Pre and Post Exposure Prophylaxis for HIV in Children, Adolescents and Adults.

Natella Rakhmanina, MD, PhD
Professor of Pediatrics

Learning Objectives

- To recognize the risks for HIV transmission and principles of post exposure prophylaxis - **PeP**
- To identify the principles of pre exposure prophylaxis of HIV- **PreP**
- To define the national, regional and institutional approach to the **PeP** and **PreP**

Post **E**xposure **P**rophylaxis - **PEP**

PEP considered for following exposures:

- Occupational (OPEP)
- Non-occupational (NPEP)

Examples of Occupational PEP in Pediatric Practice*

- **Outreach clinic calls** –resident was draining the abscess from the leg of a 4 years old boy and cut herself with the scalpel she used on the patient
- **HIV clinic –** breastfeeding nurse was giving a flu shot to a 17 years old girl and stuck herself when discarding the needle after the shot
- **Occupational Health calls -** nurse on the ward was trying to flush the GT of a 7 years old girl with perinatal HIV and CP, the fluid splashed back to her eyes

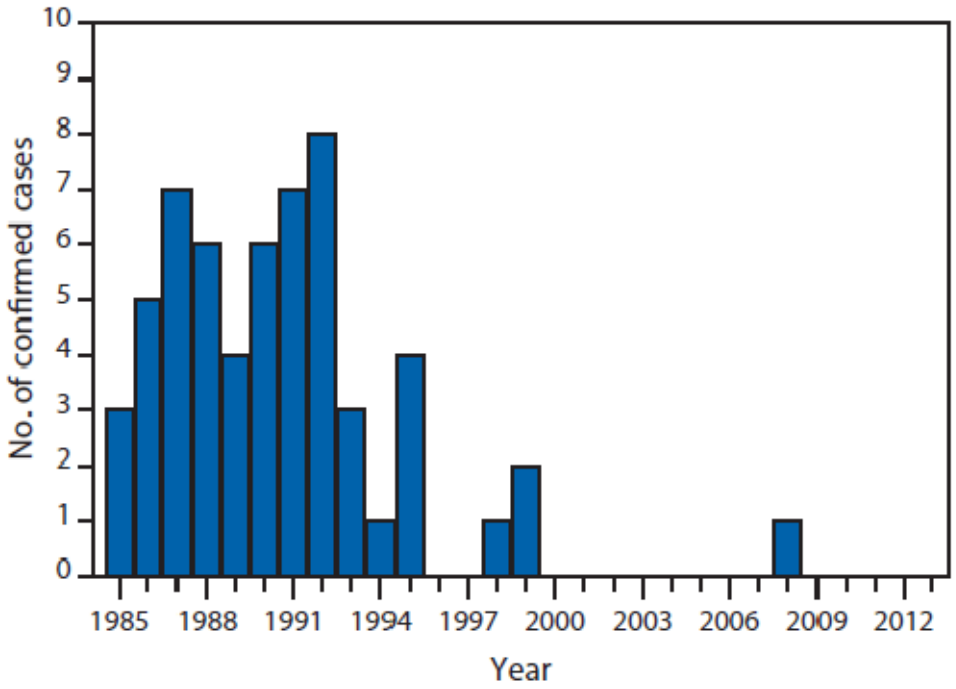
* All scenarios are adapted from real calls

Occupational HIV Exposure

- Percutaneous exposure to HIV-infected blood - 0.3% (95% confidence interval [CI], 0.2%–0.5%)
- Mucous membrane exposure - 0.09% (95% CI, 0.006%–0.5%)
- Non-intact skin exposure - < than 0.09% or blood exposures.

MMRW, January 9, 2015 / 63(53);1245-1246

Number of Confirmed Cases of Occupationally Acquired HIV, CDC, USA, 1985–2013



N=58
41.4% nurses
27.6 % lab techs, clinicians
10.3% physicians, non-surgical

MMRW, January 9, 2015, 63(53);1245-1246

Who can be Considered for Occupational Exposure

- Emergency medical service personnel, dental personnel, laboratory personnel, autopsy personnel, nurses, nursing assistants, physicians, technicians, therapists, pharmacists, students and trainees
- Contractual staff not employed by the healthcare facility, and persons not directly involved in patient care but potentially exposed to blood and body fluids (e.g. clerical, dietary, housekeeping, security, maintenance, and volunteer personnel)

INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY SEPTEMBER 2013, VOL. 34, NO. 9

US PUBLIC HEALTH SERVICE GUIDELINE

Updated US Public Health Service Guidelines for the Management of Occupational Exposures to Human Immunodeficiency Virus and Recommendations for Postexposure Prophylaxis

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Walid Heneine, PhD;[4] Vasavi Thomas, RPh, MPH;[4] Laura W. Cheever, MD, ScM;[5]
Ahmed Gomaa, MD, ScD, MSPH;[6] Adelisa L. Panlilio, MD;[1]
for the US Public Health Service Working Group

This report updates US Public Health Service recommendations for the management of healthcare personnel (HCP) who experience occupational exposure to blood and/or other body fluids that might contain human immunodeficiency virus (HIV). Although the principles of exposure management remain unchanged, recommended HIV postexposure prophylaxis (PEP) regimens and the duration of HIV follow-up testing for exposed personnel have been updated. This report emphasizes the importance of primary prevention strategies, the prompt reporting and management of occupational exposures, adherence to recommended HIV PEP regimens when indicated for an exposure, expert consultation in management of exposures, follow-up of exposed HCP to improve adherence to PEP, and careful monitoring for

Updated US Public Health Service Guidelines for the Management of Occupational Exposures to HIV

- PEP is recommended with occupational exposures
- HIV status of the exposure source patient should be determined, if possible, to guide PEP
- PEP ART should be started as soon as possible after occupational exposure to HIV and should continue for 4 weeks
- **New recommendation -** PEP regimens should contain ≥3 ARV drugs

Infect Control Hosp Epidemiol 2013;34(9):875-892

Why 3 Drugs and not Two?

