

NON-OCCUPATIONAL POST EXPOSURE PREVENTION

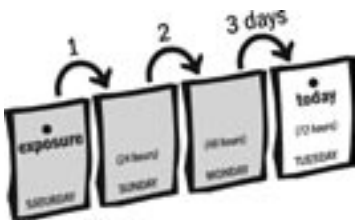
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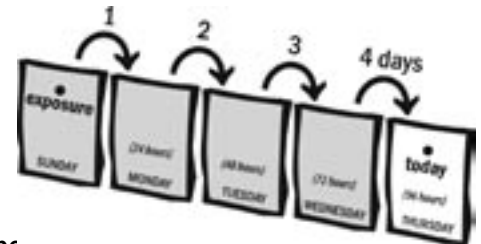
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when you think you were exposed to
hiv within the past three days



If you are reading this because you've had a possible exposure to HIV within the last 72 hours and you are considering nPEP, call your doctor, an nPEP study site or other resources (like a hospital emergency room), immediately. Take this paper to your doctor and use the insert, *Talking to Your Doctor*, to help you both in making decisions.

If it has already been longer than 72 hours since your exposure, nPEP is not a viable option for you. If you have waited longer than 72 hours before starting nPEP, there's little chance that the treatments will be able to block the establishment of HIV infection. In this case, seek out information about your HIV screening options (read Project Inform's publication, *Ways to Test for HIV*) and seek HIV prevention and risk reduction counseling. Even if you have had a possible HIV exposure, you might not be infected. HIV screening is the only way you will be able to know if you have become infected.



Post Exposure Prophylaxis (PEP) is the start of anti-HIV drug therapy within 72 hours (three days) of a suspected exposure to HIV, the virus that causes AIDS. The goal of PEP is to prevent the establishment of HIV infection in a person recently exposed to the virus. PEP is not appropriate, and may be harmful, for people with early or established HIV infection. Ideally, whenever PEP is considered or undertaken, it should be coupled with counseling about HIV risk, prevention and screening.

PEP programs for sexual or injection drug use-related exposures to HIV are open in a few centers in the US. (These types of exposures are called non-occupational exposures; see the

box on page 2. This publication refers to *non-occupational post exposure prophylaxis* as *nPEP*.) Through these programs, people who believe they might have been exposed to HIV can talk with a doctor to assess their risk for HIV infection. If their risk is high, they will be offered anti-HIV therapy (two or three drug combination) after discussing the risks and potential benefits of therapy. If they choose to take therapy, they will be encouraged to take the drugs for about a month. People who participate in nPEP studies are usually given the drugs and lab testing for free.

An individual does not have to participate in a study in order to use anti-HIV drug therapy in this situation.

However, insurance companies and other health care reimbursement programs, like Medicaid or MediCal, may not pay for its cost and related lab work for someone who has not been shown to actually have HIV infection.

Currently, using PEP for sexual or injection drug use HIV exposure is considered experimental and has not been proven to block the establishment of HIV infection in people, even when used within 72 hours. There is some evidence that it can block infection from what are called "occupational" exposures. This is when a health care worker is stuck by a needle that has had contact with HIV, or has a cut or abrasion that makes contact with HIV-infected blood.

Why do people use PEP?

Interest in using anti-HIV therapy to decrease the risk of establishing HIV infection is based on three observations. One is the observation of fewer HIV infections among health care workers with occupational exposures to HIV when anti-HIV therapy was used within hours of the exposure. Another are results from studies which show that therapy given to HIV-positive pregnant women during pregnancy/labor and to newborn children for their first six weeks of life reduces the risk of mother-to-child HIV transmission rates from 25% to about 8%. In this study, not all children received anti-HIV therapy for 6 weeks, but HIV rates were lowest among the children who did—which is perhaps the strongest argument for using PEP. There have also been animal studies where, in some cases, using PEP prevented the establishment of infection in the sexual exposure setting. These results suggest that PEP may also lower the risk of HIV infection in possible exposures in other settings, such as human sexual exposure to HIV or other needle stick exposures.

The limitations of these studies make it unclear whether these findings will apply in all HIV risk exposures. For example, in the health care worker setting, PEP is given within four hours of an exposure. It is unknown if starting PEP after four hours will have the same kind of effect in other settings.

How HIV establishes itself may be very different in a needlestick accident compared to sexual exposure.

