



# Post-exposure Prophylaxis (PEP)

## Introduction

### I. Definition of the Prevention Area

Antiretroviral post-exposure prophylaxis (PEP)--short-term antiretroviral therapy initiated soon after known or suspected exposure to HIV--aims to prevent the establishment of HIV infection in an exposed person.

PEP has become the standard of care to prevent acquisition of HIV infection after occupational exposure to blood or other bodily fluids of people infected with HIV. There is less of a consensus regarding the administration of PEP after nonoccupational exposure. While PEP is part of the package of post-sexual assault care in most countries, the use of nonoccupational PEP, outside of rape or isolated incidents of exposure, is more controversial--particularly when the HIV status of the source case is unknown. The World Health Organization (WHO) and the U.S. Department of Health and Human Services offer guidelines for nonoccupational PEP.

### II. Epidemiological Justification for the Prevention Area

Each day, new HIV infections occur among health care workers, sexual assault victims, and other individuals following known or suspected exposure to HIV in blood or genital secretions. PEP is generally considered appropriate for people with occasional high-risk exposure to HIV (such as health care workers exposed to bodily fluids of patients with HIV or people sexually assaulted by a person with documented HIV infection). It may also be appropriate following occasional accidental exposure in serodiscordant partnerships (such as when a condom breaks during sex). In other cases of possible exposure, PEP may not be warranted unless there is a strong likelihood that the source of the exposure is HIV-positive.

Evidence suggests that a simple, relatively nontoxic and effective antiretroviral PEP regimen could prevent some of these new HIV infections. Although the degree of protection offered by PEP cannot be established in placebo-controlled trials because of ethical issues, studies of people who had a known exposure to HIV and were administered PEP suggest that PEP is about 80 percent effective in preventing establishment of HIV infection. Data from macaque studies suggest that PEP is protective when administered as soon as possible after exposure and that the effect degrades over time. Thus, in order to be effective, PEP should ideally begin within 48 hours of exposure and at least within 72 hours, and PEP should continue for 28 days. Cases of seroconversion despite PEP have been documented after occupational and nonoccupational exposure to HIV.

### III. Core Programmatic Components

Successful implementation of occupational or nonoccupational PEP depends on the following: 1) identification (usually self-identification) of people at risk of exposure; 2) counseling PEP candidates on the implications of seroconversion and, if they are not infected with HIV, on risk reduction to lower the odds of recurrent exposure; 3) informed determination of the exposure risk on a case-by-case basis, including HIV testing of the source, if possible; 4) HIV testing of the PEP candidate before and after completion of PEP; 5) selection of an appropriate PEP regimen; 6) initiation of PEP within at least 72 hours of exposure; and 7) completion of a 28-day PEP course.

### IV. Current Status of Implementation Experience

WHO strongly advises national authorities to establish PEP guidelines, especially in countries with a high HIV prevalence. Studies of individuals who have undergone PEP regimens suggest which antiretroviral combinations may be most tolerable as PEP. Tenofovir and emtricitabine have attracted research attention as PEP agents because of their tolerability, once-

daily administration as a single pill, and high concentration in the female genital tract. Whether three-drug regimens hold an advantage over two-drug regimens remains uncertain, but U.S. health authorities recommend a three-drug regimen. As with any antiretroviral use, PEP poses some risk of resistance.

Despite the cost of PEP, it has been successfully implemented in low-income countries, such as Kenya (for occupational and nonoccupational exposures) and Malawi (for sexually exposed children). An analysis of four studies suggests that PEP could be cost-effective when following exposure to blood and/or body fluids known to contain HIV. PEP has been used in children and adolescents after sexual assault in both high- and low-income settings. Some work indicates higher toxicity rates and worse adherence in children and adolescents than in adults.

What we know

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Tenofovir DF Plus Lamivudine or Emtricitabine for Nonoccupational Postexposure Prophylaxis (NPEP) in a Boston Community Health Center

Mayer, K. H., Mimiaga, M. J., Cohen, D., et al. *Journal of Acquired Immune Deficiency Syndromes* (2008), Vol. 47 No. 4, pp. 494-9.

