AN ABSTRACT OF THE DISSERTATION OF

Sonia M. Kandathil for the degree of Doctor of Philosophy in Public Health presented on

March 17, 2010.

Title: Women Initiated Solutions for HIV Prevention (WISH Study): Factors Associated with Intentions to Use Microbicides and Tenofovir.

Abstract approved:

S. Marie Harvey Donna A. Champeau

With women comprising nearly 50% of HIV/AIDS infections globally, the development of new woman-initiated HIV prevention methods has become a public health imperative. To date, the female condom and the diaphragm are the only woman-initiated prevention methods available on the consumer market. Recent research has focused on two HIV/AIDS prevention technologies undergoing clinical trials: microbicides and tenofovir (PrEP). Both are being touted as female-initiated HIV/AIDS prevention technologies that women can use covertly, without a partner's knowledge, to improve their odds in protecting themselves against HIV. Use of these new technologies will not only depend on their effectiveness, but on women's willingness to use these products. This cross-sectional study used an integrative conceptual model that included both intrapersonal and interpersonal constructs to explore factors associated with women's intentions to use. Three hundred and forty-eight high-risk women in Toronto,

Canada completed self-administered questionnaires (SAQs). Results were remarkably consistent across relationship types and prevention methods examined in the study, with 60% of the women intending to use microbicides and tenofovir. Women who perceived themselves to be at greater risk for STIs, had greater microbicide self-efficacy, and more positive perceptions of microbicides were more likely to intend to use microbicides. Women with ≤ grade 12 education, greater sexual and HIV risk, greater tenofovir self-efficacy and more positive perceptions of tenofovir were more likely to intend to use tenofovir. When asked which method they preferred, 66% preferred pre-exposure prophylaxis (PrEP). Women, who had previously used a barrier method for contraception, had greater microbicide self-efficacy and more positive perceptions of microbicides were less likely to prefer tenofovir. Women, who had used hormonal methods for contraception, had greater tenofovir self-efficacy and more positive perceptions of tenofovir were more likely to prefer tenofovir. Findings have important implications including assisting researchers in the development and refinement of these products and consumer analysts in the development of marketing strategies that highlight method attributes women perceive positively. Findings will also help health care providers identify women who would potentially use these products and assist women in developing confidence in their ability to effectively use such methods.

Women Initiated Solutions for HIV Prevention (WISH Study): Factors Associated with Intentions to Use Microbicides and Tenofovir

by Sonia M. Kandathil

A DISSERTATION

Submitted to

Oregon State University

in partial fulfillment of

the requirements for the

degree of

Doctor of Philosophy

Presented March 17, 2010

Commencement June, 2010

Doctor of Philosophy dissertation of Sonia M. Kandathil presented on March 17, 2010.

APPROVED:

Co-Major Professor, representing Public Health

Co-Major Professor, representing Public Health

Chair of the Department of Public Health

Dean of the Graduate School

I understand that my dissertation will become part of the permanent collection of Oregon State University libraries. My signature below authorizes release of my dissertation to any reader upon request.

Sonia M. Kandathil, Author

ACKNOWLEDGEMENTS

I would first like to recognize my committee members, Sheryl Thorburn, Janet Lee, and Patti Watkins for their sage advice. I strongly believe their comments and suggestions improved this study.

No words can describe the gratitude I feel for my committee co-chairs, Donna Champeau and Marie Harvey who have always been accessible to me throughout my doctoral career. Across cities and in some cases continents, they always carved out time in their busy schedules to accommodate me. I thank them for their mentorship, their belief in this study, and their commitment to me as a student and future colleague.

I'd like to thank Alan Acock for his help with number crunching and for entertaining my daughter with his avuncular antics during my desperate visits to his office.

Several people deserve special thanks for their help with this study. Much gratitude goes to Jane Grier, Heather Jacobsen and all the women of Hassle Free Clinic. Without their support, this study would never have happened. I'd also like to thank Jason Altenburg, Raffi Balian, Molly Bannerman, and Sang Wan of the South Riverdale Community Health Centre who played such key roles in encouraging women to participate in this study. Their commitment to social justice is astounding.

I'd also like to thank Judy Auerbach, my former mentor and colleague at amfAR, the Foundation for AIDS Research. When I first approached her about this study, she did not hesitate to pull out her rolodex and provide me with names of additional people to contact. Due props go to Kate Morrow, Lori Heise, Susan Newcomer, Larry Severy, Polly Harrison, and Ward Cates for patiently listening to a novice researcher when I first

proposed this study. They all asked me the same question: "Have you spoken to Marie Harvey, yet?" I took their advice and did.

Much love goes to Gay Glading, Emily Byram, Monica Ruiz, and Elisha Dunn-Georgiou—all amfAR ladies at one time. We've shared many glasses of wine at the best and worst of times. The next one is on me, ladies!

Without a doubt, I must thank the Corvallis Posse—Dustin, Heather, Tumas, Michaela, and Amy. Their constant support throughout the years has taught me the meaning of friendship. It would be remiss of me not to mention my dear friend Monica Hunsberger, who was with me through thick and thin. She was also a constant source of support and although I don't see her often, she is never far from my thoughts.

I would like to thank my parents, Thomas and Lucy Kandathil for teaching me the value of learning. They were right: no one can ever take away your education. My father taught me that hard work and persistence pay off and my mother encouraged us to live a life outside of ourselves by giving to others.

I would like to thank my oldest living maternal aunt, Catherine Mathew, the former Secretary General of the YWCA. A strong role model for me, she believes in the power of women.

I wish to thank my partner, Robert Bates, without whose support I could not have completed this dissertation. We met as Peace Corps Volunteers and haven't looked backward since. Thirteen years and one daughter later, he is still my rock and best friend.

Finally, I want to thank all of the women who participated in this study. Their thoughts and perceptions will help shape the future of woman-initiated HIV prevention.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF APPENDICES

Women Initiated Solutions for HIV Prevention (WISH Study):
Factors Associated with Intentions to Use Microbicides and Tenofovir

Chapter 1 : INTRODUCTION

One area where women have achieved parity with men is in the acquisition of HIV/AIDS. At the end of 2009, nearly 33.4 million people were living with HIV/AIDS (UNAIDS, 2009). Out of this population, nearly 50% are women (UNAIDS, 2009; UNAIDS/UNFPA/UNIFEM, 2004). Globally, the epidemic continues to grow or remain stable among women, with no apparent sign of decline in the near future. The epidemic is most pronounced in Sub-Saharan Africa, where nearly 60% of all people infected by HIV are women (UNAIDS, 2009). HIV infection is 1.3 times more prevalent among adult women than men in sub-Saharan Africa, and young women aged 15-24 are three times more likely to be infected than young men of the same age (UNAIDS, 2004, 2005).

Other regions such as Latin America, Eastern Europe, Central Asia, South and South-East Asia have not been excluded from the ravages of disease, with reported increases in HIV infection occurring among women. AIDS affects women most profoundly where heterosexual sex is the primary mode of transmission, but it is also sharply noticeable among women in countries where HIV infection occurs through injection drug use and commercial sex (UNAIDS, 2009; UNAIDS/UNFPA/UNIFEM, 2004).

The North American epidemic echoes the global pandemic among women. At the end of 2007, 551,931 persons were living with HIV/AIDS in the United States. Twenty-seven percent were women. In the United States, the epidemic hits women of

color the hardest, with African American Women accounting for nearly 20 percent of all infections (Centers for Disease Control and Prevention, 2005). Similar trends exist in Canada. At the end of 2008, nearly 65,000 Canadians were living with HIV infection and women comprised nearly 20% of all people living with HIV, with the numbers continuing to grow (Public Health Agency of Canada, 2008).

Why Women Need Female Initiated Prevention Methods

In many countries around the world and in North America, women face a range of unique risks that confer greater vulnerability to HIV infection than males. Several factors explain what has been termed "the feminization of AIDS," including a) persistent gender inequality which can leave women economically dependent on their male sexual partners and make them more susceptible to poverty, violence, and sexual coercion; b) the fact that HIV prevention efforts have not been scaled-up for women; and c) the absence of female controlled HIV prevention technologies that women can use covertly, without their partner's knowledge (Germain & Woods, 2005; Heise & Elias, 1995; Morrow et al., 2003; Woodsong, 2004).

Gender-based violence, a form of gender inequality, can be a cause of HIV. It is estimated that between eight and 70% of women worldwide have been physically or sexually assaulted by a male partner (Heise, Ellsberg, & Gottemoeller, 1999; Krug, Mercy, Dahlberg, & Zwi, 2002). A recent multi-country study on violence against women confirmed that physical, sexual, and emotional violence has reached epidemic proportions, ranging anywhere from 4% to 70% of women having experienced such violence (Garcia-Moreno, Watts, Ellsberg, Heise, & Jansen, 2005). Several studies indicate that women who have a history of childhood sexual abuse are more likely to

engage in HIV risk-taking behavior including drug abuse, having a male partner at risk for HIV, having multiple partners, and exchanging sex for drugs, money or shelter (Bensley, Van Eenwyk, & Simmons, 2000; Cohen et al., 2000; O'Leary & Martins, 2000; Thompson, Potter, Sanderson, & Maibach, 1997; Wyatt et al., 2002; Zierler et al., 1991). Other studies indicate that forced sex or rape not only causes abrasions and cuts which facilitate the entry of HIV through vaginal mucosa (Jansen & et al, 2002), but can also increase HIV risk taking behaviors (Dunkle et al., 2004).

A dearth of comprehensive prevention services available to women is also an impediment to preventing the further spread of HIV/AIDS. Globally, only one fifth of those who need prevention services have access to them, yet scaled-up prevention services could avert 29 million of the 45 million infections projected to occur this decade (Global HIV Prevention Working Group, 2003). Scaling up HIV prevention means ensuring that the appropriate mix of evidence-based strategies achieves a sufficient level of coverage, uptake, intensity, and duration to have an optimal public health effect (Global HIV Prevention Working Group, 2007). Despite the fact that a wide-range of strategies exist for women, those who are most at risk for HIV infection have little or no access to these HIV prevention tools (Global HIV Prevention Working Group, 2007).

Finally, the absence of female-controlled HIV prevention technologies may enhance women's vulnerability to HIV/AIDS. Currently, the most effective HIV prevention technology on the market is the male condom, which is 80-95% effective in reducing the risk of HIV infection (Hearst & Chen, 2003; Holmes, Levine, & Weaver, 2004; Pinkerton & Abramson, 1997; Weller & Davis, 2004). Despite their high rate of effectiveness, many women find it difficult to negotiate condom use because it may

imply distrust of their partner (Jadack, Fresia, Rompalo, & Zenilman, 1997). The socio-cultural contexts of women's lives also play a key role in condom use negotiation, where women who feel disempowered in their relationships may find it difficult to insist on their use (Amaro, 1995b; Wingood & DiClemente, 2000).

In Women's Hands: The Female Condom

Today, only one option is available as a female-controlled HIV prevention method: the female condom. Researchers have cited the female condom as being the first real barrier method that women have to protect themselves not only against pregnancy, but against the acquisition of HIV/AIDS and other diseases. Perfect use of the female condom may reduce the risk of acquiring HIV/AIDS by more than 90% among women who have intercourse twice weekly with an infected male partner (Trussel, Sturgen, Strickler, & Dominick, 1994). Although acceptability of the female condom is high, women have complained about aesthetics, insertion difficulties, mechanics, partner reactions to female condom use, high cost, and provider prejudices as barriers to use (Gilbert, 2000; Mantell et al., 2005). Similar to the male condom, women were reluctant to use the female condom because of the implications of infidelity, and others feared violent reactions from their partner if they insisted on its use (Farr, Gabelnick, Sturgen, & Dorflinger, 1994). Lack of use of existing female-controlled prevention technologies, such as the female condom, that may offer some protection against acquiring HIV/AIDS further impedes prevention efforts. Because of these negative reactions from partners, the difficulty in negotiating both male and female condom use, the mechanical difficulties with the female condom, and the persistent power inequities in sexual relationships, many researchers are still looking for alternative

woman-initiated prevention methods that women can use to buttress their protective power (Woodsong, 2004). To this end, researchers have called on a concerted effort to improve the range woman-initiated HIV prevention options.

In Women's Hands: More Options Means More Control

Recent research has focused on two HIV/AIDS prevention technologies currently undergoing clinical trials: microbicides and tenofovir. Both are being touted as woman-initiated HIV/AIDS prevention technologies that women can use covertly, without a partner's knowledge, to improve their odds in protecting themselves against HIV. Microbicide refers to a range of products, potentially in gel, cream, film or suppository form**,** being developed to prevent the transmission of HIV/AIDS and other sexually-transmitted infections when topically applied (Alliance for Microbicide Development, 2005). Currently, 29 microbicide candidates are in the pipeline being developed to prevent the transmission of HIV. Microbicide efficacy is still unknown, but it is believed they will work by inactivating HIV in sexual fluids before the virus can cause infection in the first place (Wainberg, 1999) .

Another option for a female-initiated prevention method may be the pill tenofovir, a product that HIV negative individuals could take daily to reduce their risk of HIV infection (AIDS Vaccine Advocacy Coalition, 2005). Originally developed as an HIV treatment, tenofovir is now undergoing clinical safety and efficacy trials as pre-exposure prophylaxis (PrEP). Tenofovir, manufactured by the pharmaceutical firm Gilead Sciences and marketed under the name Viread™, is used solely for the treatment of HIV/AIDS. It has been tested extensively in animals and shown efficacy in preventing the transmission of HIV/AIDS. Several other conditions make it an optimal drug for

study and use in humans: a) the side-effects are minimal; b) it can be taken orally, in pill form; c) it needs to be taken only once a day; and d) it does not cause drug resistance (National Institute of Allergy and Infectious Diseases, 2005). Positive results of clinical trials have spurred Phase I/II clinical trials of Tenofovir to measure its efficacy in reducing the risk of HV infection among adults (AIDS Vaccine Advocacy Coalition, 2005).

The Importance of Acceptability Research

Both microbicides and tenofovir are not yet available, but before both products can be deemed ready for general public use, acceptability research is often conducted to determine product viability and feasibility. Researchers suggest that acceptability studies play an important role in overall product use. Product acceptability is not only influenced by its characteristics (viscosity, taste, and smell), but by its perceived effect on sexual intimacy, partner and social network perceptions, and relationship dynamics (Severy, Tolley, Woodsong, & Guest, 2005). According to Elias and Coggins (2001), acceptability is important to study because it ultimately determines use-effectiveness (Elias & Coggins, 2001) over a sustained period of time (Severy et al., 2005).

Severy and Newcomer (2005) define acceptability as the "voluntary sustained use of a method in the context of alternatives" (Severy & Newcomer, 2005). According to Severy and Newcomer (2005), acceptability studies have typically followed one of three models, fitting different stages of product development. Studies of the first type assess potential user responses to a product that is not ready for use in the target population. Subjects are asked to make hypothetical trade-offs about various aspects of a product. Studies of the second type include behavioral studies within the clinical trials used to test

the safety and efficacy of original products, providing actual information about the user's experience with the product. The third model of acceptability assesses the long-term adoption and use of a product in real-life settings, determining the relationships between the user, the product characteristics, the health system, and the socio-cultural context within which the participant lives (Severy & Newcomer, 2005).

With respect to microbicides, several studies have either examined the relative acceptability in hypothetical use studies or those embedded within clinical trials; most have focused on product characteristics (Severy et al., 2005). To my knowledge, however, there have been no acceptability studies published on tenofovir, or more specifically, on the factors that are associated with intention to use tenofovir and whether or not women would be more willing to use an oral pill as compared with a vaginally inserted microbicide to prevent the acquisition of HIV.

Purpose of the Research

The overall goal of this research is to assess the acceptability of two female initiated HIV prevention methods: microbicides and tenofovir. I am interested in assessing 1) factors associated with the acceptability of microbicides; 2) factors associated with the acceptability of tenofovir; and 3) factors associated with method preference.

Significance of the Study

Rising rates of HIV/AIDS among women have prompted an explosion of research into woman-initiated prevention technologies. Although numerous studies have been published documenting that improving the range of options for women to protect themselves will increase use of such products and their protection (Gollub, French, Latka,

Rogers, & Stein, 2001), studies on contextual factors associated with this use are often quite limited, particularly in the case of microbicides and certainly with relation to tenofovir. Furthermore, although many researchers posit that relationship dynamics, specifically relationship power and control, can affect a person's use of various products, scant scientific and empirical research support this hypothesis.

Acceptability research can help shed light on whether or not women will fully understand the benefits of using products, elements of correct use, potential side effects, and willingness to apply such knowledge to its daily use within particular relationship and social contexts. The significance of this particular study is four-fold. First, I examined the acceptability of a method, tenofovir that to my knowledge has never been studied before. Second, I assessed two potential methods for woman-initiated HIV prevention to better understand the factors associated with intentions to use. Third, I investigated the socio-cultural context of women's lives, particularly relationship control and gender-based violence, to address the gaps in a growing body of literature on microbicides. Finally, I hope the findings will help researchers, women and practitioners determine which woman-initiated methods are more likely to be used as protection against HIV. Ultimately, the findings contribute to a growing body of literature to help researchers and practitioners understand the factors associated with women's adoption and use of female initiated HIV prevention technologies, specifically microbicides and tenofovir.

Global and domestic trends in HIV among women, shedding light on the biological, behavioral, and socio-cultural risk factors for HIV, providing a detailed description of microbicides and tenofovir, summarizing the a literature on factors related

to acceptability of HIV prevention methods, and proposing a theoretical framework for this research are discussed in Chapter 2. The research design and methods including the target population, recruitment strategies, data collection procedures, study instrumentation and measures, and data analysis will be discussed in Chapter 3. Study results will be presented in Chapter 4 and findings will be discussed in Chapter 5.

Chapter 2 : REVIEW OF THE LITERATURE

HIV/AIDS Globally

Women represent the new face of HIV/AIDS. At the end of 2009, 33.4 million people were living with HIV/AIDS, and nearly half of these infections occurred among women (UNAIDS, 2009) . In 2009, nearly 15.7 million women were living with HIV, almost 1 million more than in 2003. Similar trends exist in other parts of the world, where epidemics are growing among women in South and South-East Asia, Oceania, Eastern Europe and Central Asia, but have remained stable in Latin America, the Caribbean, Western and Central Europe, and North America (UNAIDS, 2009).

HIV/AIDS among Women in North America

Despite differences in women's lives, particularly between those who live in the developing and developed world, HIV/AIDS trends remain similar across the globe. For example, although the HIV/AIDS epidemic in North America is primarily concentrated in MSM populations, recent data indicate HIV is growing fast among women (Centers for Disease Control and Prevention, 2005). In 1992, women accounted for an estimated 14% of adults and adolescents living with AIDS in the United States, but by the end of 2004, this proportion had grown to 23%. During 2004-2007, an estimated 146,692 persons in 34 states were living with HIV/AIDS; of these infections, 27% were female (Centers for Disease Control and Prevention, 2009).

Similar trends exist in Canada. At the end of 2008, nearly 65,000 Canadians were living with HIV infection as compared to 57,000 in 2005. Women comprised 22% of all people living with HIV, representing a 23% increase from 2002. Most HIV infections

among women were attributed to heterosexual contact and injection drug use, with infections attributable to injection drug use increasing slightly since 2005 (Public Health Agency of Canada, 2006a, 2006b, 2008). The province of Ontario reported the largest number of men and women living with HIV as compared to other provinces in Canada, with 25% of all reported cases of HIV infection occurring among women. The number of HIV cases diagnosed among women in 2006 was 50% greater than in 2000. Similar to national trends, 68.3% of all diagnosed cases of HIV infection among women were attributable to heterosexual transmission with 51% of these infections occurring among women from HIV endemic countries. Toronto and Ottawa bear most of the HIV burden as compared to other cities with 53% of all HIV/AIDS diagnoses among women occurring in Toronto followed by 15.7% in Ottawa. Women comprise nearly 27% of the total number of cases of HIV/AIDS in the city of Toronto (Remis, Swantee, Schiedel, & Liu, 2007).

Although all sexually active women who engage in high-risk sexual behavior encounter some possibility of contracting a sexually transmitted infection (STIs), some groups of women in North America are disproportionately affected by HIV/AIDS. For instance, in 2004, African Americans were 20.9 times more likely and Hispanics were five times more likely to be diagnosed with HIV/AIDS than their white counterparts (Prejean, Satcher, Durant, Hu, & Lee, 2005). Trends have not dissipated over time. In particular, African American women comprised 66% of HIV/AIDS cases in 2007 (Centers for Disease Control and Prevention, 2008, 2009, 2010) and also accounted for the largest percentage of HIV/AIDS cases in every transmission category, including injection drug use (IDU) and heterosexual contact.

Hispanic women are also not excluded from the ravages of HIV/AIDS. By the end of 2007, 38,340 cumulative cases of HIV/AIDS had been reported among Hispanic adult and adolescent females, with most contracting the disease through high-risk heterosexual contact and injection drug use (Centers for Disease Control and Prevention, 2009). Trends in HIV infection among women are not just associated with race and ethnicity, however. Other demographic factors, such as age, and socioeconomic status also play a significant role in the rising rates of HIV infection among women in the United States.

Rates of HIV infection vary according to age. Several studies indicate that young age, where risk behaviors are first initiated, plays a significant role in the growing rates of HIV infection among younger cohorts of women (Lee & Fleming, 2001; Valleroy, MacKellar, Karon, Janssen, & Hayman, 1998). Recent evidence indicates that from 2004-2009, the estimated number of HIV/AIDS cases increased among young adults in the United States aged 15-24, and persons aged 24-65 (Centers for Disease Control and Prevention, 2009). These data also reveal that young women are particularly vulnerable to HIV/AIDS. Nearly 15% of all HIV/AIDS diagnoses among women in 2007 occurred among those aged 13-24 years (Centers for Disease Control and Prevention, 2009). Age and race may lead to a deadly combination. Data reveal that HIV/AIDS was the leading cause of death for African American women aged 25-34 and the 4th leading cause of death for Hispanic women aged 35-44 in the United States (Centers for Disease Control and Prevention, 2008).

Similarly, in Canada, women aged 15-29 accounted for 35% of all positive HIV diagnoses in 2007. Compared to women in other age groups, the proportion of positive

HIV tests was highest among young women (Public Health Agency of Canada, 2006a). Most young adults in this age group report high-risk heterosexual contact, followed by injection drug use as the primary modes of transmission.

HIV Risk among Women: A Call to Action

Women are more vulnerable to HIV infection than men. Several factors including biology, socioeconomic status, substance use, commercial sex, multiple sexual partnerships, and inconsistent condom use play a significant role in women's overall risk.

The physiology of the female genital tract inherently makes women more susceptible to HIV than men, with recent evidence indicating that it serves as reservoir for HIV infection (Burger & Weiser, 2001; Kovacs et al., 1999). In addition, male-to-female HIV transmission is two to four times more efficient than female-to-male (European Study Group, 1992; Nicolosi et al., 1994). Finally, the presence of genital ulcer disease, such as herpes, chancroid, and primary syphilis facilitate the acquisition of HIV (Freeman et al., 2005). Biological susceptibilities combined with specific socio-cultural and behavioral factors likely increase women's risk of contracting HIV/AIDS through heterosexual intercourse.

One of these additional factors is socio-economic status. Several studies indicate that poverty and other structural inequalities may be associated with HIV risk behaviors, including drug use and sex with a high-risk partner, particularly among specific groups of women (Adimora et al., 2006; Diaz et al., 1994). Superimposed on to various demographic factors are specific behavioral and social factors that confer additional risk for HIV infection on to women.

For instance, the concomitant use of both alcohol and drugs may double the risk of contracting HIV/AIDS. Several studies have noted that women who frequently use both alcohol and drugs are at higher risk for contracting HIV than women who do not (Rasch et al., 2000; Wingood & DiClemente, 1998; Zule, Flannery, Wechsberg, & Lam, 2002). Additionally, the complex interplay between drug use and commercial sex can also facilitate the spread of HIV/AIDS among women. For example, several studies have observed that drug use may lead women to trade sex for money or more drugs, increase multiple partnerships, and promote inconsistent condom use thus increasing HIV risk (Kail, Watson, & Ray, 1995; Watkins, Metzger, Woody, & McLellan, 1992).

Complex sexual networks, including concurrent and multiple sexual partnerships also increase the risk for HIV infection among women. Several studies report that women who engage in multiple sexual partnerships and whose partners engage in multiple sexual partnerships are significantly more likely to be at risk for HIV infection (Adimora et al., 2002; Adimora et al., 2006; Finer, Darroch, & Singh, 1999; Grinstead, Faigeles, Binson, & Eversley, 1993).

Compounding matters, inconsistent condom use, particularly across partner type, can also increase HIV risk. Findings reveal that women are more likely to use condoms with casual or paying partners than they are with their primary partners (Macaluso, Demand, Artz, & Hook, 2000; Misovich, Fisher, & Fisher, 1997).

Although all of these factors play an important role in increasing HIV risk among women, many of these behaviors occur within specific social and relationship contexts that enhance HIV risk. Gender-based violence and relationship power and control are two such factors. Current estimates indicate that between 8% and 70% of women

worldwide have been physically or sexually assaulted by a male partner at least once in their lives (Heise et al., 1999). It is noteworthy that women who have experienced gender-based violence may be more vulnerable to HIV infection due to a variety of factors. Women who have experienced forced or coercive sex, may be at more risk for acquiring HIV/AIDS through resulting abrasions or cuts on the vaginal lining (Jansen & et al, 2002).

Not only does gender-based violence increase women's biological vulnerabilities to HIV/AIDS, but it may also increase risky behaviors that lead to HIV/AIDS. Multiple studies link a history of childhood sexual abuse to an increase in drug abuse, having a male partner at risk for HIV, engaging in multiple partnerships, and exchanging sex for drugs, money, or shelter (Bensley et al., 2000; Cohen et al., 2000; Thompson et al., 1997; Wingood & DiClemente, 1997a; Zierler et al., 1991). In a study of racial and ethnic minority women in the United States, women who had more sex partners, were unemployed, were less educated, had more STIs, or a more severe history of physical and sexual trauma were more likely to be HIV infected (Wyatt et al., 2002).

Relationship power may also play a key role in sexual decision-making and negotiation, particularly around condom use. Several studies have attempted to measure the effect of power dynamics in relationships on HIV risk behavior. Although some studies have had mixed results (Bowleg, Belgrave, & Reisen, 2000; Harvey, Bird, Galavotti, Duncan, & Greenberg, 2002), others have indicated that relationship power is an important factor contributing to HIV risk among women (Pettifor, Measham, Rees, & Padian, 2004). For example, gender power discrepancies may hinder women's ability to effectively negotiate condom use, thereby increasing their risk for acquiring HIV

infection (Dunkle et al., 2004; Pulerwitz, Amaro, De Jong, Gortmaker, & Rudd, 2002; Wingood & DiClemente, 2000). Women who also experience inequitable relationships may be less likely to consistently use condoms across all partnerships (Pettifor et al., 2004). Taken together, multiple factors contribute to women's increased vulnerability for HIV infection and researchers, advocates, and policy makers are increasingly turning to new HIV prevention technologies as a way of putting HIV prevention back into the hands of women.

The Need for Alternative Female Initiated Prevention Methods

Many researchers and advocates theorize that one of the underlying reasons for the rapid spread of HIV/AIDS among women is the lack of available woman-initiated prevention methods. To that end, they have called for a research effort that focuses solely on putting HIV prevention back in the hands of women (Elias & Heise, 1995; Elias & Coggins, 1996; Heise & Elias, 1995; Stein, 1990; Wainberg, 1999). Practically, this means that researchers are looking into new and useful ways and methods for women to protect themselves from HIV, without having to rely on a partner's approval or consent.

To date, only two woman-initiated HIV prevention technologies exist and they are the female condom and the diaphragm. Evidence from around the world indicates that many women are reluctant to use the female condom as a form of HIV prevention (Bounds, Guillebaud, & Newman, 1992; Farr et al., 1994; Ford & Mathie, 1993; Sly et al., 1997), despite the fact that many women find it a highly acceptable prevention method (Farr et al., 1994; Gollub, Stein, & el-Sadr, 1995; McCabe, Golub, & Lee, 1997; Schilling, el-Bassel, Leeper, & Freeman, 1991). Several barriers have limited the use of the female condom as a viable HIV prevention method, including aesthetics, insertion

difficulties, lubrication, mechanics, reduced sensation, partner objections, and other issues (Gilbert, 2000).

Studies indicate that aesthetics play a key role in use. Many women found the female condom unattractive to look at and were disappointed that it protruded outside of the vagina (Leeper, 1990). Other study participants found the noise the that the condom made during sex objectionable (Gold, 1995). Women also found the female condom difficult to insert and did not feel confident using it unless they had prior practice (Ashery, Carlson, Falck, Siegal, & Wang, 1995; Gollub et al., 1995). Ashery et al. (1995) and Gollub et al. (1995) noted that women also disliked the lubricant, with many women believing it dried too quickly or that the female condom contained too much or too little.

Women also objected to the specific characteristics of the condom. For instance, many women found the female condom too large, too long, and insisted that it did not feel normal (Farr et al., 1994). Relationship dynamics also played a key role in female condom acceptability. Women reported not liking the female condom because their partners did not like it (World Health Organization and UNAIDS, 1997) and some women reported that they bore the brunt of violent reactions from partners when they insisted on its use (Farr et al., 1994).

Recent data reveal that women's HIV risk may not be distributed equally among epithelial surfaces in the vagina and that the cervix may be particularly vulnerable to HIV infection. Therefore, current research is focusing on cervical barriers methods such as the diaphragm and cervical cap to reduce women's risk for HIV and other STIs (Moench, Chipato, & Padian, 2001). Results from several observational studies have indicated that

when used in conjunction with spermicides, the diaphragm may reduce the risk of some STIs and their associated sequelae (Kelaghan, Rubin, Ory, & Layde, 1982; Magder, Harrison, Ehret, Anderson, & Judson, 1988; Rosenberg, Davidson, Chen, Judson, & Douglas, 1992).