- Superior effectiveness of 3 drugs in reducing viral burden in HIV-infected persons
- Concerns about source patient drug resistance to commonly used ARVs
- Better safety and tolerability of new ARVs
- Potential for improved PEP adherence due to fewer side effects

Updated US Public Health Service Guidelines for the Management of Occupational Exposures to HIV

Recommended PEP :

- Dual NRTI backbone plus an INSTI , a boosted PI or a NNRTI
- Other antiretroviral drug combinations may be indicated for specific cases (e.g., exposure to a source patient with drug resistant HIV)
- Expert consultation is recommended for any occupational exposures to HIV with known resistance and other complicated scenarios
- **National Clinicians' Post-Exposure Prophylaxis Hotline (PEPline) at 888-448-4911**

Infect Control Hosp Epidemiol 2013;34(9):875-892

Updated US Public Health Service Guidelines for the Management of Occupational Exposures to HIV

Recommended PEP regimens:

- **Dual NRTI backbone** – TDF+FTC (Truvada) or TDF+3TC or ZDV+3TC (Combivir) or ZDV+FTC **plus**
  - **INSTI** - RAL
  - **Boosted PI** - DRV/RTV or ATV/RTV or LPV/RTV
  - **NNRTI** - RPV, ETR
- **Stribild** – Elvitegravir/Cobicistat, TDF, FTC

Not Recommended for PEP:

- **NRTI** - ddI
- **PIs** – NFV, TPV

Contraindicated for PEP:

- **NNRTI** – NVP

Infect Control Hosp Epidemiol 2013;34(9):875-892

Updated US Public Health Service Guidelines for the Management of Occupational Exposures to HIV

Evaluation and follow up:

- Close follow-up with counseling and monitoring for drug toxicity **within 72 hours** of an HIV exposure
- HIV testing at baseline and at **6 weeks**, **12 weeks**, and **6 months after exposure**
- Complete blood counts and renal and hepatic function tests - **at baseline** and **2 weeks** after exposure (further testing if abnormalities)

Infect Control Hosp Epidemiol 2013;34(9):875-892

Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations

Published June 27, 2014

Prepared by

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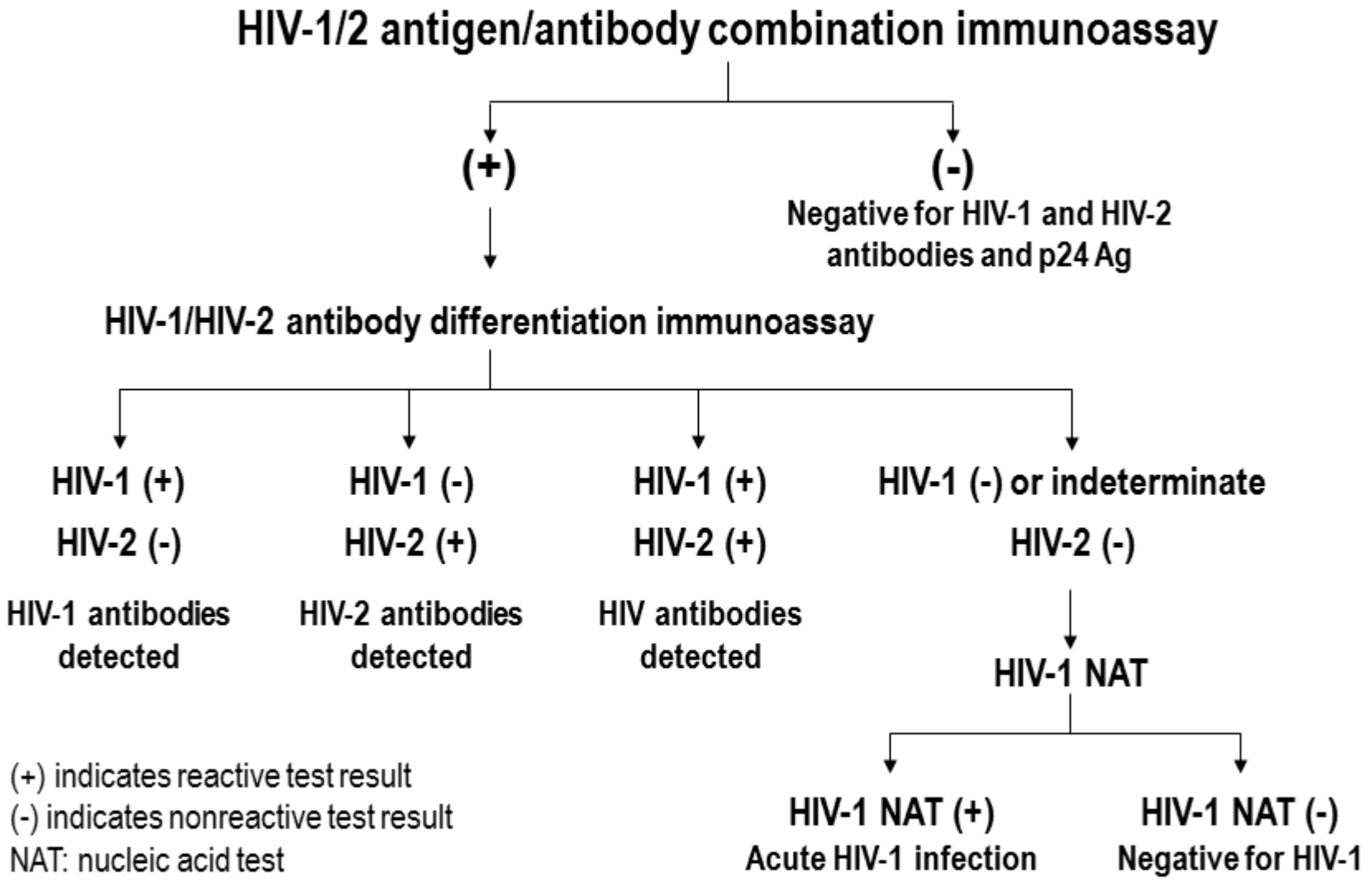

