Complete Summary

GUIDELINE TITLE

Postexposure prophylaxis in children and adolescents for nonoccupational exposure to human immunodeficiency virus.

BIBLIOGRAPHIC SOURCE(S)

Havens PL. Postexposure prophylaxis in children and adolescents for nonoccupational exposure to human immunodeficiency virus. Pediatrics 2003 Jun;111(6 Pt 1):1475-89. [122 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

AAP Policies are reviewed every 3 years by the authoring body, at which time a recommendation is made that the policy be retired, revised, or reaffirmed without change. Until the Board of Directors approves a revision or reaffirmation, or retires a statement, the current policy remains in effect.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

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

- September 10, 2007, Viracept (nelfinavir mesylate): Pfizer issued a Dear Healthcare Professional Letter to inform healthcare professionals of the presence of ethyl methanesulfonate (EMS), a process-related impurity in Viracept and to provide guidance on the use of Viracept in pregnant women and pediatric patients.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Human immunodeficiency virus infection

GUIDELINE CATEGORY

Counseling
Prevention
Risk Assessment

CLINICAL SPECIALTY

Infectious Diseases
Pediatrics
Preventive Medicine

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To provide a review of the literature focused on issues of human immunodeficiency virus (HIV) exposure uniquely related to children and adolescents and give recommendations for postexposure prophylaxis (PEP) in the following situations: injury from discarded needles, bite wounds, and other percutaneous exposures; sexual exposure; and inadvertent exposure to human milk from an HIV-infected woman

TARGET POPULATION

Children and adolescents after nonoccupational exposure to human immunodeficiency virus

INTERVENTIONS AND PRACTICES CONSIDERED

1. Assessment of the risk of human immunodeficiency virus (HIV) transmission by evaluating the type and volume of source material, concentration and viability of virus in source material, and the timing and type of contact
2. Making a decision whether to recommend postexposure prophylaxis (PEP)
3. PEP with 2 or 3 antiretroviral medications, most commonly zidovudine plus lamivudine plus nelfinavir, or selecting other regimens from antiretrovirals such as zidovudine, didanosine, stavudine, lamivudine, ritonavir, indinavir

sulfate, nelfinavir mesylate, and lopinavir/ritonavir (refer to Table 10 in the original guideline document for dosage and administration information)
4. Follow-up by reviewing drug regimen, evaluating for symptoms of toxicity, assessing adherence, testing for hepatitis B and C as appropriate, preventing possible secondary transmission of HIV

MAJOR OUTCOMES CONSIDERED

Not stated

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not applicable

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

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not applicable

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

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not applicable

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

General Considerations Regarding Recommendations for Prophylaxis

In evaluating the need for postexposure prophylaxis (PEP), the following factors should be considered: the duration of time that has passed since the potential exposure, the likelihood of HIV infection in the exposure source, the risk of transmission given the source material and type of exposure, the effectiveness of therapy at modifying that risk, the toxicity of the therapy, and the burden of adherence to antiretroviral therapy.

PEP is only recommended for exposures to material from persons with HIV infection, although PEP may be considered for exposures to material from persons of unknown infection status. Therefore, efforts should be made to learn the infection status of the exposure source. If the HIV infection status of the exposure source is unknown, HIV testing should be requested of the person who is the source of the exposure, with consent as required by local laws or regulations. Although awaiting results of testing of the exposure source, PEP may be started for the potentially exposed person and stopped if the exposure source is found not to be infected with HIV.

According to US Public Health Service (USPHS) recommendations for PEP in the nonoccupational setting, PEP should not be used for persons with HIV exposures that have a low risk of HIV transmission (eg, potentially infected body fluid on intact skin) or for persons who seek care too late for the anticipated interruption of transmission (more than 72 hours after reported exposure). Clinicians considering use of PEP after a nonoccupational HIV exposure should recognize that benefits likely would be restricted to situations in which the risk of transmission is high, the intervention can be initiated promptly, and adherence to the regimen is likely. If PEP is used, physicians experienced in the management of children and adolescents with HIV infection should be consulted. Because PEP needs to be started within 72 hours of exposure, often the most feasible approach is to start PEP with a 3-day supply of medications and refer the patient to be evaluated by a consultant within 72 hours.