Completion rates for NPEP are known to be low (less than 50 percent). This may be due, in part, to adverse side effects associated with the use of ZDV either alone, or in combination with 3TC, the regimen recommended by the U.S. Public Health Service. This article describes the results of two trials conducted at the Fenway Community Health Center in Boston that examine Tenofovir DF (TDF) in combination with either 3TC or emtricitabine (FTC) for NPEP. The study looked at the side effects, adherence to treatment, and completion rates of men treated with one or the other TDF combinations (combined n = 112) and compared outcomes with 241 men who received NPEP regimens of ZDV in combination with one or two other drugs during an earlier period at the center. Results demonstrate that both TDF regimens produced milder side effects, better adherence, and high completion rates (73 percent for TDF/FTC and 88 percent for TDF/3TC) compared to ZDV regimens, where side effects were thought to have affected completion rates, which were significantly lower: 39 and 42 percent for ZDV/3TC and ZDV/3TC + third drug, respectively. Although the sample is small, the findings warrant reconsideration of recommended NPEP regimens by the U.S. Public Health Service.

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Tolerability of HIV Post-Exposure Prophylaxis With Tenofovir/Emtricitabine and Lopinavir/Ritonavir Tablet Formulation

Tosini, W., Muller, P., Prazuck, T., et al. *AIDS* (2010), Vol. 24 No. 15, pp. 2375-2380.

According to this study, the standard of care for post-exposure prophylaxis should be a combination of tenofovir/emtricitabine and the tablet formulation of lopinavir/ritonavir, as it is better tolerated, easier to use and has higher rates of continuation than other drug regimens. Once the participants who did not need post-exposure prophylaxis were excluded, more than four fifths continued with the treatment for 28 days. The authors suggest that completion rates could be higher if preventive measures were taken against common adverse events--diarrhea, weakness, nausea and headache, with women worse affected than men.

[View Abstract](#)

Prevention of Vaginal Simian Immunodeficiency Virus Transmission in Macaques by Postexposure Prophylaxis with Zidovudine, Lamivudine and Indinavir

Bourry, O., Brochard, P., Souquiere, S., et al. *AIDS* (2009), Vol. 23 No. 4, pp. 447-54.

The study shows that a triple-antiretroviral (ARV) regimen can protect macaque monkeys from vaginal exposure to the simian immunodeficiency virus (SIV), in some conditions. Three groups of six macaques (n = 18) were vaginally inoculated with SIV. A combination of three ARVs--zidovudine (ZDV), lamivudine (3TC), and indinavir (IDV)--were administered to the experimental groups. One group received ZDV and 3TC orally and the same two drugs were administered to the second group by subcutaneous injection. Both groups received the third drug (IDV) orally; however, the subcutaneous group received a higher dose (60 mg/kg) than the oral group (20 mg/kg). Animals in the control group received placebos and all six became infected. Four of six monkeys in the subcutaneous group were afforded medium-term (230 days) protection, as compared to just one animal in the oral group. The results indicate that administering ARVs to macaques by injection versus mouth was more effective in preventing transmission of SIV; however, the reasons why some animals in both groups were protected and some were not remain unclear.

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Non-occupational Postexposure Prophylaxis for HIV: A Systematic Review.

Bryant, J., Baxter, L., & Hird, S. *Health Technology Assessment* (2009), Vol. 13 No. 14, pp. 1-82.

This document reports on a comprehensive review of selected studies that examine clinical effectiveness and cost-effectiveness of post-exposure prophylaxis (PEP) for HIV. The cost-effectiveness chapter identified four assessments that were selected for inclusion because they detailed all monetary costs of PEP treatment and conducted sensitivity analyses on cost-effectiveness measures for a range of different assumptions (i.e., hypothetical PEP effectiveness rates; high and low transmission probabilities). None of the studies included actual clinical effectiveness as an outcome measure. Instead, they used rates derived from occupational PEP effectiveness studies that were found to be about 80 percent effective for a single ARV regimen (not standard protocol for nonoccupational exposure). Overall, the studies showed PEP programs to be most cost-effective in cases where exposure to HIV occurs among men who have unprotected sex (of all types) with men. Cost savings were less evident for injecting drug users and women who had unprotected vaginal sex, unless there was a very high probability (greater than 73 percent) that a male partner was infected. The authors caution that it would be difficult to generalize results based on these four studies done in the United States and France to other contexts where HIV incidence and cost structure are likely to be quite different.

[View Report: \(PDF, 493 KB\)](#)

The Structure and Outcomes of a HIV Postexposure Prophylaxis Program in a High HIV Prevalence Setup in Western Kenya

Siika, A. M., Nyandiko, W. M., Mwangi, A., et al. *Journal of Acquired Immune Deficiency Syndromes* (2009), Vol. 51 No. 1, pp. 47-53.