HIV-1/2 antigen/antibody combination immunoassay
(+)
(-)
Negative for HIV-1 and HIV-2 antibodies and p24 Ag
HIV-1/HIV-2 antibody differentiation immunoassay
HIV-1 (+)
HIV-2 (-)
HIV-1 antibodies detected
HIV-1 (-)
HIV-2 (+)
HIV-2 antibodies detected
HIV-1 (+)
HIV-2 (+)
HIV antibodies detected
HIV-1 (-) or indeterminate
HIV-2 (-)
HIV-1 NAT
HIV-1 NAT (+)
Acute HIV-1 infection
HIV-1 NAT (-)
Negative for HIV-1
(+) indicates reactive test result
(-) indicates nonreactive test result
NAT: nucleic acid test

Updated US Public Health Service Guidelines for the Management of Occupational Exposures to HIV

Evaluation and follow up:

- **New recommendation -** if a newer **fourth-generation** combination HIV p24 antigen–HIV antibody test is utilized for follow-up HIV testing of exposed HCP, HIV testing may be concluded **4 months after exposure**
- If a newer testing platform is not available, follow-up HIV testing is typically concluded 6 months after an HIV exposure

Infect Control Hosp Epidemiol 2013;34(9):875-892

Non-Occupational **PEP (NPEP)**

"Continental breakfast, Daily Telegraph and morning after pill."

Did it grab your attention?

Estimated Risks for HIV Transmission

Types of exposure	Estimated Risk
Needle-sharing exposure to an infected source	0.67% (1 in 150)
Receptive anal intercourse with an infected source	0.5% (1 in 200) / 3.0% (6 in 200)
Receptive vaginal intercourse with an infected source	0.1% (1 in 1000) / 0.2% (2 in 1000)
Insertive anal intercourse with an infected source	0.065% (1 in 1500)
Insertive vaginal intercourse with an infected source	0.05% (1 in 2000)
Oral sex with ejaculation with an infected source	Conflicting data-however, risk is considered to be low

New York State Department of Health AIDS Institute: HIV Prophylaxis following Non-Occupational Exposure. Albany, NY: Available at: *http://www.hivguidelines.org/wp-content/uploads/2013/09/hiv-prophylaxis-following-non-occupational-exposure.pdf.*

Examples of NPEP in Pediatric Practice

- **17 years old boy** is brought in by his mother for evaluation – he told her that he was at the private tattoo party yesterday and now has 2 new tattoos
- **18 years old girl** reports that she had sex with 3 boys last week and just heard that one of them is HIV positive
- **ED calls** – 6 years old boy was sexually abused by 14 years old relative at his home

* All scenarios are adapted from real calls

Examples of NPEP in Pediatric Practice

- **4 years old boy** was playing in the park and found a used condom which he tried to blow as a balloon, his 3 years old sister stuck herself with a needle from used syringe found in the same place
- **8 years old boy** is referred by his PMD because there are multiple syringes found at home form his visiting uncle who is using IV drugs daily, he might have been stuck as well
- **6 weeks old is admitted** with human bites all over this body by his mother who is HIV positive and has multiple drug resistances

* All scenarios are adapted from real calls

NPEP Guidelines

Clinical Review & Education

Special Communication

HIV Prevention in Clinical Care Settings
2014 Recommendations of the International Antiviral Society–USA Panel

Jeanne M. Marrazzo, MD, MPH; Carlos del Rio, MD; David R. Holtgrave, PhD; Myron S. Cohen, MD; Seth C. Kalichman, PhD; Kenneth H. Mayer, MD; Julio S. G. Montaner, MD; Darrell P. Wheeler, PhD, MPH; Robert M. Grant, MD, MPH; Beatriz Grinsztejn, MD, PhD; N. Kumarasamy, MD, PhD; Steven Shoptaw, PhD; Rochelle P. Walensky, MD, MPH; Francois Dabis, MD, PhD; Jeremy Sugarman, MD, MPH; Constance A. Benson, MD

IMPORTANCE Emerging data warrant the integration of biomedical and behavioral recommendations for human immunodeficiency virus (HIV) prevention in clinical care settings.

OBJECTIVE To provide current recommendations for the prevention of HIV infection in adults and adolescents for integration in clinical care settings.

