

Position Paper:

Post-Exposure Prophylaxis for Consensual Sexual Activity in British Columbia

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STATEMENT OF THE ISSUE

There is a general lack of awareness and understanding about the use of Post-Exposure Prophylaxis (PEP) as an HIV prevention option for gay men in Vancouver. As a result, it has been reported that gay men trying to access PEP have faced challenges, resulting in people seroconverting (becoming HIV-positive).

REVIEW OF CURRENT POLICIES

The use of antiretroviral drugs to prevent HIV infection as opposed to treating an existing infection, is commonly referred to as post-exposure prophylaxis or PEP. Some jurisdictions distinguish between occupational post-exposure prophylaxis (PEP) and non-occupational post-exposure prophylaxis (NPEP). PEP is provided to those exposed through work-related activities and NPEP is provided to those exposed through consensual sexual acts or drug use. Regardless of how the exposure occurred, a course of PEP generally consists of three different antiretrovirals, typically started within 72 hours of exposure and lasting for 28 days. The cost is approximately \$1000 - \$1500 per treatment course.

In British Columbia, publicly funded antiretroviral drugs are available for exposure to HIV in occupational settings (e.g. healthcare, paramedical, or corrections personnel). Antiretrovirals are also available for sexual assault survivors where the perpetrator



is believed to be HIV-positive. The drugs are provided by the BC Centre for Excellence in HIV/AIDS (BCCFE) at St. Paul's Hospital in Vancouver. Policy guidelines published by the BCCFE state that five-day starter kits are distributed at hospital emergency departments throughout the province at the discretion of the physician on duty (BCCFE, 2009). Depending on how the exposure occurred, these drugs may be paid for by Worksafe BC or the Province of BC. When a client receives a starter kit, a more thorough assessment is

subsequently completed by the BCCFE to determine his or her eligibility for the full 28-day course of treatment. In 2008, 340 people in BC were given a 5-day starter kit. Of these, 85 were considered eligible for the full 28-day course of medication (39 occupational, 5 community, and 41 sexual assault exposures).¹

Current accidental HIV exposure guidelines from the BC Centre for Excellence in HIV/AIDS (BCCFE, 2009) state that exposures resulting from adult consensual sexual

1. Based on a Sep 3/09 e-mail exchange between HIM and Linda Akagi, pharmacist in charge at the BCCFE

activities or accidents in drug using environments are not within the mandate of their PEP program (Appendix 4). This means that gay men who are exposed to HIV during sex are not eligible for enrolment in their program.

Persons who are potentially exposed to HIV under these conditions may wish to purchase prophylaxis, if prescribed by a doctor. (BCCFE, 2009). Antiretrovirals are not a PharmaCare benefit in British Columbia, however, extended health plans may cover some or all of the cost.

NPEP for non-occupational exposure (sexual exposure and needle use) has been made available in countries like Australia, Austria, France, the United Kingdom, Germany, Luxembourg and Switzerland for many years. The City of San Francisco also provides PEP to gay men exposed to HIV. In Canada, the Province of Quebec has had a policy on the use of PEP for non-occupational exposure since 1999.

REVIEW OF WORLD HEALTH ORGANIZATION GUIDELINES

In September 2005, a joint WHO/ILO expert consultation for the development of policy and guidelines on occupational and non-occupational HIV post-exposure prophylaxis was held in Geneva. Although the needs of workers and people who have been sexually assaulted provided the focus of the Consultation, consideration was given to other types of non-occupational exposure for which PEP might be indicated: specifically, those arising from isolated or episodic injecting drug use and consensual sexual exposure. The following excerpts were summarized from a document titled Post-Exposure Prophylaxis to Prevent HIV Infection: Joint WHO/ILO Guidelines, 2007.

The WHO guidelines clearly state that PEP may never be considered 100% effective. It is therefore imperative that HIV post-exposure prophylaxis policies reinforce the importance of primary prevention and risk prevention counseling in all settings where HIV could be transmitted. PEP should never be provided in isolation, but should always form a part of a wider strategy for preventing exposure to HIV. It should also be associated with measures to prevent other blood borne diseases, such as hepatitis B and C.