In sexual exposure, different cell types may be the first targets of HIV transmission and infection. Thus it might be easier for HIV to get into cells and hide from the effects of anti-HIV therapy in the vaginal or anal cell walls. Success with PEP in the needlestick setting might not translate into success for sexual exposure to HIV.

Finally, the dynamics of the virus in animals may be very different in humans. The exposures in the animal studies were artificial and controlled, so they might not apply to humans.

In other words, no one knows if PEP is effective in the non-occupational setting or even in occupational exposures after 4 hours. Even if PEP does one day prove to be effective in other types of exposure, it's unlikely to be effective 100% of the time. So even if you choose nPEP and follow through on anti-HIV therapy as prescribed, you may still develop HIV infection.



Occupational vs. non-occupational exposure

OCCUPATIONAL exposure to HIV refers to needlestick and other accidents that happen in the health care worker setting, like a hospital. The most common occupational exposure to HIV happens when a health care worker accidentally sticks himself or herself with a needle that has been used for giving an injection or starting an IV (intravenous line) in a person living with HIV.

NON-OCCUPATIONAL exposure to HIV includes pretty much all other HIV exposures. Some examples of possible non-occupational exposures include:

- being stuck with a used syringe (accidentally or on purpose),
- sharing needles or other injection drug equipment,
- being the victim of sexual assault,
- having a condom break or not using a condom during insertive or receptive anal or vaginal sex,
- sharing sex toys, without cleaning them between use, or
- having unprotected oral sex.

This is not an exhaustive list, nor does it reflect a priority in terms of which situation is more or less likely to expose someone to HIV.

How do you assess your risk of HIV exposure?

HIV cannot be passed through casual contact. The following casual contact scenarios are not considered a risk for HIV exposure and transmission. If you fear a possible HIV exposure because of an incident similar to any of these described below, you're not at risk for HIV infection and PEP would definitely not be warranted.

- Holding hands, touching, hugging or kissing someone living with HIV.
- Being in the same room as someone living with HIV who coughs.
- Drinking from the same glass, eating off the same plate or sharing eating utensils with someone living with HIV.
- Using a telephone that was just used by someone living with HIV.

You can only become infected with HIV by being exposed to the blood or blood products, including vaginal fluids or semen, of someone living with HIV. The following chart describes the level of risk from various activities. In all the scenarios described, the HIV status of the "source" (e.g. person whose blood you were exposed to) is important in determining the risk of possible HIV exposure. The following factors may influence your risk for HIV infection:

- the amount of blood or blood products you were exposed to,
- violence or abrasion associated with the activity that might have caused open wounds or bleeding,
- the presence of other active sexually transmitted diseases and/or genital ulcers, either in yourself or in the person who is the suspected source of HIV,
- the stage or status of HIV infection in the source or that person's anti-HIV treatment status, and
- the number of these factors present in the situation.

Different methods of contact with HIV also have varying levels of risk associated with them. These risks, in turn, may be influenced by the factors listed above.

level of risk for hiv infection (risk per 10,000 exposures to an infected source)

TYPE OF ACTIVITY	ESTIMATED RISK OF INFECTION/TRANSMISSION
Blood transfusion with HIV-contaminated blood	9,000 (nearly 1 in 1) 90%
Needle sharing injection drug use	67 (.67% or 2/3 of 1%)
Receptive anal sex	50 (.50% or 1/2 of 1%)
Needlestick accident with HIV-contaminated needle (occupational exposure)	30 (.30% or less than 1/3 of 1%)
Receptive penile-vaginal sex	10 (.10% or 1/10 of 1%)
Insertive anal sex	6.5 (.065 % or less than 1/10 of 1%)
Insertive penile-vaginal sex	5 (.05% or less than 1/10 of 1%)
Receptive oral sex	1 (.01 % or 1/100 of 1%)
Insertive oral sex	0.5 (.005% or less than 1/100 of 1%)

These figures are estimates.
All sexual risks above assume no condom use
Gray boxes are highest risk.
Other boxes are moderate to high risk.

The risks for HIV transmission and infection from other activities, like oral sex, are generally considered to be lower than any of these listed above and not well enough documented to permit making numerical estimates. Risk from such activities need to be assessed on an individual basis. If you have participated in one or more of these activities, assess the risk of each by talking to a health care provider.



To nPEP or not to nPEP— what are your options?