DATA SOURCES, STUDY SELECTION, AND DATA SYNTHESIS Data published or presented as abstracts at scientific conferences (past 17 years) were systematically searched and reviewed by the International Antiviral (formerly AIDS) Society—USA HIV Prevention Recommendations Panel. Panel members supplied additional relevant publications, reviewed available

Editorial page 349

Supplemental content at jama.com

CME Quiz at jamanetworkcme.com and CME Questions page 430

JAMA. 2014;312(4):390-409.

NPEP Guidelines

EDITORIAL REVIEW

Practical guidance for nonoccupational postexposure prophylaxis to prevent HIV infection: an editorial review

Sachin Jain[a,b] and Kenneth H. Mayer[a,b]

Postexposure prophylaxis (PEP) with antiretroviral medication has been used as an HIV-prevention strategy for nearly 20 years. The fact that approximately 50 000 new HIV infections occur in the United States each year reflects marked underutilization of nonoccupational PEP (NPEP). There have been several advances in NPEP in the past 10 years. Clinical trials from different countries have demonstrated better tolerability, completion rates, and fewer drug–drug interactions with newer antiretroviral agents. Notably, there has been a shift from zidovudine-based to tenofovir-based regimens.

AIDS 2014, 28:1545–1554

NPEP Guidelines

Morbidity and Mortality Weekly Report

Recommendations and Reports | January 21, 2005 / Vol. 54 / No. RR-2

Antiretroviral Postexposure Prophylaxis After Sexual, Injection-Drug Use, or Other Nonoccupational Exposure to HIV in the United States

Recommendations from the U.S. Department of Health and Human Services

NPEP Sources

- Any possible exposure to HIV-infected blood, genital secretions, rectal secretions, breast milk or other bodily fluid visibly contaminated with blood
- Potential exposures:
  - unprotected sex
  - protected sex with condom failure
  - intravenous drug use
  - other mucosal or wound exposure
- Exposures involving the insertive oral partner and human bites do not require NPEP unless there are extenuating circumstances

NPEP Guidelines

- **TDF+FTC plus RAL** - preferred NPEP regimen based on a study*
- Theoretical advantage of blocking viral replication prior to integration within host DNA
- Few interactions with other medications compared to RTV-containing regimens

**J Acquir Immune Defic Syndr 2012; 59:354–359.*

Changes to OPEP and NPEP

	Medication Regimen	Duration
Preferred	**Truvada® (300 mg tenofovir + 200 mg emtricitabine) – one tablet once daily*** **PLUS** **Dolutegravir (Tivicay) 50 mg – one tablet once daily**	**4 weeks (28 days)**
Alternative	Truvada® (300 mg tenofovir + 200mg emtricitabine)- one tablet once daily* Plus Darunavir (Prezista®) 800 mg- One tablet once daily with food Plus Ritonavir (Norvir®)100mg – One capsule once daily with food NOTE: Alternative regimens may be used in certain circumstances based on recommendations from Adult PEP Consultant	
Adults with renal dysfunction (CrCl < 60 mL/min)	**Zidovudine dose adjusted to degree of renal function** **Lamivudine dose adjusted to degree of renal function** **PLUS** **Dolutegravir (Tivicay®) 50 mg – one tablet once daily**	**4 weeks (28 days)**
Adults with renal dysfunction (CrCl < 60 mL/min) **Alternative**	**Zidovudine dose adjusted to degree of renal function** **Lamivudine dose adjusted to degree of renal function** **PLUS** **Darunavir (Prezista®) 800 mg - 1 tablet once daily with food + Ritonavir (Norvir®) 100 mg - 1 capsule once daily with food**	**4 weeks (28 days)**

Boston Medical Center, Courtesy of Ellen Cooper

NPEP Guidelines

- NPEP should be discontinued if the source is deemed to be HIV uninfected
- If the source is HIV-infected and is on ART, obtain information about resistance profile and treatment history
- The source should also be tested for hepatitis B and hepatitis C if his or her status is unknown

NPEP Guidelines

- Empiric treatment for gonorrhea and chlamydia should be given for survivors of sexual assault
- Non-victims of sexual assault should be tested for gonorrhea, chlamydia, and syphilis, and treated if tested positive
- Emergency contraception can be offered to female victims of sexual assault within 72 h of the exposure if pregnancy test is negative

NPEP for Children and Adolescents

AMERICAN ACADEMY OF PEDIATRICS

CLINICAL REPORT
Guidance for the Clinician in Rendering Pediatric Care

Peter L. Havens, MD, and the Committee on Pediatric AIDS

Postexposure Prophylaxis in Children and Adolescents for Nonoccupational Exposure to Human Immunodeficiency Virus

ABSTRACT. Exposure to human immunodeficiency virus (HIV) can occur in a number of situations unique to, or more common among, children and adolescents. Guidelines for postexposure prophylaxis (PEP) for occupational and nonoccupational (eg, sexual, needle-sharing) exposures to HIV have been published by the US Public Health Service, but they do not directly address nonoccupational HIV exposures unique to children (such as accidental exposure to human milk from a woman infected with HIV or a puncture wound from a discarded needle on a playground), and they do not provide antiretroviral drug information relevant to PEP in children.

This clinical report reviews issues of potential exposure of children and adolescents to HIV and gives recommendations for PEP in those situations. The risk of HIV transmission from nonoccupational, nonperinatal exposure is generally low. Transmission risk is modified by factors related to the source and extent of exposure.