As of March 2010, eight planned or ongoing clinical trials were underway to either determine the diaphragm's acceptability as an effective delivery system for microbicides or to determine its effectiveness as an STI prevention method. A recently completed clinical trial had disappointing results when the diaphragm coupled with lubricant gel offered no more added protection against HIV infection than the use of a condom only (Matthews, 2006; Padian et al., 2007). This result does not rule out the continued need for research on the HIV risk reduction potential of cervical barrier methods. Although study results did not ultimately answer the question of whether the diaphragm is an effective alternative to the condom, results indicate that HIV incidence rates were similar across both arms of the study. Some scientists have argued that these data suggest that the diaphragm may offer the same protection against HIV as the male condom (Matthews, 2006).

Similar to female condoms, women have found diaphragms a highly acceptable form of contraceptive (and disease) protection (Behets et al., 2005; Bird, Harvey, Maher, & Beckman, 2004). Yet, several barriers have been cited that prevent them from using diaphragms, including provider bias, women's reluctance to touch their own genitals, and insertion difficulties (Harvey, Bird, Maher, & Beckman, 2003; Mantell, Hoffman, Exner, Stein, & Atkins, 2003).

Barriers associated with use of specific HIV prevention methods have led researchers to develop new methods for woman controlled or initiated HIV prevention. Although the terms "female-controlled" and "female-initiated" are used interchangeably, this paper will use "female-initated" as current literature indicates more frequent use of this term. Recent research has focused on two new technologies--microbicides and pre-exposure prophylaxis (PrEP)--, which can be used as woman-controlled or initiated methods. Unavailable for general use yet, these methods are currently undergoing clinical safety and efficacy trials to assess their effectiveness in reducing the acquisition of HIV, particularly among high-risk women (AIDS Vaccine Advocacy Coalition, 2010).

Microbicides.

Microbicides are topical agents, applied vaginally or rectally, to prevent the acquisition of HIV/AIDS (Alliance for Microbicide Development, 2005). The drive behind microbicide development is the urgent need for an HIV prevention technology that does not rely on male assistance to the same degree as the male condom. Another reason for the push in development has been the necessity for a method women can use covertly, or without the knowledge of their partner (Woodsong, 2004).

Microbicides comprise a range of different products, when applied topically, could prevent the sexual transmission of HIV and other sexually transmitted infections (STIs). A microbicide could be produced in many forms, including gels, creams, suppositories, films, or as a sponge or ring that releases the active ingredient over time (Alliance for Microbicide Development, 2005). Although microbicides will not be available for general consumer use for the next five or seven years, 60 products are currently in preclinical and clinical development with various mechanisms of action

targeting different phases of the HIV life-cycle (AIDS Vaccine Advocacy Coalition, 2010). Of these 60 products, 19 are currently being tested for their efficacy in preventing the acquisition of HIV in human subjects. If any of these products shows promise in preventing the transmission of HIV/AIDS or other STIs, a viable microbicide could be available by the end of this decade.

Mechanisms of Action.

Researchers are working on various mechanisms of action for microbicides to provide protection from HIV in several different ways. First, microbicides could break down the surface or envelope of some pathogens to immobilize or kill them. Second, microbicides could block infection by creating a barrier between the pathogen and the susceptible cells of the vagina or rectum. Third, some microbicides could strengthen the body's normal defenses to foster an environment that would be inhospitable for HIV. Fourth, some microbicides would inhibit viral entry by binding to viruses and bacteria to prevent them from connecting to an infected cell. Finally, some microbicides are being developed from existing HIV/AIDS treatments that already lower the viral load of HIV infected persons (Auerbach, Hayes, & Kandathil, 2006; Global Campaign for Microbicides, 2007b). When formulated as gels or creams and applied topically, they may be able to prevent the viral replication of HIV/AIDS. Each of these various mechanisms of action is being tested for their efficacy in preventing HIV infection via different delivery methods.

Efficacy.

First generation microbicides are unlikely to be 100% efficacious. In fact, researchers believe they will be less effective than the male condom (Rockefeller

Foundation, 2002a). Spieler et al. (1997) indicate that the level of protection afforded by HIV prevention technologies depends on three factors: the efficacy of the method, consistency of use within the partnership, and the extent of use in a sub-population (Spieler, 1997). This means that a low efficacy product used with high levels of consistency could offer the same protection as a high efficacy method used less consistently (Severy & Newcomer, 2005). Similar trends exist for microbicides.

Researchers insist that even a partially effective microbicide could avert as many as 2.5 million new HIV infections over the course of three years (Rockefeller Foundation, 2002b). One recent study used a mathematical model, fit to epidemiologic data from various high prevalence settings in Africa, to estimate the HIV impact of introducing a microbicide with different HIV/sexually transmitted infection (STI) efficacies. This study determined that the widespread use of microbicides would result in a greater relative reduction of HIV incidence in the two regions (Vickerman et al., 2006). Another study modeled the impact of a 40% efficacious microbicide on sex workers and their clients. Assuming a 21% HIV prevalence, researchers determined that even a partially effective microbicide would have a sizeable impact on reducing the number of infections among sex workers and their clients (Watts & Vickerman, 2001). Despite the fact that microbicides may substantially reduce new HIV infections, efficacy would vary by circumstance and setting even though patterns of use might be similar (Severy & Newcomer, 2005).

Cost.

One of the goals of developing another female controlled or initiated HIV prevention option—in this case microbicides--is to ensure its affordability and make it as

widely accessible as possible for women. The potential market for microbicides is staggering. Several studies have indicated that a large consumer market exists for microbicides (Darroch & Frost, 1999; Rockefeller Foundation, 2002b). As of 1998, of the 60 million women aged 15-44 in the United States, 21 million were estimated to be interested in using a microbicide, and 9.1 million would be interested in using a less than 100% effective microbicide if it cost a dollar or less and only protected against HIV (Darroch & Frost, 1999).

Studies from other countries also support the existence of a wide consumer market for microbicides. In an 11-country study, conducted by the European Union, even women in resource-poor countries were willing to pay a premium—up to five times as much as a male condom--for an HIV prevention method controlled by women (Hill, Ryan, Stone, & Fransen, 2000.). Another study conducted among women of low and middle socioeconomic status in Brazil indicated that up to half were willing to pay up to $5 per application (Hardy, de Padua, Osis, Jimenez, & Zaneveld, 1998). Despite these encouraging numbers, the cost of a microbicide does make a difference in interest in use. For instance, microbicide interest dropped by 20% when Darroch et al. (1999) asked respondents if they would use a less than 100% effective microbicide if it cost $2 per application and only protected against HIV.

Side Effects and Safety.

Several products have been tested to assess the side-effects and safety of topical microbicides in women. Recent research on some microbicides has indicated that most women find microbicides highly acceptable, with minimal side-effects that include itching and burning and some difficulty urinating (Bentley et al., 2000; Coggins et al.,

2000; Mayer et al., 2006). Additionally, some women may have abnormal colposcopy findings and/or slight vaginal bleeding, although this appears in very rare cases. Two studies on different microbicidal products have indicated, however, an increased risk in HIV (Global Campaign for Microbicides, 2007a; Van Damme et al., 2002)

Pre-Exposure Prophylaxis (PrEP).

In the last few years, scientists have been testing a new experimental HIV prevention strategy, pre-exposure prophylaxis (PrEP), which uses anti-retroviral therapy (ARV) to protect HIV-uninfected individuals from HIV infection (AIDS Vaccine Advocacy Coalition, 2005). Many scientists hypothesize that PrEP could be a feasible prevention strategy particularly in high HIV prevalence settings for individuals at risk of HIV infection, such as injection drug users (IDU) or sex workers (Szekeres, Coates, Frost, Leibowitz, & Shoptaw, 2004). PrEP may also be a viable prevention strategy for people in sero-discordant partnerships or for women in disempowered relationships, who are unable to insist on condom use (Szekeres, Coates et al., 2004; Youle & Wainberg, 2003a, 2003b). Similar to microbicides, several PrEP products are undergoing clinical safety and efficacy trials to assess their effectiveness in preventing the acquisition of HIV (AIDS Vaccine Advocacy Coalition, 2005). Although an effective candidate does not yet exist, PrEP is being touted as a woman-initiated intervention that in particular could protect women who are victims of sexual and physical violence, or are afraid to insist on condom use from their partners (Lange, 2005).

Although the use of antiretrovirals (ARV) before exposure to HIV may seem astounding, two parallel HIV prevention strategies have set a precedent. Post-exposure prophylaxis (PEP) is a widely used standard of HIV prevention wherein antiretroviral

therapy (ART) is administered to an individual soon after possible exposure to HIV. A groundbreaking study conducted among health workers indicated that post-exposure use of zidovudine or "AZT", an antiretroviral, provided a protective effect against HIV acquisition (Cardo et al., 1997). Another study, testing the feasibility of using PEP after sexual or drug-related exposures, showed similar results. Participants were given a four-week course of PEP within 72 hours of exposure; six months after exposure, not one participant developed HIV antibodies (Kahn et al., 2001).

Another parallel for PrEP has been the successful prevention of maternal to child transmission (PMTCT) model, where the provision of zidovudine/AZT or nevirapine is used to prevent HIV transmission during pregnancy or childbirth. Several randomized controlled trials have provided the necessary verification to support the use of ART therapy in preventing HIV among newborns. One study, conducted in the United States, resulted in vertical transmission rates declining from 25.5% to 8.3% or about 67%, by providing zidovudine before, during and after pregnancy (Connor et al., 1994). Other studies, conducted in Thailand and the Ivory Coast, assessed the effects of short course oral zidovudine, which reduced mother to child transmission by 44-50% (Shaffer, Bulterys, & Simonds, 1999; Shaffer, Chuachoowong et al., 1999; Wiktor et al., 1999). Finally, single-dose nevirapine—another ART option, was determined to reduce maternal to child transmission by 50% (Guay et al., 1999).

Success of these two prevention strategies has prompted researchers to test the efficacy of administering HIV prophylaxis before HIV infection occurs. Although several drugs are under investigation for their hypothesized efficacy in preventing HIV acquisition, the most promising agent being tested is tenofovir disoproxil fumarate (TDF)

or "tenofovir." Gilead Sciences Inc. markets tenofovir under the name Viread™ and the U.S. Food and Drug administration licensed it as an HIV treatment in 2001. Ten clinical trials are currently underway —four among women, one among injection drug users, two among both heterosexual men and women, and three among MSM-- to test its efficacy as pre-exposure prophylaxis (AIDS Vaccine Advocacy Coalition, 2010).

Mechanisms of Action.

As a non-reverse transcriptase inhibitor (NRTI), tenofovir's mechanism of action focuses on the pre-integration phases of HIV's viral life cycle. This means that it stymies HIV reverse transcriptase, an enzyme which is needed for HIV to replicate in the human body. Theoretically, drugs that block viral replication before integration are more likely to be effective than those that focus on blocking viral replication after post-integration (AIDS Vaccine Advocacy Coalition, 2005; Szekeres, Coates et al., 2004).

Efficacy.

Efficacy data from one of the ten clinical trials are due to be released in 2010. Data from non-human primate studies indicate, however, that tenofovir can prevent or delay infection of Simian Immuno-Deficiency Virus (SIV) infection and alter the viral set point in rhesus macaques (Tsai et al., 1995; Van Rompay et al., 1996). Yet, the dose, timing, and duration can vary the effects of tenofovir (Tsai et al., 1998). Research has also been conducted on macaques with tenofovir formulated as a vaginal gel. In these studies, the gel provided 100% protection from SIV before or after vaginal challenge (Miller & Rosenberg, 1996). Studies of the vaginal application of tenofovir are now underway to determine safety and effectiveness with daily use (Mayer et al., 2006).

PrEP is unlikely to confer 100% protection on any individual due to limitations in prevention approaches and lack of adherence. Although studies have not been conducted to determine the likely impact of PrEP on communities, data from vaccine studies might offer some clues. Stover (2005) examined both a Low and High vaccine coverage scenario to determine the number of HIV infections averted in the general population. In the Low scenario, an AIDS vaccine with 40% efficacy provided to 20% of the population would reduce the annual number of new infections in 2030 by 32% from 10.2 million to 7.0 million. In the High scenario, a vaccine with 95% efficacy provided to 40% of the population would reduce the annual number of new infections in 2030 by 82% to 1.8 million (Stover, 2005). The same scenario could hold true for PrEP. Low coverage with PrEP that is highly efficacious could substantially reduce the number of HIV infections as can high coverage of PrEP with low efficacy (Szekeres, Coates et al., 2004).

Cost.

As with all HIV prevention strategies, cost is an important consideration, particularly for individuals who are most in need of the product. The expected yearly cost of tenofovir will likely vary from country to country, but cost estimates in the United States are roughly $6292 per year (Szekeres, Coates Thomas J., Frost, Leibowitz, & Shoptaw, 2004). Although this dollar amount is staggering, it is possible that individual countries and insurance companies may be able to negotiate significantly reduced pricing to make PrEP more accessible for at risk populations. Questions about cost-effectiveness are the natural follow-up to discussions about cost. Will the administration of PrEP be cost-effective? Szekeres et al. (2005) determined that PrEP is more cost-effective for individuals who engage in high and extremely high rates of risk behaviors and for

situations where the efficacy of PrEP would be greater than 50% (Szekeres, Coates et al., 2004).

Side Effects and Safety.

Tenofovir, a nucleotide analogue reverse transcriptase inhibitor (NRTI), was chosen as the most suitable candidate for study because individuals can use it once daily, it has relatively low toxicity, and it does not promote viral resistance. It is formulated as a once-daily 300 mg oral tablet (Szekeres, Coates et al., 2004). Because most of the data on safety has been extrapolated from HIV infected patients, unanticipated toxicities might arise over sustained use in uninfected patients. Side effects in HIV positive patients, however, have been minimal and are similar to that of a placebo. Users indicate gastrointestinal discomfort such as nausea and diarrhea, and some patients have had renal toxicity, although the majority of these cases occurred in patients who already had renal disease. Additionally, adverse effects do not emerge when used with other drugs, but this might change if larger numbers of people use tenofovir (Szekeres, Coates et al., 2004). Animal studies have also shown that tenofovir causes no harm to fetuses, although studies among pregnant women cannot confirm this finding (Szekeres, Coates et al., 2004). Despite the relatively positive safety profile of tenofovir, long-term effects of daily use are unknown (AIDS Vaccine Advocacy Coalition, 2005).

Factors Associated with Intentions to Use HIV Prevention Technologies

Because this study focuses on the factors associated with intentions to use microbicides and tenofovir, it is important to review what the literature has previously been found to be robust predictors of intentions to use HIV prevention methods.

Self-Efficacy.

The construct of self-efficacy has, in many cases, been a powerful predictor of health behaviors. In one meta-analysis, participant ratings of self-efficacy consistently predicted health related outcomes (Holden, 1991). These findings may also be true for HIV risk behavior.

A meta-analysis conducted by Sheeran et al. (1999) on the psychosocial correlates of heterosexual condom use indicated a medium correlation for condom use self-efficacy, supporting Icek Ajzen and Albert Bandura's contention that this construct plays an important role in overall health behavior (Sheeran, Abraham, & Orbell, 1999). Yet, other studies on self-efficacy and condom use intentions have revealed disparate data (Bryan, Fisher, & Fisher, 2002; Harvey et al., 2006). A recent cross-sectional study conducted on 435 heterosexual women at risk for HIV/STIs revealed that self-efficacy was a poor predictor of condom use intentions (Harvey et al., 2006). The authors hypothesize that this may be because self-efficacy is a better predictor of condom use rather than intention to use. Other researchers believe that self-efficacy within the context of HIV prevention research has been poorly operationalized, leading to inconsistencies across measurement (Forsyth & Carey, 1998). The authors further postulate that measurements of self-efficacy should be specific to behaviors and context. Recent research on intentions to use has focused on this very issue with self-efficacy measures reflecting not only the confidence/skill with the mechanics of a prevention method, but also on an individual's situational skills as well (Morrow, Fava, Rosen, Christensen et al., 2007; Thorburn, Harvey, & Tipton, 2006).

Similar to the research on male condoms, studies on female controlled HIV prevention methods such as the female condom reveal mixed results (Bogart, Cecil, & Pinkerton, 2000a, 2000b; el-Bassel et al., 1998; Hoffman, Exner, Leu, Ehrhardt, & Stein, 2003). A study on intentions to use the female condom among African Americans revealed that self-efficacy was not a significant predictor of intention to use the female condom. One key assumption of self-efficacy theory is that a person's past experiences with an object can influence perceptions of self-efficacy. Because the participants in the study did not have previous experience with the female condom, the authors concluded that the results were not unexpected (Bogart et al., 2000b).

Other studies have indicated that self-efficacy significantly predicts intentions to use female condoms. In a study conducted on Hispanic adults, the inclusion of self-efficacy into a hierarchical regression model significantly increased outcome variability and predicted intentions to use the female condom for both men and women (Bogart et al., 2000a). To date, there has been only one study examining the relationship between intentions to use microbicides and self-efficacy. In Morrow et al's (2007) study, self-efficacy was not a significant predictor of intention to use microbicides. Nevertheless, it may be an important predictor of intention to use among different samples or within specific contexts.

Perceptions of Risk.

Another important factor associated with intentions to use is risk perception. In a meta-analysis conducted by Sheeran et al (1999), perceptions of risk for HIV/AIDS had small correlations with behavioral intentions for condom use. Furthermore, although these studies had statistically significant correlations, the belief that one is personally

vulnerable to HIV infection, feeling worried or fearful of infection, and acknowledgement of the seriousness of the disease were only weakly related to motivation to use condoms (Sheeran & Taylor, 1999).

Other researchers posit that non-specific measures undermine the predictive power of perceptions of risk as a construct. They have suggested that more specific measures may improve behavioral outcomes. Ellen et al. (2002), found that more robust measures of perceptions of risk yielded strong associations between risk and intentions to use condoms with both casual and primary sex partners. A recent meta-analysis assessing the associations between the construct of perceptions of risk and vaccine acceptability found similar results. In this study, individuals who perceived themselves at more risk for disease were more likely to get vaccinated (Brewer et al., 2007). In another study on the acceptability of the HPV vaccine, conducted with parents and other adults, vaccine acceptability was higher when the perceived likelihood of HPV infection was high (Brewer & Fazekas, 2007).

Past Behavior.

Past behavior may also be associated with intention to use. Studies on condom use intentions reveal small to medium correlations for the influence of past behaviors on future behavior. Habit was considered a strong independent predictor of condom use in one study conducted with undergraduate students at an American university, (Trafimow, 2000). A meta-analysis assessing the psychosocial correlates of heterosexual condom use found a medium-sized positive relationship between previous condom use and current or subsequent use (Sheeran et al., 1999). Another study conducted with female intravenous

drug users on the effect of habit on condom use yielded similar results. Habit was a consistent and powerful predictor of condom use (Stacy, Stein, & Longshore, 1999).

Researchers posit that habit as a predictor of future behavior is most powerful when incorporated into prospective or longitudinal study designs. For example, strong longitudinal effects have been found not only in previous studies on condom use (Boyd & Wandersman, 1991), but on exercise and mammography seeking behaviors (Lauver, Nabholz, Scott, & Tak, 1997; Valois, Desharnai, & Godin, 1988).

Subjective Norm.

Although the data on subjective norm as a predictor of behavioral intention is mixed (Armitage & Conner, 2001), some research indicates that it is a useful predictor of specific behaviors, particularly HIV prevention behaviors such as condom use (Sheeran et al., 1999; Sheeran & Taylor, 1999). For instance, a recent meta-analysis determined that the average correlation for subjective norm was .26, indicating that greater perceived pressure was moderately associated with condom use. In fact, the same study also indicated that believing that one's peer group or friends use condoms had a stronger association with individual condom use than believing that one's partner had a positive attitude toward condoms (Sheeran et al., 1999). In another meta-analysis comparing the predictive power of the constructs of both the Theory of Reasoned Action (TRA) and the Theory of Planned Behavior (TPB), subjective norm was strongly associated with condom use intentions, although in this analysis sexual partner norm had the largest effect size (Sheeran & Taylor, 1999). Similarly, another study using TRA constructs to assess condom use intention among women determined that women who perceived subjective norms in favor of condom use had higher condom use intentions (Heck, 1995).

A study assessing correlates of intention to use the female condom among women taking methadone yielded similar results. Women who intended to use the female condom were more likely to discuss the device with at least one member of their social networks (el-Bassel et al., 1998). Another study conducted with African American adults further supported these results with women having stronger perceived norms regarding the female condom than men (Bogart et al., 2000b).

Relationship Power and Control.

Although the empirical findings on relationship power and control are mixed (Bowleg et al., 2000; Harvey et al., 2002; Pulerwitz et al., 2002), some studies support the hypothesis that relationship power may play a key and central role in safer sex decision making. A study conducted among Latina women found the perception of sexual power imbalances to be strong predictors of infrequent condom use (Gomez & Marin, 1996). In other words, women who perceived less power in their relationship were less likely to use condoms. In a recent meta-analysis, researchers determined that perceptions of social power and control were strongly related to condom use (Albarracin, Kumkale, & Johnson, 2004). Boer et al. further supported this assessment in their theory-based study among South African women (Boer & Mashamba, 2007). In this study, researchers determined that in situations where gender power imbalances occur, women have to put more effort into negotiating safer sex (commonly referred to as contextual self-efficacy). Earlier studies also support this hypothesis. In another study conducted among South African women, women who experienced less power in their relationships were less likely to use condoms (Pettifor et al., 2004). In a study conducted by El-Bassel

et al., safer sex negotiation skills were related to intention to use condoms among women (el-Bassel et al., 1998).

Although these studies directly address the issue of HIV risk by measuring condom use as an outcome variable, they do not directly measure the association of relationship power and control and HIV incidence. This gap in literature has been recently rectified with a study conducted by Dunkle et al. which revealed that high levels of male control in relationships were directly associated with HIV seropositivity (Dunkle et al., 2004).

Method Characteristics.

Another factor that plays a key role in the use of different HIV prevention methods are product characteristics. Method characteristics include convenience, effectiveness of the product, side-effects and safety, minimized sexual interruption, acceptance by peers, ease of acquisition, prevention HIV and other STIS, cost, and attitudes toward the product (Beckman & Harvey, 1996). In a recent study conducted among 585 women using the diaphragm, product use was associated with the importance of barrier method attributes (Bird et al., 2004; Harvey et al., 2003) . Similar to diaphragms, acceptability of microbicides is influenced by specific characteristics including appearance, messiness, and affect on sexual pleasure (Coggins et al., 1998; Hammett, Mason et al., 2000; Hammett, Norton et al., 2000; Hardy, de Padua, Osis et al., 1998; Mason et al., 2003). More recently, in her study of 531 women in the United States, Morrow et al. (2007) determined that product characteristics were significantly related to willingness to use microbicides, although women who were less educated and had lower income were less likely to be concerned about the overall product

characteristics than women of higher education and income (Morrow, Fava, Rosen, Vargas et al., 2007). ,

Microbicide Acceptability: A Review of the Literature

Within the last ten years, recent research has focused on the acceptability of microbicides among both women and men. Because a product has not yet been brought to market and deemed efficacious enough for use in the general population, most studies on the acceptability of microbicides have followed the two models of evaluation mentioned in the introduction: hypothetical acceptability and behavioral studies embedded within clinical trials. Many studies have quantitatively and qualitatively assessed a woman's acceptability of microbicides under different conditions.

Perceptions of risk, attitudes, measurements of actual HIV/AIDS risk, assessments of current and past use of contraceptive and HIV prevention methods, partnership characteristics, and demographics have all been predictive of microbicide acceptability (Bentley et al., 2004; Darroch & Frost, 1999; Mosack, Weeks, Novick Sylla, & Abbott, 2005; Weeks et al., 2004)

This section will describe specific factors that have predicted microbicide acceptability. These factors, in addition to others that have predicted intentions to use HIV prevention methods, will be included in this study's conceptual model, and will be discussed later in this paper.

Demographics.

Specific demographics have been associated with microbicide acceptability, although studies often report disparate results. A U.S. survey of women aged 18-44, revealed that married women would be less likely to be interested in using a microbicide

(Darroch & Frost, 1999). Results from this study also reveal that women currently interested in using a microbicide were younger, had less income, were less educated, childless, and black or Hispanic (Darroch & Frost, 1999) . Results from another study yielded different results; non-Hispanic whites had significantly higher acceptability scores than Puerto Ricans/Latinas and African/Caribbean Americans (Weeks et al., 2004). Acceptability was also significantly correlated with having graduated from high school (Weeks et al., 2004).

Hammett et al.'s (2000) results were similar to the Darroch et al. (1999) findings. In their three-city study of drug-involved women, Latinas were more likely than African American or Caucasian women to say that they would use microbicides with primary and paying partners. The variation in results may have to do with the specific setting in which the study was conducted as well as other factors associated with microbicide acceptability. Another study of microbicide acceptability under four conditions of effectiveness and partner protection, conducted among 752 women in North Carolina, found Latina women more likely to use microbicides alone under three out of the four conditions (Koo, Koch, Dalberth, & Leone, 2006). The study also found that education plays a significant role in acceptability under varying conditions. For instance, less educated women were more likely to use microbicides alone if they were only half as effective as condoms and protected both partners or women only (Koo et al., 2006).

In a more recent study assessing willingness to use microbicides, the authors found that Latina and Black women were more willing to use than White women (Morrow, Fava, Rosen, Christensen et al., 2007). Although measuring race/ethnicity is important, the authors of this study postulate that the racial differences in predicting

willingness to use may have more do with other mediating and moderating factors. Indeed several researchers have indicated that effects due to race/ethnicity may have more do to with their associated factors such as socioeconomic status, cultural and health beliefs and practices, and access to health care services (Adimora et al., 2006; Brawley & Freeman, 1999; Kaplan & Bennett, 2003; O'Malley, Le, Glaser, Shema, & West, 2003). Future studies on intentions to use and acceptability of microbicides should contextualize the importance of race and ethnicity within the influence of various other mediating or moderating variables.

Women's Perceived and Actual HIV Risk Behavior.

Studies which have assessed HIV/AIDS risk, including drug use, unprotected sex, and history of STIs as predictors of microbicide interest and acceptability have yielded mixed results. A survey of a nationally representative sample of women, reported conflicting or mixed perspectives about their women's risk for contracting an STI and interest in using microbicides (Darroch & Frost, 1999). According to this study, enormous overlap between being worried about getting an STI and being interested in using a microbicide existed. Twenty-four percent of women reported that they were currently interested in using a microbicide and currently worried about contracting an STI (Darroch & Frost, 1999).

Weeks' et al (2004) study of 471 high risk women also yielded mixed results. Microbicide acceptability as opposed to interest in microbicides (the dependent variable in the Darroch study) was assessed using a 21-item scale, which limited its measurements to product characteristics. Weeks et al (2004) also measured both actual HIV risk and perceived HIV risk. Microbicide acceptability was not significantly related to drug and

sex risk conditions, but was negatively related to HIV risk perceptions. More specifically, those women who perceived themselves to be at lower risk for contracting HIV/AIDS had a higher acceptability of microbicides (Weeks et al., 2004). In another three-city study of drug-involved women, HIV negative women who were more concerned about HIV than about other problems in their lives were more likely to indicate that they would use a microbicide with their primary partners than those who were less concerned (Hammett, Norton et al., 2000). Overall, nearly 75% of drug-involved women surveyed said that they would be very likely to use microbicides if they were effective against HIV.

Another study conducted among 752 women in North Carolina measured both actual HIV risk and perceptions of risk as they relate to acceptability (Koo et al., 2006). Results found that women's risk behaviors in the past 12 months had no effect on likely use of microbicides, but that women who were somewhat or very worried about getting HIV/AIDS or an STI were more likely to use a microbicide than women who were not worried (Koo et al., 2006). Qualitative data has also been used to assess the relationship between risk and acceptability. In focus groups, conducted in Puerto Rico, Rhode Island, and Connecticut, participants with diverse drug-related sexual risk indicated that they would be interested in using vaginal microbicides in the future (Mason et al., 2003). Another qualitative study on acceptability, conducted among 98 HIV negative low-risk women in Malawi, Zimbabwe, India, and Thailand, determined that women's' risk percpetions and the stage of the epidemic within each country determined level of acceptability. For instance, in places like Zimbabwe and Malawi where the epidemic is

more advanced, women perceived themselves to be at high-risk and microbicide acceptability was unanimous (Bentley et al., 2004).

Partnership Characteristics.

Another factor that has been associated with microbicide acceptability is partnership characteristics, often operationalized as partner type. Several studies have indicated that these characteristics play a significant role in the acceptability of microbicides. For instance a three-city study conducted on drug-involved women indicated that although acceptability was high among women with primary and paying partners, percentages increased significantly with paying partners (Hammett, Norton et al., 2000). Results were confirmed in a smaller sub-study among these participants assessing the acceptability of formulations and application methods. In this study, 70% of women indicated that they would be willing to use the products with their primary partners if the products were 90% effective against HIV and STIs. Although fewer participants reported engaging in sex for money or drugs, between 74-80% indicated that they would be willing to use these products if they were 90% effective in preventing HIV infection and other STIs (Hammett, Mason et al., 2000).

