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Rapid Review #20: January 2010

Rapid Response Service

Effectiveness and Cost-Effectiveness of Pre & Post-Exposure Prophylaxis for HIV

OHTN

Key Question

How effective and cost-effective are 1) policies for HIV post-exposure prophylaxis for exposures not through sexual assault or in the workplace and 2) strategies for HIV pre-exposure prophylaxis?

Key Take-Home Messages

- There is not enough evidence to draw conclusions about the clinical effectiveness of non-occupational post-exposure prophylaxis (PEP); however, non-occupational PEP is possibly a cost-effective intervention (1). PEP has been shown to be cost-effective for men who have sex with men (MSM) and may also be cost-effective for intravenous drug users (IDU) and high-risk women (1).
- There is minimal evidence to support the use of antiretroviral chemoprophylaxis as pre-exposure prophylaxis (PrEP) (2).
- Canada does not have any national guidelines for the use of non-occupational PEP. Although national guidelines vary throughout Europe, guidelines in the US often suggest that the decision to administer non-occupational PEP should be made on a case-to-case basis (3-5).
- Most guidelines for PEP recommend either a dual- or triple-therapy regimen, initiated within 72 hours of exposure, and taken continuously for four weeks (3-9).

The Issue and Why It's Important

Although extensive research has been done on the effectiveness and cost-effectiveness of occupational post-exposure prophylaxis (PEP), little research has been conducted on PEP use after non-occupational exposures to HIV. There is even less research on the effectiveness of pre-exposure prophylaxis (PrEP).

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EVIDENCE INTO ACTION

The OHTN Rapid Response Service offers HIV/AIDS programs and services in Ontario quick access to research evidence to help inform decision making, service delivery and advocacy. In response to a question from the field, the Rapid Response Team reviews the scientific and grey literature, consults with experts, and prepares a brief fact sheet summarizing the current evidence and its implications for policy and practice.

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Although the best way to prevent HIV is to prevent exposure, PrEP and PEP provide opportunities to prevent HIV transmission before and after exposure, particularly within high-risk groups. If PrEP and PEP can be shown to be highly effective and cost-effective, then a case may be made to include these interventions in prevention initiatives.

What We Found

Pre-Exposure Prophylaxis (PrEP)

Pre-exposure prophylaxis has been discussed as a potential prevention strategy for individuals at high risk for HIV (10). At present, very few studies have been conducted on the efficacy of pre-exposure prophylaxis (PrEP) (2). Clinical trials on oral chemoprophylaxis have been scarce and conclusions from a systematic review of the literature has shown that there is little to no evidence that supports the use of chemoprophylaxis as PrEP (2).

US studies have shown that any potential benefits of PrEP may not outweigh its high costs. Although PrEP was estimated to reduce the lifetime risk of HIV infection from 44% to 25%, the incremental cost-effectiveness ratio has been estimated at $298,000 (USD) per QALY gained. Therefore, PrEP may only be a cost-effective prevention strategy if current treatment costs are greatly reduced and if treatment efficacy increases (11).

If future trials are able to show that pre-exposure prophylaxis is effective at preventing HIV transmission, then there will need to be thoughtful discussion around its widespread use and the accompanying messaging (10;12).

Post-Exposure Prophylaxis (PEP) Guidelines

A recent systematic review of non-occupational post-exposure prophylaxis found only one clinical study that met the inclusion criteria. Results of this clinical effectiveness study among high-risk HIV-negative homosexual men in Brazil showed that non-occupational PEP was cost-saving for MSM who have unprotected receptive anal intercourse. PEP was also determined to be cost-saving for unprotected heterosexual receptive anal intercourse and sharing needles for injection drug use with someone who was known to be HIV-positive. PEP was cost-effective for all MSM intercourse and possibly cost-effective for injection drug users and women at high risk of HIV transmission. The most common adverse side effects were listed as nausea and fatigue. Side effects were more likely during triple therapy PEP regimens, as compared to dual therapy regimens. PEP completion ranged from 24% to 78% among participants, with toxicity given as the main reason for stopping treatment. Due to the fact that assumptions about the effectiveness of non-occupational PEP were based on occupational studies, it is not possible to draw conclusions about the overall effectiveness of non-occupational PEP in the study (1).