INTRODUCTION

Exposure to human immunodeficiency virus (HIV) can occur in a number of situations unique to or more common among children and adolescents. Guidelines for prophylaxis after exposure to HIV in occupational and nonoccupational (eg, sexual, needle-sharing) settings have been published by the US Public Health Service (USPHS),[1–3] but they do not directly address nonoccupational HIV exposures unique to children (such as accidental exposure to human milk from a woman infected with HIV or a puncture wound from a discarded needle on a playground), and they do not provide antiretroviral drug information relevant to postexposure prophylaxis (PEP) in children.

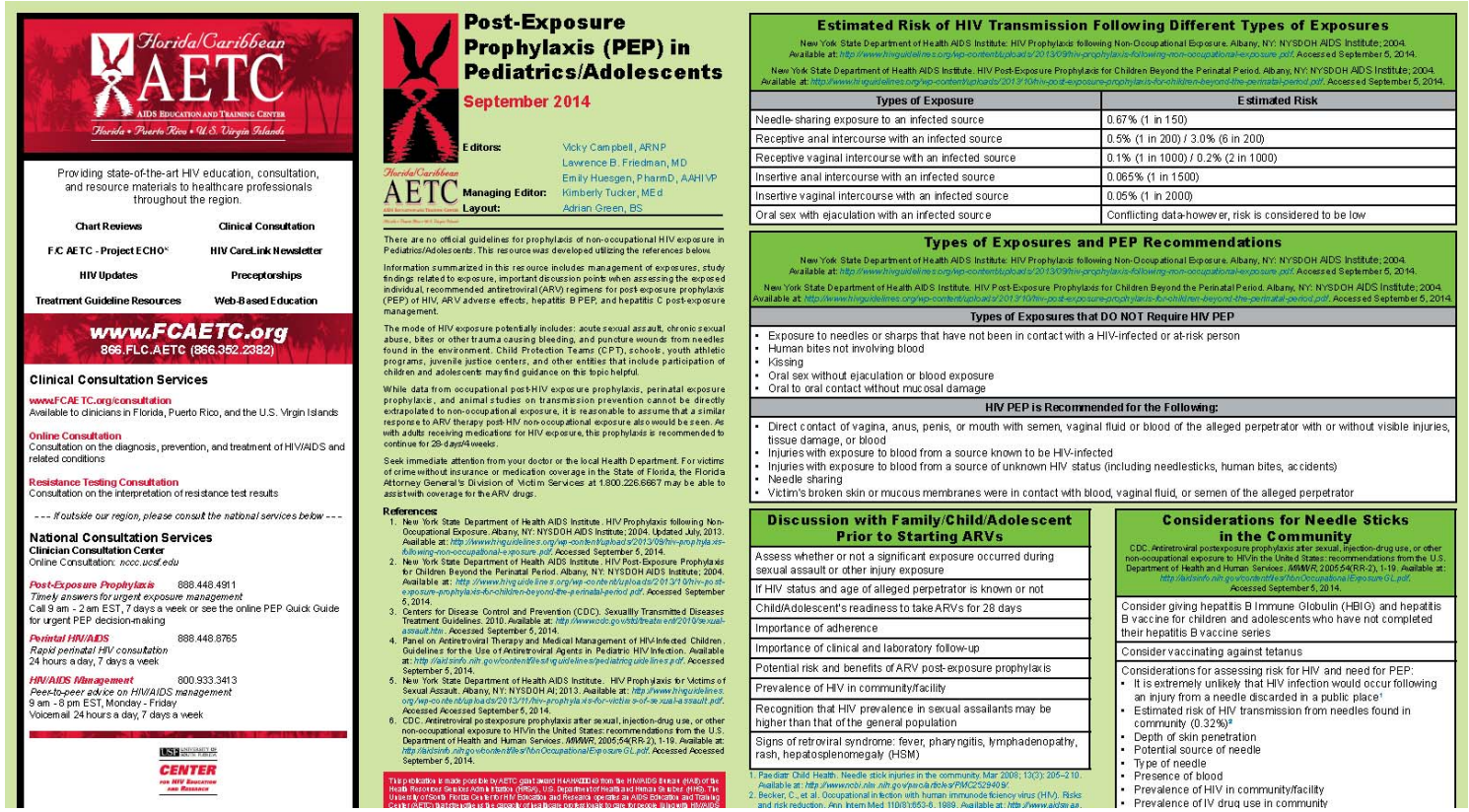
This clinical report provides a review of the liter-

Pediatrics 2003 Jun;111(6 Pt 1):1475-89

NPEP for Children and Adolescents

- Adult recommendations are frequently used for adolescents
- For children old fashioned choices such as **ZDV+3TC** plus **LPV/RTV** are mostly used, with **EFV** as alterative for children > 3 years of age
- Adherence is challenging due to adverse events and tolerability
- Poor follow up rates in several pediatric studies (most published <2010)

NPEP for Children and Adolescents



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Consultation on the interpretation of resistance test results

--- If outside our region, please consult the national services below ---

National Consultation Services
Clinician Consultation Center
Online Consultation: ncce.ucsf.edu

Post-Exposure Prophylaxis 888.448.4911
Timely answers for urgent exposure management
Call 9 am - 2 am EST, 7 days a week or see the online PEP Quick Guide for urgent PEP decision-making

Perinatal HIV/AIDS 888.448.8765
Rapid perinatal HIV consultation
24 hours a day, 7 days a week

HIV/AIDS Management 800.933.3413
Peer-to-peer advice on HIV/AIDS management
9 am - 8 pm EST, Monday - Friday
Voicemail 24 hours a day, 7 days a week

USF College of Public Health
CENTER for HIV Education and Research

Post-Exposure Prophylaxis (PEP) in Pediatrics/Adolescents

September 2014

Florida/Caribbean AETC

Editors: Vicky Campbell, ARNP; Lawrence B. Friedman, MD; Emily Huesgen, PharmD, AAHIVP
Managing Editor: Kimberly Tucker, MEd
Layout: Adrian Green, BS

There are no official guidelines for prophylaxis of non-occupational HIV exposure in Pediatrics/Adolescents. This resource was developed utilizing the references below.