Another study reported similar results with differences in microbicide acceptability varying by type of sex partner (e.g. primary, casual, or paying) (Weeks et al., 2004). In a sub-study, conducted among a smaller cohort (n=95) of the same women, 98.8%, 100%, and 100% of the participants indicated that they would use the product with primary partners, casual partners, and paying partners respectively. When they were asked how frequently they would use the product with different partners, 73.8%, 97.4%, and 96.2% of the participants reported that they would always use it with

their primary partners, casual partners, and with paying partners, respectively. Furthermore, the primary reason for wanting to use a microbicide across all types of partnerships was because "it made [the participant] feel in control of [her] health" (Mosack et al., 2005).

Partner type also proved to be significant in predicting the likelihood of using a microbicide under four conditions of effectiveness and partner protection. In this study, women with at least one casual partner in the past 12 months were much more likely to use microbicides if they were as effective as condoms and protected only the woman ($p<.05$) (Koo et al., 2006). Although not statistically significant, the authors also reported that women with two special partners were also more likely to use microbicides under the same conditions of effectiveness and protection ($p<.10$) (Koo et al., 2006). Similar results were among women who had multiple partners in the past year, where women were five times as likely as other women to be more interested in microbicides (Darroch & Frost, 1999). In a multiple regression analysis of willingness to use microbicides results also found that partner type was marginally significant (Morrow, Fava, Rosen, Christensen et al., 2007).

Qualitative analyses also assessed associations between partner type and microbicide acceptability. One study determined that the nature of the relationship with male sex partners was a potentially important factor in influencing women's perceptions about advantages and disadvantages of different microbicide formulations. For instance with commercial sex or exchanges outside of the home, women expressed concerns about the hygiene of reusable applicators and the waiting period after product insertion and sex (Mason et al., 2003). In these situations, women expressed more motivation and ease in

insisting on condom use where they perceived condoms to be "cleaner" than other types of barrier methods. On the other hand, women in steady relationships exhibited more anxiety about condoms in addition to reporting less use of them. The authors posited that this could indicate that vaginal microbicides for women in steady relationship are a much needed alternative to condoms (Mason et al., 2003). Another study conducted in Uganda used focus group discussions to assess the use of vaginal products. Although there was no data to indicate whether the study participants used the products with casual partners or not, outside the formal interview setting women stressed the possibility of using these products secretly with casual partners (Green et al., 2001).

Past History of Contraceptive and HIV Prevention Method Use.

Another predictor of microbicide acceptability is the historical use of contraceptive and other HIV prevention methods. Many of the studies have assessed the type of contraceptive or HIV prevention method women used in the past to predict future microbicide use. Similar to other research, studies have yielded mixed results (Darroch & Frost, 1999; Morrow, Fava, Rosen, Christensen et al., 2007; Weeks et al., 2004). For instance, using logistic regression analysis, one study found that a significantly higher proportion of women currently using nonpermanent methods of contraception reported a higher interest in and a perceived need of microbicides than women who have been sterilized (Darroch & Frost, 1999). Interestingly, in the same study, women who had ever used a form of vaginal contraception including gels, suppositories, creams, sponges or film were only slightly more likely to report a high interest in vaginal microbicides than women who had not used such contraceptive methods. Additionally, 38% of women currently using condoms for STD prevention were very interested in microbicide use

compared with those who did not use condoms for STD prevention (Darroch & Frost, 1999).

Hammett et al. (2000) found contrasting results in their research. In their study, women who had never used spermicides were very likely to use a vaginal microbicide (p=.001). Some of the results of the studies above were also confirmed by Weeks et al (2000). Multiple regression analysis among high-risk women revealed that prior experience with vaginal contraceptive products was positively correlated with acceptability, although these results were only marginally significant (Weeks et al., 2004). In contrast to the results reported by Darroch et al (1999), condom use in the last thirty days in this study was not a significant variable in predicting microbicide acceptability (Weeks et al., 2004).

Similar results are echoed in Koo et al.'s (2006) study of 752 women in North Carolina. In that study, women who had used condoms with more past partners were less likely to use microbicides alone and they were more likely to use condoms with microbicides. In the Morrow et al. (2007) study measuring the construct of "willingness to use," results was similar to previous studies (Darroch & Frost, 1999; Hammett, Norton et al., 2000; Weeks et al., 2004). This study indicates that frequency of condom use and a history of spermicide were significant predictors of willingness to use (Morrow, Fava, Rosen, Christensen et al., 2007).

Conceptual Model

Theory from the fields of public health, sociology, and psychology have been used to help frame the assessment of factors related to women's intention to use female-initiated HIV prevention methods. The conceptual framework (see Table 2.1) uses five

major theories and concepts, including the 1) Health Belief Model (Rosenstock, Strecher, & Becker, 1994) 2) Protection-Motivation Theory (Floyd, Prentice-Dunn, & Rogers, 2000) 3) Social-Cognitive Theory (Bandura, 1977; Bandura, 2004) 4) Expanded Theory of Reasoned Action, (Fishbein, 1967; Montano & Taplin, 1991) and 5) Theory of Gender and Power (Wingood & DiClemente, 2000). I propose a framework that not only accounts for intrapersonal behavior, but assesses the relationship dynamics and socio-cultural context in which this behavior occurs. I describe the constructs included in the conceptual framework as well as a list of the theories from which they were originated. It is important to note that that constructs may independently or collectively be associated with intentions to use microbicides and tenofovir.

Behavioral Intention as a Measure of Acceptability.

To date, only a few studies have drawn on specific theoretical models and constructs to predict acceptability of microbicides (Morrow, Fava, Rosen, Christensen et al., 2007; Mosack et al., 2005; Tolley et al., 2006; Weeks et al., 2004). Previous studies have limited measurements of microbicide acceptability to product characteristics (Hammett, Norton et al., 2000; Hardy, de Padua, Jimenez, & Zaneveld, 1998; Weeks et al., 2004). Recently, some studies have begun to assess the construct of willingness to use as a measure of acceptability, although only one of these studies has been published (Morrow, Fava, Rosen, Christensen et al., 2007). To my knowledge, studies assessing the acceptability tenofovir do not exist, so this study will use the same variables that have significantly predicted microbicide acceptability as well as other factors associated with intentions to use various HIV prevention methods.

The purpose of this study is to examine the factors that influence intentions to use microbicides and tenofovir. I draw on specific constructs of various theoretical behavioral models to help us explain intention to use microbicides and tenofovir. As a caveat, I should explain that it is beyond the scope of this study to measure actual behavior (e.g., actual use of the products) because both microbicides and tenofovir are not available for general consumer use. Thus, the outcome measure is limited to the construct of behavioral intention, which is defined as the perceived likelihood of performing the behavior (Montano, Kasprzyk, & Taplin, 1997).

Several theories, including The Theory of Reasoned Action (TRA) (Fishbein, 1967), the Theory of Planned Behavior (TPB) (Ajzen, 1991), and the Expanded Theory of Reasoned Action (EXTRA) (Fishbein, 1967) hypothesize that behavioral intention can predict actual behavior. The TRA, introduced in 1967, is concerned with the relationship between beliefs, attitudes, intentions, and behavior (Fishbein, 1967). This theory posits that the most important determinant of behavior is behavioral intention. In turn, behavioral intention is influenced by a person's attitude and subjective norm. The theory itself is a causal model indicating that behavioral and normative beliefs are connected to attitude and subjective norm, which lead to performing the actual behavior (Fishbein, 1967). Scientists have argued that the TRA and TPB may be most appropriate for assessing behaviors that are rational and where the relationship between intention and behavior is strong (Murray-Johnson et al., 2001; Noar & Zimmerman, 2005). Other researchers have felt that the constructs in the TRA and TPB are too limiting, and have suggested that other constructs, such as environmental constraints (Ajzen, 1991;

Fishbein, Triandis et al., 2001) or facilitating conditions (Triandis, 1980), may play a significant role in determining health behavior.

Empirical research suggests that for several behaviors, the intention to partake in behaviors or the probability that one will perform them is predictive of the behavior itself (Fishbein, Hennessy et al., 2001; Sheeran & Taylor, 1999). For example, medium to strong correlations between intentions and condom use were found assessing variables specified in the TRA and TPB on condom use behavior (Sheeran & Taylor, 1999). The same authors, in another meta-analysis found that intentions to use condoms were strongly correlated with condom use measures (Sheeran et al., 1999). Yet another meta-analysis found the strength of this relationship moderated by variables such as age, gender, and partner type (Sheeran & Orbell, 1998). Several other studies have been conducted assessing the relationship between intention and safer-sex behavior (e.g,. condom use) and have found similar results (Albarracin, Durantini, & Earl, 2006; Basen-Engquist, 1992; Basen-Engquist & Parcel, 1992; Bryan, Aiken, & West, 1996; Fishbein, Hennessy et al., 2001; Fisher, Fisher, & Rye, 1995; Godin, Gagnon, & Lambert, 2003; Jemmott & Jemmott, 1991; Roberts & Kennedy, 2006; Sheeran et al., 1999). The next sections describe constructs that may be associated with intentions to use from a theoretical perspective.

Method Characteristics.

Several researchers have suggested that perceptions of method characteristics may influence an individual's intentions to use. In their research on factors associated with the consistent use of barrier methods for contraception, Beckman and Harvey (1996) argue that a person's perceptions, rather than the actual method's attributes are related to

consistency of use, method discontinuation, and method acceptability. Research on perceptions of method characteristics has its foundations in Martin Fishbein's Expectancy Value Theory (EVT), originally developed to explain an individual's attitudes toward objects or actions (Fishbein & Ajzen, 1975). Using this theory as a framework, early research on contraceptive choice and continuation focused solely on the expectations women had about each method and their feelings about those expectations. Later, contraceptive researchers used a modified version of EVT to explain the decision to use or not use a method as a function of value, importance, and likelihood. With the introduction of the female condom and several observational studies reporting on the diaphragm's potential as a possible STI prevention method, recent studies have focused on investigating women's perceptions of their product characteristics and their associations with intentions to use as they relate to HIV prevention (Bird et al., 2004). Findings from contraceptive and the more recent HIV literature indicate that perceptions of method characteristics may play a key role in intentions to use microbicides and tenofovir.

User Characteristics.

Self-Efficacy.

Many researchers posit that since the TRA assumes volitional control of the behavior, it may be limiting in its measurement of the actual behavior (Montano et al., 1997). In essence, specific environmental or internal conditions may impede performance of the behavior. Therefore, Ajzen et al (1991) developed the Theory of Planned Behavior (TPB), an extension of the TRA (Ajzen, 1991), which includes the added construct of perceived behavioral control. Ajzen et al (1991) believed this

additional construct helped explain behaviors among individuals who did not have complete volitional control. This theory's key assumption is that behavioral control is an independent determinant of behavioral intention. Several other theories also include constructs similar to perceived behavioral control, including the Health Belief Model (HBM), and Social Cognitive Theory (SCT) (Bandura, 1977; Bandura, 2004; Rosenstock et al., 1994).

As a construct, behavioral control is very similar to Hochbaum and Rosenstock's and Albert Bandura's construct of self-efficacy, key components of both HBM and SCT (Bandura, 1977; Rosenstock, Strecher, & Becker, 1988). Self-efficacy is defined as the "conviction that one can successfully execute the behavior required to produce outcomes" (Bandura, 1977). Bandura argues that a person's perceived self-efficacy can influence a person's beliefs about the control they have over their motivation to perform a behavior and over their social environment (Bandura, 1977, 1989; Bandura, 2004). The construct of self-efficacy has played a significant role in health interventions where the goal has been to reduce risk behavior or to improve health outcomes and as such is important to measure in this study.

Perceptions of Risk.

In addition to self-efficacy, another useful construct to measure is perceived risk, referred to in the literature as *perceived* probability, susceptibility, likelihood, or vulnerability, a key component of many health behavior theories (Conner & Norman, 1996; Rosenstock et al., 1988; Rosenstock et al., 1994; Strecher & Rosenstock, 1997; Weinstein, 1993). These theories posit that individuals with a high perceived level of risk are more likely to engage in behaviors to reduce their risk, such as increasing their use of

condoms, reducing their weight, etc. (Floyd et al., 2000; Rosenstock et al., 1994; Strecher & Rosenstock, 1997; Sutton, 1987). A central construct of the HBM and Protection-Motivation Theory (PMT) as well as others, many health researchers have used it to predict specific health behaviors, such as condom use and vaccine acceptability. The findings of these studies and others indicate that risk perception for contracting HIV may play an important role in intention to use microbicides or tenofovir.

Past Behavior.

An individual's previous use of HIV prevention or contraceptive methods may also affect intentions to use microbicides and tenofovir. Therefore, several researchers have suggested that another important construct to measure is *habit*, which Triandis and Montano added to create the Expanded Theory of Reasoned Action (EXTRA) (Landis, Triandis, & Adamopoulos, 1978; Triandis, 1980). In EXTRA, Triandis and Montano suggest that habit or past behaviors directly affect behavioral intention. Fishbein (2005) further postulated that past behavior is a distal variable that influences attitudes, norms, and self-efficacy and thus, behavioral intention (Fishbein, 2005). Several studies indicate that habit or past behaviors may be an important predictor of behavioral intentions (Lauver et al., 1997; Sheeran & Taylor, 1999; Stacy et al., 1999).

Relationship Dynamics and Socio-cultural Context.

Commitment.

Relationship commitment may also be related to intentions to use. As previously mentioned, relationship status within the context of microbicide acceptability research has been defined many different ways, with several studies indicating differences in intentions to use with "main" versus "casual" or "paying" partners (Hammett, Norton et

al., 2000; Koo et al., 2006; Weeks et al., 2004). Previous research has found that women in long-term heterosexual relationships are less likely to perceive their partners as risky. Conversely, women in short-term relationships are more likely to perceive their partners as risky (Ellen, Adler, Gurvey, Millstein, & Tschann, 2002). Researchers have posited that as trust within a relationship builds, the tendency to practice safer sex behavior diminishes. Research on relationship commitment supports these findings with increased perceptions of safety with one's partner associated with individuals who have higher levels of commitment, which in turn can lead to lower condom use intentions and condom use (Agnew, Harvey, Sherman, & Warren, 2008; Misovich et al., 1997). Similar findings may hold true in measuring intentions to use microbicides and tenofovir, with individuals who have a higher level of relationship commitment being less likely to use an HIV prevention product.

Subjective Norm.

Another key construct of the Theories of Reasoned Action and Planned Behavior is subjective norm (Montano et al., 1997). Fishbein and Azjen strongly believe that behavioral intention is influenced by an individual's perception of his/her key referents performing a behavior. The construct is measured by what the individual perceives others are doing relative to a specific behavior (normative beliefs) and how motivated that individual is to conform with the behavior (motivation to comply) of other groups of people such as peers, religious communities, and parents (Ajzen & Fishbein, 1980; Montano et al., 1997). Fishbein's Integrated Model includes a similar measure called, norms, which is determined by an individual's normative beliefs and motivation to comply (Fishbein, 2005). Findings from various studies indicate that subjective norm

may play a key theoretical role in microbicide and tenofovir acceptability where a woman may be more likely to use a microbicide or tenofovir if she believes her friends, peers, and partners are supportive of their use.

Relationship Power and Gender-Based Violence.

Although intrapersonal and individual models of behavior change may explain a person's behavior to a large extent, many researchers have argued these constructs may not fully capture one's behavioral intention. In fact, they posit that an integrative model that supports the social-cognitive factors and relationship dynamics of women may provide a more accurate depiction of women's sexual decision-making (Amaro, 1995a). Researchers insist that cognitive models of health behavior fail to account for the socio-cultural context of women's lives (Amaro, 1995b). As a result, many researchers have studied measures of relationship power--defined as the ability of one person to influence another person in order to achieve a desired objective-- to assess the impact of cultural influences and gender role norms within women's lives (Balswick & Balswick, 1995; Pulerwitz et al., 2002; Soler et al., 2000).

Many theorists have written about gender and power, but its roots lie in feminist thought, more specifically radical-cultural feminist thought. In her seminal book, *Beyond Power*, Marilyn French believed that man's desire to control the dyad of women/nature was inherently patriarchal (French, 1986). She further postulated that this desire to control women leads to other systems of oppression (e.g. racism, classism). She referred to this dynamic as "power-over," a distinctly masculine construct, and theorized about ways in which society could undo it. French reconceived the notion of masculine power and assigned it distinctly feminine characteristics. She also believed that the most

productive kind of society was one that celebrated the feminine values of love, sharing and nurturance, just as profoundly as they celebrate status, control, and structure. French defined this feminized version of "power over" as "power to," which she further insisted was the desire to create, not destroy.

Yoder and Kahn (1992) further discuss the concepts of "power over" and "power to" at the interpersonal level. They write that the focus of the research on interpersonal "power over" has often been concentrated in two areas: sexual violence and communication (Kahn & Yoder, 1992). In the arenas of physical and sexual violence, many researchers have conducted work on power imbalances in battering, the foundations of rape, and sexual harassment policies (Claes & Rosenthal, 1990; Riger, 1991; Scully, 1988). In the realm of dyadic communication, researchers have found that the men often use "power over" strategies, and women often employ "power to" methods to convey their needs (Tannen, 1990).

More recently, within the realm of HIV/AIDS research, Wingood and DiClemente (2000), building on the Theory of Gender and Power developed by Robert W. Connell, have continued work on the nexus of power, sexual violence, and communication to define the structure, exposures and risk factors that make women more vulnerable to HIV. Connell's theory suggests that three major structures define relationships between men and women: 1) the sexual division of labor 2) the sexual division of power, and 3) the structure of cathexis (Connell, 1987). Wingood and DiClemente (2000) argue that each of these domains correspond to a level of causation that can increase a woman's risk for HIV infection.

Perhaps the domain that is most relevant for this analysis is the sexual division of power where Wingood and DiClemente (2000) believe that a set of physical exposures such as history of sexual or physical abuse, having a high-risk steady partner, and a partner who disapproves of practicing safe sex disempowers women. Additionally women who have poor condom use skills, poor assertive communication skills, and low self-efficacy to avoid HIV may also be burdened by the sexual division of power as compared to women who do not have these risk factors. Indeed, although the research on the effect of relationship power on reproductive health and HIV outcomes yields mixed results (Blanc, 2001; Cabral, Pulley, Artz, Brill, & Macaluso, 1998; Harvey et al., 2002; Pulerwitz et al., 2002; Soler et al., 2000; Wingood & DiClemente, 2000), some researchers suggest that this may be due to how relationship power and dominance are operationalized (Harvey, 2002).

Understanding relationship power may help us create a more complex picture of women's HIV risk. Scientists have argued that studying relationship power and dominance can help us create better interventions to increase women's empowerment, especially in the domain of sexuality. As such, recent HIV research has focused on the concept of "power to," or personal empowerment, which Bandura (1989) defines as the control one feels over one's thoughts, feelings and behaviors. The development of microbicides and tenofovir is a direct answer to that call and scientists posit that giving women more options to prevent the acquisition of HIV may empower women in sexual relationships (Harvey et al., 2002; Woodsong, 2004). Determining if women in disempowered relationships would be more likely to use microbicides and tenofovir versus women not in disempowered relationships will help us tailor our interventions to

reduce women's HIV risk. Based on the conceptual framework as well as previous findings from research, this research expects many of the identified constructs above to be associated with microbicide and tenofovir acceptability.

Table 2.1 ***Theoretical Framework for Intentions to Use Microbicides and Pre-Exposure Prophylaxis as Methods of HIV Prevention***

Method Characteristics[6]	*User Characteristics*	*Relationship Dynamics & Socio-Cultural Context*
Product Efficacy	Socio-demographics	Social Norms [4]
Side-Effects	Perceived Risk of HIV[1, 2]	Partnership characteristics[5]
Cost	Sexual Behavior and Risk Factors[1,2]	Control of Sexual Behavior[5]
Access	Microbicide Self-Efficacy[1,3,4]	Gender-Based Violence[5]
Mechanics	Tenofovir Self-Efficacy[1,3,4]	Commitment
Protects against HIV	Past Reproductive and Contraceptive Behavior[4]	
Covert Use/Communication		
Female Controlled		
Daily vs. per act use		

[1] Health Belief Model
[2]Protection-Motivation Theory
[3] Social Cognitive Theory
[4] Expanded Theory of Reasoned Action
[5] Theory of Gender and Power
[6]Expectancy Value Theory

Chapter 3 : METHODS

Overview and Background

This chapter provides a detailed description of the study design and methods. Included are descriptions of the research setting and study sites; the target population, including recruitment strategies; the survey instrument and measures; data collection procedures; data management and analysis; and an assessment of the calculations of statistical power. This study was quantitative in nature and data were collected from a sample of women in the city of Toronto via self-administered questionnaire (SAQ). Oregon State University's Institutional Review Board (IRB) approved all study procedures.

Research Setting and Study Sites

Participants were recruited from two community-based clinics located in the city of Toronto. A thriving metropolis, the Toronto area boasts a population of over 5 million people, although the city itself is home to 3 million residents. Because Canada has national healthcare, all of its residents are covered by the federal healthcare system. Additionally, local municipalities and cities meet the needs of marginalized populations through community-based health clinics which offer a wide range of health and social services.

Because they specifically target a high-risk, socially and ethnically diverse group of women, two community health clinics and their partners were chosen for the study sites. These clinics were the Hassle-Free Clinic and the South Riverdale Community Health Centre.

Hassle-Free Clinic provides free medical and counseling services on all issues related to sexual health. Located in downtown Toronto, it is the largest anonymous HIV testing site in Canada and serves diverse, low-income men and women.

The South Riverdale Community Health Centre is located in the Riverside area of Toronto. The clinic offers a range of health services, including harm reduction programs, which serve the city's drug-using population. They have recently expanded their program and created a women's-only harm reduction center to not only help reduce the incidence of HIV among drug-using women, but to reduce their overall HIV risk. This clinic also serves primarily low-income individuals from the area.

Target Population: Recruitment and Eligibility Criteria

Recruitment.

A non-probability sampling strategy was used to recruit the study population. In particular, purposive sampling was used to garner a large enough sample to ensure adequate statistical power for analyses. I used both indirect and direct strategies to recruit women from the two clinics. In the indirect scenario, social marketing techniques such as flyers and posters were distributed and placed in the clinics. These printed materials described the project and asked interested individuals to contact the researcher or the front desk clerk for a copy of the survey. In the direct recruitment scenario, the researcher was in attendance, and asked persons attending the clinics if they wanted to participate in this research study. In addition, when the researcher was not in attendance, clinic staff asked clients if they would like to participate in the survey.

Eligibility Criteria.

Women were eligible for the study if they were 18-55 years old, had vaginal sex with at least one male partner in the last 12 months, and were HIV negative or of unknown status. Women under the age of 18 were excluded from the study due to their status as minors and the need for additional parental consent. Similarly, women over the age of 55 were excluded from the study because it is the average age when women reach menopause. Hormonal changes due to menopause alter the surface tissues of the vagina and although this study is assessing hypothetical acceptability of microbicides, other studies testing actual use restrict involvement of women beyond the age of 55 for this reason (Altares, 2008).

Procedure for Data Collection

A self-administered questionnaire (SAQ) was used to collect data over a period of four months, from June-September 2008 (see Appendix A). The survey was distributed to women visiting both clinics by the intake representative and the study investigator. A drop box was made available in the clinic waiting room to allow respondents to place their completed survey in it with the assurance of confidentiality. The intake representative and/or the investigator handed a questionnaire to every woman and briefly explained the purpose and intent of the study and the importance of their participation. Women were told the following by clinic staff and the investigator, "We're conducting a survey on new HIV prevention methods that are being developed for women. Would you be willing to complete this short survey while you wait for your appointment? Please read the attached cover letter to determine if you are eligible and if you are not, please

return the survey to the front desk. You also have the opportunity to enter a lottery to be one of five women to win a $50 gift certificate to a local grocery store."

The cover letter attached to the survey explained its purpose and the importance of individual responses. Additionally, the letters noted that if the respondent was between the ages of 18 and 55, had been sexually active within the last 12 months, and was HIV negative or of unknown status, they were eligible to participate in the study. The letter also assured confidentiality and right to refuse participation, as well as provided contact information for the researcher if the respondent has further questions. Participants were asked to retain the cover letter for their records. Because a waiver of documentation for informed consent was requested of the Institutional Review Board (IRB) by the investigator due to the sensitive nature of many of the survey questions and because the research presented no more than minimal risk to the research participants, the completion of the survey served as consent to participate in the study. Please see Appendix B for the text of the letter.

In addition to the cover letter, another form was attached to the survey that women could complete to participate in a lottery to win one of five $50 gift certificates to a local grocery store. Women who chose to participate in this study's lottery submitted their name and their contact information (phone, address or email). Please see Appendix C for the full text of the lottery entry form. Once the winners were chosen, these forms were shredded to ensure continued confidentiality of the respondents.

Each survey was given an identification number, indicating at which clinic the survey was administered. In this way, surveys could only be traced back to the clinic, but not the respondent themselves.

Survey Instrument

The self-administered questionnaire (SAQ) was designed to take approximately 15-20 minutes to complete. According to Catania et al (Catania, Gibson, Chitwood, & Coates, 1990), SAQs may provide a more private and less threatening means of reporting sensitive behaviors than face-to-face interviews. Additionally, they can substantially reduce reporting bias and are less expensive to administer if given to people simultaneously such as in HIV testing centers or STD clinics (Gribble, Miller, Rogers, & Turner, 1999) .

The Women Initiated Solution for HIV Prevention (WISH) Survey consisted of several sections: 1) history of contraceptive and HIV prevention method use; 2) risk perceptions; 3) method characteristics and perception; 4) relationship factors; 5) HIV risk assessment; and 6) sociodemographics. Priscilla Salant's book, "How to Conduct Your Own Survey," was used to help guide in the design of the survey (Salant & Dillman, 1994). Additionally, the expertise of the dissertation committee, those knowledgeable in survey design, and other experts in the fields of sociology and women studies helped to craft the questions and/or provide comments on the survey structure and how it could be amended for further improvement. Since a relatively high-risk, low-income population was being surveyed, literacy was an issue. To ensure that respondents with at least a sixth-grade education could comprehend the survey questions, the the Flesch-Kincaid test was applied, a reading level assessment embedded in Microsoft Corporation's Microsoft Word. Although several other reading literacy tests exist, the Flesch-Kincaid test is a commonly used measure of reading assessment. The United States Medicare and Medicaid literacy guidelines recommend that all health related materials be written at

least between the 5th and 8th grade levels to reach the broadest of audiences. The test determined that the survey was at the sixth-grade level and that its ease of reading was at 72.7%. According to the scoring parameters of the Flesch-Kincaid test, which are on a scale of 1-100, a document should score between 60-70%, indicating a relatively easy level of comprehension. The higher the score, the easier the document is to read (Microsoft Corporation, 2007). Results indicated that the survey reading level was acceptable. The survey was also pre-coded for ease of entering into a data analysis program.

Pilot Testing

The survey was pilot tested with 10 individuals, who met the eligibility criteria, from each clinic for a total of 20 individuals. They included five service providers at Hasslefree Clinic, five service providers at South Riverdale Community Health Centre, five clients at Hasslefree Clinic, and five clients at South Riverdale Community Health Centre. These individuals were given the survey and asked to a) assess the survey for overall readability, including length, b) visual presentation, c) confusing questions, and d) skip patterns. The study author met with service providers from each clinic separately to receive face-to-face feedback, and she asked clients to provide feedback on hard copies of the survey. The survey was revised based on the feedback provided. The next section describes the measures used to assess specific constructs in this study.

Measures

In constructing the survey, the author looked to previous literature on the acceptability of female-initiated HIV prevention methods to determine which variables should be included in this study. The questions assessed the following areas: previous

use of birth control and HIV prevention methods; perceptions of HIV risk; perceived characteristics of microbicide and tenofovir; self-efficacy for product mechanics and negotiation of use; intention to use; product preference; relationship dynamics including; number of lifetime and recent sexual partners; relationship commitment; sexual relationship power/control; gender-based violence; overall STD and HIV risk; and socio-demographics. Questions were developed and adapted from previous studies to measure previous use of birth control and HIV prevention methods, microbicide and tenofovir self-efficacy, intention to use, method preference, and gender-based violence (Brafford & Beck, 1991; Morrow, Fava, Rosen, Vargas et al., 2007; Thorburn et al., 2006; Wingood & DiClemente, 1997b).

Other concepts were measured through scales already deemed to be valid and reliable measures of the specific constructs. These included, risk perception, method characteristics, relationship commitment, social norm, and relationship power and control (Brewer et al., 2007; Jonathan M Ellen et al., 2002; Harvey et al., 2002; Pulerwitz et al., 2002; Purcell DW et al., 2004; Sheeran et al., 1999; Trafimow, 2000).

Each construct with more than three items was assessed to determine whether it represented a unidimensional concept. As recommended by Acock (2009), model fit was assessed using principal components factor analysis (PCA). Factors were retained if eigenvalues were ≥ 1. Factor loadings were examined for each item in all scales when factors had an eigenvalue of ≥ 1. Because items loadings for factor 1 in each scale were above .3 or .4 , the scales were determined to represent a unidimensional trait (Portney, 2000). These results indicate that all scales met these criteria.

The primary outcome measures for this study were intentions to use microbicides, intentions to use tenofovir (PrEP), and product preference (microbicides or PrEP). Predictors of these outcomes included intrapersonal and interpersonal factors associated with intentions to use both female controlled HIV prevention methods as well as the factors associated with product preference.

Outcome Measures.

Microbicides Intention to Use. Participants in this study were asked about their intentions to use microbicides. Respondents were asked, "If MICROBICIDES were available today, how likely or unlikely is it that you would use them?" Response categories were (1) extremely unlikely (2) somewhat unlikely (3) somewhat likely, and (4) extremely likely. This question was modified by the author, but based on a questions developed by Morrow et al. (Morrow, Fava, Rosen, Christensen et al., 2007)) and Bird et. al.(Bird et al., 2004). For analysis, responses were collapsed and coded into a binary outcome variable so that respondents who were extremely unlikely or somewhat unlikely to use were "unlikely to use" microbicides (coded as 0), and respondents who were somewhat likely or extremely likely to use were "likely to use" microbicides (coded as 1).

