responsibilities	• Housing/food • Childcare • Medical care and pediatric care • Continuing education

Providing Care for Pregnant Adolescents

Clinicians should consider the likelihood of pregnancy when selecting specific highly active antiretroviral therapy (HAART) medications for HIV-infected

adolescents because some adolescents may not inform the clinician about a pregnancy for significant periods of time.

Clinicians should discuss options with patients who are making decisions about carrying pregnancy to term or terminating pregnancy. For adolescents who are not comfortable discussing pregnancy with their long-term provider, other trained professionals should be accessible.

Clinicians should educate pregnant adolescents who choose to carry pregnancy to term about the role of ARV therapy in optimizing maternal health and reducing the likelihood of perinatal transmission.

Clinicians should use the three-part zidovudine regimen for all HIV-infected pregnant adolescents, regardless of whether or not they are receiving HAART, unless a specific contraindication to zidovudine is known, such as a history of a severe adverse effect of zidovudine, severe anemia, or the need for an antagonistic medication such as stavudine.

The clinician should consult with an HIV Specialist to devise prenatal HAART regimens for perinatally infected adolescents.

Primary care clinicians should have referral agreements with obstetrical services that can provide care to HIV-infected females during pregnancy.

Clinicians should refer adolescent patients to supportive services available at prenatal clinics.

The adolescent's clinician should work in conjunction with the infant's pediatrician to provide the adolescent with access to training to improve parenting skills and other necessary services.

Key Point:

Although HIV-infected pregnant adolescents will be referred to obstetrical care services that can provide care to HIV-infected pregnant women, the clinician may want to remain the primary care provider for the adolescent during the pregnancy.

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 care for human immunodeficiency virus (HIV)-infected female adolescents

Subgroups Most Likely to Benefit

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

POTENTIAL HARMS

Adverse Effects of Medications

- Current data suggest that depot medroxyprogesterone acetate (Depo-Provera) can cause bone demineralization when used for prolonged periods. For this reason, the Food and Drug Administration recommends that providers limit the use of Depo-Provera to 2 continuous years followed by an interruption of its use.
- Liquid amprenavir and didanosine/stavudine in combination should be used with caution.

CONTRAINDICATIONS

CONTRAINDICATIONS

- Efavirenz is contraindicated during the first trimester of pregnancy because of teratogenicity concerns.
- Hydroxyurea should be avoided in human immunodeficiency virus (HIV)-infected female adolescents considering pregnancy or likely to become pregnant.
- Contraindications to zidovudine include a history of a severe adverse effect of zidovudine, severe anemia, or the need for an antagonistic medication such as stavudine.

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 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. Care for the HIV-infected female adolescent. New York (NY): New York State Department of Health; 2007 Mar. 12 p. [7 references]

ADAPTATION

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

DATE RELEASED

2007 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

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

This NGC summary was completed by ECRI Institute on Sept 5, 2007.

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