Information summarized in this resource includes management of exposures, study findings related to exposure, important discussion points when assessing the exposed individual, recommended antiretroviral (ARV) regimens for post-exposure prophylaxis (PEP) of HIV, ARV adverse effects, hepatitis B PEP, and hepatitis C post-exposure management.

The mode of HIV exposure potentially includes: acute sexual assault, chronic sexual abuse, bites or other trauma causing bleeding, and puncture wounds from needles found in the environment. Child Protection Teams (CPT), schools, youth athletic programs, juvenile justice centers, and other entities that include participation of children and adolescents may find guidance on this topic helpful.

While data from occupational post-HIV exposure prophylaxis, perinatal exposure prophylaxis, and animal studies on transmission prevention cannot be directly extrapolated to non-occupational exposure, it is reasonable to assume that a similar response to ARV therapy post-HIV non-occupational exposure also would be seen. As with adults receiving medications for HIV exposure, this prophylaxis is recommended to continue for 28 days/4 weeks.

Seek immediate attention from your doctor or the local Health Department. For victims of crime without insurance or medication coverage in the State of Florida, the Florida Attorney General's Division of Victim Services at 1.800.226.6667 may be able to assist with coverage for the ARV drugs.

References

1. New York State Department of Health AIDS Institute. HIV Prophylaxis following Non-Occupational Exposure. Albany, NY: NYSDOH AIDS Institute; 2004. Updated July, 2013. Available at: http://www.hivguidelines.org/wp-content/uploads/2013/09/hiv-prophylaxis-following-non-occupational-exposure.pdf. Accessed September 5, 2014.
2. New York State Department of Health AIDS Institute. HIV Post-Exposure Prophylaxis for Children Beyond the Perinatal Period. Albany, NY: NYSDOH AIDS Institute; 2004. Available at: http://www.hivguidelines.org/wp-content/uploads/2013/10/hiv-post-exposure-prophylaxis-for-children-beyond-the-perinatal-period.pdf. Accessed September 5, 2014.
3. Centers for Disease Control and Prevention (CDC). Sexually Transmitted Diseases Treatment Guidelines, 2010. Available at: http://www.cdc.gov/std/treatment/2010/sexual-assault.htm. Accessed September 5, 2014.
4. Panel on Antiretroviral Therapy and Medical Management of HIV-Infected Children. Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection. Available at: http://aidsinfo.nih.gov/contentfiles/lvguidelines/pediatricguidelines.pdf. Accessed September 5, 2014.
5. New York State Department of Health AIDS Institute. HIV Prophylaxis for Victims of Sexual Assault. Albany, NY: NYSDOH AI; 2013. Available at: http://www.hivguidelines.org/wp-content/uploads/2013/11/hiv-prophylaxis-for-victim-s-of-sexual-assault.pdf. Accessed Accessed September 5, 2014.
6. CDC. Antiretroviral postexposure prophylaxis after sexual, injection-drug use, or other non-occupational exposure to HIV in the United States: recommendations from the U.S. Department of Health and Human Services. MMWR. 2005;54(RR-2), 1-19. Available at: http://aidsinfo.nih.gov/contentfiles/NonOccupationalExposureGL.pdf. Accessed Accessed September 5, 2014.

This publication is made possible by AETC grant award H4AHA00049 from the HIV/AIDS Bureau (HAB) of the Health Resources Service Administration (HRSA), U.S. Department of Health and Human Services (HHS). The University of South Florida Center for HIV Education and Research operates as AIDS Education and Training Center (AETC) Program Region IV. These contents do not necessarily represent the policy of HRSA, HHS, and you should not assume endorsement by the Federal Government.

Estimated Risk of HIV Transmission Following Different Types of Exposures

New York State Department of Health AIDS Institute. HIV Prophylaxis following Non-Occupational Exposure. Albany, NY: NYSDOH AIDS Institute; 2004. Available at: http://www.hivguidelines.org/wp-content/uploads/2013/09/hiv-prophylaxis-following-non-occupational-exposure.pdf. Accessed September 5, 2014.

New York State Department of Health AIDS Institute. HIV Post-Exposure Prophylaxis for Children Beyond the Perinatal Period. Albany, NY: NYSDOH AIDS Institute; 2004. Available at: http://www.hivguidelines.org/wp-content/uploads/2013/10/hiv-post-exposure-prophylaxis-for-children-beyond-the-perinatal-period.pdf. Accessed September 5, 2014.

