HIV PEP Study Final Report

A Prospective Cohort Study of HIV-1 Post-Exposure Prophylaxis in Ontario Sexual Assault Victims/Survivors

EXECUTIVE SUMMARY

Each year the Ontario Network of Sexual Assault/Domestic Violence Care & Treatment Centres (SATCs) provides post-assault care for approximately 2,000 women, men and children who are victims of a sexual assault. SATCs help victims/survivors to deal with trauma and the medical consequences of assault including the possibility of contracting sexually transmitted infections. The human immunodeficiency virus (HIV) is a sexually transmitted infection with potentially fatal consequences, but it is only with the relatively recent development of more effective antiretroviral medications that prophylactic treatment has been possible.

HIV is a growing issue in Canada. Transmission through heterosexual contact is steadily increasing and now accounts for approximately one-third of all new infections annually (UNAIDS, 2005*a*). Physiologically, women are at increased risk of HIV acquisition if exposed to the virus, and this risk may significantly increase due to the presence of other factors in sexual assault (e.g., physical trauma; presence of blood or STIs). Well over 90% of SATC clients are women.

HIV post-exposure prophylaxis (PEP) has been recommended to prevent transmission of HIV following non-occupational sexual exposure (CDC, 2005), but available research and guidelines to practically implement this recommendation are limited and have often been inconsistent. The HIV PEP Study was initiated to implement a program of universal offering of HIV PEP in Ontario's SATCs and to collect data prospectively to identify factors crucial to enabling an effective and sustainable province-wide response. The HIV PEP Study was conducted by the Ontario Network of SATCs in partnership with the Centre for Research in Women's Health (CRWH) and with the support of the Ontario Women's Health Council (OWHC).

The HIV PEP Program Development

In Canada, only British Columbia (BC) has implemented guidelines and a province-wide program offering victims/survivors of sexual assault access to HIV PEP. The BC guidelines restrict access to free HIV PEP medications to those victims/survivors assessed to be at high-risk of HIV acquisition. No other Canadian jurisdiction currently has guidelines in place for the provision of HIV PEP in the context of sexual assault and the decision to offer HIV PEP to a victim/survivor of sexual assault relies completely on the discretion of an individual physician or team, and/or the awareness about HIV PEP held by the individual client.

No Ontario protocols or guidelines for provision of HIV PEP in the context of sexual assault were in place when the HIV PEP Study was initiated. In order to develop guidelines to implement a program in Ontario, the Research Team surveyed the existing literature and gathered policies for HIV PEP after sexual exposure in those few jurisdictions where policies existed. These policies including the BC guidelines were used to inform the development of medical protocols and patient handouts. The Research Team and the expert advisory group reviewed the evidence on HIV prophylaxis for occupational, non-occupational and maternal-infant exposures and decided on a drug regimen of Combivir® (1 pill orally twice a day) and Kaletra® (3 capsules orally twice a day)

for a total of 28-days. The universal HIV PEP program implemented as part of this study included the following characteristics:

- All clients to receive counselling about potential HIV risks;
- All clients whose assault poses any risk of HIV infection (known or unknown) to be offered prophylactic medication;
- Prophylaxis to be "strongly recommended" for clients assessed to be at high-risk of infection;
- Prophylaxis to begin within 72 hours of exposure;
- Prophylaxis to be prescribed for a period of 28-days;
- An intensive schedule of five follow-up visits to assist clients who choose the prophylactic drugs to cope with side effects and complete the medication course; and,
- Prophylaxis to be provided at no cost to clients.

To support the universal offering of HIV PEP, the study created a train-the-trainer program for Health Care Providers (HCP) at local SATCs and produced resources to guide client counselling on HIV risk. A network of local HIV experts was recruited to support SATC staff. It was negotiated with pharmacists and other hospital personnel that HIV medications be available within the programs of each participating SATC.

HIV PEP Study Design

The HIV PEP Study design was a prospective cohort design. Once SATCs implemented the universal HIV PEP program, data was collected prospectively on every consecutive sexual assault victim/survivor seen by the participating SATCs. Victim/survivor, assailant and assault characteristics were collected at the Initial Visit and data on victim/survivor compliance and experience on HIV PEP medications were collected at each follow-up visit. Surveys and focus groups gathered SATC HCP opinions of the universal HIV PEP program. A client satisfaction questionnaire and in-depth interviews gathered victims/survivors' opinions.