A program that provided PEP for HIV was first set up in Western Kenya (Eldoret) at the Moi Teaching and Referral Hospital in 2001. All patients who were referred for PEP during the first five years of the program (November 2001 through December 2006) were studied retrospectively using electronic medical records. The algorithm adopted for evaluating all referrals required a test for HIV status before initiating full treatment. Of the total number who originally referred (n = 446), 19 of the 91 occupational exposures (health workers) and 55 of the 355 nonoccupational exposures (82 percent were victims of sexual assault), refused testing. The PEP regimen adopted initially (in 37 percent of the sample) was a three-drug combination (stavudine/3TC/nevirapine) that may have contributed to a hepatitis-induced patient fatality. Risk of toxicity and hepatitis is known to be associated with nevirapine. In subsequent patients treated (63 percent), the

regimen used was ZDV/3TC/lopinavir-ritonavir. No differences in reported side effects or treatment completion rates were found between the two regimens. However, the completion rate for the nonoccupational cohort was less than half that (35 percent) of health workers (76 percent). The authors suggest that efforts to strengthen adherence and completion of PEP programs are necessary to improve outcomes.

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Determinants of High-risk Sexual Behavior during Post-Exposure Prophylaxis to Prevent HIV Infection

Golub, S. A., Rosenthal, L., Cohen, D. E., et al. *AIDS Behavior* (2008), Vol. 12 No. 6, pp. 852-9.

The Centers for Disease Control and Prevention (CDC) guidelines recommend providing behavioral counseling to decrease sexual risk behavior in conjunction with PEP. This study examined the sexual risk behaviors of 89 men who have sex with men (MSM) and receive PEP in Boston, Massachusetts, and specifically asked about their high-risk sexual behavior in the six months prior to PEP and during the 28-day PEP period. Nineteen men (21 percent) reported unprotected anal intercourse (UAI) during PEP; and ten of these men reported UAI with partners of positive or unknown HIV status (11 percent of the overall population). In multivariate analysis, those men with higher depression scores and histories of engagement with HIV service organizations (e.g., receiving services from an HIV-related agency, donating money to HIV-related causes, etc.) were more likely to report UAI with high-risk partners. The investigators postulated that patients engaged with HIV service organizations may be more likely to believe they are protected from HIV by PEP, and thus more willing to engage in risky sexual behavior. These results highlight the need for integration of behavioral counseling for MSM receiving PEP.

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Antiretroviral Drug Exposure in the Female Genital Tract: Implications for Oral Pre- and Post-exposure Prophylaxis

Dumond, J. B., Yeh, R. F., Patterson, K. B., et al. *AIDS* (2007), Vol. 21 No. 14, pp. 1899-907.

PEP for women is most likely to be effective when it is initiated early with a drug that quickly and effectively concentrates in the genital tract. This study examined the pharmacokinetics of oral ARV drugs in female genital secretions. Blood and cervicovaginal fluid samples were taken from 27 women on the day they started PEP, three weeks later, and then monthly for six months. All of the 11 ARV drugs examined in this study achieved detectable concentrations in genital secretions within four hours after the first dose. Of the nucleoside analogs, ZDV, TDF, 3TC, and FTC achieved higher steady-state levels in the genital tract than in the blood. The protease inhibitors studied, lopinavir and atazanavir, achieved only moderate to low concentrations in the genital secretions compared to levels in the blood; as did efavirenz, the only non-nucleoside agent studied. These findings support the use of 3TC, ZDV, TDF and FTC, nucleoside, and nucleotide reverse transcriptase inhibitors for PEP.

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Assessment of Adverse Events Associated with Antiretroviral Regimens for Post-exposure Prophylaxis for Occupational and Nonoccupational Exposures to Prevent Transmission of Human Immunodeficiency Virus

Luque, A., Hulse, S., Wang, D., et al. *Infection Control and Hospital Epidemiology* (2007), Vol. 28 No. 6, pp. 695-701.

The goal of this study was to assess adverse events associated with different antiretroviral therapy (ART) regimens for PEP with a particular focus on TDF-containing regimens. The investigators performed a retrospective chart review of 113 health care workers who received occupational PEP between 1999 and 2004, and 87 patients who received NPEP between

2002 and 2004. Nausea was reported by the majority of patients and health care workers who received ZDV-3TC-TDF (66 percent) or ZDV-3TC-IDV (54 percent), but less than half of those who received ZDV-3TC (29 percent) or ZDV-3TC-nelfinavir (NFV; 40 percent). Subjects who received ZDV-3TC-TDF were less likely to complete PEP than subjects who received treatment with ZDV-3TC-IDV or ZD-3TC. This study underscored the impact of adverse side effects on the completion of PEP in both occupational and nonoccupational settings.