Types of Exposure	Estimated Risk
Needle-sharing exposure to an infected source	0.67% (1 in 150)
Receptive anal intercourse with an infected source	0.5% (1 in 200) / 3.0% (6 in 200)
Receptive vaginal intercourse with an infected source	0.1% (1 in 1000) / 0.2% (2 in 1000)
Insertive anal intercourse with an infected source	0.065% (1 in 1500)
Insertive vaginal intercourse with an infected source	0.05% (1 in 2000)
Oral sex with ejaculation with an infected source	Conflicting data-however, risk is considered to be low

Types of Exposures and PEP Recommendations

New York State Department of Health AIDS Institute. HIV Prophylaxis following Non-Occupational Exposure. Albany, NY: NYSDOH AIDS Institute; 2004. Available at: http://www.hivguidelines.org/wp-content/uploads/2013/09/hiv-prophylaxis-following-non-occupational-exposure.pdf. Accessed September 5, 2014.

New York State Department of Health AIDS Institute. HIV Post-Exposure Prophylaxis for Children Beyond the Perinatal Period. Albany, NY: NYSDOH AIDS Institute; 2004. Available at: http://www.hivguidelines.org/wp-content/uploads/2013/10/hiv-post-exposure-prophylaxis-for-children-beyond-the-perinatal-period.pdf. Accessed September 5, 2014.

Types of Exposures that DO NOT Require HIV PEP

- Exposure to needles or sharps that have not been in contact with a HIV-infected or at-risk person
- Human bites not involving blood
- Kissing
- Oral sex without ejaculation or blood exposure
- Oral to oral contact without mucosal damage

HIV PEP is Recommended for the Following:

- Direct contact of vagina, anus, penis, or mouth with semen, vaginal fluid or blood of the alleged perpetrator with or without visible injuries, tissue damage, or blood
- Injuries with exposure to blood from a source known to be HIV-infected
- Injuries with exposure to blood from a source of unknown HIV status (including needlesticks, human bites, accidents)
- Needle sharing
- Victim's broken skin or mucous membranes were in contact with blood, vaginal fluid, or semen of the alleged perpetrator

Discussion with Family/Child/Adolescent Prior to Starting ARVs

- Assess whether or not a significant exposure occurred during sexual assault or other injury exposure
- If HIV status and age of alleged perpetrator is known or not
- Child/Adolescent's readiness to take ARVs for 28 days
- Importance of adherence
- Importance of clinical and laboratory follow-up
- Potential risk and benefits of ARV post-exposure prophylaxis
- Prevalence of HIV in community/facility
- Recognition that HIV prevalence in sexual assailants may be higher than that of the general population
- Signs of retroviral syndrome: fever, pharyngitis, lymphadenopathy, rash, hepatosplenomegaly (HSM)

Considerations for Needle Sticks in the Community

CDC. Antiretroviral postexposure prophylaxis after sexual, injection-drug use, or other non-occupational exposure to HIV in the United States: recommendations from the U.S. Department of Health and Human Services. MMWR. 2005;54(RR-2), 1-19. Available at: http://aidsinfo.nih.gov/contentfiles/NonOccupationalExposureGL.pdf. Accessed September 5, 2014.

- Consider giving hepatitis B Immune Globulin (HBIG) and hepatitis B vaccine for children and adolescents who have not completed their hepatitis B vaccine series
- Consider vaccinating against tetanus

Considerations for assessing risk for HIV and need for PEP:

- It is extremely unlikely that HIV infection would occur following an injury from a needle discarded in a public place[1]
- Estimated risk of HIV transmission from needles found in community (0.32%)[2]
- Depth of skin penetration
- Potential source of needle
- Type of needle
- Presence of blood
- Prevalence of HIV in community/facility
- Prevalence of IV drug use in community

1. Paediatr Child Health. Needle stick injuries in the community. Mar 2008; 13(3): 205–210. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2529409/.
2. Becker, C., et al. Occupational infection with human immunodeficiency virus (HIV). Risks and risk reduction. Ann Intern Med 110(8):653-6, 1989. Available at: http://www.ajdsyap...

Pre-Exposure **P**rophylaxis **(PreP)**

- Prevention of mother-to-child transmission (PMTCT)- gold standard
- Occupational - rare
- Non-occupational – on the rise

Ultimate PreP

PreP Quiz

The most effective PrEP is (select one correct answer):

a. Not to have sex
b. Not to have sex
c. Not to have sex
d. Not to have sex
e. All of the above

PreP for HIV-infected Persons

- Timely diagnosis of acute HIV infection and start of ART
- Support for adherence to ART
- Counseling on disclosure of HIV status and partner notification
- Regular assessment of sexual and substance use practices
- Individualized risk-reduction counseling
- Screening for sexually transmitted infection
- Condom provision

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 AUGUST 11, 2011 VOL. 365 NO. 6

Prevention of HIV-1 Infection with Early Antiretroviral Therapy

Myron S. Cohen, M.D., Ying Q. Chen, Ph.D., Marybeth McCauley, M.P.H., Theresa Gamble, Ph.D., Mina C. Hosseinipour, M.D., Nagalingeswaran Kumarasamy, M.B., B.S., James G. Hakim, M.D., Johnstone Kumwenda, F.R.C.P., Beatriz Grinsztejn, M.D., Jose H.S. Pilotto, M.D., Sheela V. Godbole, M.D., Sanjay Mehendale, M.D., Suwat Chariyalertsak, M.D., Breno R. Santos, M.D., Kenneth H. Mayer, M.D., Irving F. Hoffman, P.A., Susan H. Eshleman, M.D., Estelle Piwowar-Manning, M.T., Lei Wang, Ph.D., Joseph Makhema, F.R.C.P., Lisa A. Mills, M.D., Guy de Bruyn, M.B., B.Ch., Ian Sanne, M.B., B.Ch., Joseph Eron, M.D., Joel Gallant, M.D., Diane Havlir, M.D., Susan Swindells, M.B., B.S., Heather Ribaudo, Ph.D., Vanessa Elharrar, M.D., David Burns, M.D., Taha E. Taha, M.B., B.S., Karin Nielsen-Saines, M.D., David Celentano, Sc.D., Max Essex, D.V.M., and Thomas R. Fleming, Ph.D., for the HPTN 052 Study Team*