Tenofovir Intention to Use. Participants in this study were asked about their intentions to use microbicides. Respondents were asked, "If TENOFOVIR was available today, how likely or unlikely is it that you would use it?" Response categories were (1) extremely unlikely (2) somewhat unlikely (3) somewhat likely, and (4) extremely likely. This question was modified by the author, but based on a questions developed by Morrow et al. and Bird et al. (Bird et al., 2004; Morrow, Fava, Rosen, Christensen et al.,

2007). For analysis, responses were collapsed and coded into a binary outcome variable so that respondents who were extremely unlikely or somewhat unlikely to use were "unlikely to use" tenofovir (coded as 0) and respondents who were somewhat likely or extremely likely to use were "likely to use" tenofovir (coded as 1).

Product Preference. Participants in the study were asked about their product preference. The question read, "If both products were equally effective in reducing your risk for getting HIV, which would you prefer to use?" Response categories were (1) Microbicides (coded as 1) and (2) Tenofovir (coded as 2). These categories were re-coded to fit the logistic regression model, so microbicides were coded as 0 and tenofovir was coded as 1.

Intrapersonal Measures.

Past behavior. Survey items measuring past behavior included whether respondents have ever used contraceptive and HIV prevention methods in the past. The first question read as follows: "Please indicate whether or not you have ever used the birth control methods listed below." Fourteen different birth control methods were listed. For analysis, the methods were collapsed into two categories: hormonal methods and barrier methods. The hormonal method category included ever having used birth control pills, vaginal ring, hormonal patch, and Depo-Provera. The barrier method category included ever having used the female condom, diaphragm, cervical cap, spermicides, and the sponge.

Respondents were also asked "In addition to preventing pregnancy, some women find it important to protect themselves against HIV and other sexually transmitted infections like herpes, genital warts, and gonorrhea. Which if any of these methods have

you used to protect yourself from HIV or other sexually transmitted infections?" Four different methods of HIV prevention were listed. Response categories for both questions were (1) used or (2) not used. An indicator variable was created for analysis purposes with "not used" (referent) being recoded as 0 and "used" recoded as 1.

Perceived risk from behavior. Perceived risk assessed the risk of acquiring HIV or an STD in the next year and was measured using a two-item scale developed by Harvey et al. (Harvey et al., 2003), but modified by the researcher for this study. Questions had the following stem: "Please indicate, to the best of your knowledge, to what extent you agree or disagree with the statements below," and were followed by this sample statement "It is unlikely that I will get HIV in the next year." Response categories were (1) strongly agree (2) agree (3) disagree, and (4) strongly disagree. For analysis purposes, the scale was reverse scored so that (1) strongly disagree, (2) disagree, (3) agree, and (4) strongly agree. Then, a score was created by taking the average of the two items. Because there were only two items in this scale, standard recommendations suggest that reporting Cronbach's alpha is unnecessary and that a more useful measure of reliability would be reporting the inter-item correlations (Acock, 2009) . The inter-item correlation was .79. Correlations that approach .90 are high and can be considered reliable (Portney, 2000)

Perceived Characteristics of Microbicides and Tenofovir. The measures for these scales were adapted from a large body of work previously done on the acceptability of different contraceptive and HIV prevention methods, but in particular microbicides. Primarily, however, these scales were based on the Contraceptive Attributes Scale developed by Beckman et al. (Beckman, Harvey, & Murray, 1992)and the Product

Characteristic Scale developed by Morrow et al. (Morrow, Fava, Rosen, Christensen et al., 2007) . The survey included 16 items about perceptions of product characteristics for microbicides and tenofovir. The statements were preceded by a description of the product (micobicides or tenofovir) and then instructions on how to answer the question which read,

> "Please indicate to what extent you agree or disagree with the statements below. We understand that you have not used (microbicides/tenofovir) and you may feel like you don't know much about them. We are, however, still interested in learning your opinions and perceptions of microbicides/tenofovir."

These instructions were followed by statements about the product. The first statement was, "The product is easy to use." Response categories, on a four-point scale were (1) strongly agree (2) agree (3) disagree, and (4) strongly disagree. For analysis purposes, the scale was reversed scored such that (1) strongly disagree, (2) disagree, (3) agree, and (4) strongly agree. Scale scores were created for both the microbicides and tenofovir scales by calculating the mean of the 16 items for each respondent, with individual scores resulting in a range from one to four (coefficient alpha, microbicides = .91; coefficient alpha, tenofovir =.89).

Microbicide Self-Efficacy. Survey items addressing microbicide self-efficacy included whether respondents felt confident using microbicides without their partner's knowledge, discussing use with a partner, confidence in using the product correctly, and confidence of use during sex. These items were adapted from Brafford and Beck's Condom Use Self-Efficacy Scale (CUSES) and from Harvey et al. (Brafford & Beck, 1991; Harvey et al., 2006). Items had the following stem: "How confident are you?"

This stem was followed by eight items, (e.g., "That you could use microbicides without your partner knowing?"). Response categories, on a five-point scale, were (1) not at all confident (2) a little confident (3) moderately confident (4) very confident (5) extremely confident. A scale score, with a range of one to five, was created by calculating the mean of the eight items for each respondent (coefficient alpha = .91).

Tenofovir Self-Efficacy. Survey items addressing tenofovir self-efficacy included whether respondents felt confident using tenofovir without their partner's knowledge, discussing use with a partner, confidence in using the product correctly, confidence in ingesting the product, and confidence of use during sex. The items in the scale were adapted from Brafford and Beck's Condom Use Self Efficacy Scale (CUSES) and from Harvey et al. (Brafford & Beck, 1991; Harvey et al., 2006). Items had the following stem: "How confident are you…" This stem was followed by six items, a sample of which was, "That you could use tenofovir without your partner knowing?" Response categories, on a five-point scale, were (1) not at all confident (2) a little confident (3) moderately confident (4) very confident, and (5) extremely confident. A scale score, with a range of one to five, was created by calculating the mean of the six items for each respondent. The internal consistency reliability was assessed using a Cronbach's alpha coefficient.

Initial calculations revealed the internal consistency reliability to be at .46, a value that Devellis (2003) deems unacceptable. The statistical program Stata, which this researcher used to analyze this data, can generate an adjusted alpha for the removal of each item. The calculation revealed that removal of the item "How confident are you that you can swallow the pill?" greatly improved the internal consistency reliability, with a

reported alpha coefficient of .86, a "very good" indication that the remaining five items are conceptually related (DeVellis, 2003).

Sexual and HIV Risk: Sexual and HIV risk assessed whether people had engaged in risky behavior within the last twelve months. Each question began with the stem, "During the past 12 months," and were followed by eight dichotomous items (1=yes, 2=no). For example the first statement read, "I have had sex without a condom." These eight items were adapted from Harvey et al. (2006). Items were re-coded so that 0=no and 1=yes and a scale score was created summing the responses so that higher scores corresponded to greater levels of sexual and HIV risk (coefficient alpha =.71).

Interpersonal Factors.

Number of lifetime and recent sexual partners. Two questions were asked regarding this construct. Respondents were asked to indicate, in the space provided below the question, the number of people with whom they have had sex during their lifetime and the last twelve months. Because data were not normally distributed, responses to both questions were categorized. Lifetime sexual partners were categorized into four groups: 1) 1-4 sexual partners, 2) 5-10 sexual partners, 3) 11-28 sexual partners, and 4) 29 and more. This ensured that 25% of the sample was in each group. Number of recent sexual partners was categorized into three groups: 1) 1 sexual partner, 2) 2-3 sexual partners, and 3) 4 or more sexual partners. This also ensured that at least 25% of the sample was in each group. An indicator variable was created for analysis purposes with the first category as the referent.

Relationship Commitment was assessed with seven items adapted from the Investment Model of Commitment scale (Rusbult, Martz, & Agnew, 1998). Although the

full scale comprises several subscales for a total of 22 items, this study used the commitment subscale, which was composed of seven items measured on a four point scale. Only those respondents currently partnered were required to answer the questions. A sample item read, "I want our relationship to last a very long time." Response categories were (1) strongly agree, (2) agree, and (3) disagree, (4) strongly disagree. For analysis purposes, the scale was reverse scored so that (1) strongly disagree, (2) disagree, (3) agree, and (4) strongly agree. A scale score was created by calculating the average of all the items (coefficient alpha = .87).

Perceived social norm. The measure of perceived social norm scale assessed the influence of the respondent's partner and peer perceptions of safer sex on the respondent's decision-making regarding safer sex. The scale was used in the study and developed by Purcell et al (2004). A sample item was: "My partner thinks a condom should be used every time we have sex." Response categories, on a 4-point scale were (1) strongly agree (2) agree (3) disagree, and (4) strongly disagree. For analysis purposes, the scale was reverse coded so that (1) strongly disagree, (2) disagree, (3) agree, and (4) strongly agree. A composite score was created by calculating the mean of the four items for each respondent with resulting scores ranging from one to four. The internal consistency reliability for this scale was estimated using a Cronbach's alpha coefficient. Internal consistency was calculated at α=.68. It is generally recommended that the alpha coefficient be at least .8 and higher. Although .68 does not meet the typical cut off criteria, DeVellis (1991) suggests that an internal consistency reliability coefficient between .65 and .7 is minimally respectable (DeVellis, 2003).

Relationship Power and Control was assessed among respondents currently partnered with 15 items adapted from the Sexual Relationship Power Scale (Pulerwitz et al., 2002). This scale assesses relationship dynamics with a primary partner. Although the scale itself consists of two subscales, one measuring relationship control and the other measuring decision-making, this study used the relationship control subscale. A sample question read, "If I asked my partner to use a condom, he would get violent." Response categories were (1) strongly agree, (2) agree, (3) disagree, and (4) strongly disagree. For analysis purposes, the scale was reverse scored so that (1) strongly disagree, (2) disagree, (3) agree, and (4) strongly agree with higher scores indicating less power and control. A scale score was created by calculating the mean of the 15 items for each respondent resulting in a scale score of one to four (coefficient alpha = .90).

Gender Based Violence was assessed among respondents using three items, developed by the researcher, but adapted from questions first created by Wingood et al. (Wingood & DiClemente, 1997a). The questions asked if the respondent had experienced (1) physical abuse, (2) forced sex, and (3) emotional abuse with their current partner. Response categories were (1) yes, and (2) no. All items were collapsed into one variable: ever having experienced gender-based violence with current partner (1=yes, 0=no).

Socio-demographics

Several socio-demographic questions were also included in the survey: age, marital status, race/ethnicity, education level, and socio-economic status.

Age was assessed by asking respondents the question, "How old are you?" Because age was not normally distributed, the measure was categorized into the three age

groups of 18-25, 26 to 35, and 36-55. An indicator variable was created for analysis purposes with the first age category as the referent.

Current Marital status was assessed by asking, "Which of the following best describes you?" Response categories were 1) married, 2) living together, 3) single 4) divorced/separated/widowed. The marital status variable was collapsed into two categories: living together/married and single/divorced/separated/widowed. An indicator variable was created for analysis purposes with the living together/ married category as the referent.

Ethnicity was measured by following the Canadian Census guidelines. The question read as follows, "Which of the following best describes you?" Response categories were 1) Aboriginal, 2) Black-African, 3) Black-Caribbean, 4) Hispanic/Latin American, 5) Middle Eastern/Arab, 6) South Asian, 7) White-Western European, 8) White-Eastern European, and 9) Other (please specify). All respondents in the "other" category indicated that they were of East Asian descent. More than 50 percent of respondents were White-Western or Eastern European, so the variable was collapsed into two categories with 1 = White/Non Hispanic and 0 = Other. An indicator variable was created for analysis purposes with the "other" category as the referent.

Education level was measured by asking, "What is the highest grade or year of school you have completed." Question response categories were 1) never attended school or only attended kindergarten, 2) grades 1-8, 3) grades 9-11 (some high school), 4) grade 12 (high school graduate), 5) bachelor's, 6) graduate, 7) other. The education level variable was collapsed into two categories: those who completed ≤ grade 12 and those

who completed ≥ bachelor's degree. An indicator variable was created for analysis purposes with the ≥ bachelor's category as the referent.

Household Income was determined by asking respondents, "Which of the following categories best describes your yearly total household income?" Question response categories were as follows: 1) less than $15,000, 2) $15,000-24,999 3) $25,000-34,999 4) 35,000-49,999 5) $50,000-74,999, and 6) more than $75,000. Data were collapsed into two categories: 1) those with income ≤ $34,999, 2) those with income ≥ $35,000. An indicator variable was created for analysis purposes with the ≥ $35,000 category as the referent.

Data Management and Analysis

Data Management.

The completed surveys were precoded and checked twice for missing data or errors in skip patterns as recommended by Salant et al (1994). Some people ignored the skip pattern and answered questions regarding both their current and past partners. In this instance, data regarding the current partner were used, because in the final data analysis relationship factors associated with intentions to use and product preference were assessed only among women who were currently partnered. Some people had more than one answer to each question. In this instance, the researcher followed coding procedures recommended by Salant et al (1994) where if the answer was not obvious, the data should be coded as missing. The data were entered into Excel and then imported into STATA version 11IC statistical analysis program.

Data were screened for outliers through descriptive statistics and frequency distributions. All predictor variables were assessed for their distributions. Continuous

variables that did not meet the assumptions of normality were categorized, and some categorical variables were collapsed into fewer categories. Decisions were made to categorize data based on their use in previous research as well as the current distribution of the data. Colinearity diagnostics were assessed for all independent variables in preparation for multivariate analysis. Calculations of the variance inflation factors (VIF) and tolerance 1/VIF, indicated no evidence of multicolinearity. Each variable was also assessed for missing data, but each had ≤ 5% missing, thus denoting no need to replace data with numbers known a priori or with the variable or group means. The dependent variables were categorical in nature, but two (intentions to use microbicides and intentions to use tenofovir) were collapsed into fewer categories to be consistent with prior acceptability research.

Data Analysis.

Analyses were performed on two samples in this study. For an assessment of the intrapersonal factors associated with intentions to use and product preference, we used the full sample (N=348). To determine both the intrapersonal and interpersonal factors associated with intentions to use and product preference, we used only women who were currently partnered (N=218) in the multivariate analysis. Both samples were analyzed used Stata version 11IC statistical software.

Descriptive Analysis.

Descriptive analysis was conducted on all the variables (predictors and outcomes) in the study. Sample means for continuous variables (e.g., perceived risk) and percentage distributions for categorical variables (e.g., contraceptive methods, age, race/ethnicity,

relationship status) were calculated to not only describe the full sample of respondents, but the subsample (women currently partnered) as well.

Bivariate Analysis.

Bivariate relationships between intentions to use and socio-demographic, intrapersonal, and interpersonal measures were assessed among both the full and subsamples using logistic regression analyses to determine the unadjusted associations between predictor variables and the outcome variable. Significant variables (at $p<.05$) were then entered into the multivariate model for further analyses. The associations between product preference (microbicides vs. tenofovir) and the aforementioned predictor variables were assessed in the same way.

Multivariate Analysis.

Research Question 1: What are the factors associated with intentions to use microbicides?

Logistic regression analysis was used to assess the factors that were associated with intentions to use microbicides. The variables were entered into the model simultaneously for analyses, which were conducted in two parts. The first part of the analysis focused on the full sample of women and examined the socio-demographic and intrapersonal covariates (past behavior, perceived risk, product perceptions, self-efficacy) associated with intentions to use microbicides. Separate logistic regression analysis was conducted on the smaller sample of women who were currently partnered. The socio-demographic variables as well as the intrapersonal variables were retained in this model,

but we also included the variables of perceived social norm, commitment, relationship power and control, and gender-based violence.

Research Question 2: What are the factors associated with intentions to use tenofovir?

Comparable analyses to test the first research question were used to assess the factors that were associated with intentions to use tenfovir. Similar to assessing intentions to use microbicides, the variables were entered into the model simultaneously for analyses, which were conducted in two parts. The first part of the analysis focused on the full sample of women and examined the socio-demographic and intrapersonal covariates (past behavior, perceived risk, product perceptions, self-efficacy) associated with intentions to use tenofovir. Separate logistic regression analysis was conducted on the smaller sample of women who were currently partnered. The socio-demographic variables as well as the intrapersonal covariates were retained in this model, but we also included the additional covariates of perceived social norm, commitment, relationship power and control, and gender-based violence.

Research Question 3: What are the factors associated with product preference?

Analyses were conducted to determine the factors associated with product preference. Logistic regression and procedures similar to those mentioned in the previous two analyses were used to assess the factors associated with product preference. As above, the variables were entered into the model simultaneously. The first part of the analysis focused on the full sample of women and examined the socio-demographic and intrapersonal covariates (past behavior, perceived risk, product perceptions, self-efficacy) associated with product preference. Separate logistic regression analysis was conducted on the smaller sample of women who were currently partnered. The socio-demographic

variables as well as the intrapersonal covariates were retained in this model, but we also included the additional covariates of perceived social norm, commitment, relationship power and control, and gender-based violence.

Power Analysis.

For estimates of statistical power for multiple logistic regression analysis, a two-tailed test at an alpha .05 level was assumed. The statistical program NCSS/PASS was used to compare two groups of equal size for a logistic regression analyses. With the reference group having a 50% event rate, power was calculated to detect different event rates in the other group for other sample sizes. Calculations indicated 97% power to detect a difference in an event rate of .50 versus .70 when the total sample size is 350 and 82% power for the same event rates in a sample of 200 respondents. Both calculations revealed that the full sample (N=348) and subsample (N=218) provided adequate statistical power for analysis (Hsieh, Block, & Larsen, 1998).

Chapter 4 : RESULTS

This chapter reports the results of the analyses of the factors associated with intentions to use microbicides and tenofovir and factors associated with product preference. The first section includes the descriptive characteristics of the full and subsample of women. Then, bivariate analyses were conducted to determine differences among women who intend to use and do not intend to use microbicides; women who intend to use and do not intend to use tenofovir (PrEP); and women who preferred to use tenofovir over microbicides.

For both the full and subsample of women, variables that were found to have significant associations in the bivariate analyses were entered into the multivariate models for analysis. Multiple logistic regression was used to predict the likelihood of use for microbicides and tenofovir and product preference. Intentions to use a microbicide or tenofovir and product preference were the dependent variables.

Respondent Characteristics

Table 4.1 presents characteristics of the full sample of respondents. Nearly 40 percent of the sample was between the ages of 36-55, and 71% were single/divorced/separated or widowed. The majority of respondents were White/non-Hispanic and had at least a Bachelor's degree. Income levels for 60% of the sample were equal to or less than $34,999.

Nearly one-third of the respondents had never used a barrier method (e.g., diaphragm, condom, cervical cap) to prevent pregnancy. In contrast, 80% of the study participants had used a hormonal method of birth control (e.g., the birth control pill,

Depo-Provera, the hormonal patch). Twenty-five percent of the respondents reported having 29 or more lifetime sex partners, while 42% reported having had one sex partner in the last 12 months.

Table 4.1 also presents characteristics of the sub sample of respondents, women who were currently partnered. Nearly 70% of the sample was between the ages of 18-35, and 57% were single/divorced/separated or widowed. The majority of respondents were White/non-Hispanic and had at least a Bachelor's degree. Income levels for 55% of the sample were less than $34,999.

Nearly one-third of the sample had never used a barrier method (e.g., diaphragm, condom, cervical cap) to prevent pregnancy. In contrast, 83% of the sample had used a hormonal method of birth control (e.g., the birth control pill, Depo-Provera, the hormonal patch). Twenty-seven percent of the sample reported having between one and four lifetime sex partners, while 44% reported having had one sex partner in the last 12 months. Additionally, 25% reported experiencing some form of gender-based violence. The next section compares the characteristics for the respondents who intend to use and do not intend to use each product.

Table 4.1 ***Characteristics of Respondents Among the Full Sample and Women Currently Partnered***

Characteristic	Full Sample		Women Currently Partnered	
	Total n[a] (n=348)	Mean or % (SD)	Total n[a] (n=219)	Mean or % (SD)
Age				
18-25	108	31.03	76	34.70%
26-35	105	30.17	73	33.33%
36-55	135	38.79	70	31.96%
Relationship Status				
Married/Living Together	102	29.31%	94	42.92%
Single/Divorced/Separated/Widowed	246	70.69%	125	57.08%
Race/Ethnicity				
Non-White	155	44.67%	98	44.75%
Non-Hispanic White	192	55.33%	121	55.25%
Education				
≤ Grade 12	149	42.82%	86	39.27%
≥ Bachelor's	199	57.18%	133	60.73%
Yearly Household Income				
≤ $34,999	208	60.64%	118	55.14%
≥ 35,000	135	39.36%	96	44.86%
Barrier Method Use				
Used	125	35.92%	75	34.25%
Not Used	223	64.08%	144	65.75%
Hormonal Method Use				
Used	281	80.75	181	82.65%
Not Used	67	19.25%	38	17.35%
Lifetime Sex Partners				
1 to 4	83	24.34%	58	26.73%
5 to10	94	27.57%	55	25.35%
11 to 28	78	22.87%	53	24.42%
29 or More	86	25.22%	51	23.50%
Recent Sex Partners				
1	142	42.26%	95	43.98%
2 to 3	115	34.23%	72	33.33%
4 or More	79	23.51%	49	22.69%
Experience of Gender-Based Violence[¥]				
No			166	76.15%
Yes			52	23.85%
Perceived HIV and STI Risk	345	3.21(.87)	217	3.20(.85)
Microbicide Characteristics	343	2.71(.52)	215	2.69(.51)
Microbicide Self-Efficacy	346	3.20(1.01)	218	3.19(.97)
Tenofovir Characteristics	345	2.98(.54)	216	2.99(.53)
Tenofovir Self-Efficacy	347	3.77(1.02)	218	3.79(1.00)
Relationship Commitment[¥]			219	3.26(.66)
Relationship Power and Control[¥]			219	1.71(.66)
Perceived Social Norm[¥]			219	2.40(.71)
Overall Sexual and HIV Risk	334	2.13(1.66)	215	2.08(1.57)

[¥]Constructs Measured Among Currently Partnered Women Only (N=219)

Results for the Full Sample of Women

Bivariate Results.

Comparisons between women who intend and do not intend to use Microbicides.

Table 4.2 displays the unadjusted odds ratios and 95% confidence intervals from the bivariate analysis used to determine the association between sample characteristics and intentions to use microbicides. Women between the ages of 36-55 had significantly greater odds of intending to use a microbicide compared to women between the ages of 18-35. When compared to women with incomes income greater than or equal to $35,000, women with lower incomes had significantly greater odds of intending to use microbicides. Similarly women who had attended Grades 12 and lower were significantly more likely to intend to use microbicides. Women who used barrier methods for contraception also had significantly greater odds of intending to use microbicides, as did women who used the female condom for HIV prevention.

Women who intended and did not intend to use microbicides differed on other characteristics as well. For instance, women intending to use microbicides had significantly greater odds of perceiving their HIV and STI risk to be higher than women who did not intend to use microbicides. They also had significantly greater odds of perceiving microbicide characteristics more positively than those who did not intend to use microbicides. Women intending to use microbicides also had significantly greater odds of feeling more confident about using a microbicide and had higher levels of sexual and HIV risk than those who did not intend to use a microbicide.

Table 4.2 ***Respondent Characteristics and Unadjusted Associations with Intentions to Use Microbicides***

Characteristic	Intend to Use Microbicides (n = 211)	Do not Intend to Use Microbicides (n = 132)	Unadjusted OR (95% CI)
Age (%)			
18-25	27.01	37.12	1.00 (Referent)
26-35	28.91	31.82	1.25 (.72,2.16)
36-55	44.08	30.60	1.95 (1.25,3.31)**
Income (%)			
≤$34,999	65.87	52.67	1.73 (1.11, 2.71)*
≥$35,000	34.13	47.33	1.00 (Referent)
Race/ethnicity (%)			
Non-Hispanic White	45.97	57.25	0.88 (.57,1.36)
Other[¥]	54.03	42.75	1.00 (Referent)
Relationship status (%)			0.27
Living Together and Married	28.44	31.06	1.00 (Referent)
Single/Divorced/Separated/Widowed	71.56	68.94	1.13 (.71,1.82)
Education Level (%)			
≤ Grades 12	49.29	32.58	2.01 (1.28, 3.16)**
≥Bachelor's	50.71	67.42	1.00 (Referent)
Barrier Methods (%)			
Used	41.23	28.79	1.74 (1.09, 2.77)*
Not Used	58.77	71.21	1.00 (Referent)
Male Condom (%)			
Used	90.05	83.3	1.81 (.95, 3.44)
Not Used	9.95	16.7	1.00 (Referent)
Female Condom (%)			
Used	18.96	9.85	2.14 (1.10, 4.18)*
Not Used	81.04	90.15	1.00 (Referent)
Number of Lifetime Sexual Partners (%)			
1 to 4	22.22	27.91	1.00 (Referent)
5 to 10	27.05	29.46	1.15 (.63,2.10)
11 to 28	25.60	18.60	1.73 (.90, 3.31)
≥ 29	25.12	24.03	1.31 (.70, 2.45)
Recent Sexual Partners(%)			
1	43.20	41.60	1.00 (Referent)
2 to 3	33.01	37.60	.85 (.51, 1.40)
≥ 4	23.79	20.80	1.10 (.61, 1.98)
Perceptions of Risk (SD)	3.11 (0.88)	3.31 (0.87)	.77 (.59,1.00)*
Method Characteristics (SD)	2.84 (0..49)	2.52 (0.49)	3.96 (2.33, 6.7)***
Self-Efficacy (SD)	3.48 (0.94)	2.73 (0.94)	2.24 (1.75,2.89)***
Sexual and HIV Risk (SD)	2.27 (1.72)	1.90 (1.53)	1.16 (1.00, 1.34)*

* p< 0.05, ** p<0.01, *** p<0.001 according to the Wald test of significance.
[¥]The "other" category includes women who identified as Hispanic, Afro-Canadian, Asian, Arab or all other races/ethnicities.
OR = odds ratio, CI =confidence interval

Comparisons between women who intend and do not intend to use Tenofovir.

The characteristics for women who intend to use and do not intend to use tenofovir are displayed in Table 4.3. Women who had lower incomes and less education

were significantly more likely to intend to use tenofovir. Women who intended to use tenofovir were also more likely to report use of the female condom, a woman-initiated HIV prevention method, than women who did not intend to use tenofovir.

Women differed on other characteristics as well. For instance, women intending to use tenofovir had significantly greater odds of perceiving the product characteristics more positively than women not intending to use it. They also had significantly greater odds of reporting more confidence in using it than women who did not intend to use tenofovir. Lastly, women intending to use tenofovir also had significantly greater odds in reporting higher levels of sexual and HIV risk than women who did not intend to use the product.

Table 4.3 ***Respondent Characteristics and Unadjusted Associations with Intentions to Use Tenofovir***

Characteristic	Intend to Use Tenofovir	Do not Intend to Use Tenofovir	Unadjusted OR (95% CI)
	(n = 221)	(n = 127)	
Age (%)			
18-25	31.67	29.92	1.00 (Referent)
26-35	28.05	33.86	.78 (.45,1.36)
36-55	40.27	36.22	1.05 (.62, 1.79)
Income (%)			
≤$34,999	65.14	52.80	1.67 (1.07, 2.61)*
≥$35,000	34.86	47.20	1.00 (Referent)
Race/ethnicity (%)			
Non-Hispanic White	53.39	58.73	.81 (.52, 1.25)
Other[¥]	46.61	41.27	1.00 (Referent)
Relationship status (%)			
Living Together and Married	29.86	28.35	1.00 (Referent)
Single/Divorced/Separated/Widowed	70.14	71.65	.93 (.57, 1.50
Education Level (%)			
≤ Grades 12	50.68	29.13	2.50 (1.57, 3.98)***
≥Bachelor's	49.32	70.87	1.00 (Referent)
Barrier Methods (%)			
Used	81.00	80.31	1.04 (.60, 1.81)
Not Used	19.00	19.69	1.00 (Referent)
Male Condom (%)			
Used	86.88	88.98	.82 (.41, 1.61
Not Used	13.12	11.02	1.00 (Referent)
Female Condom (%)			
Used	19.00	8.66	2.47 (1.22, 5.00)**
Not Used	81.00	91.34	1.00 (Referent)
Number of Lifetime Sexual Partners (%)			
1 to 4	22.22	28.00	1.00 (Referent)
5 to 10	28.24	26.50	1.34 (.73, 2.47)
11 to 28	22.22	24.00	1.17 (.62, 2.19)
≥ 29	27.31	21.60	1.59 (.85, 2.99)
Recent Sexual Partners (%)			
1	42.06	42.62	1.00 (Referent)
2 to 3	31.78	38.52	.84 (.50, 1.38)
≥ 4	26.17	18.85	1.41 (.78, 2.54)
Perceptions of Risk (SD)	3.15 (0.90)	3.29 (0.82)	.83 (.64, 1.07)
Method Characteristics (SD)	3.10 (0.51)	2.77(0.52)	3.50 (2.15, 5.68)***
Self-Efficacy (SD)	3.95 (0.96)	3.46 (1.07)	1.59 (1.27, 1.98)***
Sexual and HIV Risk (SD)	2.33 (1.83)	1.78 (1.21)	1.26 (1.08, 1.47)***

*p<0.05, ** p<0.01, *** p<0.001 according to the Wald test of significance.
[¥]The "other" category includes women who identified as Hispanic, Afro-Canadian, Asian, Arab or all other races/ethnicities.
OR = odds ratio, CI =confidence interval

Comparisons between Women who Prefer Microbicides or Tenofovir.