Recommendations for PEP in children and adolescents vary and include: 1) no PEP; 2) consider PEP; and 3) recommend PEP. Because of the absence of data documenting safety and efficacy of PEP, clinicians may make different, reasonable decisions in similar clinical circumstances. In individual cases of potential exposure, the perceived risks of HIV acquisition may be great enough to justify the burden and potential toxicity of PEP. The final decision to undertake PEP in a specific patient depends on the clinician's recommendation and the exposed person's and/or parent's evaluation of the risk of transmission versus the toxicity of therapy.

If an exposure is serious enough to warrant PEP, 2-drug or 3-drug therapy can be chosen, balancing the theoretically improved efficacy of 3 drugs with the potentially lower toxicity of 2-drug regimens. The USPHS identifies the strength of their recommendations for PEP in the occupational setting by the number of drugs in the regimen. The recommendations in this clinical report separate the decision to start PEP from the decision about the number of drugs to include in the regimen. The Centers for Disease Control and Prevention (CDC) guidelines suggest that determining which agents and how many agents to use is largely empiric. Complete recommendations from the CDC are available online (www.hivpepregistry.org/pdf/pedipep.pdf). American Academy of Pediatrics recommendations follow.

HIV antibody testing of the exposed person is recommended at baseline and at 6 weeks, 12 weeks, and 6 months after exposure. Such diagnostic testing will identify most persons who develop HIV infection after an exposure, although a small fraction of infected persons may not develop detectable antibody until more than 6 months after exposure. Delay in HIV seroconversion may be more common if hepatitis C virus transmission occurs at the same time as HIV transmission.

Recommendation for Prophylaxis After Nonoccupational Exposure to HIV in Children and Adolescents

The risk of human immunodeficiency virus (HIV) transmission after an exposure varies by the type and severity of exposure and by the likelihood that the source is infected with HIV. (For details on types and severity of exposure and characteristics of the exposure source and risk of HIV transmission refer to tables 1-5 in the original guideline document). Evaluation of both factors allows for estimation of the risk of HIV transmission after a potential exposure. For an exposure to a person known to be infected with HIV, the baseline risk of transmission will be modified by the viral load in the exposure fluid. For an exposure to a person of unknown HIV infection status, the baseline risk of HIV transmission will be modified by the probability that the exposure source is infected with HIV.

Once the risk of HIV transmission has been estimated, a decision whether to recommend postexposure prophylaxis (PEP) needs to be made. In the absence of specific data on efficacy of PEP outside of the health care setting, this decision is best made by experienced clinicians in collaboration with the exposed person and/or parents after a careful discussion of the risks of transmission and the burden and potential complications of antiretroviral therapy. The risk of transmission and potential benefits of PEP vary for different clinical situations, as outlined in Tables 6 through 8 of the original guideline document.

Although PEP may be considered in many circumstances, it is only recommended for high-risk exposures to persons known to be infected with HIV. No PEP is given if the exposure occurred more than 72 hours previously, if the exposed person refuses PEP, or if the exposed person is unwilling or unable to commit to 28 days of therapy and appropriate follow-up.

A careful discussion of the risks and benefits of therapy guides the decision-making regarding PEP and allows appropriate postexposure care (see table 9 in the original guideline document for the details on management of patients with possible exposure to HIV). If PEP is begun, it should be started as soon as possible after the exposure (within hours, and definitely within 72 hours), and therapy should be continued for 28 days. If consultation with a clinician experienced in the care of children and adolescents with HIV is not immediately possible, a supply of medications sufficient to last until consultation occurs could be dispensed to the patient.

Sexual Exposure

Sexual exposure can result in HIV infection, and sexual abuse has resulted in HIV transmission to children. Sexual abuse may be more likely to result in HIV transmission in girls than in women because of thin vaginal epithelium in children and cervical ectopy in adolescents and because children may be repeatedly abused by the same person over a long period. In proven cases of sexual assault by a person known or suspected to have HIV infection, PEP may be considered up to 72 hours after the exposure but is likely to be most effective if given sooner, preferably within a few hours after exposure. If the exposure source has genital ulcer disease or another sexually transmitted disease or if the exposure included tissue damage, the risk of HIV transmission is greater, increasing the potential benefit of PEP relative to the burden of therapy and risks of drug toxicity. Such modifying factors might strengthen the force of the recommendation in a given clinical setting.