The WHO guidelines focus primarily on occupational exposure and exposure through sexual assault. The WHO guidelines do not provide detailed guidance relating to consensual sexual exposure or exposure through drug use.

The WHO states that post-exposure prophylaxis should only be offered for exposure that has the potential for HIV transmission. PEP should be provided following exposure of non-intact skin (through percutaneous sharps injury or skin abrasion) or mucous membranes (through sexual exposure or splashes to the eyes, nose or oral cavity) to a potentially infected body fluid from a source that is HIV-positive or has unknown HIV status.

In sexual exposure, the potential for HIV transmission arises if a condom was not used, broke or came off. The risk of transmission following receptive oral sex with ejaculation with a known HIV-positive source should be considered as very low due to the anti-HIV properties of saliva.

Post-exposure prophylaxis is not recommended:

- if the exposed person is HIV-positive from a previous exposure;
- for chronic exposure;
- if the exposure does not pose a risk of transmission, that is: exposure of intact skin to potentially infectious body fluids, sexual intercourse using a condom that remains intact, any exposure to non-infectious body fluids (such as feces, saliva, urine and sweat), exposure to body fluids from a person known to be HIV-negative, unless this person is identified as being at high risk for recent infection and thus likely to be within the window period; and if the exposure occurred more than 72 hours previously.

PEP as Prevention

According to the WHO guidelines, a balanced prevention portfolio positions PEP as part of a national HIV strategy that emphasizes primary prevention. PEP should always be regarded as a secondary prevention measure, provided as a last effort to prevent HIV infection after primary prevention strategies have failed. These services should also be used as an opportunity to reinforce primary prevention behaviour. Providing PEP should not result in reduction to funding primary prevention efforts.

Access

The WHO guidelines recognize the importance of access. Providing initial and follow-up PEP services at locations close enough to the people who need them is likely to be one of the biggest challenges facing post-exposure prophylaxis delivery systems. The closer services are, the more likely clients are to present for care and follow-up. However, in most settings, providing the entire service package for PEP at every level of the health care system is not practicable. Even in locations where comprehensive programs are available centrally, a timely initial dose of PEP may need to be provided at an accessible location, with referral to a local centre or clinic for follow-up.

Individuals are eligible for HIV PEP if:

- exposure occurred within the past 72 hours;
- the potentially exposed individual is not infected or not known to be infected with HIV;
- mucous membrane or non-intact skin was significantly exposed to a potentially infectious body fluid;
- the source is HIV-infected or the HIV status is unknown.

Estimated Risk

WHO estimates the risk of acquiring HIV infection from a single episode of consensual receptive vaginal intercourse to be between 0.1% and 1% (1 to 10 in 1000) and, from a single episode of consensual receptive anal sex, is between 1% and 5% (1 to 5 in 100).

Sexual Exposure

While the WHO guidelines do not specifically address consensual sexual acts, they make recommendations for forced or non-consensual sex acts. Recommended post-exposure prophylaxis eligibility criteria among people who have been sexually assaulted:

- less than 72 hours has elapsed since exposure;
- the exposed individual is not known to be HIV infected;
- the person who is the source of exposure is HIV infected or has unknown HIV status; a defined risk of exposure, such as: receptive vaginal or anal intercourse without a condom or with a condom that broke or slipped; or contact between the perpetrator's blood or ejaculate and mucous membrane or non-intact skin during the assault; or receptive oral sex with ejaculation; or the person who was sexually assaulted was drugged or otherwise unconscious at time of the alleged assault and is uncertain about the nature of the potential exposure; or the person was gang raped.

REVIEW OF OTHER JURISDICTIONS

Australian Government

The Australian Government published National Guidelines for Post-Exposure Prophylaxis after Non-Occupational Exposure to HIV in 2007. These guidelines clearly outline how to assess risk of HIV transmission, recommendations for drug regimens, clinical assessment, laboratory assessment; and provide resources for clinicians. The Australian Government funds the NPEP program. Those wanting to access NPEP can present to hospitals, doctors, or sexual health clinics. According to these guidelines, NPEP is recommended for exposures involving receptive anal intercourse and contaminated injecting equipment, when the source is HIV-positive or an unknown HIV status. NPEP is recommended for insertive anal intercourse only when the exposure source is known to be HIV-positive.