Canada

There are currently no specific guidelines for the use of non-occupational post-exposure prophylaxis in Canada. Many Canadian sites refer to the US Centers for Disease Control and Prevention (CDC) guidelines on the use of PEP. One study, which was based in both the US and Canada, looked at the use of post-exposures prophylaxis by physicians who treat children and adolescent patients and determined that there was very little uniformity among policies, practices,

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and suggested regimens for non-occupational PEP use in children and adolescents. Many of the surveyed physicians said that they would prescribe PEP within 24 hours after exposure; however, only one third of them had ever actually prescribed PEP in pediatric cases (13).

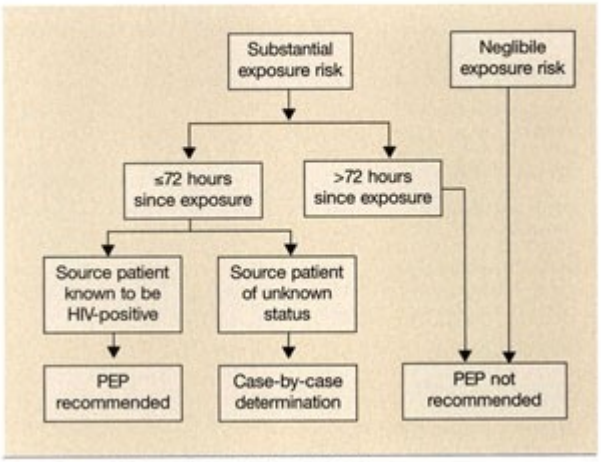
USA

The US Department of Health and Human Services (DHHS) Working Group on Nonoccupational Postexposure Prophylaxis (nPEP) has made no formal recommendations for the use of PEP after non-occupational exposures and suggests that PEP administration should be determined on a case-by-case basis. PEP is not recommended for patients who do not present with a substantial risk for HIV transmission or for those patients who seek treatment more than 72 hours after exposure. If a patient is at high risk for HIV transmission and seeks treatment after 72 hours, then the decision to administer PEP is made case-by-case. Potential adverse side effects must be weighed against potential benefits. Counseling and other support services should also be provided (5).

The US Centers for Disease Control and Prevention (CDC) provide the following chart to determine when to administer PEP:

FIGURE

Evaluation and treatment of possible nonoccupational HIV exposures



Source: Centers for Disease Control and Prevention 2005.[1]

The CDC notes that there is a lack of evidence about the effectiveness of PEP for non-occupational exposures and that PEP should be used infrequently and not continually. The CDC recommends a triple therapy regimen, started within 72 hours of exposure and continued for four weeks (3).

A number of studies in the US have concluded that the use of non-occupational PEP as part of a public health program should only occur in populations where HIV prevalence is high (14). PEP has been shown to be at least a feasible option in some high-risk groups, such as the use of PEP after sexual or injection drug use exposure, which was found in a San Francisco study (15).

One of the concerns with non-occupational PEP is its effect on HIV risk behavior. An American study examined the use of PEP after nonsexual exposure to HIV and found that HIV risk behavior was not usually negatively affected (16). Another study of gay men in San Francisco also found that there was little

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evidence to show that the availability of PEP for sexual exposure to HIV would negatively affect sexual risk behaviours (the study notes, however, that PEP may contribute to an overall sense of treatment optimism) (17).

A study of NY State guidelines for non-occupational PEP found that guidelines were not widely followed across emergency departments, especially when sexual exposure to HIV was consensual as compared to sexual assault exposure. 70% of the emergency departments in the study initiated PEP in the emergency department for patients who had experienced consensual sexual exposures, whereas 29% were given a prescription or referred elsewhere. The overall PEP initiation rate for consensual sexual exposures to HIV was 43%; this was lower than the initiation rate reported for sexual assault. Therefore, better education and adherence to protocols are important for effective and widespread administration of PEP after non-occupational exposures (18).

