

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

HIV PEP Study

FINAL REPORT

DECEMBER 20, 2005

Report by the HIV PEP Study Research Team
Submitted to The Ontario Women's Health Council

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CONTENTS

SECTION	ITEM	DESCRIPTION	PAGE NUMBER
		GLOSSARY OF TERMS	iii
		FORWARD	v
		EXECUTIVE SUMMARY	vi
		RECOMMENDATIONS	x
1		RATIONALE	1
	a)	Literature Review	1
2		PROGRAM DEVELOPMENT & ORGANISATION	9
	a)	Context of the Study	9
	b)	Partners	9
	c)	Objectives	12
	d)	Study Strategy	13
	e)	Drug Regimen	15
	f)	Training of SATCs	15
	g)	Program Guidelines	16
	h)	Research Ethics	17
	i)	Establishment of Expert Support Network for HIV PEP Program	17
3		INITIAL AND FOLLOW-UP VISITS	21
	a)	Method	21
	b)	Results	22
	c)	Summary	36
4		HCP PERCEPTIONS OF HIV PEP PROGRAM	39
	a)	HCP Survey	39
	b)	Follow-up Care Provider Survey	51
	c)	HCP Focus Groups	60
	d)	HCP Suggestions	70
5		CLIENT VIEWS OF HIV PEP PROGRAM	71
	a)	Client Satisfaction Questionnaire	71
	b)	Client Interviews	75
	c)	Client Suggestions	81
6		CONCLUSION & RECOMMENDATIONS	82
	a)	Introduction	82
	b)	The Case for Universal Offering	83
	c)	The Feasibility of Universal Offering	86
	d)	The Sustainability of Universal Offering	87
		REFERENCES	91
		LIST OF APPENDICES	96
		ACKNOWLEDGEMENTS	97

FIGURES & TABLES

SECTION	ITEM	DESCRIPTION	PAGE NUMBER
2	Figure 1	HIV PEP Risk Assessment	14
	Figure 2	Initial Visit Flow Sheet	19
	Figure 3	Follow-up Visits Flow Sheet	20
3	Figure 4	Number of Clients and Months of Participation by 18 SATCs Included in Analyses	23
	Figure 5	Eligibility for and Offering of HIV PEP by Risk Group	24
	Table 1	Reasons HIV PEP Not Offered	25
	Table 2a	Characteristics of Clients Eligible for and Offered HIV PEP	27
	Table 2b	Characteristics of the Assault Sustained by Clients Eligible for and Offered HIV PEP	28
	Figure 6	Acceptance of HIV PEP by Risk Group	29
	Table 3	Reasons HIV PEP Not Accepted	30
	Table 4	Predictors of HIV PEP Acceptance	31
	Figure 7	HIV PEP Completion by Risk Group	32
	Table 5	Client Reasons HIV PEP Not Completed	33
	Table 6	Predictors of HIV PEP Completion to Day 28	34
	Table 7	Symptoms Experienced by Clients During Follow-up	35
	Figure 8	Grade 2 to 4 Symptoms Reported by Clients During Follow-up	35
	Table 8	Health Care Provider Survey Results	40
	Table 9	Follow-up Care Provider Survey Results	52
	Table 10	Health Care Provider Focus Groups, Topics of Discussion	60
5	Table 11	Client Satisfaction Questionnaire Results	72
	Table 12	Client Interviews, Topics of Discussion	76

ACRONYMS

AIDS	Acquired Immunodeficiency Syndrome
CRWH	The Centre for Research in Women's Health
HIV	Human Immunodeficiency Virus
HIV PEP	Human Immunodeficiency Virus Post-Exposure Prophylaxis
HCP	Health Care Provider
IVDU	Intravenous Drug User
MSM	Man who has Sex with Men
MOHLTC	Ministry of Health and Long-Term Care
NIAID/NIH	National Institute of Allergy and Infectious Diseases/National Institutes of Health
(N)NRTI	(Non) Nucleoside Reverse Transcriptase Inhibitors (Antiretroviral drug)
OWHC	Ontario Women's Health Council
PI	Protease Inhibitor (Antiretroviral drug)
SANE	Sexual Assault Nurse Examiner
SATC	Sexual Assault/Domestic Violence Care & Treatment Centre
STI	Sexually Transmitted Infection

GLOSSARY OF TERMS

Antiretroviral Drugs

Medications for the treatment of infection by the retrovirus HIV. Antiretroviral drugs suppress the activity or replication of retroviruses and interfere with various stages of viruses' life cycles. Different antiretroviral drugs act at various stages of the HIV life cycle (The Body, 2005: <http://www.thebody.com/glossary.html>).

HIV Post-Exposure Prophylaxis (PEP)

Antiretroviral drugs that may prevent HIV infection if initiated following unanticipated exposure to blood, genital secretions, or other potential infectious bodily fluids of a person known to be HIV infected or known to have HIV risk factors. Recommended initiation of HIV PEP medications is less than 72 hours following exposure to potential HIV sources (Centers for Disease Control and Prevention, 2005).

Incidence

The number of new events of a specific disease during a specified period of time in a specified population. HIV incidence among Canadians is the number of new HIV infections occurring in a specified period of time in Canada (Public Health Agency of Canada, 2005).

Non-occupational Exposure

All situations in which accidental or forced contact with potentially HIV-infected blood or other bodily fluids such as semen or vaginal secretions occur, including unprotected sexual exposure, sexual exposure with broken or slipped condom, IVDUs sharing material, accidental needle stick, bite wound, or mucosal exposure (EURO-NONOPEP, 2002).

Occupational Exposure

All situations in which health care workers are exposed to potentially HIV-infected blood or other bodily fluids such as semen or vaginal secretions as a result of performing their duties in the health care setting (Centers for Disease Control and Prevention, 2005).

Prevalence

The total number of people with a specified disease or health condition living in a defined population at a particular time. HIV prevalence among Canadians is the total number of people living with HIV infection (including those with AIDS) in Canada at a particular time (Public Health Agency of Canada, 2005).

Risk Factors

An aspect of someone's behaviour or lifestyle, a characteristic that a person was born with, or an event that he or she has been exposed to that is known to be associated with a health-related condition. A behavioural risk factor describes a specific behaviour that carries a proven risk of a particular outcome. In HIV/AIDS research, the term "HIV related risk behaviour" is used to describe a behaviour that, when practiced, carries a proven risk of HIV infection (Public Health Agency of Canada, 2005).

For the purpose of this study, High-Risk was defined as:

An assault that includes both a high-risk exposure *and* a high-risk assailant.

A high-risk exposure includes: 1) oral, vaginal or anal penetration; *or* 2) an unknown assault exposure (e.g., victim/survivor was drugged and sexually assaulted and cannot recall circumstances of the assault).

A high-risk assailant is: 1) known to be HIV-positive; *or* 2) known to have HIV risk factor(s) including being an IVDU, a MSM or being from an Endemic Country.

Endemic Country – a country with an HIV prevalence of > 1% (e.g., many countries in Sub-Saharan Africa; and a few countries in the Caribbean and Latin America).

HIV-positive – a man/woman who is known to be infected with the Human Immunodeficiency Virus (HIV), a retrovirus that infects cells of the human immune system. It is widely accepted that infection with HIV causes AIDS (Acquired Immunodeficiency Syndrome), a disease characterised by the destruction of the immune system. Antibodies to HIV are one of the criteria for a diagnosis of AIDS.

MSM – a man who is known to engage in sexual activities with other men.

IVDU – a man/woman that is known to use drugs intravenously.

*For the purpose of this study **Unknown-Risk** was defined as:*

An assault that includes both a high-risk exposure *and* an unknown-risk assailant.

A high-risk exposure includes: 1) oral, vaginal or anal penetration; *or* 2) an unknown assault exposure (e.g., victim/survivor was drugged and sexually assaulted and cannot recall circumstances of the assault).

An unknown-risk assailant is: 1) unknown to the victim/survivor; *or* 2) known to the victim/survivor, but HIV status is unknown.

*For the purpose of this study, **No-Risk** was defined as:*

An assault that involves no potential exposure to HIV, including no oral, vaginal or anal penetration. Risk category of assailant is not a consideration.

Seroconversion

The root “sero” means the serum of the watery portion of blood. In HIV/AIDS research or practice, seroconversion refers to the development of detectable antibodies to HIV in the blood as a result of HIV infection. A person who goes from being HIV-negative to HIV-positive is said to have seroconverted or is a seroconverter (Public Health Agency of Canada, 2005).

Toxicity Grading

For the purposes of the study, drug toxicities (symptoms/side effects) were uniformly described as grade 1 to 4, using the National Institute of Allergy and Infectious Diseases/National Institutes of Health (NIAID/NIH) standardised toxicity-grading system. Severity of symptoms/side effects can generally be categorised as:

Grade 1 Mild Transient or mild discomfort (<48 hours); no medical intervention/therapy required

Grade 2 Moderate Mild to moderate limitation in activity; some assistance may be needed; no or minimal medical intervention/therapy required

Grade 3 Severe Marked limitation in activity; some assistance usually required; medical intervention/therapy required, hospitalisations possible

Grade 4 Life-threatening Extreme limitation in activity; significant assistance required; significant medical intervention/therapy required, hospitalisation or hospice care probable

SATC staff were asked to report serious side effects (grade 4) and deaths to the central coordinating centre, the Centre for Research in Women’s Health (CRWH); grade 1-3 toxicities were managed at the discretion of the SATC/Emergency Department physicians.

Universal Offering

Offering HIV PEP to all those sexual assault victims/survivors at risk of HIV acquisition including those assessed as high-risk or unknown-risk.

FORWARD

The Sexual Assault/Domestic Violence Care & Treatment Centres (SATC) across Ontario are appreciative of having had the opportunity to implement and evaluate a strategy for the provision of HIV Post-Exposure Prophylaxis (HIV PEP) to victims/survivors of sexual assault.

Our clients had increasingly expressed concern regarding their possible risk of HIV exposure from an assault. Given that we routinely discuss and offer prophylaxis for other sexually transmitted infections, it seemed inappropriate to not adequately address HIV concerns. Prior to this study, the care and response to this issue varied across programs. The response ranged from offering HIV PEP in certain situations to no discussion about HIV risk. Given the limited research available to guide clinical practice, it had been difficult to come to agreement about an appropriate response.

The implementation of this study has provided SATC staff with the knowledge and tools required to provide a comprehensive approach to address this issue with clients. Province-wide train the trainer sessions have enabled key staff from each SATC to attend an in-depth training which in turn assisted them in training their own team members. A resource manual, risk assessment tool, documentation form, medical protocols, client information handouts provided both staff and clients with the necessary information to assist in the decision-making process.

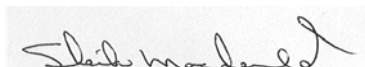
The results of the study, captured through data collection forms, Health Care Provider (HCP) surveys and focus groups, and client interviews consistently indicate that universal availability of HIV PEP for sexual assault victims/survivors is important. “Universal” means that all victims/survivors of high- or unknown-risk have the opportunity to choose the treatment. “Availability” means that the medications are stocked at the SATC for immediate use and are free of charge to the client.

The results of this study will ensure that Ontario SATCs have a standardized and consistent approach in addressing HIV prophylaxis for sexual assault victims/survivors. Other sexual assault services outside Ontario are also interested in our findings, as they are looking for guidance in responding to their own client populations.

The tremendously successful implementation of the universal HIV PEP program, accomplished by this study, has effectively created the momentum to translate research into policy.

We trust that this report provides the information required to support ongoing and secured funding for HIV prophylaxis for Ontario’s sexual assault victims/survivors.

Sincerely,



Sheila Macdonald RN, MN

Provincial Coordinator for Sexual Assault/Domestic Violence Treatment Centres (SATC)

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, 2005a). 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.

CHAPTER 1

RATIONALE

Literature Review

1. RATIONALE

a) Literature Review

Introduction

Post-exposure prophylaxis (PEP) with antiretroviral therapy has been recommended to prevent transmission of HIV following occupational and non-occupational exposures such as unprotected sexual activities and injection drug use (CDC, 2001, 2005). There is a growing recognition that victims/survivors of sexual assault should be considered and assessed for HIV PEP. Guidelines have been developed for the provision of HIV PEP following sexual assault in a number of jurisdictions and experiences of such programs have been widely reported in the literature (Bamberger, 1999; California Department of Health Services, n.d.; Comay, 1998; Fong, 2001; Gostin, 1994; Larkin, 1998; Limb *et al.*, 2002; Massachusetts, 2000; Merchant *et al.*, 2004; Moe, 2001; Myles, 2000; Stevens, 2001; Wiebe *et al.*, 2000). However, to date, there has been no prospective study examining the impact of universal offering of HIV antiretroviral therapy to sexual assault victims/survivors.

Prevalence and Incidence of HIV in Canada

At the end of 2002, the total number of people in Canada living with HIV/AIDS infection was estimated to be 56,000. The number of new infections (incidence) of HIV in 2002 was estimated to be between 2,800 and 5,200. The rate of newly infected Canadians annually has remained at a similar rate since 1999. Eighty-five percent of Canada's population resides in the provinces of Ontario, Quebec, British Columbia and Alberta. These four provinces account for over 95% of reported HIV and AIDS diagnoses (Public Health Agency of Canada, 2005).

In Canada's jails and prisons HIV prevalence is disproportionately high for two primary reasons. First, people entering prison tend to have a relatively high incidence of HIV. Second, prisons provide an environment for increased transmission of the virus due to high-risk behaviours such as IVDU, unprotected sex, and coerced/violent sex (Bamberger *et al.*, 1999; Canadian AIDS Society, 2004). The proportion of sex offenders in Canada that may have been to prison, and which may therefore be at higher risk of HIV infection, is difficult to determine.

HIV prevalence may also be disproportionate within various communities across Canada. When HIV prevalence is high within a community, the probability of being exposed to HIV during a sexual assault is increased (Roland, 2004). Assaultants that have immigrated to Canada from HIV endemic areas may pose a higher HIV risk to their victims. Sub-Saharan Africa suffers from the highest HIV prevalence rates in the world and is home to more than 60% of all people living with HIV (UNAIDS, 2005b). The absolute implication of immigration on Canada's HIV prevalence has not yet been determined, however, due to the new HIV testing policy for immigrants and refugees implemented by Citizenship and Immigration Canada on 15 January 2002 (Citizenship and Immigration Canada, 2002), there has been a marked increase in reported HIV diagnoses (Public Health Canada, 2003). In 2002 it was estimated that there were approximately 3,700 to 5,700 pre-existing infections and 250 to 450 new infections among heterosexual people who were born in a country where HIV is endemic, representing approximately 7% to 10% of the overall prevalence and 6% to 12% of new incidences of HIV in Canada (Public Health Canada, 2003).

Although men who have sex with men (MSM) and intravenous drug users (IVDU) continue to account for the greatest number of new infections (1,000-2,000 and 800-1,600, respectively in 2002), the main patterns of HIV transmission are currently shifting. The proportion of new infections attributed to heterosexual exposure has steadily increased since the beginning of the HIV/AIDS epidemic in Canada (600-1,300 in 2002) (Public Health Agency of Canada, 2005). Almost one third of new infections are transmitted through heterosexual contact (UNAIDS, 2005a).

The most recent statistics (2002) estimate that 7,700 Canadian women are living with HIV/AIDS, accounting for approximately 14% of the national total. Between 600-1,200 Canadian women became newly infected with HIV in 2002, representing 23% of all new infections. Heterosexual contact is the main risk factor for HIV infection in women (Public Health Agency of Canada, 2005).

Risk Factors in Transmission of HIV

A person infected with HIV carries the virus in body fluids (e.g., blood, semen, vaginal secretions, and breast milk). The virus is transmitted when HIV-infected fluids enter the bloodstream of another person. Transmission can occur through the linings of the vagina, rectum, mouth, or the opening at the tip of the penis, intravenous injection with a syringe, or through a break in the skin, such as a cut or sore. HIV is typically transmitted through unprotected sexual intercourse (oral, vaginal or anal) with someone who is HIV-infected, sharing needles/syringes with someone who is HIV-infected, or infection during pregnancy, childbirth, or breast-feeding (mother-to-infant transmission) (The Body, 2005).

Risk of HIV infection following exposure is dependent upon the type of exposure itself, but also on a number of co-factors, such as infectivity of the source (high plasma viral load increases risk), presence of genital/oral ulcers, and presence of sexually transmitted infections (STI) or bleeding (EURO-NONOPEP, 2002). STIs increase the risk of HIV transmission by at least two to five times (WHO, 2004).

HIV can be transmitted from women to men, men to women, and from men to men. However, women are at greater risk of HIV infection through vaginal sex due to the greater area of mucus membranes in the vaginal area. Anal sex (whether male-male or male-female) poses the highest risk to the receptive partner, because the lining of the anus and rectum is extremely thin and filled with small blood vessels that can be easily injured during intercourse (The Body, 2005).

Unprotected oral sex has been associated with HIV infection, however the actual risk of HIV transmission is difficult to assess because HIV seroconverters may underreport other higher risk sexual practices that may have lead to their seroconversion (Public Health Agency of Canada, 2005). Exposure to saliva alone presents a negligible risk for transmission due to an enzyme present in it that inhibits HIV transmission. However, oral trauma, inflammation, the presence of sores or concomitant STIs, ejaculation in mouth, and/or systemic immune suppression are factors that potentially increase risk of HIV transmission through oral sex (Public Health Agency of Canada, 2005).

Sexual Assault in Canada

The most detailed Canadian information on sexual assault is captured within the 1993 Violence Against Women national survey. A total of 39% of women reported having had experienced at least one incident of sexual assault since the age of 16 (FPT Ministers Responsible for the Status of Women, 2002). More recent information regarding sexual assault in Canada is compiled annually by

Statistics Canada based on data provided by police departments across the country. Sixty-one percent of sexual offences reported to police in 2002 were children and youth under 18 years of age. Eighty-five percent of victims/survivors of sexual offences reported to police were girls. Rates were highest among female victims/survivors aged 11 to 19, with the peak at age 13 (Statistics Canada, 2003).

The rate of reported sexual offences in Canada has remained relatively steady since 1999. In 2002, there were 27,100 sexual offences reported to police, representing a rate of 86 incidents for every 100,000 population; in 1999 the rate was 89 (Statistics Canada, 2003). It is important to note, however, that victimisation surveys suggest that less than 10% of women who are sexually assaulted report their assault to the police (FPT Ministers Responsible for the Status of Women, 2002). Police data must be weighed with the knowledge that they significantly underestimate the incidence of sexual assault and only represent a small portion of all sexual offences and offenders. Once reported, sexual offences are also less likely than other violent offences to result in charges and convictions (Du Mont & Myhr, 2000; Statistics Canada, 2003).

Risk of Contracting HIV through Sexual Assault

The risk of contracting HIV through sexual assault is dependent on a number of factors that are often difficult to determine or are unknown. These factors include the serologic and clinical status of the assailant (Hall, 1995), the type of sexual assault perpetrated (vaginal, anal, or oral), the frequency of assaults, and amount of associated trauma (Bamberger *et al.*, 1999; Gostin, 1994; Limb *et al.*, 2002), the presence of other sexually transmitted infections (Bamberger *et al.*, 1999; Royce, 1997), and the amount of exposure to sexual secretions and/or blood.

In the context of sexual exposure, receptive anal intercourse has the highest risk of HIV transmission. The reported per-contact HIV infectivity rate is approximately 20 infections per 1,000 contacts (Pinkerton, 1999; Pinkerton *et al.*, 1998) with an HIV-infected partner. The estimated per-contact HIV infectivity rate from male to female penile-vaginal intercourse has been reported as less than 2 per 1000 contacts (Downs & De Vincenzi, 1996; Pinkerton *et al.*, 1998) with an HIV-infected partner. These average risks must be interpreted cautiously, however, because the efficiency of transmission varies widely and a number of factors influence the susceptibility and infectiousness of the victim/survivor, such as physical trauma, the presence of open lesions, blood, or sexually transmitted infections (STI) (Royce *et al.*, 1997), which as noted above have been reported to significantly increase the probability of transmission. Frequently, genital injuries and high rates of STIs are documented in sexual assault victims/survivors (Reynolds, 2000).

In 2003, 96.5% (1,745/1,809) of sexual assault victims/survivors presenting to Ontario's SATCs were women (Ontario Network of Sexual Assault/Domestic Violence Care & Treatment Centres, 2003). In addition to a potentially increased risk of HIV transmission due to the nature of sexual assault, women are more physically susceptible to HIV infection than men. Male-to-female transmission during sex is approximately twice as likely to occur as female-to-male transmission (UNAIDS, 2004).

Given the multiplicity of factors affecting the risk of HIV transmission in a sexual assault situation, for the purpose of this study, the HIV infectivity rate was estimated to be in the same range as receptive vaginal or anal intercourse, between 2 to 20 infections per 1000 contacts with an HIV-infected partner. However, again, it is possible that this estimate is conservative due to the increased risks of HIV transmission associated with sexual violence.

Fear of Contracting HIV Among Sexual Assault Victims/Survivors

Fear of contracting HIV has become a major concern for sexual assault victims/survivors (Wiebe *et al.*, 2000), with some citing this fear as more worrisome than a possible pregnancy (Comay, 1998). The American National Women's Study (1992) is one of the largest and most thorough reports on the topic of sexual assault. Findings revealed that 40% of victims/survivors surveyed said they feared contracting HIV infection as a result of being assaulted. Despite this, the study found that 73% of sexual assault victims/survivors did not receive information about HIV transmission (National Victim Center, 1992). Such findings reinforce the need to ensure information on HIV is accessible to all sexual assault victims/survivors, to reassure those women who are at negligible risk and to advise those at higher risk about the medications available to potentially reduce the risk of HIV infection.

Preventing HIV Transmission after Sexual Assault

Traditional prevention programs such as safe sex initiatives cannot address the unique circumstances of sexual assault, thus a post-exposure prevention strategy to complement broader pre-exposure prevention campaigns is required.

HIV PEP medications are considered most efficacious if initiated as soon as possible following exposure to HIV (Almeda *et al.*, 2004; Bamberger *et al.*, 1999; FPT Advisory Committee on AIDS, 2002). Therefore, it is important that Health Care Providers (HCP) offer sexual assault victims/survivors information and counselling regarding HIV transmission/infection and potential treatment options (e.g., HIV PEP) as soon as possible following an assault. In 1998, the Centers for Disease Control (CDC) recommended that prophylaxis be given within 72 hours to individuals who had sexual intercourse with a known HIV-positive contact (CDC, 1998). The CDC continues to recommend this 72-hour post-exposure cut-off in their current guidelines (CDC, 2005). A 72-hour cut-off for administration of HIV PEP is also recommended and practiced across Europe (Almeda *et al.*, 2004; EURO-NONOPEP, 2002).

HIV PEP is currently widely used to address occupational exposure (CDC, 1996; Grulich, 2003) and in the prevention of mother-to-child transmission (Grulich, 2003; Peckham, 2000). Although only a small proportion of all new HIV infections occur in the occupational setting, this mode of transmission has received much more attention than transmission after sexual exposure (Grulich, 2003), within the context of HIV PEP studies.

Although HIV PEP has not been sufficiently studied in the sexual assault scenario, it has been adequately studied, and determined to be effective, in both occupational exposure and mother-to-child transmission scenarios. Cardo *et al.* (1997) conducted a case-control study of HCPs with occupational, percutaneous exposure to HIV-infected blood and concluded that the probability of HIV infection when taking HIV PEP following exposure was reduced by 81% (Cardo *et al.*, 1997). The risk of HIV transmission in the occupational setting varies from 0.9 to 3 infections per 1,000 contacts (CDC, 2001). Estimated rates of HIV transmission through sexual assault are similar to or higher than those in the occupational setting.

Equal Access to HIV PEP: Ethical and Legal Considerations

HIV PEP has been prescribed to both adults and adolescents post-sexual assault in North American hospitals and emergency departments (Babl, 2000; Merchant *et al.*, 2004; Myles *et al.*, 2000). Despite its availability, access to HIV PEP varies greatly, and largely depends upon the geographical area in

which the sexual assault occurred. In many cases, decisions to offer and initiate HIV PEP are made by an individual clinician (Stephenson, 2003), leading to further inconsistencies in HIV PEP delivery. Some sexual assault victims/survivors have been offered HIV PEP at Sexual Assault Services that established their own response to HIV and that supplied the HIV PEP medications (Moe, 2001; Wiebe *et al.*, 2000).

HIV PEP is currently available to all HCPs in Ontario that are potentially exposed to HIV while working in the Health Care (occupational) setting. Provision of HIV PEP for occupational exposure to HIV is standard practice in Canada and has been available in most jurisdictions since the late 1990s (FPT Advisory Committee on AIDS, 2002). Non-occupational transmission has not received the same focus, despite the fact that HIV transmission rates after sexual intercourse with an infected partner are similar to those in an occupational setting and may be even higher if that sexual exposure occurs in the context of a sexual assault.

The rationale for limiting HIV PEP to occupational exposure is unclear, given the risk of transmission through non-occupational exposure (Fong, 1998). Several authors question the ethics of offering HIV PEP only to those individuals with occupational exposures (National Centre in HIV Epidemiology and Clinical Research and National Centre in HIV Social Research - PEP Working Group, 2000; Herland, 1999). Fong states that “[t]he ethical principle of fairness requires that clinically similar patients be treated similarly, regardless of the route of HIV exposure” (Fong, 1998).

The basic human right to health implies not only availability of functioning health care facilities and necessary goods and services, but also involves health care being accessible to everyone without discrimination (UNESCO, 2005). Canada’s health care system is founded on this principle of equal access for all. All Canadians are equally entitled to access the health system based on health needs, and not their ability to pay (Romanow, 2002). To maintain Canada’s health care mandate of universal accessibility, governments “have a responsibility to develop and administer the health care system for the common good of all and in a manner that provides equitable access and treatment for all Canadians” (Romanow, 2002: 51). Currently, in contrast to our national health care mandate, there is no equal access to HIV PEP following non-occupational exposure to HIV in Canada.

CDC Recommendations for Provision of HIV PEP Following Non-Occupational Exposure

Recommendations regarding antiretroviral post-exposure prophylaxis after sexual, injection-drug use or other non-occupational exposures to HIV were updated and published January 21, 2005 by the U.S. Department of Health and Human Services (CDC, 2005). HIV PEP of 28-days of highly active antiretroviral therapy was recommended for persons seeking care less than 72 hours after exposure to blood, genital secretions or other potentially infectious body fluids of a person known to be HIV infected. It was also recommended that if the exposure occurred to the blood, genital secretions or other potentially infectious body fluids of a person of unknown HIV status, and the type of exposure represented a substantial risk for transmission of the HIV virus, the risks and benefits of HIV PEP should be evaluated and offered on a case-by-case basis. HIV PEP was not recommended where the exposure history represented no substantial risk for HIV transmission or for those who presented more than 72 hours after exposure. Finally, it was recommended that if a person seeks care more than 72 hours after exposure, HIV PEP could be prescribed if the risks of transmission outweigh the diminished potential benefit of the drugs and their adverse effects.

A three-drug HIV PEP regimen was recommended based on the assumption that maximal suppression of viral replication would provide the best opportunity to prevent infection. A number

of regimens were suggested, but either of the following two regimens, 1) zidovudine/lamivudine (Combivir®) *plus* lopinavir/ritonavir (Kaletra®), or 2) zidovudine *or* tenofovir *plus* lamivudine *and* efavirenz were determined to be the optimal combination. Similar guidelines were recommended for their use in the treatment of antiretroviral naïve patients for a 28-day duration. Other recommendations made by the CDC were that efavirenz should be avoided in women of child-bearing age because of the risk of teratogenicity and follow-up care should be provided for management of adverse effects, ongoing provision of therapy to encourage adherence, monitoring of renal and hepatic function, and HIV serologic testing at baseline, 4-6 weeks, 3-months and 6-months post-exposure. A specific reference to sexual assault victims/survivors highlighted the benefits of supportive services to improve adherence to HIV PEP if prescribed (CDC 2005).

Existing Non-occupational HIV PEP Program Guidelines

Currently in Canada, British Columbia is the only province with a policy to address provision of HIV PEP in the context of sexual assault (Comay, 2005, personal communication; FPT Advisory Committee on AIDS, 2002). Internationally, Europe and several US States have created guidelines for HIV PEP in sexual assault (*see Appendix A for national and international guidelines*). Commonalities among these programs include: a 72-hour cut-off for the offering of HIV PEP (with the exception of British Columbia's 36-hour cut-off for unknown-risk clients/no cut-off for high-risk clients; and New York State's 36-hour cut-off); assessment of HIV risk; assessment of the appropriateness of HIV PEP (e.g., suitability of victim/survivor to HIV PEP regimen and follow-up schedule); HIV testing at the initial visit and at follow-up visits; and, a minimum of two follow-up care visits in addition to the initial visit (with the exception of California's extremely limited guidelines for follow-up) (EURO-NONOPEP, 2002; Massachusetts Dept. of Public Health, 2005; Myles & Bamberger, 2001; Non-occupational HIV PEP Task Force, 2002; NYSDOH AI, 2004).

Limited Research into Sexual Assault and HIV PEP

Until recently, the impact of possible HIV infection on victims/survivors of sexual assault received little attention (Bamberger *et al.*, 1999; Gostin, 1994). Although research in this area is now growing, a number of limitations and weaknesses exist among the few studies that have been carried out due to small sample sizes and the retrospective nature of data collection (Limb *et al.*, 2002; Merchant *et al.*, 2004; Myles *et al.*, 2000; Wiebe *et al.*, 2000).