HIV PEP Study Results

The program operated in 24 of Ontario's 34 SATCs from September 2003 to January 2005. Of the 1,103 clients that were included in the final analyses, 81 (7.3%) clients were assessed as having no-risk of HIV exposure, 88 (8.0%) clients were considered high-risk and the remaining 934 (84.7%) were classified as unknown-risk. Most clients presented to the SATCs within 72 hours of their assault (89.0%) and only one client presented as HIV-positive. After excluding clients who presented later than 72 hours, were already HIV-positive, or were at no-risk of infection, 900 clients (81.6%) were eligible for HIV PEP.

Although the medical protocol specified offering HIV PEP universally to these clients, some refused care before the offer could be made or had life circumstances that made them unable to comply with the HIV PEP regimen. There were also some circumstances in which HCPs judged the risk of infection to be too low to offer HIV PEP, despite study protocols, reflecting the challenges of risk assessment after sexual assault. Offers and acceptance of HIV PEP and the completion of the 28-day HIV PEP regimen were as follows:

	HIV PEP Offered	HIV PEP Accepted	28-day Course Completed
High-risk	97.2%	66.7%	23.9%
Unknown-risk	87.9%	41.3%	33.2%

These data reveal remarkably high rates of both acceptance of HIV PEP and completion of the medication course, in comparison to those reported in other jurisdictions. The rates of acceptance suggest that sexual assault victims/survivors in Ontario are receptive to the provision of HIV PEP. Clients classified as high-risk were 2.2 times more likely to accept HIV PEP than those classified as unknown-risk. This was true even when controlled for the strength of the HCP's recommendation, client's overall anxiety and other factors. This suggests that a client's assessment of her/his own need for prophylactic medication was strongly influenced by an assessment of their assailant as 'high-risk'. This influence does not affect completion rates, however, as high-risk clients were no more likely to complete the regimen than the unknown-risk clients.

Other factors also influenced both acceptance of HIV PEP and completion of the medication course. Clients attacked by strangers and those whose assaults involved multiple sex acts and multiple injuries were more likely to accept HIV PEP, as were clients perceived by HCPs as having moderate or high rates of overall anxiety. Clients assaulted by strangers and those with moderate or high rates of anxiety were also more likely to complete the course of treatment. These findings underscore the value of offering HIV PEP universally, since many clients assessed at unknown-risk of infection that would accept and complete a course of HIV PEP if offered, would be ineligible for the treatment within a narrower, high-risk framework.

The completion rate for HIV PEP in this study is almost three times that reported in an earlier study in British Columbia. This suggests that the study's relatively intensive program of five follow-up visits may have been a more effective strategy for supporting clients' decisions to take prophylaxis and for helping them deal with side effects. Side effects were a significant burden to victims/survivors with 77% of those who accepted HIV PEP experiencing moderate to severe symptoms (Grades 2-4 on the NIAID/NIH toxicity grading). Although side effects were the most common reason given for discontinuing HIV PEP, their level of severity did not predict whether clients chose to stop the medications.

Health Care Provider Opinions

HCPs were surveyed about their experiences and views of the universal HIV PEP program. Respondents were 132 frontline HCPs and 21 Follow-up Care Providers. As well, 26 HCPs participated in focus groups.

It was clear from most HCP data that although the universal HIV PEP program made additional demands on staff, HCPs felt that the program improved the overall services provided to victims/survivors of sexual violence and addressed a major client concern. The extensive follow-up schedule, although resource intensive, was believed to have enhanced services by providing more opportunities to counsel clients and refer them to other agencies as needed as well as to provide support in managing HIV PEP medications. HCPs had concerns about the sustainability of the program with funding for medications being the principal concern. Some respondents also indicated

that financial support for increased staff resources and administrative time would be necessary to sustain the program.