There are no formal guidelines in place for the use of non-occupational PEP among children and adolescents in the US. US researchers have recommended taking the following into account when deciding when and how to administer PEP in pediatric cases: transmission risk, number of medications, potential side effects, and amount of information available about the exposure. It is recommended that in pediatric cases, PEP should be started within one hour of exposure. Furthermore, when information about the exposure is scarce, the strongest regimen should be given (19). Other studies have shown that the risk of HIV transmission from non-occupational, non-perinatal exposures is generally low. They also caution that PEP treatments have high levels of toxicity. General recommendations include commencing treatment within 72 hours of exposure and continuing treatment for four weeks (9).

Suggested treatment regimens vary broadly; however, studies have shown that nevirapine should not be used in PEP regimens, since the risk of severe hepatotoxicity is higher among individuals who are not infected with HIV and who are administered short-term nevirapine regimens (20). Adherence problems due to adverse side effects should be considered when determining which drugs to use in a PEP regimen. The side effects of Tenofovir may be more tolerable than those associated with Zidovudine, which may contribute to better adherence rates in non-occupational PEP use (21).

Australia

Australian studies have yielded poor results on the effectiveness and cost-effectiveness of non-occupational post-exposure prophylaxis as an HIV prevention initiative. An examination of the public health impact of post-exposure prophylaxis in Australia found that only 0.9-9.2 HIV infections were estimated to have been prevented by PEP. The study concluded that although PEP may be valuable at preventing HIV at the individual level, it may not play a substantial role in overall HIV prevention at the population level (22).

Further analysis by Anderson (23) has shown that non-occupational PEP is not a good value for its cost. PEP was estimated to prevent 2-3 HIV infections per year with a cost ratio of $190,000 per disability-adjusted life year gained. More targeted PEP use for receptive anal sex yielded a cost ratio of $48,000 per disability-adjusted life year gained. Therefore, increased targeting yields better cost-effectiveness results, but non-occupational PEP is generally not a cost-effective prevention strategy (23).

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One study that looked at homosexual men in Australia determined that non-occupational PEP was associated with unprotected anal intercourse (24). Although HIV risk behavior did not change with PEP use, the men in the study who used PEP were at significantly higher risk of becoming HIV positive (24).

Treatment adherence is also a problem with non-occupational PEP. A study of Australian prisons, found that although 82% of inmates were offered PEP, only 74% of those offered took it and only 24% of those who took it actually completed their course of treatment (25).

Europe

According to the Danish PEP Registry, PEP use has increased for sexual exposure to HIV from 1998 to 2006. PEP was usually initiated very quickly after exposure and was primarily used in cases where transmission risk was high (26).

A 2000 review of 27 European countries (Austria, Belgium, Bulgaria, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, UK) determined that only five countries have specific guidelines for the use of non-occupational post-exposure prophylaxis and only one of those countries follows US CDC guidelines. Thirteen countries do not recommend the use of PEP for non-occupational exposures and PEP is therefore only available in very limited cases. PEP is not available in eight countries. Although there was inconsistency with regimen recommendations across all of the countries who use PEP, the most common regimen is triple combination therapy over a four week period (27).

Guidelines from the Spanish Working Group on Non-Occupational Postexposure HIV Prophylaxis, recommended initiating non-occupational PEP treatment within 72 hours of exposure to HIV and continuing the regimen for four weeks. The guidelines recommended using either 2 NRTIs + 1 PI, or 2 NRTIs + 1 NNRTI for treatment (6).

A 2002 study on GUM clinics in the UK found that there was little consistency among PEP protocols from clinic to clinic; however, most clinics felt that PEP could be used for non-occupational exposures if the patient was exposed to a known HIV-positive individual through sexual assault, unprotected receptive anal, or peno-vaginal intercourse (28). In 2005, a homosexual couple in the UK took the Department of Health to court for the government's guidelines on the use of PEP for non-occupational exposure. One of the men tested positive for HIV after the condom broke during sex. The men claimed that they did not know about non-occupational PEP and that they would have used it if they had been told about it or offered it by their doctor. Thus, greater clarity and consistency are needed for non-occupational PEP administration protocols (29).