Bamberger *et al.* (1999) attempted to address the lack of meaningful guidelines for provision of HIV PEP following sexual assault and to provide practical advice to HCPs caring for sexual assault victims/survivors. In 1999, a review of available data on the HIV transmission risk associated with sexual exposure, and the efficacy of HIV PEP in occupational settings was published, following the release of the CDC's recommendation for offering HIV PEP following sexual assault. There was general agreement within the literature on the following recommendations: treatment should be initiated no later than 72-hours post-exposure; HIV testing and HIV risk counselling should be offered to all sexual assault victims/survivors; and, HIV PEP should be provided in conjunction with counselling that recognises the physical and psychological trauma experienced by sexual assault victims/survivors (Bamberger *et al.*, 1999). Since Bamberger's study, several jurisdictions have wrestled with the challenges of developing effective, operational guidelines for HIV PEP programs in North America, and internationally.

In the state of New York, Merchant *et al.*, (2004) conducted a study to determine the impact of policy guidelines upon practice. The authors examined the extent of HIV PEP provision in a New York City paediatric emergency department following the release of the 1998 New York State

Department of Health guidelines governing the provision of HIV PEP following sexual assault. A retrospective review of medical records of 25 paediatric patients treated for sexual assault from January 1999 to December 2000 was conducted. Of the 25 patients seen by this service, 14 received HIV PEP following sexual assault. Merchant *et al.* reported that HIV PEP was ordered an average of 218 minutes after the patient presented to the emergency department and that drugs were received by patients an average of 58 minutes after they were ordered. The authors concluded that, due to increased efficacy of HIV PEP medications when therapy is initiated as soon as possible post-assault, expedited HIV PEP provision in emergency departments is essential. Suggested methods for improving the delivery of HIV PEP included educating emergency department practitioners on the proper use and delivery of HIV PEP and making the medications available for direct dispensement from emergency departments (Merchant *et al.*, 2004). Due to the retrospective nature of this study, no data were collected or reported regarding follow-up or drug adherence.

Limb *et al.* (2002) conducted a retrospective chart review of 150 patients at a sexual assault service in London, England in 1999. A total of 10 of 150 patients were considered eligible for HIV PEP. Provision, uptake and completion of HIV PEP were reviewed in these 10 patients. Eight (80%) patients eligible for and offered HIV PEP accepted the medications; 5 (62.5%) of these clients completed the 28-day course of treatment. The 3 (37.5%) patients that stopped HIV PEP treatment cited side effects as the primary reason. The authors attributed the high completion rate in the sample to careful selection of patients and to the multidisciplinary approach taken by the team (including an HIV pharmacist, dietician and clinical psychologist), and concluded that these two factors were necessary to improve adherence to HIV PEP treatment. Due to the retrospective nature of this study, HIV risk assessment and the criteria for the selection of patients offered HIV PEP were not noted. Moreover, drawing conclusions from this study is not possible due to the extremely small sample size.

A study by the San Francisco Department of Public Health conducted by Myles *et al.* (2000) included a significantly larger sample size. A retrospective chart review of 376 victims/survivors (213 of whom were offered HIV PEP) was carried out in order to determine the characteristics of those who choose to accept and complete HIV PEP treatment. A total of 69 (32.4%) clients offered HIV PEP accepted a 10-day starter kit of medications; 26 (37.7%) of those that accepted HIV PEP returned one week later to receive an additional 3 weeks of medication. Male victims/survivors were significantly more likely to accept HIV PEP. Predictors of HIV PEP acceptance in women were race (white), type of assault (not vaginal), and living situation (housed). The authors acknowledged the weaknesses of their study due to its retrospective design, including incomplete information in patient charts, which impeded the determination of possible predictors of HIV PEP uptake, and patient refusal of treatment, which may not have been properly documented. The authors concluded that further studies were needed to develop sound policy recommendations (Myles *et al.*, 2000).

The most comprehensive case series to date was carried out by Wiebe *et al.* (2000) in British Columbia. The provision of HIV PEP to sexual assault victims/survivors was examined via the implementation of a 16-month HIV prophylaxis program at the Vancouver Sexual Assault Service, operated by the Children's & Women's Health Centre of British Columbia. From November 1996 to February 1998, patients determined to be at moderate- to high-risk of HIV acquisition as a result of a sexual assault were offered HIV PEP. A total of 258 patients were seen by the service; 71 (27.5%) of those patients eligible for and offered HIV PEP accepted a 5-day starter kit; and 8 (11.3%) of these completed a 28-day course of medication. Risk status (high-risk) was found to be a predictor for both acceptance and completion of HIV PEP. Drug adherence and patient follow-up

were identified as primary problems during implementation of this service (Wiebe *et al.*, 2000).

Although each of these studies has contributed to our knowledge of HIV PEP in the context of sexual assault, several weaknesses are apparent. These include the retrospective nature of their study designs, small sample sizes, and the lack of systematic evaluation of key factors related to HIV PEP in the setting of sexual assault (e.g., selection criteria for offering HIV PEP, predictors of HIV PEP uptake and completion, importance/impact of HIV risk counselling, importance/impact of follow-up counselling). Such limitations have hindered the formulation of sound evidence-based policy recommendations for provision of HIV PEP following sexual assault.

CHAPTER 2

PROGRAM DEVELOPMENT & ORGANISATION

Context of the Study

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Partners

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Objectives

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Study Strategy

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Drug Regimen

~

Training of SATCs

~

Program Guidelines

~

Research Ethics

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Establishment of Expert Support Network for HIV PEP Program

2. PROGRAM DEVELOPMENT & ORGANISATION

a) Context of the Study

In Ontario, victims/survivors of sexual assault receive care and treatment from a network of specialised Sexual Assault/Domestic Violence Care and Treatment Centres (SATCs) based in hospitals across the province. Funded by the Ministry of Health and Long-Term Care (MOHLTC), this innovative care network attends to the medical, emotional, social, and medico-legal needs of women, men, and children who have been recently sexually assaulted. It has become a model for sexual assault care provision (Du Mont *et al.*, 2002), and has been used to assist women's health organisations develop sexual assault care programs in South Africa and Costa Rica (Ontario Network of Sexual Assault/Domestic Violence Care and Treatment Centres, 2005).

Approximately 2,000 sexual assault victims/survivors are seen each year at Ontario SATCs. Some of these individuals may have been exposed to the HIV virus at the time of their assault. At the outset of this study, the available research and/or guidelines to treat these individuals with HIV post-exposure prophylaxis (PEP) were limited and often inconsistent. Limited evidence existed to support the creation of policy recommendations. Despite the lack of guidelines, emergency departments and SATCs in Ontario had to make decisions about how to prescribe prophylaxis in the sexual assault setting. Practice varied provincially, nationally, and internationally – ranging from no counselling or offering of HIV PEP to universal counselling and universal offering of HIV PEP.

To address this knowledge gap, the Ontario Women's Health Council (OWHC), an agency of the Ontario MOHLTC, approved a research study entitled: "A prospective cohort study of HIV-1 post-exposure prophylaxis in Ontario sexual assault victims/survivors" (HIV PEP Study). In October 2002, the Ontario Network of SATCs joined with the Centre for Research in Women's Health (CRWH), a partnership of Sunnybrook and Women's College Health Sciences Centre and the University of Toronto, to implement and evaluate a program of HIV counselling and offering of HIV PEP medications for all SATC clients at high- or unknown-risk of HIV acquisition.

b) Partners

The HIV PEP Study has been a collaborative effort between Ontario's Network of SATCs and the CRWH, involving a diverse Research Team, an expert Project Advisory Committee, and the study's funder, the OWHC.

Ontario Network of Sexual Assault/Domestic Violence Care & Treatment Centres (SATC)

Worldwide, there are a variety of health-based responses available to persons who have been sexually assaulted. One such response, known as the Sexual Assault Care and Treatment Centre (SATC) model, is well established in Ontario, where it has been in operation since 1984 when the province's first SATC opened its doors in Toronto. Subsequent years saw the continued need for coordinated services and expertise in the treatment of sexual assault in communities across the province. To date, 34 SATCs have been funded by the Ontario MOHLTC to provide or coordinate effective, comprehensive, and sensitive sexual assault health care services. Services provided include: crisis counselling, emergency medical and nursing care, forensic evidence documentation and

collection, medical follow-up, short-term counselling provided in-house or by other community agencies, safety appraisal and court support, and education and community consultation (excerpted from Du Mont *et al.*, 2002).

In 1993, the Ontario Network of SATCs was established to increase networking and support between SATCs, standardise service provision, and implement professional development opportunities. The MOHLTC provided funding to hire a provincial coordinator to facilitate these objectives and explore the viability of developing a Sexual Assault Nurse Examiner (SANE) program for the province of Ontario. The Ontario Network of SATCs has distinguished itself as a unique, essential, regional resource that works well with other community agencies to provide integrated, accessible, high quality care to sexually assaulted persons (excerpted from Du Mont *et al.*, 2002). The Ontario Network of SATCs is routinely involved in research studies, such as the HIV PEP Study, in an effort to optimise sexual assault care in Ontario.

The Centre for Research in Women's Health (CRWH)

CRWH is a research centre dedicated to creating knowledge that improves women's lives. Established as a partnership between an academic institution (University of Toronto) and a clinical institution (Sunnybrook and Women's College Health Sciences Centre), CRWH unites a variety of perspectives in understanding women's health. CRWH works with partners in clinical settings, academic institutions and communities around the world to create and disseminate knowledge about women's health.

CRWH provides research consultation through the Research Facilitation Office (RFO). The RFO supports all phases of research, including consultation on research methodology and design, database development, data management, and statistical consultation and analysis. In addition to clinical and practice-based research efforts, the RFO supports numerous program evaluation and quality assurance projects in a variety of clinical settings.

Ontario Women's Health Council (OWHC)

In October 2002, the OWHC accepted the HIV PEP Study proposal and agreed to fund this initiative. Established in 1998 by the Minister of Health and Long-Term Care, the OWHC acts as an advocate and a catalyst for change to improve the health of Ontario women at all stages of life. The OWHC is mandated to: advise the Minister of Health and Long-Term Care and key stakeholders on health issues affecting women; advocate for improvements in women's health in Ontario; promote women's health research and identify gaps and disseminate information on current research activities; and, communicate its activities broadly to women throughout Ontario.

Research Team

In 2002, the Research Team was assembled to design the HIV PEP Study and implement a universal HIV PEP program. Membership in the Research team reflected the diverse skills required to undertake an ambitious study of this nature: Principal Investigators Anita Rachlis, MD (Department of Medicine, Division of Infectious Disease, University of Toronto) and Mona Loufty, MD (Department of Medicine, Division of Infectious Diseases, University of Toronto); Investigators Terri Myhr, MSc (Research Facilitation Office, CRWH), Sheila Macdonald, MN (Ontario Network of SATCs), Janice Du Mont, EdD (Violence and Health Research Program, CRWH); and supported by Database Manager Terry Leeke, BA (Research Facilitation Office, CRWH) and Study Coordinator Heather Humphries, Hon BA (Research Facilitation Office, CRWH). For research team member bios, see Appendix B.

Project Advisory Committee

In 2002, a Project Advisory Committee was formed, comprised of sexual assault experts, HIV experts, and representatives from the OWHC. The purpose of the Project Advisory Committee was to:

- Provide expert guidance and feedback to the Research Team about the study;
- Advise on the development of the study protocol, medical protocols, the reference manual, and other materials related to implementation of the universal HIV PEP program;
- Advise on key documents associated with the study (consent forms, data collection forms, surveys/questionnaires);
- Advise on strategies for compliance and care management of victims/survivors on HIV PEP treatment; and,
- Monitor the progress of the study.

The Research Team met with the Project Advisory Committee bi-annually in all three years of the study. In addition to these scheduled meetings, the research team consulted with members of the Committee as needed regarding issues specific to members' areas of expertise. The complete Project Advisory Committee membership is listed in Appendix B.

Participating SATCs

The 24 SATCs that participated in the HIV PEP Study's data collection process are listed below. A brief overview of each participating SATC's infrastructure is included in Appendix B.

- **Belleville** *Domestic Violence/Sexual Assault Response Program for Hastings & Prince Edward Counties*
- **Brantford** *Sexual Assault/Domestic Violence Program*
- **Brockville** *Assault Response & Care Centre*
- **Burlington** *Nina's Place, The Regional Sexual Assault and Domestic Violence Care Centre of Halton*
- **Chatham** *Sexual Assault/Domestic Violence Treatment Centre*
- **Cornwall** *Partner Abuse Sexual Assault Care Team, Cornwall Community Hospital*
- **Guelph** *Guelph – Wellington County Sexual Assault Care and Treatment Centre*
- **Hamilton** *Sexual Assault/Domestic Violence Care Centre*
- **Kenora** *Lake of the Woods District Hospital Sexual Assault/Partner Abuse Treatment Program*
- **Kingston** *Kingston General Hospital Sexual Assault/Domestic Violence Program*
- **London** *Regional Sexual Assault & Domestic Violence Treatment Centre*
- **Mississauga** *Chantel's Place, Peel Region Sexual Assault Program Sexual Assault Care & Counselling Centre*
- **North Bay** *North Bay General Hospital Sexual Assault Treatment Centre*
- **Orangeville** *Dufferin County Sexual Assault / Domestic Violence Program*
- **Orillia** *Simcoe County/Muskoka Regional Sexual & Domestic Assault Program*
- **Peterborough** *Peterborough Regional Health Centre Sexual Assault / Domestic Violence Program*

- **Richmond Hill** *Domestic Abuse and Sexual Assault Care Centre of York Region*
- **St. Catharines** *Sexual Assault / Domestic Violence Treatment Program – Niagara*
- **Sarnia** *Bluewater Health Sexual Assault/Domestic Assault Treatment Centre*
- **Sault Ste. Marie** *Sault Area Hospitals Sexual Assault Care Centre/Partner Assault Clinic*
- **Sioux Lookout** *Sioux Lookout Assault Care and Treatment Program*
- **Smiths Falls** *Lanark County Sexual Assault Program*
- **Toronto** *Sunnybrook and Women's College Health Sciences Centre Sexual Assault/Domestic Violence Care Centre*
- **Windsor** *Sexual Assault Treatment/SAFEKIDS*

c) Objectives

The purpose of this study was two-fold:

- 1) To implement standardised guidelines for counselling on HIV risk, offering HIV PEP, and for follow-up of those who take the regimen; and,
- 2) To evaluate a universal strategy of offering HIV PEP for at-risk Ontario sexual assault victims/survivors in a systematic, prospective fashion.

Parameters of the Study

The HIV PEP Study was aimed at evaluating whether a funded universal offering approach was desirable, feasible and sustainable. The first basic step of evaluation is to determine desirability. This study concentrated on determining if there was a population of sexual assault victims/survivors that would make use of, and hence benefit from, access to HIV PEP other than those labelled as high-risk. Information was collected on consecutive clients, rates of acceptance and completion of HIV PEP were used as indicators of desirability. Feasibility and sustainability were measured through HCP surveys and focus groups.

The study's universal HIV PEP program was determined based on the best evidence available at the time of its development. Given the absence of similar prospective studies, and the time and resource limitations of the study, it was not possible to undertake a comparative analysis between a model aimed at a high-risk population and a more broadly defined target population. Nor was it within the scope of this study to evaluate the efficacy of the drug regimen selected, the appropriateness of the 72-hour post-exposure window determining eligibility for HIV PEP, or the 28-day regimen of HIV PEP medications. Emerging research suggests that despite the diverse approaches to HIV PEP delivery around the world the model adopted in this study is consistent with much of the current thinking about effective practice.

A strong knowledge base and infrastructure for province-wide HIV PEP delivery did not exist in Ontario prior to the HIV PEP Study. Therefore, in order to meet study objectives to evaluate a universal offering program and establish standardised provincial guidelines for counselling on HIV risk, offering HIV PEP, and follow-up services, this groundwork had to be laid through the study process itself. While this work was informed by the literature and experiences from other programs,

the lack of definitive best practices in HIV PEP delivery meant that it relied heavily on the expertise of the study's research team, advisory committee and SATC coordinators for its development, and the resources provided by the OWHC.

The development of standardised definitions and protocols regarding HIV PEP were needed as those protocols that did exist at SATCs were defined internally within each hospital setting or within each team. This led to enormous variations across the province, inhibiting effective data collection and making a consistent response to victims/survivors of sexual violence impossible. Knowledge about HIV and HIV PEP was also uneven across the province and amongst Health Care Providers (HCP), and access to HIV expertise depended largely on informal networks and/or geographic location. In order to address these gaps, training was developed and delivered to all participating SATCs and an expert consultation network was established to support the successful implementation of the program. Links were also developed with pharmacies and the network of Ontario Public Health Laboratories in order to facilitate access to the necessary medications and timely testing.

A further challenge to the effective establishment and evaluation of a program of universal offering of HIV PEP was the fact that Ontario's Network of SATCs had no consistent data gathering practices. Therefore, there was no way to systematically capture information on the clients presenting to their centres with whom HIV PEP was discussed, offered and/or accepted or the factors influencing these decisions. Baseline data were necessary to effectively evaluate the program. This study allowed for the development of a preliminary database, not only for HIV PEP delivery services but, if sustained, for broader service/system planning processes for SATC clients at the organisational as well as provincial levels.

d) Study Strategy

Design

The strategy of the HIV PEP Study was universal offering of HIV risk counselling and HIV PEP medications, meaning that, in addition to the routine care provided at Ontario SATCs, all victims/survivors were counselled on their HIV risk and, those that met the risk criteria, were offered HIV PEP. The study was designed as a prospective cohort study, where data were collected on every consecutive sexual assault victim/survivor seen at participating SATCs.

Risk Categories

Sexual assault victims/survivors were divided into one of three HIV-acquisition risk categories: high-risk, unknown-risk and no-risk. Criteria used to assess HIV risk are presented in Figure 1.

Sexual assault victims/survivors who were at high- or unknown-risk of HIV acquisition were offered HIV PEP and counselled about the potential side effects of the drug regimen.

Follow-up

Clients that accepted the initial offer of HIV PEP were given a 5-day starter kit of HIV PEP medications and were required to make a follow-up appointment 2 to 4 days following their Initial Visit. All further HIV PEP medications were dispensed at Follow-up Visits. At the Day 2 to 4 visit, the decision to take HIV PEP was reviewed with clients. Clients interested in continuing the

treatment were given a 10-day supply of HIV PEP medications. A 7-day supply of medications was dispensed at the Week 2 Visit, and a final 6-day supply was dispensed at the Week 3 Visit.

Data Collection

Demographic information about the client, characteristics of the assault and assailant(s), the client's risk assessment, and details regarding the offering and acceptance of HIV PEP were collected on all victims/survivors at the Initial Visit. Client satisfaction questionnaires, which included information about the program, were given to all victims/survivors at the Initial Visit. Follow-up data were collected on those who accepted HIV PEP, including abnormal client blood work results, symptoms/side effects of the HIV PEP medications, coping strategies of the client in dealing with side effects, impact of HIV PEP medications on client's daily routine, and reason for discontinuing HIV PEP (if applicable). All clients who accepted the HIV PEP medications were invited to participate in an in-depth interview about their experiences with taking HIV PEP. Surveys and Focus Groups were also conducted with SATC HCPs.

Figure 1 HIV PEP Risk Assessment

HIGH-RISK

High-Risk Exposure	High-Risk Assailant		GUIDELINES
Anal penetration Vaginal penetration Oral penetration (with or without condom) Unknown exposure (e.g., drug facilitated sexual assault)	Known HIV-positive assailant OR Known High-risk assailant (IVDU, MSM, or from an Endemic Country)	+	Strongly Recommend HIV PEP Combivir (AZT/3TC) & Kaletra Provide counselling & education about high-risk of HIV acquisition and side effects of drug regimen

UNKWON-RISK

High-Risk Exposure	Unknown-Risk Assailant		GUIDELINES
Anal penetration Vaginal penetration Oral penetration (with or without condom) Unknown exposure (e.g., drug facilitated sexual assault)	Unknown Assailant OR Known assailant with Unknown HIV status	+	Recommend HIV PEP Combivir (AZT/3TC) & Kaletra Provide counselling & education about possible risk of HIV acquisition and side effects of drug regimen

NO-RISK

No-Risk Exposure	ANY Assailant		GUIDELINES
NO vaginal penetration NO anal penetration NO oral penetration	(HIV-positive, high-risk or unknown HIV status)	+	Do NOT Offer/Recommend HIV PEP Provide counselling & education about the zero risk of HIV acquisition

e) **Drug Regimen**

The HIV PEP used in this study was Combivir® (1 pill orally twice a day) and Kaletra® (3 capsules orally twice a day) for a total of 28 days. This regimen was chosen due to its potency and efficacy at both reducing the transmission of HIV post-exposure and at preventing resistance. The guiding tenet in drug therapy is “choose a regimen to avoid treatment failure”. As such the HIV PEP regimen was chosen due to its potential to provide optimal antiretroviral potency, facilitate adherence and minimise toxicity.

Kaletra® is considered one of the most potent anti-HIV drugs when used in combination with other antiretroviral medications. Using Kaletra® in combination with other agents (AZT and 3TC) helps to reduce the chances of resistance. In addition, research demonstrates that in HIV-positive individuals, combination therapy (such as Combivir® and Kaletra®) has been shown to reduce viral load more effectively than monotherapy and to limit the development of resistance (Havlir, 2003). Presently, most of the available up-to-date guidelines recommend (and most clinicians would agree) triple therapy as the most appropriate first line HIV PEP regimen (CDC, 2005).

The chosen HIV PEP regimen is associated with a low pill burden (4 pill twice per day or 8 pills a day) as opposed to other regimens that could include up to 12 pills per day. As such, the chosen regimen facilitates adherence.

Furthermore, Kaletra® is considered to be well tolerated, aside from some mild gastrointestinal upset. In comparison to potential alternate regimens, Combivir® and Kaletra® cause fewer and less severe side effects, thus minimising toxicity.

Given the above reasons (potency, facilitation of adherence, minimal toxicity) if a client was unknowingly already HIV-positive at the time of HIV PEP administration, the same Combivir® and Kaletra® regimen would be considered appropriate as HIV treatment.

f) **Training of SATC Staff**

Standardised training of SATC nurses and physicians regarding HIV risk factors, rates of transmission, and HIV PEP was provided to ensure that HIV counselling and HIV PEP offering were consistent across the province. Training occurred in two stages:

1) ***Regional train-the-trainer sessions***

The purpose of these sessions was to teach core members of each SATC team the steps required to counsel sexual assault clients about the risks of HIV transmission, to offer HIV PEP, and to provide follow-up to clients taking the medications. All of Ontario's 34 SATCs were invited to participate in a training session. Twenty-eight SATCs received training and were divided into 6 geographical regions. One training session per region was arranged; approximately 4 to 7 sites attended each regional session. The format of the training was “train-the-trainer”. Three core SATC team members at each SATC were invited to attend a train-the-trainer session with the intention that they would return to their SATC and train the remainder of their front-line staff. Staff that participated in the train-the-trainer sessions included the nurse leader, physician leader, and lead follow-up staff member (or alternate

SATC team members at SATC discretion). To guide the training sessions, outlines and information packages were provided to each training participant. Research Team members Ms. Sheila Macdonald (HIV PEP Study Originator) and Co-Principal Investigators Drs. Mona Loutfy and/or Anita Rachlis traveled to the host SATC site of each region and instructed a full-day training session, from September to October 2003. The pilot site, Sunnybrook & Women's in Toronto, was trained separately in August 2003.

2) *Local in-house training sessions*

Subsequent to the regional training sessions, each SATC team received local in-house training conducted by those team members that had attended the regional session(s).

Reference Manual

The Research Team developed a comprehensive Reference Manual, with input from members of the Project Advisory Committee. The Manual contained detailed information that included a review of literature pertinent to the study, HIV Risk Assessment, guidelines for HCPs for the Initial Visit and for offering HIV PEP medications, guidelines for follow-up visits, health and drug contraindications to HIV PEP, HIV PEP paediatric dosing guidelines, a list of HIV Experts across the province, counselling guidelines, flow sheets for initial and follow-up visits, and all of the study documentation. Reference Manuals were used to guide the training sessions, and to be a resource for front-line staff. Each SATC was provided with two HIV PEP Study Reference Manuals. A copy of the Reference Manual accompanies the appendices.

Ongoing Support/Training

SATCs were kept current on study progress and program issues through monthly newsletters, a study website, and quarterly presentations to SATC Coordinators. The Study Coordinator was also available by e-mail/phone during business hours to provide support and guidance throughout the study.

g) *Program Guidelines*

The documents and guidelines described in the following sections were created to assist Ontario's SATCs in implementing and maintaining the universal HIV PEP program as part of the attached Reference Manual. Practice flow sheets were also created to provide HCPs with a visual aid, outlining the necessary steps for client care with respect to HIV PEP during both the Initial and Follow-up Visits. These flow sheets are included as Figures 2 & 3 of this document.

Medical Protocols & Medical Directives

HIV PEP medications were dispensed to sexual assault victims/survivors either under Medical Protocols or Medical Directives. Medical Protocols provided a guide to Registered Nurses (RNs) working with Medical Doctors (MDs) on the management of the Initial Visit and on administering the 5-day HIV PEP starter kits to sexual assault victims/survivors. Under Medical Protocols, RNs carried out the sexual assault-related care, counselling, preparations for required laboratory testing, HIV testing and follow-up for all HIV PEP Study clients, and MDs wrote the prescription for the HIV PEP medications. Under Medical Directives, registered nurses (RNs), including nurse practitioners (NPs), SANEs, and nurse examiners (NEs), were enabled to administer 5-day HIV PEP starter kits to sexual assault victims/survivors without MD orders. Medical Protocols/Directives guided the Initial Visit procedures, HIV testing, storage of HIV blood test

sample for future testing, MD referral, and HIV PEP Study follow-up procedures.

HIV Risk Assessment

SATC HCPs assessed the HIV infection risk of each sexual assault victim/survivor by following HIV risk assessment procedures detailed in Chapter 3 of the HIV PEP Study Reference Manual. Given that HIV-risk is difficult to determine and involves a number of influencing factors, HCPs discussed a range of factors with clients when determining each individual's risk. It was the HCPs' responsibility to inform clients of their possible risk and options available to them, and to allow each client to evaluate the risks and benefits of taking HIV PEP. See Figure 1.

Follow-up Schedule

Each client that accepted HIV PEP medications was scheduled to receive follow-up care at Day 2 to 4, Week 1, Week 2, Week 3, and Week 4 following her/his initial presentation to a SATC. The Research Team determined the intensity of the follow-up schedule after reviewing the literature and observing that a key problem in providing HIV PEP to victims/survivors of sexual assault was the low rate of return for follow-up care. Previous studies suggested that the reason for poor follow-up rates and lack of compliance with antiretroviral drugs might be the rate and severity of side effects (Myles *et al.*, 2000; Wiebe *et al.*, 2000). The Research Team decided to increase intensity of the follow-up schedule to support sexual assault clients throughout their 28-days of HIV PEP therapy. At each follow-up visit, HIV risk counselling, emotional support, and assessment of HIV PEP adverse events was provided. Chapter 5 of the HIV PEP Study Reference Manual provides details of the Follow-up Schedule. Additional counselling guidelines are provided in Chapter 9 of the HIV PEP Study Reference Manual.

Client Handouts

Information handouts were created for distribution to all clients at the Initial Visit. Three sets of targeted handouts were created for clients at no-risk of HIV acquisition, clients at unknown-risk or high-risk of HIV infection taking HIV PEP, and clients at unknown-risk or high-risk of HIV infection not taking HIV PEP. Handouts detail risk of HIV infection based on type of exposure, HIV follow-up, HIV PEP medications, and management of side effects.

h) Research Ethics

Prior to initiation of data collection, Research Ethics Board (REB) approval was required at each of the 24 SATC's affiliated institutions. Following REB approval by Sunnybrook and Women's College Health Sciences Centre, all necessary documents required for REB submissions were distributed to each of Ontario's SATCs. With an offer of assistance if required, the Research Team requested that each individual SATC prepare a submission to their local REB. REB approval was staggered across sites and all participating SATCs received REB approval by November 2004.

i) Establishment of Expert Support Network for HIV PEP Program

To promote sustainability of the universal HIV PEP program, an extensive support network was established to provide ongoing collaboration and consultation with the various constituents of Ontario's medical community.

HIV Experts

In the offering and administering of HIV PEP medications, there are cases in which consultation with an HIV Expert is strongly recommended. In anticipation of the SATCs' need for access to such expertise, Co-principal Investigator, Dr. Mona Loutfy, contacted HIV Experts across Ontario in September 2003 to enlist their support to the HIV PEP Study. Twenty HIV Experts agreed to be listed in a directory that was included in the HIV PEP Study Reference Manual. The directory connects each SATC with a local HIV Expert for situations in which consultation is required. All HIV Experts listed in the directory have agreed to continue to support the HIV PEP program on an on-going basis, at no cost to the SATCs that use this resource.

Ontario Public Health Laboratories

An initial/baseline HIV test is recommended for all sexual assault victims/survivors that are at risk of HIV acquisition. In September 2003, the Research Team entered into an agreement with Ontario's six Public Health Labs to expedite HIV testing (results returned within 2 to 7 days) for all HIV PEP Study clients, and for all future HIV PEP program clients initiating HIV PEP therapy. This expedited service was/is provided at no cost to SATCs. Expedited HIV testing facilitates a swift response in the case of HIV-positive clients, ensuring they receive the appropriate supports and drug regimens.

Pharmacies

Pharmacists and pharmacies were integral to implementing and maintaining the universal HIV PEP program. Great effort was expended in establishing sustainable relationships between SATCs and their affiliated pharmacies. The Research Team assisted SATCs with the significant administrative work required to inform Pharmacy Departments about the HIV PEP Study drug regimen. The Research Team provided affiliated pharmacies in Ontario with extensive information including how to order and stock HIV PEP (Combivir® & Kaletra®), package and label HIV PEP starter and follow-up kits, dispense HIV PEP medications, and store and package paediatric (liquid) HIV PEP dosages, as well as details about the HIV PEP drug regimen and return policies for expired Combivir® and Kaletra®.