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The Public Health Impact of Widespread Availability of Non-Occupational Post-Exposure Prophylaxis Against HIV

Poynten, I. M., Smith, D. E., Cooper, D. E., et al. *HIV Medicine* (2007), Vol. 8 No. 6, pp. 374-81.

The use of PEP is accepted and practiced widely in Australia, particularly among MSM. Only registered providers can prescribe ART, which allowed the authors of this study to identify and prospectively follow the cohort who received PEP from 1998 to 2004. Most of the 1,552 patients were male (95 percent), and the majority of sexual exposures were male-to-male (87 percent). PEP was initiated in 92 percent of patients within 72 hours. Of the 1,146 patients who returned for evaluation four weeks after starting PEP, 86 percent had completed the original or a modified regimen. Three subjects seroconverted within six months after PEP, all of whom had ongoing sexual risk behaviors in the time during and after PEP. Based on epidemiologic data, the investigators estimated that only between one and nine HIV infections were averted in the study population. This relatively small effect is attributed to the low likelihood of transmission in any one sexual encounter and the fact that many, or most, of the exposure sources were not actually infected with HIV.

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Seroconversion Following Non-Occupational Post-Exposure Prophylaxis against HIV

Roland, M. E., Neilands, T.B., Krone, M. R., et al. *Clinical Infectious Diseases* (2005), Vol. 41, pp. 1507-13.

In San Francisco, a feasibility study of PEP was conducted in which subjects were offered the drug treatment (either ZDV-3TC, stavudine-3TC, or stavudine-didanosine) and counseling sessions. Participants were part of a 52-week assessment on medication initiation, adherence, side effects, and seroconversion. Those who knew that their HIV-infected source partner had a detectable viral load on ART were also given NFV. Most of the subjects were male (95 percent), and the majority had had sexual exposure to HIV (96 percent). Seven seroconversions occurred in 702 subjects (1 percent) and these individuals started PEP significantly later than subjects who did not seroconvert (median 45.5 hours versus 32.5 hours). Three of the seroconverters started PEP more than 45 hours after exposure; and three reported missing several doses of medication. This study demonstrated that PEP is not 100 percent effective. To increase its chances of effectiveness, it must be started as quickly as possible and the importance of complete adherence must be emphasized to patients.

[View Article](#)

Introduction of HIV Post-exposure Prophylaxis for Sexually Abused Children in Malawi

Ellis, J. C., Ahmad, S., & Molyneux, E. M. *Archives of Disease in Childhood* (2005), Vol. 90 No. 12, pp. 1297-9.

This program was designed to improve the care of victims of child sexual abuse (CSA) in Malawi by routinely assessing eligibility for PEP, and to investigate the feasibility, safety, and efficacy of such treatment in a pediatric emergency department. Sixty-four children seen at Queen Elizabeth Central Hospital and Blantyre between January 2004 and December 2004 were assessed for eligibility for HIV PEP and followed prospectively for six months. Among these 64, all of whom presented a history of alleged CSA in the 12-month period, 17 were offered PEP. The remainder were not offered

PEP due to the absence of physical signs of abuse (sample size, n = 20), delay in presentation beyond 72 hours from assault (n = 11), repeated sexual abuse in the preceding six months (n = 15), and HIV infection found on initial testing (n = 1). No family refused an HIV test, and no ART-related side effects were reported. Of the 17 children who commenced PEP, 1 returned for a follow-up at one month, 7 returned at three months, and 2 of 15 returned at six months post-assault. None of those who returned for a follow-up seroconverted. The authors concluded that in a resource-poor setting with a high HIV prevalence, PEP following CSA is acceptable, safe, and feasible. The authors recommended that HIV PEP be incorporated into national guidelines in countries with a high community prevalence of HIV infection.

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Efficacy of Postexposure Prophylaxis after Intravaginal Exposure of Pig-Tailed Macaques to a Human-Derived Retrovirus (Human Immunodeficiency Virus Type 2)

Otten, R. A., Smith, D. K., Adams, D. R., et al. *Journal of Virology* (2000), Vol. 74 No. 20, pp. 9771-5.