If the incident that you believe put you at risk for HIV exposure/infection took place within the last 72 hours, and you are able to access nPEP within that 72 hours, generally you have two options:

OPTION 1

(consider this option whether your risk assessment suggests you are at high, moderate or low risk for HIV exposure/infection)

Consider prevention counseling and seek support resources. Consider your HIV screening options. Work with an HIV prevention counselor to develop a comprehensive HIV prevention/risk reduction strategy that fits your lifestyle.

Screen for HIV using a standard HIV antibody test at six weeks, six months and then yearly after the incident. Re-evaluate your prevention/risk reduction strategy yearly.

OPTION 2

(consider this option if your risk assessment suggests that you are at high risk for HIV exposure/infection)

Screen for HIV using a standard HIV antibody test to rule out pre-existing HIV infection. Start nPEP. This means you will start taking anti-HIV therapy within 72 hours of the possible exposure. Preferably you will start nPEP within 24 to 36 hours of the incident. Generally you will take therapy for 28 days.

Consider prevention counseling and seek support resources. Work with an HIV prevention counselor to develop a comprehensive HIV prevention/risk reduction strategy that fits your lifestyle.

Monitor for side effects associated with using anti-HIV therapy and use periodic screening for HIV (see Suggested Follow-up Schedule for nPEP, on *Talking to Your Doctor About nPEP* insert).

what are the reasons to not use nPEP?

The reason to choose nPEP is the hope that using anti-HIV drugs within 72 hours of an exposure to HIV might block the establishment of HIV infection. The following is a list of reasons why you might choose **not to use** nPEP, despite having a high-risk exposure.

ONE ...

If you have repeated high-risk exposures to HIV and can be expected to continue doing so, nPEP is generally discouraged. In this setting, side effects of anti-HIV therapies could be hard on your body, weaken your natural immune defenses and actually increase your risk of infection from repeated exposures.

TWO ...

All anti-HIV therapies have possible side effects. Some, like nausea, are at their worst during the first few weeks of use. Whether or not you will have these side effects is unknown, but it's wise to assume that this may happen. If you are not prepared to manage or put up with them, you may choose not to use nPEP.

THREE ...

If you don't think you can take the drugs routinely or have a great deal of anxiety about taking the drugs for the recommended 28 days, you might be better off not using nPEP. If you are in fact infected with HIV, taking the medications haphazardly and not strictly adhering to the prescribed regimen will almost certainly not work and could have negative long-term consequences for your future HIV treatment options.

Choosing an nPEP regimen—Which one?

There is no agreement as to which regimen is the best to use in this setting. Generally speaking, an nPEP regimen includes a combination of two or three drugs. Currently there are four kinds of approved anti-HIV therapy. They include nucleoside analogue reverse transcriptase inhibitors (NRTIs), non-nucleoside reverse transcriptase inhibitors (NNRTIs), protease inhibitors (PIs) and entry inhibitors (EIs). By mid-2007, a new class called an integrase inhibitor (II) is likely to be FDA approved and available. Each type of drug acts against HIV in a slightly different way. Essentially all the drugs work by trying to cripple HIV's ability to reproduce. (See *Drug Dosing Chart* on page 6). The charts from the Federal Guidelines for non-occupational exposure nPEP, including a cost analysis and side effects, are listed on pages Y and Z.

In choosing an nPEP regimen that's right for you, it's important to consider:

- the potency of the regimen,
- the potential side effects of each drug (some regimens may have side effects that concern you more or less than others),
- possible drug interactions between the drugs you're already taking and those in the nPEP regimen,

- the complexity of the regimen (e.g., if it requires that you take many pills at specific times, you may have difficulty taking them according to the time schedule required), and
- the anti-HIV therapy history of the source (if known); a person may transmit virus that is already resistant to certain drugs and those particular drugs are then less likely to work for you.



An nPEP regimen will include, at a minimum, two NRTIs. Some regimens will include three drugs—two NRTIs and one NNRTI or PI. As treatment advances, it's likely there will be experimentation with single-drug approaches as well. Currently both 2- and 3-drug regimens have been formulated into a single pill. What that means is that it's now possible to be on a 3-drug anti-HIV regimen that requires you to take a single pill, once daily.

Which two NRTIs should you consider?

Abacavir (Ziagen), while possibly one of the more potent drugs of this type, has a potentially life-threatening side effect that occurs in 3–5% of people taking it. Generally abacavir, or single pill combinations that include abacavir (like Trizivir or Epizcom), would not be considered as part of an nPEP regimen because of this side effect.