City of San Francisco

An interview with staff at the San Francisco City Clinic described their process for evaluating PEP for gay men following sexual exposures: In summary, gay men who report unprotected receptive anal intercourse with a known HIV-positive partner or a partner of unknown HIV status are considered eligible for PEP. Eligible clients receive a prescription at the clinic and the medications are dispensed from the pharmacy at the San Francisco General hospital. The burden of cost is on the patient or his health insurer. In cases where patients cannot pay or when they have no health insurance, all or portions of the cost may be assumed by the County health department.²

New York State

In September 2009, the New York State Health Department created an online assessment tool that walks users through a screening process to determine whether they are candidates for PEP treatment. It also provides specific information about the 28-day course of antiretrovirals and links to consent forms in 22 languages. The tool is being installed in more than 200 emergency departments in the state. The tool is continually updated with the latest medical recommendations. The application makes it clear that the first dose of antiretroviral drugs should be given as soon as possible, and patients who think they may have been exposed to the virus through sex, drug use, contact with blood or in their work, should all be given high priority.³

2. Obtained from the San Francisco City clinic website www.sfcityclinic.org

3. Obtained from the New York Times, Sept. 8. 2009 Tool to Offer Fast Help for HIV exposure

Province of Quebec

The Quebec Ministry of Health and Social Services published guidelines for non-occupational exposure in 1999. These guidelines are much more succinct than the WHO guidelines and deal specifically with sexual and injection drug use exposures.

Risk of Transmission

According to the Quebec guidelines, the risk of HIV transmission varies depending upon the type of contact. The probability of transmission through a sole exposure to an infected source is assessed using the following percentages:

- 0.67 % per injection drug use exposure
- 0.10 to 3.0 % per anal sex penetration exposure
- 0.10 to 0.20 % per vaginal penetration exposure
- The probability of transmission per oral sex exposure is not known

In violent situations such as sexual assault or a needle attack, the risk level is elevated due to potential trauma caused by the exposure.

Efficacy

The Quebec guidelines cite a study where the drug AZT was found to diminish the risk of transmission for occupational exposure by 81% and mother-infant transmission by 67%.

Risks and Costs

A potential risk of using antiretrovirals as PEP is that it could be perceived as the 'morning-after pill' of condomless sex, increasing sexual risk-taking. Frequent use could also contribute to drug resistance, making it difficult to treat HIV later, if the person eventually becomes infected.

The cost of antiretroviral treatment for HIV is between \$600 and \$1150 per month in Quebec. This cost is covered by the provincial drug plan, regardless of the type of exposure.

Access

A Quebec-wide network of physicians, health care providers and clinics that offer PEP may be accessed by calling a hotline that is open weekdays from 8:00am to 5:00pm.



REVIEW OF HIM'S POSITION

- (i) HIV/AIDS continues to disproportionately affect gay men. In 2008, gay men made up 51.1% of new HIV diagnoses in BC and 68% of AIDS cases (BC CDC, 2009). In Vancouver alone, gay men represented 62% of new diagnoses in the same year. According to data from Vancouver's M-Track study, 18.1% of gay men in Vancouver are living with HIV. Of these, 14% are unaware of their status. As a result, gay men should have access to as many prevention tools as possible in order to reduce prevalence and new infections. HIM does not believe PEP is a substitute for primary HIV prevention (i.e. condoms, risk reduction information, strategies, etc.)
- (ii) Post-Exposure Prophylaxis has been shown to be effective in occupational exposure situations, as well as sexual and drug using exposure situations. PEP is therefore a tool that should be made available to gay men and others exposed to HIV through consensual sexual contact where condoms have failed or have not been used.
- (iii) Access to PEP is one of the barriers often cited by those with non- occupational exposures to HIV. Gay men in Vancouver need to be made aware that PEP is available as an HIV prevention tool, as well as, where and how they can access it. They should also understand the cost of PEP and that it is not currently covered by any publicly funded source.
- (iv) Health care professionals and doctors working with gay men need to be made aware that PEP exists and is a viable option for HIV prevention following sexual exposures.
- (v) The guidelines should deal clearly with both sexual and drug use exposures in mind, so that physicians and patients can make informed decisions about whether PEP is necessary.

