



by Rob Gair

With studies showing success of post-exposure prophylaxis (PEP) for occupational exposure to HIV, some are asking if post-exposure prophylaxis, (a morning-after pill for HIV exposure), is a viable prevention method.

In HIV/AIDS medicine, PEP refers to the use of antiretroviral medications immediately following an exposure to HIV. Within 72 hours of exposure an antiretroviral cocktail is administered for one month. PEP appears to decrease HIV seroconversion. Historically, the use of PEP has been restricted to occupational exposures in healthcare workers, generally caused by accidental injuries from sharp objects contaminated with HIV-infected body fluids. Only a very small proportion of HIV infections result from occupational exposures, and now the debate has begun about developing guidelines for patients seeking PEP for non-occupational exposures.

History of PEP

Concerns about occupational exposures to HIV became real in 1988 when a US healthcare worker became infected after cutting her finger on a broken test tube filled with HIV-infected blood. In 1997, an international retrospective case-control study involving approximately 700 healthcare workers exposed to HIV between 1988 and 1994 was released. The study identified four factors that increased the risk of HIV infection: injuries with devices that were visibly contaminated with

blood, injuries that were deep, injuries that involved direct access to veins or arteries, and exposure to blood from patients in advanced stages of AIDS.

The study was not designed to evaluate the effectiveness of post-exposure prophylaxis. The investigators were surprised, therefore, to discover that post-exposure treatment with zidovudine (Retrovir, formerly AZT) reduced the risk of seroconversion by approximately 81%. This data is subject to serious limitations, but it was the only way to gather the information, and it became the framework for early PEP protocols that were officially instituted in 1998.

Non-Occupational Exposures

Since 1998, the use of PEP following occupational exposures has been standardized in most healthcare centres. However, the vast majority of new HIV infections occur outside occupational settings, and PEP has not been formally studied for other types of exposures. Nevertheless, it appears reasonable to conclude that if PEP works in occupational settings, it would also work for non-occupational exposures. Of course, this assumption must be balanced with the knowledge that PEP does not prevent HIV seroconversion in every case. Failures have occurred, and the use of PEP following exposure does not guarantee that HIV infection can be prevented.

Sexual Assault Victims

PEP is currently provided to sexual assault victims under guidelines for the treatment of sexually transmitted diseases to prevent HIV infection. In 1996, the Sexual Assault Service at Children's & Women's Health Centre in Vancouver and at Vancouver General Hospital were the first centres in North America to offer PEP to victims of rape. To evaluate its effectiveness, team members gathered data for the first 16 months of the program. During this time, 71 patients considered at risk for HIV infection accepted PEP. However, only eight of the 71 completed the full 28-day course of medications (12 did not return for follow-up; 51 stopped their medications early).

Will knowledge about the availability of PEP open the door to increasingly risky sexual behaviours?

Reasons for not completing the regimen included problems with side effects or fear of side effects and discovery that patients were HIV positive prior to the assault. The eight patients who fully completed the program were at the highest risk for HIV infection and none of them seroconverted. This study shows the obvious difficulty of getting people to adhere to PEP drug regimens for the full length of treatment. After the data were analyzed, the program was changed so that PEP was offered only to those at a high risk for contracting HIV.

Consensual Sex

Men who have sex with men (MSM) have great potential to benefit from PEP. In the 1990s, HIV infection rates stabilized among MSM, but recent data shows an increasing rate of infection, particularly in younger men. Several issues need to be considered when contemplating the widespread use of PEP for MSM. Perhaps the most contentious of these is whether or not knowledge about the availability of PEP will open the door to increasingly risky sexual behaviours.

The scientific data is inconclusive. Two studies, one in MSM and another involving heterosexual couples, found little evidence that availability of PEP leads to increased risk-taking. However, a 1998 survey of single MSM found that those who were less educated and those who tended to use illicit drugs or engage in high-risk sex were more likely to rely on PEP to prevent themselves from becoming infected with HIV.

A recently published San Francisco study examining the feasibility of PEP after sexual and injection drug exposure found that approximately 12% of participants sought a repeat course of PEP for additional exposures. This finding highlights the concern that PEP may cause increased risk-taking, but the authors do not believe it constitutes proof of such behavioural changes. They make the case that delivery of PEP provides a rare opportunity to counsel and educate individuals about risk reduction because people seeking PEP are motivated to avoid infection.

Cost

A single four-week PEP treatment regimen can cost up to \$1000 (lab and medical fees not included), making cost a major factor influencing availability.

The sexual assault study estimated that to prevent one HIV seroconversion, 140 patients would have to be treated at a cost of about \$100,000 total. This amount may seem high, but it is cheaper than the estimated \$150,000 a single seroconversion costs the health system. However, comparison of these costs is more complex than it seems. The use of PEP to prevent an HIV infection places the cost burden on a single program over a relatively short period of time, whereas costs associated with an actual HIV infection are spread throughout the healthcare system over a number of years.

More recent data from a local survey estimated that it would cost a minimum of \$800,000 per year to provide PEP to "at-risk gay and bisexual men" in Vancouver's West End. This amount would double the current budget for all accidental exposures in BC and not address the rapid growth of HIV infections among injection drug users. At least one critic suggests this analysis "greatly overestimates the cost of an HIV PEP program for this population." The same group then studied actual costs of providing PEP following sexual assaults and occupational exposures. They determined that program expenditures were already double the anticipated amount, and they estimated they were spending approximately \$500,000 to prevent one HIV infection. However, they also determined that approximately 50% of program participants would never have received PEP if the guidelines had been followed properly. Nevertheless, they argue that since costs are already high for the MSM population, expanding access to this group would overwhelm the program.

Summary

The use of PEP following accidental HIV exposures in health-care workers has been shown to reduce the incidence of HIV seroconversions. However, occupational exposures remain low. Consideration has been given to offering PEP to higher-risk groups, specifically non-consensual heterosexual sexual exposures and intravenous drug users. Experience in sexual assault clinics shows that it is difficult to get the majority of sexual assault victims to complete the full four-week regimen.

Concerns about MSM using PEP as a primary means of HIV prevention appear to be unfounded. The long-term benefits include possible prevention of infection and opportunities to educate people about risk reduction. The cost of providing PEP is a major factor hindering expansion of availability and little consideration is given to potential long-term cost savings. Certainly, the social and human costs of HIV infections are enormous and every effort should be made to ensure that people have access to prevention programs best suited to their needs. ⊕



Rob Gair is a pharmacist at the BC Drug & Poison Information Centre.