In response to the survey question about the optimal strategy for offering HIV PEP, 27% of HCP endorsed a "universal offering" strategy, while 55% endorsed a strategy of offering HIV PEP to high-risk clients and those unknown-risk clients who request HIV PEP. In the focus groups, where this issue could be explored in more depth, many participants expressed reservations about recommending treatment, preferring to counsel clients in a more neutral manner. As part of the "universal offering" in this study, HCP were asked to "strongly recommend" HIV PEP to high-risk clients and to "recommend" to unknown-risk clients. From the HCP responses, it appears that it is the idea of "recommending" that the HCPs were resistant to and not the idea of providing HIV PEP to all at risk clients. In fact, more than two thirds (68.9%) of HCP indicated that they believed that it is beneficial to offer HIV PEP to the unknown-risk group.
Overall, HCPs endorsed a province-wide universal program that includes broad standardised protocols and enough flexibility in program delivery to address the unique needs of each community, SATC and individual client. A sustainable universal HIV PEP program in Ontario will need a Ministry-endorsed best practices framework for the delivery of HIV PEP that addresses this need for flexibility. Training which incorporates the experiential knowledge of frontline HCPs will be crucial to any universal HIV PEP program's ongoing success.

Client Opinions
Confidential surveys were collected from 60 clients and qualitative interviews were completed with five. Clients emphatically praised the knowledge and professionalism of SATC staff and their capacity to answer questions about HIV risk and other related issues. More than 75% felt they completely understood their HIV risk as explained by their HCP as well as their options for prophylactic treatment. While 35% of clients were still very or moderately anxious about contracting HIV after speaking with a HCP, this rate was lower than that reported prior to speaking with a HCP (60%). Clients were very positive about the HIV PEP program, despite the side effects of the medications that many of them experienced. They were generally very satisfied with the care they received at the SATCs, both in terms of general post-assault care and the HIV PEP program. Many clients expressed their gratitude for having had access to the HIV PEP treatment, and called for the continuation of the program.

Cost Implications for Sustaining an Ontario Universal HIV PEP Program for Sexual Assault Victims/Survivors
The HIV PEP Study has established the framework for a vital component of a comprehensive HIV care program. High rates of uptake and completion of HIV PEP and the strong support of SATC HCPs point to the success of the program. According to client and HCP data, SATC clients are overwhelmingly grateful for these services and the opportunity to address their HIV fears. The cost for a complete 28-day course of HIV PEP medications is $1,108, a substantial burden to an individual victim/survivor. Based on the results of this study the estimated annual cost of a universal HIV PEP program in Ontario is approximately $450,000. With adequate funding and the knowledge gathered in this study, Ontario could continue to offer an effective program to prevent HIV infection of sexual assault victims/survivors. Because this study operated across the province, much of the infrastructure remains in place and could be used as the foundation of a universal program of HIV PEP. The recommendations provided in this report could guide the official roll-out of an equitable province-wide program flexible enough to meet the diverse needs of local communities.

RECOMMENDATIONS

Based on the HIV PEP Study findings, recommendations to the Ontario Women's Health Council/Ministry of Health and Long-Term Care are as follows:

- ✓ Universal offering of HIV post-exposure prophylaxis (PEP) through the Ontario Network of Sexual Assault/Domestic Violence Care & Treatment Centres (SATC) be expanded province-wide.
- ✓ Ongoing funding for universal offering of HIV PEP medications to all SATC clients at risk of contracting HIV.
- ✓ HIV PEP guidelines or a best practice statement be issued based on the findings of this study and the current research literature.
- ✓ Develop strategies for addressing differential access to effective HIV PEP treatment in rural/urban/remote communities.
- ✓ HIV PEP training be revised to include a more comprehensive discussion of risk assessment, and an integration of other issues and concerns raised by Health Care Providers and clients, and be incorporated into Sexual Assault Nurse Examiner training curriculum.
- ✓ A provincial advisory committee be formed to ensure that the HIV PEP care is evidence-based and that medical protocols are consistently updated.
- ✓ Measures be undertaken to support the ongoing monitoring of HIV PEP delivery in Ontario.
- ✓ Information about the availability of HIV PEP be distributed to the public, social service agencies, health care centres, and affiliated professional organisations in order to raise awareness in the community about the program