DATA

Efficacy of PEP

Trials to determine the efficacy of PEP are not feasible, due to the ethical problems of withholding a potentially preventative treatment, however, there are animal and observational studies in jurisdictions where PEP was administered. Both lend some insight into efficacy.

Studies of macaques have shown mixed results. All animals administered a PEP equivalent for 28 days, 12 or 36 hours after vaginal exposure, were protected. Three of four animals treated 72 hours after exposure were also protected. The fourth animal had delayed seroconversion (becoming HIV positive). These are consistent with other macaques studies (MMWR, 2005), where data indicate a small window of opportunity during which it might be possible to interrupt initial infection of cells.

More direct evidence supporting the efficacy of PEP is a study of needlestick injuries to health care workers. In this study, the prompt initiation of zidovudine was associated with an 81% decrease in the risk of acquiring HIV (MMWR, 2005).

In a study of men who have sex with men (MSM) in Brazil, seroconversions occurred in significantly fewer of those individuals who utilized PEP than those who did not, 0.7% vs. 4.1% (Harrison et al 2000, Harrison et al 2001). Further study over a 2 year period identified an overall seroincidence of 2.9% in individuals who had been given a supply of PEP with instructions to begin PEP immediately after an eligible exposure. In all but one of the seroconversions the individuals had not started PEP because they underestimated their risk of acquiring HIV (Schechter et al 2004).

In a study of rape survivors in South Africa, 480 HIV negative survivors were given PEP and followed for 6 weeks, only one woman seroconverted. She had begun taking the medications 96 hours after the assault (MMWR, 2005).

In a feasibility study in San Francisco, 401 persons with eligible sexual and injection drug use exposures were enrolled. No seroconversions were observed among those who completed treatment, those who did not complete or those who did not receive treatment (Kahn, JO, 2001). In a BC study of 590 persons who completed a course of non-occupational PEP, none seroconverted (Braitstein et al, 2001).

Cost-Effectiveness of PEP

Most studies have found that a widespread NPEP program is not cost-effective, although the intervention is cost-effective for the highest-risk exposures. It would appear that NPEP is cost-effective only after high-risk exposures, such as unprotected receptive anal intercourse, or when the source was known to be HIV positive (Guinot et al, 2008). These studies also indicated that cost-effectiveness is dependent on the proportion of high-risk exposure, the seroprevalence in the population, the proportion of sources whose HIV status was known and the treatment completion rate, as well as assumptions about the rates of HIV transmission and the effectiveness of NPEP.

These factors make NPEP an appropriate intervention for gay men, given the seroprevalence in the community, the proportion of known infections and the capacity of gay men to adhere to a drug regime.

Publicly funded NPEP has been provided in Australia since 1998 through hospitals, doctors and sexual health clinics. A study of 1601 patients found NPEP to be cost-effective after unprotected receptive anal intercourse exposure to an HIV-positive source, when the lowest risk estimates were used. NPEP was found to be cost-saving for receptive anal exposure to an HIV-positive source when the highest risk-estimates were used. NPEP was not found to be cost-effective after insertive anal intercourse, heterosexual exposure, or percutaneous exposure among injecting drug users.

The effect of NPEP on Risk-taking

There is an argument that making NPEP available to gay men will increase their sexual risk-taking if they rely on a so called 'morning-after pill' for HIV prevention, rather than condoms. A study in San Francisco suggests the opposite. Their results have found that a course of NPEP might actually reduce further risk-taking, as individuals experience a sample of life on ARV's (Martin et al, 2004). As well, NPEP provision creates another intervention opportunity to decrease high-risk behavior.

Twelve months after receiving NPEP, 83% of participants did not request a repeat course of NPEP, 73% reported a decrease in high-risk incidence, 13% reported no change and 14% had an increase in high-risk behavior. Of the sample of gay men and IDUs, three gay men seroconverted for HIV, but not as a result of the exposure they originally presented. After receiving NPEP and behavioural counseling following an exposure, most individuals did not increase their high-risk behaviour. This study concluded that NPEP should be routinely considered following high-risk exposures (Martin et al, 2004).