Respondents between the ages of 26 and 55 had significantly greater odds of preferring microbicides. This was the only sociodemographic variable that was significant in the bivariate analysis. Women who were less likely to prefer tenofovir were more likely to have used barrier methods for contraception. Other characteristics also proved to be significant in the bivariate analysis. Women who had four or more recent sexual partners were also less likely to prefer tenofovir. Additionally, women who perceived microbicide characteristics more positively were also less likely to prefer tenofovir. Women who perceived the characteristics of tenofovir more positively were more likely to prefer tenofovir. Finally, women who were highly confident about using microbicides were less likely to prefer tenofovir and women who were highly confident about using tenofovir were more likely to prefer it as an HIV prevention method (Table 4.4).

Table 4.4 ***Respondent Characteristics and Unadjusted Associations with Product Preference***

Characteristic	Microbicides	Tenofovir	Unadjusted OR (95% CI)
	(n = 116)	(n = 230)	
Age (%)			
18-25	18.10	37.83	1.00 (Referent)
26-35	37.07	26.52	.34 (.18, .63)***
36-55	44.83	35.65	.38 (.21, .67)***
Income (%)			
≤$34,999	53.91	63.88	1.15 (.98, 2.38)
≥$35,000	46.06	36.12	1.00 (Referent)
Race/ethnicity (%)			
Non-Hispanic White	50.86	57.64	1.31 (.83, 2.06)
Other[¥]	49.14	42.36	1.00 (Referent)
Relationship status (%)			
Living Together and Married	29.31	29.57	1.00 (Referent)
Single/Divorced/Separated/Widowed	70.69	70.43	.99 (.61, 1.61)
Education Level (%)			
≤ Grades 12	37.93	45.65	1.37 (.87, 2.17)
≥Bachelor's	62.07	54.35	1.00 (Referent)
Hormonal Methods (%)			
Used	76.72	82.61	1.44 (.83, 2.50)
Not Used	23.28	17.39	1.00 (Referent)
Barrier Methods (%)			
Used	47.41	30.43	.48 (.31, .76)**
Not Used	52.59	69.57	1.00 (Referent)
Male Condom (%)			
Used	87.93	87.39	.95 (.48, 1.88)
Not Used	12.07	12.61	1.00 (Referent)
Female Condom (%)			
Used	15.52	15.22	.98 (.53, 1.81)
Not Used	84.48	84.78	1.00 (Referent)
Number of Lifetime Sexual Partners (%)			
1 to 4	19.64	26.87	1.00 (Referent)
5 to 10	26.79	28.19	.77 (.40, 1.48)
11 to 28	24.11	22.47	.68 (.34, 1.34)
≥ 29	29.46	22.47	.56 (.29, 1.07)
Recent Sexual Partners (%)			
1	38.18	44.64	1.00 (Referent)
2 to 3	31.82	35.71	.96 (.56, 1.64)
≥ 4	30.00	19.64	.56 (.31, 1,00)*
Perceptions of Risk Mean Score (SD)	3.14 (0.87)	3.23 (0.87)	1.13 (.89, 1.46)
Method Characteristics Microbicides(SD)	2.80 (0.56)	2.69 (0.48)	.64 (.41, 1.00)*
Method Characteristics Tenfovir (SD)	2.90 (0.56)	3.03 (0.50)	1.62 (1.05, 2.50)*
Self-Efficacy Microbicides(SD)	3.38 (1.04)	3.11(0.96)	.76 (.60, .96)*
Self-Efficacy Tenofovir (SD)	3.57 (1.05)	3.87 (0.99)	1.33 (1.07, 1.66)**
Sexual and HIV Risk (SD)	2.16 (1.63)	2.11 (1.68)	.98 (.85-1.13)

*p< 0.05, **p<0.01, ***p<0.001 according to the Wald test of significance.
[¥]The "other" category includes women who identified as Hispanic, Afro-Canadian, Asian, Arab or all other races/ethnicities.
OR = odds ratio, CI =confidence interval

Multivariate Results.

Factors associated with Intentions to use Microbicides.

The results of multiple logistic regression analysis conducted to assess what factors significantly predict intentions to use microbicides are summarized in Table 4.5. .

Significant predictors of intentions to use microbicides among women were perceptions of HIV risk, positive perceptions of microbicide characteristics, and self efficacy. A higher scale score corresponded to a lower perception of risk, so women who perceived themselves to be at less risk for acquiring HIV or an STI were less likely to intend to use a microbicide. Greater self-efficacy and positive perceptions of microbicide characteristics were significantly associated with intentions to use a microbicide.

Table 4.5 ***Logistic Regression Analysis: Predicting Intentions to Use Microbicides***

Characteristic	Odds Ratio (OR)	SE	Confidence Interval (CI)
Age (%)			
18-25	1.00 (Referent)		
26-35	1.02	.34	(.53, 1.97)
36-55	1.34	.47	(l.71, 2.68)
Income (%)			
≤$34,999	1.56	.546	(.87, 2.79)
≥$35,000	1.00 (Referent)		
Education Level (%)			
≤ Grades 12	1.41	.45	(.76, 2.62)
≥Bachelor's	1.00 (Referent)		
Barrier Methods (%)			
Used	1.21	.37	(.66, 2.22)
Not Used	1.00 (Referent)		
Female Condom (%)			
Used	1.58	.72	(.65, 3.86)
Not Used	1.00 (Referent)	90.15	
Perceptions of Risk	.72	.12	(.51, 1.00)*
Method Characteristics	2.39	.70	(1.34, 4.24)**
Self-Efficacy Microbicides	2.07	.31	(1.54, 2.78)***
Sexual and HIV Risk	1.07	.10	(.89, 1.28)

*p<0.05, ** p<0.01, ***p<0.001 according to the Wald test of significance.
¥The "other" category includes women who identified as Hispanic, Afro-Canadian, Asian, Arab or all other races/ethnicities.
OR = odds ratio, CI =confidence interval

Factors Associated with Intentions to Use Tenofovir.

The results of multiple logistic regression analysis conducted to assess what factors significantly predict intentions to use tenofovir are summarized in Table 4.6. Significant predictors of intentions to use tenofovir were education, positive perceptions of tenofovir characteristics, self-efficacy, and sexual and HIV risk. Compared to the women with a bachelor's degree or higher, women with less than a grade 12 education

had greater odds of intending to use tenofovir. Greater self-efficacy, positive perceptions of tenofovir characteristics, and greater sexual and HIV risk was associated with intentions to use tenofovir.

Table 4.6 ***Logistic Regression Analysis: Predicting Intentions to Use Tenofovir***

Characteristic	Odds Ratio (OR)	SE	Confidence Interval (CI)
Income (%)			
≤$34,999	1.37	.39	(.79, 2.38)
≥$35,000	1.00 (Referent)		
Education Level (%)			
≤ Grades 12	2.36	.69	(1.33, 4.19)**
≥Bachelor's	1.00 (Referent)		
Female Condom (%)			
Used	1.59	.65	(.72, 3.54)
Not Used	1.00 (Referent)	90.15	
Method Characteristics	2.76	.80	(1.56, 4.88)***
Self-Efficacy Tenofovir	1.68	.24	(1.27, 2.22)***
Sexual and HIV Risk	1.22	.11	(1.02, 1.47)*

*p<0.05, ** p<0.01, ***p<0.001 according to the Wald test of significance.
OR = odds ratio, CI =confidence interval

Factors Associated with Product Preference.

The results of multiple logistic regression analysis conducted to assess what factors significantly predict product preference are summarized in Table 4.7. Similar to the previous tables, this table also highlights the results among the full sample of women. Significant predictors of product preference were barrier method use, positive perceptions of microbicide characteristics, microbicide self-efficacy, positive perception of tenofovir characteristics, and tenofovir self-efficacy. Women who used a barrier method for contraception were less likely to prefer tenofovir as a prevention method. Women who perceived microbicide characteristics more positively and had greater self-efficacy with microbicide use were also less likely to prefer tenofovir. Women who perceived the product characteristics of tenofovir more positively and had greater self-efficacy with its use were also more likely to prefer tenofovir.

Table 4.7 ***Logistic Regression Analysis: Predicting Product Preference***

Characteristic	Odds Ratio (OR)	SE	Confidence Interval (CI)
Age			
18-25	1.00 (Referent)		
26-35	.55	.19	(.28, 1.08)
36-55	.65	.23	(.34, 1.26)
Barrier Methods			
Used	.54	.14	(.32, .90)*
Not Used	1.00 (Referent)		
Method Characteristics Microbicides	.31	.11	(.15, .65)**
Self-Efficacy Microbicides	.47	.09	(.33, .68)***
Method Characteristics Tenofovir	4.05	1.52	(1.93, 8.48)***
Self-Efficacy Tenofovir	1.88	.34	(1.33, 2.67)***

* p<0.05, **p<0.01, *** p<0.001 according to the Wald test of significance.
OR = odds ratio, CI =confidence interval

Results for the Sub Sample of Women (Currently Partnered Women)

Bivariate Results.

Comparisons between Women who Intend and do not Intend to Use Microbicides.

The characteristics for women who intend to use and do not intend to use microbicides are presented in Table 4.8. Women who intended to use microbicides were more likely to have lower incomes and be less educated. Women who experienced gender-based violence had greater odds of intending to use a microbicide than women who did not. Women who perceived the characteristics of microbicides more positively and were more confident about using it also had a greater odds of intending to use microbicides.. Finally, women who reported significantly less power and control in their relationships also had greater odds of intending to use microbicides.

Table 4.8 ***Respondent Characteristics and Unadjusted Associations with Intentions to Use Microbicides, Currently Partnered Women***

Characteristic	Intend to Use Microbicides	Do not Intend to Use Microbicides	Unadjusted OR (95% CI)
	(n =130)	(n = 84)	
Age (%)			
18-25	32.31	38.10	1.00 (Referent)
26-35	30.77	36.90	.98 (.51, 1.90)
36-55	36.92	25.00	1.74 (.87,3.47)
Income (%)			
≤$34,999	63.78	42.17	2.41 (1.37, 4.25)**
≥$35,000	36.22	57.83	1.00 (Referent)
Race/ethnicity (%)			
Non-Hispanic White	50.77	61.90	.63 (.36, 1.10)
Other[¥]	49.23	38.10	1.00 (Referent)
Relationship status (%)			
Living Together and Married	41.54	46.43	1.00 (Referent)
Single/Divorced/Separated/Widowed	58.46	53.57	1.22 (.70, 2.2)
Education Level (%)			
≤ Grades 12	50.00	22.62	3.42 (1.85, 6.33)***
≥Bachelor's	50.00	77.38	1.00 (Referent)
Barrier Methods (%)			
Used	36.15	33.33	1.13 (.64, 2.02)
Not Used	63.85	66.67	1.00 (Referent)
Male Condom (%)			
Used	91.54	85.71	1.80 (.75, 4.30)
Not Used	8.46	14.29	1.00 (Referent)
Female Condom (%)			
Used	15.38	9.52	1.73 (.72, 4.12)
Not Used	84.62	90.48	1.00 (Referent)
Number of Lifetime Sexual Partners(%)			
1 to 4	25.58	28.92	1.00 (Referent)
5 to 10	24.03	28.92	.94 (.44, 1.99)
11 to 28	27.13	20.48	1.50(.68, 3.27)
≥ 29	23.26	21.69	1.21 (.55, 2.66)
Recent Sexual Partners(%)			
1	43.85	45.68	1.00 (Referent)
2 to 3	32.31	37.04	.91 (.49, 1.70)
≥ 4	23.85	17.28	1.44 (.68, 3.06)
Gender-Based Violence (%)			
No	71.32	83.33	1.00 (Referent)
Yes	28.68	16.67	2.01 (1.01, 4.01)*
Perceptions of Risk (SD)	3.10(0.84)	3.30(086)	.75 (.53, 1.05)
Method Characteristics (SD)	2.81(0.49)	2.53(0.46)	3.82 (1.93, 7.58)***
Self-Efficacy Microbicides (SD)	3.44(0.95)	2.80(0.88)	2.05 (1.49, 2.81)***
Sexual and HIV Risk (SD)	2.23(1.67)	1.84(1.41)	1.18 (.98, 1.43)
Commitment (SD)	3.26(0.65)	3.27(0.65)	.97 (.64, 1.50)
Relationship Power and Control (SD)	1.83(0.69)	1.55(0.56)	2.06 (1.27, 3.34)**
Social Norm (SD)	2.47(0.71)	2.32(0.78)	1.34 (.91, 1.99)

* p< 0.05, ** p<0.01, ***p<0.001 according to the Wald test of significance.
[¥]The "other" category includes women who identified as Hispanic, Afro-Canadian, Asian, Arab or all other races/ethnicities.
OR = odds ratio, CI =confidence interval

Comparisons between Women who intend and do not intend to Use Tenofovir.

The characteristics for currently partnered women who intend to use and do not intend to use tenofovir are displayed in Table 4.9. Women with lower income and

education levels had significantly greater odds of using tenofovir. Women who experienced gender-based violence had greater odds of using tenofovir. Women differed on other characteristics as well. For instance, women who perceived the tenofovir more positively, felt more confident about using it, and had higher levels of sexual risk had greater odds of intending to use tenofovir than women not intending to use it.

Table 4.9 ***Respondent Characteristics and Unadjusted Associations with Intentions to Use Tenofovir, Currently Partnered Women***

Characteristic	Intend to Use Tenofovir	Do not Intend to Use Tenofovir	Unadjusted OR (95% CI)
	(n = 138)	(n = 81)	
Age (%)			
18-25	37.68	29.63	1.00 (Referent)
26-35	31.16	37.04	.66 (.34, 1.30)
36-55	31.16	33.33	.74 (.37, 1.45)
Income (%)			
≤$34,999	60.74	45.57	1.84 (1.05, 3.24)*
≥$35,000	39.26	54.43	. 1.00 (Referent)
Race/ethnicity (%)			
Non-Hispanic White	52.17	60.49	.71 (.41, 1.24)
Other[¥]	47.83	39.51	1.00 (Referent)
Relationship status (%)			
Living Together and Married	45.65	38.27	1.00 (Referent)
Single/Divorced/Separated/Widowed	54.35	61.73	.74 (.42, 1.29)
Education Level (%)			
≤ Grades 12	48.55	23.46	3.08 (1.67, 5.68)***
≥Bachelor's	51.45	76.54	1.00 (Referent)
Hormonal Methods (%)			
Used	82.61	82.72	.99 (.48, 2.05)
Not Used	17.39	17.28	1.00 (Referent)
Male Condom (%)			
Used	90.58	87.65	1.35 (.56, 3.25)
Not Used	9.42	12.35	1.00 (Referent)
Female Condom (%)			
Used	15.22	8.64	1.90 (.77,4.68)
Not Used	84.78	91.36	1.00 (Referent)
Number of Lifetime Sexual Partners(%)			
1 to 4	25.74	28.40	1.00 (Referent)
5 to 10	27.21	22.22	1.35 (.62, 2.91)
11 to 28	23.53	25.93	1.00 (.47, 2.14)
≥ 29	23.53	23.46	1.11 (.51, 2.40)
Recent Sexual Partners (%)			
1	43.38	45.00	1.00 (Referent)
2 to 3	33.09	33.75	1.02 (.54, 1.91)
≥ 4	23.53	21.25	1.15 (.56, 2.36)
Gender-Based Violence (%)			
No	71.53	83.95	1.00 (Referent)
Yes	28.47	16.05	2.08 (1.03, 4.19)*
Perceptions of Risk (SD)	3.14(0.81)	3.28(0.81)	.82 (.59, 1.15)
Method Characteristics (SD)	3.10(0.50)	2.80(0.51)	3.38 (1.83, 6.22)***
Self-Efficacy Tenofovir (SD)	3.96(0.92)	3.50(1.09)	1.58 (1.19, 2.10)***
Sexual and HIV Risk (SD)	2.28(1.74)	1.73(1.20)	1.29 (1.04, 1.59)*
Commitment (SD)	3.27(0.66)	3.24(0.64)	1.09 (.72, 1.66)
Relationship Power and Control (SD)	1.77(0.67)	1.62(0.63)	1.43 (.92, 2.24)
Social Norm (SD)	2.40(0.70)	2.41(0.74)	.99 (.68, 1.46)

*p<0.05, **p<0.01, ***p<0.001according to the Wald test of significance.
[¥]The "other" category includes women who identified as Hispanic, Afro-Canadian, Asian, Arab or all other races/ethnicities.
OR = odds ratio, CI =confidence interval

Comparisons between Currently Partnered Women who Prefer Microbicides versus Tenofovir.

The characteristics of currently partnered women who prefer either microbicides or tenofovir can be found in Table 4.10. Compared with women between the ages of 18-25, women who were older had lower odds of preferring tenofovir. This was the only socio-demographic variable that was significant in the bivariate analysis. Additionally, women who had used hormonal methods for pregnancy prevention were more likely to prefer tenofovir, while women who had used barrier methods were less likely to prefer tenofovir. Compared to women with between one and four lifetime sexual partners, women with equal to or greater than 29 lifetime sexual partners had lesser odds of preferring tenofovir. Similarly, women with equal to or greater than 4 recent sexual partners had lower odds of preferring tenofovir. Furthermore women who perceived the characteristics of microbicides positively had significantly lower odds of preferring tenofovir. In contrast, women who perceived the characteristics of tenofovir more positively and who were highly confident about using it had significantly greater odds of preferring tenofovir.

Table 4.10 ***Respondent Characteristics and Unadjusted Associations with Product Preference, Currently Partnered Women***

Characteristic	Microbicides	Tenofovir	Unadjusted OR (95% CI)
	(n = 73)	(n = 145)	
Age (%)			
18-25	21.92	41.38	1.00 (Referent)
26-35	36.99	31.72	.45 (.23, .94)*
36-55	41.10	26.90	.35 (.27, .72)**
Income (%)			
≤$34,999	51.39	57.04	1.26 (.71, 2.22)
≥$35,000	48.61	42.96	1.00 (Referent)
Race/ethnicity (%)			
Non-Hispanic White	49.32	58.62	1.46 (.83, 2.56)
Other[¥]	50.68	41.38	1.00 (Referent)
Relationship status (%)			
Living Together and Married	39.73	44.83	1.00 (Referent)
Divorced/Separated/Widowed	60.27	55.17	.81 (.46, 1.43)
Education Level (%)			
≤ Grades 12	38.36	40.00	1.07 (.60, 1.91)
≥Bachelor's	61.64	60.00	1.00 (Referent)
Hormonal Methods (%)			
Used	75.34	86.21	2.05 (1.00, 4.17)*
Not Used	24.66	13.79	1.00 (Referent)
Barrier Methods			
Used	46.58	28.28	.45 (.25, .81)**
Not Used	53.42	71.72	1.00 (Referent)
Male Condom (%)			
Used	91.78	88.28	.67 (.25, 1.79)
Not Used	8.22	11.72	1.00 (Referent)
Female Condom (%)			
Used	15.07	11.72	.75 (.33, 1.69)
Not Used	84.93	88.28	1.00 (Referent)
Number of Lifetime Sexual Partners (%)			
1 to 4	19.18	30.77	1.00 (Referent)
5 to 10	21.92	27.27	.78 (.34, 1.79)
11 to 28	27.40	23.08	.53 (.23, 1.19)
≥ 29	31.51	18.88	.37 (.16, .85)*
Recent Sexual Partners (%)			
1	39.73	46.48	1.00 (Referent)
2 to 3	30.14	35.21	1.00 (.51, 1.94)
≥ 4	30.14	18.31	.52 (.25, 1.06)*
Gender-Based Violence (%)			
No	76.71	75.69	1.00 (Referent)
Yes	23.29	24.31	1.06 (.55, 2.05)
Perceptions of Risk (SD)	3.16(0.87)	3.20(0.84)	1.05 (.75, 1.47)
Method Characteristics Microbicides (SD)	2.79(0.56)	2.66(0.46)	.59 (.32, 1.05)*
Method CharacteristicsTenofovir (SD)	2.90(0.56)	3.04(0.47)	1.77 (1.00, 3.13)*
Self-Efficacy Microbicides	3.27(1.01)	3.14(0.94)	.87 (.65, 1.18)
Self-Efficacy Tenofovir	3.53(1.03)	3.91(0.97)	1.44 (1.08, 1.90)**
Sexual and HIV Risk (SD)	2.23(1.60)	2.01(1.58)	.92 (.77, 1.1)
Commitment (SD)	3.32(.058)	3.24(0.68)	.82 (.53, 1.29)
Relationship Power andControl (SD)	1.73(0.71)	1.71(0.66)	.95 (.62, 1.46)
Social Norm (SD)	2.44(0.75)	2.40(0.69)	.91 (.61, 1.36)

*p<0.05, ** p<0.01, *** p<0.001according to the Wald test of significance.
[¥]The "other" category includes women who identified as Hispanic, Afro-Canadian, Asian, Arab or all other races/ethnicities.
OR = odds ratio, CI =confidence interval

Multivariate Results.

Factors associated with Intentions to use Microbicides.

The results of multiple logistic regression analysis conducted to assess what factors significantly predict intentions to use microbicides are summarized in Table 4.11. Significant predictors of intentions to use microbicides among these women were education, positive perceptions of microbicide characteristics, and self efficacy. Women with less than or equal to Grades 12 education were more likely to intend to use microbicides. Women who perceived the product characteristics more positively and felt confident about using the product were also more likely to intend to use microbicides.

Table 4.11 ***Logistic Regression Analysis: Predicting Intentions to Use Microbicides, Currently Partnered Women***

Characteristic	Odds Ratio (OR)	SE	Confidence Interval (CI)
Income			
≤$34,999	1.35	.49	(.66, 2.76)
≥$35,000	1.00 (Referent)		
Education Level			
≤ Grades 12	2.06	1.05	(1.18, 5.74)*
≥Bachelor's	1.00 (Referent)		
Gender-Based Violence			
Yes	1.03	.54	(.37, 2.87)
No	1.00 (Referent)		
Method Characteristics	2.31	.87	(1.11, 4.84)*
Self-Efficacy	2.07	.41	(1.41, 3.05)***
Relationship Power and Control	1.73	.65	(.83, 3.63)

*p<0.05, **p<0.01, ***p<0.001according to the Wald test of significance.
OR = odds ratio, CI =confidence interval

Factors associated with Intentions to use Tenofovir.

The results of multiple logistic regression analysis conducted to assess what factors significantly predict intentions to use tenofovir are summarized in Table 4.12. This table also highlights the results among women who are currently partnered. Significant predictors of intentions to use tenofovir were education, positive perceptions

of tenofovir characteristics, and self-efficacy. Respondents with an education level less than or equal to Grade 12 were more likely to intend to use microbicides. Additionally, women who perceived the product characteristics more positively and had greater confidence about using it were more likely to intend to use tenofovir.

Table 4.12 ***Logistic Regression Analysis: Predicting Intentions to Use Tenofovir, Currently Partnered Women***

Characteristic	Odds Ratio (OR)	SE	Confidence Interval (CI)
Income (%)			
≤$34,999	1.21	.43	(1.43, 6.85)
≥$35,000	1.00 (Referent)		
Education Level			
≤ Grades 12	3.13	1.25	(.60, 2.43)**
≥Bachelor's	1.00 (Referent)		
Gender-Based Violence			
Yes	1.29	.58	(.54, 3.09)
No	1.00 (Referent)	90.15	
Method Characteristics-Tenofovir	3.23	1.20	(1.55, 6.70)**
Self-Efficacy Tenofovir	1.67	.29	(1.18, 2.36)**
Sexual and HIV Risk	1.26	.17	(.97, 1.63)

* p< 0.05, ** p<0.01, *** p<0.001according to the Wald test of significance.
OR = odds ratio, CI =confidence interval

Factors Associated with Product Preference.

The results of multiple logistic regression analysis conducted to assess what factors significantly predict product preference are summarized in Table 4.13. The only significant predictors of product preference were barrier method and hormonal method use. Respondents who used barrier methods for contraception were less likely to prefer tenofovir as an HIV prevention method and respondents who used hormonal methods for contraception were more likely to prefer it as a prevention method.

Table 4.13 ***Logistic Regression Analysis: Predicting Product Preference, Currently Partnered Women***

Characteristic	Odd Ratio (OR)	SE	Confidence Interval (CI)
Age			
18-25	1.00 (Referent)		
26-35	.64	.26	(.29, 1.44)
36-55	.60	.26	(.25, 1.41)
Barrier Methods			
Used	.50	.17	(.26, .97)*
Not Used	1.00 (Referent)		
Hormonal Methods			
Used	2.50	1.02	(.1.12, 5.58)*
Not Used	1.00 (Referent)		
Lifetime Sex Partners			
1 to 4	1.00 (Referent)		
5 to 10	.57	.27	(.23, 1.46)
11 to 28	.55	.28	(.21, 1.49)
≥29	.59	.34	(.19, 1.80)
Recent Sex Partners			
1	1.00 (Referent)		
2 to 3	1.09	.44	(.21, 1.49)
≥ 4	.72	.34	(.28, 1.84)
Method CharacteristicsTenofovir	1.64	.54	(.86, 3.11)
Self-Efficacy Tenofovir	1.26	.21	(.90, 1.74)

*p<0.05, **p<0.01, ***p<0.001according to the Wald test of significance.
OR = odds ratio, CI =confidence interval

Chapter 5 : DISCUSSION

In this chapter I provide a discussion of the results of this study. Then, public health implications, study limitations, and suggestions for future research are presented. Finally, I end the chapter with concluding remarks.

Since the early 1990s, advocates, researchers, and policymakers have argued for the development of female-initiated methods to prevent the acquisition of HIV/AIDS among women. When HIV/AIDS reached a tipping point in the late 1990s and data revealed that nearly half of all people infected by HIV/AIDS were women, it became a public health imperative. Need for a female-initiated option became critical and research efforts surged in an effort to find a viable solution for women. These attempts came in the form of the female condom, microbicides, and pre-exposure prophylaxis (PrEP). The female condom is currently available on the market for broad use, but the latter two products while passing the "proof-of-concept" phase have yet to be proven effective strategies in preventing the acquisition of HIV/AIDS.

While we wait for an effective product to be brought to the market, the findings from this study help clarify who would be potential consumers of these products. The study also furthers the dialogue about the acceptability of two female-initiated prevention technologies among women living in Toronto, Canada and raises questions about future research and challenges in developing HIV prevention products for women. Taken together, the results were remarkably consistent across relationship type and prevention methods examined in this study. Furthermore, findings suggest that it is method and user characteristics rather than relationship factors that play an important role in a woman's

intentions to use a prevention product, supporting some elements of the conceptual model outlined on page 64. Results further suggest that no magic bullet for HIV prevention exists and that what is needed is a range of options for women to fully protect themselves.

Factors Associated with Intentions to Use Microbicides, Tenofovir, and Product Preference

The conceptual model proposed that 1) method characteristics, 2) user characteristics, and 3) relationships dynamics and socio-cultural context would influence intentions to use. Some of the findings support this model, but others do not. The first important finding is that perceptions of method characteristics are strongly associated with intentions to use. Women who had positive perceptions of a method's characteristics were more likely to intend to use the product for HIV prevention. Product characteristics are defined as convenience, effectiveness of the product, side-effects and safety, minimized sexual interruption, acceptance by peers, ease of acquisition, prevention of HIV and other STIs, and cost. In this study, women who perceived the product characteristics for microbicides and tenofovir more positively were more likely to intend to use microbicides and tenofovir, respectively, to protect against HIV. Women who were less likely to prefer tenofovir as an HIV prevention method felt more positively about the product characteristics of a microbicide, whereas women who preferred tenofovir felt more positively about its characteristics. These findings parallel other studies that found women were more likely to use a product if they perceived the characteristics to be appealing (Beckman & Harvey, 1996; Coggins et al., 1998; Hammett, Mason et al., 2000; Hammett, Norton et al., 2000; Hardy, de Padua, Osis et al., 1998; Harvey et al., 2003; Mason et al., 2003; Morrow, Fava, Rosen, Vargas et al., 2007)

Several possible explanations exist for this finding, but chief among them may be that women viewed the products so positively because they were asked about hypothetical acceptability and actual use was not examined within the context of their lives. It is possible that perceptions of the products attributes would be less positive if we measured actual use because the daily stressors of life, dynamics of relationships, and socio-cultural context may directly affect use patterns. Despite the limitations in assessing hypothetical acceptability, the finding on perceptions of product characteristics is important because a woman's perceptions of a product's attributes have been strongly linked to consistency of use, method discontinuation, and overall acceptability (Beckman, Harvey, & Tiersky, 1996; Beckman, Murray, & Harvey, 1989; Harvey et al., 2003; Meekers & Richter, 2005). For instance, if women like certain characteristics or perceive them positively, they may be more likely to use the product consistently and correctly throughout the course of their sexual career.

In contrast, negative product perceptions may inhibit correct and consistent use. For example, if a woman perceives a product to be difficult to use, she may be less likely to use it during coitus. Negative perceptions could also promote method discontinuation and have a drastic effect on the product's overall effectiveness in preventing HIV. For instance, if a product is perceived negatively, but is highly effective in preventing HIV, women may be less likely to use it, negating any preventive effect of the product. On the other hand, if it is perceived positively, but has low efficacy, women may be more willing to use the product consistently, thereby improving its prevention effects (Spieler, 1997).

Another reason why women who had positive perceptions of a method's characteristics were more likely to intend to use the product may be because women who perceive a product more positively have experience using a similar product in the past. For instance, if a woman has previously used birth control pills or any other hormonal method for contraception and has had more positive experiences using them, she may perceive a pill to prevent HIV more positively. Similarly, if a woman has had experience with spermicides or any other barrier method for contraception, she may perceive the characteristics of a microbicide more positively. Experiences with similar products may also help explain why women disagree on their perceptions of method attributes, rating some methods more positively than others, suggesting that one product does not appeal to all women. This finding implies that more than one product is needed to prevent HIV, as several researchers have asserted in previous literature (Severy et al., 2005).