NRTI regimens for nPEP include any combination of AZT (Retrovir), ddI (Videx), d4T (Zerit), FTC (Emtriva), tenofovir (Viread) or 3TC (Epivir). Most of these can be safely combined with one another, except for AZT and d4T. The combination of ddI and d4T is generally discouraged. Also the drugs FTC and 3TC are very similar and rarely used together. It is assumed that any combination of these drugs is roughly equivalent. Generally speaking, if you choose a two NRTIs for nPEP, research sites would probably encourage either an AZT + 3TC (Combivir) or FTC + tenofovir (Truvada) combination, simply because the drugs are co-formulated to include two drugs in a single pill and are easy to use. The major issues to consider when choosing a regimen are side effects and ease of use. It's likely these two combination pills are equally potent when used in this setting.

AZT is the oldest drug in this class and also the most researched. Both AZT and 3TC are made by the same company and are combined into a single pill called Combivir. Thus, by taking one Combivir, twice daily, you may take a 2-drug regimen that only requires taking one pill every 12 hours (total of 2 pills daily). FTC and tenofovir are also made by the same company and combined into a single pill called Truvada. This two-drug regimen requires a single pill, once daily. Either two-drug pill is fairly easy to use. The most common short-term side effects, either of AZT or the Combivir combination pill, are headaches, nausea and vomiting, which tend to diminish with longer use. Nausea, vomiting, diarrhea, and flatulence (intestinal gas) are the most likely short-term side effects of Truvada. Other side effects are possible in long-term use, but these are generally not a concern in PEP because of the short duration of treatment.



Which NNRTI or protease inhibitor to consider?

Some nPEP sites routinely prescribe only two NRTIs. Others believe that if nPEP is going to be attempted, the best and most potent shot we have is to use three drugs. These 3-drug regimens are the standard of care for people with established HIV infection, and they have proven to be much more potent than 2-drug regimens. For people who choose a more aggressive nPEP regimen, typically they would use two NRTIs and a PI.

In general, NNRTIs are not used in nPEP regimens. While nevirapine (Viramune) is the more widely studied drug in this class, severe rash associated with nevirapine makes it somewhat unpalatable therapy for nPEP. Risk of developing a severe rash may be greater than the actual chance of HIV infection due to an exposure to HIV. The other NNRTI, efavirenz (Sustiva), has been associated with a high level of side effects, especially in its first month of use, and should not be used by pregnant women or nursing mothers because of possible harmful effects to their child. Delavirdine (Rescriptor) is considered the least potent NNRTI. It is not a widely used anti-HIV drug, so an nPEP regimen with an NNRTI as a third drug is highly unusual.

If one added a PI to make a three-drug regimen, the least likely drug to use is full dose ritonavir (Norvir) because it has a high rate of side effects compared to any of the others. In terms of short-term side effects, there's little reason to choose one vs. another of the other protease inhibitors: atazanavir (Reyataz), fosamprenavir (Lexiva), tipranavir (Aptivus), indinavir (Crixivan), saquinavir (Invirase), darunavir (Prezista), nelfinavir (Viracept) or lopinavir + ritonavir (Kaletra). However, some are considerably easier to use than others. Some require twice daily

dosing, such as Kaletra, nelfinavir, fosamprenavir and darunavir. Some of these drugs require a booster of a second drug (low doses of ritonavir) in order to be effective against HIV. It's unclear if this is also true when used as part of nPEP regimens. One protease inhibitor, atazanavir, can be taken once daily. Another factor to consider is the number of pills that must be taken each time the drug is used. Both Kaletra (because of its potency) and atazanavir (because of its ease of use) are often among the first choices considered for nPEP regimens.

Over the past decade, several anti-HIV drugs have been approved, greatly expanding the options in the fight against AIDS. Some cannot be used with other drugs (including non-HIV drugs), and/or their dose must be adjusted when combining them. For example, if atazanavir is combined with tenofovir (Viread) or single pill formulations that include those drugs (such as Atripla or Truvada), it must be used with a low dose of the protease inhibitor ritonavir to help boost its potency. The bottom line is that constructing an anti-HIV regimen to use in PEP should be done with the guidance of someone familiar with anti-HIV drugs and how to combine them. The doctor you see might not be an HIV specialist, but professional support is available to help your doctor, through the national PEpline (1-888-448-4911), in selecting and monitoring an nPEP regimen. This line is intended for use by health care professionals only.