This study investigates the critical window for initiating PEP using an animal model (macaque monkeys). The methodology was a departure from other animal studies in that vaginal exposure with a human HIV retrovirus (HIV 2), as opposed to SIV, was used. A control group (n = 4) was compared with three experimental groups (n = 4 each) that varied by treatment initiation times (12, 24, and 72 hours). The treatment regimens for the experimental groups were identical and employed a single ARV [(R)-9-(2-phosphonylmethoxypropyl) adenine (PMPA)] for 28 days. Three animals in the control group seroconverted (one, inexplicably, did not convert). All eight animals in the 12- and 24-hour treatment initiation groups were protected. The 72-hour group had mixed results: one animal converted, one died of a cause unrelated to treatment, and two remained healthy. The researchers suggest that initiating therapy sooner than the 72-hour window generally used as a cutoff in national guidelines is likely to improve the effectiveness of treatment. The authors consider the study results to represent "proof of concept" for PEP in humans.

[View Full Study](#)

Prevention of SIV Infection in Macaques by (R)-9-(2-phosphonylmethoxypropyl)adenine

Tsai, C. C., Follis, K. E., Sabo, A., et al. *Science* (1995), Vol. 270 No. 5239, pp. 1197-9.

There is an urgent need for identifying effective and well tolerated ARVs that can be used to prevent HIV infection post exposure. Drugs currently being used therapeutically, such as ZDV, often produce adverse side effects. A study that used an animal model (long tail macaques) to examine the efficacy and toxicity of a new drug showed that PMPA, a reverse transcriptase inhibitor, prevented SIV in 100 percent of the exposed animals (n = 15), regardless of whether they received pre- (48 hours prior to inoculation with SIV) or post-exposure treatment (4 hours and 24 hours after inoculation). In contrast, all animals in the control group developed SIV within a one- to three-week period. The dose given to animals in the pre-exposure group was lower (20 mg/day) than those treated post-exposure (30 mg/day). None of the animals in the treatment group were observed to have had adverse effects. The results suggest that PMPA is a promising candidate for use in PEP regimens, although the efficacy of the drug in combination with others that are used in treating humans must be conducted.

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Putting it into practice

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Nonoccupational HIV Post-exposure Prophylaxis: A 10-year Retrospective Analysis

Tissot, F., Erard, V., Dang, T., et al. *HIV Medicine* (2010), Vol. 11 No. 9, pp. 584-92.

This retrospective study, conducted in Switzerland, is the largest account of the precipitating circumstances, clinical procedures, and outcomes associated with NPEP of HIV. Of 1068 referrals for PEP, 910 eligible records were identified for the study: 734 reported sexual exposures and 179 reported nonsexual exposures, the latter were primarily users of illicit drugs who were sharing drug injecting equipment. The sample is unusual because the large majority of exposures were heterosexual (77 percent). Research reported in the literature focuses on MSM or assault victims. Following established Swiss national guidelines, if the HIV status of the source person or object is unknown or uncertain, an attempt to find the source and determine and confirm status is made. In 72 percent of the cases, the source was not known. However, 298 sources (42 percent) were found and 178 tested negative, thereby reducing the number of unnecessary PEP treatments in 31 percent of the group (n = 283). An additional 11 individuals from high-risk groups were found to be living with HIV. Of the 710 people who initiated PEP, 423 completed treatment, 108 discontinued when the source was determined to be HIV-negative, 39 dropped out because they could not tolerate the drug regimen, and a high number of 117 people (16 percent) were lost to follow-up. The researchers conclude that tracking and testing the source for the exposure is not only good clinical practice, but also cost-effective.

[View Abstract](#)

Postexposure Prophylaxis for HIV Infection

Landovitz, R. J., & Currier, J. S. *New England Journal of Medicine* (2009), Vol. 361, pp. 1768-75.

Although evidence of the efficacy of PEP for HIV has not been established in clinical trials due to cost and ethical issues, guidelines have emerged from a host of smaller studies that provide reliable parameters for when exposure indicates treatment for different exposure types (occupational and nonoccupational) and cases that have the highest risk for transmission. Elapsed time from exposure to treatment (no more than 48 hours), the duration of treatment (4 weeks), risks and benefits associated with different drug combinations, and requisite adherence to regimens are considered in turn. Useful tables on two- and three-drug combinations and laboratory tests recommended for persons exposed and treated are also included. The authors conclude that although PEP is considered to be effective when certain conditions are met, ultimately, it is the degree of risk aversion on the part of the doctor and the patient that will dictate whether PEP is initiated and completed.

[View Full Study \(PDF, 217 KB\)](#)

Occupational and Nonoccupational Postexposure Prophylaxis for HIV in 2009

Landovitz, R. J. *Topics in HIV Medicine* (2009), Vol. 7 No. 3, pp. 104-8.