For adolescents with a history of a single sexual exposure, PEP can be considered, and if given should be started as soon as possible after the exposure but certainly within 72 hours. Such exposure might occur from sexual abuse or by accidental exposure in a consensual relationship (eg, a broken condom). For persons with ongoing consensual sexual exposure to HIV, PEP is not indicated, and behavioral interventions to decrease repeated exposure probably are more appropriate.

Percutaneous Exposure

Risk of HIV transmission from a puncture wound from a needle found in the community is significantly lower than the 0.3% HIV transmission risk after needlestick injury in a health care professional from a person with HIV infection. Although it is unlikely that a true estimate of risk can be established, transmission will be related to:

- The probability that the person who used the needle has HIV infection
- The time interval since the needle was in contact with blood of the source
- The initial concentration of HIV on the needle, presence of blood or tissue that might delay drying (and, therefore, killing of the virus), or the presence of fresh blood or material that might contain viable virus

- The severity of the injury (skin contact without skin breakage, abrasion without bleeding, deeper skin penetration) in the exposed individual

In evaluating a puncture wound, the following factors are considered in assessing potential for HIV transmission (presented as lower risk category followed by higher risk category for each attribute): the depth of the wound (superficial scratch or deep puncture); the presence of blood on the needle (no visible blood or visible blood); the characteristics of the blood on the needle (dried or fresh); the type of needle (solid or hollow bore); and the location the needle was used in the source patient's body (not in artery or vein; or in artery or vein).

The risk of HIV transmission from a discarded needle in public places (often referred to as a "found" needle) seems to be low. Because data are not available on the efficacy of PEP in this circumstance for adults or children, the US Public Health Service (USPHS) is unable to recommend for or against PEP in this circumstance. Furthermore, PEP is not without risk and often is associated with significant adverse effects. Therefore, PEP is not routinely recommended in this situation. However, if the needle and/or syringe are found to have visible blood and the source is known to be HIV infected, some experts recommend that PEP be considered. Testing the syringe for HIV is not practical or reliable and is not recommended.

Bite wounds are another percutaneous body fluid exposure that may occur in children, but the risk of HIV transmission after exposure to saliva is very low. In the absence of blood in saliva and blood in the bite wound, PEP is not indicated. However, if there is blood exchange from a bite, both the person bitten and the person biting should be considered at risk of transmission of HIV and considered for PEP. Use in this setting would be extremely unusual and is potentially indicated only when there is significant exposure to deep, bloody wounds in persons with HIV infection.

Adolescents may be percutaneously exposed to potentially infectious fluids by needle sharing for injection drug use (including anabolic steroids) or for body piercing. The per-contact probabilities of HIV transmission indicated in table 3 of the original guideline apply in this setting, and for a single percutaneous exposure to blood of a person at risk for or known to have HIV infection, PEP can be considered. For adolescents with ongoing needle sharing and potential exposure to HIV, PEP is not routinely recommended, and behavioral interventions to decrease repeated exposures are more appropriate than is postexposure drug therapy after a single episode.

Human Milk Exposure

Because HIV can be transmitted via human milk, even a single exposure to human milk should be considered to confer a potential (albeit very low) risk of HIV transmission. Such exposure is possible in a hospital if stored, unpasteurized human milk is given to the wrong infant or if an infant is accidentally breastfed by a woman with HIV infection who is not the child's mother. Exposure also could occur if a mother developed HIV infection while breastfeeding or if a breastfeeding mother with established HIV infection was not tested for HIV in the prenatal period. However, in most areas of the United States, the prevalence of HIV infection in pregnant women is less than 2 per 1000. Most breastfeeding women

will have been tested for HIV during pregnancy, and women known to be HIV infected will have been counseled not to breastfeed. Therefore, the actual likelihood that exposure to HIV would occur by this route is extremely low.