Figure 2 Initial Visit Flow Sheet

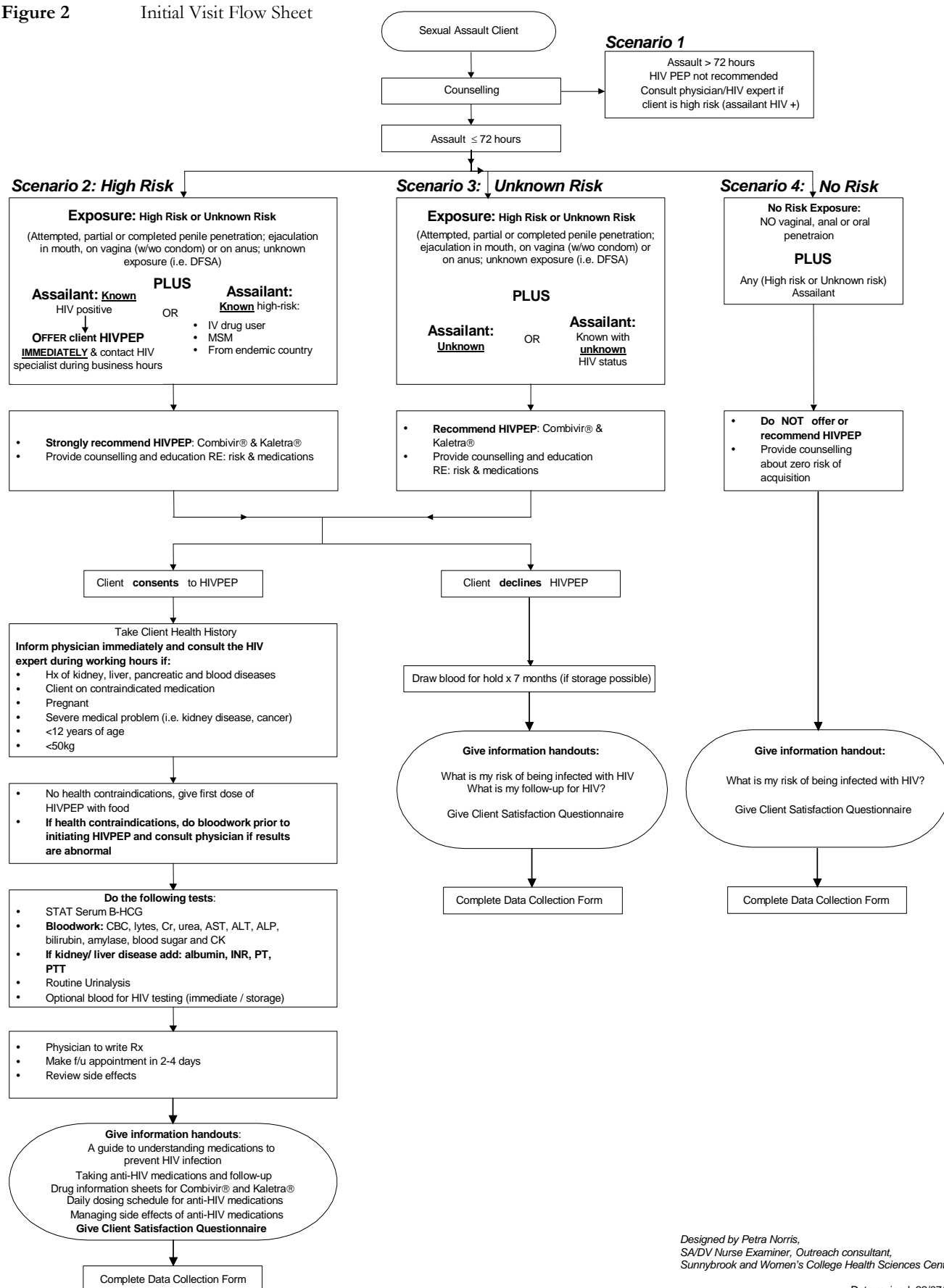
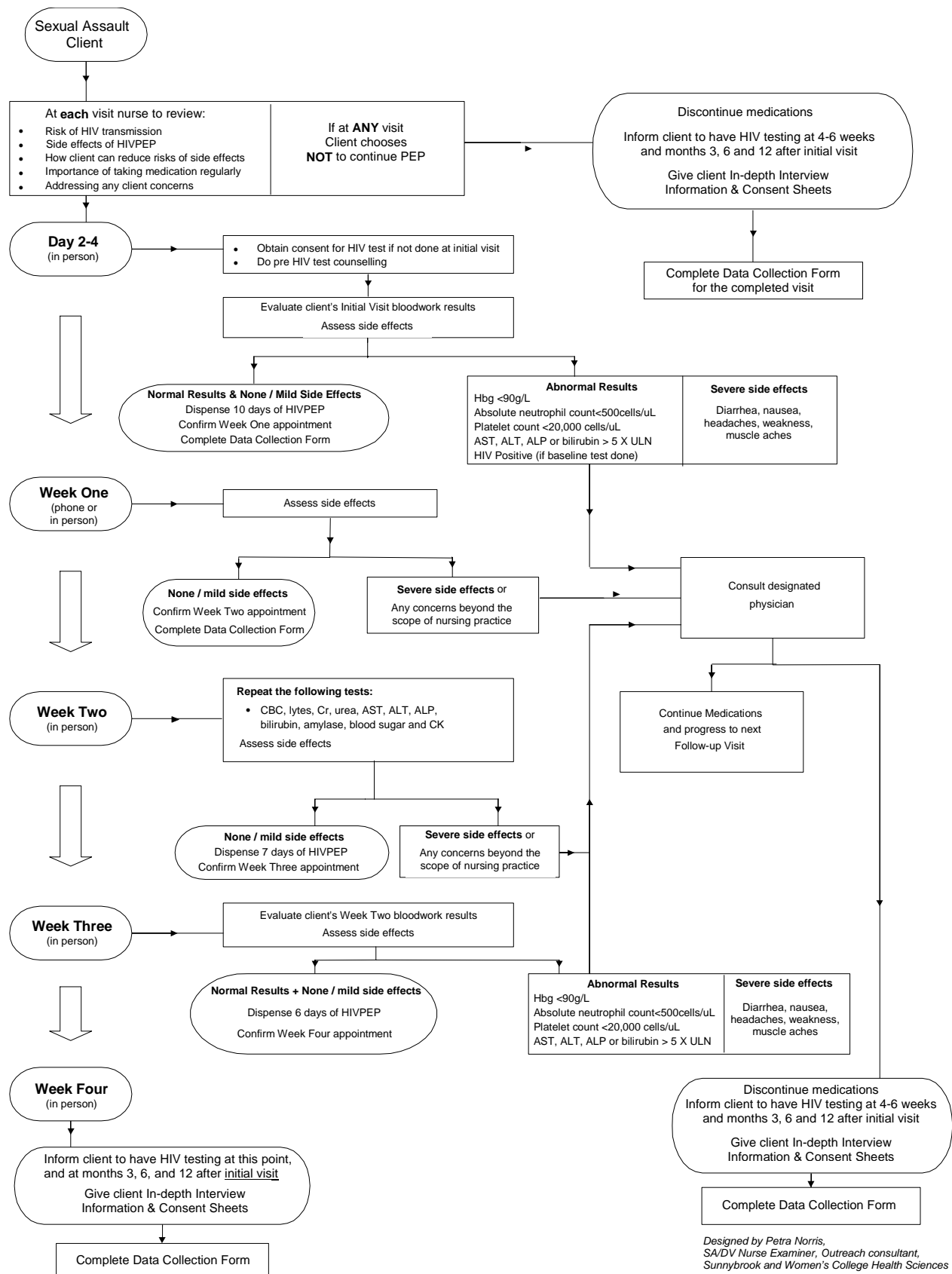


Figure 3 Follow-up Visits Flow Sheet



CHAPTER 3

INITIAL AND FOLLOW-UP VISITS

Method

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Results

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Summary

3. INITIAL AND FOLLOW-UP VISITS

a) Method

Data Collection and Management

Initial Visit Data Collection Forms were developed to capture demographic information about the client, characteristics of the assault and assailant(s), the client's risk status, the Health Care Provider's (HCP) impression of the effect of HIV counselling on the client's anxiety, the HCP's assessment of how strongly she/he encouraged or discouraged the client to accept HIV PEP, reasons that the HCP may not have offered HIV PEP despite risk status; and reasons that the client may not have accepted HIV PEP medications.

Follow-up Visits Data Collection Forms, completed following every client follow-up visit (i.e., Day 2 to 4; Week 1; Week 2; Week 3; and, Week 4 following Initial Visit presentation), were developed to capture abnormal client blood work results, symptoms/side effects of the HIV PEP medications, coping strategies of the client (e.g., use of symptom alleviating medications, support networks), impact of HIV PEP medications on client's daily routine, and reason for discontinuing HIV PEP (if applicable).

In May 2003, prior to implementation of the HIV PEP Study, the Initial Visit and Follow-up Visits Data Collection Forms were piloted with the assistance of the Coordinators from the Sudbury and Sarnia SATCs. Staff at the Hospital for Sick Children's SCAN Unit also assisted in piloting the tool from a paediatric viewpoint. A second pilot took place in collaboration with Sunnybrook and Women's College Health Sciences Centre's SATC in Toronto. Sunnybrook & Women's already practised HIV counselling and offering of HIV PEP medications to their clients, so SATC team members completed HIV PEP Study Data Collection Forms after seeing clients throughout May to July 2003. The Research Team incorporated feedback from the SATC staff who piloted the tool.

During the data collection period, HCPs completed an Initial Visit Data Collection Form for each consecutive client presenting at a participating SATC, and a Follow-up Visits Data Collection Form for every client that accepted HIV PEP. Upon completion, HCPs returned Initial and Follow-up Visits Data Collection Forms to the Central Coordinating Site, the Centre for Research in Women's Health (CRWH).

Identifying information was removed prior to data being forwarded to CRWH. Each SATC assigned a unique study identification number to each client. A list of client names and corresponding study ID numbers were kept in a locked cabinet at each SATC to ensure that Follow-up data and Initial Visit data could be linked. SATCs will destroy all records linking client names and study ID numbers following completion of the HIV PEP Study.

Data Collection Forms were kept in a secure cabinet at the CRWH. Only members of the Research Team have access to them. All Initial and Follow-up Visits Data Collection Forms were entered into an MS Access database at the CRWH. Only members of the Research Team have access to the database, which is restricted by a password.

Statistical Analyses

An optimal sample size of 1,110 was calculated based on completion rates and high-risk rates reported by Wiebe *et al.*, 2000. Descriptive statistics were calculated to describe the baseline client and assault characteristics. Proportions were calculated for categorical data and means with standard deviations were used for continuous data.

The primary analyses were the comparison of rates of acceptance and completion of HIV PEP to 28-days between those clients classified as high-risk and those classified as unknown-risk using chi-square statistics. Odds ratios and 95% confidence intervals were calculated to determine the magnitude of the differences.

Any association between baseline client/assault characteristics and rates of acceptance/completion were analysed using univariate analyses. Chi-square statistics were used for categorical data and t-tests were used for continuous data. All variables that were statistically significant in univariate analyses were included in logistic regression analyses. When a categorical variable had missing data, “missing” was considered a third response category for that variable or collapsed into the “no” category if the pattern of the dependent variable was similar between the “no” category and the “missing” category. Thus, the number of cases was maximised for performing logistic regression.

For those who accepted HIV PEP, proportions were calculated for completed weeks of follow-up and for symptoms/side effects. Symptoms were compared between those who completed and those who did not complete using chi-square statistics and odds ratios with 95% confidence intervals.

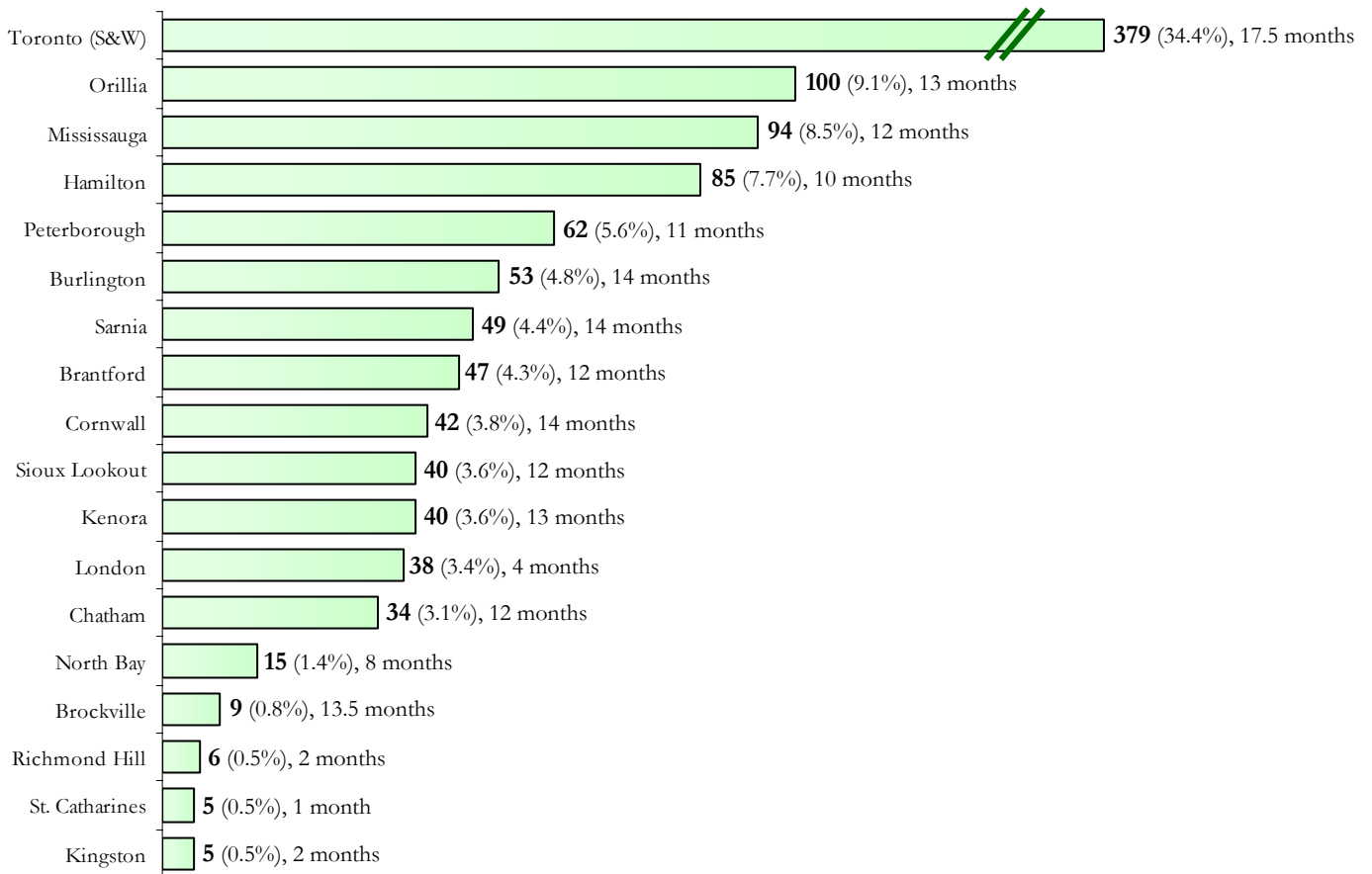
All statistical analyses were performed using SAS Version 8.2 statistical software (SAS Institute, Cary, North Carolina, USA).

b) Results

Of Ontario’s 34 SATCs, 24 participated in this study and contributed data. Of the 10 SATCs that did not participate, reasons cited were largely organisational/infrastructure barriers including inadequate staffing/follow-up services, lack of formal research ethics committee to approve the study, overly broad geographical catchment area, amalgamation of numerous hospitals, lack of local Infectious Disease specialist, high staff turn-over rate, and the lasting impact of SARS. Other barriers noted were difficulties in getting the study approved by their research ethics board in time to participate, and resistance to, or lack of support for, the universal HIV PEP program from physicians/SATC staff.

Data were collected on 1,238 sexual assault victims/survivors at Ontario’s 24 participating SATCs from September 10, 2003 to January 31, 2005. A total of 135 of these clients were excluded from analysis because of inconsistent data collection practices at 6 SATCs. Thus, 89.1% (1,103) of clients were included in the final analysis. The number of clients from each of the 18 SATCs and number of months each SATC participated are presented in Figure 4. The Toronto Sunnybrook & Women’s SATC participated in the study for the longest period (17.5 months) and contributed the most clients (34.4%); 11 (61.1%) SATCs participated in the study for one year or longer.

Figure 4 Number of Clients and Months of Participation by 18 SATCs Included in Analyses

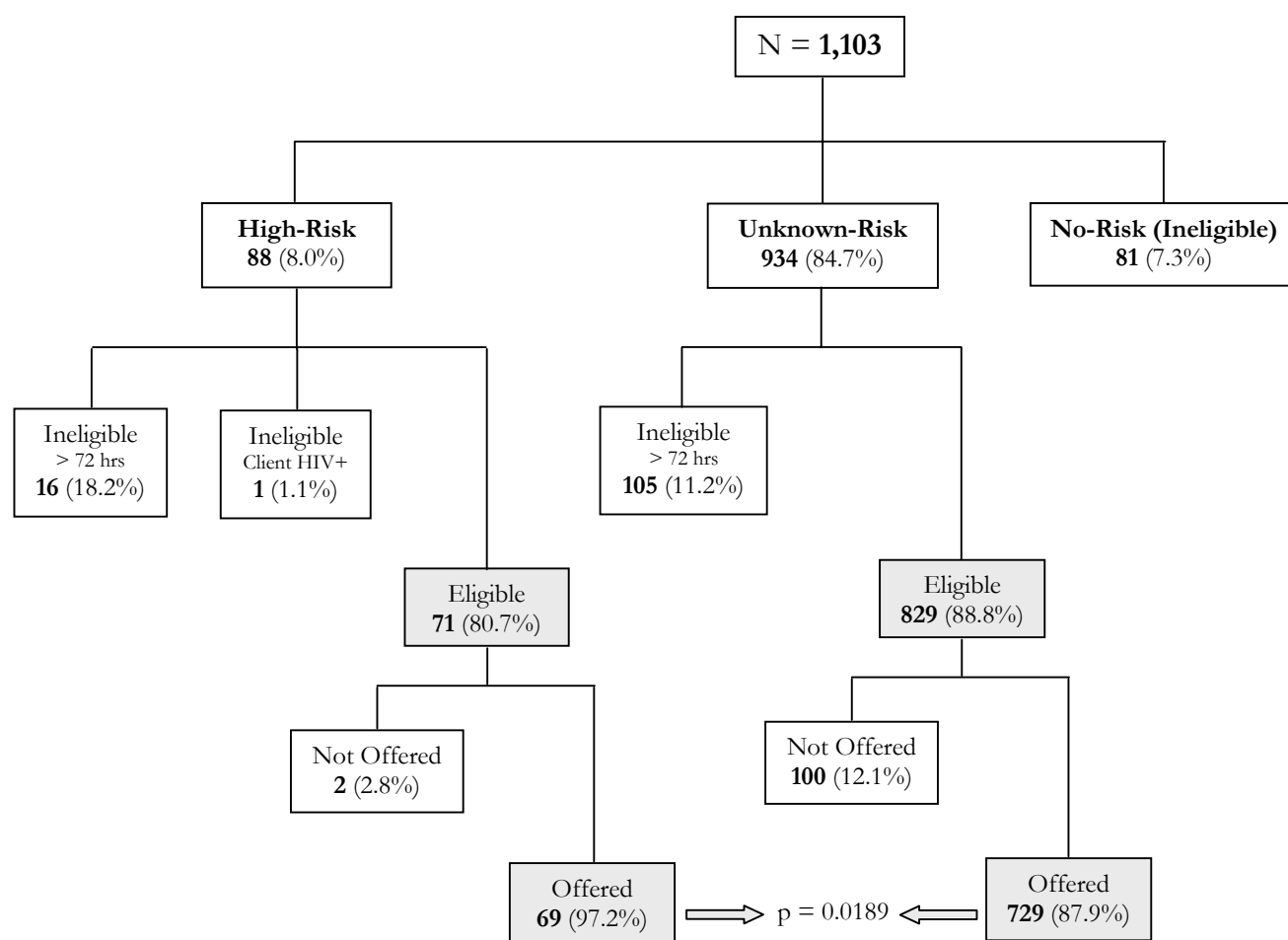


Risk Classification and Eligibility for HIV PEP

Of the 1,103 clients, eighty-eight (8.0%) clients were classified as being at high-risk of HIV acquisition, 934 (84.7%) were classified as having an unknown-risk of HIV acquisition, and 81 (7.3%) were classified as having no-risk of HIV acquisition and were therefore ineligible for HIV PEP. One hundred and twenty-one (11%) clients presented to a SATC after 72 hours of being assaulted and thus ineligible for HIV PEP. Of these, 16 were high-risk clients and 105 were unknown-risk clients. One high-risk client was HIV-positive and thus ineligible for HIV PEP. In total, 203 (18.4%) clients were ineligible and 900 (81.6%) clients were eligible for HIV PEP. Figure 5 presents the number of clients eligible for and offered HIV PEP by risk classification.

Significant differences in client characteristics between those determined to be eligible and those ineligible for HIV PEP were: more ineligible clients were accompanied by an adult (28%) than eligible clients (18%) ($p=0.0013$) and a larger proportion of ineligible clients were less than 13 years old (14.8%) than eligible clients (3.2%) ($p<0.001$). All clients under 13 years of age were accompanied by an adult.

Figure 5 Eligibility for and Offering of HIV PEP by Risk Group



Offering HIV PEP

Of the 900 clients eligible for HIV PEP, 798 (88.7%) were offered HIV PEP by the HCPs. A larger percentage of eligible high-risk clients were offered HIV PEP (97.2%) compared to eligible unknown-risk clients (87.9%) ($p=0.0184$) (Figure 5). This differential rate in offering between the high-risk and unknown-risk groups is expected since the medical protocols developed for the program stressed the importance of offering and strongly recommending HIV PEP to clients classified as high-risk.

Reasons for not offering HIV PEP are presented in Table 1. HIV PEP was not offered to two eligible high-risk clients. One of these clients was a male client whose assailant was classified as a MSM and the reasons reported for not offering HIV PEP were that the client was uncooperative with SATC staff, and the client was unable to adhere to the regimen due to his living situation or other factors. The other client was a female client whose assailant was classified as being from an endemic country and was the client's husband. The assault did not involve vaginal penetration and it was unknown if oral or anal penetration occurred. The HCP made a clinical decision not to offer HIV PEP to this client. HIV PEP was not offered to 100 eligible unknown-risk clients. The most

common reason reported was that the risk seemed too low to justify HIV PEP (5.0% of eligible unknown-risk clients). In most of these “low risk” cases there was doubt as to whether there was an actual exposure (penetration) and some cases reported prior sexual activity with the assailant. Other common reasons for not offering HIV PEP in the unknown-risk group were the client’s living situation and/or the client was unable to adhere to the regimen (3.5% of eligible unknown-risk clients), medical reasons (3.0% of eligible unknown-risk clients), and lack of client concern about HIV (2.9%).

Table 1 Reasons HIV PEP Not Offered*

High Risk (2/71)		
Client uncooperative (i.e., client refused care; client unwilling to adhere to regimen)	1	1.4%
Risk seemed too low to justify (unknown oral/anal penetration; no vaginal penetration; HIV PEP not offered because assailant was client’s husband)	1	1.4%
Unknown Risk (100/829)		
Risk seemed too low to justify HIV PEP (i.e., doubt as to actual exposure; prior sexual activity with assailant)	41	5.0%
Client's living situation and/or client unable to adhere to regimen	29	3.5%
Medical Reasons (i.e., illness; contraindicated drugs; concerns about client's ability to tolerate side effects)	25	3.0%
Lack of client concern about HIV	24	2.9%
Client unable to consent (i.e., too anxious; unable to understand)	16	1.9%
Client uncooperative (i.e., client left before HIV PEP was discussed; client refused care; client unwilling to adhere to regimen)	10	1.2%
Other reason(s)	10	1.2%
Client was 13 months old (1), or Paediatrician's discretion (3)	4	0.5%

* More than 1 reason may apply to an individual client. Percentage out of eligible clients.

Those offered HIV PEP were more likely to be accompanied by an adult (28% vs. 17%, $p=0.004$), to be less than 13 years old (20.6% vs. 1%, $p<0.0001$), to be unemployed (40.5% vs. 26%, $p=0.0255$), or to need an interpreter (5% vs. 1.6%, $p=0.0441$) than those not offered HIV PEP. HCPs reported “low” overall anxiety in 53% of clients not offered HIV PEP and in 34% of clients offered HIV PEP ($p=0.0003$). These significant differences are reflective of the reasons given by the HCPs for not offering HIV PEP.

Client Characteristics

The characteristics of clients that were offered HIV PEP are summarised in Table 2a. The mean age was 23.9 years with a range from 4 to 80 years. Most clients were female (97.1%), Caucasian/Hispanic/Middle Eastern (75.9%), and single (76.2%). Approximately one-half (49.0%) lived with family members (other than partners or children) or with roommates/friends, and 36.1% were students. Only 1.6% needed an interpreter and only 1.4% were pregnant. Approximately one-sixth (16.8%) were accompanied to the SATC by an adult or caregiver.

HCPs were asked to rate the overall anxiety level of the client, and the effect that HIV counselling had on that anxiety. A "high" level of anxiety was reported for 17.5% of clients, a "moderate" level for 46.0% of clients, and a "low" level for 32.7% of clients. HCPs reported that HIV counselling increased anxiety in 11.2% of clients, decreased anxiety in 18.5% of clients, and that the anxiety level of 63.3% of clients "stayed the same" following HIV counselling.

HCPs were also asked to describe their recommendation to the client regarding HIV PEP. Approximately one-quarter (25.9%) reported that they encouraged or strongly encouraged the client to take HIV PEP, 70.9% reported they neither discouraged nor encouraged the client to take HIV PEP, and 3.1% reported they discouraged or strongly discouraged the client to take HIV PEP.

Assault Characteristics

The characteristics of the assault sustained by clients are summarised in Table 2b. Only 3 (0.4%) of the assailants were known/thought to be HIV-positive, 12 (1.5%) to be men who have sex with men, 15 (1.9%) to be intravenous drug users and 39 (4.9%) to be from an endemic country. Twenty percent of the assailants were complete strangers to the clients and 9.6% were partners or ex-partners. Fifty-one percent of the clients had known the assailant for more than 24 hours. Most assaults were committed by one assailant (74.3%), 18.0% involved 2 or more sexual acts and 45.1% involved some type of physical assault. Only 6.4% involved the use of a weapon. At the time of the assault 15.1% of clients were unconscious and were drugged or forced to consume alcohol/drugs or had voluntarily consumed alcohol/drugs. Thirty-four (4.3%) clients had a disability or condition that may have impacted their ability to recount the details of the assault (e.g., developmental delay, mental illness). Type of penetration (suspected, partial, or completed) was reported at the following rates: 101 (12.7%) clients were anally penetrated, 519 (65.1%) clients were vaginally penetrated, and 125 (15.7%) clients were orally penetrated. Penetration was reported in 4.5% of the assaults to have involved a foreign object. Over one-half (56.2%) of clients had some form of physical injury. One-fifth (19.3%) suffered anal and/or genital injuries plus other physical injuries (non-anogenital), 17.7% suffered anal and/or genital injuries, and 19.2% did not suffer anogenital injuries but sustained other physical injuries.

Table 2a Characteristics of Clients Eligible for and Offered HIV PEP

N=798					
Average Age		23.9 years (9.1std; range 4-80)			
Age Categories (years)		Employment Status			
4-12	8 1.0%	Student 5-17 years old*	163	20.4%	
13-17	182 22.8%	Student 18 years or older	125	15.7%	
18-21	229 28.7%	Employed 16 years or older	239	29.9%	
22-29	202 25.3%	Unemployed 16 years or older**	187	23.4%	
30-44	147 18.4%	Missing	84	10.5%	
45-64	28 3.5%				
65-80	2 0.3%	Interpreter Needed			
Gender		Yes	13	1.6%	
		No	782	98.0%	
		Missing	3	0.4%	
Female	775 97.1%	Currently Pregnant (not due to assault)***			
Male	23 2.9%	Yes	11	1.4%	
Race/Ethnicity		No	703	91.1%	
		Missing	58	7.5%	
First Nations	99 12.4%	Accompanied by Adult			
Caucasian/Hispanic/Middle Eastern	606 75.9%	Yes	134	16.8%	
Black	48 6.0%	No	664	83.2%	
Asian/Pacific Islander/East Indian	41 5.1%				
Missing	4 0.5%				
Marital Status		Client's Overall Anxiety****			
Single	608 76.2%	High	140	17.5%	
Separated/divorced/widowed	72 9.0%	Moderate	367	46.0%	
Married/common-law/co-habiting	104 13.0%	Low	261	32.7%	
Missing	14 1.8%	Missing	30	3.8%	
Living Situation		HIV Counselling Affect on Client Anxiety****			
Homeless	10 1.3%	Increased	89	11.2%	
Shelter/group home/foster care/ institutional care	69 8.6%	Stayed the Same	505	63.3%	
With partner	124 15.5%	Decreased	148	18.5%	
Alone	98 12.3%	Missing	56	7.0%	
With children, without partner	70 8.8%				
With family other than partner and/or children	284 35.6%	Strength of HCP Recommendation to take HIV PEP			
With roommates/friends	107 13.4%	Strongly discouraged	5	0.6%	
Missing	36 4.5%	Discouraged	20	2.5%	
		Neither discouraged/encouraged	566	70.9%	
		Encouraged	175	21.9%	
		Strongly encouraged	32	4.0%	

*Includes 1 client <16 not currently attending school. **Includes 9 sex workers. ***Only females > 11 years of age (N=772).