This article reviews treatment protocols and new studies on combination drug regimens for HIV PEP. Guidance on elapsed times from exposure to initiation of treatment in nonoccupational cases, a critical variable in success, ranges from 36 (U.S. state of New York) to 72 hours (CDC, WHO, and others). The rationale for the differences is discussed. The author also includes useful tables with doses and common side effects of the most commonly used two-drug regimen (e.g., 3TC/ZDV) and more recent ones (TDF/FTC) as compared to triple combinations (e.g., 3TC/ZDV plus IDV or NFV). Two-drugs are better tolerated, although three-drugs are indicated when significant ARV drug resistance or high-risk exposure has been identified. Patients referred for PEP must be assessed for transmission risk (minimal to moderate). A collateral benefit of providing PEP to patients is that, in the author's view, it can be used as a valuable educational moment, an opportunity to discuss behavioral risks and suggest referrals for additional screening and counseling.

[View Full Study \(PDF, 216KB\)](#)

## Post-exposure Prophylaxis (PEP) to Prevent HIV Infection: Guidelines on the Use of Treatment Starter Kits

United Nations Organization. (n.d.).

This document provides explicit procedures that are to be adopted in any type of PEP for HIV experienced by U.N. personnel or family members who work and live in regions where medical treatment may not be immediately available. Starter kits with five days worth of a three-drug combination ARV for PEP, in addition to emergency contraception for possible pregnancy, are made available to team leaders. Rationale for the steps to be followed and information for local doctors or medical staff who may be unfamiliar with PEP are also given.

[View Report \(PDF, 96 KB\)](#)

Engendering Health Sector Responses to Sexual Violence and HIV in Kenya: Results of a Qualitative Study

Kilonzo, N., Taegtmeier, M., Molyneux, C., et al. *AIDS Care* (2008), Vol. 20 No. 2, pp. 188-90.

Societal norms underlie sexual violence perpetrated on women, but these attitudes are poorly understood and rarely discussed in African countries. To inform HIV prevention programs being set up for victims of sexual abuse in three districts in Kenya, researchers conducted 16 focus groups and 34 key informant interviews with adult and adolescent men and women, counselors, members of the police, religious organizations, and legal advocates. Results reveal that what people think constitutes consensual and coerced sex, both within and outside marriage, is ambiguous. Both men and women said that women and girls who say "no" to sex do not necessarily mean it. Counselors and police said they felt unprepared to discuss rape and provide adequate support to victims of sexual violence. In addition, there was very little awareness of the availability of PEP, what it entailed, and its value in preventing HIV. The researchers recommend that community outreach about PEP and gender training for health sector staff and others who interact with rape victims should be integral components of prevention and treatment programs.

[View Abstract](#)

Delivering Post-rape Care Services: Kenya's Experience in Developing Integrated Services

Kilonzo, N., Theobald, S. J., Nyamato E., et al. *Bulletin of the World Health Organization* (2009), Vol. 87 No. 7, pp. 555-9.

Offering integrated services for rape victims that include PEP is difficult everywhere in the world but presents significant challenges in resource-limited settings. This article describes the process used in three districts in Kenya to initiate a comprehensive sexual assault and PEP program. Based on two waves of formative research, the district health management teams, in collaboration with a Kenyan nongovernmental organization, trained personnel in hospital or clinic emergency units. The teams developed, and providers successfully used, an algorithm that detailed triage and standards of care for a full range of services for victims (clinical exam, PEP eligibility and treatment, test for HIV status, trauma counseling, emergency contraception, treatment of sexually transmitted infection, legal support, and post-treatment testing). The program provided PEP to 84 percent of the 784 rape victims referred for treatment in the three districts between 2003 and 2007. The estimated per patient cost for services (PEP, labs, and staff) was \$27. The authors believe that the model can be replicated in other resource-poor locales, and provide recommendations and lessons learned based on their experience.

[View Full Study](#)

Post-exposure Prophylaxis for HIV Infection After Sexual Assault: When is It Indicated?

Fong, C. *Emergency Medicine Journal* (2001), Vol. 18, pp. 242-5.

Determining whether to offer emergency PEP to victims of sexual violence requires doctors to rapidly assess multiple factors. The effectiveness of NPEP is not known because clinical trials have not been conducted; therefore, decisions to offer PEP treatment must be made by judging the evidence for each case individually. The author presents a three-step decision tree for assessing who should receive PEP. The three factors are the following: 1) the actual or likely HIV status of the perpetrator (if known or determinable); 2) the probable risk that the assault would lead to HIV; and 3) considerations that affect treatment effectiveness (e.g., time elapsed since the attack, trauma, likelihood of completing treatment, special needs groups such as pregnant women and children). Despite the issues outlined, the author concludes that even when the risk of transmission is small, offering victims of assault PEP may well be justifiable.