For women with known HIV infection, the best approach to preventing transmission is to avoid breastfeeding. For a woman who continues to breastfeed, potent antiretroviral therapy for herself may decrease viral load and decrease risk of transmission, but prolonged therapy for the mother or the infant so exposed is of unknown benefit. For an infant with a single exposure to human milk from a woman with HIV infection, the magnitude of risk is estimated to be approximately 100 times lower than that for other mucous membrane exposure, and PEP is likely not warranted.

Choice of Antiretroviral Medication for PEP

No clinical studies are available to determine the best antiretroviral regimen for PEP. The most extensive data in terms of potential efficacy and safety are for zidovudine (ZDV) monotherapy. A clinician with experience in treatment of persons with HIV infection should be consulted before starting PEP.

Many clinicians would use the 3-drug combination of ZDV, lamivudine, and nelfinavir for PEP in children and adolescents (for dosage and administration of selected antiviral drugs refer to Table 10 of the original guideline document). If the efficacy of PEP is in aborting early mucosal, submucosal, subcutaneous, or lymphatic HIV infection, then potent suppressive therapies, such as 2 nucleozide analog reverse transcriptase inhibitors (NRTIs) plus a protease inhibitor (PI), should be chosen, because such regimens have been shown to be more likely to suppress HIV replication than have monotherapy or dual therapy.

Taking the multiple medications required for PEP is a daunting task, and problems with drug toxicity, patient adherence, and other factors severely limit the proportion of patients who finish PEP once they have started it. Completing 28 days of a 2-drug regimen is easier than completing a 3-drug regimen and may be associated with fewer medication adverse effects. Although the burden and toxicity of a 3-drug regimen may be warranted for treatment of persons with established HIV infection, the risk-benefit ratio for PEP may favor a 2-drug regimen for some patients. Therefore, some clinicians recommend 2-drug combinations of ZDV and lamivudine for PEP, hoping that the improved ease of use and potential decrease in toxicity will balance out the theoretic decrease in efficacy. It may be reasonable to consider a 2-drug regimen for treatment of some patients. The effectiveness of a drug regimen in practice will be related to the efficacy of the drugs and the probability of completion of the course of therapy. For information on major side effects of selected antiretroviral drugs refer to table 11 of the original guideline document.

ZDV and lamivudine are each available as syrups and are available together in a single tablet (Combivir [GlaxoSmithKline, London, United Kingdom]), enhancing ease of use for adolescents. If current and/or previous therapy used by the source patient is known and drug resistance is a concern, alternatives to the standard regimen might be considered in consultation with a specialist in HIV care in children and adolescents. Stavudine or didanosine are reasonable alternative NRTIs for use if resistance to ZDV or lamivudine is suspected. ZDV and stavudine

should never be used in combination with one another because of intracellular antagonism. Because of the potential for a severe hypersensitivity reaction, the NRTI abacavir sulfate should be avoided in PEP regimens.

Nelfinavir is available as a powder for children who are unable to take pills, although some children prefer the crushed tablets to the powder. Indinavir is only available in capsule form, is associated with crystalluria and nephrolithiasis, and requires extra hydration and for these reasons is usually avoided for PEP in children and adolescents. Other PIs available in a liquid formulation appropriate for children include ritonavir, lopinavir/ritonavir (Kaletra [Abbott Laboratories, North Chicago, IL]), and amprenavir. However, gastrointestinal intolerance may be a problem with ritonavir and lopinavir/ritonavir. The liquid formulation of amprenavir has high levels of vitamin E, contains propylene glycol in a concentration that exceeds World Health Organization standards for use in infants, and should not be used in children under 4 years; therefore, it is not recommended for routine use in PEP regimens. PIs have multiple potential interactions with other drugs, and the package insert should always be consulted before prescribing any of these medications.

Nevirapine is a non-NRTI that has been shown to decrease mother-to-child transmission in a single-dose intrapartum and infant regimen. The single-dose regimen has been shown to be safe for mothers and infants. However, severe life-threatening cases of hepatotoxicity, including liver failure and death, have been reported in patients receiving nevirapine as part of a PEP regimen or as treatment of HIV infection. Therefore, nevirapine should not be used as part of a PEP regimen in children.