ABSTRACT

HPTN 052

- 9 countries, 54% of the subjects were from Africa
- 1763 couples (heterosexual and homosexual)in which one partner was HIV-1–positive and the other was HIV-1–negative
- 50% of infected partners were men
- HIV-1–infected subjects with CD4 counts 350- 550 cells/mm^3
- Randomly assigned in a 1:1 ratio to receive ART either immediately (early therapy) or after a decline in the CD4 count or the onset of HIV-1–related symptoms (delayed therapy)
- The primary prevention end point was linked HIV-1 transmission in HIV-1–negative partners

HPTN 052

- Total of 39 HIV-1 transmissions were observed (incidence rate, 1.2 per 100 person-years; 95% confidence interval [CI], 0.9 to 1.7)
- Of these, 28 were virologically linked to the infected partner (incidence rate, 0.9 per 100 person-years,95% CI, 0.6 to 1.3)
- Of the 28 linked transmissions, only 1 occurred in the early therapy group (hazard ratio, 0.04; 95% CI, 0.01 to 0.27; P<0.001)
- **Protective effect 96 (95% CI 73 to 99)!**

US Public Health Service

PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES - 2014

A CLINICAL PRACTICE GUIDELINE

PreP for HIV-negative Persons

- Daily oral PrEP with the fixed-dose combination of TDF 300 mg and FTC 200 mg (Truvada) has been shown to be safe and effective in reducing the risk of sexual HIV acquisition in adults
- Acute and chronic HIV infection must be excluded by symptom history and HIV testing immediately **before** PrEP is prescribed
- HIV infection should be assessed **at least every 3 months** while patients are using PrEP
- Renal function should be assessed **at baseline** and monitored at least **every 6 mon**ths while on PrEP

PreP for HIV-negative People

- Persons at high risk for HIV based on background incidence (>2%) or recent diagnosis of incident STI (syphilis, gonorrhea, or chlamydia)
- Individuals who have used NPEP > 2 times in the past year
- People who inject drugs and who share injection equipment, inject 1 or more times a day, or inject cocaine or methamphetamines
- PreP should be part of an integrated risk-reduction strategy
- Regular assessment of the patients' risk is required

PreP CDC Guidelines

PreP should be considered for:

- Sexually-active adult MSM (men who have sex with men) at substantial risk of HIV acquisition **(IA)**
- Adult heterosexually active men and women who are at substantial risk of HIV acquisition **(IA)**
- Adult injection drug users (IDU) at substantial risk of HIV acquisition **(IA)**
- Heterosexually-active women and men whose partners are known to have HIV infection (i.e., HIV-discordant couples) considering conception and pregnancy **(IIB)**

Pre exposure Prophylaxis for the Prevention of HIV Infection in the US, 2014 Clinical Practice Guideline

PreP for HIV-infected Drug Users

- Harm reduction services integrated with strategies to maintain adherence
- Assistance for patient- or clinician-based notification of sex and injection drug use partners to facilitate HIV testing
- Linkage to care of relevant partners and other key persons
- Needle exchange and other harm-reduction Interventions
- For people who Inject drugs medicalized heroin and medically assisted therapy (which includes opioid-substitution therapy)

PreP for Adolescents

- Currently the data on the efficacy and safety of PrEP for adolescents are insufficient

- The behavioral intervention as well as ongoing risk reduction counseling sessions have been found to be highly acceptable among a sample of racially diverse YMSM
  J HIV AIDS Soc Serv 2013;12(3-4)

PreP CDC Guidelines

- TDF alone has shown substantial efficacy and safety in trials with IDUs and heterosexually active adults and can be considered as an alternative regimen for these populations, but **not for MSM**, among whom its efficacy has not been studied. **(IC)**
- The use of other antiretroviral medications either in place of or in addition to TDF/FTC (or TDF) is **not recommended**. **(IIIA)**
- The prescription of oral PrEP for coitally-timed or other noncontinuous daily use is not recommended. **(IIIA)**

Pre exposure Prophylaxis for the Prevention of HIV Infection in the US 2014 Clinical Practice Guideline

Examples of PreP in Adolescents

- **18 years old perinatally infected MSM** with history of sustained non-adherence, profound immune suppression, high viremia, untreated perianal warts brings in partner of 2 years for PreP discussion
- **17 years old perintally infected woman** with excellent control of her disease and undetectable viremia, on oral contraceptives presents with her HIV-negative boyfriend to discuss if they can stop using condoms
- **19 years old perinatally infected man** with intermittent adherence and moderate degree of viremia tells you that his girlfriend and him want to have a baby

* All scenarios are adapted from real calls

Conclusions

- Thorough history and evaluation of risk factors are crucial
- Individualized approach is very important
- Pep and Prep both require close follow up and repeat testing and evaluations
- Recurrent PEP and PreP both needs to include counseling on risk reduction in all populations

PEP and PreP in real life…….