****Health Care Provider perception of client anxiety.

Table 2b Characteristics of the Assault Sustained by Clients Eligible for and Offered HIV PEP

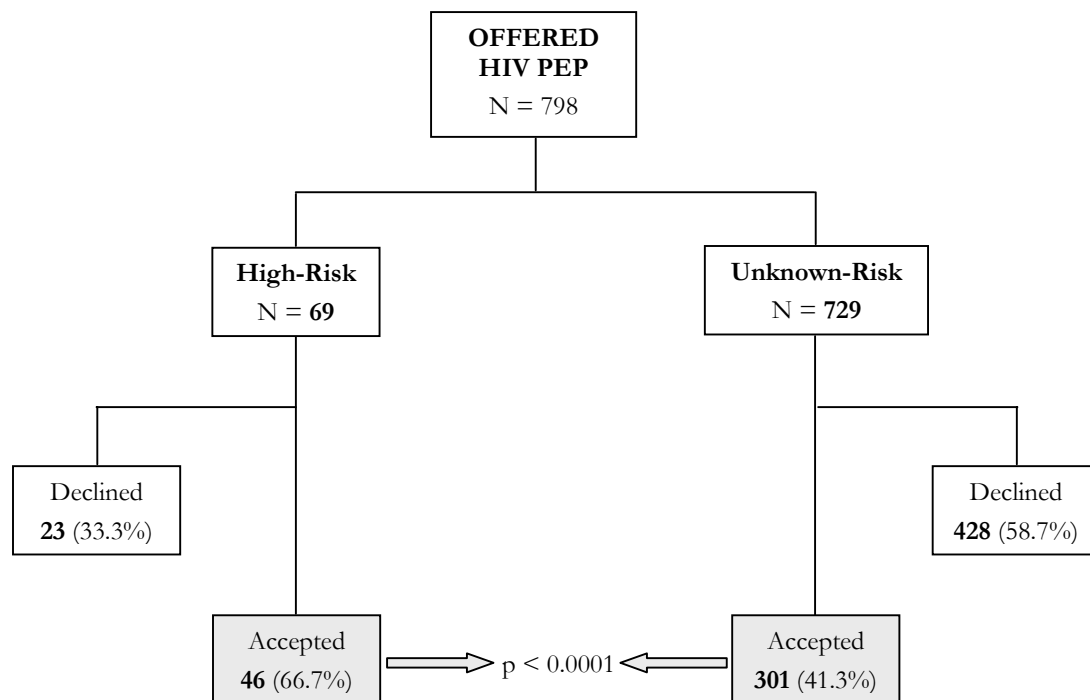
N=798					
Assailant High-Risk Status			Characteristics Potentially Affecting Client's Recall of Assault		
HIV-positive	3	0.4%	Unconscious and suspected drugging or forced consumption of alcohol/drugs	48	6.0%
MSM (man who has sex with men)	12	1.5%	Unconscious and voluntary consumption of alcohol/drugs	73	9.1%
IVDU (intravenous drug user)	15	1.9%	Suspected drugging or forced consumption of alcohol/drugs	117	14.7%
Endemic Country*	39	4.9%	Voluntary consumption of alcohol/drugs	179	22.4%
Not high-risk	67	8.4%	Asleep/unconscious	59	7.4%
Unknown-risk status	662	83.0%	Disability/condition**	34	4.3%
Assailant-Client Relationship			None	284	35.6%
Partner	38	4.8%	Missing	4	0.5%
Ex-partner	38	4.8%	Anal Penetration		
Parent/other relative	24	3.0%	Completed	61	7.6%
Friend	108	13.5%	Partial	18	2.3%
Date/co-worker	25	3.1%	Suspected	22	2.8%
Acquaintance/just met	314	39.3%	Unknown	243	30.5%
Sex work customer	6	0.8%	None	454	56.9%
Stranger	163	20.4%	Vaginal Penetration		
Missing	82	10.3%	Completed	401	50.3%
Length of Time Client Knew Assailant			Partial	33	4.1%
>24 hours	408	51.1%	Suspected	85	10.7%
< 24 hours	163	20.4%	Unknown	228	28.6%
Stranger (not at all)	163	20.4%	None	28	3.5%
Missing	64	8.0%	Not applicable (male)	23	2.9%
Number of Assailants			Oral Penetration		
One	593	74.3%	Completed	74	9.3%
Two or more	86	10.8%	Partial	32	4.0%
Missing	119	14.9%	Suspected	19	2.4%
Number of Sexual Acts			Unknown	271	34.0%
One	317	39.7%	None	402	50.4%
Two or more	144	18.0%	Foreign Object Penetration (Vaginal/Anal)		
Missing	337	42.2%	Yes	36	4.5%
Physical Assault			No	164	20.6%
Yes	360	45.1%	Missing	598	74.9%
No	248	31.1%	Physical Trauma/Injury		
Missing	190	23.8%	Anal and/or genital injury plus other physical injuries	154	19.3%
Weapon Used in Assault?			Anal or genital injury	141	17.7%
Yes	51	6.4%	Other physical injury (no anogenital)	153	19.2%
No	590	73.9%	No injury	301	37.7%
Missing	157	19.7%	Missing	49	6.1%

*A country with an HIV prevalence of > 1%. **e.g., developmental delay, schizophrenia, dementia

HIV PEP Uptake

HIV PEP was accepted by 66.7% (46/69) of high-risk clients and 41.3% (301/729) of unknown-risk clients. High-risk clients were 2.8 times more likely to accept HIV PEP than unknown-risk clients (95% CI 1.7, 4.8; $p < 0.0001$). HIV PEP acceptance rates by risk group are presented in Figure 6.

Figure 6 Acceptance of HIV PEP by Risk Group



Reasons that HIV PEP was not accepted are presented in Table 3. The most common reasons for declining HIV PEP were the same for high-risk and unknown-risk clients and included a lack of client concern about HIV (21.7% of high-risk clients and 36.9% of unknown-risk clients); client concern about the effects of HIV PEP (15.9% of high-risk clients and 26.1% of unknown-risk clients offered HIV PEP); and an inability or unwillingness on the part of the client to follow the regimen or return for follow-up (5.8% of high-risk clients and 9.6% of unknown-risk clients offered HIV PEP).

Table 3 Reasons HIV PEP Not Accepted*

High Risk (23/69)		
Lack of concern about HIV (e.g., prior sexual activity with assailant, doubt as to actual exposure)	15	21.7%
Client concern about effects of HIV PEP (e.g., side effects, drug interactions, possible disruption to routine)	11	15.9%
Client unable or unwilling to follow regimen or return for follow-up (e.g., unable to swallow pills, afraid of bloodwork)	4	5.8%
Client needed time to think about taking HIV PEP	3	4.3%
Client afraid others would find out about assault	1	1.4%
Unknown Risk (428/729)		
Lack of concern about HIV (e.g., prior sexual activity with assailant, doubt as to actual exposure)	269	36.9%
Client concern about effects of HIV PEP (e.g., side effects, drug interactions, possible disruption to routine)	190	26.1%
Client unable or unwilling to follow regimen or return for follow-up (e.g., unable to swallow pills, afraid of bloodwork)	70	9.6%
Client afraid others would find out about assault	25	3.4%
Client needed time to think about HIV PEP	16	2.2%
Client concern about pregnancy or breastfeeding	16	2.2%
Client overwhelmed/confused/unable to understand/impaired	7	1.0%
Other reason(s)	6	0.8%
No reason reported	22	3.0%

*More than 1 reason may apply to an individual client. Percentage out of number offered.

Predictors of HIV PEP acceptance are presented in Table 4. The odds ratio for risk status after adjusting for all other significant factors is slightly reduced from the raw odds of 2.8 to an adjusted odds of 2.2 (95%CI 1.2, 4.0) but remains statistically significant ($p=0.0097$). The high-risk group was 2.2 times more likely to take HIV PEP than the unknown-risk group. The strongest predictor of HIV PEP uptake was the strength of the HCP's recommendation to take HIV PEP. Clients that were encouraged or strongly encouraged to take HIV PEP were 3.6 times more likely to accept HIV PEP than clients that were neither discouraged nor encouraged. Other predictors of uptake included client anxiety (clients with moderate or high overall anxiety were 3.1 times more likely to accept HIV PEP than clients with low anxiety), client-assailant relationship (clients assaulted by a stranger were 3.3 times more likely to accept HIV PEP than those assaulted by a partner or ex-partner), age (clients between the ages of 4 to 17 were twice as likely to accept HIV PEP than those between the ages of 18 to 21, and 1.7 times more likely to accept than those between the ages of 30 to 80), multiple sexual acts (clients whose assault involved two or more sexual acts were 1.8 times more likely to accept HIV PEP than clients whose assault involved one or an unknown number of sexual acts), and extent of physical trauma suffered (clients with multiple injuries were twice as likely to accept HIV PEP than those without multiple injuries).

Table 4 Predictors of HIV PEP Acceptance

	Adjusted Odds Ratio (95% CI)*	P-value
Risk Status		
Unknown-risk**		
High-risk	2.2 (1.21, 3.95) [†]	0.0097
Age (in years)		
4-17**		
18-21	0.5 (0.31, 0.74) [†]	
22-29	0.8 (0.52, 1.28)	
30-80	0.6 (0.38, 0.99) [†]	0.0066
Physical Trauma		
Anal and/or genital injury plus other physical injury**		
Anal and/or genital injury	0.5 (0.31, 0.87) [†]	
Other physical injury (no anogenital)	0.5 (0.32, 0.89) [†]	
None/unknown	0.5 (0.33, 0.78) [†]	0.0131
Number of Sexual Acts		
One or unknown number**		
Two or more	1.8 (1.19, 2.77) [†]	0.0055
Client-Assailant Relationship		
Stranger**		
Partner or ex-partner	0.3 (0.15, 0.60) [†]	
Other	0.9 (0.59, 1.32)	
Unknown	1.3 (0.68, 2.29)	0.0025
Client's Overall Anxiety		
Low**		
Moderate or high	3.1 (2.15, 4.44) [†]	
Unknown	1.7 (0.71, 3.89)	<0.0001
Strength of HCP Recommendation of HIV PEP		
Neither discouraged nor encouraged**		
Encouraged or strongly encouraged	3.6 (2.51, 5.25) [†]	
Discouraged or strongly discouraged	0.3 (0.11, 1.09)	<0.0001

† Statistically significant. *Odds ratios are for the odds of accepting HIV PEP.

**Reference group (all other categories are compared to the reference group).

HIV PEP Completion

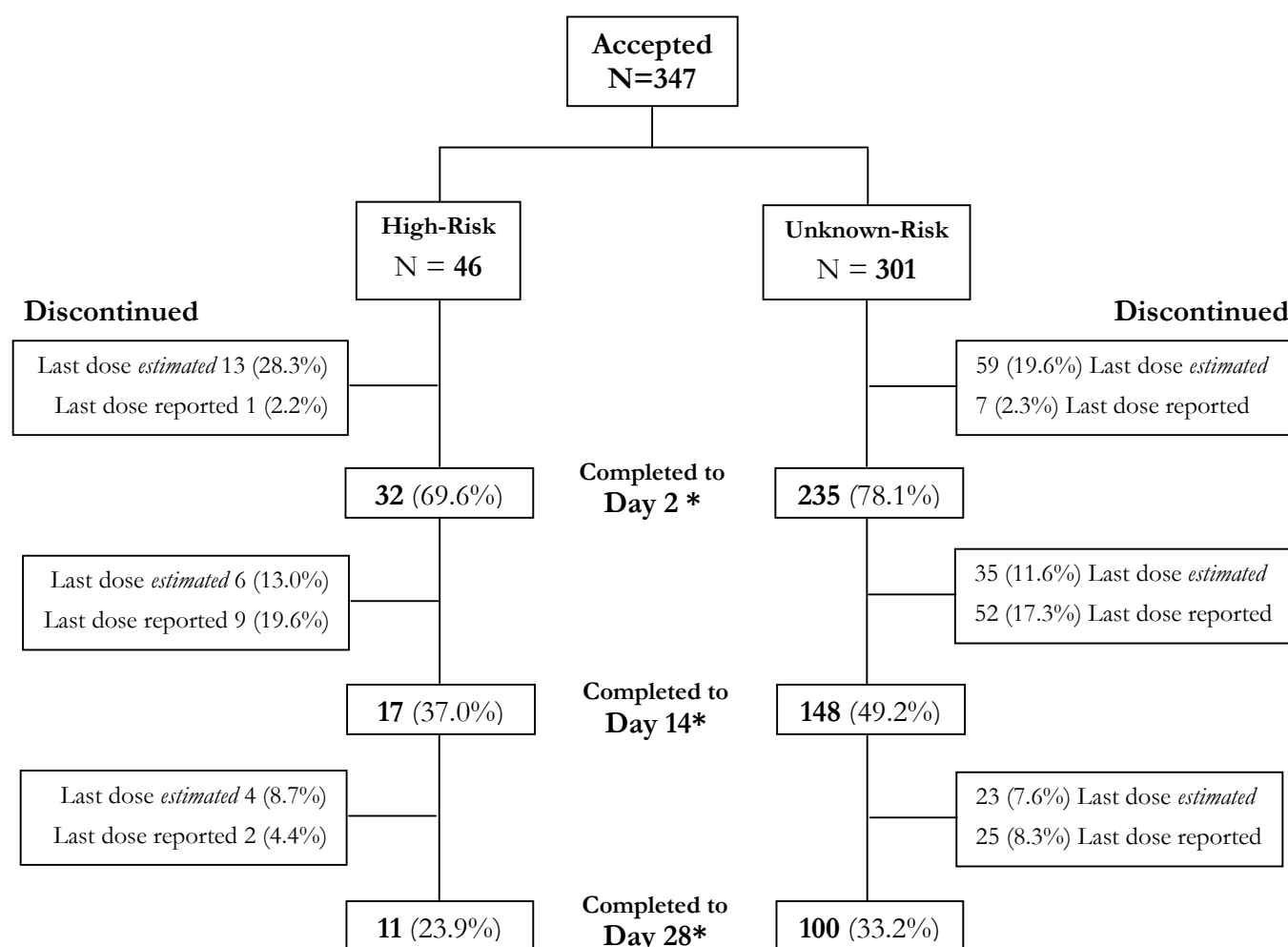
The HIV PEP completion rates by risk group are presented in Figure 7. The full 28-day course of HIV PEP was completed by 23.9% of high-risk clients that accepted HIV PEP and by 33.2% of unknown-risk clients. Although the rate is lower for high-risk clients, it is not statistically significantly different from the rate for unknown-risk clients (Odds Ratio=0.63; 95% CI 0.31, 1.30; p=0.2074).

Of the 236 clients that accepted HIV PEP but did not complete the full 28-day course, the actual date that the client stopped taking HIV PEP was reported in only 96 (40.7%) cases. The remaining 140 clients did not return for follow-up after stopping HIV PEP at some point in the course of their 28-day regimen, including 72 clients (20.7% of all clients who accepted HIV PEP) that were not seen again after accepting the initial 5-day starter kit of HIV PEP. In order to estimate HIV PEP

completion to Day 2 and Day 14, clients that did not return for follow-up after stopping HIV PEP were assumed to have taken their last dose of HIV PEP on the date of their last visit. As a result, estimates of HIV PEP completion at these interim time points are conservative.

HIV PEP was completed to day 2 by 69.6% of high-risk clients and by 78.1% of unknown-risk clients (Odds Ratio=0.64; 95% CI 0.32, 1.27; $p=0.2020$). HIV PEP was completed to day 14 by 37% of high-risk clients and 49.2% of unknown-risk clients (Odds Ratio=0.61; 95% CI 0.32, 1.15; $p=0.1224$).

Figure 7 HIV PEP Completion by Risk Group



* Rates not statistically significant between high- and unknown-risk

Reasons that clients did not complete HIV PEP are presented in Table 5. Of the 182 clients that stopped HIV PEP prior to Day 14, follow-up information was only available for 69 (37.9%). The remaining 113 (62.1%) clients did not return for follow-up after stopping HIV PEP at some point prior to Day 14. The most frequently reported reasons for stopping HIV PEP between Day 1 and Day 13 reported by the 69 clients were side effects from the drugs (81.2%), inability to carry out

their usual routine while on the drugs (42.0%), inability to take time off work, school, or other activities (21.7%), and belief that HIV PEP was unnecessary (18.8%).

Of the 54 clients that stopped HIV PEP between Day 14 and Day 27, follow-up information was only available for 27 (50%). The remaining 27 clients did not return for follow-up after stopping HIV PEP at some point between Day 14 and Day 27. The most commonly reported reasons for stopping HIV PEP between Day 14 and Day 27 by these clients were 1) side effects from the drugs (40.7%), 2) inability to carry out their usual routine while on the drugs (18.5%), and 3) other or undisclosed reasons (37.0%).

Table 5 Client Reasons HIV PEP Not Completed

Reasons reported for why HIV PEP stopped between Day 1 and Day 13 (N=69)*		
Side effects from the drugs	56	81.2%
Unable to carry out usual routine while on the drugs	29	42.0%
Unable to take time off work, school, or other activities	15	21.7%
Thought HIV PEP was unnecessary	13	18.8%
Influenced by family members, partner, or friends	7	10.1%
Taking the drugs reminded them of assault	5	7.2%
Could not remember to take the drugs	3	4.3%
Unable to come for follow-up visits to get the drugs	2	2.9%
Nurse or doctor at SATC or HIV Clinic advised stopping the drugs	1	1.4%
Other healthcare professional (e.g., family doctor) advised stopping the drugs	1	1.4%
Others might find out about the assault because of the drug	1	1.4%
Unwilling to follow study or medication protocol	1	1.4%
Other or unknown	9	13.0%
Reasons reported for why HIV PEP stopped between Day 14 and Day 27 (N=27)*		
Side effects from the drugs	11	40.7%
Unable to carry out usual routine while on the drugs	5	18.5%
Could not remember to take the drugs	3	11.1%
Nurse or doctor at SATC or HIV Clinic advised stopping the drugs	1	3.7%
Other healthcare professional (e.g., family doctor) advised stopping the drugs	1	3.7%
Influenced by family members, partner, or friends	1	3.7%
Taking the drugs reminded them of assault	1	3.7%
Unable to come for follow-up visits to get the drugs	1	3.7%
Thought HIV PEP was unnecessary	1	3.7%
Other or unknown	10	37.0%

* Only includes reasons reported for clients who were followed up after stopping HIV PEP.

More than 1 reason may apply to an individual client.

Predictors of HIV PEP completion to 28-days are presented in Table 6. The strongest predictor of HIV PEP completion was client anxiety. Clients with moderate or high overall anxiety at the Initial Visit were 2.4 times more likely to complete HIV PEP than clients with low anxiety or unknown anxiety. Other predictors of HIV PEP completion to 28-days included the length of time the client knew the assailant (clients assaulted by strangers or assailants known for less than 24 hours were 2.3 times more likely to complete HIV PEP than clients that knew their assailants for more than 24 hours), and physical assault (clients that were not physically assaulted were 2 times more likely to complete HIV PEP than clients that were physically assaulted). Physical assaults included restraint, confinement, or gagging; pushing, grabbing, or shoving; slapping, hitting, or kicking; biting; hitting with an object; beating; choking; stabbing; or shooting.

Table 6 Predictors of HIV PEP Completion to Day 28

	Adjusted Odds Ratio (95% CI)*	P-value
Client's Overall Anxiety		
Low/unknown**		
Moderate/high	2.4 (1.23, 4.51) [†]	0.0096
Length of Time Client Knew Assailant		
More than 24 hours**		
Not at all/less than 24 hours	2.3 (1.42, 3.87) [†]	
Unknown	1.2 (0.47, 3.19)	0.0035
Physical Assault		
Yes**		
No	2.0 (1.18, 3.47) [†]	
Unknown	0.9 (0.48, 1.82)	0.0198

[†] Statistically significant. *Odds ratios are for the odds of accepting HIV PEP.

**Reference group (all other categories are compared to the reference group).

Adverse Events and Follow-Up

Symptoms experienced by clients while on HIV PEP are reported in Table 7. Symptoms were graded according to the National Institute of Allergy and Infectious Diseases/National Institutes of Health (NIAID/NIH) toxicity grading (see glossary, page iii for definition of toxicity grading). Of the 275 clients who started HIV PEP and had one or more follow-up visits, 96% reported experiencing some form of symptom. Two hundred and twelve (77.1%) clients reported at least one Grade 2-4 symptom at some point during the follow-up period. Only 1.1% of clients had Grade 4 symptoms and did not complete HIV PEP to Day 28. Clients experienced an average of 3 different Grade 2-4 symptoms during the follow-up period (median 3, range 1-8). Neither the number of reported Grade 2-4 symptoms nor the Grade of the symptoms had an effect on completion rates. Of those clients who completed, 77.5% had Grade 2-4 symptoms and of those who did not complete, 76.8% reported Grade 2-4 symptoms.

The most common Grade 2-4 symptoms were fatigue (58.5%) and nausea (49.5%), followed by diarrhoea (22.5%), headache (20.7%), mood changes (20.4%), and vomiting (16.4%). Figure 8 depicts the rates of these symptoms by those that completed and those who discontinued the HIV PEP regimen. Those who experienced Grade 2-4 vomiting were less likely to complete than those

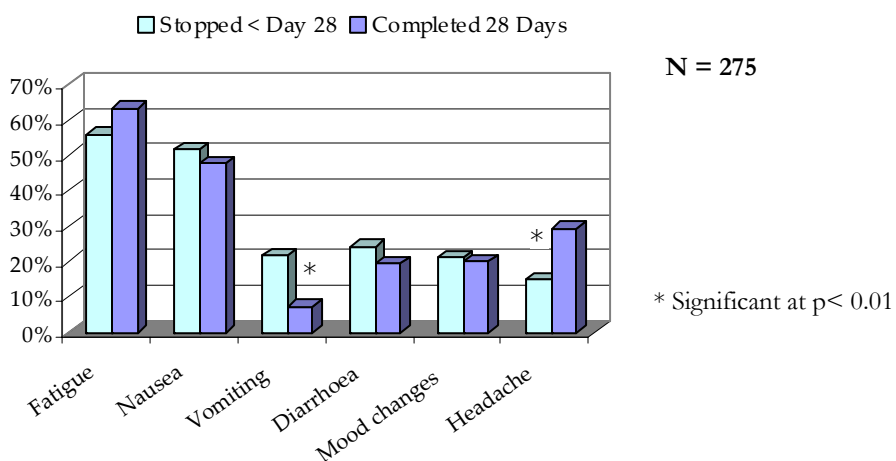
who did not experience vomiting (Odds Ratio=0.27; 95% CI 0.12, 0.6; p=0.0007). Those who experienced a Grade 2-4 headache were more likely to complete than those who did not experience headaches (Odds Ratio=2.5; 95% CI 1.4, 4.5; p=0.0024).

Table 7 Symptoms* Experienced by Clients During Follow-up (N=275)

	Grade 1	Grade 2	Grade 3	Grade 4	Grade 2-4
Highest Grade reported on any symptoms	53 (19.3%)	138 (50.2%)	71 (25.8%)	3 (1.1%)	212 (77.1%)
Highest Grade reported by symptom					
Fatigue	77 (28.0%)	112 (40.7%)	48 (17.5%)	1 (0.4%)	161 (58.5%)
Nausea	112 (40.7%)	111 (40.4%)	23 (8.4%)	2 (0.7%)	136 (49.5%)
Diarrhoea	149 (54.2%)	57 (20.7%)	5 (1.8%)		62 (22.5%)
Headache	75 (27.3%)	52 (18.9%)	5 (1.8%)		57 (20.7%)
Mood change	89 (32.4%)	46 (16.7%)	9 (3.3%)	1 (0.4%)	56 (20.4%)
Vomiting	101 (36.7%)	39 (14.2%)	5 (1.8%)	1 (0.4%)	45 (16.4%)
Muscle weakness	74 (26.9%)	23 (8.4%)	9 (3.3%)		32 (11.6%)
Rash	20 (7.3%)	9 (3.3%)	3 (1.1%)		12 (4.4%)
Shortness of breath	41 (14.9%)	12 (4.4%)			12 (4.4%)
Cough	71 (25.8%)	11 (4.0%)			11 (4.0%)
Allergic reaction	16 (5.8%)	4 (1.5%)	2 (0.7%)		6 (2.2%)
Constipation	34 (12.4%)	4 (1.5%)	1 (0.4%)		5 (1.8%)
Painful neuropathy	53 (19.3%)	4 (1.5%)			4 (1.5%)
Fever	38 (13.8%)	3 (1.1%)			3 (1.1%)

*Worst reported Grade at some point during follow-up.

Figure 8 Grade 2 to 4 Symptoms Reported by Clients During Follow-up



Of the 275 clients who started HIV PEP and were followed-up with one or more times, 203 (73.8%) reported taking medications to manage the symptoms/side effects of HIV PEP. The most common medications taken were Gravol (176 clients, 81.3% of whom reported it helpful), Tylenol (79 clients, 74.7% of whom reported it helpful), Imodium (60 clients, 71.7% of whom reported it helpful), and Ibuprofen (26 clients, 84.6% of whom reported it helpful).

Bloodwork was taken at the Week 2 Visit (median Day 14; Interquartile Range Day 13, Day 16). Results were reported for 159 clients. Eight clients (5.0%) were reported to have abnormal blood results \geq Grade 2 toxicity, specifically WBC (1 client), ABS Neutrophil (1 client), glucose (2 clients), AST/SGOT (1 client), total bilirubin (2 clients), and serum amylase (1 client). One of the eight clients was diabetic and reported to have a glucose level of Grade 4 toxicity (28.3 mmol/L).

c) Summary

Data were collected on 1,238 consecutive sexual assault victims/survivors seen at 24 Ontario SATCs, September 10, 2003 to January 31, 2005. Six SATCs did not collect data on all consecutive clients and their data was removed from the data analyses. Of the 1,103 (89.1%) clients that were included in the final analyses, only 7.3% of clients had no-risk of HIV exposure during their assault. Eight percent of clients were classified as high-risk based on their knowledge or assumptions of the assailant's HIV status or HIV risk factors and the assault circumstances, and the remaining 84.7% were classified as unknown-risk. After excluding clients who were ineligible for HIV PEP (no-risk, presentation more than 72-hours, HIV-positive), 900 (82%) clients remained eligible for HIV PEP.

Although the study protocol specified offering of HIV PEP universally to these clients, there were some circumstances in which HCPs determined that it was inappropriate to offer HIV PEP (life circumstances that made clients unable to comply with an HIV regimen or medical reasons). In some cases HCPs were unable to offer HIV PEP as the clients were in a state that did not allow them to understand the implications of HIV PEP or they refused care before the offer could be made. As well, there were several cases in which the HCPs deemed the risks too low for HIV PEP to be offered. This suggests that there were situations in which HCPs believed that the risk categories as defined in the study were insufficient to assess the appropriateness of offering HIV PEP.

Rates of offering, acceptance, and completion of the 28-day 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%
Overall		43.5%	32.0%

The 43.5% overall rate of acceptance in this study is much higher than the 27.5% (71/258) uptake rate reported in the British Columbia study (Wiebe *et al.*, 2000) and the 32.3% (69/213) uptake rate documented in the San Francisco study (Myles *et al.*, 2000) (both studies were retrospective chart reviews). It is difficult to know why the overall acceptance rate is higher in this study but it does suggest that sexual assault victims/survivors in Ontario are receptive to the provision of HIV PEP.

The analysis of the predictors of acceptance show that clients who have information about the assailant's HIV status or HIV risk factors (high-risk group) are 2.2 times more likely to accept HIV PEP than those who do not (unknown-risk group), independent of all other significant factors. This suggests that a client's assessment of their own need for prophylactic medication was strongly influenced by an assessment of their assailant as 'high-risk'. HCP recommendations also have an influence on whether a client accepts HIV PEP or not. Those with moderate or high overall anxiety were more likely to accept HIV PEP as well as those who were assaulted by a stranger and those whose assault involved multiple sexual acts or multiple injuries.

Clients between the ages of 4 and 17 are more likely to accept HIV PEP than those 18 to 21 years old and those 30 to 80 years old. In the 4 to 17 year old cohort, only 8 were under the age of 12 and only 1 of those accepted HIV PEP so the high acceptance rate is driven by the 13 to 17 year olds. Seventy percent of those between 13 and 17 years were accompanied by an adult. However the trend in the data showed that those accompanied by an adult were more likely to refuse HIV PEP. The higher acceptance rate in this young cohort may be an indication that the younger clients without an accompanying adult rely more heavily on HCP recommendations. The 22 to 29 year old cohort also had significantly higher acceptance rates than the 18 to 21 year old cohort (Odds Ratio=1.7; 95%CI 1.1, 2.6). Future research is needed to explore these differences in acceptance rates between age cohorts.

In the BC study, over half of clients who began HIV PEP did not return for their first follow-up visit (Day 2 to 5). When contacted to determine the reason for failing to return or continue with the treatment, many suggested that they had re-evaluated their situation when they got home and reviewed the materials provided, determining that "it wasn't worth it" (Wiebe *et al*, 2000, p.643). In this study, 72 of 347 clients (20.7%) were lost to follow-up before their first scheduled follow-up visit (Day 2 to 4). Although we cannot know their reasons for discontinuing the treatment, this finding may indicate that, similar to the BC study, these clients re-evaluated their risk and determined that HIV PEP was not required.

For those clients that continued on the medications beyond the Initial Visit but did not complete the full HIV PEP regimen, both clients and their HCPs identified symptoms/side effects as the primary reason that the HIV PEP regimen was not completed. Symptoms were a significant burden with 77.1% of all clients experiencing at least one at the Grade 2 to 4 level. There was not an association between grade of symptom and completion rates. Although the number one reason for not completing HIV PEP was symptoms/side effects, many clients were able to complete the course of drugs despite their symptoms.