In nPEP, where drugs are only taken for 28 days, it's fair to assume that both 2- and 3-drug regimens are roughly equal or at least adequate. The true differences in these approaches and among the different drugs probably

rest in their ability to suppress HIV replication over a long period of time. In the short-term, for a 28-day nPEP regimen, either approach should be adequate.

NNRTIs are generally better tolerated than any of the PIs, which may make them more desirable for nPEP. Moreover, some PIs have more drug interactions than NNRTIs.

drug i.d. chart

TRADE NAME	GENERIC NAME
Protease inhibitor	
Agenerase	amprenavir
Aptivus	tipranavir
Crixivan	indinavir
Invirase	saquinavir hgc
Kaletra	lopinavir+Norvir
Lexiva	fosamprenavir
Norvir	ritonavir
Reyataz	atazanavir
Viracept	nelfinavir
Nucleoside (NRTI) and nucleotide (NtRTI) analogue reverse transcriptase inhibitor	
Combivir	3TC+AZT
Emtriva	emtricitabine (FTC)
Epivir	lamivudine (3TC)
Epzicom	3TC+abacavir
Retrovir	zidovudine (AZT)
Trizivir	3TC+AZT+abacavir
Truvada	FTC+tenofovir
Videx	didanosine (ddI)
Videx EC	didanosine enteric-coated (ddI EC)
Viread	tenofovir
Zerit	stavudine (d4T)
Ziagen	abacavir
Non-nucleoside reverse transcriptase inhibitor (NNRTI)	
Rescriptor	delavirdine
Sustiva	efavirenz
Viramune	nevirapine
NRTI + NNRTI	
Atripla	Emtriva+Sustiva+Viread
Entry inhibitor	
Fuzeon	enfuvirtide (T20)

How the anti-HIV therapy history of the source factors in

It is not always possible or comfortable to ask the “source” their current and/or past use of anti-HIV medications. Yet, this information may help you make a better decision about your nPEP regimen.

If, for example, the person has never taken anti-HIV drugs, the choices of therapies to use will be easiest, as worrying about resistant virus is less of a concern. In this setting, some nPEP programs choose to use two drugs for nPEP, though no one knows if a 2- or 3-drug regimen is best.

On the other hand, if the person had used many different anti-HIV drugs, it's possible that they have developed resistance to many of the medications. (Resistance happens when the HIV in their body mutates to evade the effects of the anti-HIV drugs.) If this is the case, then using a combination of drugs that the person had not used before as your nPEP regimen might be the most effective approach. The more you know about the source's anti-HIV drug therapy history, the better informed you and your doctor will be at making the best nPEP choice for you.

Where can you get nPEP?

Federal Recommendations on using nPEP for non-occupational exposure to HIV were published in January 2005. These are available at: www.ucsf.edu/hivcntr/Clinical_Resources/Guidelines/PDFs/NE_012105.pdf.

Currently nPEP is not routinely available at public health clinics or through federal reimbursement programs, like Medicaid. Only one state (Arizona) covers the cost of nPEP through its AIDS Drug Assistance Program (ADAP). In all other states, ADAPs only cover the cost of therapies to manage HIV disease, for people living with HIV, who are uninsured and underinsured and who do not qualify for Medicaid. Some health departments throughout the country support nPEP programs. (For more information about your state's ADAP, contact your local or state Department of Public Health, or contact the Access Project at 1-800-734-7104 or visit their website at www.aidsinfo.org. Contact your local health department for information about nPEP programs in your area. Not all areas will have programs in place or guidelines.)

Currently, some people can get their insurance to cover the cost of nPEP and related lab tests. Because nPEP is considered experimental, a person's ability to access it may vary dramatically. The kinds of factors that might influence a provider's willingness to prescribe nPEP might include their knowledge about HIV and comfort level in prescribing and monitoring the effects of anti-HIV medication. The cost of 28-day nPEP regimens range from \$300–\$1,800, depending on the regimen, not including costs for lab work and follow-up visits to your doctor.

these sites make nPEP available



San Francisco, CA and Bay Area

Together with the SF Department of Public Health, San Francisco General Hospital's nPEP program has led the way in defining the issues about nPEP and making information available (415-487-5538). The San Francisco program also includes extensive HIV prevention counseling. nPEP and related lab work is provided free of charge to those who qualify.