All antiretroviral agents have potential adverse effects. It is critical to review the drug regimen, assess adherence, and evaluate the child for any symptoms of drug toxicity at all follow-up visits.

CLINICAL ALGORITHM(S)

An algorithm is provided in the original guideline document for postexposure prophylaxis in children and adolescents for nonoccupational exposure to human immunodeficiency virus.

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

Antiretroviral treatment of the human immunodeficiency virus (HIV)-infected individual may be associated with decreased risk of sexual and perinatal HIV transmission

POTENTIAL HARMS

Antiretroviral therapy used for postexposure prophylaxis (PEP) is associated with significant toxicity. Refer to Table 11 in the original guideline document for details on major toxicities of selected antiretroviral drugs.

CONTRAINDICATIONS

CONTRAINDICATIONS

- Postexposure prophylaxis (PEP) is not recommended if:
    - The exposure occurred more than 72 hours ago
    - The exposed person refuses PEP
    - The exposed person is unwilling or unable to commit to 28 days of therapy and appropriate follow-up
- ZDV and stavudine should never be used in combination with one another because of intracellular antagonism.
- Because of the potential for a severe hypersensitivity reaction, the nucleoside analog reverse transcriptase inhibitor (NRTI) abacavir sulfate should be avoided in PEP regimens.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.
- Because no studies have directly measured the effectiveness of postexposure prophylaxis (PEP) in decreasing the risk of HIV transmission in nonoccupational settings or after mucosal exposure, the potential benefit of PEP in modifying transmission risk is extrapolated from data regarding HIV pathogenesis in animals, from information about PEP for needlestick injuries in occupational settings, and from studies of vertical transmission of HIV.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The human immunodeficiency virus (HIV) infection status of the exposure source should be sought. If the source person is known but HIV status unknown, then HIV testing with appropriate counseling and consent should be requested.

Wounds should be washed completely with soap and water. Mucous membranes should be flushed with water or saline solution. Tetanus booster and other wound care should be provided as needed.

A discussion of risks and benefits of postexposure prophylaxis (PEP) with the family of an exposed toddler will differ from the discussion with a potentially exposed adolescent, whose family may be specifically excluded from knowledge of the whole event. Treating adolescents in this setting should follow state and local laws regarding confidentiality of medical care. Because of the need to begin prophylaxis as quickly as possible after an exposure, office or clinic staff should be instructed to act immediately on telephone calls concerning possible HIV exposure, and the clinician should not wait until the end of the clinic day to return a call. Such staff education might be incorporated into OSHA-mandated bloodborne pathogen training.

Emergency departments should have protocols concerning possible need for postexposure HIV prophylaxis, and a "starter kit" of 3 days of antiretroviral medicines should be available at all times to ensure immediate institution of PEP therapy. Careful follow-up is crucial to ensure that the rest of the medications can be obtained easily and that consultation with a specialist in pediatric and adolescent HIV care occurs, to monitor toxicity, and to provide support for medication adherence and psychologic stress.

IMPLEMENTATION TOOLS

Clinical Algorithm

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

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness
Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Havens PL. Postexposure prophylaxis in children and adolescents for nonoccupational exposure to human immunodeficiency virus. Pediatrics 2003 Jun;111(6 Pt 1):1475-89. [122 references] PubMed

ADAPTATION

Not applicable: Guideline was not adapted from another source.

DATE RELEASED

2003 Jun

GUIDELINE DEVELOPER(S)

American Academy of Pediatrics - Medical Specialty Society

SOURCE(S) OF FUNDING

American Academy of Pediatrics

GUIDELINE COMMITTEE

Committee on Pediatric AIDS

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

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GUIDELINE AVAILABILITY

Electronic copies: Available from the American Academy of Pediatrics (AAP) Policy Web site.

Print copies: Available from American Academy of Pediatrics, 141 Northwest Point Blvd., P.O. Box 927, Elk Grove Village, IL 60009-0927.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on December 11, 2003. The information was verified by the guideline developer on February 5, 2004. This summary was updated by ECRI Institute on October 2, 2007, following the U.S. Food and Drug Administration advisory on Viracept (nelfinavir mesylate).

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