Being unable to carry out their usual routine while on the medications and being unable to take time off were other factors that affected clients' ability to complete the regimen. These may be related to the high rate of side effects. It is interesting to note that very few clients were advised to stop the drugs by HCPs, indicating that the medications did not cause severe health concerns in this population. More research is required to determine the range of factors that affect clients' decisions to complete/not complete the HIV PEP treatment and their respective influence. This may provide information about how best to support those clients who wish to continue the treatment but experience difficulties in completing the full regimen.

The 32% overall completion rate of HIV PEP to 28-days in this study is considerably higher than

the 11.3% reported by Wiebe *et al.*, 2000. The exceptional completion rates captured within the HIV PEP Study may be attributed to the well-structured regimented follow-up schedule. The schedule of drug dispensement differed significantly from those identified in the literature (Wiebe *et al.*, 2000; Myles *et al.*, 2000). Rather than dividing the medication into two dispensing episodes, the HIV PEP Study's 28-day supply of drugs was distributed over four visits, at the Initial Visit, Day 2-4, Week 2 and Week 3. Increasing the number of follow-up visits during HIV PEP therapy increased the amount of support clients received during the difficult weeks following their assault, while on HIV PEP. The study findings suggest that the additional support offered through this follow-up schedule leads to an increased proportion of clients that continue and complete HIV PEP therapy.

Although a statistically significant result was not found in completion rates between the two risk groups, there was a trend indicating that the unknown-risk group may have higher completion rates than the high-risk group. These results run counter to published and anecdotal comments that clients that fit into the high-risk classification are most likely to complete HIV PEP. The analysis of predictors of completion to 28-days shows that clients who are assaulted by strangers or those they have known for less than 24-hours, and clients with moderate or high overall anxiety were more likely to complete HIV PEP. Interestingly, clients who were not physically assaulted were more likely to complete the HIV PEP regimen than those who were physically assaulted. One hypothesis for this result is that clients with physical injuries stemming from the assault may be less able to cope with the side effects of the HIV PEP regimen. Again, further research is needed to more fully explore the issue of compliance in order to put in place supports to assist all clients in completing the regimen if they so choose.

The uptake and completion rates for victims/survivors assessed at both high-risk and unknown-risk are high in the HIV PEP Study, pointing to a clear demand for the program and willingness by a significant proportion of clients to follow through with the full regimen.

CHAPTER 4

HCP PERCEPTIONS OF HIV PEP PROGRAM

HCP Survey



Follow-up Care Provider Survey



HCP Focus Groups



HCP Recommendations

4. HCP PERCEPTIONS OF THE HIV PEP PROGRAM

Quantitative and qualitative data were collected from Health Care Providers (HCP) to gather feedback on the universal HIV PEP program to determine perceptions of its viability, effectiveness and sustainability. The techniques used to gather this information included: a HCP Survey, a Follow-up Care Provider Survey, and HCP Focus Groups.

a) HCP Survey

Method

This tool was designed to capture HCPs' views regarding the universal offering of HIV PEP and HIV counselling, including how these two components of care affected their workload and overall patient care (see Table 8 for specific survey questions). Prior to distribution, the HCP Survey was piloted in October 2004 with the assistance of several SATC coordinators and staff members across the province.

Along with self-addressed, postage-paid, return envelopes, surveys were distributed to the Coordinator of each participating SATC for distribution among staff in November 2004. All HCPs (Nurses, Physicians, Pharmacists, Social Workers, etc.) that participated in the HIV PEP Study were asked to complete an anonymous and completely voluntary survey. No identifying information was collected. Reminders to distribute surveys among staff were sent to SATC Coordinators via e-mail 2, 6, and 8 weeks post-distribution.

Surveys were returned to the Centre for Research in Women's Health (CRWH), where they were entered into an MS Access database and then filed in a secure cabinet. Only members of the Research Team have access to the surveys and the database, which is restricted by password.

Analysis

Frequencies were generated for each question using MS Access. Respondents were left space to provide comments following each question. The questions were grouped into the following categories: Decision-Making (Questions 2 & 4); Quality of Care (Questions 3, 5, & 6); Delivery Model (Questions 7 & 8); and Sustainability (Question 1). Respondent comments were organised by the response chosen under each question. The comments were summarised by content or mentioned verbatim.

Results

There was a 35.2% (132/375) response rate for the HCP Survey. See Table 8 for an overview of HCP responses. The majority (n=80, 60.6%) of respondents were Sexual Assault Nurse Examiners (SANE). Respondents also included 20 (15.2%) SATC Coordinators, 14 (10.6%) physicians, 9 (6.8%) social workers, 8 (6.1%) pharmacists, and other HCPs.

Table 8 Health Care Provider Survey Results

N = 132			
	Yes	No	Don't Know or Not Sure
1 Thinking about the impact that HIV PEP and universal offering had on the Health Care Providers (nurses, physicians, administrators, pharmacists, social workers) at your hospital, do you think universal offering of HIV PEP to SATC clients is sustainable at your hospital on a long-term basis?	86 (65.2%)	12 (9.1%)	34 (25.8%)
2 Thinking about the SATC clients that you cared for, do you think, in general, that clients are able to make an informed decision (i.e., weigh the potential risks and benefits) to take/not take HIV PEP?	83 (62.9%)	15 (11.4%)	34 (25.8%)
3 Given the spectrum of care you are required to provide to SATC clients, did you have the time and opportunity to provide sufficient counselling about HIV PEP?*	83 (74.8%)	16 (14.4%)	12 (10.8%)
4 Do you think clients' decisions to take/not take HIV PEP was significantly influenced by whether (or how strongly) it was recommended to them?	63 (47.7%)	38 (28.8%)	31 (23.5%)
5 Based on your observations and feedback you received from clients, were clients generally satisfied with the HIV care they received?	77 (58.3%)	1 (0.8%)	54 (40.9%)
6 Thinking about the time/effort involved in providing universal offering of HIV PEP, do you think that other aspects of client care were compromised because of universal offering?	28 (21.2%)	77 (58.3%)	27 (20.5%)
7 Despite not knowing the risk of HIV acquisition in the unknown risk group, do you think it is beneficial to offer HIV PEP to this group?	91 (68.9%)	15 (11.4%)	26 (19.7%)
8 There are a variety of possible strategies for offering HIV PEP to SATC clients. Please think about your experiences with HIV PEP and universal offering. What do you think is the OPTIMAL strategy for offering HIV PEP to SATC clients? If one of the options below represents your opinion of the "optimal" strategy, please check the appropriate box. Please use the "Comments" section to describe your optimal strategy if none of the options fit, or to refine or qualify your choice.			
Counsel all clients; only offering HIV PEP to all "high risk" clients, and offering HIV PEP to those "unknown risk" clients (e.g., penetration + unknown risk assailant) who request it.			73 (55.3%)
Counsel all clients; "Universal offering" of HIV PEP.			36 (27.3%)
Counsel all clients; only offering HIV PEP to "high risk" clients (e.g., penetration + high risk assailant).			11 (8.3%)
HIV PEP not offered to SATC clients.			6 (4.5%)
Counsel all clients; only offering HIV PEP to clients at risk who express concern about HIV.			3 (2.3%)
Did not respond.			3 (2.3%)

* 21 respondents did not provide counselling

Decision-Making: Ability of Clients to Make Informed Decisions

When asked whether they thought clients were able to weigh the potential risks and benefits to taking or not taking HIV PEP, more than three-fifths (n=83, 62.9%) of HCPs stated, "yes". A Social Worker elaborated, "*Our nurses did an excellent job providing enough information so clients could make their own decisions without becoming overwhelmed*" (Respondent 99). A Nurse who had provided initial care qualified

her response, “*For the most part. Certainly there are some clients unable to make those decisions*” (Respondent 62). This concern was also articulated by several other HCPs who felt that the ability to make an informed decision was sometimes compromised by personal and situational factors such as age, language, cognitive ability, home situation, drug and alcohol use, stress, and time constraints.

Difficulty with patients with language barriers - usually they come during the night: no reading material/ interpreter services (SANE, Respondent 135).

The issue of alcohol consumption that can have impact on how competent the client is in making an informed decision is still a concern we deal with (Coordinator/SANE, Respondent 79).

Our program found that in order to really have ability to make informed decision required a lot of time. Unable to do it in 20 minute as has been suggested (Coordinator/SANE, Respondent 43).

However, several Nurses who had provided both initial and follow-up care cited the importance of the follow-up visit in overcoming the problem of consent being informed,

They are making an important decision under stress, however, follow-up can/ should provide an opportunity for clients to continue to explore whether they want to continue or not (Nurse, Respondent 100).

Over one-third of respondents either did not believe (n=15, 11.4%), or were unsure (n=34, 25.8%) whether clients were able to make an informed decision to take HIV PEP. Again, several comments centered on personal and situational factors as captured in part by a SANE who was “*unsure*” whether clients’ decisions were always informed,

In most cases clients are able to make informed decisions. In some cases, however, trauma, mental illness and/ or intoxication impair clients’ ability to make informed decisions (Respondent 4).

The main barrier raised by HCPs, however, was client distress – the inability to make an informed decision while in a crisis situation. One SANE who responded, “*no*” to the question captured this succinctly, “[*T*]hey are traumatized and not thinking clearly or listening well” (Respondent 102). This appears to have been made more difficult by the fear that clients exhibit in contracting HIV as a whole, as noted by two physicians who did not think that such decisions could be informed,

So much fear about HIV that knowledgeable choices during time of assessment difficult (Respondent 35).

Decision-Making: Influence of HCP Recommendation

When asked whether they thought clients’ decisions to take or not take HIV PEP were significantly influenced by whether or how strongly it was recommended to them, approximately half (n=63, 47.7%) responded “*yes*”. A SANE commented, “*sure - many clients ask, ‘what would you do?’*” (Respondent 135). A colleague further explained,

We are health care professionals and generally clients trust our opinion. In fact, many clients are looking to us to make decisions for them at a time when they are too overwhelmed and traumatized (SANE, Respondent 4).

There was some suggestion from HCPs that influence on client decisions was related to the ethos of certain centres or the views of particular examiners,

I work with a group that strongly believe in HIV PEP (Nurse, Respondent 117).

[I] see that certain nurses on team have more clients accepting PEP than others (SANE, 133).

Others stated that “*younger clients*” were most easily influenced (Nurse, Respondent 14).

Although staff had been trained to “*strongly recommend*” HIV PEP to “*high-risk*” and “*recommend*” to “*unknown-risk*” clients, one Coordinator/Social Worker commented,

“[N]urses report that if the patient's status is high-risk then they strongly recommend and this influences the patient. If unknown-risk, nurses tend to remain neutral and let the patient come to her own decision” (Respondent 42).

Another Coordinator/SANE took this latter stance even further, “*I don't think that it is my role to strongly encourage. Our role is giving information to make an informed decision. If they are not committed to taking the medications my encouragement won't help*” (Respondent 73).

Half the sample thought that they either had not (n=38, 28.8%), or were unsure (n=31, 23.5%) whether they had, influenced clients’ decisions to take HIV PEP. Most of those that responded “*no*” and commented further, stated that this was because they had presented the facts in an unbiased manner. As several SANEs explained,

I work very hard to remain neutral and not influence their decisions (Respondent 37).

I provide information and answer questions to allow patient to make their own decisions (Respondent 87).

Several HCPs who responded “*not sure*” also stated that they attempted to remain neutral in counselling clients. A Coordinator/Nurse observed, “*I found that I did not recommend – neither encouraged nor discouraged*” (Respondent 1).

Quality of Care: Counselling About HIV PEP

When asked if there was time and opportunity to provide sufficient counselling for HIV PEP, fully three-quarters (n=83, 74.8%) of HCPs responded “*yes*”. A number stated that they either were “*not limited with time*” (SANE, Respondent 104) or that they “*made the time*” (Nurse, Respondent 51) even though counselling “*added significantly to the time needed for the initial visit*” (SANE, Respondent 13). One SANE who had provided both initial and follow-up care went so far as to write that she believed that the HIV PEP counselling had benefited clients generally,

I feel by adding this element to our care, it has increased the time spent counselling the clients and improving their overall care (Respondent 19).

A small minority of HCPs who responded affirmatively subsequently qualified their response. Some “*felt that the counselling was rushed*” (Respondent 76); others that the clients were just too tired or overwhelmed to take in much,

[C]lients can be exhausted by all the issues we have to talk to them about and HIV PEP is another big issue (SANE, Respondent 128).

Occasionally client is too exhausted to absorb much information. ... [C]an provide written resources and opportunity to return within 72 hours. Still see clients in follow-up who lack knowledge or are taking medications incorrectly or with no anti-emetics. Can mean the difference between stopping medications and completing course (Nurse, Respondent 133).

One SANE stated that increased visit time due to counselling had negative implications for clients,

[A]ll response calls seem to be very labour intensive now and take much longer - average time to do study and [forensic] kit is at least 4 hours, more like 4 to 6 hours. Have had the next client have to wait 1 1/4 hours before I could complete all the paperwork! (Respondent 61).

It is important to note, however, that strategies to resolve such issues were posed by several SANEs,

Our program has changed so that we deal with the HIV PEP question at the start of the visit. We have changed the order of our chart to reflect this (Respondent 53).

I try to keep it simple and basic then provide the literature for patient to follow-up at home to read. Of course I answer any questions (Respondent 54).

Often found on initial contract the counselling given wasn't always taken in if long, but if kept short, key aspect was okay. Then on next visit with follow-up nurse counselling was redone - the person got more of the message (Respondent 79).

Just over one-quarter of HCPs felt that there was not (n=16, 14.4%), or they were unsure (n=12, 10.8%) whether there was, enough time or opportunity for sufficient HIV PEP counselling. One of the main reasons given for a “no” response was the amount of material to cover,

Seeing a client ... is exhausting both for the client and nurse. After forensic exam and going over all other health concerns - spending a whole chunk of time on HIV PEP was hard on the nurse and client, therefore the process was often rushed (Nurse, Respondent 4).

Several others stated that adequate counselling was not possible due to some clients’ desire to shorten the therapeutic encounter or the impact on them emotionally of discussing HIV,

Depends - some clients (most) very anxious and exhausted and want to be finished and go home. Also very overwhelmed, which can keep them from wanting to discuss or participate in counselling (SANE, Respondent 107).

At the time of caring for the victims of sexual assault - the majority are unable to absorb and comprehend information regarding HIV PEP - once they hear HIV it further stresses them (SANE, Respondent 105).

Again, however, several HCPs cited follow-up visits as an opportunity to “provide ... more ... counselling” (SANE, Respondent 102).

Quality of Care: Client Satisfaction

When asked whether clients were generally satisfied with the care received, almost three-fifths (n=77; 58.3%) responded, “yes”. HCPs who commented further, cited evidence from those receiving care themselves as well as from their family members. A Nurse who had provided both initial and

follow-up care noted emphatically, *“VERY SATISFIED, I received Christmas cards from three”* (Respondent 117). A SANE elaborated further, *“Because I make frequent phone calls between visits and patients are aware they can call me with any question they may have, I have received a lot of positive feedback from patients and their family (usually a mother)”* (Respondent 53). A Coordinator/SANE importantly noted, *“Most [clients] indicate they were thinking about AIDS but didn't know how to ask so were glad and relieved when I spoke about HIV/AIDS”* (Respondent 79). Follow-up care was mentioned by several HCPs to have been central to client satisfaction.

Only 1 (0.8%) HCP, a Nurse, stated that clients were not happy with the care received. Her opinion was based very indirectly on the fact, *“many ... did not follow through with HIV PEP”* (Respondent 110). That *“many have dropped out [of treatment]”* was the reason given also by several HCPs who were unsure (n=54, 40.9%) clients were satisfied with care (Respondents 111). A substantial proportion that responded *“not sure”* further stated that they could not judge client satisfaction as the issue had never arisen, or they had neither been involved in recommending treatment nor in providing follow-up care.

Quality of Care: Impact on Other Areas of Care

When asked whether other aspects of client care were compromised as a result of universal offering of HIV PEP, nearly three-fifths (n=77, 58.3%) of HCPs responded *“no”*. Although several made comments that, *“it certainly added to the time required”* to care for a patient (Coordinator/Nurse Respondent 1), it was also importantly noted that the *“exams [are] not time-limited”* (Respondent 95) – *“nurses spend as much time as needed with the individual”* (Respondent 35), *“extra time, if necessary, [is taken]”* (Respondent, 53). In fact, several HCPs felt that the overall service provided to clients had improved,

I believe client care is enhanced because of the time it takes to explain HIV PEP - so many other conversations are started from that (Nurse, Respondent 106).

I feel that this has enhanced their care up. [U]ntil this [program implementation], we had not done a lot of follow-up care and [this] has definitely improved our service (Coordinator/SANE, Respondent 19).

Two SATC Coordinators, nonetheless, expressed concern,

[I]t does make the nurses ‘nervous’ as - takes extra time and changes known routine - drug interactions and side effects (Respondent 72).

I am concerned that it seems to take precedence over the sexual assault due to needing to assess risk so medications can begin (Respondent 97).

In contrast, another poignantly noted, *“What would be more important than HIV seroconversion?”* (Respondent 115).

Only one-fifth (n=28, 21.2%) of HCPs thought, *“too much time spent on HIV PEP counselling meant other issues got less time”* (Physician, Respondent 103). A couple noted specifically the areas of care they thought compromised,

Other issues such as safer sex, police involvement, PTSD[Post Traumatic Stress Disorder], STDs (Coordinator/SANE, Respondent 86).

Follow-up care is definitely compromised ... as the minority of clients who are on HIV PEP monopolise the time of the follow-up nurses (SANE, Respondent 4).

Many of those who felt care had suffered gave reasons why. A SANE opined, *“the study has placed a lot of emphasis during the first encounter on discussing HIV which, in our community, is the least likely adverse effect of sexual assault”* (Respondent 83). Others commented that clients are *“overwhelmed when HIV [is] brought up”* (SANE, Respondent 18), in part, related to the overall amount of information to be assimilated,

There is so much information given to the client at the time of treatment. It is difficult for the client to regroup and focus on other important issues (Nurse, Respondent 82).

A Nurse further observed, *“some clients do not wish to spend the time required to get all of the information available and, if they do, other areas of care are rushed”* (Respondent 127).

Just over two-fifths (n= 27, 20.5%) of HCPs were unsure whether care had been compromised by universal offering of HIV PEP. A SANE's comments capture some of this uncertainty,

Yes and no. No, because I feel universal offering is very important but yes, because there is a lot of stress/pressure at the beginning of the assessment with a new client to determine if they ‘fit the criteria’. I feel it forces them to make a decision regarding HIV PEP early on when some have other concerns they would like to be addressed first (Respondent 135).

Several aspects of care were thought to be impacted,

PTS [Post Traumatic Stress]/emotional support/counselling needs were often put on hold initially (Social Worker, Respondent 55).

Because we offer HIV PEP early on. Sometimes the patient is anxious to complete ‘the rest’ and can be less cooperative, that is, not able to give the time required to gather evidence - starts to decline things to expedite their discharge (SANE, Respondent 69).

HIV PEP Delivery Model: Benefits for Unknown-Risk Group

When HCPs were asked, *“Despite not knowing the risk of HIV acquisition in the unknown-risk group, do you think it is beneficial to offer HIV PEP to this group?”* more than two-thirds (n=91, 68.9%) responded, *“yes”*. A few emphatically elaborated: *“Yes! Yes! Yes!”* (Nurse, Respondent 106); *“Absolutely – I would want it if I were the patient. We need to provide that option”* (SANE, Respondent 128); and *“Ethically and morally required as well!”* (SANE, Respondent 87). Several commented that the gains to those with unknown-risk status offset the potential risks,

Benefits far outweigh the side effects of medications if the attacker was [HIV] positive (Nurse, Respondent 5).

Better to take opportunity to protect self now than risk being HIV positive for the rest of life (SANE, Respondent 125).

Women can never be 100% sure of no-risk/ low risk status, even when assaulted by long-term partner (Social Worker, Respondent 99).

According to one Nurse, this was the position of many receiving care as well, “*Clients have stated, ‘better to take this now than not take it and find out later that I became HIV positive and should have taken it when I had the chance’*” (Respondent 88). A Coordinator/Social Worker noted, it “*gives a victim/survivor some ‘peace of mind’ and control over her health care’*” (Respondent 42).

The risk of liability was an additional concern articulated by one Nurse, who posed the question,

Because the risk is ‘unknown’ are we in danger of a lawsuit if it is not offered? And more importantly, how would we feel if this patient became HIV positive had we neglected to offer PEP (SANE, Respondent 53).

Although only two HCPs qualified their affirmative responses with, “*we should not offer to low risk groups*” (SANE, Respondent 4), several others noted that it was essential once HIV PEP was offered to let clients choose whether or not to take it, “*It’s important to permit the patient to decide*” (SANE, Respondent 67).

Among those that thought the unknown-risk group would not benefit from HIV PEP (n=15, 11.4%), the reasons given were similar to those who stated that they were unsure (n=26, 19.7%). Most thought that the benefits did not outweigh the risks,

Compliance is a big factor - If people start antiretrovirals and then discontinue, what are the long-term implications? (SANE, Respondent 39).

Unless someone is very concerned - otherwise I worry we cause people needless anxiety at time of trauma/crisis already (Coordinator/Social Worker, Respondent 97).

I personally think without some evidence increasing the risk (even anecdotal) that the risks outweigh the benefits (SANE, Respondent 109).

Because the risk is so low here and we are unsure of benefit of a few days dosage, I am really unsure of the benefit when it takes up a big part of our meeting with client (Nurse, Respondent 31).

Two Coordinator/SANEs who responded “not sure” made two further but related points,

This is a very difficult group particularly if it is a drug facilitated sexual assault and we don’t know if anything actually occurred (Respondent 19).

Almost all of our clients are ‘unknown’ category because they don’t know the assailant’s status. Many are not sure if there was penetration because they were passed out (Respondent 73).

HIV PEP Delivery Model: Optimal Strategy

When HCPs were asked what they thought was the optimal strategy for offering HIV PEP to clients, more than one-quarter (n=36, 27.3%), endorsed the option, “*counsel all clients and offer HIV PEP universally*”. As one SANE who had provided both initial and follow-up care explained, “*most clients have many unknowns in our area. Being unknown-risk is not the same as being low risk*” (Respondent 95). Another SANE stated, “*Estimating risk is just that ... an estimate. Low risk does not mean no-risk*” (Respondent 85). She went on to further say, “*I think we inform, educate, then allow patient to make decision*”. Several other respondents endorsing the universal offering option agreed with this sentiment, again, suggesting some unease among some health care professionals with ‘recommending’ HIV PEP,

I think it should be the client's decision upon knowledge of appropriate facts (Physician, Respondent 25).

Clients should be aware of all available treatments, then make an informed choice (SANE, Respondent 57).

[T]his must ultimately be the clients' choice with informed counselling by the health care professional (SANE, Respondent 125).

Two respondents suggested improvements to the program. A pharmacist recommended, “*the counselling be multidisciplinary including pharmacists with specialized HIV knowledge*” (Respondent 15). A SANE thought, “*the use of better tools (i.e., information booklet regarding drugs, etc.) could be improved for ease of use and less paperwork*” (Respondent 37).

Over one-half (n=73, 55.3%) of HCPs endorsed the option, “*counsel all clients and offer HIV PEP to all those who meet 'high-risk' criteria and to those who meet 'unknown-risk' criteria and request it*”. A Nurse thought this the most optimal strategy as, “*clients would be more likely to take it who need it and follow through*” (Respondent 31). A Coordinator/Social Worker explained the importance of and what she perceived might be the challenges in embracing this strategy,

Many of our physicians are reluctant to sign standard orders when risk is unknown. They feel the risk of the drug is greater. High-risk is not a problem for them. If a client, after being counselled regarding their risk, side effects, etc., requests the treatment, they should not be denied the medication. We have to sort out this issue with the emergency room doctors (Respondent 42).

Again, there was some concern noted around recommending versus offering the drug regimen, “*as not everyone needs HIV PEP*” (Coordinator/SANE, Respondent 72).

A very small proportion (n=11, 8.3%) of HCPs thought that HIV PEP should be offered only to those meeting “*high-risk*” criteria, although a SANE who had provided care to clients at Initial Visits, qualified her response, “*High-risk can be somewhat modified. While we can't positively state this person is good or bad, etc., I do think judgement calls have a place. SANEs, etc., have experience and I think this is ignored so far*” (Respondent 109).

Even fewer respondents thought that HIV PEP should be offered only to clients at risk who express concern about HIV (n=3, 2.3%) or not offered at SATCs at all (n=6, 4.5%). Endorsing the latter option, a SANE explained, “*[HIV PEP] should not be offered during acute visit - client supersaturated with information and other medication, i.e., antibiotics and pregnancy prophylaxis. The combined side effects of all these medications lead to clients not completing regimen*” (Respondent 105). Other SANEs suggested, “*the patient's own family doctor*” (Respondent 7) or “*Public Health Unit*” (Respondents 111) take the lead in providing these services. Three (2.3%) HCPs did not endorse any specific strategy.

Sustainability of HIV PEP Program

When asked whether they believed that the universal offering of HIV PEP was sustainable over the long-term, nearly two-thirds (n=86, 65.2%) of respondents stated, “*yes*”. Two nurses who had been involved in providing direct client care further elaborated,

The centre I work at is experiencing tremendous success with the HIV PEP project. I believe it is entirely sustainable (Respondent 106).

I believe all of our group pharmacists, doctors, nurses have all found it to be a well-organized program, easy to follow and definitely beneficial to the client (Respondent 117).

The success in implementing the program at some hospitals was related to staff dedication. A Social Worker noted, “Nurses are highly committed and the clinical leader has established an excellent follow-up strategy” (Respondent 99). Along similar lines, a SANE wrote, “Contact with our pharmacy department has been very positive. They have even changed their drug regime (for staff and patients) to correspond to our HIV PEP regime” (Respondent 54).

Some HCPs who answered affirmatively qualified their response. Concerns centered primarily on the resources required to sustain the program. Several were concerned about the monies to support the program generally as indicated by one pharmacist’s comment, “who will fund the treatment?” (Respondent 59). Others were concerned about the funding of the drug regimen specifically. A Medical Director/Physician noted that the “hospital will not cover 1/12 of the cost of medications” (Respondent 22). A nurse stated, “[I] can’t see clients using their own health plans to cover the cost of antivirals [because of the] lack of confidentiality” (Respondent 133). Still others were worried about funding of staff hours particularly for follow-up personnel. A Coordinator/SANE’s statement is illustrative,

With the nurses taking the lead as we have been [the program] can continue. Staff funding resources for the follow-up nursing role will be a potential barrier that on a long-term basis would need to be addressed. We would need more funds to increase the follow-up nursing positions to full time (Respondent 79).

A number of HCPs who thought the program sustainable had concerns about the expertise and commitment required to maintain it. One Coordinator/Social Worker noted, “emergency room physicians need to continue to be educated about HIV” (Respondent 42). One SANE had concerns that “the resistance by staff, etc., to a new procedure could be very lengthy” (Respondent 67), although another SANE (and Coordinator) noted, “although emergency physicians put up some ‘road-blocks’ at first, [they] are getting used to [the program]. They have actually ordered the medications themselves not going through our medical director” (Respondent 24).

Slightly over one third of HCPs either thought that the universal HIV PEP program was not sustainable (n=12, 9.1%) or were unsure whether it was sustainable (n=34, 25.8%). Most of the reasons given centered again on adequate resources being available, comments made simply as “money” by several HCPs who responded “not sure” (Respondents 118, 120, 121). Among those who responded “no” it was also noted that staffing would be an issue, in terms of resources, expertise, and commitment to the program.

[I] heard from pharmacy it was added workload. I did all the follow-ups - do not have clerical support - calling, rebooking, etc. It is difficult when programs see 25 or less [clients] per year. Requires a lot of arranging each time through the emergency room where I am manager (Coordinator/SANE, Respondent 43).

There is universal shortage of all HCPs; this is another ‘job’ to be done. The number of jobs, complexity, is rising and the number who can do this is falling (Emergency Room Physician, Respondent 114).

We have an ongoing difficulty with medication orders. Medical directives never taken to MAC. Certainly should not be considered unless all stakeholders (Medical Director, HIV Expert) are all on board (SANE, Respondent 105).

The time to provide HIV PEP counselling was also described as a barrier to sustainability by several HCPs. According to one SANE who had provided both initial and follow-up care and responded, “no” noted, *“It takes an extremely long time to go through all advantages and disadvantages of HIV PEP and to set up the follow-up appointments”* (Respondent 26).

Additional Comments

HCPs were invited to comment further on anything they thought had been missed in the survey. Many used the opportunity to extend further support for the universal HIV PEP program as implemented,

Thank you for advocating regarding women's health and right to universal offering of HIV PEP (and men's). It is so crucial and important (SANE, Respondent 107).

I believe this is a very important program to keep going. Many clients have been so thankful to receive the medications as they would not be able to afford them otherwise (SANE, Respondent 128).

My clients were all extremely happy this program was available!! (Nurse, Respondent 117).

Several HCPs again acknowledged the demands of HIV PEP on clients,

Offering HIV PEP is important as HIV is a risk to sexual assault clients and we have a way of decreasing that risk. However, we must also be aware that offering HIV PEP is a very heavy burden for clients in a traumatic state. More often than not they did not know HIV PEP existed. Therefore, it creates a whole set of worries and decision-making. In most cases, it's something that needs to be discussed, but I think it will always maximize a client's anxiety rather than minimize it! (SANE, Respondent 4).

I really feel that doing all these tests at the time [clients] come to our unit is more invasive and can be condemning to their defence when it comes time for trial especially if they are HIV positive or have some STD positives (Respondent 7).