Boston, MA

The Fenway Community Health Center (617-267-0900) has been providing nPEP to those seeking the option for over two years and they are currently in the process of establishing a statewide nPEP registry. These sites provide nPEP and related lab work free of charge to those who qualify.

New York, NY

Gabriel Torres from the private practice of Bentley-Salick Medical Practice (212-358-2400) in New York established an nPEP program, funded by industry. Drugs and lab follow up are provided free of charge.

Other non-occupational HIV PEP programs may be available through emergency rooms or local clinics. Your city or state department of public health may have more information about HIV nPEP programs in your area. This list merely reflects formal programs that we are aware of at the time of publication.

Commentary on non-occupational post exposure prevention

The decision to use nPEP is a difficult one. Even if you participated in an activity that put you at high risk for HIV infection, the difficulties of taking nPEP, the risk of side effects from the regimen and the many unknowns about the value of nPEP may provide enough reason not to use nPEP. The bottom line is that nPEP is not right for everyone.

The Centers for Disease Control and Prevention issued recommendations regarding the use of nPEP in January 2005. The 28-page document provides extensive data on the rationale behind using nPEP as well as guidance for those who might best benefit from intervention. This document is available through the UCSF link above in a PDF format, or directly through the CDC at www.cdc.gov/mmwr/preview/mmwrhtml/rr5402a1.htm. It also offers guidance on treating and monitoring people seeking nPEP. Moreover, the CDC has established a national nPEP surveillance registry that accepts voluntary reports by clinicians. Information about the registry is available from the Non-occupational HIV PEP Registry: 877-448-1737 (toll-free 24 hours) or www.HIVpepre registry.org.

An activity called pre-exposure prophylaxis (PrEP) is also becoming increasingly popular among young people and people at high risk for HIV infection. This involves taking anti-HIV medications before a night on the town, of risky sex and/or needle sharing. Taking anti-HIV drugs as a way to prevent HIV infection is currently being studied and is possibly harmful. Theoretically, it's possible that these drugs may weaken the immune system when used in this way and might actually increase the risk of

HIV infection if an exposure occurs. Some of the anti-HIV medications should not be used with alcohol and others have potentially lethal drug interactions when used with "street drugs." For the time being, there's no information to support the use of anti-HIV drugs for PrEP.

While you may be concerned about HIV exposure or infection after a risky activity, the truth is that many other infectious diseases are passed much easier and may have serious health consequences. Hepatitis, for example, is much more easily passed than HIV. Needle-sharing, needlestick accidents and unsafe sex all are transmission risks for hepatitis B and C. Exposure to fecal matter and urine not only carries a hepatitis transmission risk but also a risk of exposure to cryptosporidium and parasites. Sexually transmitted diseases, including chlamydia, gonorrhea, syphilis, herpes and warts (HPV), are of equal concern. Some of these are readily treatable and they should all be monitored for and treated should they occur. If risk of hepatitis exposure is considered high, explore PEP for hepatitis. If you have not been exposed to hepatitis B, strongly consider hepatitis B vaccination.

Many people considering nPEP are people who have experienced sexual assault or are the victims of domestic violence. Seeking support from rape crisis counselors is strongly encouraged. For people in relationships where domestic violence is an issue,

there are resources available to you. No one deserves to be abused and it's important that you reflect on what is happening to you and remember that it is wrong. An important fact: your risk of HIV infection is greater if the perpetrator of rape or violence is someone you know, rather than a stranger.

The best way to prevent HIV infection is to develop a comprehensive prevention plan that you can live with. For some people this might include gradually improving your HIV risk reduction approaches. For others, it might be easy to eliminate all HIV risk activities or behaviors from your life. It's important that whatever strategy you use, it's one that is reasonable and fits your life. nPEP is not a long-term solution; HIV prevention is.

Finally, if you find out that you are HIV-positive, there are things you can do. You are not dying and you are not alone. Project Inform can help you learn about HIV disease, therapies to treat it and provide you with publications on developing a relationship with a health care provider and a long-term strategy for managing HIV disease.

Project Inform has publications on new developments in HIV research and treatments, available free of charge to all those who need them. We also have a toll-free hotline at 1-800-822-7422 and a website at www.projectinform.org containing information on hundreds of topics.

www.projectinform.org



Go online around the clock and get connected to treatment information in the privacy of your own home!