[View Abstract](#)

HIV PEP Guidelines After Sexual Assault

Harborview Medical Center. (2007).

These guidelines for PEP, revised in April 2010, describe three levels of risk for HIV based on the type of perpetrator (e.g., HIV-positive, MSM), extent of injury and/or type of assault (e.g., vaginal, rectal, oral), and elapsed time since the event. Considered together, the three indicators are used to determine likelihood of transmission and the type of PEP treatment (none, basic, or expanded) that would be recommended. Useful case management guidance and additional guidance on determining PEP eligibility is also given in the appendix, which details five case examples of sexual assault and risk.

[View Report \(PDF, 80 KB\)](#)

Tools and Curricula

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Post-exposure Prophylaxis to Prevent HIV Infection: Joint WHO/ILO Guidelines on Post-exposure Prophylaxis (PEP) to Prevent HIV Infection.

World Health Organization (WHO), & International Labor Organization (ILO). (2007).

These are joint WHO and ILO guidelines on PEP to prevent HIV infection. They aim to provide a unified framework to guide both PEP policy development and the implementation of services for occupational and nonoccupational HIV exposures, with a focus on occupational exposure and exposure through sexual assault. This document does not provide detailed guidance relating to exposure through injecting drug use or through consensual sex.

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Management of Non-Occupational Post Exposure Prophylaxis to HIV (NONOPEP): Sexual, Injecting Drug User or Other Exposures.

European Project on Non-Occupational Post Exposure Prophylaxis (EURO-NONOPEP). (n.d.).

EURO-NONOPEP is a collaboration of 14 European countries. The goals of the collaboration are to collect and describe the PEP guidelines of all participants to evaluate PEP-related knowledge among patients and providers, and to maintain a registry of nonoccupational HIV exposures.

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Antiretroviral Post-exposure 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.

CDC. *MMWR* (2005), Vol. 54, pp. 1-20.

The CDC recommends prompt initiation of PEP with highly active ART (HAART) for persons who seek care within 72 hours after a nonoccupational exposure to infectious body fluids of a person with known HIV infection, if the exposure event presents a substantial risk for transmission. HAART should be continued for 28 days. Exposures are defined as "any direct mucosal, percutaneous, or intravenous contact with potentially infectious body fluids that occurs outside perinatal or occupational situations. Potentially infectious body fluids are blood, semen, vaginal secretions, rectal secretions, breast milk, or another body fluid that is contaminated with visible blood." When the HIV status of the source is not known and the patient seeks care within 72 hours after exposure, the CDC does not recommend for or against PEP but encourages clinicians and patients to weigh the risks and benefits on a case-by-case basis. When the transmission risk is negligible or when patients seek care more than 72 hours after a substantial exposure, PEP is not recommended. However, clinicians might consider prescribing PEP for patients who seek care more than 72 hours after a substantial exposure if, in their judgment, the diminished potential benefit of PEP outweighs the potential risk for adverse events from ARV medications.

[View Full Study \(PDF, 353KB\)](#)

Post Exposure Prophylaxis Guidelines for Occupational Exposure

National AIDS Control Organisation (NACO)-India. (n.d.).

This document gives NACO's clear and concise guidelines for preventing and responding to occupational injuries that expose hospital workers and others to HIV. Separate flow charts detailing the differential levels of risk associated with types of injuries and the HIV status of the exposure source were developed to evaluate whether PEP would be recommended, and if so, the type of regimen that is most appropriate.

[View Report \(PDF, 100 KB\)](#)

Offering HIV Post-Exposure Prophylaxis (PEP) Following Non-Occupational Exposures: Recommendations for Health Care Providers in the State of California

California Task Force on Non-Occupational PEP & California Department of Health Services. (2004).

This document offers a comprehensive discussion of the critical issues that medical providers must consider before offering PEP for HIV in cases of nonoccupational exposure. Areas covered include the elapsed time from the event to referral, type of exposure and its associated risk (e.g., receptive/insertive anal or vaginal intercourse; shared needle), and the actual or likely HIV status of the source person or instrument. A summary of key studies on these issues and research on drug regimens used in different circumstances provides good background information for providers. Also useful are the patient information sheets on frequently asked questions, patient information forms, and provider scripts on topics that should be discussed with patients, which are provided in appendices.

[View Report \(PDF, 359 KB\)](#)

HIV PEP: Now There is a Treatment that May Prevent HIV Infection After the Virus has Entered the Body

Terrence Higgins Trust. (2004).