Concerns regarding client compliance were also reiterated. According to one Coordinator/SANE, *“Follow-up is an issue - most of our clients haven't returned for follow-up so they have not completed the course of medications. It is a huge workload issue for tracking clients, organizing follow-up, completing the paperwork”* (Respondent 73).

HCPs commented on the difficulty in bringing physicians on board with the program. A SANE remarked on the *“on-going issues with some ... emergency room doctors”*,

The majority is great and accepts our recommendation. However, we have a couple who really give us a hard time. They either just don't think it is necessary, or they give all kinds of ‘stats’ which of course they insist are correct. This certainly increases the stress level of our team (Respondent 53).

Another SANE observed, *“emergency room physicians who work with us feel the risk of therapy outweighs HIV seroconversion risk. They have frequently refused to order HIV PEP”* (Respondent 44).

Summary

It is important to note that although just over one-quarter of respondents endorsed universal offering of HIV PEP as the optimal strategy of care for SATC clients, *MOST* thought that:

- The program was sustainable over the long-term at their hospital;
- Other aspects of care had not been compromised;
- They had the time and opportunity to provide sufficient counselling;
- Majority of HCPs believe that the unknown-risk group should be offered HIV PEP;
- Clients were able to make an informed decision to take or not take HIV PEP; and
- Clients were generally satisfied with the HIV care received.

In fact, despite not knowing the risk of HIV acquisition in the unknown-risk group, over two-thirds thought it beneficial to offer HIV PEP to this group.

HCPs had been trained to “*strongly recommend*” HIV PEP to clients meeting high-risk criteria and to “*recommend*” to those in the unknown-risk group. However, less than half of those who responded to the survey thought clients’ decisions to take or not take HIV PEP were actually influenced by whether or how strongly it was recommended. Some comments made by some respondents suggest that they may not have been recommending HIV PEP to clients at all, that it was thought important to “*remain neutral and not influence their decisions*” (SANE, Respondent 37). This view may not be surprising given that they have been trained to provide all other options of care (e.g., collection of forensic evidence) in an objective manner, to “*give choices [and] respect autonomy*” (Sexual Assault Nurse Examiner Training Manual, 2005).

Although several HCPs thought the overall care provided at SATCs had improved as a result of the universal HIV PEP program, others raised concerns in their comments. They noted that ultimate success of such a program would require ongoing, stable, and external funding and staff commitment and expertise. Although client consent, compliance, and distress were also raised as issues for consideration in moving forward, follow-up visits were repeatedly mentioned as a critical opportunity “*for clients to explore whether they want to continue [with treatment] or no*” (Nurse, Respondent 100), to ensure that clients “*are not taking medications incorrectly*” (Nurse, Respondent 133), and to “*provide more counselling*” (SANE, Respondent 102). Indeed, a Coordinator described, “*counselling and follow-up by RN [as the] most critical factor in successful completion of drug regimen and client satisfaction*” (Respondent 115).

b) Follow-up Care Provider Survey

Method

Because the universal HIV PEP program was designed with a strong emphasis on follow-up care for clients taking HIV PEP medications, data regarding Follow-up Care Provider opinion was integral to the development of an optimal HIV PEP program. The objective of this survey was to determine the effectiveness and sustainability of the follow-up schedule as laid out in the HIV PEP Study protocol. See Table 9 for specific survey questions. Prior to distribution, the Follow-up Care Provider Survey was piloted in January 2005 with the assistance of Follow-up nurses at Sunnybrook and Women's College Health Sciences Centre, SATC.

Along with self-addressed, postage-paid, return envelopes, surveys were mailed directly to the primary Follow-up Care Provider at each participating SATC in February 2005. The survey was anonymous and completely voluntary. No identifying information was collected. Reminders to complete and return the survey were sent to all Follow-up Care Providers via e-mail, 2 and 4 weeks post-distribution.

Surveys were returned to the CRWH, where they were entered into an MS Access database and then filed in a secure cabinet. Only members of the Research Team have access to the surveys and the database, which is restricted by password.

Analysis

Frequencies were generated for each question using MS Access. Respondents were left space to provide comments following each question. These comments were organised by the response chosen under each question and summarised by content or mentioned verbatim.

Results

There was an 80.1% (21/26) response rate for the Follow-up Care Provider Survey. All Follow-up Care Provider respondents were Nurse Examiners. See Table 9 for an overview of Follow-up Care Provider responses.

Table 9 Follow-up Care Provider Survey Results

N = 21				
The follow-up schedule for clients taking HIV PEP medications in the HIV PEP Study was follow-up at 2-4 days, 1 week (in person or by phone), 2 weeks, 3 weeks, and 4 weeks after initial presentation. Do you think this schedule of follow-up care is sustainable at your hospital on a long-term basis?	Yes	No	Don't Know or Not Sure	
	13 (61.9%)	3 (14.3%)	5 (23.8%)	
Frequent follow-up visits may have provided the essential support some clients needed to complete the full 28-day course of HIV PEP. For others, frequent follow-up visits may have been a deterrent to completing HIV PEP medications (travel, inconvenience, being reminded of assault, etc.). Overall, what impact do you think the follow-up schedule had on whether or not clients completed the full 28-day course of HIV PEP medications?	Positive Impact	Negative Impact	No Impact	Don't Know or Not Sure
	15 (71.4%)	0	2 (9.5%)	4 (19.0%)
Given your answer to the above question, do you think follow-up care should be provided less frequently, more frequently, or with the same frequency?	Less Frequently	More Frequently	Same Frequency	Don't Know or Not Sure
	1 (4.8%)	1 (4.8%)	18 (85.7%)	1 (4.8%)
During follow-up visits, did you find that time was spent responding to client needs that were unrelated to HIV and/or HIV PEP (e.g., general medical care, general counselling, emotional support regarding the assault, etc.)?	Yes	No	Don't Know or Not Sure	
	15 (71.4%)	4 (19.0%)	2 (9.5%)	

Impact of Follow-Up Schedule on HIV PEP Regimen Completion

Almost three-quarters of respondents (n= 15, 71.4%) stated that the follow-up visits had a positive impact on completion.

I think that frequent follow-up visits are more of an incentive to people to continue their medications. . . (Respondent 3)

I believe the follow-up was good for the person involved - one person there for them - I had positive comments - had a significant impact on the person taking the meds. (Respondent 13)

The clients that came for regular follow-up tended to complete the med regimen. (Respondent 21)

This positive impact was deemed to be due to the range of supports that could be provided at these visits: counselling, legal assistance, sexually transmitted infections (STI) testing, workers travelling to clients for follow-up visits, encouragement and emotional support, and information about medication and side-effects.

...able to provide more info re: community resources i.e. counselling and legal assistance; STI testing; were able to be flexible and work with clients schedules and travelling barriers (outreach visits done at P.H.U. in region). (Respondent 2)

Gave them the opportunity to ask questions about meds, side effects, other SA issues when they were not in immediate crisis and had a chance to absorb/think about what had happened. (Respondent 15)

They liked and found it great to talk with the nurse about the meds and SA issues at same time without having to retell the reason for coming. (Respondent 19)

In addition, some respondents highlighted the fact that the structured follow-up sessions, “*emphasize the importance of closer supervision while taking these medications. (Respondent 3)*” One respondent stated that the follow-up sessions allow the client to re-evaluate their decision to take the medication, while another cited the importance of being able to evaluate the effects of the medication on the client, “[d]uring the follow-up visits for HIV PEP we also accomplished positive reinforcement of client's choices...” (Respondent 2)

One respondent indicated that in her/his hospital they have developed new strategies to provide support to their clients:

Each visit provides additional support, encouragement, reassurance and acceptance. Clients feel empowered by the action they are taking to protect themselves. We are able to provide tokens and even taxi chits if travel is an issue. On the other hand some clients did not accept PEP because they would not take time off work/school or were keeping assault a secret. We have also written letters to places of employment, schools to excuse clients from responsibilities due to ‘current treatment’. Also to social services to ask for financial assistance with respect to PEP. (Respondent 10)

Another respondent suggested that flexibility on the part of the HCP was a key element of supporting compliance: “*The impact increases if the follow-up nurse is willing to adjust her schedule to accommodate the client e.g., staying after hours for an appointment. (Respondent 7)*

Another mentioned the challenges of transportation for some clients but suggested that “*clients still follow through better when there is a schedule of follow-up appointments*”, adding that she “*think[s] the follow-up design is excellent and very well designed.*” (Respondent 11)

Two (9.5%) of the respondents stated that the follow-up schedule had no impact on HIV PEP completion, and four (19.0%) that they were unsure of its effect. The challenges facing some clients to attend follow-up visits due to transportation barriers was the key issue of concern for the majority of these respondents. One stated that they visited the client rather than having the client come to the SATC for follow-up sessions, while another recommended 14-day supplies of medication, so less traveling would be necessary.

Frequency of Follow-up Sessions

When asked if the frequency of follow-up sessions as set by the HIV PEP Study should be maintained or should be either increased or decreased, a strong majority of respondents supported maintaining the current frequency of contacts (n=18, 85.7%), some suggesting that it was this schedule that supported compliance with the HIV PEP medications:

I think it is very important to keep all 5 visits, especially Day 2-4. Clients will experience the worse side effects at this time. (Respondent 1)

Less frequent visits, I think, may result in less compliance taking these meds. And I don't think it's

necessary to see more frequently - my patients had my phone number and were encouraged to call if they had a question or a problem. (Respondent 3)

However, one recurring theme raised by Follow-Up Care Providers was the need for flexibility in the frequency and type of contact with clients. Many mentioned the importance of face-to-face contact for the first few follow-up visits, and the possibility of phone contact for the remainder.

Every effort should be made to adapt to client's need and choices - at times visits were done at day 2-4 and week 2 in person and the other visits were done via telephone (w/ 1, 3+4). (Respondent 2)

With some clients I had more frequent phone contact to help through difficult times, but on a whole scheduling was sufficient. (Respondent 6)

Recommend same frequency but we have to be very flexible, depending on client and program. (Respondent 18)

Increased and decreased frequency of follow-up visits received support from only one respondent each (4.8%). Similarly, one respondent was unsure of the ideal frequency for follow-up visits.

Focus of Follow-Up Sessions

Almost three-quarters (n=15, 71.4%) of respondents stated that follow-up visits involved support/time beyond counselling on HIV and HIV PEP, citing the provision of general emotional support post-assault, legal advice, trust building with clients, and safety monitoring.

[A] client's needs change during the first month and the HIV PEP provides excellent opportunity to allow discussion between nurse and client; builds on therapeutic relationship. (Respondent 2)

At times this allowed time to care for their general well being and provide support if they were not ready to go for counselling in a formal setting. (Respondent 4)

Yes and this is an added benefit of seeing the client so frequently and so soon after assault. Able to provide education re HIV. Much better follow-up re HIV testing compared to other clients not on PEP. ... Support of clients' total needs provides for increased acceptance and follow-up through with options for care. (Respondent 10)

I found that each visit was unique - 50-50 split talking about HIV - great opportunity to do health teaching. (Respondent 13)

It was a great opportunity to see if they had accessed counselling, were they safe, how they were feeling. (Respondent 15)

Four respondents (19%) stated that discussions focused exclusively on HIV and HIV PEP, although they all then indicated in their comments that emotional support was also provided, as needed, during these meetings:

There are always some clients who have greater needs and need extra support. (Respondent 1)

Some extra emotional support but that is part of the job. (Respondent 7)

Not for the most part. Usually med directed conversations. (Respondent 9)

I was probably 50/50 between concerns around HIV and general emotional care. (Respondent 12)

Two respondents (9.5%) indicated that they were unsure of whether follow-up visits were used beyond providing medical support around HIV and HIV PEP. One stated that a referral had been made to a social worker upon request, and the other suggested that follow-up sessions were tailored to the needs of the client and that visits were usually a combination of HIV-related medical care and other types of advice and help.

Sustainability of Follow-Up Schedule

The same three factors affecting the sustainability of the HIV PEP Study's follow-up schedule were raised by respondents regardless of whether they ultimately felt it was sustainable: staffing levels, number of clients served and staff time. Of those that answered that their hospitals could maintain the schedule of follow-up visits (n=13, 61.9%), additional comments suggested that this sustainability often depended on a number of factors including the willingness of doctors to do the follow-up visits, the availability of nurses, the continuing timely turn-around of blood work, etc.

Would require additional follow-up services - more hours of follow-up nurse availability, more secretarial support to look up results, set up HIV PEP documentation tools, schedule appt for clients etc Could be costly in terms of being available, PEP appointments open for new clients coming in (ie just in case slots). Sometimes f/u for clients not on PEP was delayed due to appt. commitments to PEP clients. Often bloodwork results (day 14 or prn) aren't available at end of day. No one in clinic next day or w/e to f/u these results. (Respondent 10)

We are hoping that our team docs will continue to handle follow-up for us. Waiting to hear from them. (Respondent 18)

For respondents (n=3, 14.3%) that stated the current schedule was unsustainable, issues of access and staffing were mentioned by two out of three respondents as a barrier to sustainability. Similarly, three of the five (23.8%) respondents that answered that they were unsure of its sustainability cited staffing numbers as the main barrier to follow-up visits. Another mentioned access, as several of her/his clients lived on reserve with no phone or means of transportation:

Barriers for us was travel into remote communities. It was difficult to bring people back out for follow-up. In the future telehealth maybe an option. We rarely had the HIV results by their first follow-up visit. (Respondent 15)

Unsure whether will have qualified staff to provide the service. (Respondent 16)

Several of our clients live on reserves out of town with no phones and travel challenges which we creatively work around with some success. The schedule is good but the flexibility to modify it around client's needs will be a guiding influence. (Respondent 19)

Additional Comments

Recommendations were made by several respondents and included the improvement of documentation tools for quicker understanding and completion, providing preloaded dosettes to

facilitate compliance, and networking with other nurses that work nearer clients who may be able to provide support. Further suggestions for handling challenges to an effective follow-up program involved holding follow-up visits in the community of the client when necessary, medical professionals being flexible in order to work with clients' specific/individual needs, flexibility in prescribing drugs to overcome problems of access to the clinic (e.g., during statutory holidays), monitoring other medications the client may be taking and any possible contraindications, reinforcing to clients the need for doses to be taken at 12-hour intervals, offering liquid Kaletra® for those clients having difficulty with side effects, as well as Gravol and Immodium at no cost to clients who cannot afford them, and finally, the use of telehealth or phone follow-up appointments for rural clients:

We have found that providing f/u to the client in their community at the P.H.U's (Public Health Unit) a great improvement with follow-up. (Respondent 2)

We struggled to follow-up during holidays/vacations. Our medical director was available and flexible with orders around changing med orders ie week 2 visits we might provide 11-13 days of medication instead of 7 days to get us through a long weekend etc. (Respondent 9)

For us telehealth or phone follow-up is a better option. We see them once before they are discharged home and then usually lose them. We had very few who completed the meds. (Respondent 15)

Outstanding challenges were also identified by several respondents, including a lack of support by some medical professionals, the challenges for clients in accessing services outside clinic hours, the costs and length of time required for visits, the concern that 72 hours is not long enough to make an informed decision to take HIV PEP, a lack of knowledgeable staff resulting in some clients taking the drugs who should not and a low compliance rate as a result, a lack of a confidential place for a client to phone the clinic and to receive phone calls, and a lack of affordable and accessible transportation to the clinic:

We need to have a better relationship with some of our doctors. Sometimes they were known to undermine our suggestions (based on their personal feelings - not documented information). Unfortunately, I have no suggestions to improve this problem, but it was a very definite problem in our program. (Respondent 3)

It is a lot of info to absorb and make a decision when you are in crisis. It is unfortunate they only have 72 hrs to decide as most clients it seems change their minds and don't complete. No one phoned our follow-up phone number to ask questions etc. (Respondent 15)

Follow-up needs to be provided by someone well-qualified to do this. I think a large majority of our clients were started on PEP without proper knowledge or counselling. (Respondent 16)

We have a hard time here to have the clients show up (this is not unusual) and I don't know what can be done about it. (Respondent 21)

Two respondents noted some very positive effects of the study – it reduces the risk of patients falling through the cracks in the system, follow-up visits have allowed clients to re-evaluate previous decisions (referrals, medication, etc.), more clients are completing Hepatitis-B immunisation and other follow-up testing, more parents are becoming involved in helping their children and therefore are more aware of how to respond to their children's needs, it provides an opportunity for sexual

health education and safety education, and it promotes greater flexibility on the part of medical staff. In addition, one respondent stated that even equipment, supplies and patient education information have improved because of the standardisation offered by the program.

One of the things that the HIV PEP Study did was bring the whole issue of follow-up care forward. Many patients were falling thru the cracks after the initial visit. Now ALL patients are seen/contacted at 48 hrs - if only a rationale for consent to process blood for HIV testing - and the health education and follow-up care and referral care for all patients is enhanced. Many clients revisit their decisions and opt for care options (STD prophylaxis) or referrals (police, counselling etc) that they initially declined. Also I find that most are getting physical exams at 4-6 weeks for PAP's, UDRL's etc because care is better communicated and co-ordinated thru family doctors, sexual health clinics etc. Also I know that many patients are completing their full course of Hep B immunization and FU N/U testing that would not have otherwise. The other areas that I notice a big change in are:

- 1.) Parents/support people often are involved during FU and this is so helpful to clients - esp. for parents of children 18 and under - knowing how to be involved and treat their children.*
- 2.) Education re safety (safe-sex practices, personal risk assessment and safety planning – prevention date rape and DFSA etc) is making an impact.*
- 3.) The more we realize the full picture, the better our protocols are becoming.*

I would like to see some standardized documentation for the FU visits and most importantly I would like to see the role of the follow-up nurse continued ... because the overall program is so much better and 1 person dedicated to the follow-up - The 2/A is built into the program because each case on FU is reviewed against the standards – any errors or omissions are corrected - information is shared as a learning experience - even equipment, supplies, patient education info etc is better because of this. Patients/families always have a contact and they are generally very happy and relieved by this level of care. (Respondent 14)

Several respondents also expressed support for sustained maintenance of universal HIV PEP program:

Follow-up care at our treatment centre was very positive. I believe with support given to clients (in person, via telephone) the outcomes are positive. (Respondent 1)

For my program, it went well and clients are continuing to return for their 3 months, 6 months etc. (Respondent 4)

Great program, well-organized and delivered! (Respondent 6)

Thank you very much for setting up the protocol for HIV PEP. We would never gotten it off ground without you! I think of the number of clients we have sent home with nothing and now we can really address the concerns of HIV. I have been pleased with the structure that was set out. The final visit is posing a problem because the client has completed the meds and just needs the final blood test, which can be done at another location. It's good to have the appointment scheduled but compliance is going to be difficult for the final appointment. (Respondent 11)

Summary

- Follow-up care is essential and supports the HIV PEP program;
- The follow-up schedule enables SATCs to provide all clients with improved follow-up care;
- Increased number of follow-up visits for clients taking HIV PEP improves compliance on the drugs, and positively impacts completion of the 28-day regimen due to the range of supports available and flexibility of SATC programs;
- The majority agree that the follow-up schedule is sustainable, but sustainability would be dependent on factors such as: willingness of doctors to do the follow-up visits; availability of nurses; and, timely turn-around of blood work.

c) HCP Focus Groups

Method

The intent of the Focus Groups was to explore in more depth the HCP experience of providing HIV PEP, and to provide a forum for HCPs to share their experiences with each other. Focus Groups served as an opportunity to gather qualitative data regarding opinions of universal offering of HIV PEP and the impact of the program on routine sexual assault services, enriching quantitative data collected in the HCP and Follow-up Care Provider Surveys. See Table 10 for topics of discussion explored within each HCP Focus Group.

All members of SATC teams that participated in the HIV PEP Study were invited to take part in a HCP Focus Group. One Focus Group was conducted in-person, and three Focus Groups were conducted via teleconference in November and December 2004.

Focus Groups were recorded and later transcribed. No identifying information was included in the transcripts. Focus Group recordings and transcripts are secured in a locked cabinet at CRWH. Only members of the Research Team and the transcriber have access to them.

Analysis

HCP Focus Group transcripts were provided by an external consultant. A CRWH staff member (independent of the Research Team and experienced in qualitative analysis) reviewed the recordings to check transcriptions. Transcripts were read to determine broad descriptive or generalised themes. A theme sheet was produced in which all data relating to the theme were placed. Data were reduced into subcategories and research themes were expanded. Many quotes from the data cut across more than one theme. Data themes were linked to the focus group topics of discussion: viability, effectiveness and sustainability of the universal HIV PEP program.

Results

There were 26 HCPs that participated in 4 Focus Groups. Participation by HCP profession/discipline at each of the 4 Focus Groups is as follows: Focus Group 1, November 17, 2004: 14 participants (1 MD, 1 Coordinator; several nurses, several social workers); Focus Group 2, November 25, 2004: 2 participants (1 Coordinator, 1 Nurse); Focus Group 3, December 3, 2004: 6 participants (2 Coordinators, 3 Nurses, 1 Social Worker); and, Focus Group 4, December 6, 2004: 4 participants (1 Coordinator, 3 Nurses).

The focus groups allowed for a more in-depth exploration of the experiences and perceptions of HCPs in delivering the universal HIV PEP program. The findings of these focus groups were consistent with the information that had emerged from the HCP Survey described above.

Table 10 Health Care Provider Focus Group, Topics of Discussion

N = 26

Core Question 1

Thinking about the many aspects of HIV PEP and universal offering (e.g., medications, counselling, follow-up), is it worth it?

Probe Questions

Do the risks for clients (e.g., increased anxiety, side effects of meds, etc) of HIV PEP/universal offering outweigh the benefits (e.g., decreased anxiety, potential prevention of HIV, etc)?

Does the HIV counselling that you need to provide for universal offering compromise other aspects of care?

Is the care of clients not taking HIV PEP somehow compromised by the needs of those clients who are taking HIV PEP?

Core Question 2

Thinking about HIV PEP as an ongoing program, do you think your SATC can keep it going?

Probe Questions

Do you think that your hospital and SATC would be supportive?

Would your SATC be able to continue providing the kind of support and counselling that are needed to continue with “universal offering”?

Core Question 3

Based on your experiences with this study, what is the best strategy for offering HIV PEP?

Probe Questions

How could this program be changed to fit your client and staff needs?

Do you think that staffing changes or shifts in roles would be necessary to keep providing HIV PEP?

Do potential benefits of universal offering vs. high-risk offering justify the increased demands on your SATC's resources?

Core Question 4

Rates of uptake and completion of HIV PEP have been high compared to the numbers found in the literature. Thinking about your interactions with clients, why do you think this is?

Probe Questions

Does HIV counselling affect clients' anxiety level? How?

After counselling, do you feel that clients are making informed decisions about taking or not taking HIV PEP?

Are clients able to assess their risk level? How?

Does follow-up counseling impact completion rates?

Decision Making

When asked if they thought that clients were able to make informed decisions, most respondents answered affirmatively. However, many acknowledged that a range of factors could influence decision-making.

I do think that there's a lot of, you know, for people for us, with travel and being exhausted and maybe being hung over there's a huge amount of information to absorb. ... You know, all the choices that you're making

just for the care, for forensic evidence collections and medications and then absorbing all the HIV information. (FG 3, Respondent 5)

Follow-up visits were seen as a critical support to informed decision-making.

We try to bring them back the next morning just to the clinic to go over it again because it's just a huge amount of information (FG 3, Respondent 5)

I think that there's no way that you can do everything a hundred percent that first night, for clients that need, you know, the full range of treatment including HIV. So I think it puts a lot more onus on the follow-up visit. . . . because you need it for the HIV but you absolutely need it for all the other things as well (FG 3, Respondent 14)

Other participants emphasised the need to ensure that materials and discussions are culturally appropriate. One HCP highlighted her strategy when working with First Nations clients of ensuring the information shared could be “relate[d] back into, within the Native context” . . . and that “really being able to do that related into their context and their world, really made an impression and I think it helped”, and therefore recommended that, “individually you’ve got to look at what’s the population you’re dealing with”. (FG 4, Respondent 1)

Despite the positive support for the program, several focus group participants reiterated concerns raised by survey respondents about discussing and offering HIV PEP to clients who are in crisis. One nurse felt that discussing HIV with clients who already have fears, overwhelms them. In her opinion, the HIV issue tended to eclipse everything else once it was raised by SATC staff.

They’re scared and they’ve been raped and now you’re scaring them as well by saying HIV. I think a lot of the times a lot of clients I have, the ones I offered HIV to, they haven’t really thought about it, and that seems to take over, you know, HIV. They couldn’t seem to concentrate on anything else. (FG 1, Respondent 11)

Anxiety

Although there was an even divide in the focus groups about whether HIV counselling helps to reduce anxiety levels of the clients regarding HIV risk, most participants felt that it was helpful to clients in a number of ways.

For some HCPs, a direct reduction of anxiety was described:

I think the counselling really reduces their anxiety level regardless of whether they choose to go on the medications or choose not to go on medications and I feel it really has helped the overall thinking process as far as HIV and acquiring that disease . . . it was almost like there was a sigh of relief from the clients that accepted and completed the course of medications and are continuing with their follow-up (FG 3, Respondent 3)

For others, while acknowledging that anxiety remained, HIV counselling and PEP was seen as empowering to clients in their recovery process.

It seems to me that by agreeing to begin this treatment program, they’re sort of taking the first step in terms of recovering from what’s happened. They’re actively participating in their own recovery and maybe thereby

speeding up their psychological recovery from what's happened. I wonder if it sort of empowers them in a sense that they're doing something actively themselves to get better. (FG 1, Respondent 20)

Side Effects

Very few respondents commented when asked whether the risks of HIV PEP outweigh its benefits, but the ones that did felt that the benefits outweighed the risks (interpreted primarily to mean the experience of side effects). In fact, the participants identified that, in general, side effects were not a major factor for the clients they had seen through the study. One HCP suggested that “...*by no means did any of the clients feel that the side effects were that severe.*” (FG 3, Respondent 3) Another concurred, “[t]he same for us. *Very few side effects; some nausea.*” (FG 3, Respondent 5)

One participant felt that the impact of side effects on decisions to continue or discontinue treatment was minimal.

If people didn't finish taking the medications, it wasn't because, you know, generally it wasn't because of the side effects of the medications. It was for other reasons. (FG 3, Respondent 14)

This participant also pointed out that when clients experience side effects and are asked about them during the follow-up visits, careful consideration must be given to distinguishing side effects of the medication and those symptoms stemming from the assault itself.

A lot of them [side-effects], like mood and fatigue, they're like a given after an assault.... So it's difficult for a lot of people to, even though I would say, as a result of the medications. I think it's hard for people to differentiate for that ... (FG 3, Respondent 14)

Quality of Care

The majority of focus group participants felt that while implementation of the universal HIV PEP program was challenging in terms of the required paperwork, the development of protocols, and the increased time required to complete the assessment process, it improved the quality of care provided to their clients.

My team has indicated they really felt that it has been worth it for the clients as well as for their own benefits of being able to provide an improved quality of care. (FG 4, Respondent 1)

Initially it was a concern because of, you know, with the learning curve and starting to feel comfortable and offering and who would accept that that type of thing. I think that initially there might have been a [negative impact on quality of care] because our focus seemed to be offering and supporting clients with the HIV program, but overall I think everything has settled down and it's really enhanced our service tremendously (FG 3, Respondent 3)

Furthermore, it formalised procedures,

I think it's been worthwhile both for the patient but also for the nurse that's dealing with the patient. It's given us some really good guidelines. (FG 2, Respondent 12)

Feedback from clients was also very positive and reinforced the HCPs sense of their efforts to implement the program having been worthwhile:

There's a lot of education but I think it was worth it based on what we're hearing from our clients and how grateful they are that they have this opportunity to access the HIV PEP, so it was worth it. (FG 3, Respondent 4)

The universal HIV PEP program gave nurses a possible solution to offer clients who were at risk of HIV transmission and enhanced the sense of comfort and knowledge HCPs had when discussing HIV with clients:

And it's great for the patients too. I mean, in the past when they came in and you had nothing to offer them, you know, I'm worried about HIV. You know, it was like, uh, yeah, yeah. There was just nothing to say. Now, you know, I'm so worried about HIV. Well, we have something we can offer you so yeah, I think it's very worthwhile. (FG 2, Respondent 13)

I think it was really worth it. I worked in an anonymous test clinic. We had many, many women come through here who were just absolutely terrified of HIV and there was nothing they could do but wait twelve weeks to get tested, so I think it was worth it. (FG 4, Respondent 7)

The other thing it did for nurses and for not just for our clients but for the people that we worked with – it really made us much more comfortable with talking about HIV with everyone. It increased you know, our knowledge and our comfort you know, just with dealing with the whole issue. (FG 3, Respondent 14)

When asked if they believed that other aspects of care were compromised as a result of the introduction of HIV PEP, most said that it had not. Of those that believed that some aspects of care had been affected, several mentioned that, as they got comfortable with the process, it no longer interfered with other aspects of care.

Just more with me getting used to introducing it to the patient at first. It was something new for me so my comfort level and variety of information to the patient, once I did it more often, then it took less time. (FG 1, Respondent 23)

Initially it was a concern because of, you know, the learning curve and starting to feel comfortable and offering and who would accept and that type of thing. I think initially there might have been a little bit because our focus seemed to be offering and supporting clients with the HIV program, but overall I think everything has settled down and it's really enhanced our service tremendously. (FG 3, Respondent 3)

Some participants indicated that the quality of care provided to their clients was improved through the universal HIV PEP program.

I think it enhances the quality of care. (FG 4, Respondent 1)

I think it only enhances other aspects of care. I mean, it does take a few times to go through an explanation but I think that's providing more options and more stability for someone's decision making. I think it's enabling someone to have further strong decision making skills and you're laying everything out for them, so no, I don't think so at all. And um, I guess it covers really, really broad um, active listening skills and also trying to receive any information you might be missing, or any other things the person, the client you're dealing with might not have asked, so, yeah. (FG 4, Respondent 17)

Follow-Up Care

Several participants also indicated that the follow-up service had improved and more clients were returning for follow-up care, not only for HIV PEP treatment but for additional supports as well.