In a behavioural intervention trial of 4,295 MSM in the US, researchers found that individuals who use NPEP are more likely to engage in high risk sex, however, the availability of NPEP did not increase risk-taking among individuals reporting low or high risk activities (Donnell et al, 2010).

Experiential Anecdotes⁴

Case 1

Male (MSM) client presented at the clinic stating he had relapsed on cocaine after 4 years of abstinence. He has been in a monogamous relationship with an HIV negative partner for 18 months. His last HIV test was one year prior. During the previous days he had gone to a bathhouse and had unprotected receptive anal sex with multiple anonymous partners. Twenty four hours after the exposure he had presented at the emergency department of St Paul's Hospital and requested assistance. At that time he was counseled not to take post-exposure prophylaxis as the risks of taking the medication outweighed the risk of acquiring HIV. He was told that his chances of acquiring HIV were less than 1 in 5000.

The client was anxious regarding his risks and able and eager to pay for PEP himself. When the client came to the clinic it was approximately 50 hrs post-exposure and I advised him to go to Vancouver Hospital and request PEP. Once again he was advised that PEP was not warranted due to the unknown HIV status of his partners. The client accepted this advice. Client subsequently attended the clinic (2 months after the incident) and tested for HIV. That test was reactive for HIV.

Case 2

Male (MSM) client presented at the clinic for HIV testing. Client was tested for HIV six months prior and test was non-reactive. The client stated that he was engaging in consensual anal sex with a partner of unknown status when that partner despite being requested to use a condom for penetrative anal sex, removed the condom during sex and ejaculated into the client. Client discovered this afterwards. Client states that he went to St Paul's hospital emergency department for assistance 36 hours after. The physician declined to write a prescription for PEP as the risk of seroconversion was not significant enough. Client was told to test for HIV in 3 months. Client was not given the option of paying for the meds himself. The client's HIV test came back reactive.

4. Experiential Anecdotes were submitted by a Street Nurse from the BC CDC who regularly tests gay men in Vancouver.

Case 3

Male (MSM) client states that after engaging in consensual unprotected receptive anal sex with a partner he had met 'online', he found HIV medications in the man's bathroom. The client went to the emergency department of St Paul's Hospital 12 hours later and asked for post-exposure prophylaxis. At that time he was told that he did not meet the criteria for post-exposure prophylaxis. Client was not given the option of paying for the meds himself. Client was clear that he wished to take PEP. Client left without a prescription. Client's HIV test done one week post-exposure was negative. Subsequent testing for HIV was reactive.

RECOMMENDATIONS

Protocols and guidelines for physicians should be developed for non-occupational PEP, similar to those for occupational exposure, independent of the issue of payment. The protocol needs to include procedures whereby clients may obtain a prescription from a qualified physician. These guidelines are best developed and supported by the appropriate agency, in this case, the BC Centre for Excellence in HIV/AIDS.

Awareness and the responsible use of PEP as an HIV prevention tool should be promoted by a local, trusted community organization, with expertise in knowledge translation. This information should also be disseminated through the medical system to caregivers in an easy-to-apply format, and made available to the community in an appropriately accessible medium.

Counseling should be made available to men seeking PEP, so that they might make informed decisions, and seek out support in reducing future risk events.

A protocol should be developed to determine who pays for PEP when accessed as the result of a non-occupational exposure.

ACTIONS

The Health Initiative for Men will request, on behalf of gay men in Vancouver, for the BC Centre for Excellence in HIV/AIDS to further develop their PEP guidelines and protocols to address exposures related to consensual sex.

The Health Initiative for Men will collaborate with stakeholders, including the gay community, to determine and disseminate a process for access to PEP for exposures related to consensual sex.

The Health Initiative for Men will promote and create an awareness of PEP as an HIV prevention tool for gay men as a part of its comprehensive risk-reduction and harm-prevention strategies.

HIM will continue to promote their Health Promotion, Peer Support and Counseling services to gay men wishing to reduce their sexual risk-taking.

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