In addition to method characteristics, several user characteristics were related to intentions to use and product preference. Self-efficacy, a key user characteristic and theoretical construct measured in this study, was significantly associated with intentions to use both methods for the full sample and the subsample of women. Several plausible explanations may exist for this finding. First, women may feel confident about the product mechanics, contextual factors and relationship issues associated with use. For example, women who intend to use the product feel more confident discussing use with their partner, using it when they are sexually excited, or using it correctly. This finding is consistent with some studies (Bogart et al., 2000a), but inconsistent with results found in Morrow and Fava (2007) where self-efficacy did not significantly predict intentions to

use. The findings on self-efficacy may also augment or work in tandem with the results on product perceptions, with women feeling more confident about using a product because they perceive its characteristics positively.

Although self-efficacy did not significantly predict product preference among currently partnered women, previous use of a contraceptive method did. Women who used hormonal methods for contraception in the past were more likely to prefer tenofovir and those who used barrier methods were less likely to prefer tenofovir. As Beckman and Harvey (1996) point out, prior experiences with contraception can influence method use. For example, women who have used a particular method for contraception in the past may like it or feel comfortable with its characteristics. If, therefore, the new method resembles the method they have used in the past, they may be more likely to perceive the characteristics of a new HIV prevention product positively and feel confident about using it. This result is consistent with other findings in the literature (Darroch & Frost, 1999; Morrow, Fava, Rosen, Christensen et al., 2007). Moreover, the finding is consistent with the tenet of self-efficacy wherein Fishbein and Triandis (2001) suggest that past experiences with an object strongly influence an individual's self-efficacy appraisals (Fishbein, Triandis et al., 2001). The results also buttress the predictive utility of some constructs in the Expanded Theory of Reasoned Action, with past behavior possibly serving as a distal variable influencing self-efficacy, which in turn influences behavioral intention. These data strongly suggest that prior contraceptive experience may contribute to the eventual adoption of a new HIV prevention method.

Another important finding among the full sample of women that lends further support to the importance of user characteristics is risk perception. Women who

perceived themselves to be at greater risk for acquiring HIV/AIDS or an STI in the next 12 months were more likely to intend to use microbicides, a result that is consistent with that of Tolley and Eng (2006) and other studies (Darroch & Frost, 1999; Hammett, Norton et al., 2000; Koo et al., 2006). One possible explanation for this result is that women with high risk perception may find microbicides more attractive than current HIV prevention options, such as the male condom, because it is woman-initiated. Risk perception was not, however, significantly associated with intentions to use tenofovir. This finding was unexpected and difficult to interpret. Similar to microbicides, I expected women with higher risk perceptions to be more likely to intend to use tenofovir, but this was not the case. More investigation is needed to determine if this finding can be replicated and to better understand why women with high risk perception found tenofovir a less attractive option for HIV prevention. Significant findings on microbicides and risk perception, a key construct of the Health Belief Model, also support the need for more studies using an integrative model to predict intentions to use.

It is noteworthy that perceived risk was not a significant predictor of intentions to use among currently partnered women. A likely explanation for this finding may be that women who have a primary partner with whom they are having sex may feel less vulnerable to HIV infection than women who do not have a primary partner and who engage in casual sexual relationships. Indeed, Ellen et al. (2002) found that among adolescents, perceptions of risk were greater with a casual partner than a main partner. A likely scenario is that currently partnered respondents felt that their primary relationship offered them some protection against acquiring an STI or HIV and they did not need a method.

Education, another user characteristic, was also a significant variable in predicting intentions to use tenofovir for the full sample of women and in predicting intentions to use microbicides and tenofovir for currently partnered women. Across relationship types, respondents with a Grade 12 education or less were more likely to intend to use the tenofovir pill than respondents with more education, a finding that is consistent with research from the contraceptive literature where less education was significantly associated with birth control pill use (Harvey, Beckman, & Murray, 1989). A possible explanation for this is that less educated women may feel uncomfortable using a barrier method for contraception as previous research on the sponge and diaphragm have shown (Harvey et al., 1989). In contrast, more educated women may be suspicious of the pill or other hormonal methods and their proposed side-effects and are, therefore, reluctant to use it as an HIV prevention method.

Finally, respondents with higher levels of HIV risk were more likely to intend to use tenofovir. This finding remains consistent with the results of one qualitative study (Mason et al., 2003) but not of other quantitative studies in the microbicide literature (Koo et al., 2006; Morrow, Fava, Rosen, Christensen et al., 2007; Weeks et al., 2004). In contrast, previous studies on condom use intentions, have indicated that women with more sexual and HIV risk, such as a having had an STI in the last 12 months, had greater condom use intentions (Rosengard et al., 2005). One possible explanation for the present study's finding is that women who had a relatively high level of sexual and HIV risk, were more likely to prefer a prevention method that was not coitus-dependent. Nearly 20% of the respondents traded sex for money or drugs. In such sexual scenarios, a pill does not require the same type of negotiation that a barrier method, including a

microbicide, might. Thus, for these women, intentions to use an innovative product that offers them protection against HIV in pill form would be high.

Relationship dynamics and socio-cultural context were not significantly associated with intentions to use or product preference, a finding that did not support the proposed conceptual model. Several researchers and advocates have argued that although product characteristics are important to assess in the overall acceptability of a product, factors such as relationship power and control, experiences of gender-based violence, and other relationship factors may influence use patterns. In other words, relationship context matters just as much as the product itself. Previous studies have indicated that less powerful women have difficulty insisting on condom use, and thus would be interested in using a woman-initiated option that confers power to the woman to make HIV prevention decisions (Pettifor et al., 2004). Findings on relationship dynamics and socio-cultural context in the present study did not parallel results of other studies where relationship dynamics or more specifically, having less relationship power and contro,l were significantly associated with intentions to use (Mosack et al., 2005; Wang et al., 2008; Weeks et al., 2004). Several reasons may exist for this result, but chief among them is that women who intend to use microbicides and tenofovir felt just as powerful as women who do not intend to use tenofovir and microbicides. This finding suggests that women who perceive equal power in relationships may have the skills and ability to negotiate HIV prevention method use. Second, women were asked about their acceptability of two woman-initiated products where negotiating use with a male partner is not an issue. Instead, if this study compared the acceptability of a woman-initiated method to a

partner-dependent method such as the male condom, relationship power may have influenced intentions to use and preference.

The findings on relationship power and control may be related to subjective norm, another construct that was not significantly associated with intentions to use. Consistent with findings from Morrow and Fava (2007), respondents' intentions to use microbicides or tenofovir were not influenced by their perceived partner and peer norms regarding sexual behavior. However, this finding does not parallel other results where subjective norm was significantly associated with intentions to use condoms (Sheeran & Taylor, 1999). One possible explanation is that partner or peer perceptions regarding safe sex behavior had little influence on women because they felt relatively powerful and autonomous in their relationships.

The weak role of gender-based violence as a predictor was not an unexpected finding, chiefly because experiences of gender-based violence have not been found to predict intentions to use microbicides in previous literature (Mosack et al., 2005; Weeks et al., 2004). Microbicides are less covert than tenofovir and I wanted to determine if women who have experienced gender-based violence at the hands of their partner may be more likely to use a more covert method, such as a pill to protect against HIV. A possible explanation for this finding may be related to the construct of relationship power and control where women, in general, felt they had strong negotiation skills and did not feel the need to use more covert methods of HIV prevention.

Public Health Implications

The findings from this particular study have important implications for public health, from building the skills and awareness of women who may be at risk for HIV or

STIs to the development of new products. As mentioned previously, women who perceived the product more positively were more likely to use it. This finding informs the development and design of new products for HIV prevention. Researchers and scientists need to understand what women really want in an HIV prevention product to make sure that its characteristics are perceived positively. As Beckman and Harvey (1996) argue one of the ways to improve use of prevention products is to change consumers' perceptions of method attributes. This approach involves tailored marketing strategies that reframe perceived negative attributes more positively. For example, if consumers perceive that a product causes pain or irritation, marketers will need to allay fears with campaigns that serve to improve and highlight positive perceptions of a product and ease concerns about use. Providers will have the same task when counseling and recommending prevention methods to women.

Perceptions of product attributes also work in tandem with the importance women place on them. Researchers and consumer product analysts should take a measured approach with the potential female consumer and ask them to rate the characteristics women not only find important in an HIV prevention method, but also how they perceive the characteristics of new methods. A strong disconnect between the two constructs may exist as consumers could rate several characteristics as important, but perceive that the new methods do not have these attributes. As an example, if a consumer thinks ease of use is important in a product, but perceives the product to be difficult to use, the method will likely not be used. Scientists will need to develop a product that is easy to use or focus on ways in which to make the product easier to use.

Another important implication of this study is the reinforced need for skills building and education around new HIV prevention products. As stated previously, women who felt more confident about the product were more likely to intend to use it. For these women, skills building and education will not necessarily be an issue, but for women who feel less confident about using the products substantial training may be warranted to encourage future use. For instance, once a product is developed, providers and planners will need to work with potential consumers to boost their education about the characteristics of the product, including efficacy rates, potential side effects, and affordability. This type of education may also help shift negative product perceptions. Women also need to be armed with skills and instructions on proper use of the product, including vaginal or oral insertion. Previous studies have indicated that with proper education and counseling about a prevention method, women have no trouble acquiring the skills that they need to use a product and the problems that arise with use may diminish over time (van der Straten et al., 2005).

The findings on self-efficacy may have important implications for developers and marketers of new products as well. As posited previously, women who felt confident about intending to use the product had previous experience with similar products. As a result, women may be more likely to use a product that bears a strong resemblance to a product with which they have had a relatively good experience using in the past. Developers may want to think about producing methods that are similar to products that women have used before. Furthermore, as a strategic point, marketers may want to initially promote their new HIV prevention method among a customer base that has used similar products for pregnancy prevention. For example, PrEP needs to be taken once

daily, like the birth control pill. If it is deemed efficacious and ready for public consumption, a marketing strategy that a company or provider might employ would be to publicize PrEP among high-risk, current users of the birth control pill or any other hormonal method to prevent pregnancy.

The finding on perceptions of risk is equally important, but has some troubling implications. As mentioned above, women who perceived themselves to be at greater risk for acquiring HIV/AIDS or an STI in the next 12 months were more likely to intend to use microbicides, but among women who were currently partnered no significant associations were found. I posit that one possible reason for this finding is that women who are either married or believe that their relationship is monogamous may feel more comfortable not using any form of protection against HIV and STIs in a relationship with high levels of trust. For a risky proposition, this belief may make women more vulnerable to HIV infection, since several studies have indicated that marriage can be a primary risk factor for HIV/AIDS, especially in contexts outside of the West (Mmbaga et al., 2007; Newmann et al., 2000). Marketing strategies will need to focus on encouraging partnered women with low to medium risk perception to protect themselves. Additionally, women need more education about the risk of STI and HIV acquisition within the contexts of partnerships so that they can adequately protect themselves.

Similar to risk perception, the finding on education may also have some alarming implications. Women who were more educated were less likely to use either microbicides or tenofovir to prevent HIV. Providers and educators will have to play a key role in encouraging more educated women to use a prevention product, highlighting the product's positive attributes. Additionally, because more educated women may

perceive microbicides or tenofovir to have more side effects, marketers will have to develop advertising campaigns that diminish their importance. Product developers will also have an important role in easing the reservations of more educated women, by working to moderate the actual side-effects of both products.

The final implication of these findings is that women need a range of products to protect themselves against HIV and STIs. In fact, women may be more likely to protect themselves from STIs when presented with a plethora of choices, rather than with one option. One study found that when women were counseled on a variety of prevention methods versus one method only, women in the former group were more likely to protect themselves against HIV and STIs (Gollub et al., 2001). In other words, when presented with a cafeteria of prevention options, women will probably be more likely to protect themselves against disease. This outcome has strong implications for future product development. Product developers will have to heed this call and develop a variety of products that not only prevent disease, but that women perceive positively and feel confident about using.

Limitations

The results of this study must be interpreted within the context of the study limitations. First, this was not a population based survey. Instead I relied on a purposive sampling technique, recruiting women who attended sexual and reproductive health clinics and their partner organizations in the city of Toronto, so it is clearly not a representative sample. Thus, findings cannot be generalized to all women in Toronto, much less women in Canada.

Second, this study relied exclusively on self-report data. According to Portney and Watkins (2000), potential for bias or inaccuracy in self-reports may always be present, especially if there are questions that are personal or controversial in nature. Several of the questions in this survey dealt with sexual and relationship histories. For instance, women were asked to recall the number of lifetime sexual partners and the number of sexual partners they had within the last 12 months. Several women may have inaccurately reported these numbers because they could not recall correctly, were embarrassed or ashamed by the number of sexual partners they did or did not have, and/or were insulted by the question itself. Within the context of HIV, some scientists have argued that intentional misrepresentation and inaccurate recall may introduce measurement error in self-report surveys (Catania et al., 1990). Although some of these factors may be at play in this survey, the recommended use of validated and appropriate measures, language that was easily understood, techniques to improve recall, and appropriate sequencing were all methods employed to reduce measurement error (Weinhardt, Forsyth, Carey, Jaworski, & Durant, 1998). Additionally, the use of a confidential self-administered questionnaire (SAQ) provided respondents with more privacy and the opportunity to be more frank about their behavior than other survey modes.

The final limitation of this study was that it did not measure actual use of either of the products, so responses regarding microbicides and PrEP were based on respondent's perceptions of the hypothetical characteristics of the products. This study assessed potential user responses to a product that is not ready for use among the general public. In essence, we asked respondents to make hypothetical trade-offs among various aspects

of the product. Severy and Newcomer (2005) argue that this type of study can provide researchers with valuable information, but that it does not give us actual information about the user's experience with the product nor does it assess the long-term adoption and use of a product in real-life settings. This study examined the intrapersonal factors, interpersonal factors, and the socio-cultural context within which the participant lives, but it could not do so with an actual product and thus the study could only suggest women's likely interest in both microbicides and PrEP within certain contexts.

Future Research

Several studies have been conducted to assess intentions to use microbicides and although this study is not unique in that respect, it was the first study, to my knowledge, to assess the factors associated with intentions to use tenofovir or PrEP. It was also the first study to assess the factors that are associated with product preference (e.g. Microbicides vs. PrEP). Specific factors were found to be associated with intentions to use microbicides, PrEP and product preference and others were not, among this sample of women. Future research is needed to better inform product acceptability among diverse samples of women.

First, more research should be conducted on the role of product perceptions in determining the acceptability of woman-initiated HIV prevention products. Future investigations should assess perceptions of product attributes among different samples of women. More specifically, Western women may perceive the characteristics of a product differently than women in Sub-Saharan Africa where socio-cultural norms play a significant role in women's health and reproductive choices.

Second, future research should also focus on the connections between self-efficacy and its relationship to product perceptions and previous contraceptive use among other populations. In this study, all three factors were associated with intentions to use both microbicides and tenofovir, but among a different population results may vary. It will be important to determine if these results can be replicated across populations so that researchers and marketers get a better idea of how women respond to new products and what factors can be manipulated with simple interventions such as skills building and education to promote future use.

Third, although relationship factors did not prove to be significantly associated with intentions to use or product preference among this population of women, future research on these variables, especially in different socio-geographical settings, is warranted. From context to context, social and cultural norms may play a significant role in influencing a woman's decision-making regarding the use of HIV prevention products. As such, in societies where power imbalances exist, intentions to use an HIV prevention product may vary among women, especially in situations where women have less power.

Fourth, more research must be conducted on assessing women's choice and preference in prevention products. It is clear from these findings that all women do not prefer one product, but that a range of prevention options from which to choose is needed. In this study, product perceptions, self-efficacy, and previous experience with contraception were significantly associated with product preference. Future research should focus on other factors that may be associated with preference as they may help complete the picture of women intending to use various HIV prevention products.

Finally, future research is also warranted on the dual role of HIV and pregnancy prevention that both microbicides and PrEP could have. Many respondents indicated in the last, qualitative question of the survey that they hoped microbicides and tenofovir would have a contraceptive effect. Scientists are currently developing microbicides with the primary intention of preventing HIV and other STIs, but insist that a "dual-action" microbicide will not be available until its second or third generation iteration. Similarly, the drug currently being tested as PrEP, tenofovir, does not have contraceptive properties. With advocates and policymakers pushing to integrate reproductive health and HIV programs, the development of a woman-initiated dual protection method other than the female condom and diaphragm, is imperative. It is quite possible that the factors associated with intentions to use microbicides and PrEP would shift if each of these products prevented both disease and pregnancy.

Conclusion

With women comprising nearly 50% of all HIV infections, no better time than now exists for the introduction of a female-initiated prevention method that is both efficacious and women find acceptable. Until we have an effective product, however, it is important to determine what factors are associated with acceptability so that developers, marketers, and providers can get a complete picture of who would use these products.

Findings from various studies have built a body of research that support women's interest in a woman-initiated prevention product (Darroch & Frost, 1999; Weeks et al., 2004), and this study has helped complement their results, presenting a fuller picture of who these women are. Women who perceive the product positively, feel confident about

using them, and have had experiences with similar products would be more likely to intend to use them. These findings are important because there are several strategies that researchers, marketers, and providers can employ including highlighting the positive characteristics of a product, enhancing education about products, and promoting skills-building around product use. Findings have also suggested that relationship/interpersonal factors may not matter in the broader context of a woman's decision-making process to use a product, a striking result given the importance of these factors in other studies. More importantly, this study underscores the need for a wide range of prevention options for women and that scientists should not place their hopes on the "magic bullet," but on many "magic bullets" that provide women with essential protection.

For many, the development of a female-initiated prevention method could not happen soon enough. In his speech at the 2004 Microbicides Conference in London, Stephen Lewis, the former U.N. Special Envoy to Africa, implored the audience of advocates, scientists and policymakers to urgently develop a microbicide, but his words may be applicable to the development of any woman-controlled method.

> I ask only that you see [woman controlled prevention], not merely as one of the great scientific pursuits of the age, but as a significant emancipation for women whose cultural and social and economic inheritance have put them so gravely at risk. Never in human history have so many died for so little reason. You have a chance to alter the course of that history. Can there be any task more noble?

REFERENCES

Acock, A. (2009). Reporting the Reliability of a Two-Item Scale. Corvallis.

Adimora, A. A., Schoenbach, V. J., Bonas, D. M., Martinson, F. E., Donaldson, K. H., & Stancil, T. R. (2002). Concurrent sexual partnerships among women in the United States. *Epidemiology, 13*(3), 320-327.

Adimora, A. A., Schoenbach, V. J., Martinson, F. E., Coyne-Beasley, T., Doherty, I., Stancil, T. R., et al. (2006). Heterosexually transmitted HIV infection among African Americans in North Carolina. *J Acquir Immune Defic Syndr, 41*(5), 616-623.

Agnew, C. R., , , Harvey, S. M., , , Sherman, C. A., & Warren, J. (2008). *Relationship commitment and condom use in young adults: Initial results from the Project on Partner Dynamics*. Paper presented at the American Public Health Association 136th Annual Meeting.

AIDS Vaccine Advocacy Coalition. (2005). *Will a Pill A Day Prevent HIV?* New York: AIDS Vaccine Advocacy Coalition.

AIDS Vaccine Advocacy Coalition. (2010). Microbicide and PrEP Candidates in Ongoing Clinical Trials: Summary as of September 2009. Retrieved February 15, 2010, from http://www.avac.org/ht/a/GetDocumentAction/i/3109

Ajzen, I. (1991). The Theory of Planned Behavior. *Organizational Behavior and Human Decision Processes, 50*, 179-211.

Ajzen, I., & Fishbein, M. (1980). *Understanding Attitudes and Predicting Social Behavior*. Englewood Cliffs, NJ: Prentice Hall.

Albarracin, D., Durantini, M. R., & Earl, A. (2006). Empirical and Theoretical Conclusions of an Analysis of Outcomes of HIV-Prevention Interventions. [Article]. *Current Directions in Psychological Science, 15*(2), 73-78.

Albarracin, D., Kumkale, G. T., & Johnson, B. T. (2004). Influences of social power and normative support on condom use decisions: a research synthesis. *AIDS Care, 16*(6), 700-723.

Alliance for Microbicide Development. (2005). What is a Microbicide. Retrieved February 1, 2006, 2006

Altares, D. (2008). Age and Eligibility Criteria for Microbicide and PrEP Trials. Washington D.C.

Amaro, H. (1995a). Love, sex, and power. Considering women's realities in HIV prevention. *Am Psychol, 50*(6), 437-447.

Amaro, H. (1995b). Love, Sex, and Power: Considering Women's Realities in HIV Prevention. *American Psychologist, 50*(6), 437-447.

Armitage, C. J., & Conner, M. (2001). Efficacy of the Theory of Planned Behaviour: a meta-analytic review. *Br J Soc Psychol, 40*(Pt 4), 471-499.

Ashery, R. S., Carlson, R. G., Falck, R. S., Siegal, H. A., & Wang, J. (1995). Female condom use among injection drug- and crack cocaine-using women. *Am J Public Health, 85*(5), 736-737.

Auerbach, J., Hayes, R., & Kandathil, S. (2006). *Preventing HIV/AIDS in young people. A systematic review of the evidence from developing countries. Introduction and rationale; Overview of effective and promising interventions to prevent HIV infection*.

Balswick, J. O., & Balswick, J. K., . (1995). Gender relations and marital power. In B. B. Ingoldsby & S. Smith (Eds.), *Families in multicultural perspective.* (pp. 297-315). New York, NY, US: Guilford Press.

Bandura, A. (1977). *Self-Efficacy: Toward a Unifying Theory of Behavioral Change*: Psychological Review.

Bandura, A. (1989). Perceived self-efficacy in the exercise of control over AIDS infection. In V. M. Mays, G. W. Albee & S. F. Schneider (Eds.), *Primary prevention of AIDS: Psychological approaches.* (pp. 128-141): Sage Publications, Inc.

Bandura, A. (2004). Health promotion by social cognitive means. *Health Education & Behavior, 31*(2), 143-164.

Basen-Engquist, K. (1992). Psychosocial predictors of "safer sex" behaviors in young adults. *AIDS Educ Prev, 4*(2), 120-134.

Basen-Engquist, K., & Parcel, G. S. (1992). Attitudes, norms, and self-efficacy: a model of adolescents' HIV-related sexual risk behavior. *Health Educ Q, 19*(2), 263-277.

Beckman, L., & Harvey, S. (1996). Factors affecting the consistent use of barrier methods of contraception. *Obstetrics And Gynecology, 88*(3 Suppl), 65S-71s.

Beckman, L. J., Harvey, S. M., & Murray, J. (1992). Dimensions of the contraceptive attributes questionnaire. *Psychol Women Q, 16*(2), 243-259.

Beckman, L. J., Harvey, S. M., & Tiersky, L. A. (1996). Attitudes about condoms and condom use among college students. *J Am Coll Health, 44*(6), 243-249.

Beckman, L. J., Murray, J., & Harvey, S. M. (1989). The contraceptive sponge: factors in initiation and discontinuation of use. *Contraception, 40*(4), 481-496.

Behets, F., Turner, A. N., Van Damme, K., Rabenja, N. L., Ravelomanana, N., Zeller, K., et al. (2005). Acceptability and feasibility of continuous diaphragm use among sex workers in Madagascar. *Sex Transm Infect, 81*(6), 472-476.

Bensley, L. S., Van Eenwyk, J., & Simmons, K. W. (2000). Self-reported childhood sexual and physical abuse and adult HIV-risk behaviors and heavy drinking. *Am J Prev Med, 18*(2), 151-158.

Bentley, M. E., Fullem, A. M., Tolley, E. E., Kelly, C. W., Jogelkar, N., Srirak, N., et al. (2004). Acceptability of a microbicide among women and their partners in a 4-country phase I trial. *Am J Public Health, 94*(7), 1159-1164.

Bentley, M. E., Morrow, K. M., Fullem, A., Chesney, M. A., Horton, S. D., Rosenberg, Z., et al. (2000). Acceptability of a novel vaginal microbicide during a safety trial among low-risk women. *Fam Plann Perspect, 32*(4), 184-188.

Bird, S. T., Harvey, S. M., Maher, J. E., & Beckman, L. J. (2004). Acceptability of an existing, female-controlled contraceptive method that could potentially protect against HIV: a comparison of diaphragm users and other method users. *Womens Health Issues, 14*(3), 85-93.

Blanc, A. K. (2001). The effect of power in sexual relationships on sexual and reproductive health: an examination of the evidence. *Stud Fam Plann, 32*(3), 189-213.

Boer, H., & Mashamba, M. T. (2007). Gender power imbalance and differential psychosocial correlates of intended condom use among male and female adolescents from Venda, South Africa. *Br J Health Psychol, 12*(Pt 1), 51-63.

Bogart, L. M., Cecil, H., & Pinkerton, S. D. (2000a). Hispanic adults' beliefs, attitudes, and intentions regarding the female condom. *J Behav Med, 23*(2), 181-206.

Bogart, L. M., Cecil, H., & Pinkerton, S. D. (2000b). Intentions to Use the Female Condom Among African American Adults. *Journal of Applied Social Psychology, 30*(9), 19223-11953.

Bounds, W., Guillebaud, J., & Newman, G. B. (1992). Female condom (femidom) a clinical study of its use-effectiveness and patient acceptability. *British Journal of Family Planning, 18*, 36-41.

Bowleg, L., Belgrave, F., & Reisen, C. (2000). Gender roles, power strategies, and precautionary self-efficacy: implications for black and Latina women's HIV/AIDS protective behaviors. *Sex Roles, 42,* 613–635.

Boyd, B., & Wandersman, A. (1991). Predicting undergraduate condom use with the Fishbein and Ajzen and the Triandis attitude)ehavior models: Implications for public health interventions. *Journal of Applied Social Psychology, 21*(22), 1810-1830.

Brafford, L. J., & Beck, K. H. (1991). Development and validation of a condom self-efficacy scale for college students. *J Am Coll Health, 39*(5), 219-225.

Brawley, O. W., & Freeman, H. P. (1999). Race and outcomes: is this the end of the beginning for minority health research? *J Natl Cancer Inst, 91*(22), 1908-1909.

Brewer, N., Chapman, G., Gibbons, F., Gerrard, M., McCaul, K., & Weinstei, N. (2007). Meta-analysis of the relationship between risk perception and health behavior: the example of vaccination. *Health Psychology: Official Journal Of The Division Of Health Psychology, American Psychological Association, 26*(2), 136-145.

Brewer, N. T., & Fazekas, K. I. (2007). Predictors of HPV vaccine acceptability: A theory-informed, systematic review. *Prev Med.*

Bryan, A., Fisher, J. D., & Fisher, W. A. (2002). Tests of the mediational role of preparatory safer sexual behavior in the context of the theory of planned behavior. *Health Psychology: Official Journal Of The Division Of Health Psychology, American Psychological Association, 21*(1), 71-80.

Bryan, A. D., Aiken, L. S., & West, S. G. (1996). Increasing condom use: evaluation of a theory-based intervention to prevent sexually transmitted diseases in young women. *Health Psychol, 15*(5), 371-382.

Burger, H., & Weiser, B. (2001). Biology of HIV-1 in women and men. *Clin Obstet Gynecol, 44*(2), 137-143.

Cabral, R., Pulley, L., Artz, L., Brill, I., & Macaluso, M. (1998). Women at risk of HIV/STD: the importance of male partners as barriers to condom use. *AIDS & Behavior, 2*(1), 75-85.

Cardo, D. M., Culver, D. H., Ciesielski, C. A., Srivastava, P. U., Marcus, R., Abiteboul, D., et al. (1997). A case-control study of HIV seroconversion in health care workers after percutaneous exposure. Centers for Disease Control and Prevention Needlestick Surveillance Group. *N Engl J Med, 337*(21), 1485-1490.

Catania, J. A., Gibson, D. R., Chitwood, D. D., & Coates, T. J. (1990). Methodological problems in AIDS behavioral research: influences on measurement error and participation bias in studies of sexual behavior. *Psychol Bull, 108*(3), 339-362.

Centers for Disease Control and Prevention. (2005). *HIV/AIDS Surveillance Report 2004* (No. 16). Atlanta, Georgia: Centers for Disease Control and Prevention.

Centers for Disease Control and Prevention. (2008). HIV/AIDS Among Women. *Centers for Disease Control and Prevention Fact Sheets* Retrieved January 25, 2009, from http://www.cdc.gov/hiv/topics/women/resources/factsheets/women.htm

Centers for Disease Control and Prevention. (2009). *Cases of HIV infection and AIDS in the United States and Dependent Areas, 2007*. Atlanta: Centers for Disease Control and Prevention.

Centers for Disease Control and Prevention. (2010). HIV AIDS Surveillance in Women. *Centers for Disease Control and Prevention Presentations* Retrieved February 10, 2010, from http://www.cdc.gov/hiv/topics/surveillance/resources/slides/women/

Claes, J. A., & Rosenthal, D. M. (1990). Men who batter women: A study in power. *Journal of Family Violence, 5*(3), 215-224.

Coggins, C., Blanchard, K., Alvarez, F., Brache, V., Weisberg, E., Kilmarx, P. H., et al. (2000). Preliminary safety and acceptability of a carrageenan gel for possible use as a vaginal microbicide. *Sex Transm Infect, 76*(6), 480-483.

Coggins, C., Elias, C. J., Atisook, R., Bassett, M. T., Ettiegnene-Traore, V., Ghys, P. D., et al. (1998). Women's preferences regarding the formulation of over-the-counter vaginal spermicides. *Aids, 12*(11), 1389-1391.

Cohen, M., Deamant, C., Barkan, S., Richardson, J., Young, M., Holman, S., et al. (2000). Domestic violence and childhood sexual abuse in HIV-infected women and women at risk for HIV. *Am J Public Health, 90*(4), 560-565.