I think overall it's given a better awareness of following up with the clients and ongoing care. (FG 3, Respondent 3)

It was also an opportunity to do better follow-up with our clients, and for us, because we're dealing with remote Aboriginal communities, when we could get people in for follow-up it was a great opportunity to make sure that they'd been for their counselling or gone through with some of their other referrals and a lot of times our patients are falling through the cracks here just because of travel and so it was sort of a second chance to catch them, so that part was sort of a bonus. (FG 3, Respondent 5)

I agree with the follow-up comment, the one that [Respondent 5] made, that's true for us too, that our follow-up services have increased, the amount of women that we do are able to follow-up with and offer not just HIV but all the other follow-up services has enhanced with this study. (FG 3, Respondent 4)

Enhanced Compliance

The HCPs felt that the frequency of the follow-up schedule, the flexibility in scheduling appointments and the overall support provided to clients contributed to the high completion rates.

I think we do a lot extra to get them to do what they need to do to stay on medications if that's what their choice is. Even time commitments when, I mean, being late for an appointment, you know, being flexible with the appointment times so they can make it. (FG 1, Respondent 2)

One HCP expressed that ultimately, supporting HIV PEP should be based on providing client-centred care:

We wanted to make it about them and if they told us they wanted to finish, we would do whatever we could to help them finish. But certainly, you know, it was fine if they wanted to stop and I do find that sometimes they do. (FG 1, Respondent 20)

Optimal Strategy for Offering HIV PEP

The majority of the respondents indicated that universal offering is the best method of offering HIV PEP.

I think it should be universal. (FG 1, respondent unknown)

HIV has to be addressed. I really believe that. No matter what. Universally addressed. . . . I would hate to go back to the way it was where we didn't have the structure to offer something for it (FG 1, Respondent 2)

One respondent indicated that universal offering was consistent with the value-base of the SATC network:

...I think it would really be typical to our philosophy of care to just let patients decide in terms of self-determination; we give them the information but it's always based on what they want to know and not

necessarily our opinion or our advice – we don't give that, but we certainly given information in a non-judgmental manner so they can make their own decisions (FG 1, Respondent 9)

Many HCPs raised concerns about a lack of clarity in risk assessment and that even a low risk of infection is still a risk.

I have a real problem with that high-risk and low risk though. I truly believe in my heart that everyone is unknown-risk. I have no clue. As much as I can say my partner is, you know, I know him intimately, I mean, do you really? So that's why I really find it difficult, maybe because I don't believe it and I've worked with a lot of HIV + people that had no clue that their partner had HIV, that they were participating in high-risk factors with HIV and ended up giving it to them. So that's why I think, I think I don't believe in that high-risk/unknown-risk thing. I think everybody is at unknown-risk (FG 1, Respondent 2)

I think too we might have people who are at high-risk but we don't know that. We think it's a low risk, but they may in fact be high-risk. If we don't offer to them, then that makes them vulnerable (FG 4, Respondent 1)

Well, as [Respondent 1] said, I mean, unknown-risk, they may well be high-risk, so how do you decide? You don't know, that's why they're unknown. It would be nice to offer and let them decide. You know, we really don't know and that's the bottom line. They need to make this decision for themselves, what they're comfortable with and if we can't offer universally then we take away that option for those unknown people that may well be at high-risk. (FG 4, unknown respondent)

There was discomfort expressed regarding the possibility of having to make the decision of who is offered HIV PEP. One benefit of universal offering is that the decision is not left solely in the hands of the HCP, or equally problematically for respondents, in the hands of a physician who may have reservations about the program.

...a risk is a risk. I mean, if it were me sort of thing and there's a one in one thousand risk, and I can't imagine saying to someone . . . I just say the risk is low but when there's contact there's always risk and I can't decide for them. Maybe if we're doing high-risk offering then we're already making the decision for them and that's not something that I want to take responsibility for (FG 1, Respondent 2)

One of the issues we've struggled with for certain doctors were you know 'Oh it's a partner assault, well, there's no risk there. She's been consenting to have sex with him for a long period of time.' And there's various, or other situations where they would, they would question and not want to sign our standard order forms to get the meds so we had a bit of struggle with that unknown category. (FG 3, Respondent 4)

I think a lot of them [physicians] are just so set in their ways and so interested in not being proven wrong about something. Or not willing to take the chance that maybe they're wrong. Because I know one that we've had problems with, she keeps quoting statistics that she's pulled off the internet. But when we try to counteract it, she says, well hers are right and ours are wrong. Well, like at 2 o'clock in the morning, it's a little difficult to deal with that. (FG 2, Respondent 12)

One participant expressed her concerns about the unknown-risk definition and hoped that, if a universal offering model was not adopted, that the criteria used to assess risk be clarified in order to give HCPs more guidance in decision-making.

I have another concern about the unknown. It's not so much about the unknown category but I'm hoping when it's all finished, if there is direction, you know, for that category and how to give it, that it's very clear, because one of my fears is that it will be left up to individual practitioners, you know, on duty, to decide if it's appropriate in this situation and just from getting them to sign standards doctors orders sheets, everybody, you know, many different physicians have different opinions and just because of who's on duty that night. And one of the things about the study is you know, they either fit the criteria or they didn't. And it took all that, you know, personal opinion away from it. I would be afraid that if there was, you know, no matter which way we go that there need to be, you know, very definite criteria to avoid those situations. . (FG 3, Respondent 14)

Financial Implications of Universal Offering

One participant reluctantly raised the concern about the financial sustainability of a universal offering model. Although she declared herself to be “the last person that ever thinks about this kind of thing”, she worried that scarce resources would make decision-making in providing HIV PEP extremely difficult as the program expands:

...this was a very expensive treatment and that there's not an endless amount of money available to give to the program, to give drugs to people and you know, if you have a finite number of dollars... with which to spend on a program like this and you had to start designating and being the one to make a decision, like who warrants the sum of money that's required for the treatment and who doesn't, it's very difficult for us as individuals to take that into consideration when the woman is sitting in front of you and you've got to decide whether she's worth \$1,500 or not for the treatment and yet if you are dealing with an infinitesimally small risk with someone who is not considered a high-risk person and you've only got so much money, you know, is that something that you have to take into consideration? Maybe in the infancy program like this, you're not really thinking that way, but as you get more involved in it, and the numbers will add up over the years and the available number of dollars is not going to get greater in all probability, you have to start thinking that way. (FG 1, Respondent 20)

Several HCPs raised the need for a more evidence-based approach to HIV PEP, highlighting the lack of research available to support the efficacy of the program. However, another respondent pointed that a body of literature did support the effectiveness of the treatment in other populations.

I guess we need to have more evidence that this is an effective treatment – which we don't have that yet. You know, we do need more information about that. We don't know. That's a lot of money for – maybe. (FG 1, Respondent 25)

We do know theoretically that these medications really work, based on, you know, pregnant, HIV + pregnant women that are giving it to their fetus, so there is, although we're not, the studies haven't done their research based on sexual assaults but there is information available for occupational exposure so I mean, we're not blindly just giving them stuff. There is research, just not with the population (FG 1, Respondent 2)

Sustainability

The majority of focus group participants indicated that the universal HIV PEP program could be sustained as long as specific concerns were addressed. The main concern was the funding of the HIV PEP medications. Without external funding for the drugs, most participants believed that the hospitals would not be able to continue the program.

As long as the funding isn't an issue, certainly providing the program I don't think is one. . . I think that the fact that we now have a guideline that we can follow, of things to remember to tell people, I think that it's wonderful and I think that the only disadvantage would be financial – if we weren't funded for it. (FG 2, Respondent 12)

I think if we can get the ongoing funding for the medications for the clients there will be no problems on sustaining the program here (FG 3, Respondent 3)

...I think if the medication is covered and our program continues to have the same resources it has, we would probably be able to do the follow-up to support the clients who are taking the meds and I think our hospitals would, I'm hoping our hospitals would continue to be supportive with us. (FG 3, Respondent 4)

Specific sustainability issues were raised in regards to Aboriginal communities, including jurisdictional issues in terms of funding, distance, and a lack of community-based agency supports for the program:

One of the medications is covered for Aboriginal clients but the other one isn't so we'd have to look at funding for, I can't remember which one it is, but the second medication so we're okay with about half of the treatments. So I think we could [sustain the program]. (FG 3, Respondent 5)

Their concern was again, the cost of the meds because that's an issue for some of us. And then, just some of the other barriers that locally we know that we have dealing with First Nations with being able to get in because some of the women are two and three hours away. And getting back and forth with the follow-up, that's something we've got to look at to come up with some better creative ways about dealing with it. (FG 4, Respondent 1)

This worker mentioned attempts to connect with nurses on the reserve to support the implementation of the project but that they “were in a constant state of flux” and were therefore reluctant to get involved in the study. She highlighted that this was an outstanding issue in successfully implementing the model and preventing unnecessary ‘drop offs’ from the program. (FG 4, Respondent 1)

Sustainability: Institutional Support/Resistance

In regards to the universal HIV PEP program's sustainability several HCPs indicated strong support from their hospital, affiliated health professionals and community agencies, while others reiterated the challenges of working with physicians who did not have the necessary information or refused to support the program.

Our hospital is supporting us. As a matter of fact our Pharmacy Department has switched their HIV PEP meds to the same ones that we're using so they're always the same (FG 2, Respondent 12)

Our pharmacist really would love to see this continue on. He thought it was great and he's willing to continue to be a support for us. Our Chief of Staff and our medical advisory pointed out to me that they thought this would be a better route to go if we did continue this and did do the follow-up with these people, with the clients, like we have been vs. trying to push this back on the physicians who really don't know enough. That it's better if it stays in our hands, especially as it relates to the issues about violence, we can better cope with it. They would prefer that we continued from those kinds of issues. Community partners, in talking with them

just recently with staff, they feel again that we do the better job and therefore can support the woman through all of this. (FG 4, Respondent 1)

The only thing I don't feel good about offering to everyone is you know, talking to these women, you know, would you be interested in this medication? It's very, very difficult when we talk to them, and they answer yes, I'd be interested. So you take a history and then you go speak to a physician who refuses to order the medication. (FG 2, Respondent 13)

Several participants indicated that sustainability would also require external support systems that would ensure that the program was updated and current on HIV information including client handouts and the optimal HIV PEP regimen to be offered. An ongoing HIV expert consultation group would also be needed by SATCs when specific concerns arose.

The other piece we talked about was if we do continue it without the study in place, the study has given us invaluable support and information and education, to keep us updated in all this stuff and where would we, we would be somewhat at a loss of where we would access that information. (FG 3, Respondent 4)

Yes, even keeping, you know the latest information in the client booklets, you know, information booklets, I'm sort of saying we need someone to support us with the latest information so that we're able to you know, provide a consistent program (FG 3, Respondent 14)

And the other thing I would be interested in knowing is if the HIV experts that are participating in this study will continue to give us, um, consultation information if we require it (FG 3, Respondent 3)

A vital component of program sustainability was the ability to be flexible in program delivery. This included both follow-up and medication schedules as well as the development of creative solutions for addressing unique client or community needs.

I think we tend to accommodate them as opposed to them accommodating us in a lot of ways, which helps (FG 4, Respondent 2).

And we also created some flexibility because we had to with a couple of individuals and we gave them a little bit more and they called in and reviewed things. So we created flexibility around what was the need they had. How they, the woman, and the nurse felt things were going. ...I think it has to be something that becomes a flexible type of protocol or situation. ...I think if there were parameters as such that are broadened, and then you, in your own centre, looked at your own issues and established some additional things and parameters, then I think that would work. (FG 4, Respondent 1)

Additional Comments

One HCP noted that there was considerable public awareness about the availability of HIV counselling and universal offering of HIV PEP and indicated her concern about the impacts if the program were to be discontinued.

I think we're going to run into a lot of trouble if we've been able to offer it and now have to take it away...I think the patients are more informed. (FG 3, Respondent 5)

Another participant highlighted the enormous wealth of information developed as a result of the study and recommended a process by which these lessons learned could be shared between

participating centres, as particularly to engage the remaining centres into the program:

I think that there could be some lessons learned around that as well as just some questions around what kind of infrastructure you need to support it and expenses that are often incurred and that are hidden. We did training. We had to do a three hour training and developed that and complications with a number of people that we collaborated with, in order to have that done. There's a lot of unseen work and unrecognized work. I think that certainly we were very supported and have felt supported throughout the whole process by the research team, it's not to be critical of that, but more about just how difficult the work is through a process. (FG 1, Respondent 9)

Summary

- HIV PEP program is valued by HCPs. Most respondents felt it improved their SATC service by formalising procedures and that more clients completed HIV PEP medications due to the structured follow-up schedule;
- Universal offering was identified as the optimal strategy by 25/26 focus group participants.
- The majority of HCPs agreed that the universal HIV PEP program is sustainable if funding for HIV PEP medications was received.
- Flexibility in the delivery of care is necessary to provide optimal care to all clients.
- Lessons learned from the study should be shared among SATCs.

d) HCP Suggestions

In the HCP Survey, Follow-up Care Provider Survey, and HCP Focus Groups, many HCPs provided suggestions regarding the universal HIV PEP program throughout their written or verbal comments. All suggestions made have been collected and synthesised as follows, whether expressed by one HCP or several:

1. External funding must be provided to accommodate the costs of the drugs, staff resources, and administrative personnel time and administrative costs;
2. Information handouts/booklets should be issued explaining the benefits of the program to all HCPs and administrative staff in order to promote/encourage their support;
3. HCPs should be provided with ongoing access to external experts (to answer questions, concerns, and provide up to date information), or funding should be provided to hire a HIV specialist internally;
4. A flexible HIV PEP program must be allowed to permit individual SATCs to accommodate the needs of their particular community and clinic. A rigid program could result in the isolation of some SATCs. For example, rural SATCs may need to recruit the help of nurses on outreach stations, use telehealth or become mobile in the completion of follow-ups;
5. SATC staff must be flexible in accommodating client needs, where possible, in terms of appointment times, length of time between follow-ups, and quantity of drugs prescribed at each follow-up;
6. The first follow-up session should be used to reassess that the client wants to continue with the HIV PEP regimen, ensure that they fully understand what this means in terms of side-effects, determine what medications the client may already be taking that might be contraindicated and reinforce the 12 hour time gap between doses;
7. Written resources for clients need to be simplified for those with lower abilities and should be produced in different languages, reflecting the language needs of the local community;
8. Client information booklets should contain culturally sensitive food choices;
9. Clients should be given more time to decide whether to take HIV PEP (e.g., clients could be provided with an information pack and be allowed a few hours to go home and think about taking HIV PEP – but the amount of time taken to make their decision should be limited as much as possible due to the increased efficacy of initiating HIV PEP as soon as possible post-exposure);
10. A list of medicines that are contraindicated to HIV PEP should be provided;
11. If HIV PEP is not to be offered universally, clearer guidance is needed between the different risk categories;
12. Some form of support, or help should be offered to high-risk clients who present more than 72 hours after the assault;
13. Preloaded dosettes should be provided to patients, to assist them in remembering to take the medications;
14. Liquid Kaletra® should be offered as an alternative to pills, especially for young clients and clients who experience difficulties in swallowing pills;
15. Gravol and Imodium should be offered to low income clients at no cost;
16. More evidence-based research should be provided on the benefits of HIV PEP;
17. Research evidence is needed that shows which patients are more likely to comply with the program, so resources can be targeted to specific clients;
18. Education awareness programs should be delivered to the general population on HIV and AIDS;
19. Standardised paperwork should be developed that can be adapted for different SATCs needs; and,
20. Documentation should be made available to clients for their employers so they may take time off work while on HIV PEP.

CHAPTER 5

CLIENT VIEWS OF HIV PEP PROGRAM

Client Satisfaction Questionnaire



Client Interviews



Client Recommendations

5. CLIENT VIEWS OF THE HIV PEP PROGRAM

Quantitative and qualitative data were collected from clients to gather feedback on the impact of HIV counselling (i.e., whether HIV counselling created anxiety where none existed before); to understand how the client assesses her/his own risk and whether or not the Health Care Provider's (HCP) perception of the client's risk influenced the client's decision to take HIV PEP; and, to determine perceptions of client satisfaction and the overall effectiveness of the program. The techniques used to gather this information included: a Client Satisfaction Questionnaire; and, a small number of in-depth client interviews.

a) Client Satisfaction Questionnaire

Method

The Client Satisfaction Questionnaire was designed to capture clients' perceptions of the overall care they received at their Initial Visit to the SATC, the impact of HIV counselling, and client anxiety surrounding the issue of HIV. Information about the evaluation of HIV care was provided to clients in the introductory section of the questionnaire. In April 2003, this tool was piloted with the assistance of the two Community Representatives (former SATC clients) that sat on the Project Advisory Committee.

Each consecutive client that presented (Initial Visit) to a participating SATC during active study implementation was provided a short, anonymous, voluntary questionnaire along with a self-addressed, postage-paid, return envelope. Client Satisfaction Questionnaires were provided to all clients, whether or not they accepted HIV PEP medications. No identifying information was collected. See Table 11 for questions.

Questionnaires were returned to the Centre for Research in Women's Health (CRWH), where they were entered into an MS Access database and then filed in a secure cabinet. Only members of the Research Team have access to the surveys and the database, which is restricted by password. Questionnaires were assigned a unique identification number when entered into the database, thus some respondent numbers are greater than the total number of questionnaires returned to the CRWH (N=60).

Analysis

Frequencies were generated for each question using MS Access. Respondents were left a place following the last question to provide any additional comments. These comments were organised into 4 common themes: Anxiety, Decision Making, Quality of Care, and Satisfaction.

Results

60 Client Satisfaction Questionnaires were returned. It is difficult to determine an accurate response rate because frequently, HCPs did not provide clients with a questionnaire at their Initial Visit due to trauma and extenuating circumstances. If the total number of clients seen at the Initial Visit is used as a denominator, the response rate is 4.8% (60/1,238).

This response rate, while low, is to be expected given the circumstances within which the survey is distributed. Therefore, while client data must be interpreted with caution, it does provide some indications of the experience of victims/survivors of sexual assault who present to SATCs and who undergo an HIV PEP assessment.

Table 11 Client Satisfaction Questionnaire Results

N = 60						
How would you rate the overall care that you received from staff at the Sexual Assault Treatment Centre?	Poor 1 (1.7%)	Fair 0	Good 8 (13.3%)	Excellent 51 (85.0%)		
Did you feel that the staff addressed your concerns related to sexual assault?	Not at all 1 (1.7%)	Somewhat 1 (1.7%)	Mostly 13 (21.7%)	Completely 45 (75.0%)		
During or immediately after the assault, how anxious did you feel about the possibility of being exposed to HIV?	Not Anxious 8 (13.3%)	Minimally Anxious 16 (26.7%)	Moderately Anxious 12 (20.0%)	Very Anxious 24 (40.0%)		
Did you have any concerns about HIV during your visit to the Sexual Assault Treatment Centre?	Yes 42 (70.0%)	No 18 (30.0%)				
Did you raise your concerns about HIV with the health care provider?	Yes 44 (74.6%)	No 15 (25.4%)	Missing 1			
During your visit, do you recall your health care provider raising the issue of HIV with you?	Yes 55 (91.7%)	No 5 (8.3%)				
After talking with the health care provider, did you experience any change in your degree of anxiety about getting HIV?	Significantly Decreased 14 (24.6%)	Somewhat Decreased 22 (38.6%)	Not at all 6 (10.5%)	Somewhat Increased 9 (15.8%)	Significantly Increased 6 (10.5%)	Missing 3
After talking with the health care provider, how anxious were you about HIV?	Not Anxious 16 (28.6%)	Minimally Anxious 20 (35.7%)	Moderately Anxious 12 (21.4%)	Very Anxious 8 (14.3%)	Missing 4	
Did you understand the health care provider's explanation of your risk of possible exposure to HIV?	Not at all 0	Somewhat 2 (3.5%)	Mostly 11 (19.3%)	Completely 44 (77.2%)	Missing 3	
Did you understand the health care provider's explanation of your options for care for HIV exposure?	Not at all 1 (1.8%)	Somewhat 3 (5.3%)	Mostly 8 (14.0%)	Completely 45 (78.9%)	Missing 3	
How would you rate the HIV counselling overall?	Poor 0	Fair 2 (3.5%)	Good 14 (24.6%)	Excellent 41 (71.9%)	Missing 3	

Anxiety

Clients indicated that the services offered by the SATCs, including the information provided, access to HIV PEP medications and the empathy of the staff helped to reduce their anxiety to some degree.

Invaluable. Assessed quickly and respectfully, kept well-informed and continued support for management of side-effects of HIV PEP meds. All contributed to overall feeling of having received best available medical treatment, brought situation into context by allaying fear of unknown. Thank-you. (Respondent 5)

Thank you for your help. I feel much better even if the anxiety is still there and will be for the next 3 months!! (Respondent 25)

As a second time having been through this, it is much easier to try and move forward. There is a lot more peace having used the HIV PEP. Last time that wasn't even offered words can't describe how you feel. Honestly, knowing that if you may have contracted HIV and at least have some of a chance to fight it, this gives a little piece back of what was stolen from you. It may not be much, but it sure was a start. Thank-you! (Respondent 48)

Decision-Making: Information Provided

The information that clients received from the SATC staff both verbally and in writing was seen as very valuable and accessible by the clients, assisting them in addressing their fears and decision-making around HIV and HIV PEP.

. . . kept well-informed and continued support for management of side-effects of HIV PEP meds. (Respondent 5)

The nurses . . . spent a lot of time with me to reassure me of the facts of HIV transmission. They were very good about leaving treatment choices with me, but at the same time offering many treatment options. Thank you for the HIV treatment study, the booklet is excellent. This program removed a very stressful component from my assault experience (anxiety about HIV). (Respondent 27)

. . . I understood clearly and all questions were answered. (Respondent 72)

Quality of Care: SATC Staff

Client satisfaction with the quality of care they received was very high. They found the SATC staff to be knowledgeable, respectful and supportive.

. . . They made me feel more comfortable and relaxed. (Respondent 61)

I was given the greatest care and was treated with respect in a situation that no one wants to deal with . . . (Respondent 73)

Great facility and nurses. I didn't feel pressured (to feel anything I was not feeling) no pressure to talk, cry etc... Very knowledgeable and made me feel extremely comfortable. Thanks for everything! (Respondent 17)

They are wonderful, trained employees who deal very well with the individual in such a stressful situation. They are very informed and provide you with the necessary information. I never thought I would need a S.A.T.C., but I am so thankful they did exist when I needed one. Thank you. (Respondent 56)

Quality of Care: HIV PEP

Clients were very positive about their experiences of HIV PEP specifically, again referencing the fact that staff made sure they were fully informed, and expressing their gratitude for having access to the medications.

The HIV care at the sexual assault treatment centre helped me to understand all of my risks of getting HIV, but with the medication they gave me, they helped me understand that they can still give me chance of not developing HIV. But over all they helped me understand all the risks. Thanks (Respondent 41)

. . . I was so touched and felt so fortunate that the opportunity to have HIV Prophylaxis treatment was an option that could be provided to hopefully lessen the risk of potential infection. I must say "Thank-you" - please continue this opportunity/ treatment as an offer to others under these circumstances!! (Respondent 50)

. . . This program removed a very stressful component from my assault experience (anxiety about HIV). (Respondent 27)

Overall Client Satisfaction: Access to SATC & HIV PEP Program

Overall, clients were very satisfied with the care they received at the SATCs, both in terms of general post-assault care and the universal HIV PEP program.

I think it is a great idea to have this system for girls and it helped me to keep my mind off of what happened to me. Thank-you allot. I feel better. (Respondent 10)

. . . I'm thankful that there are people trained to deal with victims of sexual assault and the impact of what HIV might have with my life. (Respondent 11)

Summary

- Written information, HIV counselling, and the high quality of care provided by SATC staff helped reduce client anxiety surrounding HIV;
- Of those clients that commented, many felt that they were provided with enough information to make decisions about taking/not taking HIV PEP;
- Clients valued the information presented to them and that the option of HIV PEP was available to them.

b) Client Interviews

Method

Client Interviews captured basic demographic information, client assessment of their own risk, whether or not the HCP's perception of the client's risk influenced the client's decision to take HIV PEP, whether the HIV counselling created anxiety where none existed before, coping mechanisms that helped clients deal with HIV PEP side effects, and any additional in-depth information about the experiences of clients who accept HIV PEP medications.

All clients that accepted HIV PEP medications in the Initial Visit were invited to participate in a Client Interview. This included clients that completed the entire 28-days of treatment, as well as clients that initiated HIV PEP therapy, but did not complete the entire 28-day regimen. At each Follow-up Visit, HCPs informed their clients of the Client Interview process. If a client showed an interest in participating in an interview, they were provided with a "Client Interview Information and Consent Package". See Table 12 for interview topics of discussion.

All Client Interviews were conducted by phone. Clients interested in participating in an interview were instructed to call a 1-800 number (available in the Client Interview Information and Consent Package) to schedule an interview. This 1-800 number was set-up specifically for the purposes of Client In-depth Interviews and ensured the anonymity of clients. Due to a lack of client response, recruitment procedures were modified in July 2004 enabling clients to schedule interviews through their Follow-up Care Provider in addition to being able to schedule interviews themselves by calling the 1-800 number. Interviews were available in English and French. An independent researcher with sexual assault sensitivity training facilitated the interviews. A review of the consent form, and each participating client's verbal consent was collected at the start of each interview.

Client interviews were recorded and later transcribed by the independent researcher. No identifying information was included in the transcripts. Interview recordings and transcripts are secured in a locked cabinet at CRWH. Only members of the Research Team and the transcriber have access to them. Interview tapes will be destroyed after the results are published.

Analysis

Client interview recordings were transcribed by the independent researcher. Interview transcripts were reviewed for accuracy by a staff member of CRWH, independent of the Research Team. Transcripts were read to determine broad descriptive or generalised themes. Summary sheets, consisting of the main themes emerging from each interview, were produced from the five client interview transcripts. A theme sheet was produced in which all data relating to the theme were placed. Data were reduced into subcategories and research themes were expanded. Many quotes from the data cut across more than one theme. Data themes were linked to the client interview topics of discussion: client assessment of their own risk, HCP's influence on decision to take HIV PEP, and coping mechanisms used when taking HIV PEP to deal with symptoms/side effects.

Limitations of client interview data

Of the five interviews, two transcripts were annotated due to recording malfunction. One client interview was conducted with the assistance of the nurse from who the client interviewee received care; this may have influenced the client's responses. The nurse actively participated in this client's interview, often providing additional answers to the questions posed by the interviewer.

Results

Five Client Interviews were conducted in total; all interviews were conducted in English. All clients were female, 4 lived alone and 1 lived with her parents, all had supportive people in their lives, 3 clients were employed and 2 were students.

Table 12 Client Interviews, Topics of Discussion

N = 5

Experience of HIV Counselling

If you think back to your Initial Visit at the SATC, how did you feel about being counselled about possible risk of HIV exposure? Had you thought about this danger before the question was raised by the nurse?

Were you concerned about getting HIV at the time of the assault? Did HIV counselling affect or change any of your concerns about HIV exposure? If so, how? What was it that worried you about getting HIV?

How concerned are you about getting HIV right now?

Did follow-up visits influence your feelings or concerns about HIV? If so, can you tell me how?

What did you think/feel when the option of taking anti-HIV medications was discussed with you?

Can you tell me how you made the decision to take HIV PEP, and what influenced that decision? (*Probe: client's anxiety about HIV/ taking the drugs, the influence of the HCP's counselling*).

Experience of Taking HIV PEP Medications

Did taking the drugs influence your feelings or concerns about HIV? If so, how?

Did you stop taking HIV PEP before the 28-day completion date? If so, at what point did you stop taking the drugs? Why did you stop taking the drugs? (*Probe: side effects, advice of others, lack of ability for self-care, barriers to follow-up services, lack of social/emotional supports*)

Can you tell me how long ago you stopped taking the drugs?

Did you have any difficulties taking the anti-HIV medications? If so, what difficulties did you experience? What helped you reduce or overcome these difficulties in taking the anti-HIV medications? What helped you to continue taking the drugs? (*Probe: side effect management, self-care, ease of accessing follow-up services, support of HCP*).

Supporting Clients & Improving Overall HIV Services

What additional information, resources, or supports do you feel could have been helpful to you while taking the medications? At the initial visit? At follow-up visits?

What did you find helpful/supportive about HIV counselling received? At the initial visit? At follow-up visits?

Was there anything that you found unhelpful about the HIV counselling you received?

What suggestions would you have that would help us to improve HIV care for clients?

Is there anything else that we haven't talked about yet which you believe it would be important for us to know?

Anxiety Related to HIV Exposure Post-Assault

For three of the respondents, concern about contracting HIV was a significant concern, one citing this as the primary reason she sought SATC services. All three had fears about HIV before the issue was raised by SATC staff:

I worried about losing my life since my spirit was already gone. (Interviewee 2)

Yes, it was a vital component after sexual assault where there's unknown-risk . . . this was probably the highest concern. (Interviewee 3)

Yes, I did. . . . I brought up the HIV and they asked me about it. (Interviewee 5)

The two remaining respondents indicated that they had not considered the issue before it was mentioned by staff and did not feel anxiety about the risk of HIV contraction.

Anxiety Related to HIV Exposure After Counselling & Follow-Up Visits

The three respondents that had experienced anxiety regarding HIV before presenting to a SATC stated that the counselling they received helped relieve their concerns and anxiety about contracting HIV. Their feelings ranged from finding the information “*mildly comforting*” (Interviewee 2) to it helping “*put [her] mind at ease*” (Interviewee 3). However, all 3 stated that they were still concerned about the possibility of being HIV-positive after the counselling and follow-up visits. As one client explained, “*Once the three month test comes back I'll let people use the same coffee mug [laughs]*” (Interviewee 3).