This colorful five-page booklet is intended to raise awareness among MSM about the availability of emergency PEP for HIV. Using a question and answer format ("We had unsafe sex . . . the condom broke. . . is it worth asking for PEP?"), and written in plain, nontechnical language, the pamphlet describes the who, what, where, and when of PEP--namely,

eligibility, factors affecting success, how and where treatment is administered, and possible side effects.

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PEP Online Self-Assessment

Terrence Higgins Trust. (2004).

This website offers a brief online questionnaire that assesses eligibility for PEP. A series of questions establish when the exposure occurred and the actual or likely HIV status of the partner and recommends whether PEP is indicated or not. The site also offers links to a sexual assault hotline, how to find PEP administration centers, and easily accessible information about PEP that can be downloaded.

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Development of Guidelines on Nonoccupational HIV Postexposure Prophylaxis for the State of Rhode Island

Merchant, R. C., Mayer, K. H., & Browning, C. A. Public Health Reports (2004), Vol. 119, pp. 136-40.

This article describes the history of the U.S. state of Rhode Island's developing PEP guidelines. Rhode Island was the first state to establish such guidelines, which were disseminated in 2002. The key elements of the guidelines (context, timing, consent and testing, and recommended regimens) are summarized. However, the information in the guidelines is not as clear, nor as comprehensive, as guidelines that were published subsequently by the U.S. Government or by international organizations. Also, the drug regimens do not take into account recent research on adverse side effects associated with some multidrug regimens.

[View Report \(PDF, 58 KB\)](#)

Learn more

**Antiretroviral Agents Used by HIV-Uninfected Persons for Prevention: Pre- and Postexposure Prophylaxis**

Grant, R. M. Clinical Infectious Diseases (2010), Vol. 50 Suppl. 3, pp. S96-101.

The author reviews the range of biomedical prevention therapies from prevention of mother-to-child transmission to pre-exposure prophylaxis (PrEP) and PEP. The author also discusses issues that challenge research on new prophylactic approaches and individual and societal barriers that affect provision and use. PEP is not commonly offered where resources are scarce because questions about treatment efficacy and regimen safety prevail. The author also considers issues that have been raised with respect to PrEP (a daily oral dose of a single ARV or in combination) and microbial (ARV in gel form) prevention approaches for high-risk populations. A concern raised is that prevention options like these confer safety from HIV and may lead individuals to believe that they can engage in risky sexual behavior. Clinical trials currently underway will provide answers to some of these concerns and will help inform decisions by implementers and policymakers in determining what programs are offered in resource-poor locales. The author cautions that community acceptance and support for biomedical approaches like these are critical to adherence and successful outcomes.

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**Narrative Review: Antiretroviral Therapy to Prevent the Sexual Transmission of HIV-1**

Cohen, M. S., Gay, C., Kashuba, A. D. M., et al. Annals of Internal Medicine (2007), Vol. 146 No. 8, pp. 591-601.

This summary focuses on the findings of prevention studies for PrEP and PEP within the larger literature review covered by the article. The rationale for PEP is based on a series of studies conducted with rhesus and macaque monkeys that provide the critical parameters of treatment--namely, beginning ARVs not later than 72 hours after exposure and continuing with the regimen for 28 days. The limitations of animal studies for PEP reflect shortcomings of studies conducted with humans. Rigorous trials have not been carried out because they require very large samples and are prohibitively expensive or face ethical dilemmas. Therefore, studies use small samples and do not address long-term patient outcomes. In fact, only one study with humans has proven that PEP is effective in preventing HIV. This was a retrospective case control study of medical accidents with sharps (n = 679). An 81 percent reduction in risk was registered when ZDV (or another ARV drug) was administered to workers who were exposed. Protocols and guidelines used worldwide are based on this research and the series of animal studies. The authors discuss a number of potentially harmful consequences if widespread use of ART for prevention is adopted, including increased high risk behaviors on the part of people who believe themselves to be safe, emergence of drug resistance strains, and provision of ARVs to those with low probability for HIV transmission.

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### **National HIV/AIDS Clinicians' Consultation Center**

University of California, San Francisco. (2010).

This U.S.-based center hosts a PEP hotline for providers seeking clinical guidance related to the treatment occupational exposure to HIV.

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URL: print 'http://'.\$\_SERVER['HTTP\_HOST'].str\_replace('/printpdf/', '/', str\_replace('/print/', '/', \$\_SERVER['REQUEST\_URI'])); ?>