Connell, R. (1987). *Gender and Power*. Stanford, CA: Stanford University Press.

Conner, M., & Norman, P. (1996). *Predicting Health Behavior: Research and Practice with Social Cognition Models*. Philadelphia: Open University Press.

Connor, E. M., Sperling, R. S., Gelber, R., Kiselev, P., Scott, G., O'Sullivan, M. J., et al. (1994). Reduction of maternal-infant transmission of human immunodeficiency virus type 1 with zidovudine treatment. Pediatric AIDS Clinical Trials Group Protocol 076 Study Group. *N Engl J Med, 331*(18), 1173-1180.

Darroch, J., & Frost, J. (1999). Women's Interest in Vaginal Microbicides. *Family Planning Perspectives, 31*, 16.

DeVellis, R. F. (2003). *Scale development : theory and applications / Robert F. DeVellis* (2nd ed. ed.). Thousand Oaks, Calif. :: SAGE Publications.

Diaz, T., Chu, S. Y., Buehler, J. W., Boyd, D., Checko, P. J., Conti, L., et al. (1994). Socioeconomic differences among people with AIDS: results from a Multistate Surveillance Project. *Am J Prev Med, 10*(4), 217-222.

Dunkle, K. L., Jewkes, R. K., Brown, H. C., Gray, G. E., McIntryre, J. A., & Harlow, S. D. (2004). Gender-based violence, relationship power, and risk of HIV infection in women attending antenatal clinics in South Africa. *Lancet, 363*(9419), 1415-1421.

el-Bassel, N., Krishnan, S. P., Witte, S., Schilling, R. F., Catan, V., & Pollin, S. (1998). Correlates of intention to use the female condom among women taking methadone. *Womens Health Issues, 8*(2), 112-122.

Elias, C., & Coggins, C. (2001). Acceptability research on female-controlled barrier methods to prevent heterosexual transmission of HIV: Where have we been? Where are we going? *J Womens Health Gend Based Med, 10*(2), 163-173.

Elias, C., & Heise, L. L. (1995). Nonoxynol-9: the need for policy in the face of uncertainty. *Aids, 9*(3), 311-312.

Elias, C. J., & Coggins, C. (1996). Female-controlled methods to prevent sexual transmission of HIV. *Aids, 10 Suppl 3*, S43-51.

Ellen, J. M., Adler, N., Gurvey, J. E., Dunlop, M. B., Millstein, S. G., & Tschann, J. (2002). Improving Predictions of Condom Behavioral Intentions With Partner-Specific Measures of Risk Perception. *Journal of Applied Social Psychology, 32*(3), 648-663.

Ellen, J. M., Adler, N., Gurvey, J. E., Millstein, S. G., & Tschann, J. (2002). Adolescent condom use and perceptions of risk for sexually transmitted diseases: a prospective study. *Sex Transm Dis, 29*(12), 756-762.

European Study Group. (1992). Comparison of female to male and male to female transmission of HIV in 563 stable couples. European Study Group on Heterosexual Transmission of HIV. *Bmj, 304*(6830), 809-813.

Farr, G., Gabelnick, H., Sturgen, K., & Dorflinger, L. (1994). Contraceptive efficacy and acceptability of the female condom. *Am J Public Health, 84*(12), 1960-1964.

Finer, L. B., Darroch, J. E., & Singh, S. (1999). Sexual partnership patterns as a behavioral risk factor for sexually transmitted diseases. *Fam Plann Perspect, 31*(5), 228-236.

Fishbein, M. (1967). *Readings in Attitude Theory and Measurement*. New York: Wiley.

Fishbein, M. (2005). Implications of Behavioral Theory for Developing Persuasive Communications. Retrieved July 26, 2007, from http://cancercontrol.cancer.gov/brp/presentations_1/PDFs/fishbein_presentation.pdf

Fishbein, M., & Ajzen, I. (1975). *Belief, Attitude, Intention, and Behavior: An Introduction to Theory and Research*. Reading, MA: Addison-Wesley.

Fishbein, M., Hennessy, M., Kamb, M., Bolan, G. A., Hoxworth, T., Iatesta, M., et al. (2001). Using intervention theory to model factors influencing behavior change. Project RESPECT. *Eval Health Prof, 24*(4), 363-384.

Fishbein, M., Triandis, H. C., Kanfer, F. H., Becker, M., Middlestadt, S. E., & Eichler, A. (2001). Factors influencing behavior and behavior change. In A. Baum, T. A. Revenson & J. E. Singer (Eds.), *Handbook of Health Psychology*. (pp. 3-17). Mahwah, NJ: Lawrence Erlbaum.

Fisher, W. A., Fisher, J. D., & Rye, B. J. (1995). Understanding and promoting AIDS-preventive behavior: insights from the theory of reasoned action. *Health Psychol, 14*(3), 255-264.

Floyd, D. L., Prentice-Dunn, S., & Rogers, R. W. (2000). A Meta-Analysis of Research on Protection Motivation Theory. *Journal of Applied Social Psychology, 30*(2), 407-429.

Ford, N., & Mathie, E. (1993). The acceptability and experience of the female condom, Femidom among family planning clinic attenders. *The British Journal of Family Planning, 19*, 187-192.

Forsyth, A. D., & Carey, M. P. (1998). Measuring self-efficacy in the context of HIV risk reduction: research challenges and recommendations. *Health Psychology: Official Journal Of The Division Of Health Psychology, American Psychological Association, 17*(6), 559-568.

Freeman, E., Weiss, H., Glynn, J., Cross, P., Whitworth, J., & Hayes, R. (2005). Herpes simplex virus type 2 infection increases HIV acquisition in men and women: systematic review and meta-analysis of longitudinal analysis. *submitted*.

French, M. (1986). *Beyond Power: On Women, Men and Morals*. New York City: Ballantine Books.

Garcia-Moreno, C., Watts, C., Ellsberg, M., Heise, L., & Jansen, H. (2005). *WHO Multi-country Study on Women's Health and Domestic Violence Against Women*. Geneva: World Health Organization.

Germain, A., & Woods, Z. (2005). Women's Sexual and Reproductive Health and Rights: A Key to Ending HIV/AIDS. *Development, 48*(4), 56-60.

Gilbert, L. (2000). *The Female Condom in the US: Lessons Learned*: University of Idaho.

Global Campaign for Microbicides. (2007a). Background Information for Advocates on the Premature Closure of the Cellulose Sulfate trials. Retrieved March 6, 2007

Global Campaign for Microbicides. (2007b). Fact Sheet #2: Frequently Asked Questions About Microbicides. Retrieved May 4, 2007

Global HIV Prevention Working Group. (2003). *Access to HIV Prevention: Closing the Gap*. Washington DC: Kaiser Family Foundation.

Global HIV Prevention Working Group. (2007). *Bringing HIV Prevention to Scale: An Urgent Global Priority*. Washington DC.

Godin, G., Gagnon, H., & Lambert, L. D. (2003). Factors associated with maintenance of regular condom use among single heterosexual adults: a longitudinal study. *Can J Public Health, 94*(4), 287-291.

Gold, M. A. (1995). New progestin oral contraceptives and the female condom. *Pediatr Ann, 24*(4), 211-216.

Gollub, E. L., French, P., Latka, M., Rogers, C., & Stein, Z. (2001). Achieving safer sex with choice: studying a women's sexual risk reduction hierarchy in an STD clinic. *J Womens Health Gend Based Med, 10*(8), 771-783.

Gollub, E. L., Stein, Z., & el-Sadr, W. (1995). Short-term acceptability of the female condom among staff and patients at a New York City Hospital. *Fam Plann Perspect, 27*(4), 155-158.

Gomez, C., & Marin, B. (1996). Gender, Culture, and Power: Barriers to HIV-Prevention Strategies for Women. *Journal of Sex Research, 33*(4), 355-362.

Green, G., Pool, R., Harrison, S., Hart, G. J., Wilkinson, J., Nyanzi, S., et al. (2001). Female control of sexuality: illusion or reality? Use of vaginal products in south west Uganda. *Soc Sci Med, 52*(4), 585-598.

Gribble, J., Miller, H., Rogers, S., & Turner, C. (1999). Interview Mode and Measurement of Sexual Behaviors: Methodological Issues. *Journal of Sex Research, 36*(1), 16-24.

Grinstead, O. A., Faigeles, B., Binson, D., & Eversley, R. (1993). Data from the National AIDS Behavioral Surveys. I. Sexual risk for human immunodeficiency virus infection among women in high-risk cities. *Fam Plann Perspect, 25*(6), 252-256, 277.

Guay, L. A., Musoke, P., Fleming, T., Bagenda, D., Allen, M., Nakabiito, C., et al. (1999). Intrapartum and neonatal single-dose nevirapine compared with zidovudine for prevention of mother-to-child transmission of HIV-1 in Kampala, Uganda: HIVNET 012 randomised trial. *Lancet, 354*(9181), 795-802.

Hammett, T. M., Mason, T. H., Joanis, C. L., Foster, S. E., Harmon, P., Robles, R. R., et al. (2000). Acceptability of formulations and application methods for vaginal microbicides among drug-involved women: results of product trials in three cities. *Sex Transm Dis, 27*(2), 119-126.

Hammett, T. M., Norton, G. D., Mason, T. H., Langenbahn, S., Mayer, K. H., Robles, R. R., et al. (2000). Drug-involved women as potential users of vaginal microbicides for HIV and STD prevention: a three-city survey. *J Womens Health Gend Based Med, 9*(10), 1071-1080.

Hardy, E., de Padua, K. S., Jimenez, A. L., & Zaneveld, L. J. (1998). Women's preferences for vaginal antimicrobial contraceptives. II. Preferred characteristics according to women's age and socioeconomic status. *Contraception, 58*(4), 239-244.

Hardy, E., de Padua, K. S., Osis, M. J., Jimenez, A. L., & Zaneveld, L. J. (1998). Women's preferences for vaginal antimicrobial contraceptives. IV. Attributes of a formulation that would protect from STD/AIDS. *Contraception, 58*(4), 251-255.

Harvey, M. (2002). Couple-Level Theoretical Model: Relationship Power. Oregon State University.

Harvey, S. M., Beckman, L. J., Gerend, M. A., Thorburn, S., Posner, S. F., Hustzi, H., et al. (2006). A conceptual model of women's condom use intentions: Integrating intrapersonal and relationship factors. *AIDS Care, 18*(7), 698-709.

Harvey, S. M., Beckman, L. J., & Murray, J. (1989). Factors associated with use of the contraceptive sponge. *Fam Plann Perspect, 21*(4), 179-183.

Harvey, S. M., Bird, S. T., Galavotti, C., Duncan, E. A., & Greenberg, D. (2002). Relationship power, sexual decision making and condom use among women at risk for HIV/STDS. *Women Health, 36*(4), 69-84.

Harvey, S. M., Bird, S. T., Maher, J. E., & Beckman, L. J. (2003). Who continues using the diaphragm and who doesn't: implications for the acceptability of female-controlled HIV prevention methods. *Womens Health Issues, 13*(5), 185-193.

Hearst, N., & Chen, S. (2003). *Condom for AIDS Prevention in the Developing World: A Review of the Scientific Literature*: University of California.

Heck, J. A. (1995). *Low-risk sex practices: Employing the theory of reasoned action to predict intentions to use condoms in women treated at planned parenthood.*, ProQuest Information & Learning.

Heise, L., & Elias, C. (1995). Transforming aids prevention to meet women's needs: a focus on developing countries. *Soc Sci Med, 40*(7), 931-943.

Heise, L., Ellsberg, M., & Gottemoeller, M. (1999). Ending violence against women. *Popul Rep L*(11), 1-43.

Hill, R., Ryan, J., Stone, A., & Fransen, L. (2000.). Vaginal Microbicides for the prevention of HIV/AIDS: assessment of the potential market. *International Journal of Pharmaceutical Medicine*(14), 271-278.

Hoffman, S., Exner, T., Leu, C., Ehrhardt, A., & Stein, Z. (2003). Female-condom use in a gender-specific family planning clinical trial. *American Journal of Public Health, 93*(11), 1897-1903.

Holden, G. (1991). The relationship of self-efficacy appraisals to subsequent health related outcomes: a meta-analysis. *Social Work In Health Care, 16*(1), 53-93.

Holmes, K. K., Levine, R., & Weaver, M., PhD,. (2004). Effectiveness of condoms in preventing sexually transmitted infections. *Bulletin of the World Health Organization, 82*(6).

Hsieh, F. Y., Block, D. A., & Larsen, M. D. (1998). A Simple Method of Sample Size Calculation for Linear and Logistic Regression. *Statistics in Medicine,, 17*, 1623-1634.

Jadack, R. A., Fresia, A., Rompalo, A. M., & Zenilman, J. (1997). Reasons for not using condoms of clients at urban sexually transmitted diseases clinics. *Sex Transm Dis, 24*(7), 402-408.

Jansen, H., & et al. (2002, July 7-12). *Forced sex and physical violence in Brazil, Peru, and Thailand: Who Multi-Country Results.* Paper presented at the XIV International AIDS Conference, Barcelona, Spain.

Jemmott, L. S., & Jemmott, J. B., 3rd. (1991). Applying the theory of reasoned action to AIDS risk behavior: condom use among black women. *Nurs Res, 40*(4), 228-234.

Kahn, A. S., & Yoder, J. D. (1992). Toward a feminist understanding of women and power. *Psychology of Women Quarterly, 16*(4), 381.

Kahn, J. O., Martin, J. N., Roland, M. E., Bamberger, J. D., Chesney, M., Chambers, D., et al. (2001). Feasibility of postexposure prophylaxis (PEP) against human immunodeficiency virus infection after sexual or injection drug use exposure: the San Francisco PEP Study. *J Infect Dis, 183*(5), 707-714.

Kail, B. L., Watson, D. D., & Ray, S. (1995). Needle-using practices within the sex industry. National AIDS Research Consortium. *Am J Drug Alcohol Abuse, 21*(2), 241-255.

Kaplan, J. B., & Bennett, T. (2003). Use of race and ethnicity in biomedical publication. *Jama, 289*(20), 2709-2716.

Kelaghan, J., Rubin, G. L., Ory, H. W., & Layde, P. M. (1982). Barrier-method contraceptives and pelvic inflammatory disease. *Jama, 248*(2), 184-187.

Koo, H., Koch, M., Dalberth, B., & Leone, P. (2006, April 23-26). *Acceptability of Microbicides under Four Conditions of Effectiveness and Partner Protection.* Paper presented at the Microbicides 2006, Cape Town, South Africa.

Kovacs, A., Chan, L. S., Chen, Z. C., Meyer, W. A., 3rd, Muderspach, L., Young, M., et al. (1999). HIV-1 RNA in plasma and genital tract secretions in women infected with HIV-1. *J Acquir Immune Defic Syndr, 22*(2), 124-131.

Krug, E. G., Mercy, J. A., Dahlberg, L. L., & Zwi, A. B. (2002). *The world report on violence and health*. Geneva: World Health Organization.

Landis, D., Triandis, H. C., & Adamopoulos, J. (1978). HABIT AND BEHAVIORAL INTENTIONS AS PREDICTORS OF SOCIAL BEHAVIOR. [Article]. *Journal of Social Psychology*

106(2), 227.

Lange, J. M. (2005). We must not let protestors derail trials of pre-exposure prophylaxis for HIV. *PLoS Med, 2*(9), e248.

Lauver, D., Nabholz, S., Scott, K., & Tak, Y. (1997). Testing theoretical explanations of mammography use. *Nursing Research, 46*(1), 32-39.

Lee, L. M., & Fleming, P. L. (2001). Trends in human immunodeficiency virus diagnoses among women in the United States, 1994-1998. *J Am Med Womens Assoc, 56*(3), 94-99.

Leeper, M. A. (1990). Preliminary evaluation of reality, a condom for women. *AIDS Care, 2*(3), 287-290.

Macaluso, M., Demand, M. J., Artz, L. M., & Hook, E. W., 3rd. (2000). Partner type and condom use. *Aids, 14*(5), 537-546.

Magder, L. S., Harrison, H. R., Ehret, J. M., Anderson, T. S., & Judson, F. N. (1988). Factors related to genital Chlamydia trachomatis and its diagnosis by culture in a sexually transmitted disease clinic. *Am J Epidemiol, 128*(2), 298-308.

Mantell, J. E., Hoffman, S., Exner, T. M., Stein, Z. A., & Atkins, K. (2003). Family planning providers' perspectives on dual protection. *Perspect Sex Reprod Health, 35*(2), 71-78.

Mantell, J. E., Myer, L., Carballo-Dieguez, A., Stein, Z., Ramjee, G., Morar, N. S., et al. (2005). Microbicide acceptability research: current approaches and future directions. *Soc Sci Med, 60*(2), 319-330.

Mason, T. H., Foster, S. E., Finlinson, H. A., Morrow, K. M., Rosen, R., Vining, S., et al. (2003). Perspectives related to the potential use of vaginal microbicides among drug-involved women: focus groups in three cities in the United States and Puerto Rico. *AIDS Behav, 7*(4), 339-351.

Matthews, J. (2006). Clinical Trials Testing the Effectiveness of the Diaphragm in Preventing the Acquisition of HIV/AIDS. Boston.

Mayer, K. H., Maslankowski, L. A., Gai, F., El-Sadr, W. M., Justman, J., Kwiecien, A., et al. (2006). Safety and tolerability of tenofovir vaginal gel in abstinent and sexually active HIV-infected and uninfected women. *Aids, 20*(4), 543-551.

McCabe, E., Golub, S., & Lee, A. C. (1997). Making the female condom a "reality" for adolescents. *J Pediatr Adolesc Gynecol, 10*(3), 115-123.

Meekers, D., & Richter, K. (2005). Factors associated with use of the female condom in Zimbabwe. *Int Fam Plan Perspect, 31*(1), 30-37.

Microsoft Corporation. (2007). Microsoft Office Help: Test Your Document's Readability. Retrieved April 25, 2008

Miller, C., & Rosenberg, Z. (1996). *Use of topical PMPA to prevent vaginal transmission of SIV*. Paper presented at the Ninth International Conference on Antiviral Research.

Misovich, S. J., Fisher, J. D., & Fisher, W. A. (1997). Close relationships and elevated HIV risk behavior: Evidence and possible underlying psychological processes. . *Review of General Psychology, 1*(1), 72-107.

Mmbaga, E. J., Hussain, A., Leyna, G. H., Mnyika, K. S., Sam, N. E., & Klepp, K. I. (2007). Prevalence and risk factors for HIV-1 infection in rural Kilimanjaro region of Tanzania: implications for prevention and treatment. *BMC Public Health, 7*, 58.

Moench, T. R., Chipato, T., & Padian, N. S. (2001). Preventing disease by protecting the cervix: the unexplored promise of internal vaginal barrier devices. *AIDS, 15*(13), 1595-1602.

Montano, D., E.,, Kasprzyk, D., & Taplin, S. H. (1997). The Theory of Reasoned Action and The Theory of Planned Behavior. In K. Glanze (Ed.), *Health Behavior and Health Education*. San Francisco: Jossey-Bass.

Montano, D., & Taplin, S. (1991). A test of an expanded theory of reasoned action to predict mammography participation. *Social Science & Medicine (1982), 32*(6), 733-741.

Morrow, K., Rosen, R., Richter, L., Emans, A., Forbes, A., Day, J., et al. (2003). The acceptability of an investigational vaginal microbicide, PRO 2000 Gel, among women in a phase I clinical trial. *J Womens Health (Larchmt), 12*(7), 655-666.

Morrow, K. M., Fava, J. L., Rosen, R., Christensen, A. L., Vargas, S., & Barroso, C. (2007). Willingness to Use Microbicides Varies by Race/ Ethnicity, Experience with Prevention Products, and Partner Type. *Health Psychology*.

Morrow, K. M., Fava, J. L., Rosen, R. K., Vargas, S., Barroso, C., Christensen, A. L., et al. (2007). Willingness to use microbicides is affected by the importance of product characteristics, use parameters, and protective properties. *J Acquir Immune Defic Syndr, 45*(1), 93-101.

Mosack, K. E., Weeks, M. R., Novick Sylla, L., & Abbott, M. (2005). High-risk women's willingness to try a simulated vaginal microbicide: results from a pilot study. *Women Health, 42*(2), 71-88.

Murray-Johnson, L., Witte, K., Boulay, M., Figueroa, M. E., Storey, D., & Tweedi, I. (2001). Using Health Education theories to explain behavior change: a cross country analysis. *International Quarterly of Community Health Education, 20*, 323-345.

National Institute of Allergy and Infectious Diseases. (2005). Questions and Answers: Study of Daily Oral Tenofovir to Preventio HIV-1 Infection Among Women at High Risk of HIV Infection in Cambodia. Bethesda, MD.

Newmann, S., Sarin, P., Kumarasamy, N., Amalraj, E., Rogers, M., Madhivanan, P., et al. (2000). Marriage, monogamy and HIV: a profile of HIV-infected women in south India. *Int J STD AIDS, 11*(4), 250-253.

Nicolosi, A., Correa Leite, M. L., Musicco, M., Arici, C., Gavazzeni, G., & Lazzarin, A. (1994). The efficiency of male-to-female and female-to-male sexual transmission of the human immunodeficiency virus: a study of 730 stable couples. Italian Study Group on HIV Heterosexual Transmission. *Epidemiology, 5*(6), 570-575.

Noar, S. M., & Zimmerman, R. S. (2005). Health Behavior Theory and cumulative knowledge regarding health behaviors: are we moving in the right direction? *Health Educ Res, 20*(3), 275-290.

O'Leary, A., & Martins, P. (2000). Structural factors affecting women's HIV risk: a life-course example. *Aids, 14 Suppl 1*, S68-72.

O'Malley, C. D., Le, G. M., Glaser, S. L., Shema, S. J., & West, D. W. (2003). Socioeconomic status and breast carcinoma survival in four racial/ethnic groups: a population-based study. *Cancer, 97*(5), 1303-1311.

Padian, N. S., van der Straten, A., Ramjee, G., Chipato, T., de Bruyn, G., Blanchard, K., et al. (2007). Diaphragm and lubricant gel for prevention of HIV acquisition in southern African women: a randomised controlled trial. *Lancet, 370*(9583), 251-261.

Pettifor, A. E., Measham, D. M., Rees, H. V., & Padian, N. S. (2004). Sexual power and HIV risk, South Africa. *Emerg Infect Dis, 10*(11), 1996-2004.

Pinkerton, S. D., & Abramson, P. R. (1997). Effectiveness of condoms in preventing HIV transmission. *Soc Sci Med, 44*(9), 1303-1312.

Portney, L. G. (2000). *Foundations of clinical research : applications to practice / Leslie Gross Portney, Mary P. Watkins* (2nd ed. ed.). Upper Saddle River, N.J. :: Prentice Hall Health.

Prejean, J., Satcher, A., Durant, T., Hu, X., & Lee, L. (2005). Racial/Ethnic Disparities in Diagnoses of HIV/AIDS --- 33 States, 2001--2004. *Morbidity and Mortality Weekly Report, 55*(05), 121-125.

Public Health Agency of Canada. (2006a). *HIV/AIDS Epi Updates*. Ottawa: Surveillance and Risk Assessment Division, Centre for Infectious Disease Prevention and Control.

Public Health Agency of Canada. (2006b). *HIV/AIDS in Canada: Surveillance Report to June 30, 2006*. Ottawa: Public Health Agency of Canada.

Public Health Agency of Canada. (2008). Summary: Estimates of HIV Prevalence and Incidence in Canada, 2008. Retrieved February 10, 2010

Pulerwitz, J., Amaro, H., De Jong, W., Gortmaker, S. L., & Rudd, R. (2002). Relationship power, condom use and HIV risk among women in the USA. *AIDS Care, 14*(6), 789-800.

Purcell DW, Metsch LR, Latka M, Santibanez S, Gómez CA, Eldred L, et al. (2004). INSPIRE Study Group. Interventions for seropositive injectors-research and evaluation: an integrated behavioral intervention with HIV-positive injection drug users to address medical care, adherence, and risk reduction. *J Acquir Immune Defic Syndr., 1*(37 Suppl 2:S110-8.).

Rasch, R. F., Weisen, C. A., MacDonald, B., Wechsberg, W. M., Perritt, R., & Dennis, M. L. (2000). Patterns of HIV risk and alcohol use among African-American crack abusers. *Drug Alcohol Depend, 58*(3), 259-266.

Remis, R. S., MD, MPH, , Swantee, C., BSc,, Schiedel, L., RN BScN,, & Liu, J. M. (2007). *Report on HIV/AIDS in Ontario*. Toronto: University of Toronto.

Riger, S. (1991). Gender dilemmas in sexual harassment policies and procedures. *American Psychologist, 46*(5), 497.

Roberts, S. T., & Kennedy, B. L. (2006). Why are young college women not using condoms? Their perceived risk, drug use, and developmental vulnerability may provide important clues to sexual risk. *Arch Psychiatr Nurs, 20*(1), 32-40.

Rockefeller Foundation. (2002a). *Preparing for Microbicide Access and Use*. New York.

Rockefeller Foundation. (2002b). The Public Health Benefits of Microbicides in Lower-Income Countries: Model Projections. *A Report by the Public Health Working Group of the Microbicide Initiative*.

Rosenberg, M. J., Davidson, A. J., Chen, J. H., Judson, F. N., & Douglas, J. M. (1992). Barrier contraceptives and sexually transmitted diseases in women: a comparison of female-dependent methods and condoms. *Am J Public Health, 82*(5), 669-674.

Rosengard, C., Clarke, J. G., DaSilva, K., Hebert, M., Rose, J., & Stein, M. D. (2005). Correlates of partner-specific condom use intentions among incarcerated women in Rhode Island. *Perspect Sex Reprod Health, 37*(1), 32-38.

Rosenstock, I. M., Strecher, V. J., & Becker, M. H. (1988). Social learning theory and the Health Belief Model. *Health Educ Q, 15*(2), 175-183.

Rosenstock, I. M., Strecher, V. J., & Becker, M. H. (1994). The health belief model and HIV risk behavior change. In R. J. DiClemente & J. L. Peterson (Eds.), *Preventing AIDS: Theories and methods of behavioral interventions.* (pp. 5-24): Plenum Press.

Rusbult, C. E., Martz, J. M., & Agnew, C. R. (1998). The Investment Model Scale: Measuring commitment level, satisfaction level, quality of alternatives, and investment size. *Personal Relationships, 5*(4), 357-387.

Salant, P., & Dillman, D. A. (1994). *How to Conduct Your Own Survey*: John Wiley & Sons.

Schilling, R. F., el-Bassel, N., Leeper, M. A., & Freeman, L. (1991). Acceptance of the female condom by Latin- and African-American women. *Am J Public Health, 81*(10), 1345-1346.

Scully, D. (1988). Convicted Rapists Perceptions of Self and Victim: Role Taking and Emotions. *Gender and Society, 2*, 213.

Severy, L. J., & Newcomer, S. (2005). Critical Issues in Contraceptive and STI Acceptability Research. *Journal of Social Issues, 61*(1).

Severy, L. J., Tolley, E., Woodsong, C., & Guest, G. (2005). A framework for examining the sustained acceptability of microbicides. *AIDS Behav, 9*(1), 121-131.

Shaffer, N., Bulterys, M., & Simonds, R. J. (1999). Short courses of zidovudine and perinatal transmission of HIV. *N Engl J Med, 340*(13), 1042-1043.

Shaffer, N., Chuachoowong, R., Mock, P. A., Bhadrakom, C., Siriwasin, W., Young, N. L., et al. (1999). Short-course zidovudine for perinatal HIV-1 transmission in Bangkok, Thailand: a randomised controlled trial. Bangkok Collaborative Perinatal HIV Transmission Study Group. *Lancet, 353*(9155), 773-780.

Sheeran, P., Abraham, C., & Orbell, S. (1999). Psychosocial correlates of heterosexual condom use: a meta-analysis. *Psychological Bulletin, 125*(1), 90-132.

Sheeran, P., & Orbell, S. (1998). Do intentions predict condom use? Meta-analysis and examination of six moderator variables. *The British Journal Of Social Psychology / The British Psychological Society, 37 (Pt 2)*, 231-250.

Sheeran, P., & Taylor, S. (1999). Predicting Intentions to Use Condoms: A Meta-Analysis and Comparison of the Theories of Reasoned Action and Planned Behavior. *Journal of Applied Social Psychology, 29*, 1624-1675.

Sly, D. F., Quadagno, D., Harrison, D. F., Eberstein, I. W., Riehman, K., & Bailey, M. (1997). Factors associated with use of the female condom. *Fam Plann Perspect, 29*(4), 181-184.

Soler, H., Quadagno, D., Sly, D. F., Riehman, K. S., Eberstein, I. W., & Harrison, D. F. (2000). Relationship Dynamics, Ethnicity and Condom Use Among Low-Income Women. *Family Planning Perspectives, 32*(2), 82-101.

Spieler, J. (1997). *Behavior Issues in Dual Protection.* Paper presented at the Paper Presented at the Psychosocial Workshop; Population Association of America, Washington D.C.

Stacy, A., Stein, J., & Longshore, D. (1999). Habit, intention, and drug use as interactive predictors of condom use among drug abusers. *AIDS & Behavior, 3*(3), 231-241.

Stein, Z. A. (1990). HIV prevention: the need for methods women can use. *Am J Public Health, 80*(4), 460-462.

Stover, J. (2005). *Estimating the Gobal Impact of an AIDS Vaccine*. New York: International AIDS Vaccine Initiative.

Strecher, V. J., & Rosenstock, I. M. (1997). The Health Belief Model. In K. Glanz, F. M. Lewis & B. K. Rimer (Eds.), *Health Behavior and Health Education: Theory, Research, and Practice* (Second ed.). San Francisco: Jossey-Bass, Inc.