Decision-Making Related to Taking HIV PEP Medications

All 5 respondents took HIV PEP and all but one completed the full course of medications.

A multiplicity of reasons were cited for taking the medication: two respondents made their decisions based on prior knowledge of the assailant (e.g., IVDU) or the benefits of the HIV PEP medications, and as such, were less influenced by the advice provided by the SATC. Another interviewee based her decision on her own assessment of her risk and her willingness to “*do anything*” to help prevent the contraction of HIV. When asked if her decision was influenced by the counselling she received, she replied simply “*nope*” (Interviewee 1).

Two interviewees cited the influence of HCPs in making their decision to take the drugs. One described her experience in the following way: “*I was spinning with pain, thoughts, information and somehow through the cloud of chaos thought it might make me sick for a month but better to go through that than contract HIV. It was a moment of realization*”. She made her decision by “*talking to the counsellor and then having some time to think and then talking to the counsellor again*” (Interviewee 2).

For one interviewee, the determining factor in deciding to take the drugs was a concern for her family and inadvertently passing the disease on to them. Therefore, she felt that taking the drugs was as much for them (if not more so) as it was for her.

We [client and her partner] both have teenage kids and someone accidentally used my toothbrush – if I hadn't taken it [HIV PEP] I would have felt much more concerned (Interviewee 3).

All of the interviewees were asked about resources and how helpful they found them. The feedback was generally positive. Most clients thought that the documentation was useful and that the client materials explained the “*breakdown of risk*” (Interviewee 3), and described the drugs and “*possible side effects*” (Interviewee 4). One interviewee did not read the material right away but later, “*when [she] threw up for the first time*” (Interviewee 2), she reviewed it. It reminded her about the schedule of 12-

hour periods between doses. Overall interviewees felt that they were given enough information to understand their options for care and to make decisions to continue/discontinue treatment.

Perceptions of HIV Counselling

The feedback regarding the quality of HIV counselling was mixed. One interviewee described a very positive experience, while others discussed both positive and negative elements. Interviewees referred to the staff in glowing terms, and stressed the importance of feeling that their *“concerns were not diminished”* (Interviewee 3). One interviewee expressed concern that a counsellor was not available immediately and that she should have had access to more frequent counselling sessions. When asked about her experience being counselled on HIV, she replied, *“I don’t really know if I’d use the words counsel”*. She did find the information about the drug regimen helpful, including what to expect in terms of side effects, and that the staff *“were really supportive”*. Nonetheless, she felt that the counselling service needed improving. *“... I only saw the counsellor twice . . . during the whole 28 day period and at the time I had to, kind of, had to deal with it by myself . . . So I think that is like a big thing is to have somebody like who’s that profession to like come and talk to you about it . . . like the day you go there.”* (Interviewee 1).

Interviewee 2 had a very positive experience at her Initial Visit, stating, *“it was reassuring to have someone taking me seriously who was non-judgemental”*. She appreciated that the counsellor gave her the necessary information, allowed her the time she needed to make an informed decision, and once she had decided to take the medications, *“acted on it right away”*. However, she was shocked on her first follow-up visit to find a different counsellor than she had met initially. After that visit, she was able to schedule appointments with her initial counsellor, but found the experience of being passed between counsellors upsetting.

Once she had reconnected with the original counsellor, she described her experience as very positive.

I spoke to [my counsellor] a few times over the phone which helped, she could answer my questions, gave me her pager number and told me she was available any time . . . I always felt I had someone to call. . . [The counsellor was] sympathetic and caring and knows what I’m going through.” (Interviewee 2)

Another client felt that having to go back for follow-up visits in order to get the next dose of medication was inconvenient, but when asked if her experience with HIV counselling was adequate, simply answered ‘yes’. (Interviewee 4)

Perceptions of SATC Staff

While clients were not asked directly about their feelings about their interactions with the staff, several interviewees made specific reference to this central element of their care experience.

One client mentioned that she *“liked that the nurse [at the SATC] was very calm and explained what was available and didn’t push at all to take them . . . She didn’t bully me into taking [the medication]. . . [The] nurse immediately answered all questions.”* (Interviewee 2)

Another client referred to SATC staff as *“very caring and very thoughtful”*, and remarked upon the *“genuineness with which they care . . . They’d be a model for any clinic”*. (Interviewee 3)

Perceptions of the Availability and Administration of HIV PEP

One client highlighted the importance of follow-up appointments in order to access medications and to provide a sense of structure to the treatment process:

[It] “helped to go to the hospital for new batches [of medication] because [being given everything] all at once would have been too overwhelming.” Going to the hospital “week by week it feels like treatment is trucking along” (Interviewee 2).

She also highlighted the importance having free access to the HIV PEP medications, stating that *“it really helped that I didn’t have to pay for the medications and that all I had to worry about in order to get to the clinic was bus tokens” (Interviewee 2).*

When asked what she felt was particularly helpful or supportive in the care experience, another client mentioned that *“the biggest thing was the fact that it was there . . . to have taken”. To have the medications. Just having it” (Interviewee 4).* When asked if she had found anything in the process unhelpful, she answered that, although she understood that it was necessary, the follow-up schedule was inconvenient, *“in terms of finding time to make the appointment again, but that was probably the only drawback” (Interviewee 4).*

Experiences of Side Effects

Four out of the five clients interviewed experienced physical side effects, ranging from headaches, to nausea, exhaustion/fatigue, vomiting, and loss of appetite. These clients either devised their own coping strategies, or followed advice from HCPs to manage their situations. However, one client experienced such bad side-effects that she stopped taking Kaletra® two weeks into the 28-day course. She had been so ill that she couldn’t go to school: *“She couldn’t keep anything down and she wasn’t going to school either, she just couldn’t get out of bed” (SANE, facilitated interview for Interviewee 5).* These side effects also had an impact on her follow-up sessions, at which she was so concerned about vomiting during the counselling that she didn’t concentrate on what was being said. Having to quit the drug regimen caused her considerable distress as her fears about contracting HIV were amplified.

Another client was given the option of switching to a liquid form of the medications after experiencing difficulties with the pills, which she did.

Two clients indicated that taking the anti-HIV medication had a positive psychological impact on their well-being.

“... Being able to take them, I think, what’s the word, it helped in terms of concerns . . . I think part of it was just the actual action of doing it. It reassured me in that I could do something. Like it gave me some sort of mode of action to take. And then again, just knowing how the drugs work and knowing that I was taking them helped, like I considered that I was doing something and they could be effective in reducing the risk of me contracting HIV” (Interviewee 4).

Finally, one client highlighted a positive side to taking the drugs, and took *“any opportunity to take a nap – and didn’t feel guilty. . . I’m very energetic – what I found that I enjoyed was that it levelled out my energy levels.”* Further, when asked how taking the drugs influenced her concerns or feelings about HIV, she replied, *“Because of the physical reaction [to the drugs] it just made me more aware and sensitive to people who have contracted HIV” (Interviewee 3).*

Summary

- Overall, clients were satisfied with the care received from SATC staff;
- Many factors influence the decision to take HIV PEP medications including the recommendation of HCPs, previous knowledge about the assailant, counselling/information about HIV PEP, and client anxiety levels;
- All (5) interviewees felt that they had enough information to be able to make the best decision for them;
- Clients have numerous coping strategies for dealing with symptoms/side effects experienced while taking HIV PEP;
- The follow-up schedule was seen as positive by some clients while others felt it was inconvenient to make time to return to the SATC for medications (although it was seen as a necessary inconvenience).

c) Client Suggestions

Several client respondents made comments or suggestions regarding the universal HIV PEP program in the survey and interviews. Compiled suggestions are as follows, whether expressed by one client or several:

1. Continue universal offering of HIV PEP to sexual assault victims;
2. Continue all aspects of the HIV PEP program (information, drug therapy, counselling, testing etc.);
3. Provide other forms of medications – liquid, needle, etc.;
4. Reinforce at the first follow-up some of the initial information that was provided at the first meeting: storing the medications, time between each dose, and potential side effects;
5. Provide the option of group counselling;
6. Make follow-up appointments more easily accessible for rural clients. Consideration should be made for HCPs visiting clients in cases where the client is too ill to attend the clinic, or has transportation problems;
7. Provide documentation for a client to submit to her/his work, so time can be taken off, without disclosures being made to employers;
8. Provide a 24-hour help line;
9. Create a booklet on types of side-effects most commonly experienced and how to cope with them; and,
10. Ensure that the same counsellor is assigned to a client for each follow-up session.

CHAPTER 6

CONCLUSION & RECOMMENDATIONS HIV PEP PROGRAM

6. CONCLUSION & RECOMMENDATIONS

a) Introduction

The HIV PEP Study was launched at a time when little concrete knowledge existed about offering HIV PEP in the context of sexual assault. Since then the issue has been given increasing attention and a number of jurisdictions have begun to explore how best to implement an HIV PEP program for victims/survivors of sexual assault. To date, however, there have been no prospective studies done to examine a strategy for delivery of this service.

Programs to address occupational exposure to HIV are currently in place in all provinces and territories across Canada. However, the Canadian response to non-occupational exposure to HIV and the offering of HIV PEP has been uneven. In 1998, the first national conference on HIV PEP in the context of non-occupational exposure was held in Montreal to discuss the medical, legal and ethical issues surrounding the subject. In 2000, a Federal-Provincial-Territorial (FPT) Committee was tasked with exploring the issue of non-occupational exposure to HIV, including exposure through sexual violence. Despite these initiatives, only British Columbia has implemented guidelines and a province-wide program offering free HIV PEP medications to those victims/survivors of sexual assault assessed to be at high-risk of HIV acquisition (see Appendix A, page 1 for BC guidelines).

In most Canadian jurisdictions, the decision to offer HIV PEP to a victim/survivor of sexual assault relies entirely on the discretion of an individual physician/team, their awareness about HIV PEP and/or the ability of the client to pay for the treatment. At the time of implementation of the HIV PEP Study in Ontario, no provincial protocols or guidelines for provision of HIV PEP after a sexual assault were in place. In December 2000, the Ontario Advisory Committee on HIV/AIDS (OACHA) made four recommendations on non-occupational exposure HIV PEP to the Ontario government, including:

1. Make treatment available to all, regardless of how the exposure to HIV occurred;
2. Continue aggressive personal and community efforts to prevent exposure; non-occupational exposure HIV PEP is not a substitute for these;
3. Create infrastructure and capacity, including knowledge and counselling skills, to provide accurate assessments, supportive counselling, education and timely access to the right treatment and follow-up services, unhindered by an [individual's] inability to pay; and,
4. Collect and monitor data on non-occupational exposure HIV PEP for the purposes of program evaluation and adjustment.

(as reported by FPT Advisory Committee on AIDS, 2002)

To date, the government of Ontario has not acted on the OACHA recommendations. However, the decision to fund this study, through the Ontario Women's Health Council (OWHC), is an important step towards establishing a structured response to the needs of individuals at risk of HIV infection through one form of non-occupational exposure - sexual violence.

The purpose of this study was to evaluate a universal strategy of offering HIV PEP to Ontario sexual assault victims/survivors at-risk of acquiring HIV. In order to do this, it was necessary to

prospectively determine the proportion of at-risk victims/survivors that accept HIV PEP and the proportion that complete HIV PEP, as well as to determine the predictors of HIV PEP uptake and completion.

The study methodology was not a comparison of a universal offering program to a high-risk offering program. Therefore, we cannot definitively determine whether universal offering (offered to all those at some level of risk of acquiring HIV) or high-risk offering (offered to those that have additional factors that increase their risk of acquiring HIV) is a more effective strategy in preventing HIV transmission. Although a comparison of this nature is not possible within the parameters of this study, we know that HIV PEP was accepted and valued by clients in cases in which the circumstances of their assault meant that no accurate risk assessment could be made. By building on lessons learned from the extant research literature with the rich data collected in this study, we believe that a case for universal offering can be made.

b) The Case for Universal Offering

It had been hypothesised in previous studies that providing HIV PEP programs to clients at unknown-risk of HIV infection would be ineffective given (assumed) low rates of uptake and completion. This study demonstrates that, in fact, when clients have access to HIV PEP medications, along with effective support and follow-up services, a considerable proportion of those with unknown-risk status choose to take them (41.3%) and, of those, a significant proportion complete the regimen (33.2%). Although high-risk clients for whom the assailant's risk of HIV could be assessed were more likely to accept HIV PEP, once on the medications the unknown-risk group completed the course of treatment at the same rate. The uptake and completion rates for victims/survivors assessed as both high-risk and unknown-risk are high in this study, pointing to a clear demand for such a program and a willingness by a significant proportion of clients to follow through with a full regimen of drugs. This suggests that the universal offering of HIV PEP is worthwhile and that such a program can add value to the already highly successful services delivered at SATCs.

Challenges in Effective Risk Assessment

The strongest case for promoting universal access to HIV PEP for victims/survivors of sexual assault is the imprecision and inadequacy of any assessment of risk. Despite several decades of research into HIV and AIDS, there remains much that is unknown. Additionally, given the primary routes by which HIV is contracted - sexual contact and intravenous drug use – there is significant stigma associated with these activities which serves to further inhibit clear assessments of risk and makes the development of prevention strategies challenging. The silence and shame that can surround sexual violence further exacerbates the problem of effectively evaluating and responding to the risk of HIV transmission.

As described in Bamberger *et al* (1999), in the case of sexual assault, it is very difficult to definitively know the HIV status of the assailant, even in cases of acquaintance or family assault. In the HIV PEP Study, 86% of clients did not know the HIV status of the assailant and 41% had known the assailant for less than 24 hours. Therefore, the HIV status of the assailant cannot be used as the primary determinant in a risk assessment that regulates access to HIV PEP medications. The New York Guidelines for Non Occupational Exposure to HIV, informed by the work of Bamberger, state, “PEP should be recommended based on the nature of the exposure, and not the likelihood of

HIV infection in the assailant or local prevalence of HIV” (NYSDOH AI, 2004, 5B:9-10). Instead, characteristics of the assailant, including known high-risk behaviours, should be used to inform the discussion between the Health Care Provider (HCP) and client when making decisions about taking HIV PEP drugs. These guidelines recommend therefore that a two-staged assessment process should be implemented; the first to determine eligibility for the drugs and the second, to support the client to evaluate the cost/benefits of the HIV PEP program in her/his individual context. Findings from the HIV PEP Study suggest that some HCPs are not comfortable in deciding whether it is in the best interests of the individual client to take the drugs, given the lack of clear guidelines and the enormous consequences of making the decision. Universal offering allows victims/survivors the opportunity to hear all the facts and make informed choices, in consultation with their HCPs.

Both the literature and the feedback from HCPs in this study indicate that effective risk assessment is challenging, if not impossible. Although jurisdictions use a variety of methods to determine the risk of HIV transmission, these are by definition probabilistic. It is incredibly difficult for standardised tools to effectively weigh the complexities of individual lives and take all the relevant elements into account when determining whether HIV PEP should be offered. In the absence of an effective way to evaluate risk, therefore, it is necessary to offer treatment to all at-risk sexual assault victims/survivors in order to provide them with the same protections that we offer to other ‘at-risk’ communities (occupational and mother-child transmission).

Factors identified in this study that influenced both acceptance of HIV PEP and completion of the course of medications are not usually part of a risk assessment process. The study data showed that irrespective of risk status, clients attacked by strangers and those whose assaults involved multiple sexual acts and multiple injuries were more likely to accept HIV PEP. Clients assaulted by strangers 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 who would clearly accept and complete a course of HIV PEP would otherwise be ineligible for the treatment within a narrower, high-risk framework.

The risk assessment framework used in this study provides a useful model for differentiating those victims/survivors at no risk of HIV infection and ensuring those at any level of risk have access to the medications with appropriate concomitant counselling.

Choice and Empowerment of Sexual Assault Victims/Survivors

A clear theme emerging from the study findings was that the risk of HIV acquisition was a major concern of many SATC clients. The majority (70%) of client survey respondents reported that they had concerns about HIV. A further 60% reported that they were moderately to very anxious about the possibility of being exposed to HIV. According to clients (and this was affirmed by HCPs as well), having access to HIV PEP and being supported in making decisions to promote their own health helped them to regain a sense of control taken away during the assault.

SATC clients that took HIV PEP medications frequently expressed feelings of empowerment with respect to regaining control in their lives. HCPs and clients alike attribute such feelings and attitudes to taking HIV PEP medications. Taking these medications frequently had a positive impact on sexual assault victim/survivor recovery; citing their decision to take HIV PEP as an enabling factor by which they actively took part in their healing process. HCPs commented that clients became empowered with the realisation that they had a choice and that they could make decisions regarding their own health.

This feedback is consistent with the literature on sexual assault that describes sexual violence as an exertion of power by one person over another (Lenskyj, 1992). Sexual assault victims/survivors lose control over the integrity of their bodies during the assault and can be left feeling profoundly disempowered. SATC support is there to provide them with the first step in reclaiming their own power and autonomy, providing them with the opportunity to take part in decision-making about their treatment (Du Mont *et al.*, 2002). The universal HIV PEP program supports SATC staff by providing them with an additional opportunity to intervene in a way that promotes healing and well-being for all their clients.

Offering versus Recommending HIV PEP

Several HCPs indicated that their primary role in working with victims/survivors of sexual assault is empowering them to make choices for themselves. This may explain some of the apparent resistance that some HCPs had to making recommendations to clients to take or not take the HIV PEP treatment. Our data showed that 70% of all clients were neither discouraged nor encouraged by HCPs to take HIV PEP. In fact, despite the medical protocol guidelines, only 42% of high-risk clients were encouraged or strongly encouraged to take HIV PEP. Given the influence that some HCPs surveyed and interviewed stated they have on the decision-making of clients, particularly young, vulnerable and highly traumatised individuals, they may have been uncomfortable in deliberately influencing their decisions, with words like “strongly recommend”. Nearly half (47.7%) of HCPs surveyed thought their recommendations had a significant influence on the client’s decision. This was confirmed by the study data, which showed that those who were “encouraged or strongly encouraged” to take HIV PEP did so at a higher rate than those who were “neither encouraged nor discouraged” (67.6% vs. 35.9%). A few HCPs reported that they felt it was their role to give clients a thorough understanding of the levels of risk and once they had provided that information, to trust them to make good decisions for themselves, within their own individual context.

When HCPs were asked what they thought the optimal strategy for offering HIV PEP should be, they offered seemingly contradictory responses with regard to the concept of universal offering. Although 69% of survey respondents agreed that HIV PEP should be offered to clients at unknown-risk, only 27% endorsed universal offering. Nonetheless, 55% responded that HIV PEP should be offered to high-risk clients and unknown-risk clients who request it after HIV counselling. This seeming contradiction may reflect the confusing concepts/language around counselling, offering and recommending. A few of the surveyed HCPs expressed discomfort with recommending treatment when so much of SATC care focuses on client decision-making and empowerment. In the focus groups, where this issue could be more broadly explored, some participants expressed reservations about recommending treatment, preferring to counsel clients in a more neutral manner and to offer HIV PEP to all at risk clients. Discussion about caregiver neutrality, treatment recommendations, and the appropriate language to support but not supplant client decision-making must be an important component of future training initiatives.

Quality of Care

The positive feedback from clients in the study was an endorsement not only of the universal HIV PEP program but also of the general medical care offered at SATCs. For clients, it was simply perceived as one element of their treatment experience. The quality of care provided was perceived very highly and is an apparent source of comfort, knowledge and healing for clients. For staff, HIV PEP counselling opened the doors to improved care on a number of levels, as follow-up provided

them with an opportunity to continue the support and knowledge exchange valuable to victims/survivors of sexual violence. This suggests that the universal HIV PEP program is a worthwhile initiative that can enhance existing services offered to victims/survivors of sexual assault. It is a valuable addition to the highly successful existing model of service delivery at the SATCs.

Given the enormous diversity in the experiences of clients presenting to SATCs, a one-size fits all program cannot effectively address the needs of this population. Each client must be seen on a case-by-case basis and assessed based on their needs and expressed concerns as the best practice experience of SATC staff and their affiliated partners. A universal offering program allows this flexibility because it provides a framework within which to evaluate the needs of individual clients based on their individual contexts. A program limited to high-risk offering, by contrast, requires a more rigid approach, based on criteria that may or may not capture the real needs of the client. Services must be tailored in order to provide the best care to each presenting client, rather than assuming they will fit into a pre-established model.

Study findings indicate that universal offering is the optimal way of delivering HIV PEP services to victims/survivors of sexual violence. Such a model must be predicated on effective training, current knowledge and educational materials, respectful partnerships and adequate resources.

c) The Feasibility of Universal Offering

A program of universal offering of HIV PEP has been successfully implemented in 24 of the 34 SATCs (70.6%). It has been well received by HCPs and sexual assault victims/survivors across these centres. Of the 10 SATCs that were unable to participate in this study, only two stated that a universal program of offering HIV PEP was not feasible. Both of these sites service rural communities and did not have enough staff to offer HIV PEP universally and provide sufficient follow-up. Two SATCs were dealing with new procedures surrounding organisational changes and were unable to accommodate a new program at the time of our study. One SATC had just been established and was dealing with getting services up-and-running. Finally, two SATCs were unable to get the study through ethics and two were unable to get support from emergency/administrative personnel.

Three quarters (74.8%) of HCPs surveyed reported that they had the time and opportunity to provide sufficient counselling about HIV PEP. Almost three-fifths (58.3%) of the HCPs responded that other aspects of client care were not compromised due to universal offering. In fact, most respondents from the focus groups felt that the program improved their SATC service overall by enhancing the follow-up care provided to clients.

The ability of the victim/survivor to provide informed consent to accept HIV PEP was raised as a concern prior to this study. Of the HCPs surveyed, 62.9% felt that in general clients are able to make an informed decision. The main barrier raised by some was client distress – the inability to make an informed decision while in a crisis situation. Several HCPs noted that the first follow-up visit was essential in helping clients re-address their decisions to take/not take HIV PEP.

The study results demonstrate that a program of universal offering of HIV PEP is feasible in Ontario's SATCs. However, in order to establish a truly effective and accessible provincial universal

HIV PEP program, those SATCs that faced barriers to implementation must be engaged. A knowledge-sharing plan should be developed that allows SATCs that have successfully implemented to share their strategies with others. An informal network of support should be established.

Standardised Care across the Province of Ontario

Prior to implementation of the universal HIV PEP program, the offering of HIV PEP to Ontario's sexual assault victims/survivors was inconsistent geographically and practice varied among team members within SATCs. Some SATCs provided HIV counselling and offered HIV PEP to some clients, while others offered no HIV counselling or HIV PEP. As was clearly articulated in the letters of support of the universal HIV PEP program written by SATC Coordinators from across the province (Appendix C), knowledge surrounding HIV was minimal and varied greatly among teams prior to the study. Further, medical and nursing teams were often uncomfortable with the complex drug regimen, laboratory testing, and HIV counselling required to adequately address and discuss HIV. By and large, access to HIV PEP was dependent on which SATC the victim/survivor accessed following their assault and which team member was responsible for their care.

The HIV PEP Study has built a strong foundation of knowledge in the sexual assault HCP community from which to respond to possible HIV exposure subsequent to assault. The study has succeeded in developing and delivering standardised training to HCPs about HIV in the context of sexual assault, HIV PEP and the protocols for offering it, and about providing supportive and structured follow-up. This increases the likelihood of a more consistent care experience for Ontario's sexual assault victims/survivors. A viable infrastructure has been created to serve as the foundation for a province-wide program of universal offering.

d) The Sustainability of Universal Offering

Almost two thirds (65.2%) of HCP respondents believed that universal offering of HIV PEP was sustainable from a staffing perspective over the long-term. A majority (61.9%) of Follow-up Care Providers also believed that the follow-up schedule was sustainable on a long-term basis. The majority of focus group participants indicated that the universal HIV PEP program could be sustained as long as specific concerns were addressed. While a majority of respondents from all three groups asserted that the current program was sustainable, they shared concerns raised by those who were unsure of, or doubted, its sustainability. The main concern was funding for HIV PEP medications. Without external funding for the drugs, most participants believed that the hospitals would not be able to continue the program. They also identified staff resources, outside expertise to support ongoing learning, increased flexibility in the program to accommodate individual client and community needs and sufficient time to effectively deliver the service, as elements needed for a sustainable program.

Strategies for Sustainability

In order to build upon the established infrastructure, strategies to facilitate knowledge transfer must be developed, an appropriate balance must be struck between flexibility and consistency in service delivery, and adequate resources for medications and staffing of the program must be provided.

Knowledge Transfer

There is clearly a need for ongoing education and training of SATC staff about HIV and HIV PEP to maintain this high quality of care and expertise. Ongoing opportunities for consultation, sharing

of information and questions must be provided. The Ontario Network of SATCs is situated to provide the infrastructure for these activities, incorporating these activities into the Sexual Assault Nurse Examiner (SANE) training. Perhaps as importantly, SATC affiliated health professionals (emergency room doctors and pharmacists, among others) need access to HIV PEP training. At a minimum, this should take the form of an orientation, but ideally these professionals could participate in a full HIV PEP training session in order to understand the structure of the universal HIV PEP program and the evidence upon which it has been built. This may serve to reduce resistance to the program and prevent some of the challenging situations identified by several HCPs in trying to provide their clients with access to HIV PEP medications. The training materials developed for the HIV PEP program should be revised to integrate the findings of this study and the research knowledge that has been developed in other jurisdictions since the outset of the program.

At the start of this study, in order to increase awareness about the universal HIV PEP program, many SATCs informed their communities, as well as the referring agencies within their communities, of the availability of free HIV PEP medications to all sexual assault victims/survivors at-risk of HIV acquisition due to sexual assault. This message was widely disseminated throughout Ontario communities. Following the completion of the study, however, this type of outreach activity has continued inconsistently across the province. If HIV PEP is to be expanded province-wide, a focused strategy is required to ensure that community-based organisations working with victims/survivors of sexual violence are aware of the program and understand what it means for their clients. Family practitioners should also be a target group for this information.

Public education is equally important, as this program is only effective if sexually assaulted persons know it is available. HIV PEP provides one important strategy in the promotion of the mental and physical well-being of victims/survivors of sexual violence. Given this study's findings that a majority of the victims/survivors presenting to the SATCs were women under the age of 30, specific outreach strategies aimed at younger women may be required. Given that many victims/survivors of sexual assault in Ontario never access SATC services, the availability of HIV PEP might convince them to come in and meet with the SATC staff thereby enabling them to receive referrals to other agencies and, if deemed appropriate after counselling, HIV PEP medications. Given the positive client response in this study to services offered by SATCs, it is vital that all victims/survivors know that HIV PEP is available.

To ensure information about new HIV PEP medications and/or materials are kept current and regularly communicated to Ontario's SATCs, Sheila Macdonald, Provincial Coordinator of the Ontario Network of SATCs, is establishing an ongoing committee to monitor and support the HIV PEP program. The committee will facilitate communication between the Network of SATCs, HCPs, and HIV Experts in an ongoing fashion, thereby ensuring continued availability of expertise and support regarding drug and/or health contraindications or complications.

Flexibility

There is a need to strike an appropriate balance between providing standardised HIV PEP care and ensuring that program delivery remains flexible and adaptable to the needs of the individual client, staff member, SATC and community.

The particular needs of SATCs serving rural and remote communities may also require additional exploration. Some HCPs and clients indicated that effective implementation and access to services

will require more creative solutions, which may include partnerships with community agencies, travel subsidies for follow-up visits or travel by SATC staff to visit clients in their own communities. Other innovative technological and structural solutions must also be considered. For those SATCs serving Aboriginal victims/survivors living on reserves, additional solutions may be needed to address the lack of community agency support, the increased need for services due to high incidences of HIV in some communities and the need for culturally appropriate services.

Resources

The HIV PEP Study offered access to medications to victims/survivors of sexual violence in a way that did not have financial implications for them and, other than human resource requirements, did not place an additional burden on the budgets of Ontario's SATCs. Now that this study has ended, the future funding of these medications must be secured. The current cost for a complete 28-day course of HIV PEP medications is \$1,108.24. This is a significant expense for the SATC client population who are predominately students or unemployed and younger than 30 years old. SATC staff clearly indicate that it is not within the budgets of their organisations to continue to support the HIV PEP program without an investment of resources by the Ministry of Health and Long-Term Care to cover the costs of the medications. Based on the results of this study, the estimated annual cost of a universal HIV PEP program in Ontario is approximately \$450,000 (Appendix D). This estimate is based on the HIV PEP Study acceptance rates, completion rates at each follow-up visit and the estimated total number of sexual assault victim/survivors seen at all SATCs across Ontario (approximately 2,000).

Other concerns include the human resources necessary to support this program. Many SATCs have found creative ways to address the increased workload accompanying the program's implementation and have expressed their ability to carry on unaided. Other SATCs have identified human resource needs that require additional staff hours to handle the increased complexities and follow-up visits necessary in supporting HIV PEP clients.

The sustainability of this highly successful universal HIV PEP program depends on stable funding to cover the costs of the medications distributed to clients. Limited additional financial support may be required to enable certain SATCs, particularly those in rural/remote areas, to continue to provide the high quality HIV PEP services offered to clients to date.

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.

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APPENDICES

Appendix A:	Non-occupational HIV PEP Programs: Canada & International
Appendix B:	Partners in the HIV PEP Study (Research Team; Project Advisory Committee; Ontario Network of Sexual Assault/Domestic Violence Care & Treatment Centres (SATC); Ontario Women's Health Council (OWHC).
Appendix C:	HCP Support Letters (Brockville; Burlington; Cornwall; Hamilton; Kenora; Kingston; Mississauga; Owen Sound; Richmond Hill; Sault Ste. Marie; Sioux Lookout; Toronto – Sunnybrook & Women's)
Appendix D:	HIV PEP Universal Offering Cost Estimate

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