A survey of Swiss physicians showed that PEP was most commonly administered after sexual exposure to HIV, followed by needle injury exposure. The HIV status of the source individual was usually unknown and most people were administered a triple therapy regimen. Mild side effects were common, but a couple of patients experienced severe side effects as a result of treatment

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As of 2004, there were still few national guidelines for the use of non-occupational PEP in Europe. A 2004 European study recommended PEP for unprotected receptive anal intercourse or syringe exchange when the source person was known to be HIV positive or from a group with high HIV prevalence. It was suggested that PEP should be initiated within 72 hours of exposure and continued for four weeks. Any combination of antiretroviral drugs used for people living with HIV was deemed acceptable for use as PEP, although the simplest and least toxic medications were preferred. Diagnostic tests, continued monitoring and periodic counseling were also recommended. Researchers concluded that non-occupational PEP should not be employed as a primary prevention strategy, but rather, should be decided on a case-by-case basis (7).

A comparison of 2004 Euro-NONOPEP guidelines with the 2005 United States Department of Health and Human Services guidelines determined that although there are some similarities between protocols, recommendations differ in many areas. Both European and US guidelines recommend the use of PEP when there is a substantial risk of HIV transmission after exposure with a person who is known to be HIV positive and suggest that HAART should be administered for a four week period. Both guidelines suggest that PEP administration should be determined based on the overall risk of HIV transmission; however, European and US risk estimates differ from one another. Although the US states that the administration of PEP should be determined on a case-to-case basis when HIV status of the source person is unknown, European guidelines are more specific – citing that if the patient is from a high prevalence group, then PEP should be administered after receptive anal sex and should be considered for other exposures. If the patient is not from a high-risk group, then European guidelines state that PEP should only be considered after receptive anal sex. The US cautions that the potential side effects of PEP treatment may outweigh any potential benefits if the HIV status of the source patient is unknown. Recommended treatment regimens also differ. Europe recommends triple therapy, but says that dual therapy is also an option, whereas the US says that that there is no evidence to suggest that triple therapy is better than dual therapy and so potential side effects should be considered when deciding which regimen to administer (8).

Post-Exposure Prophylaxis (PEP) Cost-Effectiveness

US cost-effectiveness studies have shown that PEP after sex or drug-related exposures could be a cost-effective prevention option when used along with other HIV prevention strategies (31;32). A study of 96 metropolitan cities across the US examined the use of PEP after sexual and injection-related exposure to HIV and estimated that PEP would reach approximately 20,000 individuals at a total cost of 22 million USD (31). The projected cost-utility ratio across all cities was $12,567 per quality-adjusted life-year saved (31). A similar study which looked at a PEP program in San Francisco found that PEP was cost-effective in most cases and that it was even cost-saving among clients who were exposed to HIV during male-male receptive anal intercourse (32). The PEP program prevented 1.26 infections and the cost-utility ratio was $14,449 per

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quality-adjusted life-year saved (32).

In contrast, a cost-effectiveness study in Australia found that -- at a cost of $1,616 (Australian) per year -- non-occupational PEP was not generally cost-effective (33). The cost per quality-adjusted life-year was determined to be between A$40,673 and A$176,772, depending on risk assumption (33). Better targeting within high-risk groups could improve cost-effectiveness of non-occupational PEP as an HIV prevention initiative in Australia (33).

Factors that May Impact Local Applicability

There are no formal guidelines for non-occupational PEP use in Canada. Guidelines in the US, Europe and Australia differ from one another, possibly due to different estimations of HIV transmission risk and existing HIV prevalence rates in each country. Therefore, studies may not be generalizable to the Canadian context. Furthermore, many existing studies on the effectiveness of PEP involve assumptions based on occupational exposures, which may not be generalizable to non-occupational exposures. Further research that specifically studies the efficacy of non-occupational PEP is needed.

What We Did

To identify any systematic reviews we first conducted hand searches of the reviews and protocols from the HIV/AIDS Cochrane review group and searched www.health-evidence.ca (hand searched the acquired immunodeficiency syndrome' and 'HIV' categories) and the Reproductive Health Library from the World Health Organization. To locate additional reviews and primary literature we then searched PubMed using combinations of relevant text terms

Text terms searched: (pre-exposure prophylaxis AND hiv) OR (preexposure prophylaxis AND HIV); PEP OR PrEP

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