Sutton, S. (1987). Social-psychological approaches to understanding addictive behaviours: attitude-behaviour and decision-making models. *Br J Addict, 82*(4), 355-370.

Szekeres, G., Coates, T., Frost, S., Leibowitz, A., & Shoptaw, S. (2004). *Anticipating the Efficacy of HIV Pre-Exposure Prophylaxis (PrEP) and the Nees of At-Risk Californians*. San Francisco: AIDS Partnerhsip California.

Szekeres, G., Coates Thomas J., Frost, S., Leibowitz, A., & Shoptaw, S. (2004). *Anticipating the Efficacy of HIV Pre-Exposure Prophylaxis (PrEP) and the Nees of At-Risk Californians*. San Francisco: AIDS Partnerhsip California.

Tannen, D. (1990). *You Just Don't Understand: Women and Men in Conversation*. New York: Ballantine.

Thompson, N. J., Potter, J. S., Sanderson, C. A., & Maibach, E. W. (1997). The relationship of sexual abuse and HIV risk behaviors among heterosexual adult female STD patients. *Child Abuse Negl, 21*(2), 149-156.

Thorburn, S., Harvey, S. M., & Tipton, J. (2006). Diaphragm acceptability among young women at risk for HIV. *Women Health, 44*(1), 21-39.

Tolley, E. E., Eng, E., Kohli, R., Bentley, M. E., Mehendale, S., Bunce, A., et al. (2006). Examining the context of microbicide acceptability among married women and men in India. *Cult Health Sex, 8*(4), 351-369.

Trafimow, D. (2000). Habit as both a direct cause of intention to use a condom and as a moderator of the attitude-intention and subjective norm-intention relations. *Psychology & Health, 15*(3), 383-393.

Triandis, H. C. (1980). *Values, attitude, and interpersonal behavior*. Lincoln, NE.: University of Nebraska Press.

Trussel, J., Sturgen, K., Strickler, J., & Dominick, R. (1994). Comparative Contraceptive Efficacy of the Female Condom and Other Barrier Methods. *Family Planning Perspectives, 26*(2).

Tsai, C. C., Emau, P., Follis, K. E., Beck, T. W., Benveniste, R. E., Bischofberger, N., et al. (1998). Effectiveness of postinoculation (R)-9-(2-phosphonylmethoxypropyl) adenine treatment for prevention of persistent simian immunodeficiency virus SIVmne infection depends critically on timing of initiation and duration of treatment. *J Virol, 72*(5), 4265-4273.

Tsai, C. C., Follis, K. E., Sabo, A., Beck, T. W., Grant, R. F., Bischofberger, N., et al. (1995). Prevention of SIV infection in macaques by (R)-9-(2-phosphonylmethoxypropyl)adenine. *Science, 270*(5239), 1197-1199.

UNAIDS. (2004). *AIDS Epidemic Update*. Geneva: Joint United Nations Programme on HIV/AIDS and World Health Organization.

UNAIDS. (2005). *AIDS Epidemic Update*. Geneva: Joint United Nations Programme on HIV/AIDS and World Health Organization.

UNAIDS. (2009). *AIDS Epidemic Update: November 2009*. Geneva: United Nations.

UNAIDS/UNFPA/UNIFEM. (2004). *Women and HIV/AIDS: Confronting the Crisis*.

Valleroy, L. A., MacKellar, D. A., Karon, J. M., Janssen, R. S., & Hayman, C. R. (1998). HIV infection in disadvantaged out-of-school youth: prevalence for U.S. Job Corps entrants, 1990 through 1996. *J Acquir Immune Defic Syndr Hum Retrovirol, 19*(1), 67-73.

Valois, P., Desharnai, R., & Godin, G. (1988). A comparison of the Fishbein and Ajzen and the Triandis attitudinal models for the prediction of exercise intention and behavior. *Journal Of Behavioral Medicine, 11*(5), 459-472.

Van Damme, L., Ramjee, G., Alary, M., Vuylsteke, B., Chandeying, V., Rees, H., et al. (2002). Effectiveness of COL-1492, a nonoxynol-9 vaginal gel, on HIV-1 transmission in female sex workers: a randomised controlled trial. *Lancet, 360*(9338), 971-977.

van der Straten, A., Kang, M. S., Posner, S. F., Kamba, M., Chipato, T., & Padian, N. S. (2005). Predictors of diaphragm use as a potential sexually transmitted disease/HIV prevention method in Zimbabwe. *Sex Transm Dis, 32*(1), 64-71.

Van Rompay, K. K., Cherrington, J. M., Marthas, M. L., Berardi, C. J., Mulato, A. S., Spinner, A., et al. (1996). 9-[2-(Phosphonomethoxy)propyl]adenine therapy of established simian immunodeficiency virus infection in infant rhesus macaques. *Antimicrob Agents Chemother, 40*(11), 2586-2591.

Vickerman, P., Watts, C., Delany, S., Alary, M., Rees, H., & Heise, L. (2006). The importance of context: model projections on how microbicide impact could be affected by the underlying epidemiologic and behavioral situation in 2 African settings. *Sex Transm Dis, 33*(6), 397-405.

Wainberg, M. A. (1999). The need for microbicides: why aren't women's groups more involved in the fight against AIDS? *AIDS Res Hum Retroviruses, 15*(5), 405-406.

Wang, Y., Liao, S. S., Weeks, M. R., Jiang, J. M., Abbott, M., Zhou, Y. J., et al. (2008). Acceptability of hypothetical microbicides among women in sex establishments in rural areas in Southern China. *Sex Transm Dis, 35*(1), 102-110.

Watkins, K. E., Metzger, D., Woody, G., & McLellan, A. T. (1992). High-risk sexual behaviors of intravenous drug users in- and out-of-treatment: implications for the spread of HIV infection. *Am J Drug Alcohol Abuse, 18*(4), 389-398.

Watts, C., & Vickerman, P. (2001). The impact of microbicides on HIV and STD transmission: model projections. *AIDs, 15*, S43-S44.

Weeks, M. R., Mosack, K. E., Abbott, M., Sylla, L. N., Valdes, B., & Prince, M. (2004). Microbicide acceptability among high-risk urban U.S. women: experiences and perceptions of sexually transmitted HIV prevention. *Sex Transm Dis, 31*(11), 682-690.

Weinhardt, L. S., Forsyth, A. D., Carey, M. P., Jaworski, B. C., & Durant, L. E. (1998). Reliability and validity of self-report measures of HIV-related sexual behavior: progress since 1990 and recommendations for research and practice. *Arch Sex Behav, 27*(2), 155-180.

Weinstein, N. D. (1993). Testing four competing theories of health-protective behavior. *Health Psychol, 12*(4), 324-333.

Weller, S., & Davis, K. (2004). Condom effectiveness in reducing heterosexual HIV transmission. *Cochrane Database Syst Rev*(1), CD003255.

Wiktor, S. Z., Ekpini, E., Karon, J. M., Nkengasong, J., Maurice, C., Severin, S. T., et al. (1999). Short-course oral zidovudine for prevention of mother-to-child transmission of HIV-1 in Abidjan, Cote d'Ivoire: a randomised trial. *Lancet, 353*(9155), 781-785.

Wingood, G. M., & DiClemente, R. J. (1997a). Child sexual abuse, HIV sexual risk, and gender relations of African-American women. *Am J Prev Med, 13*(5), 380-384.

Wingood, G. M., & DiClemente, R. J. (1997b). The effects of an abusive primary partner on the condom use and sexual negotiation practices of African-American women. *Am J Public Health, 87*(6), 1016-1018.

Wingood, G. M., & DiClemente, R. J. (1998). The influence of psychosocial factors, alcohol, drug use on African-American women's high-risk sexual behavior. *Am J Prev Med, 15*(1), 54-59.

Wingood, G. M., & DiClemente, R. J. (2000). Application of the theory of gender and power to examine HIV-related exposures, risk factors, and effective interventions for women. *Health Educ Behav, 27*(5), 539-565.

Woodsong, C. (2004). Covert use of topical microbicides: implications for acceptability and use. *Int Fam Plan Perspect, 30*(2), 94-98.

World Health Organization and UNAIDS. (1997). *The Female Condom*. Geneva: World Health Organization.

Wyatt, G. E., Myers, H. F., Williams, J. K., Kitchen, C. R., Loeb, T., Carmona, J. V., et al. (2002). Does a history of trauma contribute to HIV risk for women of color? Implications for prevention and policy. *Am J Public Health, 92*(4), 660-665.

Youle, M., & Wainberg, M. A. (2003a). Could chemoprophylaxis be used as an HIV prevention strategy while we wait for an effective vaccine? *Aids, 17*(6), 937-938.

Youle, M., & Wainberg, M. A. (2003b). Pre-exposure chemoprophylaxis (PREP) as an HIV prevention strategy. *J Int Assoc Physicians AIDS Care (Chic Ill), 2*(3), 102-105.

Zierler, S., Feingold, L., Laufer, D., Velentgas, P., Kantrowitz-Gordon, I., & Mayer, K. (1991). Adult survivors of childhood sexual abuse and subsequent risk of HIV infection. *Am J Public Health, 81*(5), 572-575.

Zule, W. A., Flannery, B. A., Wechsberg, W. M., & Lam, W. K. (2002). Alcohol use among out-of-treatment crack using African-American women. *Am J Drug Alcohol Abuse, 28*(3), 525-544.

Appendix A: Survey Instrument

WOMEN INITIATED SOLUTIONS FOR HIV PREVENTION (THE WISH SURVEY)

A SURVEY BY: SONIA M. KANDATHIL, PHD CANDIDATE,
DONNA CHAMPEAU, PHD, ASSOCIATE PROFESSOR AND S. MARIE HARVEY PHD, PROFESSOR,
DEPARTMENT OF PUBLIC HEALTH, OREGON STATE UNIVERSITY

The purpose of this survey is to learn more about what women think regarding methods that women can use to protect themselves against sexually transmitted infections (STIs). By STIs, we mean diseases

like gonorrhea, herpes, and HIV, the virus that causes AIDS. We would like to remind you that all of your answers will remain confidential.

Q1. Please indicate whether or not you have <u>ever used</u> the birth control methods listed below *(Indicate USED or NOT USED by circling one number for each)*.

Birth Control Method	Used	Not used
a. Birth control pills	1	2
b. Male condom	1	2
c. Female Condom	1	2
d. Diaphragm	1	2
e. Cervical Cap	1	2
f. Spermicides	1	2
g. Vaginal Ring	1	2
h. Hormonal Patch	1	2
i. Vasectomy	1	2
j. Tubal Ligation (Tied Tubes)	1	2
k. Abstinence	1	2
l. Depo-Provera	1	2
m. Sponge	1	2
n. IUD	1	2
o. Other (please indicate)		

Q2. In addition to preventing pregnancy, some women find it important to protect themselves against HIV and other sexually transmitted infections like herpes, genital warts, and gonorrhea. Which, if any of these methods have you used to protect yourself from HIV or other sexually transmitted infections? *Please circle only one number to indicate your answer.*

HIV Prevention Method	Used	Not Used
a. Male condom	1	2
b. Female Condom	1	2
c. Monogamy	1	2
d. Abstinence	1	2

Q3. Please indicate, to the best of your knowledge, to what extent you agree or disagree with the statements below.

	Strongly Agree	Agree	Disagree	Strongly Disagree
a. It is unlikely that I will get HIV in the next year.	1	2	3	4
b. It is unlikely that I will get a sexually transmitted infection other than HIV in the next year.	1	2	3	4

Studies are currently being done to determine the effectiveness of new methods of HIV prevention. We are going to ask you about two methods that are being developed to protect yourself from HIV/AIDS: Microbicides and Tenofovir

Microbicides are a product that would be in the form of a gel, film, foam, cream, suppository, or sponge that a woman could insert into her vagina before having sex. Microbicides are not available yet, but it is hoped that when they are they could reduce a woman's risk for contracting HIV, even when her partner is not wearing a condom.

Q4. Please indicate to what extent you agree or disagree with the statements below. We understand that you have not used microbicides and you may feel like you don't know much about them. We are, however, still interested in learning your opinions and perceptions of microbicides.

	Strongly Agree	Agree	Disagree	Strongly Disagree
a. The product is easy to use.	1	2	3	4
b. Is affordable.	1	2	3	4
c. Will not cause side effects like burning, bleeding, or weight gain.	1	2	3	4
d. Will not cause pain or irritation.	1	2	3	4
e. Can be bought without seeing a health care provider or getting a prescription.	1	2	3	4
f. Will not decrease sexual pleasure for me or my partner.	1	2	3	4
g. Is a method that I can control.	1	2	3	4
h. Will not require me touching my genitals.	1	2	3	4
i. Will reduce my chance of getting HIV.	1	2	3	4

Question 4 is continued on the next page

	Strongly Agree	Agree	Disagree	Strongly Disagree
j. Will reduce my chance of getting STDS other than HIV.	1	2	3	4
k. Is also effective in preventing pregnancy.	1	2	3	4
l. Needs to be used when you have sex.	1	2	3	4
m. It is not messy to use.	1	2	3	4

n.	**It does not have to be washed or stored.**	1	2	3	4
o.	**It can be used without your partner knowing.**	1	2	3	4
p.	**It is a method your partner would like.**	1	2	3	4

Listed below are some statements about using microbicides. We understand that you have not used them, but we are still interested in your thoughts about microbicides.

Q5. We would like to know how confident you are that you could do each of these things.

	How confident are you:	Not at all Confident	A Little Confident	Moderately Confident	Very Confident	Extremely Confident
a.	**That you could use microbicides without your partner knowing.**	1	2	3	4	5
b.	**That you could use a microbicide even if your partner didn't like it.**	1	2	3	4	5
c.	**That you could discuss using a microbicide with your partner.**	1	2	3	4	5
d.	**That you could put a microbicide in your vagina.**	1	2	3	4	5
e.	**That you could use a microbicide correctly.**	1	2	3	4	5
f.	**That you could use a microbicide without breaking the sexual mood with your partner.**	1	2	3	4	5
g.	**That you would remember to carry microbicides with you in case you needed it.**	1	2	3	4	5
h.	**That you could use a microbicide if you were sexually excited.**	1	2	3	4	5

Q6. If MICROBICIDES were available today, how likely or unlikely is it that you would use them?

1 Extremely unlikely
2 Somewhat unlikely
3 Somewhat likely
4 Extremely likely

Tenofovir is a product in the form of a pill that you would swallow. Like the birth control pill, you would have to take it every day. Tenofovir is not available yet, but it is hoped that when it is, it can reduce a woman's chance of getting HIV, even if her partner does not wear a condom.

Q7. Please indicate to what extent you agree or disagree with the statements below. We understand that you have not used tenofovir and you may feel like you don't know much about it. We are, however, still interested in learning your opinions and perceptions of tenofovir.

	Strongly Agree	Agree	Disagree	Strongly Disagree
a. The product is easy to use.	1	2	3	4
b. Is affordable.	1	2	3	4
c. Will not cause side effects like burning, bleeding, or weight gain.	1	2	3	4
d. Will not cause pain or irritation.	1	2	3	4
e. Can be bought without seeing a health care provider or getting a prescription.	1	2	3	4
f. Will not decrease sexual pleasure for me or my partner.	1	2	3	4
g. Is a method that I can control.	1	2	3	4
h. Will not require me touching my genitals.	1	2	3	4
i. Will reduce my chance of getting HIV.	1	2	3	4
j. Will reduce my chance of getting STDS other than HIV.	1	2	3	4
k. Is also effective in preventing pregnancy.	1	2	3	4
l. Needs to be used when you have sex.	1	2	3	4
m. It is not messy to use.	1	2	3	4

Question 7 is continued on the next page

	Strongly Agree	Agree	Disagree	Strongly Disagree
n. It does not have to be washed or stored.	1	2	3	4
o. It can be used without your partner knowing.	1	2	3	4
p. It is a method your partner would like.	1	2	3	4

Listed below are some statements about using tenofovir. We understand that you have not used it, but we are still interested in your thoughts about tenofovir.

Q8. We would like to know how confident you are that you could do each of these things.

	How confident are you:	Not at all Confident	A Little Confident	Moderately Confident	Very Confident	Extremely Confident
a.	That you could use the tenofovir pill without your partner knowing?	1	2	3	4	5
b.	That you could use the tenofovir pill even if your partner didn't like it?	1	2	3	4	5
c.	That you could discuss using the tenofovir pill with your partner?	1	2	3	4	5
d.	That you could swallow the tenofovir pill?	1	2	3	4	5
e.	That you could use the tenofovir pill correctly?	1	2	3	4	5
f.	That you would remember to take the tenofovir pill every day?	1	2	3	4	5

Q9. If TENOFOVIR were available today, how likely or unlikely would you be to use it?

1 Extremely unlikely
2 Somewhat unlikely
3 Somewhat likely
4 Extremely likely

Q10. If both products were equally effective in reducing your risk for getting HIV, which would you prefer to use? Please circle only one.

1 Microbicides
2 Tenofovir

Q11. During your lifetime, how many people have you had sex with?

1 NONE **(GO TO Question 23, Page 12)**
2 Please indicate the number in the space provided _____

Q12. During the last 12 months, how many men have you had sex with?

1 NONE **(GO TO Question 23, Page 12)**
2 Please indicate the number in the space provided _____

Q13. Right now, is there a man that you're having sex with that you would consider your partner (like a husband, lover, or boyfriend)?

1 NO **(GO TO QUESTION 18, Page 9)**
2 YES

The following statements discuss your relationship with your current primary male sexual partner.

Q14. These next several questions are going to *ask you about how you feel about the relationship you have with your current male sexual partner.*

	Strongly Agree	Agree	Disagree	Strongly Disagree
a. I want our relationship to last a very long time.	**1**	**2**	**3**	**4**
b. I am committed to maintaining my relationship with my partner.	**1**	**2**	**3**	**4**
c. I would not feel very upset if our relationship were to end in the near future.	**1**	**2**	**3**	**4**
d. It is likely that I will date someone other than my partner within the next year.	**1**	**2**	**3**	**4**
e. I feel very attached to our relationship -- very strongly linked to my partner.	**1**	**2**	**3**	**4**
f. I want our relationship to last forever.	**1**	**2**	**3**	**4**
g. I am oriented toward the long-term future of my relationship (for example, I imagine being with my partner several years from now).	**1**	**2**	**3**	**4**
h. I intend to stay in this relationship.	**1**	**2**	**3**	**4**

Q15. Please tell me to what extent you agree or disagree with each statement. We want to remind you that all of your answers will remain confidential.

	Strongly Agree	Agree	Disagree	Strongly Disagree	Don't Know
a. My partner thinks a condom should be used every time we have sex.	1	2	3	4	99
b. When it comes to safer sex, I want to do what my partner thinks we should do.	1	2	3	4	99

c. Most people who are important to me think that some form of protection from HIV and STDS should be used with my partner when we have sex.	1	2	3	4	99
d. When it comes to safer sex with my partner, I want to do what most people who are important to me think I should do.	1	2	3	4	99

Q16. Please indicate to what extent you agree or disagree with each statement. Again, we want to remind you that all of your answers will remain confidential.

	Strongly Agree	Agree	Disagree	Strongly Disagree	Don't Know
a. If I asked my partner to use a condom, he would get violent.	1	2	3	4	99
b. If I asked my partner to use a condom, he would get angry.	1	2	3	4	99
c. Most of the time, we do what my partner wants to do.	1	2	3	4	99
d. My partner won't let me wear certain things.	1	2	3	4	99
e. When my partner and I are together, I'm pretty quiet.	1	2	3	4	99
f. My partner has more say than I do about things that affect us.	1	2	3	4	99
g. My partner tells me who I can spend time with.	1	2	3	4	99
h. If I asked my partner to use a condom, he would think I'm having sex with other people.	1	2	3	4	99
i. I feel trapped or stuck in our relationship.	1	2	3	4	99
j. My partner does what he wants, even if I don't want him to.	1	2	3	4	99
k. I am more committed to our relationship than my partner is.	1	2	3	4	99

Question 16 is continued on the next page

	Strongly Agree	Agree	Disagree	Strongly Disagree	Don't Know
l. When my partner and I disagree, he gets his way most of the time.	1	2	3	4	99
m. My partner gets more out of our relationship than I do.	1	2	3	4	99
n. My partner always wants to know where I am.	1	2	3	4	99
o. My partner might be having sex with someone else.	1	2	3	4	99

The next few questions ask about the physical relationship between you and your partner. We want to remind you that all of your answers will remain confidential.

Q17. Please indicate YES or NO for each question. We want to remind you that all of your answers will remain confidential.

	YES	NO
a. My primary partner has hurt me by punching, kicking, hitting, or slapping me.	1	2
b. My primary partner has forced me to have sex when I did not want to.	1	2
c. My primary partner has belittled, humiliated, or intimidated me.	1	2

NOW SKIP TO QUESTION 22 ON PAGE 11.

The following statements discuss your relationship with your last sexual partner.

Q18. These next several questions are going to *ask you about how you feel about the relationship you had with your last primary male sexual partner.*

	Strongly Agree	Agree	Disagree	Strongly Disagree
a. I wanted our relationship to last a very long time.	1	2	3	4

b. I was committed to maintaining my relationship with my partner.	1	2	3	4
c. I did not feel upset when our relationship ended.	1	2	3	4
d. It was likely that I would have dated someone other than my partner within the following year.	1	2	3	4
e. I felt very attached to our relationship -- very strongly linked to my partner.	1	2	3	4
f. I wanted our relationship to last forever.	1	2	3	4
g. I was oriented toward the long-term future of my relationship (for example, I imagined being with my partner for several years).	1	2	3	4
h. I intended to stay in this relationship.	1	2	3	4

Q19. Please tell me to what extent you agree or disagree with these statements. We want to remind you that your answers will remain confidential.

	Strongly Agree	Agree	Disagree	Strongly Disagree	Don't Know/Not Sure
a. My last partner thought a condom should be used every time we had sex.	1	2	3	4	99
b. When it came to safer sex, I wanted to do what my last partner thought we should do.	1	2	3	4	99
c. Most people who are important to me thought that some form of protection from HIV and STDS should have been used with my last partner when we had sex.	1	2	3	4	99
d. When it came to safer sex with my last partner, I wanted to do what most people who are important to me thought I should do.	1	2	3	4	99

Q20.This series of statements discuss your general relationship with your last partner. Please tell me to what extent you agree or disagree with each statement.

	Strongly Agree	Agree	Disagree	Strongly Disagree	Don't Know
a. If I asked my partner to use a condom, he would get violent	1	2	3	4	99
b. If I asked my partner to use a condom, he would get angry.	1	2	3	4	99

c. Most of the time, we did what my partner wanted to do.	1	2	3	4	99
d. My partner wouldn't let me wear certain things.	1	2	3	4	99
e. When my partner and I were together, I was pretty quiet.	1	2	3	4	99
f. My partner had more say than I did about things that affected us.	1	2	3	4	99
g. My partner told me who I could spend time with.	1	2	3	4	99
h. If I asked my partner to use a condom, he would have thought I was having sex with other people.	1	2	3	4	99
i. I felt trapped or stuck in our relationship	1	2	3	4	99
j. My partner did what he wanted even if I did not want him to.	1	2	3	4	99
k. I was more committed to our relationship than my partner was.	1	2	3	4	99
l. When my partner and I disagreed, he got his way most of the time.	1	2	3	4	99
m. My partner got more out of our relationship than I did.	1	2	3	4	99
n. My partner always wanted to know where I was.	1	2	3	4	99
o. My partner might have been having sex with someone else.	1	2	3	4	99

The next few questions ask about the physical relationship between you and your last partner. We want to remind you that all of your answers will remain confidential. Please circle one number for each.

Q21. Please indicate YES or NO for each question. We want to remind you that all of your answers will remain confidential.

	YES	NO
a. My last partner has hurt me by punching, kicking, hitting, or slapping me.	1	2

b. My last partner has forced me to have sex when I did not want to.	1	2
c. My last partner has belittled, humiliated, or intimidated you.	1	2

The next few questions are about your personal sexual behavior. Again, I want to remind you that your answers are confidential. For all of the following questions, "sex" could be oral, vaginal, or anal intercourse.

Q22. Thinking about the last 12 months, please tell me if these situations apply to you. *(Indicate YES, NO, or DON'T KNOW by circling one number for each)*.

During the past 12 months:	**YES**	**NO**	**Don't know**
a. I have had sex without a condom.	1	2	99
b. I have had sex with someone I knew or suspected was having sex with another person.	1	2	99
c. I have shared needles to shoot drugs or use steroids.	1	2	99
d. I have had sex with a person who has shared needles to shoot drugs or steroids.	1	2	99
e. I have had an STD.	1	2	99
f. I have had sex with a person who I knew or suspected had an STD.	1	2	99
g. I have had sex with a person who I knew or suspected had HIV or AIDS.	1	2	99
h. I have had sex for money or drugs.	1	2	99

The following questions are for statistical purposes only. We want to remind you that your answers will remain confidential.

Q23. How old are you?_____

Q24. Which of the following best describes you? *Please circle one answer*.

1 Married
2 Living together
3 Single
4 Divorced/Separated/Widowed
5 Other_____-

Q25. Which of the following best describes you? *Please circle only one*.

1 Aboriginal
2 Black-African
3 Black-Carribean
4 Hispanic/Latin American
specify)_____
5 Middle Eastern/Arab
6 South Asian
7 White-Western European
8 White—Eastern European
9 Other (please

Q26. What is the highest grade or year of school you have completed?

1 Never attended school or only attended kindergarten
2 Grades 1-8
3 Grades 9-11 (some high school)
4 Grades 12 (high school graduate)
5 Bachelor's
6 Graduate
7 Other

Q27. Which of the following categories best describes your yearly total household income*? Circle only one answer.*

1 Less than $15,000
2 $15,000-24,999
3 $25,000-34,999
4 $35,000-$49,999
5 $50,000-$74,999
6 More than $75,000

28. Thank you for taking the time to fill out this questionnaire. If you have any comments, please write them in the space below.

Appendix B: IRB Protocol Statement

DEPARTMENT OF PUBLIC HEALTH
Oregon State University, 256 Waldo Hall,
Corvallis, Oregon 97331
Tel 541-737-2686| **Fax** 541-737-4001
|publichealth @oregonstate.edu
|http://www.hhs.oregonstate.edu/ph/

Dear Friend,

You are being invited to take part in a research study to help us figure out what type of HIV prevention methods women prefer in the future. In this survey, we will ask you questions about some of the new products that are being developed and we'll ask you a series of questions about your sexual behavior and your relationships. The results of this survey will be used in a student's doctoral thesis. Your answers will help us understand the types of women who would use these HIV prevention methods and which type of product they would prefer using.

You are eligible to be in this study if you are a woman 1) who is HIV negative or of unknown status, 2) who is between the ages of 18-55, and 3) who has had vaginal sex with at least one male partner in the last 12 months.

At your visit to this clinic, you will be asked to take a 28 question survey while you are waiting for your appointment. All of the questions, except for number 28, are multiple-choice. If you agree to participate in this study, the survey will take you 15-20 minutes to complete.

At certain times during this study, we might ask you questions that make you uncomfortable. If you become upset during or after taking the survey you may contact the following organizations to receive counseling services:

- **The South Riverdale Community Health Centre Counseling Services; Phone: 416-461-1925.**
- **Nellie's Women's Shelter; 970 Queen St. East, P.O. Box 98118, Toronto, Ontario M4M 1J0; Phone: 416-461-1084.**
- **Interval House; 131 Bloor Street West, Suite 200 Toronto, Ontario M5S 1R8; Phone: 416-924-1491.**

We do not know if you will benefit from being in this study, but we hope your answers will help future researchers figure out which type of HIV prevention methods different women intend to use to protect themselves.

If you decide to take this survey, you can include your name in a lottery to win one of five $50 gift certificates to Loblaws Grocery Store on the cover page.

The information you provide during this research study will be kept anonymous. To help protect your anonymity, we will remove the front cover of the survey once it is complete. If the results of this project are published your identity will not be made public.

You will not be treated differently if you decide not to take part in the study. You are free to skip any questions that you would prefer not to answer.

If you have any questions about this research project, please contact: **Sonia M. Kandathil 416-551-9841; sonia.kandathil@yahoo.com.**

If you have questions about your rights as a participant, please contact the **Oregon State University Institutional Review Board (IRB) Human Protections Administrator, at (541) 737-4933 or by email at IRB@oregonstate.edu.**

Sincerely,

Sonia M. Kandathil
Student Researcher, Oregon State University

Appendix C: Lottery Entry Form

Dear Friend,

Thank you for agreeing to participate in the Women Initiated Solutions for HIV Prevention (WISH) Study. Your answers are important and will help researchers determine which HIV prevention methods women prefer in the future. As a token of our appreciation for your participation in this survey, your name will be entered into a lottery to eligible to win one of five $50 gift certificates to Loblaws Grocery Store. If you would like to participate in this lottery, please fill in the blank spaces below.

Once you have written down all of your contact information, we will remove this front cover from the survey so that your name will not be associated with this survey. Your answers on this survey will be kept totally confidential. **This information will not be used for any other purpose than the lottery. You will not receive any other mail, email or phone calls from us except to let you know if you've won the lottery.** Once winners are contacted, your contact information will be destroyed.

Thank you in advance for your participation in this very important project. If you have any questions about this survey, please feel free to contact the researcher via phone at 416-551-9841 or via her email at sonia.kandathil@rogers.com.

Sincerely,

Sonia M. Kandathil

Please fill in the information below if you would like to participate in the lottery to receive a $50 gift certificate to Loblaws Grocery Store.

Name:_____

Address:_____

City:_____ **Province**:_____**Zip Code**:_____

Phone Number (optional):_____

Email Address (optional):_____